March 19, 2025

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

AbbVie Corporation - Submission to the consultation on *PMPRB Draft Guidelines*

Submitted via the PMPRB Website Consultation Submission Portal

This submission is made on behalf of AbbVie Corporation in response to the consultation on *Draft Guidelines for PMPRB Staff* [1] (the "Draft Guidelines"), which were published on December 19, 2024.

AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. AbbVie is one of the largest biopharmaceutical companies operating in Canada. We have offices in Montreal and Markham and directly employ over 1,000 Canadians. We operate almost 500 clinical trial sites that benefit patients across the country.

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 Guidelines. The purpose of our input is to provide additional context from an AbbVie perspective.

Core Principles to Inform Future Guidelines

The PMPRB's Guidelines are a critical element of pharmaceutical policy and must create a framework that does not impede the launch of innovative medicines in Canada. New medicines support healthcare system sustainability and our economy by allowing people to return to work and active living sooner and avoid costly hospital stays and surgical procedures.

Future PMPRB Guidelines must also be consistent with the law. The Federal Court of Appeal ruling in the *Alexion*[2] decision held that the PMPRB's legislative mandate is to prevent 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*[3]. The *Patent Act* grants the PMPRB the authority to determine whether a price is excessive; the *Act* does not grant the PMPRB the authority to 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.

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 Agency (CDA, formerly CADTH) and Quebec's INESSS[4] and

[1] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines-pmprb-staff.html
[2] 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)
[3] *Patent Act*, RSC 1985, c P-4.
[4] https://www.cadth.ca/ and https://www.inesss.qc.ca

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5
Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
abbvie.ca

net price negotiations conducted by the pan-Canadian Pharmaceutical Alliance (pCPA). CDA, 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 $3.72 billion annually.[5] Moreover, private insurance companies in Canada habitually conduct new product assessments to ensure value for their plan sponsors.

Future PMPRB Guidelines cannot introduce rules that go beyond the PMPRB's jurisdiction and attempt to address matters that fall within provincial jurisdiction from a constitutional perspective or within the scope of drug plan management from an operational perspective.

Recommendations & Rationale

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

- Retain the highest international price for the International Price Comparison
- Reference only the highest price in therapeutic class comparisons
- Conduct Annual Price Reviews in relation to the CPI only, not the International Price Comparison
- Grandfather existing medicines and provide a transition period for new medicines launched in the Interim Period
- Take steps to reduce the uncertainty associated with In-Depth Reviews

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

Retain the highest international price for the International Price Comparison

The Draft Guidelines state:

51. Staff uses a patented medicine's first semi-annual price filing to conduct an Initial Review against the highest international price among the Schedule Countries filed by the Rights Holder ("HIP") based on paragraph 85(1)(c) of the Act. …

AbbVie agrees with the selection of the highest international price (HIP) for purposes of the International Price Comparison. 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 reducing the prices of new medicines, so the use of a price comparison based on any level below the highest international price in the PMPRB 11 goes beyond the regulation of *excessive* pricing.

It should be noted in this context that the PMPRB's most recent annual report[6] shows that average list prices in Canada rank eighth when compared to the 11 reference countries at purchasing power parity.

[5] https://www.pcpacanada.ca/sites/default/files/eng/pCPA_Dashboard_June_2024.pdf
[6] https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2022.html

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5
Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
abbvie.ca

Reference only the highest price in therapeutic class comparisons

The Draft Guidelines state:

Appendices:
Assessment of individual subsection 85(1) factors, separately
… When initiating an In-Depth Review, Staff begins by considering the individual subsection 85(1) factors separately. Information considered by Staff during this phase of the review may include but is not limited to the following:
85(1)(b) – the prices at which other medicines in the same therapeutic class have been sold in the relevant market:

- *Is this medicine a line extension? A combination product? A biosimilar? A patented generic?*
- *How many indications is this medicine approved for?*
- *How many comparators were identified during the Scientific Review?*
- *Do the comparators share the same indication as the medicine, or are used in the same way without a shared approved indication?*
- *How strong are the levels of similarity across the comparators?*
- *What is the range in treatment costs? Tight? Narrow?*
- *Are there any high or low outliers among the treatment costs?*
- *Have any of the comparators been genericized?*
- *If the medicine is a patented biologic, are any of the comparators biosimilars?*
- *Did the Rights Holder express disagreement with any aspect of the Scientific Review? If so, on what grounds?*

In the proposed approach to therapeutic class comparison (TCC), above, the Draft Guidelines direct PMPRB Staff to consider information that is not relevant in the context of an excessive price analysis.

