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

Via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: *Notice and Comment – On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions* (July 15, 2021)

Dear Dr. Levine,

Janssen Inc. strongly opposes the proposed Guideline amendments, with the exception of the change to the definition of the Gap medicines. In contrast to the PMPRB's stated rationale for the proposed amendments [1], the change to the international price tests for Grandfathered medicines and their line extensions (and the consequent need to change the references to the comparator countries from "PMPRB11" to "Scheduled Countries") is not "appropriate" and adds greater pricing complexity and uncertainty for patient access to the most effective medications. Furthermore, Janssen continues to challenge the constitutionality of the existing PMPRB regime, as well as the Amendments and associated Guidelines as unconstitutional, as the federal patent power does not allow the federal government to regulate drug prices, in the absence of patent abuse. [2]

These unwarranted, and yet consequential, changes reinforce the unpredictability within the Canadian pharmaceutical and life sciences market, thus making it less attractive for new investments and timely launches of innovative medicine and vaccines. The latest actions of the PMPRB undermine the objectives of Canada's Biomanufacturing and Life Sciences Strategy [3] and places Canada at a disadvantage with respect to future pandemic readiness and managing other healthcare crises. Furthermore, the timing of the proposed Guideline amendments and consultation completely

[1] "The proposed consequential changes to the new Guidelines described above are believed to be an appropriate response to the most recent six-month extension in the coming-into-force date of the Regulations, to January 1, 2022. In particular, the changes in dates, terminology and transition measures address the need for further clarity at the Guidelines level…" (https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-references-comparator-countries.html)

[2] Janssen Inc is a litigant in a case challenging the constitutionality of the PMPRB regime as well as the Amendments and associated Guidelines currently pending before the Quebec Court of Appeal. Nothing in this submission is an admission in, or derogation from, Janssen's position as expressed in these proceedings.

[3] Government of Canada. Canada's Biomanufacturing and Life Sciences Strategy. (https://www.ic.gc.ca/eic/site/151.nsf/vwapj/Biomanufacturing_Strategy_EN_WEB.pdf/$file/Biomanufacturing_Strategy_EN_WEB.pdf)

disregards the underlying rationale behind the government's decision to extend the coming-into-force date of the Amended Regulations[4], adding additional burden to patentees and other stakeholders during a time when focus and resources should remain on responding to the COVID-19 crisis. Given the government's decision to delay the implementation of the Amended Regulations, we also raise serious concerns with the circuitous route being taken by the PMPRB to impose substantial Guideline changes in the absence of regulation implementation. At a minimum we believe this process should be halted while parliament is dissolved.

The proposed change to the price test for Grandfathered medicines and their line extensions should be immediately reversed, and the PMPRB should remain consistent with its previous decision to benchmark Grandfathered medicines and their line extensions to the highest of the basket of comparator countries.

The proposed change to benchmark Grandfathered medicines and their line extensions to the median of the PMPRB7 basket is not rooted in an excessive pricing standard and renders the Guidelines even less clear. The PMPRB had previously aligned to using the highest of the PMPRB11 comparator basket as the non-excessive price benchmark for Grandfathered medicines and their line extensions. The rationale provided by the PMPRB for the change in the price test ("appropriate response to the most recent six-month extension") does not align with the PMPRB's remit of regulating patent abuse nor does it provide an adequate explanation as to why the highest of the basket of comparator countries is no longer an appropriate standard for excessive pricing. Furthermore, the introduction of multiple baskets of international comparator countries and new sub-categories of Grandfathered medicines and their line extensions (i.e., first sale prior to July 1, 2021 vs. first sale after July 1, 2021) adds unnecessary complexity.

Patentees and other health system stakeholders have made business decisions and planned resourcing based on the amended Guidelines that were finalized in October 2020. This major departure from the previously aligned to price test for Grandfathered medicines and their line extensions will place undue administrative burden on patentees and multiple stakeholders throughout the pharmaceutical distribution chain (including wholesalers, pharmacies, generic companies and payors). By the PMPRB's own account, it estimates that the list prices of Grandfathered medicines will decline on average by 10%, and 51% of medicines will require a price reduction (including 55% of drugs for rare diseases).[5] Compared to previous estimates from the PMPRB, the proposed price test change will also increase the financial impact to patentees by at least two-fold, which may limit patentees' ability to provide the same level of patient support services in the future.

The transition period for Grandfathered medicines to become compliant to new list price ceilings should remain as two reporting periods (from the effective date of the Amended Regulations), as outlined in the PMPRB Guidelines finalized in October 2020 and further confirmed by the Board in April 2021.

As stated by the PMPRB, the "operative date for assessing compliance for Grandfathered, Line Extension and Gap medicines with the MLP will remain July 1, 2022".[4] In effect, patentees,

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[4] "The main anticipated benefit of the Regulations is to allow drug manufacturers and health system partners to remain focused on responding to the COVID-19 pandemic" (https://gazette.gc.ca/rp-pr/p2/2021/2021-07-07/html/sor-dors162-eng.html)

[5] Frequently asked questions. Notice and Comment: On the change to the definition of Gap medicines, the references to comparator countries and the international price tests for Grandfathered medicines and their line extensions (https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-references-comparator-countries/frequently-asked-questions.html)

wholesalers, pharmacies and payors will have half the time (i.e., one reporting period from the effective date of the Amended Regulations) to implement these wide-scale price changes compared to the Board's two previous decisions regarding compliance timelines for Grandfathered and Gap medicines (i.e., two reporting periods). This new compliance timeframe will increase administrative burden and costs throughout the pharmaceutical supply chain. Instead, two reporting periods from the effective date of the Amended Regulations (i.e., compliance assessed December 31, 2022) provides a more reasonable timeframe to implement price changes and minimize disruption and burden across the supply chain.

Janssen is supportive of the federal government's Biomanufacturing and Life Sciences Strategy and its objective of enabling innovation by ensuring world class regulation. The instability and unpredictability introduced by the PMPRB, through the Amended Regulations and Guidelines, will overshadow and likely impede the Federal government's efforts to "grow a strong and competitive domestic life sciences sector and ensure Canada's readiness for future pandemics or other health emergencies"[2]. We will continue to strongly urge the government to intervene in this matter and work with industry to create a workable solution that maintains a predictable, understandable pricing system which preserves Canada's international position for access to medicines and enhances efforts to grow Canada's life sciences sector.

Sincerely,

Jorge Bartolome
President

cc. Rt. Hon. Justin Trudeau, Prime Minister of Canada
cc. Hon. Patty Hajdu, Minister of Health
cc. Hon. Francois Phillipe Champagne, Minister of Innovation, Science and Economic Development
cc. Ms. Janice Charette, Clerk of the Privy Council and Secretary to Cabinet