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Patented Medicine Prices Review Board

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Subject: Constitutional Coalition Submissions re: Revised Proposed Practice Directions

The industry coalition that brought the constitutional challenge before the Quebec Superior Court and Court of Appeal, composed of Merck, Janssen, Boehringer Ingelheim, Bayer, and Servier (the “**Constitutional Coalition**”), welcomes the opportunity to comment on the PMPRB’s Revised Proposed Practice Directions (the “**Revised Practice Directions**”). These submissions build on the Coalition’s prior consultation submissions, including its written submissions of May 4, 2026, and should be read in conjunction with them.

Introduction

The Coalition recognizes that the Revised Practice Directions reflect much of the Coalition’s feedback on the initially proposed Practice Direction, including the increase in default page limits and the recalibration of motion timelines. The Coalition appreciates the Board’s responsiveness to stakeholder input on these points.

That said, the Coalition reiterates that any procedural instrument issued by the Board, however framed, must remain anchored in the PMPRB’s constitutionally-limited mandate and adjudicative role as confirmed by the Courts, including the Quebec Court of Appeal’s decision in *Merck v. Canada*, 2022 QCCA 240. Its jurisdiction to receive, consider, and act on evidence is bounded by the statutory factors set out at section 85 of the *Patent Act*. Given these Practice Directions on Hearings will shape how evidence is exchanged and considered, they cannot be permitted to functionally expand the PMPRB’s jurisdiction.

The submissions below address four areas where the Coalition believes the Revised Practice Directions require further refinement to remain consistent with these limits and with basic principles of procedural fairness.

1. Document Exchange: Relevance Must Govern

Revised Proposed Practice Direction 2 on Facilitating Document Exchange operates against the backdrop of Rule 6, which frames the Board’s evidentiary power in terms of receiving “any evidence that it considers appropriate.” The Coalition submits that “appropriateness” is not, and



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cannot be, the governing standard for the exchange or admission of evidence in Board proceedings. Nor can the threshold be what the Board considers appropriate in a given case. Evidence must instead be objectively relevant to the matters properly in dispute before the Board, i.e. whether the price of a patented medicine is excessive as a function of patent abuse, assessed by reference to the statutory factors set out in section 85 of the *Patent Act*.

“Appropriateness” is not grounded in the rules of evidence, nor in administrative law principles governing the scope of a tribunal’s statutory mandate. It risks inviting the exchange and filing of evidence that falls outside the scope of the section 85 factors. As a matter of evidence, relevance is the threshold for admissibility. Similarly, administrative law requires an administrative decision-maker to consider only those legal and factual considerations that fall within its enabling statutory framework. For the Board, the only factors from which the relevance of evidence can properly be assessed are the statutory factors enumerated at section 85 of the *Patent Act*. It is those factors that define the scope of the Board’s adjudicative mandate as confirmed by the Courts.

The Coalition submits that the Revised Practice Direction on document exchange should expressly confirm that document requests, and evidence more generally, must be objectively relevant to the matters properly in issue before the Board, being the section 85 factors. The Practice Directions should not functionally expand or restrict the categories of evidence the Board may receive or rely upon beyond that statutory scope.

2. Disclosure of the In-Depth Review File on Transfer to the Hearing Stage

Revised Proposed Practice Direction 2 on Facilitating Document Exchange reiterates the principle that disclosure obligations are met where the subject of the inquiry is advised of the case it has to meet and is provided with all documents that will be relied on. The Coalition agrees with this articulation of the governing standard, in principle, but submits that the Revised Practice Directions do not adequately explain how that standard will be applied where a matter transitions from an in-depth review (“IDR”) to a Board hearing.

Board Staff conduct the IDR and, in doing so, control and possess the underlying investigative record. Where that record informs the case the Staff will bring before the Board, it forms part of “the case [the patentee] has to meet” and must be disclosed entirely at the document exchange stage. It must not be produced piecemeal or only on request.

The Coalition submits that the Revised Practice Direction on document exchange should expressly confirm that, on transfer of a file from IDR to hearing, Staff must disclose the complete IDR file as part of its affidavit of documents, including all records of the scientific review especially pertaining to the basis for which therapeutic class comparators were chosen or omitted from scientific review and the basis for the Staff’s assessment of their level of comparability.

Absent such clarification, there is a real risk that Staff could rely on analysis or materials generated during the IDR without those materials ever being disclosed as part of the evidentiary exchange, undermining a patentee’s ability to know and respond to the case against it, in violation of the principles of procedural fairness.



3. The Need for a Protective Order Governing Exchange of Confidential Information

The Coalition welcomes the Board's development of a model Confidentiality Order governing the treatment of confidential information filed in a Board proceeding, and the clarification in the Revised Practice Direction that disputed materials will be treated as confidential on an interim basis pending resolution of confidentiality issues.

The Coalition also acknowledges the deemed undertaking in Direction 2, section 6, which provides that all parties and their counsel are deemed to undertake to use confidential evidence or information disclosed in a Board proceeding only for the purposes of that proceeding. However, that undertaking should be expressly provided for in a distinct procedural instrument, such as a model protective order, and supported by clear, enforceable obligations governing the treatment of confidential information as between the parties.

As currently framed, the model Confidentiality Order is insufficient for that purpose. In particular, it is directed to the disclosure of confidential information into the public record and the treatment of confidential materials as between a party and the Board. It does not address the confidentiality obligations that should govern the exchange of sensitive information between the parties at the evidentiary stage, including permissible use, further disclosure within a party's organization, retention and destruction obligations, and remedies for breach as between the parties.

The Coalition therefore submits that the Revised Practice Directions should provide for a model protective order, as is the case in the Federal Court, rather than leaving these issues to case-by-case discretion. Indeed, leaving these matters to the discretion of the Board by way of case management does not provide adequate certainty to a party required to disclose commercially sensitive information, including pricing, cost, strategic planning, and other confidential business information routinely implicated in Board proceedings.

A model protective order should set out rules addressing the permissible use of confidential information, the persons within a party's organization to whom such information may be disclosed, safeguards against external disclosure, including in response to access to information requests, obligations concerning retention and destruction of confidential materials after the proceeding, and remedies for breach. This approach would be consistent with the practice in Federal Court and would provide parties with greater comfort that sensitive information disclosed in Board proceedings will be protected from use or disclosure outside the proceeding.

4. Page Limits on Expert Reports Remain Inappropriate

The Coalition acknowledges and appreciates the Board's responsiveness to stakeholder feedback in removing the fixed 15-page limit on expert reports, providing instead that such limits will be set on a case-by-case basis at case management. This is a meaningful improvement over the initial proposal.

The Coalition submits, however, that a page limit on expert reports, even where left to case management, remains inappropriate. No such page limit applies to expert reports in Federal Court proceedings, nor is one imposed by other comparable federal tribunals. Given that Board practice

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is expressly meant to draw on Federal Court guidance, the same approach should be followed here. Expert reports should not be subject to any page limit, whether fixed by default or set through case management.

The complexity of PMPRB proceedings, particularly given the technical, economic, and international and therapeutic comparability issues that arise in assessing the section 85 factors, does not lend itself to page-limited expert evidence. Imposing any page limit risks constraining an expert's ability to fully explain methodology, assumptions, and conclusions, to the ultimate prejudice of the patentees and the Board's own ability to adequately decide the issues before it. The Coalition therefore submits that the Revised Practice Direction should be further amended to remove any reference to page limits for expert reports, consistent with Federal Court practice.

The Constitutional Coalition thanks the PMPRB for the opportunity to provide feedback on the Revised Proposed Practice Directions.

Sincerely,

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