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

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Douglas Clark
Executive Director
Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Doug;

We read with interest the recently released report by the Patented Medicine Prices Review Board (PMPRB) entitled "*Market Intelligence Report*: Biologic Response Modifier Agents, 2015". In the report it states that the intent of these reports is "to inform policy decisions, aid in evidence-based decision making and to provide Canadians with a more comprehensive view of issues pertaining to pharmaceutical drug pricing and utilization in Canada and internationally." If this is the true intent, then the content of the above report is deeply concerning as it is far from being comprehensive and lacks important information that provides the necessary context required to truly understand the data that is described therein.

Even more concerning is that these reports are being used by stakeholders to make important decisions that have a meaningful impact on patients' lives. If the data within them are not reliable or the report is missing critical contextual information, then it is reasonably foreseeable that such information will result in decisions that produce negative outcomes. In its 2015 to 2018 Strategic Plan, the PMPRB states that it wants to "cultivate a reputation as an honest broker and source of timely and impartial market intelligence for its stakeholders". If this is the case, then respectfully, we are of the view that there is a great deal of work to be done which is why we felt compelled to share with you our feedback after considering the content of this latest report.

Firstly, we would like to address the issue of transparency. There is no clear description in the report as to why or for whom it was commissioned. With the issue of transparency being a priority for the federal government, it should be a basic requirement that the PMPRB disclose the reason a particular report was generated and identify the audience for whom it was written. In order to fulfil the mandate of reporting on pharmaceutical trends in an unbiased way, PMPRB needs to discuss the policy issue forwarded by the analyses. Understanding the goals the PMPRB is trying to achieve is important context for the reader when they are assessing the content of the report.

We are also concerned that there is important context missing from the report, including:

- Absent information about the challenges with comparing prices across jurisdictions;
- Absent information on the benefit these medications provide to patients and the healthcare system and how the cost relates to that benefit;
- Absent information on the epidemiology of the diseases which biologics treat, including the fact that the incidence of inflammatory bowel disease is higher in Canada than the comparator countries, thereby accounting for the increased use of biologics by Canadians.[1]

[1] http://www.isupportibd.ca/pdf/ccfc-ibd-impact-report-2012.pdf

- Absent information on the value (and savings) brought to the healthcare system from the manufacturer-supported infusion clinics, or the positive impact such patient support programs have on patient adherence or retention on medication;

As a result of this missing context, readers are left with an incorrect impression that the manufacturers of biologics in general, and Janssen more specifically, are actively engaging in pricing practices designed to overcharge payers and patients in Canada. This is simply not true.

Janssen is committed to pricing our products appropriately for the value they bring to patients and the healthcare system, and works diligently to ensure our prices are compliant with the PMPRB guidelines. The price of REMICADE® is not out of compliance with these guidelines. The report's characterization that the price of REMICADE® is the highest in the world is false and needs to be corrected. As you are well aware, accurate International Price comparisons are difficult due to the presence of multiple price lists, exchange rates which change over time, and the presence or absence of rebates/contracts within list prices. In fact, given that the specific price sources and exchange rates used to support the statements in the report are not cited, our analysts have been unable to replicate those international prices referred to in the report using publicly available sources. This includes using price lists outlined in the PMRPB Guidelines as "usual and customary sources". In the spirit of transparency and accuracy, the PMRPB needs to provide more detail about the price sources and exchange rates used in its report. The PMPRB should also conduct sensitivity analyses using the range of price sources and multiple exchange rate assumptions.

The report discusses the high use of biologics by Canadians, however, if the intent were to truly give Canadians a full picture of the current biologics market in Canada, far more work and context is required. Unfortunately, it seems the PMPRB failed to do its homework on the reasons why utilization of some biologics referred to in the report is higher in Canada than elsewhere in the world. Perhaps the PMPRB was not aware that Canada has the highest prevalence of Inflammatory Bowel Disease (IBD) in the world, and biologics including REMICADE®, Humira and SIMPONI have transformed the treatment paradigm and patient outcomes in the devastating inflammatory diseases.[2] [3] Therefore, it is not surprising that REMICADE® and biologics in general have high utilization in Canada. In addition to the positive clinical outcomes for patients, successful management of IBD with REMICADE® and other biologics results in significant decreases in spending in other high cost areas of the healthcare system, including decreased surgeries and hospital stays.[4] [5] [6] [7] [8] [9] [10] [11] [12] In reality, the value of REMICADE® and biologics is clearly demonstrated in this report, as the data shows an increasing number of patients benefiting from them over time. As one of the stated goals of this report is to inform policy, the PMRPB needs to clearly state that cost and price are one part of the evidence required for any decision-making process and to outline other variables that need to be considered, such as those described above. Context is critical. Without it, the logical conclusion of someone with no additional background in the area would be that no one should be paying for biologics because they are expensive. This does not seem representative of the type of balanced, unbiased analysis the PMPRB is striving to be known for.

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[2] CÔté-Daigneault et al. 2015 United Eur Gastroenterol J. 3(5): 2538-2547

[3] Singh, et al. 2012 Arthritis Care Res. 64(5): 625–639.

[4] Jones et al. Poster presented at the International Society for Pharmacoeconomics and Outcomes Research 19th Annual Meeting. May 31-June 4, 2014. Montreal, QC, Canada. Abstract PGI26.

[5] Reinisch et al. 2007 Inflamm Bowel Dis 13:1135–1140.

[6] Reich et al. 2014 Aliment Pharmacol Ther 40(6): 629-638.

