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

January 13, 2016

Mr. Guillaume Couillard
Director, Board Secretariat, Communications and Strategic Planning
Patented Medicine Prices Review Board
Box L40
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1

Dear Mr. Couillard:

On behalf of Janssen Inc., I am pleased to provide our submission to the Patented Medicine Prices Review Board with regards to the proposed amendments to the Compendium of Policies, Guidelines and Procedures ("Guidelines") issued for Notice and Comment on December 4, 2015.

Summary

Proposal #1: Reasonable Relationship Test Amendment

Janssen recognizes the issue regarding the Reasonable Relationship Test (RR Test) that this proposal is intending to address and appreciates the effort by PMPRB to develop a solution. While this proposal will be, for some cases an improvement, it does not adequately address the fundamental issue with the existing Guidelines and, in some cases, remains an unreasonable approach to the pricing of line extensions. As set out below, contrary to the statement in the December Notice and Comment, the proposal can negatively affect consumer interests by discouraging manufacturers' investment in, and introduction of, line extensions that deliver improvements in therapeutic outcomes and discouraging reductions to customers. Subject to further comments in the body of this letter, Janssen proposes the following:

> **When applying the RR Test, if the new drug and the comparable drug product(s) are owned by the same patentee, the Board Staff (a) will use the greater of (i) the lowest of the six publicly available sources and the (ii) non-excessive National Average Transaction Price of the comparable drug product(s) when establishing the Maximum Average Potential Price for the new patented drug product and (b) will not apply an "any market" introductory price review.**

Proposal #2: List Price Relative to Maximum Average Potential Price (MAPP) Verification (Section C.11) Amendment

It is Janssen's position that the PMPRB does not have the jurisdiction to implement this proposal, based on its enabling statute and related regulations. Further, this proposal contains the same policy flaw as does Proposal #1; namely, it will discourage reductions to customers. **Janssen proposes that the PMPRB discard this initiative.**

In discouraging reductions to customers, both proposals run directly counter to the intention of Parliament in crafting the legislative framework within which the PMPRB operates. As held by Justice Blais in *Leo Pharma Inc.* v. *Canada (Attorney General)* 2007 FC 306, Parliament intended to encourage reductions to customers:

> "...it seems much more reasonable to assume that Parliament, through section 4 of the Regulations, sought to increase access to patented medicines for Canadians, many of whom do not have extensive drug insurance coverage. To achieve this objective, the Regulations were drafted so as to provide incentives for patentees to distribute free medicine, by allowing them to include these goods in the average price calculation under section 80, and by extension section 85, regardless of their actual 'intent' in distributing such free goods."

* * * * * * * * * * * * * * * * * *

Discussion

Proposal #1: Reasonable Relationship Test Amendment

We appreciate the PMPRB is attempting to address the results of the 2010 Guideline amendments, where the lowest of the six price sources (AQPP, IMS Health, McKesson Canada, ODB, PPS Pharma, and RAMQ) was to be utilized to establish the MAPP. However, the proposed solution can still result in situations where an introductory price could be deemed excessive despite common sense indicating otherwise. The issue with the proposal is that it does not allow for a price parity introduction due to the fact that an "any market review" will be conducted upon the introduction of the line extension. By conducting an "any market review", situations will arise where a product would be considered to have an excessive price in a given market even though the improved product has the same ATP as the original compliantly priced product in that given market. This is because there are frequently ATP differentials across markets and customer classes, even though the N-ATP may be compliant with the Guidelines.

It cannot be considered reasonable that pricing compliant under the Guidelines becomes non-compliant by virtue of a simple line extension. Take the example of a line extension that delivers the same amount of active ingredient but with an improvement in formulation that increases patient compliance (but not so as to justify a therapeutic reclassification). A price parity introduction means that no person pays more anywhere in Canada on introduction of the improved line extension than that person paid for the previous product. But Proposal #1 can result in a situation where the patentee must *reduce* the price to certain customers, *for a better product.*

In addition, there is no provision in the proposed changes for situations where the comparator product's N-ATP is lower than the cited six public sources. The December Notice and Comment states that in 16% of RR Test cases, the N-ATP of the comparator was greater than the lowest publicly available price. This means that in 84% of cases, the N-ATP was the same as, or lower than, the lowest publicly available price. In the latter case, using the N-ATP is a disadvantage for new medicines and is a disincentive for patentees to provide benefits to customers for an established product. It must be understood that in most cases, line extensions are introduced based on a clinical need or convenience to patients. If a reasonable non-excessive price cannot be achieved for the proposed new product format, the PMPRB is discouraging patentees from launching line extensions in Canada.

In Janssen's respectful submission, not only does Proposal #1 not address unreasonable treatment of line extensions in certain circumstances, but it also embodies flawed policy.

