Janssen Inc.

19 Green Belt Drive
Toronto, ON M3C 1L9
1.800.387.8781 toll free
416.449.9444 tel
416.449.2658 fax

www.janssen.ca

September 11, 2024

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 Written Submissions

Re: Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines (June 26, 2024)

Dear Mr. Digby,

Janssen Inc., a Johnson & Johnson company (J&J) appreciates the opportunity to comment on the Patented Medicine Prices Review Board's (PMPRB) Discussion Guide for the Consultation on the Board's Guidelines. Of note, J&J fully endorses the submissions by our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada, in addition to the feedback provided by the industry coalition that brought the Constitutional Challenge in Québec (of which J&J is a member).

J&J appreciates the collaborative approach from PMPRB throughout the development of new guidelines, and we look forward to future engagements that "…uphold the principles of fairness, transparency, openness, and predictability"[1] as under the 2010 Guidelines.

J&J has provided comments on specific topics in the Discussion Guide. In the absence of the context of a complete set of draft Guidelines, it is challenging to respond to certain topics and questions posed within the Discussion Guide. Once the new draft Guidelines are available for stakeholder input, J&J will be pleased to conduct a thorough review and provide comment on the full context which they encompass. Furthermore, J&J proposes that the PMPRB conducts a financial impact study of the new draft Guidelines so that all stakeholders may understand their significance.

Background

J&J wishes to emphasize that in drafting new Guidelines, the PMPRB must consider the scope of its mandate. Federal jurisdiction over "patents of invention and discovery," under section 91(22) of the *Constitution Act, 1867*, is a narrow power, recently commented upon in a decision rendered by the Québec Court of Appeal: to prevent the abuse of patents and excessive pricing of patented medicines.[2] Furthermore, the Québec Court of Appeal indicated that any move towards seeking a reasonable price is unconstitutional and exceeds the PMPRB's mandate.[3]

---

[1] PMPRB. Compendium of Policies, Guidelines and Procedures, Updated February 2017.

[2] Merck Canada c Canada, 2022 QCCA 240 ¶ 143-146, 153, 163, 179.

[3] Merck Canada c Canada, 2022 QCCA 240 ¶ 156, 204, 228, 235

This is to say that the PMPRB should exercise its mandate on excessive pricing and patent abuse, while the provincial agencies should ensure that they can negotiate appropriate prices for medicines. Price control is a provincial mandate and should be managed by the appropriate process.

In a 2022 ruling, the Québec Court of Appeal defined an excessive price of a patented medicine as "…a price that, without justification, exceeds the price of other medicines in the same therapeutic class or that otherwise exceeds the price for the same medicine in countries reasonably compared to Canada."[4] It is imperative that the new Guidelines reflect these limits as defined within the Québec Court of Appeal decision.

Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review
The introductory price review of new patented medicines should be based on the highest international price (HIP) (Option 2). The new basket no longer contains countries with free market pricing, and each country has specific policies in place to regulate list prices. Using the HIP as the price level is simple, and offers predictability and transparency while aligning with recent jurisprudence. Any other price level (e.g. MIP or midpoint between MIP and HIP) would be arbitrary, and inconsistent with a reasonable definition of excessive price.

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criterion for an Existing medicine is met
J&J believes that existing medicines that were compliant with their NEAP should be "grandfathered" and deemed compliant going forward. A similar practice was employed by the PMPRB when the Guidelines were updated in 2010.

Special consideration should be afforded medications launched after Jan 1, 2022 without a Non-Excessive Average Price (NEAP) or Maximum Average Potential Price (MAPP), regarding the timeline to comply with new guidelines. These medications were launched under the uncertainty associated with the Interim Guidance period, and should be allowed at least 3 years to come into compliance.

Topic 3: In-depth review based on CPI increase criteria
J&J recommends that CPI increase criteria allow for combined CPI of the past two years (Option 2).

Topic 4: The individuals/groups permitted to submit a complaint
Complaints should be limited to the Federal/Provincial/Territorial Minister of Health (Option 1).

Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines.
Medicines that should only be subject to an in-depth review following a complaint include:

- Vaccines
- Biosimilars
- Patented medicines that have lost exclusivity (i.e. biosimilar or generic competition exists)
- All medicines procured exclusively through government tenders (e.g. Canadian Blood Services / Héma-Quebec)

Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC.
J&J is unable to provide a specific recommendation on Topic 6, without more context and clarity on how the therapeutic class comparison (TCC) would be conducted. Given the mandate of the PMPRB

[4] Merck Canada c Canada, 2022 QCCA 240 ¶ 49

to ensure prices are not excessive, the price test associated with TCC should be the highest. Overall, a medicine should be allowed the higher of HIP or TCC. J&J recommends a working group be established to explore this topic.

Topic 7: Future role of HDAP

J&J recommends that HDAP continue to provide an independent advisory role to PMPRB Staff. The specific role and mandate of HDAP should be explored in the same working group proposed for Topic 6.

Apart from the specific topics & questions in the Discussion Guide, J&J offers the following additional feedback & recommendations:

- Prices should be evaluated once, upon first sale. In the absence of a valid complaint or a price that exceeds the allowable CPI increase, no further price reviews should be required. Historically, the PMPRB has not "re-benchmarked" products, as other mechanisms exist to address the affordability concerns of payers (public and private product listing agreements). Re-benchmarking may create arbitrary price changes throughout a product's life cycle, which does not align with recent jurisprudence or the mandate of the PMPRB, and also reduces predictability and transparency
- New guidelines should provide more clarity around the specific process for conducting therapeutic class comparisons and the price threshold that is applied. Regardless of methodology, the price threshold applied should be highest of the class
- Mechanisms to alleviate unnecessary administrative burden should be specified in new guidelines:
    - Reasonable timelines to comply with international price comparisons, to avoid unnecessary in-depth reviews
    - Introductory pricing assessments should not be performed until prices are available in a minimum of five countries, or three years has elapsed
    - Accommodation for fluctuations in exchange rates, and thresholds of tolerance vs international price targets (e.g. plus or minus 5% vs PMPRB11 HIP) to avoid unnecessary in-depth reviews

J&J appreciates the opportunity to provide feedback on the Discussion Guide, and thanks the PMPRB for considering our feedback in the overall development of new Guidelines.

Sincerely,

Berkeley Vincent

Digitally signed by Berkeley Vincent
DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=31001005, cn=Berkeley Vincent
Reason: I am the author of this document
Date: 2024.09.11 13:54:47 -04'00'
Adobe Acrobat Reader version: 2020.013.20064

Berkeley Vincent
President