abbvie

July 18, 2022

Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Submitted via the PMPRB Website Consultation Submission Portal

RE: AbbVie Submission to the PMPRB's Interim Approach Consultation

This submission is made on behalf of AbbVie Corporation in response to the PMPRB's June 30, 2022, *Notice and Comment: PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations*.[i]

AbbVie is a highly focused research-driven biopharmaceutical company that discovers and delivers innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. AbbVie strives to make a remarkable impact on people's lives across several therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health, and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio.

AbbVie is a member of Innovative Medicines Canada (IMC), and we are aligned with the recommendations contained in IMC's submission to the PMPRB Interim Approach Consultation. The purpose of this submission is to provide additional context from an AbbVie perspective.

AbbVie continues to have significant concerns regarding changes to the PMPRB regime and future Guidelines that will implement the revised schedule of international reference countries.[ii] Future PMPRB Guidelines and the Interim Approach must be consistent with the Federal Court of Appeal ruling in the *Alexion*[iii] decision. The PMPRB's legislative mandate is to ensure that prices of patented medicines are not "excessive"; the PMPRB does not have a mandate of consumer protection at large or any general authority with respect to price-control. Specific price tests and adjustments proposed in future Guidelines must be clearly justified according to the PMPRB's mandate which precludes some price tests and price sources, for example "lower-of", "lowest-among", average- or median-style tests that attempt to control prices as opposed to being aimed at ensuring that prices are not excessive.

The federal government has acknowledged a dramatic shift in the pharmaceutical landscape in the wake of the COVID-19 pandemic and the need to support innovation and investment in the pharmaceutical sector.[iv] This shift is reflected in the federal government's *Biomanufacturing and Life Sciences Strategy*, which seeks to build Canada's competitive position on the global stage. Of note in relation to the current PMPRB consultation is the fifth pillar of this strategy, world class regulation, which is rightly positioned as an enabler of innovation: "this will make Canada a more attractive destination for leading life sciences firms to establish and grow."[v]

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The PMPRB regime has been a deterrent for life science companies considering business in Canada and has affected the number of new medicines entering the Canadian market in recent years. Between 2017 and 2021, the number of new active substance launches in Canada declined each year and lagged the number launched globally, and particularly in the United States. Fewer than 60% of the products introduced in the US since 2017 were launched in Canada. In the five years prior, Canada launched more than 80% of the products marketed in the US. In addition, Canadian launches occurred after a median delay following the first global launch of 2.1 years since 2012, ranking it ninth out of the top-23 launch countries. Previously Canada ranked either fourth or fifth globally. [vi]

This trend is of concern for patients and also for governments because new medicines contribute to the sustainability of the healthcare system by allowing people to return to work sooner and avoid costly hospital stays, surgical procedures and other lengthy treatment regimes. On the matter of affordability, pharmaceutical companies already participate in net price negotiations conducted by the pan-Canadian Pharmaceutical Alliance (pCPA) on behalf of government-funded drug plans. [vii] Those drug plans are best placed to assess the value of a medicine to the health system at large and manage their budgets through these negotiations.

The PMPRB's Guidelines are an important element of pharmaceutical policy in Canada and the stakes are high for patients and the healthcare system. Accordingly, the consultation process for future Guidelines should be robust and meaningful. The consultation should incorporate working tables with stakeholders alongside written submissions. Working tables with industry technical experts will be particularly important, given that patentees are the regulated stakeholders.

In furtherance of the above, AbbVie requests consideration of the following recommendations in relation to PMPRB's price review approach:

1. **Medicines Launched in the Interim Period**

In relation to medicines launched in the Interim Period, the Proposed Interim Guidance states:

> *The PMPRB will not conduct a price review of any new patented medicines or open any investigations in respect of them until the new guidelines come into effect.*

For medicines with a first sale during the Interim Period, there must be a further commitment by the PMPRB that it will not seek the payment of "excessive revenues" for any sales during the Interim Period. It would be inappropriate to seek such payments when patentees are launching without visibility to the future Guidelines that will apply to the medicine's introductory price.

2. Considerations for Existing Medicines

In relation to existing medicines, the Proposed Interim Guidance states:

> *… an existing patented medicine will not trigger an investigation provided: 1) its national average transaction price (N-ATP) remains at or below its most recent non-excessive average price (NEAP) established under the existing Guidelines, and; 2) its list price does not increase during the Interim Period.*

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It is AbbVie's position that an existing medicine not currently under investigation should not trigger an investigation during the Interim Period if its *list price* remains at or below its list price in effect on June 30, 2022.

AbbVie further notes that, "Changes in the Consumer Price Index" is an explicit factor in the *Patent Act* that should be reflected in future Guidelines. Unlike many other types of businesses, including our suppliers, pharmaceutical companies are not able to impose surcharges to accommodate for inflation. Under the Proposed Interim Guidance, patentees will absorb the cost of inflation, which is now running significantly higher than the Bank of Canada target. Global inflationary impacts should be taken into consideration when developing the future Guidelines and in the context of an investigation when considering if the Canadian price is excessive.

For patented medicines with sales first reported in the first half of 2022, the PMPRB should allow patentees to report PMPRB 7 prices or make similar allowances to ensure that PMPRB 7 pricing informs list prices that have not yet been assessed. Introductory price reviews should be completed using PMPRB 7 countries and current Guidelines to support the review process.

3. **Transition Period for Future Guidelines**

The Proposed Interim Guidance is silent on the matter of the transition period.

The transition period should commence *following* the finalization of new Guidelines, whenever that may occur, and should be a minimum of twelve-months (two reporting periods) in length. This time frame is necessary to allow patentees to adjust their business plans to the new regime as reflected in the final version of the Guidelines. It is not reasonable for the Interim Period to be considered part of the transition period, as patentees do not have visibility to the future Guidelines that will be applied to their pricing during this period.

4. **Grandfathering**

AbbVie's position is that medicines with a first sale reported prior to July 1, 2022, should be grandfathered and not subject to the future Guidelines. Medicines launched under the current regime are not excessively priced under the PMPRB's rules, and commercial decisions have already been made based on the existing framework. Grandfathering will provide greater stability and continuity in the industry and will further the federal government's goal of supporting innovation and investment in the pharmaceutical sector.

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Thank you for your consideration of AbbVie's recommendations. If you have questions regarding this submission, I can be reached at e-mail: arima.ventin@abbvie.com or mobile: 416-458-0705.

Sincerely,

DocuSigned by:
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Arima Ventin
Executive Director
Market Access and Government Affairs

[i] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-price-review-approach.html
[ii] https://www.gazette.gc.ca/rp-pr/p2/2022/2022-07-06/pdf/g2-15614.pdf
[iii] Alexion Pharmaceuticals Inc. v. Canada (Attorney General), 2021 FCA 157 (https://www.canlii.org/en/ca/fca/doc/2021/2021fca157/2021fca157.html?autocompleteStr=alexion&autocompletePos=1)
[iv] https://www.canada.ca/en/health-canada/news/2022/04/statement-from-minister-of-health-on-the-coming-into-force-of-the-regulations-amending-the-patented-medicines-regulations.html
[v] https://ised-isde.canada.ca/site/biomanufacturing/en/canadas-biomanufacturing-and-life-sciences-strategy
[vi] https://lifesciencesontario.ca/wp-content/uploads/2022/06/ENGLISH.pdf
[vii] https://www.pcpacanada.ca/about