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Patented Medicine Prices Review Board
Standard Life Centre
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Ottawa, Ontario K1P 1C1

AbbVie Submission to the Consultation on the *PMPRB Draft Guidelines 2022*

Submitted via the PMPRB Website Consultation Submission Portal

This submission is made on behalf of AbbVie Corporation in response to the consultation on the *PMPRB Draft Guidelines 2022*¹, which were published on October 6, 2022.

AbbVie is a 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 positions and recommendations contained in IMC's submission to the consultation on the *PMPRB Draft Guidelines 2022* (the "draft Guidelines"). The purpose of this submission is to provide additional context from an AbbVie perspective.

Executive Summary

The draft Guidelines represent a completely new and experimental approach to federal regulation of patented medicine prices, the core features of which have not been consulted on previously. The established system of voluntary compliance with transparent price tests has been replaced by "investigation triggers", making it difficult for manufacturers to predict an allowable price. Moreover, the investigation triggers are misaligned with the PMPRB's legislative mandate and the direction of the courts on preventing excessive pricing. A 60-day written consultation is not sufficient to address these significant concerns.

Accordingly, we have concluded that **the current Guidelines consultation process should be suspended** allowing for a fulsome consultation and analysis to generate predictable, clear Guidelines that are aligned with government's stated commitment to support innovation in the life sciences and reflect the mandate of the PMPRB, applicable law and recent court decisions. IMC has similarly called for a suspension of the current Guidelines consultation.²

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

¹ <https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines-2022/Draft-Guidelines-2022.pdf>

² <https://innovativemedicines.ca/newsroom/all-news/implementation-patented-medicine-prices-review-boards-proposed-guidelines-will-harm-canadian-patients/>

pharmaceutical sector.³ The importance of this sector is reflected in the federal government's *Bio manufacturing and Life Sciences Strategy*, which seeks to build Canada's competitive position on the global stage. Of note in relation to the current PMPRB Guidelines 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."⁴

The draft Guidelines run counter to the *Bio manufacturing and Life Sciences Strategy*

and, if implemented, risk aggravating the established trend of fewer new innovative medicines entering the Canadian market. Between 2017 and 2021, the number of new innovative medicines launched in Canada declined each year and lagged the number launched globally, and particularly in the United States. Fewer than 60% of the medicines introduced in the US since 2017 were launched in Canada. This is a dramatic decline from the five years prior, when Canada launched more than 80% of the medicines introduced in the US. In addition, Canadian launches occurred after a median delay of 2.1 years following the first global launch.⁵

This trend is of concern for Canadian patients, physicians, and taxpayers, who expect a leading health care system, including timely access to innovative medicines. It is also a concern for governments because new innovative medicines contribute to the sustainability of the health care system by allowing people to stay healthier longer, return to work sooner and avoid costly hospital stays, surgical procedures, and other lengthy treatment regimes. Moreover, this trend puts at risk Canada's international standing as a destination for clinical trials; these trials measure improvements over the standard of care and cannot be conducted in a jurisdiction where the standard of care is not available. Fast-moving therapeutic areas like oncology are at particular risk in this regard.

The PMPRB's Guidelines are an important element of pharmaceutical policy in Canada and the stakes are high for patients and the health care system. Accordingly, **the consultation process for the Guidelines should be robust and meaningful**. The consultation should incorporate an impact analysis, case studies and working tables with stakeholders alongside written submissions. Working tables with industry technical experts are particularly important, given that patentees are the regulated stakeholders. Prior to the most recent set of PMPRB consultations, initiated in 2016, this approach was a regular feature of PMPRB-led consultation processes. That consultative and inclusive approach is absent here.

Recommendations

In furtherance of the above, AbbVie requests consideration of the following recommendations in relation to the *PMPRB Draft Guidelines 2022*:

- Provide Clear and Predictable Rules that Enable Voluntary Compliance
- Align Guidelines with the PMPRB's Legislative Mandate
- Grandfather In-Market Medicines

³ <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>

⁴ <https://ised-isde.canada.ca/site/bio manufacturing/en/canadas-bio manufacturing-and-life-sciences-strategy>

⁵ <https://lifesciencesontario.ca/wp-content/uploads/2022/06/ENGLISH.pdf>

- Provide Stable Price Ceilings
- Preserve the Incentive to Seek New Indications
- Allow Price Adjustments aligned with Inflation
- Allow Flat Pricing
- Regulate List Price
- Commence Jurisdiction from the Patent Publication Date
- Promote Transparent and Confidential Discussions with PMPRB Staff

A detailed description and rationale for each of these recommendations is provided below.

