Jorge Bartolome
President

19 Green Belt Drive
Toronto, ON M3C 1L9
1.800.387.8781 toll free 416.382.4888 tel
416.382.4889

www.janssen.ca

February 15, 2021

Douglas Clark, Executive Director
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: Patented Medicine Prices Review Board (PMPRB) Notice and Comment – Change to the definition of Gap medicines and the timeline for compliance

Dear Mr. Clark,

Thank you for the opportunity to comment on the two proposed consequential amendments to the Patented Medicine Prices Review Board (PMPRB) January 1, 2021 Guidelines ("the Guidelines") that had been published on January 15, 2021. Please find below the response from Janssen Inc.[1]

Janssen Inc. ("Janssen") continues to have serious concerns with the new PMPRB regulatory framework and the Guidelines. Fundamental issues raised by Janssen, industry associations and various stakeholders in previous regulation and guideline consultations[2], including gaps and inconsistencies within the Guidelines, increased regulatory and administrative burden, confidentiality risk, pricing uncertainty and the consequential impact on access to new medicines in Canada, have not been adequately addressed.

Janssen fully endorses the submissions by our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada. We have no additional comments regarding the proposed amendment to the definition of a Gap medicine. However, Janssen does not support the proposed amendment to reduce the timeline for compliance to the Maximum List Price (MLP) for Grandfathered and Gap medicines to one reporting period.

Contd..2/-

[1] Janssen Inc is a litigant in a case questioning the constitutional validity of the Board, the Regulations and its Guidelines in the Quebec Superior Court. Nothing in this submission is an admission in or derogation from Janssen's position as expressed in the Quebec Superior Court proceeding.

[2] Please refer to Janssen Inc. and J&J submissions to the June 2016 discussion paper consultation, June 2017 proposed regulatory amendments (pre-publication in Canada Gazette [CG-1]) consultation, February 2018 draft regulations (post-CG-1 publication) consultation, February 2020 draft guidelines consultation and June 2020 draft guidelines consultation

Douglas Clark, Executive Director
Patented Medicine Prices Review Board (PMPRB)

We continue to find the PMPRB Regulations and proposed Guidelines to be unacceptable. At the very least, in the short term, we strongly recommend that the compliance timeline be increased back to at least two reporting periods, as per the Guidelines published on October 23, 2020. The reduction in the timeframe for compliance to one reporting period (i.e., compliance by end of 2021) places undue administrative burden on patentees and other stakeholders across the pharmaceutical distribution chain (including wholesalers, pharmacies, public and private payors), during a critical time in the COVID-19 recovery period. Furthermore, the proposed change is not operationally feasible, as it reduces the compliance timelines from approximately 10 months to less than three to four months.

The increased burden on patentees is further compounded by the use of the Non-Excessive Average Price (NEAP) to set the MLP of a Grandfathered or Gap medicine. Janssen recommends that the NEAP be removed as a price test, and that the lower of the highest compliant Canadian list price or the relevant international price comparison (for greater clarity, highest international price comparison for Grandfathered Medicines and median international price comparison for Gap medicines) be used to set the MLP for Grandfathered and Gap medicines.

Given recent court rulings on the reporting of payor rebates, the resulting uncertainty on the application of the economic factors, as well as numerous outstanding issues with the Guidelines, a further pause on implementation is warranted to allow for further discourse on alternatives to better address the complex issues that the new Regulations have not tackled.

Sincerely,

Jorge Bartolome
President,
Janssen Canada