Eli Lilly Canada Inc.
3650 Danforth Avenue
Toronto, ON M1N 2E8
Canada

www.lilly.ca

June 13, 2013

Ms. Sylvie Dupont
Director, Board Secretariat
Patented Medicine Prices Review Board
Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
K1P 1C1

RE: PMPRB Notice and Comment May 2013: proposed changes to the CPI Adjustment Methodology and to the Patented Medicines Regulations – Lilly Canada Written Feedback

Dear Ms. Dupont,

Eli Lilly Canada, Inc. (Lilly) appreciates the opportunity to provide input to the Patented Medicine Prices Review Board (PMPRB) regarding the Proposed Changes to the Consumer Price Index (CPI) Adjustment Methodology and to the Filing Requirements. Lilly believes that any changes to the existing Guidelines should be premised on a commitment to:

- Simplify processes so as to avoid unnecessary complexity;
- Promote an environment that supports pharmaceutical innovation and research while guarding against excessive prices, in the manner intended in the Patent Act; and
- Maintain the ability of patentees to offer benefits to patients.

For each of the proposed initiatives, our views are outlined below; we would be happy to discuss any of these points further, should you desire.

Initiative #1: Eliminate the Use of Forecast CPI and Transition to the use of Actual Lagged CPI as part of the CPI Adjustment Methodology

Proposal for Consideration: Maintain current CPI Adjustment Methodology for existing drug products, except replace the use of the forecast CPI with actual CPI in calculating the CPI Adjustment Factor for the forecast period.

Lilly recognizes that the intent of this proposed change is to move toward more certainty on the CPI-based calculation of price increases, and would reduce administrative burden. We are supportive of the proposed new methodology as it provides greater certainty on the CPI used in any given year and it reflects the actual movements in inflation in the Canadian economy.

If the proposed change is adopted for 2014, the 2013 CPI figure that is issued on January 24, 2014 should apply for 2014. The transition should not leave manufacturers in a position where the ability to raise prices is curtailed for a year during the transition.

Initiative #2: Reduction of Regulatory Filing Requirements

Proposal for Consideration – Existing Patented Drugs: For existing drug products, to replace the semi-annual regulatory filing of Form 2- Information on the identity and prices of the medicine by an annual filing.

We recognize that this would significantly decrease the burden on the PMPRB staff members who are currently responsible for reviewing all of these submissions. For the manufacturers, though, it does not decrease the need to continually monitor pricing levels to ensure that we are tracking to be on target to our NEAP for each product. However, when combined with Initiative #1, Lilly believes that this creates a positive opportunity for the PMPRB to issue the full year NEAP levels to each manufacturer along with the previous year's compliance report that we currently receive in mid March. Lilly sees this very much as a benefit as it would provide us with earlier certainty as to the ATP level that we need to reach at the end of the year for each DIN.

Proposal for Consideration – New Patented Drugs: To eliminate the requirement to submit Form 2 information for the first day of sales of a patented drug product in Canada and to add a section in the Form 1-Medicine Identification Sheet to report the publicly available ex-factory price in Canada on the date of first sale.

The removal of the requirement to file Form 2 for day one of sales within 30 days and then again for the benchmark period eases the filing burden on both the PMPRB and the patentee and Lilly supports its adoption. However, this proposal does not eliminate the requirement to submit the sales for the initial benchmark period (first six month period or portion therein) so as to calculate the benchmark price against which the drug is then measured in all subsequent periods. The burden for the patentee would be further reduced if the publicly available ex-factory price was used to compare to the MAPP when setting the benchmark price instead of having to report on the initial benchmark period. This would further reduce the reporting burden on both sides and provide manufacturers with more certainty on its pricing when launching a new drug.

We trust that Lilly's comments will be given due consideration as the PMPRB proceeds with its review of the Regulations and the proposed revision to the Guidelines. If the Board has questions or requires additional information, please contact Chris Scroggie, Government & Economic Affairs at Tel.: 416-693-3774 or E-mail: scroggie_chris@lilly.com.

Sincerely,

Lauren Fischer
Vice President, Corporate Affairs