Johnson&Johnson

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March 19, 2025

Ms. Anie Perrault
Acting Chairperson, Patented Medicine Prices Review Board (PMPRB)
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 7C1

Dear Ms. Perrault,

Submitted *via* the PMPRB consultation website

Re: PMPRB Phase 3 Consultation on new Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation (December 2024)

Janssen Inc., a Johnson & Johnson (J&J) company, is pleased to provide its written feedback in response to the PMPRB's Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation ("Draft Guidelines") published on December 19, 2024. Of note, J&J fully endorses the submissions by our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada, as well as the written submission provided by the industry coalition that brought the Constitutional Challenge in Québec (of which J&J is a member).

J&J acknowledges the PMPRB's efforts to advance Draft Guidelines that align recent amendments to its Regulations[1] with judicial guidance on the scope of its mandate and powers[2] and integrate feedback from stakeholder consultations conducted over the past several years.

To ensure that the Final Guidelines uphold the principles of fairness, transparency, openness, and predictability,[3] as well as comply with the constitutional division of powers, J&J's submission emphasizes the need for additional revisions to the Draft Guidelines to facilitate objective evaluations of patented medicine pricing within the framework intended by the *Patent Act*.

Background and Context
The case law to date has established the following principles:

- Federal jurisdiction over "patents of invention and discovery," under section 91(22) of the *Constitution Act, 1867*, is a narrow power.[4]
- The scope of the PMPRB's constitutional mandate is to prevent excessive prices stemming from an abuse of the monopoly granted by a patent.[5]

[1] Effective June 1, 2022.

[2] *Merck Canada c Canada*, 2022 Quebec Court of Appeal (QCCA); *Alexion v Canada*, 2021 Federal Court of Appeal (FCA).

[3] PMPRB *Compendium of Guidelines, Policies and Procedures (June 2009); Implementation: January 1, 2010*; PMPRB *Compendium of Guidelines, Policies and Procedures – Updated February 2017*.

[4] *Merck Canada c Canada*, 2022 QCCA 240 ¶143-146, 153, 163, 179, 243-244.

[5] *Merck Canada c Canada*, 2022 QCCA 240 ¶143-146, 153, 163, 179, 216, 243. See also *Galderma v. Canada (AG)*, 2024 FCA 208 ¶12-19.

- The PMPRB is not a price regulator. Its role is "to determine an introductory price in Canada that is not excessive, and which may subsequently evolve in accordance with the CPI without triggering a more thorough inquiry by the Board."[6]
- Any efforts to exceed this scope to achieve optimal pricing or to drive prices below non-excessive thresholds would violate federal patent authority.[7]

Review Process: Initial Review + Annual Review

The Draft Guidelines describe a two-step review process for patented medicines sold in Canada. The first step - Initial Review and Annual Review - prioritizes cases for In-Depth Review. The Initial Review uses the highest international price (HIP) among Schedule Countries (PMPRB11) set by the Rights Holder, while the Annual Review uses both the HIP and the Consumer Price Index (CPI).

J&J supports the position of the Constitutional Coalition and our industry associations, IMC and BIOTECanada, that in accordance with the Court of Appeal for Quebec's decision in *Merck Canada c Canada*, 2022 QCCA 240 (the QCCA Decision), the HIP is the only appropriate international price comparator for Initial Review, and that after Initial Review, the allowable CPI increase is the only appropriate factor for Annual Reviews. The PMPRB cannot re-assess or re-benchmark the price of a medicine at the Annual Review against any criteria other than the allowable CPI increase, without venturing beyond its mandate into a constitutionally inappropriate exercise of price regulation/control.

The Appendix accompanying J&J's written feedback provides two illustrative examples (**Example 1** and **Example 2**) to substantiate this position.

Review Process: Existing Medicines

To ensure alignment with judicial guidance regarding the scope of the PMPRB's mandate and powers, J&J asserts that the Final Guidelines should explicitly state that Existing Medicines are exempt from an Initial Review.

