Eli Lilly Canada Inc.

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January 29, 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

RE: Eli Lilly Canada response to PMPRB Guidelines Notice & Comment

Dear Mr. Couillard,

Eli Lilly Canada Inc. (Lilly) appreciates the opportunity to provide input on proposed changes to the PMPRB's Compendium of Policies, Guidelines and Procedures (the Guidelines) issued on December 4th, 2015. In particular, these changes include amendments to the Reasonable Relationship Test (RRT) and a provision verifying that Canadian list prices must be lower than the Maximum Average Potential Price (MAPP). The PMPRB is generally recognized for its robust consultations with industry. The current process, which is occurring subsequent to the implementation of the changes, raises concern that it may be out-of-step with the meaningful consultations that have occurred to date.

Lilly supports the feedback submitted to the PMPRB by Innovative Medicines Canada on the proposed changes to the Guidelines, with particular emphasis on three areas of concern:

1. The **lack of a meaningful consultation** between industry and the PMPRB, in both time and due process, for the proposed Guidelines changes.
2. The **limited analysis and lack of clarity** around how the proposed changes to the RRT affect new products when the comparator offers benefits in a market.
3. The **objective** of the proposed provision that list prices must be below the MAPP is not clear, particularly whether its regulation is necessary to meet the PMPRB's mandate or falls within its jurisdiction.

Recommendation: Given the concerns around the proposed Guidelines changes, a delay in implementation is warranted to allow adequate time for a meaningful consultation with industry. During this time, Lilly requests that a working group is created to assess the implications of the proposed changes.

Consultation Process

The PMPRB has a long history of rigorous and meaningful consultations with industry. This is in keeping with the spirit of consultations outlined in the *Patent Act* and has been exemplified by previous changes to the Guidelines. Lilly is concerned and disappointed that, in this instance, a meaningful consultation has not occurred. Implementation of the proposed changes is to take effect January 1, 2016, *prior* to completion of the industry consultations, raising concern of the legitimacy of the process. In addition, previous changes to the Guidelines have included a full

year implementation period, unlike what is being proposed currently. This approach is inconsistent with the PMPRB's standard practice and the expectations of its stakeholders in both the quality of the consultation process and the length of the implementation period.

Reasonable Relationship Test

The proposed Guidelines changes would see the Maximum Allowable Potential Price (MAPP) for line extensions be set by the National Average Transaction Price (N-ATP) instead of the lowest of the six publicly available sources used by the PMPRB. Although this provision only affects a small number of products, Lilly feels the PMPRB's limited analysis does not provide a substantive evaluation of the impact of this change for all relevant product scenarios. In particular, when benefits have been offered in certain markets, the PMPRB suggests a case-by-case basis evaluation would take place. The implications of this are not well understood, and yet could be significant. For example, where a product has the same list price in all provinces, and benefits have been offered in certain markets lowering its N-ATP, would the price of a line extension by the same patentee be required to include the same level of benefits– potentially lowering the N-ATP below what may have been allowed under the current Guidelines (i.e. lowest of the six sources)? The lack of clarity on the implementation and exceptions to the proposed rule change creates uncertainty around the implications for industry stakeholders, limiting our ability to consult in a meaningful capacity.

List Price Relative to the Maximum Average Potential Price

Under the proposed policy, the list price of a product could not be higher than the MAPP established by the PMPRB. This would be the case even when the N-ATP is below the price ceiling. Lilly would like to better understand the objective of this proposed change and how it fits within the PMPRB's regulatory mandate of *non-excessive* pricing. Traditionally, interpretation of the *Patent Act* suggests the PMPRB's jurisdiction includes the actual selling price of a product. It is both unclear whether list prices are within the PMPRB's jurisdiction and whether its regulation is necessary to meet its mandate. It is also uncertain how the PMPRB would enforce this policy when a product's N-ATP is not excessive.

Of note, the proposed change may have the unintended consequence of preventing benefits from being offered. For example, where a manufacturer could currently provide and report benefits to lower the N-ATP of a product to a compliant level, under the proposed changes, that product would now be out of compliance simply because the list price is above the MAPP.

Recommendation

It is evident that more study and discussion is warranted as the complexities of the proposed changes are unclear and could have unintended consequences for the market. It is difficult for stakeholders to evaluate and comment on these changes in a meaningful way, given the short period for comments and accelerated implementation. We also note that the PMPRB's published analysis of these issues is limited and should be expanded to help inform the consultation

process. As suggested by Innovative Medicines Canada, Lilly also strongly recommends that the PMPRB defer the implementation of these changes by at least one year in order to allow further analysis and appropriate consultation. We propose that a working group with industry be established to study the proposals in detail, as has been demonstrated by the Board with previous policy and Guidelines changes.

Again, Lilly appreciates the opportunity to provide feedback on the proposed changes. Should you have any further questions, please feel free to contact me.

Sincerely,

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cc: Mary Catherine Lindberg, Chair
cc: Doug Clark, Executive Director