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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 re: *A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines*

Submitted via the PMPRB Website Consultation Submission Portal

This submission is made on behalf of AbbVie Corporation in response to *A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines*[1] (the "Discussion Guide"), which was published on June 26, 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 have over 490 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 Discussion Guide. 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 supports 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. To this end, future Guidelines must respect the legislative mandate of the PMPRB as an agency intended to prevent excessive prices, and they must enable predictability and voluntary compliance.

Future Guidelines must 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 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*[3]; 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 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.

Accordingly, prices within the range of available prices of the reference countries listed in the *Patented Medicines Regulations* (the "PMPRB 11") cannot be considered excessive.

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[1] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/discussion-guide-phase2.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.

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

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 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 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.

The Guidelines should enable predictability and 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; ….*

Moreover, the PMPRB's December 2023 *Scoping Paper*[6] describes the purpose of Guidelines as follows:

> *.... In particular, rights holders should be provided with sufficient information to allow them to evaluate their risk of being subject to a hearing by explaining how staff analyses price information and makes recommendations to the Chairperson regarding whether an investigation should be closed, closed subject to an undertaking, or lead to a Notice of Hearing.*

We are concerned that the proposed framework in the June 2024 Discussion Guide is moving away from predictability and voluntary compliance toward a regime where PMPRB staff directly weigh the possible relevance of the *Patent Act*'s Section 85(1) pricing factors[7] on a case-by-case basis. This is particularly relevant for annual reviews and "in-depth reviews", where rights holders may not be able to determine an allowable price at the time of product launch or through the life cycle of a product.

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 formal and informal international price referencing is the norm. Future Guidelines must enable rights holders to reliably predict an allowable price at launch and over time.

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[4] https://www.cadth.ca/ and https://www.inesss.qc.ca

[5] https://www.pcpacanada.ca/sites/default/files/eng/pCPA_Dashboard_June_2024.pdf

[6] https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/scoping-paper/PMPRB%20Scoping%20Paper_EN%20FINAL.pdf

[7] *Patent Act*, RSC 1985, c P-4.

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

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.

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

- Remove Annual Price Reviews from the proposed framework
- Use the Highest International Price for the International Price Comparison (Topic 1)
- Grandfather existing medicines (Topic 2)
- Apply a two-year rule for CPI increases (Topic 3)
- Limit permission to submit a complaint to F/P/T Ministers of Health (Topic 4)
- Add novel antibiotics to the list of medicines for complaint-based review (Topic 5)
- Convene a technical working group with industry experts to collaboratively define the approach to Therapeutic Class Comparison (TCC) (Topic 6)
- Keep the Human Drug Advisory Panel (HDAP) and ensure a consistent approach to when and how HDAP advice is employed (Topic 7)
- Preserve the incentive to seek Health Canada authorizations for new indications

A detailed description and rationale for each of these recommendations is provided below in connection with the proposed regulatory framework and consultation topics contained in the Discussion Guide.

Remove Annual Price Reviews from the proposed framework
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. 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, which adds another layer of complexity in the financial planning for such specialty medicines in Canada.

Use the Highest International Price for the International Price Comparison (Topic 1)
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*[9]. 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

[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
[9] 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)

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Téléc. / Fax: 514-906-9701
abbvie.ca

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 test 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[10] shows that average list prices in Canada rank 8th when compared to the 11 reference countries at purchasing power parity.

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*[11]. For example, there may be circumstances where international prices are below prevailing prices in Canada for drugs in a therapeutic class. The new Guidelines must be reflective of these situations to ensure that the PMPRB's role is respected.

Grandfather existing medicines (Topic 2)
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*[12] 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 the future Guidelines provided that their prices remain stable, subject to allowable inflation-based price adjustments.

Apply a two-year rule for CPI increases (Topic 3)
If the cumulative increase in list price over the past two years does not exceed the combined Consumer Price Index (CPI) for the last two years, then a list price should not be considered excessive (Option 2). A two-year rule appropriately provides greater operational flexibility to rights holders.

The future Guidelines should offer clear and predictable rules governing price adjustments aligned with CPI. PMPRB is requested to clarify the source/reference for "CPI as reported by Statistics Canada".

Limit permission to submit a complaint to F/P/T Ministers of Health (Topic 4)
Complaints to the PMPRB regarding patented medicine prices should be limited to federal, provincial and territorial ministers of health (Option 1). This option appropriately balances the PMPRB's obligations under the *Patent Act* with its stated objective of administrative efficiency (Discussion Guide, p. 4). As noted above, public payers negotiate net prices bilaterally with rights holders as a matter of course. Net prices and other terms are codified in product listing agreements mutually agreed by the parties, which are informed by pharmacoeconomic assessments that consider cost offsets in the health care system, as well as benefits such as improved productivity. Other stakeholders do not typically have access to the information required to properly substantiate a complaint to the PMPRB. Finally, as noted in the Discussion

[10] https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2022.html
[11] *Patent Act*, RSC 1985, c P-4.
[12] Idem

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Téléc. / Fax: 514-906-9701
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Guide, individuals who may have concerns regarding patented medicine pricing may address the complaint to an elected representative.