Provide Clear and Predictable Rules that Enable Voluntary Compliance

The PMPRB's July 1988 *Newsletter* outlined the following "Guiding Principles":

This Compliance Policy is founded on the premise that the most effective and efficient way to protect the public from excessive prices and achieve maximum compliance is through primary reliance on voluntary action by patentees. The Board believes that voluntary compliance can best be achieved by clear, understandable guidelines that provide, to the maximum extent possible, certainty and predictability for patentees in the definition of excessive price;

As described in the *Backgrounder⁶ to the PMPRB Draft Guidelines 2022*, the draft Guidelines represent a dramatic departure from more than three decades of clear, transparent price tests intended to enable voluntary compliance. Per the proposed new approach, PMPRB staff (the "Staff") would have significant discretion to determine allowable prices, case-by-case, when investigations are triggered. Investigations, the length of which are indeterminate, may be triggered after the first sale of a medicine by a complaint, the absence of international prices, a price increase higher than the Consumer Price Index (CPI), or additional criteria to be discussed further below.

At the November 3, 2022, *PMPRB Guidelines – Pharma Industry Webinar*, Staff could not share any price tests associated with the conduct of such investigations or articulate an overarching objective related to aggregate prices of new medicines subject to the new regime. This is very troubling, signaling that there will be no certainty or predictability for patentees. Moreover, Staff indicated there had not been an impact analysis related to this major shift in approach. Rather, an assessment would be conducted after-the-fact as part of a Guidelines Monitoring and Evaluation Plan (GMEP).

We note that the PMPRB Human Drug Advisory Panel (HDAP) would be relegated to an advisory role under the newly proposed approach, brought in for advice at the discretion of Staff. Per Appendix XIII.A of the draft Guidelines, "On an ad hoc basis, Staff may consult with the HDAP to provide clinical context pertaining to the scientific information that is being considered by Staff." Current and past iterations of the Guidelines provided for scientific assessments by the HDAP to be conducted separately from price reviews by Staff, with a therapeutic contribution assessment by HDAP being key to the determination of whether a

⁶ <https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/2022-proposed-updates-guidelines.html>

medicine's price is excessive. The proposed new approach gives PMPRB Staff unchecked power to determine: (i) when they will involve HDAP, (ii) how they involve HDAP (i.e., on which points do they seek HDAP's input), (iii) whether they are consistent in how they involve HDAP, across patented medicines and patentees, and (iv) how they interpret HDAP's input, all in a non-certain, non-predictable and non-transparent manner.

The draft Guidelines do not offer “bright-line guidance” as purported by the PMPRB, nor do they offer the clarity, predictability and transparency required of a regulatory agency. The PMPRB has not provided any assurance that it will employ a consistent regulatory approach across investigations. Planning for the launch of a new medicine begins more than two years in advance and requires significant human and financial investments in an environment where international price referencing is the norm. The uncertainty and lack of predictability as to whether patentees would be compliant will result in patentees delaying or abandoning entirely their plans to launch patented medicines in Canada. The Guidelines must enable patentees to reliably predict an allowable price at launch and over time; otherwise, the downward trend of new medicines launched in Canada will not be reversed.

Align Guidelines with the PMPRB's Legislative Mandate

Paragraph 35 of the draft Guidelines states that any of the following criteria may trigger investigations of new medicines:

- *The list price exceeds the median international price for the PMPRB11; or*
- *The list price falls between the median and the lowest international price for the PMPRB11, but exceeds the top of the domestic therapeutic class comparator prices (“dTCC”); or*
- *The list price exceeds the midpoint between the top of the dTCC and lowest international price for the PMPRB11, and the top of the dTCC is more than 50% lower than the lowest international price.*

It is AbbVie's position that the PMPRB Guidelines must be consistent with the Federal Court of Appeal ruling in the *Alexion*⁷ decision. This recent decision held that the PMPRB's legislative mandate is to prevent the abuse of patents through excessive pricing, and not to ensure reasonable pricing or affordable medicines. The PMPRB does not have a mandate of consumer protection at large or any general authority with respect to price-control. “Lower-of” or median-style criteria attempt to control prices and are not aligned with the PMPRB's mandate to prevent excessive pricing.

The PMPRB's role is unique, separate, and apart from the role of other drug assessment and funding agencies in Canada. Pharmaceutical companies participate in health technology assessments through the Canadian Agency for Drugs and Technologies in Health (CADTH)⁸ and net price negotiations conducted by the pan Canadian Pharmaceutical Alliance (pCPA). Although these organizations require modernization and improvement, their mandate is to assess the value of innovative medicines to the health care system and manage health care

⁷ *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>)

⁸ <https://www.cadth.ca/>

budgets. We note that, through the pCPA, pharmaceutical companies are making a highly meaningful contribution to public drug plan sustainability. Cost savings on innovative medicines to government-funded drug plans have reached \$2.67 billion annually.⁹ Through negotiations, payors consider the value of a medicine and its place in therapy; it is not the role of the federal government to negotiate net prices on behalf of payors that are responsible for managing their drug spend.

Grandfather In-Market Medicines

Paragraph 35 of the draft Guidelines states that the following criterion may trigger investigations of existing medicines:

The list price of any dosage form or strength of the medicine exceeds the highest international price for the PMPRB11 based on pricing information provided by the rights holder.

