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March 18, 2025

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Submitted via PMPRB Online Submission Form

Dear Ms. Perrault,

On behalf of Organon Canada, we wish to provide feedback on the Patented Medicine Prices Review Board's ("PMPRB") Draft Guidelines issued in December 2024.

Organon is an independent global healthcare company with a strategy to help improve the health of women throughout their lives. Organon's diverse portfolio offers more than 60 medicines and products in women's health, biosimilars, and a large franchise of established medicines across a range of therapeutic areas. In addition to Organon's current products, the company invests in innovative solutions and research to drive future growth opportunities in women's health and biosimilars. Organon has a global footprint with significant scale and geographic reach, world-class commercial capabilities, and approximately 10,000 employees with headquarters located in Jersey City, New Jersey.

As a subsidiary of Organon, Organon Canada greatly values the PMPRB's ongoing engagement with stakeholders and appreciates this opportunity to contribute to the consultation on the draft Guidelines. To this effect, Organon Canada wishes to bring to PMPRB's attention three points of key importance for your consideration: 1) impact of patent dedication; 2) international pricing sources; 3) PMPRB's jurisdiction.

1. Impact of Patent Dedication

Organon submits that the final version of the Guidelines must accurately reflect that the PMPRB ceases to have jurisdiction in the event of patent dedication.

The Draft Guidelines for PMPRB Staff continue to inaccurately assert that the PMPRB has jurisdiction over medicines whose patents have been dedicated to the public:

> 32. The PMPRB's jurisdiction over the price at which a patented medicine is sold in any market in Canada persists after the patent has been dedicated and until the cancellation or surrender of the patent pursuant to the express provisions of the Act or the expiry of the term of the patent. Patent dedication is not expressly recognized in the Act as a mechanism by which patent rights may be terminated before the normal expiry of the patent term.[8]

In support of this position, the PMPRB quotes a 1992 decision, *Genentech Canada Inc. (Re)* (1992), 44 CPR (3d) 316. However, in *Parke Davis Division v. Canada (Minister of Health)*, 2002 FCA 454 the Federal Court of Appeal specifically held that Genentech does not establish a general rule that patent dedication is impossible or not recognized by the Patent Act.

Instead, the Federal Court of Appeal confined the *Genentech* case to its very specific facts (namely an attempt to use a backdated dedication to retroactively deprive the PMPRB of jurisdiction), writing that *Genentech* "does not establish that it is impossible as a matter of law to surrender patent rights by means of a dedication to public use" (para 79) and that "the *Genentech* case is not on point because none of the Warmer-Lambert dedications were backdated" (para 83). Reliance on *Genentech* as creating a general rule that is impossible to dedicate a patent is inconsistent with contrary rulings from the Federal Court of Appeal.

Similarly, the Guidelines suggest that because patent dedication "is not expressly recognized in the Act" it is impossible. Once again, the Federal Court of Appeal has rejected this position in the *Parke Davis* case, writing that the Patent Act's "silence on this matter, however, is not determinative" (para 81).

The effectiveness of patent dedications has been recognized in multiple subsequent cases: *Sandoz Canada Inc. v. Abbott Laboratories*, 2010 FCA 168 at paras 30-40; also *G.D. Searle & Co. v. Merck & Co*, 2002 FCT 540 at para 96; Merck & Co. Inc. v. Canada (Health), 2010 FC 1043 at para 30. They are quite clear that dedication is a recognized and effective means of terminating patent rights. As the Federal Court held in *G.D. Searle* (later approved by the Federal Court of Appeal in *Sandoz*): "Applying the reasoning in *Parke Davis*, *supra*, and considering section 58 of the Act, I find that the dedication of certain claims to the public terminates a patentee's rights to a monopoly on the subject matter described in those claims" (para 96 of *G.D. Searle*, paragraph of *Sandoz* 33, 38). All of these decisions are binding upon the Board. Similarly-clear language was used in the Merck & Co case: "The Court recognizes that a dedication is an effective means by which a patentee can relinquish its patent rights" (para 30.1).

The Courts therefore recognize that dedication is an effective and legal way by which a patentee can relinquish its patent rights.

If a patentee relinquishes its patent rights on a medicine via dedication, then that medicine is no longer protected by a patent and accordingly, the PMPRB no longer has jurisdiction over that medicine.

Any other approach is inconsistent with the Federal Court of Appeal's recent decision in *Galderma Canada v Canada (AG)*, (2024 FCA 208) which clearly holds that :

> Quite simply, under the Constitution, the Patent Act and the jurisprudence under each, the Board does not have the power to regulate the prices of unpatented medicines during the period they are unpatented.(at para. 8).

