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Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON, K1P 1C1

Subject: Constitutional Coalition Submissions *re:* PMPRB 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**"), takes this opportunity to provide written feedback on the PMPRB's Proposed Practice Directions (the "**Practice Directions**"), which are intended to provide guidance on procedural matters related to PMPRB hearings not specifically addressed in the PMPRB's *Rules of Practice and Procedure*.

These submissions are in keeping with the Constitutional Coalition's prior consultation submissions made since the 2019 regulatory amendments, including its written submissions in September 2024 and March 2025.

The Constitutional Coalition recognizes and supports the PMPRB's stated objective of modernizing and improving hearing efficiency and predictability, including through procedural tools that are adapted to modern technologies. At the same time, and consistent with the Coalition's longstanding position, procedural reform must remain anchored in (i) the PMPRB's adjudicative role and principles of administrative law applicable thereto and (ii) the constitutional limits of the Board's jurisdiction as confirmed by the Courts.

Executive Summary

The Constitutional Coalition provides the present written submissions with the objective of ensuring that the PMPRB's hearing practices, whether articulated through non-binding Practice Directions or otherwise, remain consistent with the PMPRB's constitutional mandate, as defined in the Québec Court of Appeal's decision in *Merck c Canada*, 2022 QCCA 240 (the "**QCCA Decision**"), and the legal principles established therein. In particular:

1. **Procedural instruments cannot functionally expand jurisdiction.** While the Proposed Practice Directions are described as non-binding defaults, they will in practice shape how hearings are conducted and therefore must remain consistent with the PMPRB's constitutionally-limited mandate and adjudicative function.

2. **Consistency and administrative efficiency must not come at the expense of procedural fairness and necessary flexibility.** The current context has introduced additional uncertainty and complexity in international pricing, making it especially important that PMPRB hearing practice preserve the ability to tailor procedure to the circumstances of each case. PMPRB practice must ensure a procedurally fair and meaningful opportunity for patentees to know the case they have to meet and be heard, especially where there is a risk of penal consequences such as before the Board.

Legal Context & Background

The Coalition understands that well-designed default procedures can promote predictability and efficiency. However, it is important to reiterate that PMPRB hearing practice, like the PMPRB's other substantive instruments including its Guidelines, must remain anchored to the PMPRB's constitutionally-bound mandate. As the QCCA Decision confirms, the PMPRB is not a general price regulator; its mandate is limited to preventing excessive prices flowing from an abuse of the monopoly granted by a patent.[1]

In this regard, the Coalition notes that the QCCA Decision characterizes an "excessive price" as "a price that, without justification, exceeds the price of other medicines in the same therapeutic class or that otherwise exceeds the price for the same medicine in countries reasonably comparable to Canada."[2]

This "without justification" component has direct procedural implications. A fair hearing process must permit parties to adduce and test evidence relevant to such justification and other context specific issues, particularly in the current volatile and complex global pricing environment, notably due to "most-favoured-nation" ("**MFN**") pricing initiatives.

The Coalition members urge the Board to ensure that its hearing practice fully respects the constitutional parameters as set out by the relevant jurisprudence.

Detailed Submissions

The Coalition's submissions seek to preserve the PMPRB's objectives of efficiency and consistency while ensuring that the Board's procedure is tailored to complex evidentiary needs and that parties retain a full and fair opportunity to present their case where the circumstances warrant it. The Coalition's principal concerns relate to four areas identified below:

- Default written record;
- Strict page and time limits;
- Expedited failure-to-file proceedings; and

[1] *Merck Canada c Canada*, 2022 QCCA 240 ¶143-146, 153, 163, 179. See also *Galderma v. Canada (AG)*, 2024 FCA 208 ¶12-19.

[2] *Merck Canada c Canada*, 2022 QCCA 240 ¶49.

- Overall impartiality concerns.

It is important to recognize that the Board exercises quasi-criminal powers (section 76.1 of the *Patent Act*). Given the potential for penal consequences, a party brought before the Board must be afforded robust procedural guarantees.

The Coalition members are concerned that certain aspects of the proposed Practice Directions may compromise the procedural safeguards to which patentees are entitled in this context. While consistency and efficiency are worthy objectives for the PMPRB, they must not come at the expense of procedural fairness.

The Coalition therefore urges the PMPRB to continue adhering to the well established rules of procedure followed by other tribunals and the Federal Court. Adhering to these rules is not only a matter of natural justice, they are tried and tested mechanisms that ensure procedural fairness for all parties – which in the context of proceedings with penal consequences, such as those before the Board, takes on particular significance. Framing departures primarily as matters of "consistency" or "efficiency" suggests that procedural fairness is being subordinated rather than protected.

1. ***Default Written Record***

The Proposed Practice Direction 1 provides for a paper-based record as the default for the evidentiary portion of proceedings (i.e. written testimony and out-of-court cross-examinations), with hearings limited to oral argument and final written submissions following oral argument.

