

# Consultation on the Patented Medicine Prices Review Board (PMPRB) Proposed Practice Directions

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In its new five-year Strategic Plan, the PMPRB commits to provide organized and efficient administrative services through, among other strategies, the conduct of efficient hearings. As part of that effort, the PMPRB is considering the issuance of new non-binding Practice Directions to provide guidance on procedural matters related to PMPRB hearings not specifically addressed in the PMPRB's *Rules of Practice and Procedure*<sup>1</sup> and is consulting interested parties as per the requirements for consultation set out in s.96(5) of the *Patent Act*.

The proposed PMPRB Practice Directions set out in this document seek to supplement the *Rules* by clarifying expectations, outlining processes and promoting consistency and efficiency in PMPRB hearings. They provide guidance on what parties and the public can expect of the PMPRB, and what the PMPRB expects of parties.

These proposed Practice Directions draw on the PMPRB's 30+ years of experience with conducting hearings and on existing best practices identified across other courts and tribunals. They are designed to ensure procedural fairness and consistency across PMPRB hearings while also promoting procedures which are simpler, faster, less cumbersome and more adapted to modern approaches and technologies.

The proposed PMPRB Practice Directions are not legally binding, and do not replace or amend the *Rules*. Rather they present a base "default" for hearing procedures which may be departed from at any time by PMPRB hearing panels<sup>2</sup> at their discretion in order to ensure the fair and expeditious conduct of any proceeding.

The Practice Directions should be read in conjunction with the Board's *Rules*, the *Patent Act*<sup>3</sup> and the *Patented Medicines Regulations*.<sup>4</sup>

Once finalized after consultation, the Practice Directions will be issued with a coming-into-effect date and will be published on the PMPRB's website. Certain aspects of the final Practice Directions may be revisited in the future by the PMPRB as circumstances change. If any changes to the Practice Directions are contemplated because of an internal review, interested parties will be consulted by the PMPRB as per subsection 96(5) of the *Patent Act*.

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

<sup>2</sup> Consistent with Rule 2 of the *Rules*, for the purposes of hearings, the Board members – also known as the hearing panel- assigned by the Chairperson under subsection 93(2) of the *Patent Act* to deal with a matter constitute the Board, and are therefore referred to as "the Board" in the Practice Directions that refer to the hearing panel.

<sup>3</sup> *Patent Act* (R.S.C., 1985, c. P-4)

<sup>4</sup> [Patented Medicines Regulations](#) (SOR/94-688)

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

Historically, the PMPRB's public hearings were "live," meaning that all argument<sup>5</sup> and evidence was presented in person to the Board, with "live" witnesses for direct and cross-examination, printed physical documents were used, and all parties were physically present in the same room at the same time. This procedure would often lead to expensive, lengthy and logistically complicated hearings.

More recently, as technology has improved, and also in response to social distancing requirements during the COVID19 pandemic, the PMPRB has held hearings that, in whole, or in part utilize electronic records, are conducted through videoconferencing technology, or where some of the arguments and/or evidence are presented in writing only, without an oral presentation component (a procedure often known as "paper hearings").

The PMPRB seeks to promote the increased use of "paper hearing" procedures for the evidentiary portion of its hearings while reserving the use of "oral hearing" procedures for the live argument portion of its hearing through the following proposed practice direction:

1. Paper is the default mode for the evidentiary portion of Board proceedings. This includes written testimony and paper cross-examinations (transcripts).
2. Parties are encouraged to file joint statements of fact and/or joint books of authorities when possible.
3. The Board's default mode is to reserve the live portion of the hearing for oral argument.
4. If all parties agree at the case management conference, the Board may adopt a 6-month expedited hearing process to promote efficiency.
5. Parties are directed to submit witness testimony in affidavits (Rule 6(2)(b)) within the time prescribed at a case management conference or as otherwise directed by the Board.
6. Parties are directed to coordinate cross-examinations on affidavits filed with the Board.
7. Parties must file with the Board any cross-examination transcripts they intend to rely on.
8. A party or parties may, via letter, request that the Board hear oral testimony and/or oral cross-examinations.
9. The Board may also request oral testimony and/or cross-examinations.

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<sup>5</sup> Note that as per the PMPRB *Rules*, parties also provide written materials such as memoranda of fact and law, expert witness reports and affidavits, pleadings, etc. as part of the hearing record.