Consistent with the requirement to align the Guidelines with the PMPRB's legislative mandate to prevent excessive pricing, an approach to the TCC should adhere to the following principles. Firstly, the comparator set for multi-source medicines should include relevant branded/ innovative medicines, not only generic and biosimilar medicines. Secondly, prices within the range of available prices in the comparator set should not be considered excessive; the PMPRB should apply the same approach as it proposes for the IPC, i.e., the highest price in the range of comparators. Stated otherwise, the appropriate reference point is the "top of the TCC". Finally, patented medicines should be allowed the *higher of* the "top of the TCC" and the Highest International Price (HIP) in order for the assessment to detect excessive pricing only.

Conduct Annual Price Reviews in relation to CPI only, not the International Price Comparison

The Draft Guidelines state:

56. … The Annual Review applies the same IPC identification criteria (the HIP) and methodology (e.g. foreign exchange, selection of price when multiple prices are filed for a country, etc.) used during the Initial Review, but focuses on the most recently filed domestic and international pricing data.
57. Note that since the Annual Review will compare the list price(s) of a patented medicine against the HIP based on the prevailing list prices in the Schedule Countries, changes in the HIP could render the applicable threshold lower or higher in subsequent years than it was at introduction, depending on how the international landscape evolves. …

It is critically important that the PMPRB ensure price predictability over the life cycle of a patented medicine. Specifically, once the Initial Review of a medicine has been conducted in

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5
Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
abbvie.ca

relation to the IPC following its introduction to the Canadian market, PMPRB staff should not "re-benchmark" the price over time for any reason other than allowable inflation-based adjustments.

Price predictability is foundational to any industry and is especially important to sustain the development of innovative medicines that require very long research, development, and planning timelines. In addition, Canada is unique in the OECD in that specialty medicines, which account for a significant proportion of new medicines, require substantial manufacturer investments in patient support programs to reach patients. This adds another layer of complexity in the financial planning for such specialty medicines in Canada.

Grandfather existing medicines and provide a transition period for new medicines launched in the Interim Period

The Draft Guidelines state:

55. … "New medicines" and "Existing medicines" are subject to the same Annual Review process, although Existing medicines will be reviewed starting one (1) year from the date these Guidelines go into effect. New medicines will be reviewed immediately after these Guidelines come into effect.

Medicines with a first sale reported prior to July 1, 2022, are not excessively priced under the PMPRB's rules. Review of the prices of these medicines should not be a priority for enforcement; in this regard, the PMPRB can exercise its regulatory discretion through the application of the Guidelines. The prices of those medicines that were sold before July 1, 2022, have been assessed through consideration of the factors in Section 85(1) of the *Patent Act*[7] and have not been deemed to be excessive. The PMPRB can consider these medicines and their line extensions to be grandfathered and not subject to investigations under future Guidelines provided that their prices remain stable, subject to allowable inflation-based price adjustments.

Most existing medicines under the PMPRB's jurisdiction have been subject to negotiations with public and/or private payers. Enforcing new rules to lower list prices could be considered a "market-changing event" that would disrupt product listing agreements and inappropriately affect other investments in supply chains and patient support programs.

For medicines with a first sale reported during the Interim Period (between July 1, 2022, and the entry into force of final Guidelines), there must be a commitment by the PMPRB to apply an appropriate transition period prior to review. These medicines were launched without visibility to the future Guidelines that will apply to the introductory price. As such, these medicines should be reviewed no sooner than one year after the entry into force of final Guidelines to provide reasonable minimum notice to Rights Holders to implement price changes and to modify their commercial plans based on such adjustment. Rights Holders have a reasonable expectation that they will be afforded sufficient time to adjust their operations. Given the complexities of the Canadian pharmaceutical market and numerous stakeholders in the drug supply and reimbursement chain, one year is the minimum time necessary for an orderly transition to the new rules.

Take steps to reduce the uncertainty associated with In-Depth Reviews

Planning for the launch of a new medicine in Canada begins more than two years in advance and requires significant human and financial investments in an environment where formal and

[7] Idem

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5

Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
abbvie.ca

informal international price referencing is the norm. Future Guidelines must enable Rights Holders to reliably predict an allowable price at launch and over the life cycle of a medicine.

The principle of predictability is fundamental to achieve regulatory transparency and accountability, as set out in the Government of Canada's "Policy on Regulatory Transparency and Accountability" applicable to federal organizations.[8] This principle requires meaningful guidance to regulated stakeholders regarding their regulatory obligations and risks. In line with this principle, future Guidelines must provide patentees with certainty and predictability in determining allowable prices.

The Draft Guidelines propose a regime wherein PMPRB staff directly weigh the possible relevance of the *Patent Act*'s Section 85(1) pricing factors on a case-by-case basis. Steps should be taken to reduce the inherent uncertainty of this approach. To this end, AbbVie recommends the following specific changes to the Draft Guidelines.

The Draft Guidelines state (s *50):* *No "margins" are provided to account for exchange rate or other temporary price fluctuations when determining whether a patented medicine meets the criteria for In-Depth Review, ...*

The Draft Guidelines should include some reasonable margin to ensure that changes in exchange rates – which are outside the control of Rights Holders - do not result in unnecessary regulatory burden when domestic prices are otherwise stable.

