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IMC Response to the Consultation on the Patented Medicine Prices Review Board (PMPRB) Proposed Practice Directions

1. INTRODUCTION

Innovative Medicines Canada ("IMC") is the national association representing Canada's innovative pharmaceutical industry. We advocate for policies that enable the discovery, development, and delivery of innovative medicines and vaccines to improve the lives of all Canadians. IMC also supports its members' commitment to being valued partners in the Canadian healthcare system. Collectively, the industry supports more than 110,000 jobs, invests $3.2 billion in research and development annually, and contributes $18.4 billion to Canada's knowledge-based economy. As patentees subject to the jurisdiction of the Patented Medicine Prices Review Board (the "Board"), IMC's members have a direct interest in the procedures governing Board hearings.

IMC welcomes the Board's initiative to streamline its hearing procedures and appreciates the opportunity to provide comments on the proposed Practice Directions. We recognize and share the Board's stated goal of promoting hearings that are efficient, consistent, and adapted to modern practices, and are supportive where the proposed updates meaningfully advance those objectives without compromising the rights of the parties who appear before the Board.

However, IMC has significant concerns regarding a number of the proposed Practice Directions. PMPRB hearings are quasi-judicial, adversarial proceedings in which Rights Holders face enforcement action by Board Staff, with potentially severe financial and reputational consequences. In that context, the fundamental requirements of procedural fairness must take priority over institutional efficiency.

It is IMC's submission that several of the proposed Practice Directions fail to meet that standard. Rather than preserving the procedural rights of Rights Holders, they restrict evidentiary rights and impose additional procedural burdens on the very parties who already bear the burden of responding to enforcement proceedings initiated by a well-resourced institution. In some cases, the proposed Practice

Directions deviate from the standards applied by comparable courts and administrative tribunals in Canada without adequate justification.

IMC respectfully urges the Board to reconsider those provisions and to ensure that any final Practice Directions strike a proportionate balance between administrative efficiency and the procedural rights of the parties that appear before it.

2. SUMMARY OF IMC'S RECOMMENDATIONS

Our principal recommendations are summarized below, with reference to the corresponding Section of our submission that contains a more detailed explanation for each recommendation:

Mode of Hearing Constraints (Section 3): The conduct of hearings is highly fact specific. The mode of hearing (in-person/virtual, paper/live-testimony), as well as page limits on written arguments, are best determined by case management in discussion with the parties. Remove the 15-page default cap for expert witness reports entirely, consistent with Federal Court practice.

Motion Timelines and Page Limits (Section 4): Adopt default motion timelines consistent with Federal Court Rule 369 (10 days to respond; 4 days to reply) and a default 30-page limit for motion submissions consistent with Federal Court Rule 70(4). Replace the undefined "exceptional circumstances" threshold for timeline extensions under PD 3 with a consent-based mechanism and case management as a fallback. The default page limit under PD 4 should be set at a level that minimizes the need for parties to bring formal page limit extension requests.

Failure-to-File (FTF) Proceedings (Section 5): FTF proceedings should not be expedited by default. The 90-day compressed schedule and paper-only format should be available only on consent of both parties, with each proceeding subject to case management to determine an appropriate schedule.

AI Disclosure: Scope and Clarity (Section 6): Confirm on the face of the Practice Direction that disclosure obligations apply to all parties including Board Staff. Define "use of AI" consistently with the Federal Court's May 2024 AI Notice: disclosure required only where AI has functioned as a co-author, not for editing assistance, automation, or critique of human-generated content.

Procedural Clarity and Board Obligations (Section 7): Define key procedural terms and cross-reference them against the existing Rules. Commit the Board to corresponding timelines for its own rulings so that procedural predictability runs in both directions.

3. EVIDENTIARY AND HEARING PROCESS RESTRICTIONS

The proposed Practice Directions impose structural constraints on the evidentiary record that Rights Holders can place before the Hearing Panel. It does this both by capping the time available at oral hearings and by restricting the length of expert reports. Taken together, these measures risk compromising the quality and completeness of the record on which consequential pricing determinations are made, and primarily at the expense of the respondent party.

A. Default Hearing Constraints: PD 1 (Mode of Hearing), paras. 10-11

IMC appreciates the Board's willingness to consider different modes of hearing (paper/live testimony, in-person/virtual) as these options can facilitate important flexibilities and access to justice of the parties concerned. However, there is no one-size-fits-all approach to hearing requirements, which are highly fact-specific. There should be no paper or virtual default, particularly for witness and/or expert examinations where it is important for the Board to weigh credibility as part of its decision-making process. When combined with other proposed restrictions on argument and expert report page limits (discussed below), these default mechanisms present serious constraints on Rights Holders' abilities to make their case before the Board panel. The mode of hearing is best determined by case management informed by input from the parties and the facts of each case.[1]

For proceedings where an oral hearing takes place, the proposed Practice Direction imposes a "chess clock" model capping hearing time at 5 hours per day over 5-7 days, with 1-2 additional days for oral argument as agreed between the parties. While a structured hearing schedule is a sensible case management tool, the proposed default cap raises concerns in complex excessive price proceedings that may involve multiple expert witnesses, substantial documentary records, and contested legal and scientific questions.