The PMPRB11 cannot be used to arbitrarily reduce the prices of Existing Medicines that were deemed non-excessive under the former Regime as this would amount to price control. A price that has already been determined to be non-excessive cannot suddenly become excessive if any increase is limited to adjustments reflecting the CPI. Evaluating Existing Medicines based on any criteria other than the CPI is outside the constitutional authority of the PMPRB.

Initial Review: Sufficient International Price Data

The Draft Guidelines acknowledge that during the initial launch period of a New Medicine, the prevailing HIP is sensitive to the availability of list prices in the Schedule Countries (i.e. the HIP threshold for triggering an In-Depth Review may increase once the medicine is listed in another Schedule Country). It follows that conducting an Initial Review for a New Medicine with limited

[6] *Merck Canada c Canada*, 2022 QCCA 240 ¶143-146. See also *Innovative Medicines Canada v. Canada (Attorney General)*, 2020 FC 725 ¶199.

[7] *Merck Canada c Canada*, 2022 QCCA 240 ¶146, 197, 228, 243-244.

international price reference data may lead to misleading conclusions about whether a New Medicine's introductory list price reflects an abuse of patent monopoly.

Example 3 in the Appendix to this letter reinforces this position.

Implementing the criterion that an Initial Review will occur once one or more prices for the medicine are reported in any of the Schedule Countries in the Final Guidelines may result in Rights Holders delaying the launch of New Medicines in Canada until another Schedule Country establishes the HIP, which could significantly impact the health and quality of life of Canadians.

The *Patent Act* aims to ensure that the prices of patented medicines sold in Canada remain competitively objective and do not exceed the prices of the same or similar medicines in countries that are reasonably comparable to Canada. As outlined in the QCCA Decision, the PMPRB's mandate is limited to preventing excessive prices resulting from the abuse of the monopoly granted by a patent.

To address this issue, J&J recommends that the Final Guidelines maintain the current parameters for conducting the Initial Review of a New Medicine: (i) three years from the introduction of the patented medicine in Canada, or (ii) when the patentee provides international price information from at least five of the PMPRB11 countries. Applying these criteria will facilitate an objective and constitutionally appropriate assessment of patent abuse, as well as enable the PMPRB to allocate its resources more effectively.

In-Depth Review Process

J&J shares the concerns raised by IMC and BIOTECanada that the In-Depth Review process in the Draft Guidelines lacks the clarity needed to uphold the principles of fairness, transparency, openness, and predictability.

For instance, the inclusion of Associated DINs and each of their approved indications may result in unpredictable Therapeutic Class Comparison (TCC) outcomes for medicines with multiple indications and various dosage presentations — such as vials for intravenous infusions, pre-filled syringes, auto-injectors, and vials for subcutaneous injections — based on a single initiating DIN.

J&J contends that DINs not meeting the criteria for initiating an In-Depth Review should be excluded from the process. By incorporating DINs for patented medicines priced below the HIP, the PMPRB is overstepping its patent jurisdiction.[8] Furthermore, to align with judicial guidance, the In-Depth Review process should employ the "top of TCC" approach, wherein the highest-priced brand product among comparators with similar characteristics establishes the standard.

Additionally, the PMPRB's proposed practice of issuing deferral letters — potentially multiple times — combined with unclear In-Depth Review procedures and indefinite excess revenue accruals creates a burdensome and unpredictable pricing environment. This uncertainty may compel Rights Holders to delay the launch of New Medicines, ultimately diminishing health outcomes and the quality of care for Canadian patients.

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[m] *Merck Canada c Canada*, 2022 Quebec Court of Appeal (QCCA); *Alexion v Canada*, 2021 Federal Court of Appeal (FCA).

Complaints

J&J submits that the "Special Provisions for Complaints" should be removed from the Final Guidelines, as the *Patent Act* does not provide a legal basis for such complaints. In the alternative, any complaints process should be confined to the Federal, Provincial, and Territorial Ministers of Health and should only address issues specifically related to the criteria in Section 86(2) of the *Patent Act*. Allowing complaints from for-profit insurance companies and their associations would create conflicts of interest due to their profit-driven nature.

