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November 10, 2016

Chris Halyk
President, Janssen Inc.
19 Green Belt Drive
Toronto, ON M3C 1L9

RE: *Market Intelligence Report: Biologic Response Modifier Agents, 2015*

Dear Mr. ^{Chris}Halyk:

Thank you for your interest in the PMPRB's recent publication *Market Intelligence Report: Biologic Response Modifier Agents, 2015* ("*Market Intelligence Report*"). We welcome feedback from stakeholders on our work and are pleased to provide the following response to the concerns expressed in your November 7, 2016, letter.

As you know, the PMPRB is a consumer protection agency with a dual regulatory and reporting mandate. Part of its reporting role is to provide stakeholders with information on pharmaceutical trends. The National Prescription Drug Utilization Information System (NPDUIS) initiative is an integral part of the PMPRB's reporting mandate. Through this initiative, the PMPRB provides policy makers and public drug plan managers with timely, accurate and impartial information on drug price, utilization and cost trends.

The *Market Intelligence Report* was published under the NPDUIS banner and is subject to the same limitations and qualifications of all such reports past and future. While there may be any number of factors that influence health-care policy decisions beyond price, utilization and cost, it is not within the PMPRB's mandate or expertise to make value judgments in this regard. For instance, when we observe that Canadian consumption rates of biologic DMARDs are relatively high, nowhere do we imply that this is too high or too low. Similarly, nowhere do we imply that infusion clinics negatively affect prices of Remicade in Canada and we take no position in the report on their overall value or lack thereof to the health care system.

As reflected in the PMPRB's December 2015 strategic plan, which you allude to in your letter, and the June 2016 discussion paper on guideline modernization, transparency is extremely important to our organization and the studies conducted under the NPDUIS initiative are no exception. Detailed information on the creation and operation of the NPDUIS initiative is available on our website. In short, an Advisory Committee composed of representatives of the jurisdictions participating in the NPDUIS initiative supports the PMPRB in establishing research priorities, developing research

methodologies and interpreting analytical results. Accordingly, all NPDUIS reports contain the following disclaimer: "NPDUIS is a research initiative that operates independently of the regulatory activities of the Board of the PMPRB. The statements and opinions expressed in this report do not represent the position of the PMPRB with respect to any regulatory matter."

In so far as the intent behind the *Market Intelligence Report* is concerned, its content and scope was determined in consultation with the participating jurisdictions and reflects their analytical priorities. In terms of methodology, the PMPRB has reported extensively on how it conducts international price comparisons, including exchange rate conversion. All of the NPDUIS reports use data sources that differ from those used by the PMPRB for regulatory purposes. In the specific case of the *Market Intelligence Report*, the data is derived from a variety of publically available databases, including the MIDAS™ Database, which is an internationally recognized source for sales and utilization data and is referenced in many international studies.

While the prices relied on in the report do not necessarily reflect what public drug plans in Canada are actually paying, because of confidential rebates and discounts which are the industry standard globally, this limitation is understood by the participating NPDUIS jurisdictions and is acknowledged in all our studies. Notwithstanding these obvious limitations, it is interesting to note that in an era of imperfect pricing information, most countries continue to reference international public list prices as a mechanism to set prices and/or contain pharmaceutical expenditures. That said, should pharmaceutical manufacturers be willing to consider providing their confidential pricing information to the PMPRB in the context of future NPDUIS studies for an assessment of the impact this might have on market comparisons, we would be eager to have that discussion.

I trust that the foregoing is responsive to your concerns. The PMPRB consulted extensively with the participating NPDUIS jurisdictions in developing and interpreting the results of the *Market Intelligence Report* and we stand by the report's quality, accuracy and impartiality. While no updates are being contemplated to the study, to the extent you continue to have questions with respect to its methodology, we would be pleased to meet with you to explain this in more detail.

Sincerely,



Douglas Clark
Executive Director

Cc: Julia Brown, Vice President, Government Affairs and Market Access, Jansen Inc.
Alaine Grand, Vice President, Law, Jansen Inc.
Carole Watson, Director, Strategic Pricing, Janssen Inc.
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