IMC's concern is not with structured scheduling per se, but with the application of a fixed time cap as the default across all proceedings regardless of complexity. Hearings on excessive pricing matters are not uniform. Some may be resolved within the proposed parameters whereas others, such as those involving novel questions of pricing methodology, therapeutic class comparisons, or international pricing data, may require significantly more time. Given the numerous questions and areas for inquiry that Board Staff may pursue in an in-depth review (see the Appendices to the PMPRB Guidelines), hearing panels will frequently be asked to resolve multiple complex issues in a single proceeding.

[1] See e.g., the Federal Court and Competition Tribunal and their use of case management for hearings.

The practical burden of applying for additional time, which is itself an adversarial procedural step that consumes time and resources, should not be the primary mechanism for accommodating complex proceedings. IMC recommends that hearing length be determined through submissions of the parties at the case management conference based on the specific circumstances of each matter, with the proposed defaults available as an option where the parties agree.

B. Overly Restrictive Page Limits, Including on Expert Reports: PD 4 (Electronic Filing and Page Limits), paras. 6-8

The proposed Practice Direction on Electronic Filing and Page Limits establishes a default cap of 15 pages for expert witness reports filed in Board proceedings. IMC considers this limit to be fundamentally incompatible with the nature and complexity of expert evidence routinely required in PMPRB excessive price hearings.

Expert reports in PMPRB proceedings commonly address pharmacoeconomic modelling, comparative clinical evidence, international pricing analysis, and therapeutic class assessments, often across multiple drug indications and markets. Arbitrarily limiting such reports to 15 pages risks producing less rigorous evidence that undermines the quality of the record on which the Hearing Panel must decide, and denies Rights Holders a fair opportunity to fully plead their case in proceedings where the financial consequences can be significant.

The PMPRB's own Rules of Practice and Procedure already establish substantive criteria that expert reports must address.[2] Confining those reports to 15 pages would make it practically impossible for experts to satisfy the Board's own requirements. Furthermore, the Rules already regulate the number of expert witnesses a Rights Holder may call without leave. Imposing an additional page cap is therefore unnecessary as a means of managing expert evidence and serves only to restrict the depth of analysis that can be placed before the Hearing Panel.

The Federal Court of Canada does not impose page limits on expert reports in proceedings before it. There is no compelling basis for the Board to depart from that approach in proceedings whose complexity and consequences are comparable, and especially where experts do not testify before the Hearing Panel. IMC recommends that the 15-page default cap for expert reports be removed entirely, consistent with court practice.

More broadly, the proposed Practice Directions impose overly restrictive page limits in several other areas of concern to Rights Holders: written submissions on motions are capped at 10 pages (with only 5 pages for reply), and written submissions in

[2] *Patented Medicine Prices Review Board Rules of Practice and Procedure, SOR-2012-247.pdf [**PMPRB Rules**], ss. 8(2) and 8(3)(a).*

FTF proceedings are capped at 15 pages. These limits are addressed further in Sections 4 and 5 respectively. Page limits for written arguments in full hearings should be determined through case management based on input from the parties.

4. MOTION TIMELINES AND PAGE LIMITS: PD 3 (Standardizing Motions), paras. 4, 6, 7; PD 4 (Electronic Filing and Page Limits), paras. 5–7

A. Motion Timelines

The proposed Practice Direction on Standardizing Motions establishes the following default timelines: a responding party must indicate within 2 business days of service whether it intends to respond, and must file a complete motion response (including a supporting affidavit, written submissions, a statement of the order sought, and a list of authorities) within 5 business days of service of the notice of motion. A reply, where required, must be filed within a further 2 business days.

IMC submits that these timelines are unreasonably compressed and inconsistent with the standards applied in comparable federal proceedings. By way of direct comparison, Rule 369 of the *Federal Courts Rules* provides 10 days for a respondent to file its response and 4 days for reply. Five business days to prepare a complete motion response is inadequate for any motion of substantive significance, such as confidentiality disputes, expert witness objections, and production requests, all of which can involve complex facts and legal questions with material consequences for the proceeding and with no urgency justifying such compressed timelines.

