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

RE: PMPRB Notice and Comment August 2008: Draft Revised Excessive Price Guidelines– 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 Draft Revised Excessive Price Guidelines (the Guidelines) of August 28, 2008. In doing so, Lilly reiterates its fundamental position that the justification for the current revisions to the Guidelines remains unclear, given that the PMPRB's own data demonstrate that excessive pricing of patented medicines has not occurred. Since 1993, Canadian drug prices have remained, on average, below the international median price and have been increasing at rates at or below the consumer price index. Interestingly, over this period of relative compliance by patentees, the regulatory machinery and budget of the PMPRB has grown exponentially, more than doubling from $5.3 million in 2005-06 to $11.6 million in 2008-09. One can only speculate as to the further expansion that will be required to support the increased reporting and oversight proposed in the draft revised guidelines.

At root, Lilly maintains that the PMPRB has overstepped the regulatory and reporting mandates established in the 1987 Patent Act (the Act), and in doing so, has created a climate of uncertainty for patentees that has the potential to further erode the stability and attractiveness of the Canadian market for investment. Pricing uncertainty, over-regulation and onerous reporting practices undermine the very spirit of the Act, which was to create an environment that is conducive to innovation and growth in the Canadian economy. At the same time, Lilly does acknowledge the considerable effort by the PMPRB to resolve the existing disagreements over the application of the Board's Category 3 definition and its CPI methodology.

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The attached document outlines Lilly's position in three areas of pre-eminent concern:

1. In the strongest possible terms, Lilly opposes a review and re-setting of the MNE based on new scientific evidence as unwarranted and further contributing to a climate of increased commercial uncertainty for patentees. In the case of new evidence that may indicate lower standards of efficacy or safety than at the time of the introductory MNE, changes in regulatory approval, formulary access, and prescribing practice serve as powerful and sufficient corrective forces in the marketplace. Further intervention by PMPRB is unnecessary.

2. Lilly believes that the price test for the newly established category of moderate therapeutic improvement must include a criterion that will prevent the very real possibility of the setting of a price that is below the lowest international price for designated comparator countries. An example is provided in the attached document. Lilly is confident that the absence of such provision in the draft guidelines is a simple oversight on the part of PMPRB and will be corrected in subsequent versions of the draft. Clearly the Patent Act did not intend such an unfavourable outcome for an innovative drug.

3. The proposed guidelines have not achieved a de-linking of the ATP from the MNE Price in any meaningful sense, while adding complexity, the threat of frequent investigations and any market price reviews, and concomitant increased workload for both patentees and the PMPRB.

In light of the concerns expressed by individual member companies and Canada's Research-Based Pharmaceutical Companies (Rx&D), Lilly urges the PMPRB to reconsider the full implications of the revisions set out in Draft Excessive Price Guidelines. Lilly believes that any changes to the existing Guidelines should be premised on a commitment to:

- simplify processes so as to avoid unnecessary complexity and duplication with other agencies;
- promote an environment that simultaneously supports pharmaceutical innovation and research while guarding against excessive prices;
- avoid the unintended consequences of discouraging patentees from offering benefits to patients and payers (in the form of rebates, services, free or discounted product) and undermining a positive investment environment.

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 Andrew Merrick, Director of Government & Economic Affairs at Tel.: 416-693-3843 or E-mail: merrick_andrew@lilly.com

Sincerely,

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Lilly's Response to the PMPRB
Notice and Comment: Draft Excessive Price Guidelines, August 2008

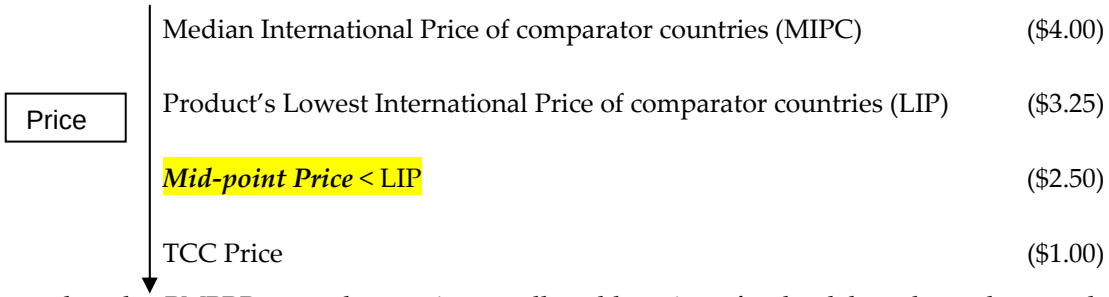
Lilly feels compelled to offer comment on specific areas of core concern where it feels efficient and effective business practice and the delivery of optimal access of medications to patients are being compromised by the Guidelines. Lilly's comments and solutions to outstanding issues are based on the principles defined in the attached cover letter.

