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

AbbVie Corporation - Submission to the PMPRB on its Consultation on the 2023 Proposed *Amendment to the Interim Guidance re: New Medicines*

Submitted via the PMPRB Website Consultation Submission Portal

This submission is made on behalf of AbbVie Corporation in response to the consultation on the 2023 proposed *Amendment to the Interim Guidance re: New Medicines* (the "Draft Guidance"[1]), which was published on June 20, 2023.

AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience and eye care - and products and services across our Allergan Aesthetics portfolio.

AbbVie is a member of Innovative Medicines Canada (IMC) and is aligned with the positions and recommendations contained in IMC's submission to the consultation on the Draft Guidance. The purpose of this submission is to provide additional context from an AbbVie perspective.

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.[2] The importance of the sector 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."[3]

The PMPRB regime has been a deterrent for life science companies considering business in Canada and has negatively impacted the number of new medicines entering the Canadian market in recent years. 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.[4]

[1] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-new-medicines.html
[2] 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
[3] https://ised-isde.canada.ca/site/biomanufacturing/en/canadas-biomanufacturing-and-life-sciences-strategy
[4] https://lifesciencesontario.ca/wp-content/uploads/2022/06/ENGLISH.pdf

This trend is of concern for Canadian patients, physicians, and citizens, who expect a leading health care system, including timely access to innovative medicines. It is also of 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.

In furtherance of the above, AbbVie requests consideration of the following recommendations in relation to the Draft Guidance:

1-Align with the PMPRB's Legislative Mandate to Prevent Excessive Pricing

The Draft Guidance states (emphasis added):
*Medicines without a MAPP (Maximum Average Potential Price) or NEAP (Non-Excessive Average Price) as of July 1, 2022, are considered reviewed if **their list price is below the median** international price for the PMPRB11 countries.*

The Draft Guidance and future Guidelines must be consistent with the law. The Federal Court of Appeal ruling in the *Alexion*[5] decision held that the PMPRB's legislative mandate is to prevent the abuse of patents through excessive pricing. The PMPRB does not have a mandate of consumer protection at large or any general authority with respect to price-control.

Selection of a reference point "below the median" attempts to control prices and is not aligned with the PMPRB's mandate to prevent excessive pricing and the ruling in *Alexion*. Prices within the range of available prices of the new PMPRB 11 schedule of reference countries should not be considered excessive. Two higher reference price countries (the United States and Switzerland) have been removed from the schedule, and lower reference price countries have been added. This already has the effect of constraining the prices of New Medicines.

Moreover, there may be circumstances where prices above the range of the PMPRB 11 schedule may be justifiable in relation to the pricing factors in Section 85(1) of the *Patent Act*[6].

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 by Canada's Drug and Health Technology Agency (CADTH) and Quebec's INESSS[7] and net price negotiations conducted by the pan Canadian Pharmaceutical Alliance (pCPA). CADTH, INESSS and pCPA have mandates to assess the value of innovative medicines on behalf of drug plans to ensure value-based spend for Canadians. Through the pCPA, pharmaceutical companies are making a highly meaningful contribution to drug plan sustainability reflecting a cost savings on innovative medicines to public drug plans of at least $2.67 billion annually.[8] The Draft Guidance cannot introduce rules that go beyond the PMPRB's jurisdiction and attempt to address matters that fall within the scope of drug plan management.

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[5] 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)
[6] https://www.canada.ca/en/patented-medicine-prices-review/services/legislation/act-regulations.html
[7] https://www.cadth.ca/ and https://www.inesss.qc.ca
[8] https://www.pcpacanada.ca/about

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2-Provide Stable Price Ceilings

The Draft Guidance is silent on whether the PMPRB will conduct price reassessments or "re-benchmarking" for medicines deemed to have been "reviewed". It is AbbVie's position that the PMPRB should provide stable price ceilings. Specifically, once the ceiling price of a medicine is established at its introduction to the Canadian market, PMPRB staff should not reassess the ceiling price over time for any reason.

Price predictability is foundational to any industry and is especially important to sustain the development of innovative medicines that require long research, development, and planning timelines. This approach will further the federal government's goal of supporting innovation and investment in the pharmaceutical sector.

3-Allow Price Adjustments Aligned with Inflation

The Draft Guidance states (emphasis added):

During the interim period, the price of a patented medicine will not trigger an investigation if:

1. *its national average transaction price (N-ATP) remains at or below the NEAP (Non-Excessive Average Price) as projected in the most recent compliance letter from PMPRB staff to the relevant patentee, and;*
2. ***its list price does not increase**.*

The inability to take any price increase is inconsistent with the law. "Changes in the Consumer Price Index" is an explicit factor set out in Section 85(1) of the *Patent Act* [9] that must be considered when assessing if a medicine has been sold at an excessive price. A price increase in the range of CPI for 2023 and thereafter should not, in and of itself, cause a medicine to be "under review" or trigger an investigation. The future Guidelines should offer clear and predictable rules governing price adjustments aligned with the Consumer Price Index.

Unlike many other types of businesses, including suppliers of active and other ingredients used in medicines, pharmaceutical companies are not able to impose surcharges on their customers to accommodate 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.

4-Conduct a Robust and Meaningful Consultation Process on New Guidelines

The preamble to the Draft Guidance states:

> *The PMPRB intends to re-engage its stakeholders in the coming months and consult on a new set of guidelines, which are anticipated to be finalized in 2024.*
> *The proposal aims to provide … more time to advance a fulsome consultation process on the new guidelines.*

The PMPRB's Guidelines are an important element of pharmaceutical policy in Canada and the stakes are high for patients and for the entire health care system. Accordingly, the consultation process for the Guidelines should be robust and meaningful. AbbVie strongly encourages the PMPRB to begin the consultation with a higher-level dialogue on principles to inform future

[9] https://www.canada.ca/en/patented-medicine-prices-review/services/legislation/act-regulations.html

Guidelines. When draft Guidelines are released, 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.

AbbVie thanks the PMPRB for considering this submission and welcomes the opportunity to participate in robust consultation.

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