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Secretary of the Board
Patented Medicine Prices Review Board
Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
K1P 1C1

RE: Review of the Board's *Excessive Price Guidelines* – Lilly Canada Written Submission

Secretary of the Board,

I am writing in regard to the Board's request for written submissions in follow-up to the face-to-face bilateral consultation on September 11, 2007.

Eli Lilly Canada Inc. ("Lilly") appreciates the opportunity to provide input to the Patented Medicine Prices Review Board (PMPRB) regarding its review of the *Excessive Price Guidelines* ("the Guidelines").

Lilly supports the submission to the Board of Canada's Research-Based Pharmaceutical Companies (Rx&D), dated October 31, 2007. As noted in Rx&D's submission, patentees are the only stakeholders subject to regulatory oversight by the Board and are, therefore, its principal stakeholders. The PMPRB's effort to set up a more formal consultation process with patentees is welcomed.

Further, Lilly would like to underscore Rx&D's point that the large number of issues being reviewed by the Board has become a source of considerable uncertainty for patentees. Any investment decision must contemplate the attractiveness of the market where the investment will reside. The pricing regime is an important element in the comparative evaluation of competing investment locations for pharmaceutical companies. Lack of certainty with respect to pricing, and the possibility of further restrictions, act to discourage commercial investment in Canada.

We would encourage the PMPRB to clearly identify the problems it wishes to resolve, focus its review efforts on those, and identify timelines for completion of the review. It is not clear what problems the current review exercise seeks to address. PMPRB data demonstrate that excessive pricing has not occurred – even by the PMPRB's own rigid definition of it. Since 1993, Canadian drug prices have, on average, remained below the international median. At the bilateral session on September 11, 2007, however, there was broad consensus concerning the

existence of two problems: the number, length and expense of Board Hearings; and a fall in R&D investment by patentees. Further, it was agreed that most Hearings relate to disagreements over the application of the Board's Category 3 definition and its CPI methodology.

With respect to the issue of **categories**, Lilly supports Rx&D's position that a price test based on the statutory standard of "excessive" and the factors in the *Patent Act* does not require the categorization of new medicines. When Canada's Parliament created the PMPRB, its intention was to ensure that there was not excessive pricing of patented medicines as a result of *Patent Act* amendments that restricted the issuance of compulsory licenses. The PMPRB Guidelines and their application deviate significantly from Parliament's original intent. The Guidelines would better reflect that intent if excessive pricing were defined as pricing that exceeds the range of prices in other countries and the CPI-adjusted prices of all other drugs in the therapeutic class.

Regarding **price increases** and the Board's CPI methodology, Lilly would encourage new language allowing for CPI to be applied each year to the Maximum Non-Excessive (MNE) price, rather than the lower of the Average Transaction Price (ATP) and the MNE price. Such a reform would be pro-competitive in that would greatly facilitate competition of patented medicines with generics in multi-source situations.

As noted in Lilly's comments on the proposed amendments to the *Patented Medicines Regulations,* Lilly would also support a complaints-based approach to the regulation of patented medicines that are subject to generic competition. Once generics enter the market, there is mandatory substitution in all provinces to the lowest cost alternative. The underlying premise of regulating drug prices through the *Patent Act* is to ensure that patentees do not abuse their patent monopoly by charging excessive prices. Once that monopoly is lost and generic competitors appear, the rationale for continued active price regulation by the PMPRB is unclear.

The Board has not demonstrated any need to pursue the issues of **international therapeutic class comparisons; "any market" reviews; costs of making and marketing; and re-benchmarking**. No changes to the Guidelines pertaining to these issues are required. With respect to international therapeutic class comparisons, the Board should continue to apply this factor of the *Patent Act* case-by-case, in a flexible way, to assist in the resolution of disagreements with patentees. With respect to reviews of "any market", the Board already has the power to order sub-national data. Such reviews can be undertaken on a case-by-case basis, where warranted.

We trust that Lilly's comments will be given due consideration as the PMPRB proceeds with its review of the Guidelines. If the Board has questions, or requires additional information, please contact the undersigned at Tel.: 416-699-7446 or E-mail: fischer_lauren@lilly.com.

Sincerely,

Lauren Fischer
Sr. Manager, Government & Economic Affairs