Proceedings of this nature also require input and alignment from multiple functions within a pharmaceutical company, both across Canadian organizations and those with (often internationally based) parent corporations, and the proposed timelines do not account for Rights Holders' often complex organizational structures.

PD 3 permits Rights Holders to request timeline extensions by letter in cases of exceptional circumstances, but this is an inadequate substitute for reasonable default timelines. The "exceptional circumstances" threshold is undefined in the Practice Directions and based on its plain meaning, implies a high standard. In practice, the compressed timelines themselves may not provide a Rights Holder sufficient time to prepare and file a request for an extension before the deadline has passed.

B. Motion Page Limits

The 10-page limit for motion submissions compounds the timeline concern. Federal Court Rule 70(4) sets a 30-page limit for memoranda of fact and law. IMC recommends that the default page limit for written submissions on motions before the Board be set at 30 pages, consistent with this established benchmark. A more

generous default also reduces the administrative burden on both the parties and the Board associated with frequent applications for page limit extensions. While PD 4 provides a less onerous mechanism for seeking additional pages (i.e., a written request to the Board explaining the basis), the need to bring a formal request is itself a procedural burden that a more generous default limit would avoid.

IMC recommends that: (i) the default timeline for motion responses be aligned with Federal Court Rule 369 (10 days to respond, 4 days to reply); (ii) the default page limit for motion submissions be set at 30 pages; (iii) the "exceptional circumstances" threshold for timeline extensions under PD 3 be replaced with a consent-based mechanism, with case management as a fallback where the parties cannot agree; and (iv) the default page limit under PD 4 be set at a level that minimizes the need for parties to bring formal page limit extension requests.

5. FAILURE-TO-FILE PROCEEDINGS: Relevant Provisions: PD 5 (Expediting Failure-to-File Proceedings), paras. 1–7; PD 4 (Electronic Filing and Page Limits), paras. 6, 7

IMC wishes to address the proposed Practice Direction on Expediting Failure-to-File ("FTF") Proceedings with particular emphasis, as this is among the most consequential of the proposed directions for our members.

The Board contends that FTF proceedings are typically straightforward and capable of resolution on a compressed schedule, and "often do not involve complex legal questions and may be based on smaller evidentiary records." IMC, however, submits that this does not reflect the reality of these proceedings or what is at stake in them.

FTF proceedings typically arise when a Rights Holder does not file pricing information because it disputes that a medicine is subject to Board jurisdiction. Resolving this issue is neither simple nor inconsequential. A finding that a medicine falls within the Board's jurisdiction can expose the Rights Holder to liability for years of unreported sales and, potentially, concurrent excessive price proceedings. As an example, the Board's most recent FTF hearing (re: Galderma) concerned whether the Board had jurisdiction over a medicine that had not been reported for almost 7 years. The relatively limited case law on the PMPRB's FTF jurisdiction means that resolution of the legal issues at an FTF hearing is unlikely to be a simple matter.

The proposed Practice Direction establishes a default 90-day compressed schedule for all FTF proceedings, running from the date of the Notice of Hearing. Within that window, parties must confer, propose a schedule, file all evidence, complete any cross-examinations, and file written submissions. This is an exceptionally compressed timeline for any contested proceeding, particularly in circumstances where there is no urgency requiring an expedited determination, and where no harm results from a decision reached on a fuller and more appropriate timeline. The

proposed direction acknowledges that "unusually complex" FTF cases may warrant a different approach, but provides no criteria for making that determination, no mechanism for early identification of complexity, and no clear process for transitioning a matter out of the expedited stream once initiated. A Rights Holder who believes its case does not belong in the expedited track must apply for an oral hearing by letter and establish "exceptional circumstances", which is itself a burdensome and undefined threshold.

IMC's position is that FTF proceedings should not be expedited by default.[3] Each FTF proceeding should be subject to case management to determine an appropriate schedule based on the specific facts and legal issues involved. The proposed 90-day, or any other compressed schedule, and paper-only format should be available as an option, but only on the consent of both parties.

Taken together with the absence of a default oral hearing, the compressed timelines, and the reduced page restrictions (15 pages for submissions on the merits, 10 pages for reply), the proposed expedited FTF framework would significantly curtail the ability of Rights Holders to mount a full defence in proceedings that are often anything but routine, thereby raising a real risk that the Board's duty of procedural fairness is not met. IMC recommends that the default page limits for standard proceedings apply to FTF proceedings unless the parties consent to reduced limits appropriate to the specific matter, and that those limits be determined through case management.

