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

AbbVie Corporation - Submission to the PMPRB on its Consultation re: the *Scoping Paper for the Consultations on the Board's Guidelines, November 2023*

Submitted via the PMPRB Website Consultation Submission Portal

This submission is made on behalf of AbbVie Corporation in response to the consultation on the *Scoping Paper for the Consultation on the Board's Guidelines*[1] (the "Scoping Paper"), which was published on November 10, 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 Scoping Paper. The purpose of this submission is to provide additional context from an AbbVie perspective.

AbbVie requests consideration of the following recommendations in relation to the future Guidelines:

- Align Guidelines with the Biomanufacturing & Life Sciences Strategy
- Provide Clear and Predictable Rules that Enable Voluntary Compliance
- Align Guidelines with the PMPRB's Legislative Mandate
- Grandfather In-Market Medicines
- Provide Stable Price Ceilings
- Allow Price Adjustments aligned with Inflation
- Preserve the Incentive to Seek New Indications
- Allow Flat Pricing
- Promote Candid, Confidential Discussions with PMPRB Staff

A detailed description and rationale for each of these recommendations is provided below in connection with the themes of the Scoping Paper.

[1] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/scoping-paper-board-guidelines.html

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Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives

Align Guidelines with the *Biomanufacturing & Life Sciences Strategy*

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 regulatory 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]

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.

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; ….*

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. Future 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.

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[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

Align Guidelines with the PMPRB's Legislative Mandate
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[5] 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 public drug plan sustainability with aggregate cost savings on branded innovative medicines now reaching at least $3.14 billion annually.[6] Moreover, private insurance companies have the ability to conduct net price negotiations with pharmaceutical companies. Future Guidelines cannot introduce rules that go beyond the PMPRB's jurisdiction and attempt to address matters that fall within the scope of drug plan management.

Theme 1: Efficient Monitoring of Prices without Price Setting

Align Guidelines with the PMPRB's Legislative Mandate (continued)
Future Guidelines must be consistent with the law. The Federal Court of Appeal ruling in the *Alexion*[7] decision held that the PMPRB's legislative mandate is to prevent the abuse of excessive pricing that could result from the monopoly conferred by patent rights. The powers of the PMPRB are limited to those found in sections 79 to 103 of the *Patent Act*; these powers are specific and separate from other provisions under the Act relating to patent abuse. The *Patent Act* grants the PMPRB the authority to determine whether a price is excessive, not assess whether a price is reasonable. The PMPRB does not have a mandate of consumer protection at large or any general authority with respect to price-control.

Reference country median-style criteria attempt to control prices and are 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 reference countries listed on the schedule of the *Patented Medicines Regulations* (the PMPRB 11) should not be considered excessive. Two countries with historically higher prices than Canada (the United States and Switzerland) have been removed from the schedule, and new countries with typically lower reference prices have been added. This change in the basket of reference countries already has the effect of constraining the prices of new medicines, so the use of a price test based on the median of the PMPRB 11 goes beyond the regulation of *excessive* pricing.

Moreover, there may be circumstances where prices above the range of those in the PMPRB 11 countries may be justifiable in relation to the pricing factors in Section 85(1) of the *Patent Act*[8]; all such pricing factors must be taken into consideration when the PMPRB is assessing whether a medicine has been priced excessively. For example, there may be circumstances where international prices are below prevailing prices in Canada for drugs in a therapeutic class. The

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

new Guidelines must be reflective of these situations to ensure that the PMPRB's role is respected.

An expedited price review mechanism based on prices being below the Median International Price (MIP) would be inappropriate given the PMPRB's mandate to prevent excessive pricing and would not serve to accelerate the introduction of innovative medicines in Canada. AbbVie supports policy advancements to improve timely access to medicines by Canadian patients who rely on public drug plans. These policy advancements, however, sit within the scope of drug plan management and outside the jurisdiction of the PMPRB.

Theme 2: Transition to PMPRB 11 – New versus Existing Medicines

Grandfather In-Market Medicines

Medicines with a first sale reported prior to July 1, 2022, are not excessively priced under the PMPRB's rules. Review of the pricing of these medicines should not be a priority for enforcement; PMPRB can exercise its regulatory discretion through the application of the Guidelines. The price of those medicines that were sold before July 1, 2022, has been assessed through consideration of the factors in Section 85(1) of the *Patent Act* and has not been deemed to be excessive. PMPRB can consider these medicines and their line extensions to be grandfathered and not subject to investigations under the future Guidelines provided that their price remains stable subject to allowable inflation-based price adjustments.

Theme 3: Price Reviews during Product Life Cycle

Provide Stable Price Ceilings

It is critically important that the PMPRB provides stable price ceilings over the life cycle of a patented medicine. Specifically, once the ceiling price of a medicine is established at its introduction to the Canadian market, PMPRB staff should not "re-benchmark" (i.e., reassess) the ceiling price over time for any reason other than allowable inflation-based adjustments.

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

Allow Price Adjustments aligned with Inflation

"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, 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

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

Guidelines and in the context of an investigation when considering if the Canadian price is excessive.

Preserve the Incentive to Seek New Indications
Medicines can have multiple indications, which are added to Health Canada's Product Monograph as research evolves over the product's life cycle. Under the previous Guidelines, new indications granted for an in-market medicine did not trigger a price review. It is important that this approach is maintained. This would preserve the incentive to seek new indications for existing medicines in Canada, including indications for small populations, as well as pediatric indications.

Allow Flat Pricing
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.

Theme 4: Investigations and Referral to Hearing

Commencing an Investigation
AbbVie is supportive of having the Guidelines outline criteria for the commencement of an investigation. However, the listed criteria should describe situations where an investigation *may be* commenced as opposed to creating a mandatory requirement for Board staff to conduct an investigation. Furthermore, the criteria should be narrow, both to promote predictability and, importantly, to ensure that the PMPRB is investigating within the scope of its authority. For example, under the former Guidelines, an investigation would be commenced if "PMPRB receives a complaint"; this is overly broad and could result in Board staff commencing investigations when a frivolous complaint is received.

Promote Candid, Confidential Discussions with PMPRB Staff
The Guidelines should expressly provide that the PMPRB staff will consider "without prejudice" discussions with patentees on a good faith basis to foster resolutions without resorting to a hearing. This will promote open and candid discussions between PMPRB Staff and patentees, where solutions can be explored on a confidential basis in an attempt to avoid litigation.

The PMPRB should continue to use Undertakings as an investigation closure mechanism, with the understanding than an Undertaking would only be pursued after a patentee has been afforded the opportunity to consider the issues raised by the PMPRB and discuss the same. Given the complexities of global pricing, it is expected that there will be many investigations that would be closed without an Undertaking where a patentee provides justification for why a price is properly considered to be non-excessive.

Conclusion
The PMPRB's Guidelines are an important element of pharmaceutical policy in Canada and the stakes are high for patients and the entire health care system. The consultation process for the

Guidelines should be robust and meaningful. 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 on future Guidelines.

AbbVie Corporation
8401 Trans-Canada Highway
Saint-Laurent, Quebec H4S 1Z1