1. Re-setting of the MNE Price:

Lilly continues to oppose the re-setting of the MNE price due to new scientific evidence, even on a case-by-case basis at the discretion of Board Staff. The vagueness of the current draft provides no substantive direction as to what degree or level of evidence might trigger a review, thereby serving to create a high level of commercial unpredictability for patentees. This runs counter to Parliament's intention in creating the Bill C-22 amendments to the *Patent Act*, which was to provide regulatory certainty. Furthermore, the review of emerging scientific evidence is already being conducted by other agencies: Health Canada (from a safety and efficacy perspective), the agencies within CADTH (from a safety, efficacy and value perspective), and the provincial/territorial formularies (from a safety, efficacy, value, and pricing perspective). Increased action by PMPRB in this area would serve as unnecessary duplication with no added benefit for the public and would also contribute to increased complexity in review and number of board hearings.

2. Levels of Therapeutic Improvement and Associated Price Tests:

Notwithstanding Lilly's past comments on the lack of need for therapeutic classes to determine excessive price, the addition of a fourth class of therapeutic improvement within the current categorization system - aimed at acknowledging moderate improvement - is a positive step. However, at the same time, Lilly believes that the price test associated with the new category has the potential to result in an unfair maximum allowable price that would, in certain circumstances, undermine the intent of patent provisions. Within this new "mid-point" price test, if the application of TCC test results in a price that is sufficiently below the price of the MIPC test – say in the case where relevant TCC products are old and of very low price - the resultant mid-point price could be below the *lowest* international price in comparator countries, for the new drug. For example:



Given that the PMPRB caps the maximum allowable price of a *breakthrough* product at the median international price on the upper end, it seems reasonable that a product that generates a *moderate* improvement and so, too, represents significant innovation, should have downward pricing protection to prevent it from falling below the *lowest* international price of comparator countries at the bottom end. In

fact, it seems implausible that PMPRB could justify a price for a new product as excessive if it was at the lowest international price of comparator countries. To force patentees to comply with a maximum allowable price that is below the lowest price that other developed countries pay is a clear step beyond the mandate of PMPRB, which is to ensure that prices are not excessive.

Given the intent of PMPRB to implement a "moderate improvement" category, Lilly asserts that the associated price test must include the following clause: *the resultant maximum allowable price from this price test will not be below the lowest international price of this product in comparator countries*.

3. Impact of Reporting Benefits/"De-linking of the ATP from the MNE Price":

Instead of achieving the goal of *de-linking*, the PMPRB has added complexity and confusion through vague terms such as "dip" and "gap", and the associated convoluted rules. A non-PMPRB pricing expert will have difficulty deciphering how these excessive price tests will work. As case-in-point, after the release of the draft guidelines, the PMPRB had to issue four pages of examples to clarify and illustrate the intent of the new methodology. Therefore, in and of themselves, the Guidelines are vague and subject to various interpretations, which will most certainly stymie the efforts of patentees toward compliance.

Lilly contends that a simpler, more transparent methodology is required and so has consistently proposed fair alternatives which ensure that the patentee is not penalized for providing benefits in either the introductory or subsequent reporting periods. These benefits, of course, serve to lower the average transaction price and in doing so, accrue value to the patient and/or the payer. Certainly this added value in the form of improved access to medicines must be a central aim of the Canadian health care system. As the Guidelines stand now, patentees will be motivated to withdraw benefits, such as negotiated product listing agreements with provinces and hospitals, in an attempt to maximize their ATP. Of particular note, the current Guidelines allow for hospitals to benefit from preferred pricing arrangements, based on a long-standing tender system - one which has provided substantial savings to the benefit of Canadian patients for many years. This system may be jeopardized under the revised draft guidelines.