6. ARTIFICIAL INTELLIGENCE DISCLOSURE: Relevant Provisions: PD 6 (Use of Artificial Intelligence in Proceedings), paras. 1, 4, 5

IMC supports the principle that parties and counsel bear responsibility for the accuracy of materials filed in Board proceedings and that the use of AI tools should be subject to appropriate oversight and professional accountability. The proposed Practice Direction's emphasis on counsel's ongoing responsibility and ethical obligations in the context of AI use reflects sound practice. It is also consistent with requirements being adopted by other courts and tribunals, most notably the Federal Court's Notice on the Use of Artificial Intelligence in Court Proceedings (May 7, 2024).

IMC raises two concerns with the proposed Practice Direction as drafted.

[3] See for e.g., Competition Tribunal, "Expedited Proceeding Process before the Tribunal" (January 2019) (illustrates operation of a flexible expedited process).

A. Application to Board Staff Should Be Made Explicit

The proposed Practice Direction states that "counsel and parties" must disclose their use of AI. As Board Staff is defined as a "party" under the PMPRB Rules of Practice and Procedure, this obligation technically applies to Staff as drafted. However, given that the PMPRB's own five-year Strategic Plan expressly states that Staff will explore AI tools for data processing, IMC recommends that the final Practice Direction make this application to Staff explicit on the face of the document. Clarity on this point is important to ensure that the rationale for AI disclosure (*i.e.*, accuracy, reliability, and fairness in adversarial proceedings) is seen to apply equally to all participants.

B. The Scope of "Use of AI" Requires Clarification

The proposed Practice Direction requires disclosure wherever AI has been used in "the preparation of any materials" for Board proceedings, without defining what constitutes such use. The concept of "use of AI" encompasses a wide variety of tools and applications, ranging from large language models generating substantive legal argument, to grammar-checking software, to document management automation. Applying the disclosure obligation uniformly across all of these would be unworkable in practice.

The Federal Court's May 2024 AI Notice provides a workable framework wherein a declaration is required where AI resembles the role of a co-author and content is directly provided by AI, but not where AI has been used to suggest changes, critique human-generated content, or perform automation and document editing functions. IMC recommends that the final Practice Direction adopt the same framework as the Federal Court, or a materially equivalent one.

7. PROCEDURAL CLARITY AND BOARD OBLIGATIONS

IMC notes that several provisions in the proposed Practice Directions accelerate party timelines without addressing the Board's own corresponding procedural obligations. Where Rights Holders are held to compressed deadlines, it is reasonable to expect the Board to commit to corresponding timelines for its own rulings on motions, page limit requests, and other matters requiring Board action. The final Practice Directions should set out what parties can expect in terms of the Board's response times. Predictability must run in both directions.

IMC also notes that the proposed Practice Direction on Standardizing Motions uses the terms "notice," "response," and "reply" in ways that do not always align clearly with their usage in the existing Rules of Practice and Procedure. For example, paragraph 4 refers to a party indicating within 2 business days whether it "wishes to respond", which appears to be a preliminary notice of intent distinct from the

formal response due within 5 business days, but this is not made explicit. Where the consequences of missing a deadline include the risk that a motion proceeds unopposed, clarity in the drafting is a procedural fairness requirement. IMC recommends that the final Practice Directions define these key terms and cross-reference them against the relevant provisions of the existing Rules, as failing to do so may well lead to further disputes between the parties who will seek recourse in the Federal Court; an outcome that would consume more time and resources for all participants and undermine the efficiency objectives of the Practice Directions.

8. CONCLUSION

IMC and its member companies support the PMPRB's objective of modernizing its hearing processes and promoting proceedings that are efficient, consistent, and proportionate. We recognize that the proposed Practice Directions reflect the Board's genuine effort to draw on its institutional experience and to adapt to evolving best practices across courts and administrative tribunals in Canada. Several aspects of the proposed Practice Directions, including the adoption of electronic filing as the default format and the formalization of virtual proceedings, reflect sensible modernization that IMC supports.

However, as set out in this submission, a number of the proposed Practice Directions would, if implemented as drafted, compromise the procedural rights of Rights Holders in ways that are not justified by the efficiency gains they are designed to achieve. PMPRB hearings are consequential enforcement proceedings. The parties who appear before the Board as respondents do so in an inherently asymmetric institutional environment, facing an experienced, well-resourced opponent in Board Staff, before a decision-maker drawn from within the same institution that initiated the proceeding. In that context, robust procedural protections are not "nice to haves" or a barrier to efficiency, but a necessity to ensure the foundation of a fair, credible, and legitimate process.

IMC respectfully requests that the Board consider the concerns and recommendations set out in this submission before finalizing the proposed Practice Directions. We would welcome the opportunity to discuss any aspect of our submission further and remain committed to constructive engagement with the Board on these important procedural matters.

Sincerely,

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