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July 18, 2022

Dr. Mélanie Bourassa Forcier
Vice-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 – PMPRB Price Review Approach During the Interim Period following publication of the Amendments to the Patented Medicines Regulations (June 30, 2022)***

Dear Dr. Bourassa Forcier:

Janssen Inc. (Janssen) appreciates the opportunity to comment on the PMPRB's proposed approach for reviewing patented drug prices while the PMPRB consults with its stakeholders on new guidelines.

Specifically, during the interim period (i.e., from July 1, 2022, until the new guidelines become effective), the PMPRB "…is proposing to adopt a '*status quo*' approach to carrying out its regulatory mandate."[1] We agree with and fully support the objective of maintaining the *status quo* during the interim period.

However, we note that the proposed Interim Guidance differs from the *status quo* by deferring price reviews for all new drugs, potentially applying new and unknown guidelines retroactively. The result is that patentees would be introducing new drugs at risk during the interim period.

Therefore, in staying consistent with the current *status quo* objective and to ensure greater certainty during the interim period, Janssen proposes that PMPRB's existing guidelines remain in effect until the new guidelines are adopted following appropriate consultation. Specifically, this would mean:

1. New patented drugs will continue to be reviewed under the current guidelines, including reference to the PMPRB7 for those launched between January – June 2022, until the new guidelines come into effect.
2. Similarly, for existing drugs the PMPRB will continue to apply the guideline provisions based on the Consumer Price Index (CPI).

[1] Notice and Comment – PMPRB Price Review Approach During the Interim Period following publication of the Amendments to the Patented Medicines Regulations https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-price-review-approach.html

As stated on April 16, 2021, PMPRB committed to a 12-month (i.e., two reporting periods) transition period after the finalization of the new Guidelines.[2] Janssen maintains that this period, at a minimum, will be required after the new Guidelines are finalized so that patentees have sufficient time to implement price changes and minimize disruption and burden across the supply chain.

By maintaining a true *status quo* throughout this Interim Period, the Canadian pharmaceutical and life sciences market will have greater certainty, which will foster an environment that is amenable to attract new investments and timely launches of innovative medicines and vaccines.

Janssen is supportive of the Federal Government's Biomanufacturing and Life Sciences Strategy, and its objective of enabling innovation by ensuring world class regulation.[3] In our collective response to the pandemic, industry and government developed productive partnerships that have demonstrated significant value for patients, the healthcare system, and our economy. We look forward to the opportunity to build on this momentum.

Sincerely,

Jorge Bartolome
President

cc. Rt. Hon. Justin Trudeau, Prime Minister of Canada
cc. Hon. Jean-Yves Duclos, 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

[2]Decision resulting from the consultation on the definition of Gap medicines and the timeline for compliance (Message from the Board – April 16, 2021) https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-definition-gap/decision-definition-gap-medicines.html

[3] Government of Canada. Canada's Biomanufacturing and Life Sciences Strategy https://ised-isde.canada.ca/site/biomanufacturing/en/canadas-biomanufacturing-and-life-sciences-strategy