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December 20, 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 – Scoping Paper for the Consultations on the Board's Guidelines (November 10, 2023)*

Dear Mr. Digby,

Janssen Inc. (Janssen) appreciates the opportunity to comment on the Patented Medicine Prices Review Board's (PMPRB) Scoping Paper for the Consultation on the Board's Guidelines. Of note, Janssen fully endorses the submissions by our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada, in addition to that provided by Fasken on behalf of the Constitutional Coalition.

Janssen is pleased with the PMPRB's collaborative approach during this consultation period, and we look forward to future engagements that "…uphold the principles of fairness, transparency, openness, and predictability"[1] as under the 2010 Guidelines.

For the purpose of this submission, Janssen opts to comment on specific points rather than on all of the themes or questions put forth in the Scoping Paper. In the absence of the context of a complete set of draft Guidelines, it is challenging to respond to the questions posed within the Scoping Paper. Once the new draft Guidelines are available for stakeholder input, Janssen will be pleased to conduct a thorough review and provide comment on the full context which they encompass. Furthermore, Janssen proposes that the PMPRB conducts an impact study of the new draft Guidelines so that all stakeholders may understand their significance.

The Canadian healthcare ecosystem is complex, with very specific constitutionally mandated provincial and federal roles and responsibilities. The division of powers between the federal Parliament and provincial legislatures is the cornerstone of the federal bargain struck in 1867. It remains one of the foundational pillars of our constitutional order down to the present day. It was designed to ensure that each head of power was assigned to the level of government best positioned to exercise that power. When it comes to the regulation of particular business activities, as well as healthcare, the provinces were recognized as being best positioned to calibrate legislation to their unique circumstances. The courts have repeatedly confirmed that price control, as well as healthcare, both fall under the exclusive jurisdiction of the provinces.

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

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]

Janssen joined the Québec Constitutional challenge to ensure that federal and provincial agencies were following their appropriate mandates. 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.

As such, the introductory price review of new patented medicines should be based on the higher of the highest (i.e., noting that the price is not excessive if it does not exceed the highest international price [HIP] of the PMPRB11 plus allowable Consumer Price Index [CPI] increases once pricing is available from five countries, or after three years, whichever comes first). This approach is simple, and it offers predictability and transparency while aligning with recent jurisprudence.

In addition, there should be no distinction in price tests used between existing and new medicines. The use of different price thresholds here would signal an attempt to ensure prices fall below non-excessive levels. Specifically, Janssen believes that existing medicines should be grandfathered and deemed compliant going forward. A similar practice was employed by the PMPRB when the Guidelines were updated in 2010.

Moreover, prices should be evaluated once, upon launch. In the absence of a valid complaint or a price that exceeds the allowable CPI increase, no further price reviews should be required. This offers the ecosystem predictability, fairness, openness, and transparency. Historically, the PMPRB has not rebenched products, as public and private product listing agreements (PLAs) address the affordability concerns of payers over time. Furthermore, rebenching would effectively create arbitrary price changes during the product's life cycle and this does not align with recent jurisprudence and the PMPRB's mandate.

[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

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

Janssen aspires to have an efficient, predictable, and non-duplicative system that respects the constitutional mandate of the federal and provincial governments. If Guidelines are clear and predictable, we expect that voluntary compliance would be likely, and investigations would be infrequent. This, in itself, will provide a strong foundation to the Canadian life sciences sector ensuring Canadians have access to the best innovative treatments both today and tomorrow.

Sincerely,

Berkeley Vincent

Berkeley Vincent
President

Berkeley Vincent

Digitally signed by Berkeley Vincent
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