Submission to the Patented Medicine Prices Review Board's Consultation on Proposed Practice Directions

AbbVie Corporation

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AbbVie Canada welcomes the opportunity to provide comments on the Patented Medicine Prices Review Board's (PMPRB) consultation on the proposed Practice Directions. AbbVie wishes to express its support for the submission of Innovative Medicines Canada (IMC) and aligns with IMC's positions and recommendations as set out in its detailed submission.

AbbVie also shares the Board's objective of promoting procedures that are efficient, consistent, and reflective of modern practices. We agree that procedural modernization can be beneficial where it enhances clarity and predictability without compromising the procedural fairness required in proceedings. AbbVie's comments are intended to complement IMC's submission by situating the proposed Practice Directions within the rapidly evolving global political and policy environment affecting pharmaceutical pricing and access, which forms an important part of the context in which the Board operates.

Broader global context: changing policy dynamics and risks to medicine access

Global pharmaceutical policy is undergoing significant change, most notably following the May 2025 Executive Order issued by the United States Administration to advance "Most Favored Nation" (MFN) drug pricing for U.S. patients. The Executive Order initiated concrete actions to benchmark U.S. prices against those in a basket of reference countries, including Canada.

Importantly, MFN approaches risk delaying or preventing the launch of new medicines in lower-priced reference markets, as prices set in those jurisdictions may directly trigger price reductions in the United States. Canada is explicitly included in the MFN basket in part because U.S. policymakers view Canadian drug pricing as government-regulated and not proportionately reflective of contributions to global pharmaceutical innovation.[1] This perception is reinforced by the fact that U.S. per-capita spending on innovative medicines is approximately double that of Canada (0.78% versus 0.32% of GDP).[2]

Canada already faces challenges with delayed and foregone launches of new medicines, and MFN-style dynamics risk exacerbating this trend.[3] These access challenges also have broader economic implications, including reduced attractiveness for clinical trials, biopharmaceutical investment, and R&D activity that supports high-value employment and economic growth.

Against this backdrop, improving the Canadian policy environment for pharmaceuticals has become increasingly important, particularly as the U.S. advances MFN-based approaches. While AbbVie recognizes that the PMPRB does not have jurisdiction to alter its regulatory framework through Practice Directions, the Board nonetheless operates within this broader international context and may increasingly be called upon to offer informed perspectives as policymakers seek to balance affordability, access, and innovation.

[1] https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/
[2] https://cdn.aglty.io/phrma/Attachments/NewItems/Report%20-%20High-Income%20Country%20Spending%20on%20Innovative%20Medicines%20-%20June%202025_20250716125138.pdf
[3] The Conference Board of Canada, "Access and Time to Patient" (Jan. 2024) available at: https://www.conferenceboard.ca/wp-content/uploads/2022/10/access-and-time-to-patient_jan2024.pdf

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Support for IMC's procedural fairness recommendations

Within this context, AbbVie supports IMC's core submission that procedural fairness must remain central in PMPRB proceedings. As IMC notes, Board hearings are adversarial and quasi-judicial in nature, where Rights Holders face enforcement action initiated by a well-resourced institution with potential financial and reputational consequences. Procedural efficiency should not come at the expense of a complete evidentiary record or the parties' ability to meaningfully present their case.

AbbVie supports IMC's key recommendations, summarized below, and encourages the Board to adopt them in the final Practice Directions:

Evidentiary and hearing process

AbbVie agrees with IMC that several proposed measures, when considered cumulatively, risk constraining the evidentiary record in complex excessive price proceedings.

- **Hearing Time ("Chess Clock")**: AbbVie supports IMC's recommendation that default hearing time should not be fixed across all proceedings. Excessive pricing cases vary significantly in complexity, and hearing length should be determined through case management following joint submissions from the parties, with proposed defaults available only where appropriate. In terms of defaults, the default should not be a truncated paper hearing: the length and mode of hearing (paper/in-person/virtual) should be determined by case management on a case-by-case basis.
- **Expert Report Page Limits**: AbbVie agrees with IMC that the proposed 15-page default cap for expert reports is inconsistent with the nature of evidence routinely required in PMPRB proceedings and departs without justification from Federal Court practice. Expert reports addressing pharmacoeconomic modeling, international pricing, and comparative clinical evidence cannot reasonably be confined to such limits without diminishing the quality of the record. AbbVie supports IMC's recommendation to remove this cap and determine page limits through case management where needed.

Motions practice

AbbVie agrees with IMC that the proposed motion timelines and page limits are unreasonably compressed and inconsistent with comparable federal proceedings.

- Aligning default timelines with Federal Court Rule 369 and adopting a 30-page default limit for written submissions would promote fairness, reduce unnecessary procedural disputes, and enhance efficiency for both parties and the Board.
- AbbVie also supports replacing the undefined "exceptional circumstances" standard for extensions with a consent-based mechanism, with case management as a fallback.

Failure-to-file proceedings

AbbVie supports IMC's position that Failure-to-File (FTF) proceedings should not be expedited by default. Each FTF proceeding should be subject to case management, with compressed schedules and paper-only formats available only with the consent of both parties.

Artificial intelligence disclosure

AbbVie agrees with IMC that disclosure obligations regarding AI should be clear, proportionate, and aligned with the Federal Court's May 2024 AI Notice.

- Disclosure requirements should apply explicitly to all parties, including Board Staff.
- "Use of AI" should be defined to capture circumstances where AI functions as a co-author, while excluding routine editing, automation, and document-management tools that are ubiquitous and do not raise quality, accuracy or transparency concerns.

Procedural clarity and board obligations

Finally, AbbVie supports IMC's recommendation that the Practice Directions provide greater clarity and symmetry by:

- Defining key procedural terms and aligning them with the existing Rules of Practice and Procedure; and
- Committing the Board to corresponding timelines for its own rulings, ensuring predictability runs in both directions.

For example, the consultation document proposes the exchange of affidavits of documents. Under the present PMPRB Rules, there is no documentary discovery.[4] However, there are disclosure obligations—namely to produce all documents that will be relied on. Under the proposal outlined in the consultation, this will change—and change significantly. In paragraph 3(a) a party would be obligated to identify any "documents that are relevant to any matter in issue that are or were in the possession, power or control of the party". Relevance is not defined. (In Federal Court, relevance is defined to be those documents upon which a party intends to rely, or documents that tend to adversely affect the party's case or support another party's case (Federal Court Rule 222)—and not every document that is or was in a party's possession, power, or control). The proposed approach is far too onerous for an administrative proceeding that is to be conducted expeditiously—and far beyond the reach of a Board that is already operating under a statutory scheme of mandatory reporting.

About AbbVie:
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 625 clinical trial sites that benefit patients, hospitals and researchers across the country.

[4] The PMPRB Rules are silent as to document exchange, subject to case management procedures to discuss the filing of evidence (Rule 22(c)) and the mode of tendering documents (Rules 6(1)(a), 6(2), 10, and 14).