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June 18, 2021

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

Via online feedback form and email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: Janssen response to the PMPRB Consultation on the Guideline Monitoring and Evaluation Plan (GMEP)

Dear Dr. Levine,

Janssen Inc. fundamentally disagrees with the new Patented Medicine Prices Review Board (PMPRB) regulatory framework, as it will not improve affordability for the majority of Canadians and will negatively impact access to innovative medicines in Canada, both commercially and through clinical trials. As stated in our previous submissions, as well as by various stakeholders, including industry, patient groups and life sciences organizations, the proposed Regulations and associated Guidelines add unnecessary complexity, increase pricing uncertainty, and create unfavourable business conditions in which to bring innovative medicines and pharmaceutical investment to the Canadian market. The negative consequences of the Regulations will most profoundly affect patients.

At Janssen, we believe Government should pursue a more inclusive and comprehensive approach to address affordability in the context of the industry's contribution and presence in Canada. Industry is offering to contribute to this larger effort and help create workable solutions. The goals of an alternative approach to pricing should be a predictable, understandable system which preserves Canada's international position for access to medicines.

Specifically, we strongly urge that the implementation of the Regulations be paused, and a multi-stakeholder table be convened to develop an alternative solution that meets the stated goals of government, and our common goals of protecting patients and maintaining a vibrant life sciences ecosystem in Canada. In the event the Regulations are implemented unamended on July 1st, our feedback on the PMPRB proposal regarding the Guideline Monitoring and Evaluation Plan (GMEP) is provided below. Janssen fully endorses the submissions by our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada.

While we acknowledge the importance of evaluating the impacts of the PMPRB reforms, many of the elements proposed for evaluation in the GMEP are outside of the scope and regulatory mandate of the PMPRB (e.g., clinical trial intensity, system coordination – health technology assessment, price negotiation and reimbursement), duplicates the work conducted by other government agencies (e.g., economic footprint, R&D investment), and are driven by multiple factors over-and-above price. Furthermore, the GMEP proposes to evaluate regulatory elements which have been partially

invalidated by recent court decisions (e.g., alignment between the estimated therapeutic value of medicines and their Canadian prices cannot be evaluated, as reporting of third-party rebates has been struck down by the courts), calling into question the relevance and accuracy of these evaluations.

In order to increase transparency, accountability and external validity, we recommend that the evaluation of the PMPRB reforms be conducted by an independent third party, with oversight by a multi-stakeholder governance body. The independent third party conducting the analysis should have technical expertise in program evaluation. The governance body should be comprised of program evaluation experts and key stakeholders, including (but not limited to) representatives from the PMPRB, the pharmaceutical industry, patient groups, life sciences organizations, and other relevant government agencies (e.g., Statistics Canada). Membership within the governance body should be published and the composition of the group should be balanced. Key research questions, methodologies (including data sources, definition of baseline period, etc.) and metrics should be clearly defined upfront and remain consistent from year-to-year, be vetted, and approved by the governance body in advance and should be clearly articulated in GMEP reports (or published separately). The GMEP in its current form does not provide enough detail to allow for specific and meaningful feedback.

We urge the PMPRB to take a more collaborative approach to developing and implementing the GMEP, to quickly identify consequences of the PMPRB Regulations and Guidelines, take corrective action in a timely fashion and improve the health and well-being of Canadians. We welcome the opportunity to partner with the PMPRB and other stakeholders in shaping the GMEP.

Sincerely,

Jorge Bartolome
President

cc. Hon. Patty Hajdu, Minister of Health