Janssen Inc.

19 Green Belt Drive
Toronto, ON M3C 1L9
1.800.387.8781 toll free
416.449.9444 tel
416.449.2658 fax

www.janssen.ca

February 14, 2019

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) Guidelines 2019 (draft) Consultation

Dear Dr. Levine,

Please find enclosed the submission from Janssen Inc. to the Patented Medicine Prices Review Board (PMPRB) in response to the draft PMPRB Guidelines 2019 issued on November 21, 2019 (the "Guidelines").[1] We appreciate the opportunity to participate in this ongoing consultation process. Janssen fully endorses the submissions by our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada.

Janssen Inc. supports the goals of improving access to and affordability of prescription medicines to all Canadians. However, we fundamentally disagree with the new PMPRB regulatory framework as it will not improve affordability for the majority of Canadians, it will negatively impact access to medicines, and it will substantially increase the regulatory burden for government and patentees. As a whole, the amended Patented Medicines Regulations and proposed Guidelines represent a sharp shift away from the Board's mandate of ensuring prices for patented medicines are not excessive and establish an unprecedented degree of revenue control and price setting. We have serious concerns about the impacts of the proposed PMPRB Guidelines on access for patients to innovative medicines in Canada, the feasibility of implementing the Guidelines, and the consultation process to date.

The proposed Guidelines add unnecessary complexity, increase pricing uncertainty and risk confidentiality of net pricing, all of which create a very unfavourable business environment within which to bring innovative medicines to market. Ultimately, this will negatively impact patient access to new medicines and and will result in poorer health outcomes for Canadians. In addition, these conditions will create a very unstable setting within which to commence clinical trials, as the standard of care used to treat patients in Canada gradually diverges from other more progressive jurisdictions, making it difficult to conduct global-run comparative clinical trials in Canada. From an economic perspective, these changes will have additional unintended consequences on the future health of the life sciences sector and Canadian jobs within the sector.

[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.

We have grave concerns about multiple sections of the proposed Guidelines, as outlined in the submission from Innovative Medicines Canada and BIOTECanada. The details provided below relate to the specific areas of the proposed Guidelines that are most concerning to Janssen.

The Maximum Rebated Price (MRP) concept and methodology is flawed and adds unnecessary complexity and unpredictability within an excessive price regime.

Management of rebated prices (e.g., setting rebated price ceilings) by the PMPRB does not align with an 'excessive price standard'. Furthermore, implementation of a regulated net price ceiling by the PMPRB reduces the flexibility that payers have to pursue agreement structures that better meet their needs. For example, outcome guarantees and tiered or hard budget cap agreement models that better address payer concerns are less likely to be implemented, as they are more challenging to manage within a regulated net price ceiling context.

From a technical standpoint, the proposed use of pharmacoeconomics (cost-utility analyses) and market size by the PMPRB is flawed and are inappropriate as price regulation tools. The *Patented Medicines Regulations* amendments from August 21, 2019, do not stipulate that pharmacoeconomics and/or market size must be used to set price ceilings.

Pharmacoeconomics

We fundamentally disagree with the use of pharmacoeconomics to set price ceilings within a price regulation context, due to the subjectivity and lack of consistency of the assumptions used in economic models and the unacceptable price uncertainty they introduce.[2] It is impossible for manufacturers to reliably predict how CADTH (or INESSS) will manipulate the pharmacoeconomic model assumptions to determine the base case cost-utility analysis that will be used by the PMPRB in establishing a price ceiling. This greatly increases the uncertainty during the period when a manufacturer is focused on global launch prioritization, clinical trial site selection and global investment allocation. This level of uncertainty has a negative impact on how Canada is viewed amongst its global counterparts on the scale of innovation and opportunity.

The use of cost-utility analyses to determine a Pharmacoeconomic Price (PEP)/MRP is particularly problematic for rare disease medicines, oncology products (especially those used in combination regimens) and curative therapies. Based on previous reviews, CADTH recalculated base case analyses would often result in Pharmacoeconomic Prices that are not commercially viable[3], and in some cases, approach $0, which does not align to the value that was recognized in the CADTH clinical review of the same product.

Market Size

The proposed market size adjustment is a revenue/budget control mechanism that clearly extends beyond the mandate of the PMPRB as envisioned under the *Patent Act*. Market size should not be used as a tool to set regulated price ceilings.

---

[2] Pharmacoeconomic analyses are inherently uncertain, as they are based on modelling of multiple assumptions that can be varied across a range of values. There are many examples of large differences in the results of these analyses between publicly-funded Health Technology Agencies (HTAs) within Canada and between HTAs and manufacturers, based solely on the assumptions used. Furthermore, there are several examples of a single HTA agency (e.g., CADTH) using different 'base case' assumptions for products within the same therapeutic space, signaling a lack of internal consistency.

[3] Rawson N, Lawrence D. New patented medicine regulations in Canada: updated case study of a manufacturer's decision-making about a regulatory submission for a rare disorder treatment. *Canadian Health Policy,* January 2020. Toronto: Canadian Health Policy Institute, www.canadianhealthpolicy.com.

The proposed MRP methodology introduces serious confidentiality risks, which have global implications that can impact our ability to launch new products and indications in Canada in a timely fashion.