As an alternative to the proposed system, Lilly recommends that:

1. The introductory period MNE price be defined as the price that does not exceed the range of prices in other countries, and the CPI-adjusted prices of all other drugs in the therapeutic class. If the introductory period ATP is below this MNE (i.e., due to the inclusion of benefits), then the subsequent period MNE is to be calculated off of the introductory period MNE and *not* the introductory period ATP.
2. The subsequent period MNE is calculated off of the previous period's MNE with an allowable CPI adjustment.
3. In a market where price increases have not been taken for multiple periods (regardless of whether benefits have been offered in that market), the one-year price increase cannot be higher than a (to be determined) multiple of that year's CPI. Discontinuation/fluctuation of a benefit is not equivalent to taking a price increase.

When compared to the de-linking provisions set out in the Guidelines, Lilly's proposal truly and fairly "de-links" the MNE from the ATP in a manner that does not penalize patentees for providing patient benefits and so encourages them to continue to offer significant opportunities to its customers. Moreover, it is simple to understand and implement, and so promotes adherence by patentees while protecting markets from large one-year price increases. It further avoids an excessive reporting burden for patentees and the PMPRB alike. Given that the impact of benefit reporting remains a pre-eminent concern for patentees and PMPRB, Lilly requests that PMPRB engage in further collaborative discussion in this area.

4. Any Market Review:

Lilly continues to assert that PMPRB has not articulated a clear rationale for changes to the current procedure regarding any market price review. This is based on the PMPRB's own evidentiary conclusions (2006) that pricing by patentees for all drugs by class of customer, and by province and territory, are overwhelmingly within the range of 5% of the national maximum non-excessive (MNE) price or lower. Therefore, the current compliance mechanism is sufficient to capture the very few cases where a price in a particular market may appear inconsistent with the Guidelines. Lilly respectfully reminds the PMPRB that there is a difference between *variability* in price – which is permitted - and *excessiveness*, which is the only regulatory mandate of the PMPRB. An ATP in any market that is below the MNE is compliant, whether or not it is below or above that of another market due to differences in the amount of benefits offered amongst markets and sub-markets. The PMPRB should not be concerned with investigating these discrepancies.

Though subsequent to the release of the draft guidelines the PMPRB has stated that it does not intend to carry out extensive sub-market price reviews, the Guidelines do appear to leave that option open, creating concern that any market reviews will be conducted with greater frequency and less predictability. Patentees are left with an inherent uncertainty that will restrict their willingness to engage in beneficial agreements within and across classes of customers. The four pages of examples provided by the PMPRB illustrate the potential for increased confusion, where a price deemed non-excessive in one market might be deemed otherwise for another (examples 4 and 6). Lilly contends, once again, that in making revisions, the PMPRB would do well to observe the principle of enhanced simplicity. The additional reporting volume would generate a significant amount of additional non-value-added work for both the manufacturer and the PMPRB reviewers. If extensive sub-market review is not intended, the Guidelines should state that plainly.

Other Comments:

Lilly also confirms its support for other areas of concern raised by Rx&D and BIOTEC in their responses to the Draft Revised Guidelines, most notably those pertaining to the unnecessary reporting of all benefits, the lack of consultation around new provisions for the Reasonable Relationship and TCC tests, and the uncertainty that will result from the unclear definition of what constitutes an "appropriate public source" for the prices of comparable products used to calculate introductory price using a TCC test. In terms of the last one, the appropriate source should be the highest domestic publicly-available prices for comparator drugs and this should be spelled out in the Guidelines.

In general, it would appear that proposed changes to PMPRB regulations and practices have the potential to create additional complexity and uncertainty for patentees with no incremental benefit to the Canadian public. As a result, compliance will become more difficult, negotiations with the PMPRB more cumbersome and an increasing number of cases will be decided at expensive legal hearings. Most certainly, the proposed changes will be to the detriment of the investment climate in Canada and the willingness of manufacturers to offer additional benefits in the marketplace. The real loser will be the patient.