

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

The following document constitutes the response from Amgen Canada Inc. (“Amgen” or “we”) to the consultation on the Patented Medicine Prices Review Board (“PMPRB”) Proposed Practice Directions issued by PMPRB in March 2026 (“Directions”).

We support the response to the proposed Directions submitted by Innovative Medicines Canada. We will, however, make some supplementary comments on the proposed Directions.

We support the PMPRB’s effort to modernize its hearing processes and improve efficiency, consistency, and fairness. Clear procedural defaults can help reduce unnecessary burden and promote predictability. At the same time, the outcome of PMPRB proceedings can have significant consequences for rights holders, and hearings ought to reflect this reality. The proposed Directions confer significant discretion on the PMPRB in managing proceedings. While flexibility is important, greater guidance on how that discretion will be exercised would improve predictability and consistency. Our suggested changes recommend revisions on confidentiality, expert evidence, and hearing format in an aim to support PMPRB’s efficiency efforts while ensuring adequate protections and procedural fairness for parties.

Confidentiality requires a clearer default framework

The *Patent Act* recognizes that information filed with the Board may be commercially sensitive and protected unless and until disclosed at a public hearing. In our view, many of the documents that will be filed with the board or referred to in written or oral submissions will contain highly sensitive commercial, scientific, and strategic information that would be detrimental to parties if it became public. Our concern is that the proposed Directions do not provide a consistent or explicit framework for how this confidential information will be handled, and instead leaves the issue to ad hoc case management.

The proposed Directions currently require parties to identify confidential documents, provide grounds for confidentiality, and contemplates possible Board inspection and a deemed undertaking. These are helpful starting points, but they do not provide a sufficiently complete procedural framework. For example, the proposed Directions do not address what standard the Board will apply in assessing confidentiality claims, what level of protection is available, and who may access confidential materials. This uncertainty may generate unnecessary motion practice and undermine the efficiency the proposed Directions are intended to promote.

We recommend that the final Directions require confidentiality to be addressed expressly at the first case management conference, and should expressly provide that:

1. Parties may file confidential and public redacted versions of materials where appropriate;
2. Information designated as confidential will remain protected unless and until the Board orders otherwise;

3. Disputed materials will be treated as confidential on an interim basis pending determination of any challenge;
4. The Board may adopt enhanced protective measures, including restricted-access or counsel-and-experts-only arrangements, where justified by the sensitivity of the information; and
5. Production requests must remain proportionate, targeted, and no broader than necessary.

These measures would provide a practical structure for protecting commercially sensitive information without preventing the fair testing of evidence.

Expert reports should not be subject to a fixed page limit

We are concerned with fixed page limits for expert reports in complex matters. PMPRB hearings can be scientifically and economically complex proceedings that involve novel fact patterns, international elements, innovative drugs with few, if any, reference products, and cover multiple DINs and/or patents.

Expert evidence sufficient to address all these issues and explain the evidence cannot necessarily be presented adequately within a rigid page cap. Given the potentially significant consequences of PMPRB proceedings, an inflexible page cap could be materially prejudicial.

The final Directions should either avoid a fixed cap for expert reports or adopt a more realistic approach, such as requiring a concise executive summary while excluding appendices, schedules, literature, and CVs from any page count.

In-person hearings should not require exceptional circumstances

We are further concerned that non-paper portions of PMPRB hearings will presumptively proceed virtually. In-person hearings should be available where fairness requires them and not only in exceptional cases. These hearings may involve contested factual records, conflicting expert opinions, and extensive testimony on confidential commercial matters. In such cases, an in-person hearing would materially assist the Board in assessing the reliability and credibility of the witnesses and evidence, manage confidential exhibits, and ensure a fair and efficient hearing.

The final Directions should provide that, on request, the Board will consider ordering an in-person hearing where credibility or reliability is in question, there is extensive expert evidence, the materials are highly confidential, or other circumstances in which a virtual hearing is inappropriate.

We appreciate the opportunity to comment on the proposed Directions and would welcome further engagement as the PMPRB considers revisions. Thank you for considering these comments.

Respectfully submitted,

Signed by:

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Amgen Canada Inc.