The Draft Guidelines state (s 54): *The Initial Review service standard for Staff is to advise Rights Holders whether their patented medicine(s) is subject to an In-Depth Review within 60 days of the filing deadline for their first semi-annual filing.*

The reality of global launch sequencing for new medicines must be considered when determining when a HIP should be established. The requirement that just one launch country across the PMPRB 11 be sufficient for the HIP calculation effectively means global pricing targets and bands for many countries must be considered before launching in Canada and vice-versa. In this context, requiring that a product to be sold in at least five PMPRB 11 countries before reviewing the Canadian price in relation to the HIP would be a more prudent approach.

Deferring the Initial Review offers a more accurate reflection of international prices. This approach would avoid triggering In-Depth Reviews based on temporarily low international prices and can help the PMPRB better prioritize its resources. Moreover, this will incentivize earlier product launches; the current approach could delay launches in Canada until after authorization is granted in key PMPRB 11 countries as Rights Holders will seek greater predictability before commercializing in Canada.

The Draft Guidelines state (s 66): *In addition, for all other patented medicines, the receipt of a complaint from an approved individual or organization (see para. 67) who believes that the price of a patented medicine may be excessive in any market in Canada will automatically lead to an In-Depth Review even if the Initial Review or Annual Review criteria have not otherwise been met.*

[8] https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/requirements-developing-managing-reviewing-regulations/guidelines-tools/policy-regulatory-transparency-accountability.html

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5
Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
abbvie.ca

Eligibility for complaints should be restricted to the federal Minister of Health or any of his/her provincial or territorial counterparts. Moreover, it is not appropriate to apply automatically an In-Depth Review simply on the basis that a complaint has been made. This could create perverse incentives for arbitrary complaints and lead to unnecessary review burden. The PMPRB should validate complaints against the HIP standard and resolve complaints where pricing is at or below the HIP.

The Draft Guidelines state (s 95): *Generally, an In-Depth Review could take between 12 and 28 months to complete, depending on its complexity (e.g. number of comparators during the Scientific Review, IPC calculations).*
The Draft Guidelines state (s 74): *… Depending on the PMPRB's internal resources, other patented medicines may receive deferral letters. It is possible that some patented medicines with list prices above the HIP may be deferred multiple times depending on the PMPRB's internal resources. Deferral letters do not provide relief from any calculation of excess revenue by a Hearing Panel that may be accruing during the period of deferral.*

While a patented medicine is subject to an In-Depth Review, a Rights Holder does not have certainty on whether its price will be considered non-excessive and may need to take a reserve of revenues or make other accounting adjustments. This can have significant impacts on a company's operations.

In the event of a post-marketing review, any excess revenue calculations should not be retroactive to the time of product launch; rather, they should only apply to the period following the receipt of a complaint or the initiation of an In-Depth Review. Market dynamics change regularly, which affects the mix of possible therapeutic comparators. Right Holders should not be held to a different set of comparators and pricing well after the date of first sale versus what existed at the time of first sale.

The Draft Guidelines state: *Once an In-Depth Review is initiated, the Staff scientific team identifies the comparators for the purpose of conducting a Therapeutic Class Comparison ("TCC"). Comparators are identified for each approved indication or use of the patented medicine under In-Depth Review at the time the In-Depth Review is initiated.* (s 75)

Rights Holders whose patented medicines are identified for In-Depth Review cannot avoid or prematurely terminate In-Depth Review by unilaterally changing their list prices once the In-Depth review is initiated, … (s 96)

Patentees should have the opportunity to avoid or terminate In-Depth Review by changing list prices. The PMPRB's mandate is to address excessive pricing. The PMPRB can exercise its discretion and accept a voluntary undertaking from the Rights Holder to adjust the medicine's list price, rather than proceeding to a lengthy In-Depth Review. This is a reasonable solution and compromise that would save time and resources of both the Rights Holders and the PMPRB and is consistent with the overarching rationale to prevent excessive pricing.

The Draft Guidelines state (s 97): *If the result of the In-Depth Review is a recommendation to the Chairperson to issue a Notice of Hearing, Staff informs the Rights Holder of that recommendation when it is submitted to the Chairperson. Rights Holders are not provided with details of Staff's analysis in the Pricing Review beyond what is provided in respect of the Scientific Review (see para. 84, above).*

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5

Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
abbvie.ca

All review documents, including the full Price Review, should be provided to Rights Holders. This is necessary for transparency in the review process and ensures that Rights Holders are provided with clear and meaningful reasons for the decision of Staff to recommend a hearing. Procedural fairness requires that Rights Holders are afforded an explanation for the decision that is coherent, logical, and that accounts for relevant facts and context. PMPRB Staff should be able to work with Rights Holders when drafting Undertakings to In-Depth Reviews.

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5

Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
abbvie.ca