10. In the event of an oral hearing, the Board will adopt a 'Chess Clock' process in which the parties must confer and agree upon a hearing schedule for up to 5 hours a day over 5-7 days with 1-2 additional days for oral argument. Counsel are responsible for deciding how to allocate and use the available hearing time to greatest effect. The Board will finalize and approve the hearing schedule at a pre-hearing conference.
11. A party or parties may, via letter, request that the Board allot more time for an oral hearing if exceptional circumstances arise.
12. Final written submissions are to be filed with the Board following oral argument.
13. All live non-paper portions of PMPRB hearings will be presumptively scheduled virtually to be heard remotely. However, the Board may direct, or the parties may request that a live portion of the hearing be heard in-person.
14. Notice for any oral testimony or oral cross-examination, confirmation of whether the live portions of the proceeding will be conducted virtually or in person, and a hearing schedule will be given during a case management conference (Rule 22) or pre-hearing conference (Rule 23).

## 2. Proposed Practice Direction on Facilitating Document Exchange

There is no formal discovery process for the disclosure of documents in PMPRB proceedings and the Board's *Rules* do not provide specific guidance on document exchange. However, Rule 6 addresses the Board's power to receive any evidence that it considers appropriate, and Rule 14 addresses the filing of evidence with the Board.

Board, Federal Court, and Federal Court of Appeal decisions<sup>6</sup> have established that, in PMPRB proceedings, disclosure obligations are met if the subject of the inquiry is advised of the case it has to meet and is provided with all the documents that will be relied on. This is less onerous and time consuming than traditional discovery, which often requires a more extensive disclosure of documents and includes examinations for discovery.

Historically, the Board has provided directions for document exchange on a case-by-case basis as part of the case management process. To streamline the Board's process, the Board is proposing this practice direction to standardize the process for the exchange of any documents and requested productions:

1. Disclosure for Board proceedings is to be done through affidavits of documents.
2. Parties must, within the time prescribed at a case management conference, serve each other party and file with the Board an affidavit of documents with copies of the relevant documents attached.
3. An affidavit of documents should include:
  - (a) a list identifying the documents that are relevant to any matter in issue and that are or were in the possession, power or control of the party;
  - (b) any claim that a document is confidential or contains confidential information; and
  - (c) a statement of the grounds for each claim of confidentiality.
4. Upon the motion of a party who has been served an affidavit of documents and who opposes a claim for confidentiality of another party, the Board may inspect the document and determine the validity of the claim.

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<sup>6</sup> [Decisions/Reasons PMPRB-94-1/HABITROL/PHC; CIBA Geigy Canada Ltd. v. Canada \(Patented Medicine Prices Review Board\) \(T.D.\)](#), 1994 CanLII 3489 (FC), [1994] 3 FC 425; and [Ciba-Geigy Canada Ltd. v. Canada \(Patented Medicine Prices Review Board\)](#), 1994 CanLII 19507 (FCA), 56 CPR (3d) 377.

5. All parties and their counsel are deemed to undertake to only use confidential evidence or information disclosed in a Board proceeding for the purposes of the proceeding in which the evidence was obtained.
6. A party who has served an affidavit of documents and who comes into possession or control of additional relevant document(s), or who becomes aware that the affidavit of documents is inaccurate or deficient, should, as soon as possible, serve a supplementary affidavit of documents listing the additional document(s) or correcting the inaccuracy or deficiency.
7. Parties must serve each other party and file with the Board any expert witness report(s) and affidavit(s) within the time prescribed at a case management conference or as otherwise directed by the Board.
8. A party who objects to any expert witness or their reports may file a motion with the Board. Unless otherwise directed by the Board, any such motion will be dealt with through a paper process.
9. A party seeking production of specific documents should file a motion with the Board seeking production. Unless otherwise directed by the Board, any such motion will be dealt with through a paper process.

### 3. Proposed Practice Direction on Standardizing Motions

Interlocutory and preliminary issues often arise during Board proceedings. It is not uncommon for parties to bring motions to the Board seeking clarification or relief. During a proceeding, the Board routinely hears multiple motions, which can be a source of delay and a drain on the resources of the parties and the Board.

The *Rules* provide limited guidance with respect to motions. For example, the *Rules* do not specify when the responding party must provide its response, the content of that response, or how leave for oral testimony and cross-examination must be sought. The following proposed practice direction provides guidance on these and other issues. It also encourages parties to confer prior to bringing a motion to informally resolve issues which could give rise to a motion if possible:

1. Rules 25 – 27 address how and when motions will be commenced, the content of motion records, and filing requirements for motions. This practice directive provides guidance regarding issues not covered in the *Rules*.
2. The same process applies to all types of interlocutory motions, including motions for disclosure, confidentiality, requests for production, objections to expert reports, leave to intervene, and settlement agreements.
3. Prior to filing notices of motion, parties are directed to confer with each other to attempt to mutually resolve issues which could give rise to a motion.
4. Under Rule 25 the moving party must file the notice of motion and accompanying memorandum and affidavit with the Board and serve them on each party. Within two business days of service of a notice of motion, a party must indicate whether they wish to respond. Any motion response must be filed within five business days of the date of service of the notice of motion.
5. A motion response must include an affidavit setting out the facts on which the response is based that do not appear on the record of the proceeding, written submissions that set out the points at issue, a concise statement of the order sought, and a list of relevant authorities.
6. Any motion reply must be filed within two business days of the date of service of the response.
7. A party or parties may, via letter, request that the Board grant extensions to this motion filing schedule if exceptional circumstances arise.
8. The default format for motions will be paper unless the Board determines otherwise.
9. A party or parties may, via letter, request that the Board hear a motion orally, whether in person or virtually.

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

The *Rules* address the filing and service of paper and electronic documents but do not provide guidance on page limits for documents filed with the Board. In recent years, electronic filing has become the predominant format for filing submissions for most tribunals and courts. There has also been a general move toward less formal and more concise legal writing, which has reduced the length required for many legal documents and pleadings.

Historically, the Board has provided directions for page limits on a case-by-case basis as part of the case management process. This practice direction is being proposed to adopt electronic filing as the Board's preferred filing format and standardize the formatting and page limits for documents and submissions received by the Board:

1. Electronic filing is the default format for submissions to the Board.
2. Unless the Board directs otherwise, electronic documents (including all references in the body of the document) should be in 12-point Times New Roman or Arial font, and each page of the document shall measure 21.5 cm by 28 cm (8½ in. by 11 in.), have top and bottom margins of not less than 2.5 cm and left and right margins of not less than 3.5 cm, and have no more than 30 lines (exclusive of headings).
3. Rule 14(4) states that if a document is filed electronically, three paper copies of that document must be filed with the Board Secretary within 48 hours of electronic filing. However, the Board is using its discretion under Rule 5(3) to waive this requirement to better align with the Board's new electronic registry and ensure the expeditious conduct of proceedings. Therefore, when electronic documents are filed, parties will be exempted from the requirement to file paper copies of those documents unless otherwise directed by the Board.
4. If a party is unable to file documents electronically, paper copies may be filed in accordance with Rule 14. Paper documents should follow the same page formatting as electronic documents.
5. Unless the Board directs otherwise, any written submissions on the merits in a proceeding before the Board shall be no more than thirty (30) pages. Any reply submissions shall be no more than twenty (20) pages.
6. Unless the Board directs otherwise, any written submissions on the merits in an abbreviated failure-to-file (FTF) proceeding before the Board shall be no more than fifteen (15) pages. Any reply submissions shall be no more than ten (10) pages.

7. Unless the Board directs otherwise, any written submissions on a motion to the Board shall be no more than ten (10) pages. Any reply submissions shall be no more than five (5) pages.
8. Unless the Board directs otherwise, expert witness reports shall be no more than fifteen (15) pages.
9. A party seeking to file submissions or expert reports longer than contemplated by these directions shall make a request in writing via letter explaining the basis for their request to the Board. Any submissions in opposition to a party's request for additional pages shall be made by way of a letter to the Board.
10. Factors the Board will consider when deciding whether to permit the filing of longer documents may include the complexity of the case, potential prejudice to the parties, special circumstances, and the timeliness of the request.

## 5. Proposed Practice Direction on Expediting Failure-to-File Proceedings

The Board may issue excessive price orders under s.83 of the *Patent Act* if it has determined that a rights holder has sold, or is selling, a patented medicine at an excessive price. The Board may also issue failure-to-file (FTF) orders under s.81(1) of the *Patent Act* requiring rights holders to file information, including pricing information, required by the *Patented Medicines Regulations*. These are very different orders with different consequences for rights holders.

FTF cases often do not involve complex legal questions and may be based on smaller evidentiary records. Adopting a simpler, expedited procedure for FTF proceedings will permit the Board to more efficiently address filing concerns.