In closing, J&J would like to thank the PMPRB for the opportunity to provide its feedback on the Draft Guidelines. We remain committed to working collaboratively to ensure that patients have timely access to our innovative therapies while maintaining a sustainable healthcare system. We look forward to continuing this partnership for the benefit of all stakeholders involved.

Sincerely,

Berkeley Vincent
President

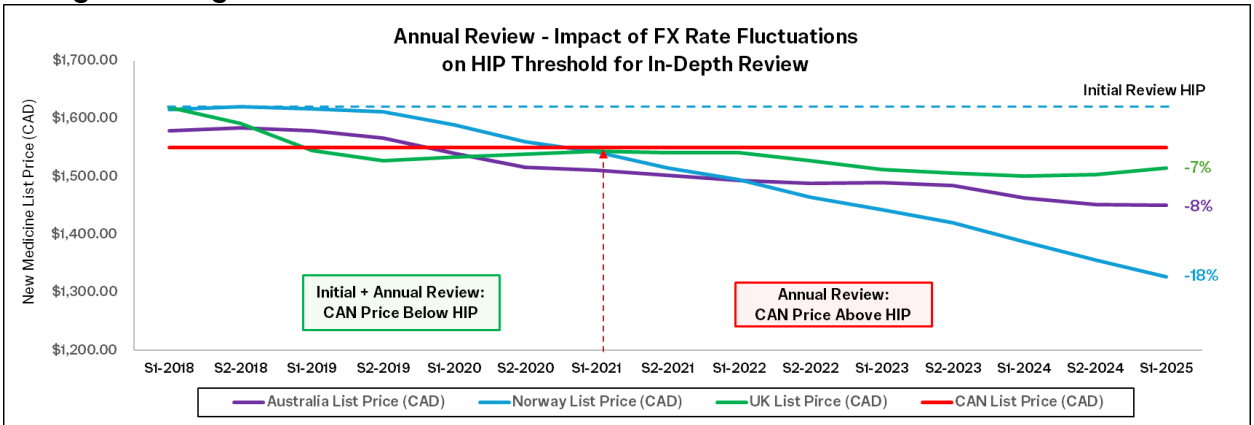
APPENDIX

Example 1 - Draft Guidelines' Annual Review Process Exceeds PMPRB's Mandate

For illustrative purposes, the Draft Guidelines' Initial + Annual Review process is applied to a "New Medicine" launched in Canada, Australia, Norway and the United Kingdom (UK) in January to June 2018 (**Figure 1**). This timeframe was selected to leverage PMPRB's 36-month average exchange rates for the S1-2018 to S1-2025 semi-annual filing periods.

Figure 1 demonstrates that re-benchmarking the price of the New Medicine against the HIP during the Annual Review process would lead to an In-Depth Review solely due to foreign exchange fluctuations, which exceeds PMPRB's mandate. The role of the PMPRB is "to determine an introductory price in Canada that is not excessive, and which may subsequently evolve in accordance with the CPI without triggering a more thorough inquiry by the Board."[9]

Figure 1: Annual Review Process – In-Depth Review Triggered Solely Due to Fluctuations in Foreign Exchange Rates



PMPRB FX rate	S1-2018	S2-2018	S1-2019	S2-2019	S1-2020	S2-2020	S1-2021	S2-2021	S1-2022	S2-2022	S1-2023	S2-2023	S1-2024	S2-2024	S1-2025
Australia	0.98096944	0.98395556	0.98059167	0.97280278	0.95630000	0.94142500	0.93840278	0.93269722	0.92769722	0.92452222	0.92553056	0.92187778	0.90856667	0.90195000	0.90084722
Norway	0.157658333	0.158108333	0.157725	0.157291667	0.155066667	0.152266667	0.150461111	0.147825	0.145861111	0.142888889	0.140816667	0.138555556	0.135325	0.132316667	0.129428241
UK	1.799824081	1.769148284	1.716568576	1.697592308	1.703513889	1.710230556	1.715566667	1.712158333	1.713136111	1.696752778	1.679833333	1.673883333	1.668002778	1.670038889	1.682753241

CAD: Canadian dollars; CAN: Canadian; FX: PMPRB 36-month average foreign exchange rate; HIP: highest international price; UK: United Kingdom.
Notes: (A) For illustratrie purposes the new patented medicine in this example is referred to as a "New Medicine." (B) Introductory list prices for New Medicine in local dollars - CAN = $1,550.0000 CAD; Australia: $1,610.0000 AUD; Norway: 10,250.0000 NOK; United Kingdom: 900 GBP.