[7] Moore et al. 2014 Dis Colon Rectum 57: 83–90.

[8] Kaplan et al. 2012 Am J Gastroenterol 107:1879–1887.

[9] Park et al. 2014 Inflamm Bowel Dis 20(7):1242-9.

[10] van der Valk et al. 2014 Gut 63: 72-79

[11] Feagan et al. 2000 Am J Gastroenterol 95(8): 1955-1960

[12] Machado et al. 2016 BMC Musculoskeletal Disorders 17:298-308.

The report also infers that because REMICADE® is supplied in large part through manufacturer-supported infusion clinics in Canada, this somehow contributes to the price of REMICADE®. The report makes a point to mention several times that medicines purchased by and used in hospital settings are less expensive and provided more efficiently than through retail outlets. The BioAdvance system of infusion clinics was created due to limited public infusion services available for non-cancer infusions, making it impossible for patients to access REMICADE® even after Health Canada approval. Janssen is proud of the support services we provide to patients who are prescribed REMICADE®, including the provision of infusion services free of charge to patients and to our taxpayer-funded healthcare system. Each year thousands of infusions are given in BioAdvance clinics that otherwise would have been a cost to the healthcare system. Ministers of Health themselves have commented on the value that this infusion network brings to Canadians. Neglecting to include this information in the report leaves the reader with the impression that the manufacturer-supported infusion clinics are somehow negatively affecting the price of REMICADE® and do not provide value to the healthcare system.

The report does mention the limitation that the results are based on list prices and acknowledges the existence of agreements and contracts that lower the cost of these products for payers. Janssen works with private payers, individual provincial governments and the Pan-Canadian Pharmaceutical Alliance to deliver cost effective solutions and ensure patients and physicians have affordable access to our medicines. Therefore the prices listed in your report are not what the payers are paying and the costs and expenses attributed to the various plans are incorrect. We believe that the report should have gone a step further than it did, and stated that no conclusions can be drawn from these data, nor can they inform policy decisions, as using list prices is completely irrelevant in this context, and frankly, brings the entire report into question. Janssen has been working with the public payers to enable affordable access for REMICADE®, but recently pCPA has declined to engage in further negotiations. Interestingly a significant portion of the savings attributed to the use of biosimilars in this report could have already been realized had pCPA chosen to continue negotiations with Janssen. At Janssen, we support decisions that preserve choice for physicians and patients. We strongly believe the use of biosimilars in Canada should be based on what physicians determine is in the best interest of their patients and not driven by efforts to save costs that restrict treatment choice in any way.

It is stated that biosimilar uptake is lower than in other countries. Again, additional context needs to be added to this discussion in that the reader needs to know that Health Canada has not deemed biosimilar infliximab interchangeable with REMICADE®, clearly stating that they are not analogous to small molecule generics, where higher uptake is expected. Inflectra was only recently approved for the IBD indications in Canada so again, it is not surprising that uptake has been slower than in Europe. The PMPRB has again left out important context for policy makers and Canadians.

Finally, we are particularly concerned about the section in the report that discusses drug plan spending split out by individual companies. Janssen develops and supplies high quality, safe and effective drugs in a wide variety of therapeutic areas, including mental health, cancer, inflammatory disease, HIV/AIDs, diabetes, pain and hepatitis C. Given that Janssen is the largest pharmaceutical company in Canada and the public payers are responsible for paying upwards of 50% of all drug costs, it is not surprising that 6-12% of drug plan spending is used for Janssen products. It is unclear what the purpose was for even discussing the entire portfolio of a company's products in a report about biologics, unless it was to leave a misinformed impression with the reader that a company like Janssen is somehow charging the public drug plans too much for their products. Given that these data do not provide any insights into the cost and utilization of biologics in Canada, it appears that they were included to cast a negative light on Janssen's reputation.

As the content of the report is lacking in multiple areas, we request the following updates to this report:

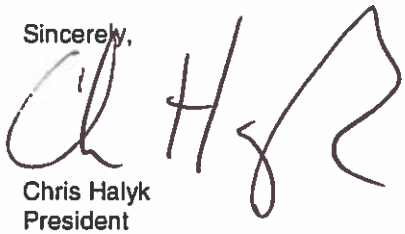
- Provide transparency as to which stakeholder(s) requested this information, and for what specific purpose
- For international price comparisons, conduct and include results from systematic sensitivity

analyses using various price sources and appropriate exchange rates.

- Correct the statement that the Canadian price of REMICADE® is the highest in the world
- Provide context on the value that REMICADE® and biologics bring to patients and the healthcare system and acknowledge that providing these products is a net benefit to Canadians
- Clearly state that no conclusions can be drawn from the cost information because of the existence of confidential listing agreements and contracts with both public and private payers
- Discuss the benefits of a patient support network that provides infusion services at no cost to the taxpayer-funded healthcare system
- Provide context as to why ~10% of public drug plan costs are for Janssen products and information on the value these products bring to Canadians

We will contact your office directly to set up a meeting to discuss this report in more detail and timelines for an updated version to be developed and released.

Sincerely,



Chris Halyk
President

cc: Julia Brown, Vice President, Government Affairs and Market Access, Janssen Inc.
Alaine Grand, Vice President, Law, Janssen Inc.
Carole Watson, Director, Strategic Pricing, Janssen Inc.
Tanya Potashnik, Director, Policy and Economic Analysis, Patented Medicine Prices Review Board
Imran Ali, Senior Manager, pan-Canadian Pharmaceutical Alliance
Federal/Provincial/Territorial Drug Plan Managers