This proposed practice direction outlines an expedited process that is flexible and designed to adapt to the facts in each case. In cases where there are complex scientific or therapeutic questions at issue in an FTF, the Board recognizes that it may be more appropriate to follow a process similar to an excessive price hearing to ensure adequate procedural fairness to assess the evidence and legal issues:

1. The Board has adopted an abbreviated paper format for failure-to-file (FTF) proceedings.
2. Unless the Board specifies otherwise, abbreviated FTF proceedings require the early delivery of written evidence on a ninety (90) day compressed schedule.
3. For greater efficiency there will be streamlined case management and pre-hearing conferences for FTF cases. Issues that will be considered at case management and pre-hearing conferences include whether to reduce or eliminate certain procedural steps to facilitate expedition.
4. Prior to a FTF case management conference, parties are required to confer and submit to the Board a proposed schedule for filing evidence, any cross-examinations, and written submissions within the 90-day period beginning on the date the Notice of Hearing (NOH) is issued which initiates a proceeding under Rule 15.
5. If the parties cannot agree, each party should file a proposed timetable prior to the case management conference. The proposed timetables will be circulated prior to the case management conference to provide a basis for discussion.
6. Filing dates for compressed schedule will be fixed at the case management conference.
7. A party who wishes to have an oral FTF proceeding shall, via letter, make a request in writing to the Board. The Board will consider whether there are exceptional circumstances, such as unusually complex FTF cases that require an oral hearing.

## 6. Proposed Practice Direction on the Use of Artificial Intelligence (AI) in Proceedings

In its new five-year Strategic Plan, the Board states that its staff will explore new tools, such as those driven by AI, for processing data. While the Board is looking at the potential advantages of using AI in the conduct of its work, it is not contemplating using AI in making its judgments and orders.

The Board is proposing this practice direction on the use of AI by parties in proceedings because of its commitment to ensuring the effective and ethical use of AI:

1. It is the responsibility of counsel and parties to guarantee accuracy when preparing materials for use in Board proceedings, particularly when using AI.
2. The use of AI can result in the generation of fictitious legal authorities, inaccurate data and the mischaracterization of information. All of which may negatively impact the conduct and fairness of Board proceedings.
3. To avoid these risks, counsel and parties must exercise careful, informed, and ongoing oversight at all times when they or their staff use AI for Board proceedings.
4. Counsel and parties must disclose their use of AI in the preparation of any materials used in Board proceedings. This should be done by including a declaration in the first paragraph of any document which utilizes AI stating that AI was used to prepare the document and specifying which sections of the document were generated using AI technology.
5. The use of AI by legal counsel for Board proceedings must comply with counsel's professional duties and ethical obligations.

## 7. Proposed Practice Direction on Virtual Proceedings

In 2020, there was a rapid adoption of virtual hearings by most courts and tribunals due to the COVID-19 pandemic. During the pandemic, the PMPRB responded by putting in place a virtual hearing protocol for the “Procysbi”<sup>7</sup> hearing. Since the pandemic virtual proceedings have been widely adopted as a new default process for many boards and tribunals. The Board is proposing this practice direction to reflect best practices for virtual proceedings.

The advantages of virtual hearings include that they cost less for all parties by reducing travel expenses and time commitments. Virtual hearings also provide an opportunity to increase public access and transparency. They are inherently flexible, and a proceeding may be conducted virtually, in whole or in part, depending on the circumstances. Because of these many benefits, the PMPRB will continue to make greater use of virtual hearings for any parts of a proceeding that will not be conducted through paper.

This will most often mean conducting oral arguments virtually because the Board is promoting the increased use of “paper hearing” procedures for the evidentiary portion of its hearings and reserving the use of “oral hearing” procedures for the live argument portion of its hearing, unless an exception applies and the Board decides to hear virtual witness testimony and/or virtual cross-examinations. However, the Board recognizes that in certain circumstances live in-person proceedings will be more appropriate than a virtual proceeding in which case live in-person proceedings may be scheduled:

1. Individuals attending a virtual Board proceeding must conduct themselves as if they were physically in a hearing room.
2. Parties should advise the Secretary of the Board of any accommodations that may be needed for a virtual proceeding prior to the proceeding.
3. Prior to the virtual proceeding, parties are responsible for ensuring that their internet connection and all technology they, and their witnesses, will be relying on is functioning.
4. Counsel and parties should join the virtual proceeding at least 15 minutes before the scheduled start time to ensure there are no technical issues that could delay the proceeding.
5. Counsel and witnesses appearing in a virtual proceeding must ensure that their cameras are turned on, they are appearing from a private space (i.e., no one else is present with them off camera), and their backgrounds are professional.

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<sup>7</sup> *In the matter of Horizon Pharma and the medicine Cysteamine Bitartrate sold under the trade name Procysbi.* Notice of Hearing issued on January 14, 2019, decision rendered on September 1, 2022.

6. To reduce background noise during virtual proceedings, counsel and witnesses may use a headset with an integrated microphone or a tabletop microphone.
7. Counsel and parties appearing in a virtual proceeding must provide a screen name which includes their given name.
8. The Board will record audio and video of the virtual proceeding. While the recording is turned on, an alert will appear to indicate to all participants that video and audio are being saved.
9. Parties participating in a virtual proceeding are not permitted to record or broadcast the proceeding.