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August 18, 2023

Mr. Thomas Digby
Chair, Patented Medicine Prices Review Board (PMPRB)
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Submitted via the PMPRB Website: Consultation Submission Portal

Re: Notice and Comment – Amendment to the Interim Guidance re: New Medicines (June 20, 2023)

Dear Mr. Digby,

Janssen Inc. (Janssen) appreciates the opportunity to comment on the PMPRB's proposed amendments to the Interim Guidance for new medicines. Of note, Janssen fully endorses the submissions by our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada.

Specifically, the PMPRB has proposed that "Medicines without a MAPP (Maximum Average Potential Price) or NEAP (Non-Excessive Average Price) as of July 1, 2022, are considered reviewed if their list price is below the median international price for the PMPRB11 countries. New Medicines that do not meet this criterion will continue to be under review until the new guidelines are in place."¹

Janssen understands that reducing pricing uncertainty is an objective of this consultation. However, we note that the proposed amendments to the Interim Guidance (i.e., list price less than the median international price [MIP] of the PMPRB11) are at odds with recent jurisprudence, which constrains the role of the PMPRB to the prevention of excessive pricing and patent abuse.^{2,3} As such, Janssen disagrees with using the MIP of the PMPRB11 as a benchmark when determining non-excessive pricing of patented medicines. Rather, we suggest that medications whose list prices fall below the highest international price (HIP) of the PMPRB11 should be deemed compliant with the Interim Guidelines.

Furthermore, Janssen notes that the proposed amendments to the Interim Guidance exclude any mention of updated NEAPs and patentees' ability to take consumer price index (CPI) -based price adjustments on existing medicines under the *Patent Act*. In the "Decision resulting from the consultation on the PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations" (issued August 18, 2022), the PMPRB stated that it was "...committed to completing the consultation process and issuing new Guidelines before

¹ Notice and Comment – Amendment to the Interim Guidance re: New Medicines (issued June 20, 2023)

<https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-new-medicines.html>

² FCA Alexion 2021

³ QCCA Merck 2022

January 1, 2023. If it is necessary to extend the Interim Period beyond that date because the Guidelines are not yet in place, the PMPRB will revisit the issue.”⁴ As the PMPRB has not implemented new Guidelines, Janssen is concerned that the PMPRB has also not posted updates online regarding 2023 CPI-based price adjustments, and to have learned that the Board’s intent is to have the 2022 NEAPs “...remain in place for the entirety of the Interim Period.”⁵

Therefore, for consistency with recent jurisprudence and the PMPRB’s mandate, Janssen proposes the following to ensure greater certainty during the Interim Period:

1. New Medicines (i.e., those without a MAPP or a NEAP as of July 1, 2022) should be considered reviewed and compliant if their list price is below the HIP of the PMPRB11. In this case, no re-evaluation or benchmarking should occur provided that the list price does not increase by more than the allowable CPI factors.
2. The PMPRB will provide patentees with updated NEAPs for existing products including consistently updating CPI-based price adjustment factors on an ongoing basis.

We sincerely appreciate the opportunity to provide our perspective on how best to foster an environment in Canada that attracts new investments and timely launches of innovative medicines and vaccines for Canadian patients.

Sincerely,

Berkeley Vincent
President

⁴ Decision resulting from the consultation on the PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations. (issued August 18, 2022)
<https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-price-review-approach/decision-price-review-approach.html>

⁵ Email correspondence between Carmen Osborne, Senior Regulatory Officer, Regulatory Affairs & Outreach Branch of PMPRB and David Zante, Director of Strategic Pricing at Janssen Inc. (March 27, 2023).