January 15, 2016

Mr. Guillaume Couillard
Director, Board Secretariat, Communications and Strategic Planning
Patented Medicines Prices Review Board
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RE: Amgen Canada response to PMPRB Notice and Comment on incremental reforms to the *Compendium of Policies, Guidelines and Procedures*

Dear Mr. Couillard,

Amgen Canada is pleased to provide the following comments in response to the PMPRB's Notice and Comment associated with the proposed changes to the *Compendium of Policies, Guidelines and Procedures* ("Guidelines"). We are aligned with the Innovative Medicines Canada parallel response on these initiatives, and would like to emphasize the below points.

1. Re: Reasonable Relationship Test ("RRT") (*Schedule 4*) Amendment

Amgen applauds the apparent intent of this amendment to simplify the calculation of the Maximum Average Potential Price for line extensions in certain circumstances. However, we object to the proposed change as it is currently described, as the details and potential consequences raise a number of concerns.

For line extensions of products whose list prices are approximately the same in all provinces, the launch price will be forced down to the national average transaction price ("ATP") of the reference product, including all reported rebates, benefits, etc. Since such ATP could be lower than the lowest of the publicly-available list price sources, this amendment acts as a disincentive to provide and report benefits on current products that may have future line extensions, and is therefore detrimental to the consumer, PMPRB and the patentee. We also believe that this amendment would have the unintended consequences of discouraging manufacturers from launching line extensions because it may have the effect of lowering a manufacturer's revenue and because a manufacturer may be concerned that the launch price of a line extension may provide insight to competitors about the average transaction price of the reference product.

Potential alternative revisions to the RRT to consider– via an appropriately robust consultation process – include removing the IMS Health CDH dataset from the basket of publicly-available sources and changing the calculation to allow line extensions of the same patentee to be the higher of (1) the national ATP and (2) the lowest of the publicly-available sources.

2. Re: List Price relative to Maximum Average Potential Price (MAPP) Verification (*Section C.11*) Amendment

Amgen does not understand the objective of this proposed amendment, and sees it as problematic for several reasons.

First, Amgen's view is that PMPRB does not have jurisdiction to regulate list price. The authority of the PMPRB is granted under the Patent Act, and it is our view that the entire regulatory framework of the PMPRB is based on the regulation of actual price, not list price. Our view is based on a reading of several relevant sections of the Patent Act, including the following (emphasis added):

- Subsection 80(1) of the Patent Act provides 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…"
- Subsection 83(1) of the Patent Act provides that the PMPRB may make an order directing 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) provides 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". Furthermore, 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…"

Additionally, although 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…", this is just a reporting requirement and does not grant the PMPRB the explicit authority to regulate list prices.

Therefore, Amgen's view is that nowhere in the Patent Act or Patented Medicines Regulations is the PMPRB given jurisdiction to regulate list prices.

The manner in which this proposed amendment is to be implemented and enforced is unclear as the excess revenue calculation is based on ATP, not list prices.

Where a manufacturer could currently provide and report benefits from launch, with the effect of lowering ATP to a compliant level, that product would be out of compliance under this amendment. This can hamper the ability of a manufacturer to provide benefits and is therefore detrimental to the consumer.

As a related aside, to the extent that PMPRB does find need to refer to list prices, for the RRT or otherwise, we continue to strongly oppose the usage of the IMS Health CDH dataset within the basket of publicly available sources. CDH is an ever-adjusting calculation based on discounted and marked up revenues (discounted by manufacturers in some instances and marked up by 3rd parties for all products) divided by number of units – not a list price as the other sources are – and is therefore a misleading and irrelevant value. We ask that it be removed from the set of publicly available sources, except potentially in the very rare instance that none of the other five sources are available.

We work hard to ensure our ATPs are within PMPRB guidelines, and additional regulation on list prices is unnecessary and excessive. Amgen recommends this proposed amendment be rejected.

3. Consultation Process

Amgen is concerned with the Notice and Comment process PMPRB is following in this instance, in contrast to the previous one of November, 2013, where the objectives were clear and stakeholder input was sought in advance and appeared to be thoughtfully considered. The objectives and mode of implementation of the current two proposed changes are unclear. Additionally, PMPRB has itself stated that the analysis done to support both changes was brief – and therefore even more likely to result in unintended consequences jeopardizing product launches for which plans and investments are made years in advance. We also must point out that applying changes retroactive to a period prior to the due date for response to this Notice and Comment seems unnecessarily rushed and we are concerned that it does not allow sufficient time for PMPRB to appropriately evaluate stakeholder comments or for manufacturers to plan for and accommodate new pricing regulations.

4. Recommendation

Amgen recommends that these two proposed amendments be deferred until sufficient multi-stakeholder consultation can be held, preferably via working group(s) as that format has proven to yield robust and implementable outcomes in the recent past. If the result of such appropriately thorough consultation is for amendment(s) to the Guidelines, we recommend that the earliest date for such to be January 1, 2017.

Sincerely,

H. L. Jordan

Helen Jordan
Vice President and General Manager

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