Issue/Facts:

- During the Initial Review, the Canadian list price for the medicine is less than the HIP set by Norway. The Canadian list price is also lower than the list prices filed for the medicine in Australia and the UK.
- After its launch, the list price for the medicine in local dollars remains unchanged in these countries.
- During the 2021 Annual Revew, the Canadian list price is above the HIP. This triggers as In-Depth Review.

[9] *Merck Canada c Canada*, 2022 QCCA 240 ¶143-146.

- The Canadian list price remains above the HIP from S1-2021 to S1-2025, which triggers another In-Depth Review during the third subsequent reporting period after the initial In-Depth Review was closed.

Analysis:

- The introductory Canadian list price for the medicine does not meet the criteria for abuse of patent monopoly because it is lower than the list prices for the medicine filed in the Schedule Countries that launched the product.
- The Canadian list price exceeded the Annual Review HIP threshold solely due to fluctuations in foreign exchange rates.
- The Canadian list price for the medicine cannot reasonably be deemed excessive following an Annual Review because its list price did not evolve.
- Although the list price for the medicine in local dollars remained unchanged, fluctuations in foreign exchange rates from S1-2018 to S1-2025 led to declines of -7%, -8%, and -18% in its Canadian-equivalent list price for Australia, the UK, and Norway, respectively. A buffer of ±10% would not have prevented triggering an In-Depth Review.
- An In-Depth Review conducted because of fluctuations in exchange rates is also an inefficient application of resources, both of the PMPRB and the manufacturer – creating unnecessary burden and cost.

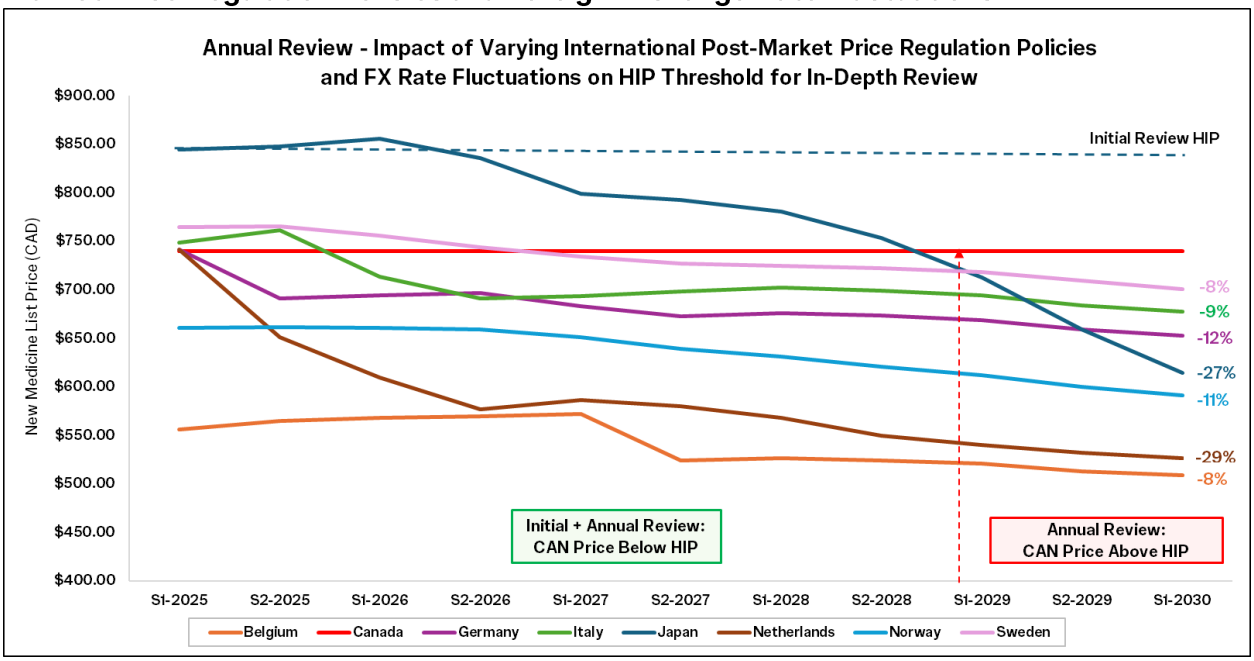
Example 2 - Draft Guidelines' Annual Review Process Exceeds PMPRB's Mandate