The Coalition raises the following concerns regarding the proposed default written record:

(a) *Written record may be an appropriate default, but the PMPRB must preserve meaningful flexibility*

The Coalition acknowledges that written-record proceedings may help reduce cost and complexity in appropriate cases. However, as currently proposed, parties who wish to deviate from this default must submit a written request to the Board, and the Board must accept such a request before oral testimony or other live evidentiary steps can be pursued.

The Coalition submits that the PMPRB should preserve the ability of parties to seek oral testimony or other live evidentiary steps as a default. Matters before the Board typically involve complex evidentiary issues such that that a paper record risks undermining a patentee's ability to present a full defence as well as the panel's ability to fully assess the matter. A paper-based record may also be inadequate in instances where third-party testimony is required and a party is unable to file a written affidavit. Allowing the Board discretion to deny an oral hearing based on its own assessment of the complexity of the issues may compromise a party's right to a full and fair hearing.

For example, the Practice Direction should expressly confirm that, where necessary to ensure procedural fairness including where evidentiary completeness so requires, case management may tailor the evidentiary format without either party having to seek approval from the Board by way of written request.

(b) *Sequencing of steps should facilitate clarity and fairness*

The Practice Direction proposes that oral argument should be followed by final written submissions. This risks reducing the utility of oral argument as a mechanism for the panel to test and understand the parties' positions and for the parties to respond meaningfully to each other's arguments.

The Practice Direction should provide for a default sequencing in which main written submissions precede oral argument, with oral argument serving to clarify and respond to questions from the panel and to address reply issues. This is consistent with adjudicative best practices, including at the Federal Court and other federal administrative tribunals, including those in other areas of intellectual property, i.e. the Patent Appeal Board, the Trademarks Opposition Board, and the Copyright Board.

(c) *Mode of hearing should allow for greater flexibility in complex cases*

While the Coalition agrees that virtual hearings can enhance accessibility and efficiency, the parties should be permitted to seek in-person hearings via case management rather than having to make such a request to the Board in writing. This approach would foster greater procedural flexibility and responsiveness, allowing the hearing process to be tailored to the specific needs of each proceeding, particularly where the complexity of issues and scope of evidence so require. The ability to request in-person hearings through case management, without the additional hurdle of a formal written request to the Board, would reduce unnecessary procedural burden and potential delays, supporting a fair and efficient process. Moreover, in-person hearings may be especially important and appropriate in cases where the evidentiary record is highly technical or voluminous, as they allow for more effective engagement between the parties and the panel.

In addition, the proposed "chess clock" format is overly restrictive and may not be suited to matters where there is a voluminous and complex evidentiary record. Strict time allocations could inadvertently disadvantage patentees where, as mentioned above, they may be required to present more extensive evidence to justify a higher price in relation to the applicable thresholds, potentially undermining the thoroughness and fairness of the proceedings. Flexible time management tailored to the circumstances of each case would ensure that all parties have a meaningful opportunity to present their case, and that the panel is able to fully consider all relevant evidence and arguments.

(d) *Clear and transparent acceptance criteria for written requests*

In the event the Board continues to require written requests to depart from standard procedures, the Practice Directions should clearly specify transparent and objective criteria that the Board will use to assess and approve such requests. Importantly, the threshold for permitting such deviations

should not be so stringent as to require the demonstration of "exceptional circumstances." Instead, the criteria should allow parties to seek alternative formats or processes where justified by the complexity of the issues or the evidentiary needs of the case, ensuring flexibility and procedural fairness.

2. ***Strict Time and Page Limits***

The Coalition reiterates that the international pricing environment has become more uncertain and complex (notably due to MFN-style initiatives). In this context, rigid defaults may prevent parties from adequately contextualizing evidence and fully addressing justification and comparability issues that are central to the adjudicative function of the Board, as described in the QCCA Decision.

Specifically, Practice Directions 3 and 4 contemplate compressed motion timelines and strict default page limits, including page limits for expert reports, that are likely to be unworkable or procedurally unfair in complex proceedings, particularly where evidentiary records are significant, confidentiality constraints are acute, or where the panel must adjudicate "justification" issues that require detailed factual and expert testimony. As well, Practice Direction 2 fails to account for all forms of privilege in document exchange practices. We address these concerns below:

(a) *Motion timelines: defaults should be realistic and extensions should not require "exceptional circumstances"*

Despite the fact that hearings before the Board are not intended to be expedited, the proposed timelines impose unnecessarily and unreasonably compressed schedules without clear justification. This approach creates an artificial sense of urgency that is at odds with the complexity of Board proceedings, and risks undermining parties' ability to present comprehensive evidence and arguments.

Specifically, the proposed timelines imply that a responding party must make rapid decisions and file a responding record within a matter of days, with reply materials due shortly thereafter, and with extensions framed as available only in "exceptional circumstances." As above, the "exceptional circumstances" threshold is inherently vague and subjective, creating uncertainty for parties and a risk of inconsistent application. This standard is also overly strict and may deter parties from seeking necessary extensions, even in situations where additional time would be reasonable and justified. As well, aside from procedural fairness concerns, the proposed timelines do not account for the complex organizational structures and internal approval processes of patentees which can be lengthy.

