

## Submission to the Patented Medicine Prices Review Board

Consultation on Proposed Practice Directions

Submitted on behalf of: Pfizer Canada

Submission deadline: 4 May 2026

Pfizer Canada appreciates the opportunity to provide comments on the Consultation on the Proposed Practice Directions released by the Patented Medicine Prices Review Board (PMPRB) on 5 March 2026. Pfizer supports efforts to enhance procedural efficiency, predictability, and consistency in PMPRB hearings; however, several proposed Practice Directions raise concerns regarding procedural fairness and flexibility.

### 1. Proposed Practice Direction on the Mode of PMPRB Hearings

#### Potential Issue(s):

- Restrictions on length of oral hearing subject to “exceptional circumstances”. While paper hearings are the default, if there is an oral hearing, the Board has restricted the hearing time to 5-7 days (based on 5 hour days), with 1-2 additional days of oral argument. More time can only be allotted if “exceptional circumstances” arise.
- The Board’s most recent hearings have been approximately 20 days, which makes adopting a shorter hearing cap subject to “exceptional circumstances” concerning.
- What constitutes “exceptional circumstances” has also not been defined. However, use of the word “exceptional” connotes a high standard. For example, the dictionary definition for “exceptional” is “rare” or “unusual”.

#### Proposed alternative:

- Abandon any “**exceptional circumstances**” standard and leave this issue to be determined by letter request to PMPRB hearing Case Management.
- This process is currently addressed at s. 22(e) of the Patented Medicine Prices Review Board Rules of Practice and Procedure (**PMPRB Rules**),<sup>1</sup> which provides that the “expected duration of the hearing” will be determined at the Case Management Conference.

### 2. Proposed Practice Direction on Facilitating Document Exchange

#### Potential Issue(s):

- No major issues identified.

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<sup>1</sup> Patented Medicine Prices Review Board Rules of Practice and Procedure, [SOR-2012-247.pdf](#) [**PMPRB Rules**].

- A Party seeking production of specific documents should file a motion, which will be addressed in writing. Comments on motion procedures are provided directly below.

### 3. Proposed Practice Direction on Standardizing Motions

- **Potential Issue(s):**

- The timeframe proposed for responding to a motion is very short: a responding record must be filed within 5 days of the date of service of the notice of motion (para 4). Any reply must be filed within 2 days of the response (para 6). While the Board allows that extensions can be granted, the timeframe provides little time to do so and responding parties must satisfy the standard of “**exceptional circumstances**”. These additional procedures for extensions of time and short timeframes will be burdensome for Rights Holders.

- **Proposed alternative:**

- We propose 30 days for responding and 10 days for reply. At a minimum, the Board should apply the default timeframes for motions in writing heard by the Federal Court. Rules 369 of the *Federal Courts Rules* governs motions in writing. The Respondent has 10 days to respond, with 4 days for Reply.
- Moreover, consistent with regular court practice, extending this timeframe should not require “exceptional circumstances” (see above, which standard is not defined), but a request via letter. The Board should allow motion scheduling requests made on consent of the parties.

### 4. Proposed Practice Direction on Electronic Filing and Page Limits

- **Potential Issue(s):** Certain page lengths are overly restrictive.

- Written submissions “on the merits” are limited to 30 pages, with any “Reply” at no more than 20 pages (para 5). It is unclear if the 30-page restriction applies to both moving and responding submissions.
- Written submissions on the merits in an abbreviated failure-to-file (FTF) proceeding are limited to 15 pages, with reply submissions set at 10 pages (para 6). It is unclear if “on the merits” is intended to apply to both moving and responding submissions.
  - Capping Rights Holders’ submissions at 15 pages in FTF proceedings is highly prejudicial, especially when (as set out below) the Board proposes to decide FTF matters in writing, without oral hearings.
- Written submissions on a motion limited to 10 pages, with a Reply of 5 pages (para 7).
- Expert reports limited to 15 pages (para 8).

- **Proposed alternative:**

- 30-page limits should apply to all written submissions (in-chief and responding), including on motions. There should be no page limits on expert reports. The length of written submissions made at the hearing on

the merits should be determined by Case Management based on the facts and issues being presented at hearing. These are the default rules on pages limits before the Federal Court, and there is no reason for the PMPRB to adopt a different approach. Given that the PMPRB would like to decide more matters based on a paper-record, it is even more important that Rights Holders have sufficient space to defend their legal positions.

## 5. **Proposed Practice Direction on Expediting Failure-to-File (FTF) Proceedings**

- Potential Issue(s):
  - The Board explains that expedition is justified because FTF “are very different orders with different consequences for rights holders”, “often do not involve complex legal questions” and “may be based on smaller evidentiary records”. However, in practice, none of these explanations are justified. For example, the Board’s last FTF hearing (re: Galderma) concerned whether the Board had jurisdiction over a medicine that Galderma had not been reporting for almost 7 years. Determining whether a medicine is under Board jurisdiction can have serious financial consequences for patentees who can then be liable for years of unreported sales (possibly also at excessive prices).
    - 90 days is a very compressed timeframe to set a schedule, file evidence, conduct cross-examinations and written submissions.
    - As set out above, the default of determining FTF in writing compounds the prejudice of limiting written submissions in FTF proceedings to only 15 pages.
- Proposed alternative:
  - FTF issues should only be expedited on consent of the parties, otherwise the regular hearing timelines and procedures should apply.

## 6. **Use of Artificial Intelligence in Proceedings**

- **Potential Issue(s).**
  - It is common practice for courts to require similar declarations concerning AI use. See for example the Federal Court’s [“Notice: The Use of Artificial Intelligence in Court Proceedings”](#) (May 7, 2024). However, what constitutes use of AI should be further defined in the Practice Direction.
- **Proposed Alternative:**
  - The Practice Direction should further define what constitutes use of AI. Namely, a declaration should only be required for content that is created or generated by AI.

## 7. **Proposed Practice Direction on Virtual Proceedings**

- No issues identified

Pfizer Canada encourages the PMPRB to adjust the proposed Practice Directions to preserve procedural fairness while pursuing efficiency, particularly by relying on case-specific case management.