The Schedule Countries in PMPRB's reference pricing basket were chosen because they all have established policies and regulations for pricing patented medicines.

Figure 2 shows how different international price regulations and foreign exchange rate changes affect the HIP threshold for triggering an In-Depth Review for a patented IV oncology medicine that loses its patent exclusivity in several Schedule Countries. In Canada, IV-infused oncology drugs are almost exclusively funded by Public Payers. The net prices for these drugs are controlled at the Provincial and Territorial levels based on the confidential terms of negotiated product listing agreements.

This example provides further support that using the HIP to re-benchmark the price of a patented medicine in its Annual Review exceeds the PMPRB's mandate.

Figure 2: Annual Review Process – In-Depth Review Triggered by Varying International Post-Market Price Regulation Policies and Foreign Exchange Rate Fluctuations



CAD: Canadian dollars; CAN: Canadian; FX: PMPRB 36-month average foreign exchange rate; HIP: highest international price; IV: intravenous.
Notes: (A) %he list price percentage decreases reported in Figure 2 represent the difference in the New Medicine's list price (in CAD) in S1-2025 vs. S1-2030; (B) To model the impact of foreign exchange rate fluctuations, PMPRB's 36-month average exchange rates from S1-2018 were applied to S1-2025, the 36-month average exchange rates from S2-2018 were applied to S2-2025, the S1-2019 rates were applied to S1-2026, the S2-2019 rates were applied to S2-2026, etc.

<u>Issue/Facts:</u>

- During the Initial Review, the Canadian list price is less than the HIP set by Japan. The Canadian list price is also less than the list prices filed in Sweden and Italy and is comparable to the list prices filed in Germany and the Netherlands.
- After its launch, the Canadian list price for the medicine remains unchanged; however, the Canadian-converted international reference prices for the medicine decline due to foreign

exchange rates. In several of the Schedule countries, biosimilar entry pricing regulations contribute to its decline.
- An In-Depth Review is triggered during the 2029 Annual Review because the Canadian list price is above the HIP threshold.

Analysis:

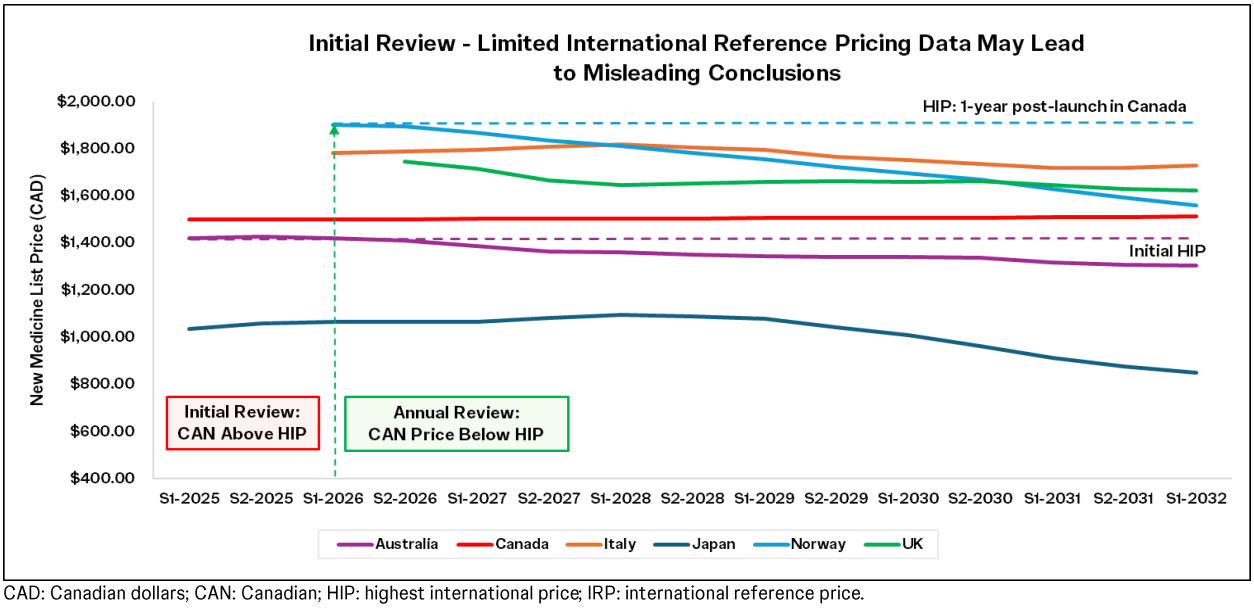
- As per case law, the PMPRB cannot re-assess or re-benchmark the price of a medicine at the Annual Review against any criteria other than the allowable CPI increase.
- The In-Depth Review was not triggered because the Canadian list price exceeded the allowable CPI increases.
- Variations in PMPRB11 post-market pricing regulations can not be used to arbitrarily reduce the prices of patented medicines that do not evolve beyond thier introductory list price and allowable CPI increases.

Example 3 – Draft Guidelines' Introductory Price Review Policy May Lead to Misleading Conclusions

The Patent Act aims to ensure that the prices of patented medicines sold in Canada remain competitively objective and do not exceed the prices of the same or similar medicines in countries that are reasonably comparable to Canada.

Figure 3 demonstrates the impact of conducting an introductory price review with limited international price reference data.

Figure 3: Initial Review Process – Limited IRP Data Triggers In-Depth Review That Considers All Associated DINs



CAD: Canadian dollars; CAN: Canadian; HIP: highest international price; IRP: international reference price.
Notes (A) To model the impact of foreign exchange rate fluctuations, PMPRB's 36-month average exchange rates from S1-2018 were applied to S1-2025, the 36-month average exchange rates from S2-2018 were applied to S2-2025, the S1-2019 rates were applied to S1-2026, the S2-2019 rates were applied to S2-2026, etc.

Issue/Facts:

- The New Medicine's first semi-annual price filing, which includes list prices for the medicine in two Schedule Countries (Australia and Japan), is used to conduct its Initial Review.
- The Canadian list price for the New Medicine exceeds the HIP set by Australia during the Initial Review.
- An In-Depth Review is triggered, which considers all Associated DINs.
- The New Medicine's third semi-annual price filing now includes list prices for the medicine in five Schedule Countries.
- The Canadian list price is less than the new HIP set by Norway, as well as less the international reference prices in Italy and the UK.

Analysis:

- Although the Canadian list price for the New Medicine exceeds the HIP during the Initial Review, additional international price reference data filed in its third semi-annual price

filing demonstrates that the Canadian price is competitively objective and does not exceed the prices of the same medicines in countries that are reasonably comparable to Canada.

- Conducting an introductory price review with limited international price reference data may lead to a misleading conclusion that its introductory price is an abuse of its patent monopoly. This may also lead to an arbitrary reduction in its list price, as well as lead to arbirtrary price reductions for its Associated DINs.
- Importantly, the manufacturer may wish to avoid triggering an In-Depth Review and choose to delay selling this medicine in Canada for a year, until additional countries (e.g. Norway) have launched and established a new HIP.