Default motion timelines should be recalibrated to be workable across the range of PMPRB proceedings and the parties' internal administrative realities. The Coalition suggests to align motion timelines with those provided for in the *Federal Courts Rules* as a default, and extensions should be available on consent without having to meet a rigid "exceptional circumstances" threshold.

(b) *Page limits: defaults should better reflect complexity and evidentiary volume*

Proposed Practice Direction 4 contemplates strict page limits for merits and motions submissions, namely 30 pages for submissions on the merits (20 pages in reply) and 10 pages for motions (5 pages in reply), as well as a 15-page limit for expert reports. These page limits are subject to extension on written request only and with justification.

The Coalition submits that these limits risk constraining the parties' ability to present a coherent and complete case where proceedings involve complex economic evidence, international comparability issues, and confidential pricing dynamics. In addition to concerns of procedural fairness and flexibility, the practical effect may be to increase satellite disputes (such as requests for extensions) rather than to streamline proceedings.

The Coalition submits that default page limits should be increased to more realistically reflect the complexity of PMPRB hearings. In particular, there should be no page limit for expert reports. Given the technical and evidentiary complexity of the issues raised in these proceedings, expert evidence cannot be meaningfully or fairly constrained by arbitrary page limits. No other comparable tribunal imposes page limits on expert reports, including the Federal Court and other federal administrative tribunals such as the Competition Tribunal and the Copyright Board. Doing so here would risk undermining the ability of experts to fully explain their methodology, assumptions, and conclusions, to the prejudice of the parties and, ultimately, the Board's ability to properly decide the issues before it.

(c) *Privilege and confidentiality protections*

Finally, Practice Direction 2 on document exchange practices should expressly account for all forms of privilege in the document exchange framework, including solicitor-client and litigation privilege, given the sensitivity and confidentiality of pricing and commercial information often implicated in PMPRB matters.

3. ***Expediting Failure-to-File Proceedings***

In Proposed Practice Direction 5, the PMPRB premises that Failure-to-File (FTF) cases "often do not involve complex legal questions and may be based on smaller evidentiary records." FTF proceedings are therefore intended to be expedited by default, with a default abbreviated paper format (15 pages for submissions and 10 pages for reply) and a compressed schedule (90-day timetable).

The Coalition notes that the scope of PMPRB jurisdiction and related filing issues can be contested and evolving, and FTF cases should not be procedurally constrained on an assumption of simplicity. Rather, the Coalition submits that FTF matters often raise complex issues, such as whether a patent "pertains" to a medicine within PMPRB jurisdiction or whether a party qualifies as a "rights holder" required to file. An "expedited by default" model risks undermining fairness and increasing disputes about whether the matter should in fact be expedited.

Expedited FTF proceedings should be available only by agreement or where the panel determines following case management or after having heard the parties, as required, that the issues are genuinely straightforward and the evidentiary record is limited. The Practice Direction should expressly preserve the availability of an oral hearing component where warranted, rather than treating oral process as exceptional.

Finally, the Proposed Practice Direction uses language that may create ambiguity between an "abbreviated" process and an "expedited" process, potentially generating uncertainty. The Coalition encourages the PMPRB to clarify the terminology and articulate clear criteria for the adoption of an abbreviated/expedited stream where the scope of the matter so permits.

4. ***Overall Impartiality Concerns***

In addition to the above, the Proposed Practice Directions must be explicit in confirming that all procedural requirements apply equally to both parties. This is important because PMPRB staff may be at an advantage before the Board in a context where the Staff are effectively acting in a prosecutorial role. Indeed, the Staff have conducted the in-depth review, and they control and possess the underlying investigative record. If the Board Staff are permitted to place that record before the Board in support of their case, this would effectively allow them to "argue their case twice" – first during the review process and again at the hearing.

This creates procedural fairness concerns, particularly given the close institutional relationship between Staff and the Board and the risk that the Board is exposed to the Staff's theory of the case before the patentee has a full and equal opportunity to respond. Unlike a neutral tribunal counsel, Staff are not simply assisting the Board but are actively seeking an outcome, i.e. a finding of excessiveness and remedial orders.

In this context, it is especially important to clarify how documents and records held by Board staff are managed when a file proceeds from an in-depth review to a Board hearing. For example, Staff should be required to disclose the in-depth review record to the patentee in advance of the hearing. Ensuring procedural fairness means patentees must know the case they have to meet and must be afforded the same latitude to present their case before the Board.

Conclusion

The Coalition supports the PMPRB's objective of improving efficiency and predictability in hearings, but urges the PMPRB to ensure that default procedures do not become rigid constraints that undermine procedural fairness, particularly in complex cases and in the current international pricing landscape. The proposed Practice Directions unjustifiably undermine patentees' procedural rights in favor of administrative efficiency.

Above all, the Coalition reiterates that PMPRB procedure must remain anchored within the PMPRB's adjudicative role and constitutional jurisdiction, and that procedural instruments cannot functionally expand jurisdiction or undermine limits set by the Courts, as well as thwart the PMPRB's duty of procedural fairness.

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

Sincerely,

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