Organon therefore urges the Board to reconsider its position regarding patent dedication and to follow the clear position of the Federal Court of Appeal in *Parke Davis* and subsequent cases.

2. International Pricing Sources

Organon encourages the PMPRB to provide greater clarity on the international price sources the PMPRB relies upon in its pricing assessments or will accept from patentees in their reporting.

Organon notes that the PMPRB provides a non-exhaustive list of potential international price sources at the following web page: "Potential Sources for Foreign Prices: PMPRB11." This list non-exhaustive and only provides examples of potential sources. It is furthermore not identified in the Draft Guidelines. and not all of the potential sources provide publicly available data.

Without further clarity or precision from the PMPRB on accepted international price sources, patentees should be given greater flexibility in the sources they provide as part of their reporting to the PMPRB, namely where public pricing information is not available.

3. Ensuring the PMPRB's jurisdiction extends only to patented medicines

Organon notes that paragraph 31 of the Draft Guidelines does not reflect the current state of the law as it relates to the scope of the PMPRB's jurisdiction. Indeed, the Federal Court of Appeal issued a decision in 2024, *Galderma Canada v Canada (AG)*, 2024 FCA 208, which expressly held that the PMPRB's jurisdiction extends only to patented medicines. The Court of Appeal held unanimously that: "Quite simply, under the Constitution, the Patent Act and the jurisprudence under each, the Board does not have the power to regulate the prices of unpatented medicines during the period they are unpatented."

This rule must be reflected in the new Guidelines' discussion of s. 79(2) of the Patent Act, since the Federal Court of Appeal provided clear guidance ruled that "Subsection 79(2) of the Patent Act does not give the Patented Medicine Prices Review Board the power to review unpatented medicines." This conclusion remains true even if a different, but related, medicine is under patent: "Nowhere does the Patent Act say that the Board can regulate an unpatented medicine just because a patented medicine

might be used in its place or because it shares some unpatented properties of the patented medicine (here, the unpatented ingredient adapalene)."

Organon therefore urges the PMPRB to ensure the current state of the law is accurately reflected in the Guidelines, notably that reference is made to the 2024 Galderma decision. In particular, paragraph 31 of the guideline should be amended:

- To remove the reference to *Galderma Canada Inc. v. Canada (Attorney General)*, 2017 FC 1023, since both that judgment and the Board's underlying decision were overturned on appeal (*Canada (Attorney General) v. Galderma Canada Inc.*, 2019 FCA 196).
- To replace the reference to I*CN Pharmaceuticals, Inc. v. Canada (Patented Medicine Prices Review Board)* [1996] F.C.J. No 1065 (C.A.) with a reference to *Galderma Canada v Canada (AG)*, 2024 FCA 208. Relying on the *ICN* decision and its "slender thread" metaphor risks leading the PMPRB Staff and later the Board itself into error.
- To add a bullet point clearly stating the overriding requirement that the Board's regulatory jurisdiction is limited to medicines protected by an active patent, and that the Board does not regulate the prices of unpatented medicines. For example: "Notwithstanding anything else in these Guidelines, the jurisdiction of this Board does not extend to unpatented medicines, that is, medicines which do not fall within the scope of an active Canadian patent *Canada (Attorney General) v. Galderma Canada Inc.*, 2019 FCA 196."
- To amend the discussion of clinical similarities in order to clarify that clinical similarities between a patented and unpatented medicine do not justify the price regulation of the latter. Once again the 2024 Galderma decision specifically considered clinical similarities between Differin and Differin XP at paragraph 12, then ruled that this did not justify regulation of the unpatented medicine at paragraph 13. Indeed, the Federal Court of Appeal even ruled that there was an "absence of alternative options available to the administrative decision-maker [i.e. the Board] on the facts of the case."

These amendments are necessary to conform the Board's draft Guidelines to the law as set out in the judgments of the Federal Court of Appeal. As that Court stated in its most recent Galderma judgment: the Board must temper its dedication and enthusiasm in pursuing its mandate "with a firm and unwavering obedience to legality and the rule of law."

Conclusion

Organon thanks the PMPRB for this opportunity to provide feedback on this final phase of consultations for the Final Guidelines and is committed to working cooperatively with the PMPRB to implement these Guidelines.

Sincerely,

Geneviève Gauthier
Executive Director, Corporate Affairs & Community Engagement
Organon Canada