Recommendation:

Janssen recommends that Proposal #1 be amended as follows:

> **When applying the RR Test, if the new drug and the comparable drug product(s) are owned by the same patentee, the Board Staff (a) will use the greater of (i) the lowest of the six publicly available sources and the (ii) non-excessive National Average Transaction Price of the comparable drug product(s) when establishing the Maximum Average Potential Price for the new patented drug product and (b) will not apply an "any market" introductory price review.**

Janssen believes that this amended proposal would address many situations where the application of the RR Test to comparable drug products owned by the same patentee would produce an unreasonable result. We believe, however, that the PMPRB must build into the Guidelines a concept of flexibility in the application of the rules so as to prevent unreasonable or unintended consequences. For example, even with Janssen's amended Proposal #1; there can be a sales mix shift on introduction of a line extension that causes the N-ATP of the line extension to be higher than the N-ATP of the comparator product, despite regional parity pricing. In this case, even Janssen's amended Proposal #1 would have to be adjusted to produce a fair and reasonable result, perhaps by clarifying that section C.12.4 of the Guidelines would apply to the new product. Another example would be where the N-ATP of the comparator product is artificially depressed by time limited benefits but will be adjusted upwards in the future by the application of the DIP methodology – the MAPP of the line extension should not be held to the artificially depressed N-ATP of the comparator. These are just examples but clearly indicate the need for an express requirement of flexibility in the Guidelines to prevent unforeseen consequences.

Proposal #2: List Price Relative to MAPP Verification

Under the second proposal, the Guidelines would be amended at section C.11 "Review of Prices of New Patented Drug Products at Introduction" so that patentees would be required to "ensure that domestic list prices for new drugs are below the [MAPP]". In essence, the PMPRB is proposing that a product's list price be compliant at introduction, rather than only requiring that the ATP be compliant.

As an initial point, the proposal lacks clarity on how the new rule would be implemented and enforced. It is not clear from the proposal whether the staff intends to require ongoing list pricing compliance, or only list price compliance at introduction. This should be clarified. Further, there is no information in the proposal regarding the consequences of non-compliance with the proposed rule. The December Notice and Comment states that if list prices in the six publicly-available sources exceed the MAPP, they "will be presumed to be excessive". But there is no guidance as to how the "excess revenues" are to be calculated. It is not surprising that there is no such guidance – as will be seen below, there is no mechanism provided in the PMPRB's constituting statute or related regulations to calculate "excess revenues" based on list prices, because this was beyond the intention of Parliament.

Thus, the larger issue is that the PMPRB does not have jurisdiction under the *Patent Act* to regulate list price at any time or for any product. The PMPRB is based on statute and has no jurisdiction beyond the limits of that statute, the *Patent Act*. As the PMPRB correctly states in the Guidelines, its mandate is "[t]o ensure that the prices charged by patentees for patented medicines sold in Canada are not excessive."

The entire regulatory framework of the PMPRB is based on the regulation of actual price, *not* list price. Subsection 80(1) of the *Patent Act* states that a patentee must report, "as required by and in accordance with the regulations…the price at which the medicine is being or has been sold in any market in Canada…" In turn, subsection 83(1) of the *Patent Act* states that the PMPRB may direct a patentee to reduce the maximum price at which the patentee sells a patented medicine to a non-excessive level, where the PMPRB finds that the patentee is selling the medicine in any market in Canada at an excessive price. Subsection 85(1) states that, in making its determination under section 83, the PMPRB shall take into consideration "the prices at which the medicine has been sold in the relevant market". The "price at which the medicine has been sold" and the price at which the

patentee "is selling the medicine" are defined in the *Patented Medicines Regulations* in subsection 4(4) as "...the *actual price* after any reduction..." Nowhere in the *Patent Act* or *Patented Medicines Regulations* is the PMPRB given jurisdiction to regulate list prices.[1] List price is not correlative with the actual price at which a drug is sold, and if it were necessary to substantiate this point, the December Notice and Comment does so.

The PMPRB states that there is a concern that the ratio of domestic Block 5 prices to N-ATP has been increasing, but has not systematically analyzed the reasons for this increase. While the increasing ratio could be a result of increasing list prices, it could also be a result of increasing benefits to consumers – which is a desirable outcome from a consumer perspective and, as noted, within Parliament's objectives for the PMPRB regime. In any event, whatever the reasons for the increase, it is the statute that defines the PMPRB's jurisdiction.

With respect to the reference to "price discrimination" in the December Notice and Comment, that is a pejorative expression of a key element of the PMPRB as constituted by the *Patent Act*. The very concept of "average pricing" enshrined in the legislation allows pricing differentials. Applying reductions in calculating average price per package or net revenue from sales (and the PMPRB's own DIP methodology) are acknowledgements of the reality and appropriateness of differential pricing. The *Leo Pharma* decision implicitly acknowledges differential pricing by acknowledging the propriety of giving reductions to certain customers and not others.

Contrary to the statement in the December Notice and Comment, regulation of list prices is not a "tool at [the PMPRB's] disposal". List price regulation is beyond the jurisdiction of the PMPRB.

Recommendation:

> **Janssen recommends that Proposal #2 should not be implemented on the basis that regulation of list price is beyond the jurisdiction of the PMPRB.**

Finally, Janssen is supportive of the input provided by Innovative Medicines Canada with regards to this matter and we are aligned with their approach requesting a detailed collaborative consultation period for these proposed changes.

We thank you for your attention to these important matters and appreciate being afforded the opportunity to provide these comments.

Sincerely,

Chris Halyk
President

cc: Carole Watson, Director, Strategic Pricing, Janssen Inc.
Douglas Clark, Executive Director, PMPRB
Mary-Catherine Lindberg, Chairperson, PMPRB

[1] Subparagraph 4(1)(f)(ii) requires a patentee to *report* "the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold...to each class of customer in each province and territory...", but that no more entitles the PMPRB to regulate list prices than subsection 88(1) entitles the PMPRB to regulate research and development expenditures.