Janssen Inc.

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August 4, 2020

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

re: Patented Medicine Prices Review Board (PMPRB) June 2020 Draft Guidelines Consultation

Dear Dr. Levine,

Please find below the response from Janssen Inc. to the Patented Medicine Prices Review Board (PMPRB) consultation on the June 2020 Draft Guidelines issued June 19, 2020 (the "revised draft Guidelines").[1]

Janssen Inc. ("Janssen"), a pharmaceutical company of Johnson & Johnson (J&J), has been an innovator in the Canadian healthcare industry for over 50 years. Our goal is to help people live healthy lives. Janssen is a major supplier of prescription medicines in Canada in an important range of therapeutic areas, including Infectious Diseases & Vaccines and Oncology. Our innovative products improve health outcomes and quality of life for patients and help to lower costs in other parts of the health care system.

Janssen continues to have serious concerns with the new PMPRB regulatory framework and the revised draft Guidelines. The revised draft Guidelines are significantly more complex than the previous draft Guidelines and a number of key operational issues remain. Furthermore, fundamental issues raised by Janssen, industry associations and various stakeholders in previous regulation and guideline consultations[2], including confidentiality risk, pricing uncertainty and the consequential impact on access to new medicines in Canada, have not been adequately addressed.

We fully endorse the submissions by our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada. Please refer to the IMC and BIOTECanada submissions for a comprehensive discussion on ongoing issues, information gaps and areas requiring clarification.

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[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 and the February 2020 draft guidelines consultation

In light of the recent Federal Court of Canada ruling (*Innovative Medicines Canada v. Canada [Attorney General] 2020 FC 725*) and the significant gaps with the revised draft Guidelines, a further pause on the implementation of the Guidelines is warranted to allow for further discourse on Guideline alternatives that better address the complex issues raised by the new PMPRB Regulations.

Sincerely,

Jorge Bartolome
President

cc.
Doug Clark, Executive Director, Patented Medicine Prices Review Board
Beena Kuriakose, Director – Strategic Pricing, Janssen Inc.