The MRP calculation, coupled with publicly available data, risks exposure of commercially sensitive confidential net pricing information, which, in turn, will negatively impact global launch prioritization decisions. While pharmacoeconomic value and market size are used by payers in Canada and other jurisdictions within the context of reimbursement decision-making and product listing agreement negotiations, other factors (such as need for budget certainty, outcome guarantees, risk-sharing, unmet need, etc.) are also taken into account, making it difficult to calculate the estimated negotiated net price. Contrary to messaging from the PMPRB, the proposed use of these tools would make Canada an outlier.

Similar price tests as employed in the current regime should be used for "grandfathered" products (i.e., DIN prior to August 21, 2019). In addition, appropriate transition measures should be put into place to minimize disruption to the marketplace and to ensure patentees are able to comply with the changes.

The term "grandfathered" used in the draft Guidelines would suggest that products approved before the amendments to the PMPRB Regulations were enacted would continue to follow the pricing rules in place at the time the product was approved. As presented in the amended Regulations and draft PMPRB Guidelines, no product is truly "grandfathered".

Recognizing that the application of the new basket is mandated in the amended Regulations, it would be more appropriate to apply the current pricing rules (highest international price comparison or HIPC) to establish the list price ceiling (MLP) for existing medicines. Even with the HIPC, list price reductions will be achieved for existing products, as a result of the change in the international reference basket (PMPRB11).

Furthermore, the Guidelines propose using the "patented medicine's ceiling under the Guidelines applicable prior to the issuance of these Guidelines". The current ceiling is the "non-excessive average price" or NEAP, which represents a net price, not a list price. It is inappropriate to set a list price ceiling based on a price that is net of benefits.

In addition, a more gradual transition for existing (DIN prior to August 21, 2019) and 'gap' (introduced between August 21, 2019 and July 1, 2020) products is needed in order to minimize disruption to the pharmaceutical distribution chain (wholesalers, pharmacies, hospitals, payers), and more time is required to work through the various deficiencies in the Regulations and draft Guidelines.

The draft Guidelines are complex and are not sufficiently complete to be implemented on July 1, 2020.

There are several areas in the draft Guidelines that lack clarity or operational feasibility. It is incumbent upon the PMPRB to set aside an appropriate amount of time to engage more deeply with Industry prior to finalizing the Guidelines. It is also critical for the PMPRB to better understand the implementation challenges presented by the currently drafted Guidelines while working together with the innovative pharmaceutical industry to develop Guidelines that:

- are operationalizable and reduce regulatory burden on the PMPRB and patentees;
- address the concerns raised by Industry regarding pricing predictability and confidentiality; and
- are consistent with the mandate of the PMPRB.

We support PMPRB's proposal to strike bilateral Technical Working Groups, with PMPRB staff and industry representatives, to address key policy and implementation issues.

Conclusion

Pricing uncertainty and degree of price reduction, particularly for the most innovative breakthrough medicines (e.g., rare disease medicines, oncology drugs, curative therapies), are serious barriers to timely introduction of these new medicines into the Canadian market. Delay in accessing these new medicines will negatively impact patient care and outcomes in Canada.

We have serious concerns with the regulatory framework that underpins the draft PMPRB Guidelines. We strongly recommend a pause to review the mandate of the PMPRB and its overreach and to consider amendments to the *Patented Medicines Regulations*.

We recommend the implementation of the Guidelines be put on hold to ensure the appropriate time is taken to design a regime that is right for Canadian patients and the population as a whole. The draft Guidelines are currently scheduled to come into effect on July 1, 2020, which does not provide adequate time for the PMPRB to appropriately assess and incorporate stakeholder feedback into final Guidelines. The proposed timing does not permit manufacturers the required time to respond to or fully comply with changes.

We urge the Board to consider the full impact of these draft Guidelines on patients before finalizing them and strongly encourage a meaningful engagement with Industry to maintain an environment that is conducive to timely access to innovative medicines and clinical trials. We recommend the immediate establishment of Technical Working Groups to develop alternative solutions that strike a more appropriate balance between the desire to drive ongoing innovation for the benefit of patients and consumer protection concerns.

We look forward to partnering with the PMPRB to work through the complex issues raised by the currently proposed Guidelines and to develop revised Guidelines that are clear, increase price predictability, and can be operationalized with ease by the PMPRB and patentees alike.

Sincerely,

Jorge Bartolome
President

cc.
Hon. Patty Hajdu, Minister of Health
Sabina Saini, Chief of Staff, Office of the Minister of Health
Kathryn Nowers, Director of Policy, Office of the Minister of Health
Stephen Lucas, Deputy Minister of Health
Karen Reynolds, Executive Director, Office of Pharmaceuticals Management Strategies, Health Canada
Hon. Navdeep Bains, Minister of Innovation, Science and Industry
Ryan Dunn, Chief of Staff, Office of the Minister of Innovation, Science and Industry
Simon Kennedy, Deputy Minister of Innovation, Science and Economic Development Canada
Sheryl Groeneweg, Director General, Ministry of Innovation, Science and Economic Development
Rick Theis, Policy Advisor, Prime Minister's Office

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