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 should continue to be subject to the existing Guidelines framework.

Provide Stable Price Ceilings

Under the current Guidelines, the maximum Non-Excessive Average Price (NEAP) is set two years after first sale, or launch in five international markets, whichever comes first. Thereafter, the price ceiling remains stable. At the November 3, 2022, *PMPRB Guidelines – Pharma Industry Webinar*, Staff indicated that they intend to review allowable price on an annual basis. Specifically, if the median international price changes, then a price investigation may be triggered. No tolerances were specified by Staff at this Webinar.

It is AbbVie's position that the PMPRB Guidelines should continue with the current approach instead of implementing annual reassessments. Maintaining the current approach will provide greater price predictability, stability and continuity, which are foundational to our industry, and will further the federal government's goal of supporting innovation and investment in the pharmaceutical sector.

Preserve the Incentive to Seek New Indications

At the November 3, 2022, *PMPRB Guidelines – Pharma Industry Webinar*, Staff indicated they are consulting on whether new indications granted for an existing medicine should prompt Staff to conduct a new domestic Therapeutic Class Comparison test, potentially triggering a price investigation.

Under the current Guidelines, new indications granted for an in-market medicine do not trigger a price review. It is AbbVie's position that the current approach should be maintained. This would preserve the incentive to seek new indications for existing medicines in Canada, which is particularly important in therapeutic areas such as oncology and immunology, where medicines often have multiple indications.

⁹ <https://www.pcpacanada.ca/about>

Allow Price Adjustments aligned with Inflation

In a further departure from current and previous iterations of the Guidelines, the draft Guidelines do not offer clear and predictable rules governing price adjustments aligned with the Consumer Price Index (CPI). “Changes in the Consumer Price Index” is an explicit factor set out in Section 85(1) of the *Patent Act* that must be considered when assessing if a medicine has been sold at an excessive price. The impact of changes to CPI should be reflected in the Guidelines. Unlike many other types of businesses, including suppliers of active and other ingredients used in medicines, pharmaceutical companies are not able to impose surcharges to accommodate for inflation. Global inflationary impacts should be taken into consideration in the Guidelines and in the context of an investigation when considering if the Canadian price is excessive.

Allow Flat Pricing

The draft Guidelines provide that where there are multiple strengths of a patented medicine on introduction, a reference strength will be selected. Then, if other strengths are later introduced, an investigation will be triggered if the price of a new strength is higher than the price per standard unit of the reference strength. In addition, PMPRB Staff may redetermine the reference strength when other strengths are introduced.

Allowance and flexibility for flat pricing across strengths is a feature of current and previous iterations of the PMPRB Guidelines, where pricing is determined by innovation (e.g., innovative regimen of initiation doses, titration doses, pediatric doses) and not determined by price per standard unit. AbbVie recommends that clear guidance be provided to allow for flat pricing, to support the launch of medicines with initiation doses and titration schedules, as well as the launch of pediatric dosages.

Regulate List Price

The draft Guidelines propose that regulation focus on List Price instead of Average Transaction Price (ATP), as historically has been the case. AbbVie supports the proposed shift in focus to List Price regulation by the PMPRB, as ATPs may be prone to annual fluctuation based on patient benefits provided by manufacturers or sales-mix shifts. However, we reiterate the need for clear and predictable rules for List Prices under this new regulatory framework, which is critical to support and foster innovation in the Canadian life sciences sector.

Commence Jurisdiction from the Patent Publication Date

The draft Guidelines propose that the PMPRB has jurisdiction over pricing of a patented medicine from the patent application date (rather than the patent publication date), should a patent issue. This proposal is at odds with patentees’ rights to compensation for infringing activities after the publication (not after the filing) date, and only if the invention claimed in the published application is substantially identical to that of the issued patent. The PMPRB is proposing to broaden its pricing jurisdiction in a way that is not supported by the *Patent Act*.

Promote Transparent and Confidential Discussions with PMPRB Staff

The Guidelines should promote transparent and confidential discussions between PMPRB Staff and patentees, to attempt to avoid litigation. However, the draft Guidelines provide that PMPRB Staff will not consider “without prejudice” discussions with patentees and that information shared in discussions may be subject to disclosure under Canada’s *Access to Information Act*. This approach will discourage transparent and confidential discussions.

Conclusion

The federal government moved in the right direction earlier this year by removing two components of its *Patented Medicines Regulations*, but the *PMPRB Draft Guidelines 2022* run counter to government's priority of building a stronger life sciences sector and health system. They remove the predictability and clarity that have been the foundation of three decades of voluntary compliance. Moreover, the draft Guidelines are not aligned with the PMPRB's mandate as a regulator of excessive price. The PMPRB should suspend the current consultation process, conduct a robust analysis and meaningful consultation, and generate revised draft Guidelines that provide predictable, clear approaches that are aligned with the PMPRB's mandate and government's aspirations for the life sciences sector.

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