Add novel antibiotics to the list of medicines for complaint-based review (Topic 5)
The PMPRB should expand the list of products that would only be subject to complaint-based review to include not only vaccines, but also novel antibiotics.

According to the World Health Organization, antibiotic resistance represents a potential next global pandemic[13], and antimicrobial resistance (AMR) has become a top health policy priority worldwide[14]. The 2023 *Pan-Canadian Action Plan on Antimicrobial Resistance*[15] acknowledges that the low return on investment has disincentivized investment in antimicrobial R&D and has discouraged manufacturers from marketing existing antibiotics. Only 3 of the 18 new antibiotics that entered the global market between 2010 and 2019 are marketed in Canada as of May 2023[16], limiting treatment options for Canadians.

In 2023, the federal government commissioned a study[17] to identify policies needed to increase the availability of existing antibiotics and committed $640 million over five years to help the Public Health Agency of Canada (PHAC) secure new antibiotics for Canadians.

AbbVie is encouraged by the federal government's commitment to close the gap with peer countries and implement policy changes to improve the availability of new antibiotics. In the context of the PMPRB's current consultation, we support complaint-based review of novel antibiotics. This approach is aligned with the important public health objective of encouraging the launch of new antibiotics in Canada. Moreover, most novel antibiotics aimed at fighting antimicrobial resistant infections are treated as last-resort options to preserve their effectiveness and are reserved for hospital use.[18] In most provinces, antibiotics administered in hospital are subject to negotiation between manufacturers and hospital Group Purchasing Organizations, reducing the risk of excessive pricing.

Convene a technical working group with industry experts to collaboratively define the approach to Therapeutic Class Comparison (TCC) (Topic 6)
The Discussion Guide does not provide enough information for AbbVie to articulate a position on Topic 6, "Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC".

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[13] World Health Organization. (2023, August 8). *Antimicrobial Resistance:* Key Facts. https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance#:~:text=It%20requires%20urgent%20multisectoral%20action,development%20of%20drug%2Dresistant%20pathogens

[14] World Health Organization. (2023). Global Action Plan on Antimicrobial Resistance. https://www.emro.who.int/health-topics/drug-resistance/global-action plan.html#:~:text=Global%20Action%20Plan%20on%20Antimicrobial%20Resistance%20(2015)Antimicrobial%20resistance%20(,enduring%20threat%20from%20infectious%20diseases

[15] Government of Canada. (2023). Pan-Canadian Action Plan of Antimicrobial Resistance. https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/drugs-health-products/pan-canadian-action-plan-antimicrobial-resistance/pan-canadian-action-plan-antimicrobial-resistance.pdf

[16] CCA (Council of Canadian Academies). (2023). Overcoming Resistance. Ottawa (ON): Expert Panel on Antimicrobial Availability, CCA.

[17] Idem

[18] Among the three novel antibiotics launched in Canada since 2010, two of them (ceftolozane/tazobactam and dalbavancin) are on Health Canada's reserve list. https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/reserve-list-antimicrobial-drugs.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

AbbVie requests that the PMPRB convene a technical working group with industry experts to collaboratively define the approach to the TCC. Such a working group is appropriate, since rights holders are the regulated stakeholders, and they possess the necessary subject matter expertise to provide operational advice. Prior to the most recent set of PMPRB consultations, initiated in 2016, this approach was a regular feature of PMPRB-led consultation processes.

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 multisource medicines should include branded medicines as well as generic and biosimilar medicines. Secondly, prices within the range of available prices in the comparator set should not be considered excessive. Stated otherwise, the appropriate reference point is the "top of the TCC". Finally, as noted above, patented medicines should be allowed the *higher of* the "top of the TCC" and the Highest International Price (HIP).

Keep the Human Drug Advisory Panel (HDAP) and ensure a consistent approach to when and how HDAP advice is employed (Topic 7)
Past iterations of the Guidelines provided for scientific assessments by HDAP to be conducted separately from price reviews by PMPRB staff, with HDAP's assessment being key to the determination of whether a medicine's price was excessive.

Under the proposed framework in the Discussion Guide, HDAP would be relegated to an advisory role, brought in for advice at the discretion of staff. This new approach represents a significant departure from past practice. It gives PMPRB staff the 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 rights holders, and (iv) how they interpret HDAP's input.

PMPRB should preserve HDAP as a resource for advice on scientific issues and questions that arise during price review. New patented therapeutics represent novel technologies and mechanisms of action, and data packages are characterized by rising complexity. Staff review of new medicines should be informed by expert, independent advice, reflecting a clinical perspective. Moreover, future Guidelines should ensure fairness and consistency regarding when and how HDAP advice is employed by Staff.

Preserve the incentive to seek Health Canada authorizations for new indications
Medicines can have multiple indications, which are added to Health Canada's Product Monograph as research continues over a 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 Health Canada authorization for new indications in Canada, including indications for small populations, as well as pediatric and adolescent indications.

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

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abbvie.ca