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April 27, 2009

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 March 2009: 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 of March 26, 2009. While Lilly is pleased that the PMPRB engaged in board-to-board consultations with Rx&D after the last iteration of the guidelines (August, 2008), we are concerned that the most recent draft document fails to incorporate the most important substantive contributions of industry, and the collaborative intent of the Board-to-Board discussions. As the most obvious case-in-point, the current draft introduces new changes that have not been vetted in previous consultation with stakeholders.

If implemented, the sum of the proposed changes by PMPRB will serve to increase both regulatory burden and commercial pricing uncertainty for patentees. This stands at odds with the spirit of the 1987 Patent Act (the Act), which was to create an environment that is conducive to innovation and growth in the Canadian economy. Lilly supports the Rx&D position with regard to the latest draft guidelines; the following represent three areas of pre-eminent concern for Lilly:

1. Lilly opposes the use of a "public price sufficiently close to the National Non-Excessive Average Price (NEAP)" for new product therapeutic class comparisons. The NEAP of a particular product is a confidential price that in many cases incorporates confidential reductions offered by a patentee. As PMPRB correctly notes, it is highly unlikely that a public price close to the NEAP will even exist. A patentee seeking to benchmark its new product price will be unable to determine if the lowest publicly-available price is sufficiently close to the NEAP of the comparator product. This is further complicated by the fact that NEAPs can vary significantly from period-to-period depending on the timing and magnitude of benefits offered. Further, if PMPRB discloses a price that is (close to) the NEAP for benchmarking, this may impact the capacity of the PMPRB to protect pricing confidentiality.

2. The proposed guidelines have not achieved a de-linking of the ATP from the MNE Price in any meaningful sense, while at the same time, the regulatory burden of patentees has been increased through the imposition of market-specific NEAPs. As noted by Rx&D, patentees will move from

monitoring one national ATP and MNE to 17 NEAPs and will be required to track and extract contract-specific fluctuations across all markets related to contract expirations (or changes in terms). Lilly is further concerned that the PMPRB intends to publish when a price "*appears excessive*", rather than waiting for the outcome of the PMPRB investigation which, as PMPRB's own examination of pricing to date has shown, is likely to reveal that the great majority of prices are complaint with the guidelines. The sum of additional changes, such as the Maximum Average Potential Price (MAPP) terminology and the complicated DIP methodology provide an onerous reporting environment for patentees that overstep the bounds of the PMPRB to set a ceiling price for excessive pricing and not to restrict price variations beneath that ceiling. The CPI-adjusted MAPP should be this ceiling for price excessiveness, which in the current proposed guidelines, is not the case.

3. Lilly remains concerned that the price test for the newly established category of moderate therapeutic improvement has the very real possibility of setting a price that is below the lowest international price for designated comparator countries, and that the PMPRB has not provided a criterion to prevent this. Clearly the Patent Act did not intend to have an *innovative* drug priced lower than the lowest price of comparator countries. In the latest guidelines, the PMPRB has taken the *additional* step of restricting the ability of secondary factors to improve a new product's assessment beyond moderate improvement. This change was made without consultation and is at odds with recommendations of the Working Group on Therapeutic Improvement.

In light of the concerns expressed by individual member companies and Canada's Research-Based Pharmaceutical Companies, Lilly urges the PMPRB to reconsider the full implications of the proposed revisions. 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;
- Avoid discouraging patentees from offering benefits to patients and payers

In light of the ongoing concerns about the proposed guidelines, and the complications for patentees in dealing with mid-year changes, Lilly urges the PMPRB to suspend implementation of the guidelines until further consultation with stakeholders can occur.

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 Jason Lee, Government & Economic Affairs at Tel.: 416-693-3684 or E-mail: leeja@lilly.com.

Sincerely,

Terry McCool
Vice President, Corporate Affairs

Lilly's Response to the PMPRB
Notice and Comment: Draft Excessive Price Guidelines, March 2009

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.

De-linking

First, it is essential that PMPRB provide a fair price benchmark for new product comparison, and a meaningful de-linking of the maximum non-excessive price from the average transaction price for existing products. The intent of the proposed guidelines to: a) use the NEAP for new product TCCs, and b) the "DIP" methodology for existing products serves to dissuade patentees from offering benefits. By being complex and opaque, these two guidelines create significant commercial uncertainty for both new and existing product pricing, especially when a patentee is contemplating offering benefits. Lilly contends that a simpler, more transparent methodology is required—one that ensures 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. Under the latest proposed terminology, Lilly recommends that the PMPRB make the CPI-adjusted Maximum Average Potential Price (MAPP) the ***relevant*** benchmark for comparison for both new product TCCs, and to evaluate price excessiveness of an existing product. PMPRB's current regulations clearly allow that once a product's maximum non-excessive price has been established, if a patentee offers no benefits, future price increases are allowed subject to CPI and highest international price limitations—this is the MAPP. However, if a patentee chooses to offer benefits for Canadians, the PMPRB should not penalize and discourage this by reducing that product's NEAP if benefits are offered. The "DIP" methodology is complex and any "rebound" in price is only allowed if a benefit terminates, if adequate proof is provided, and as appears to be the case, only if the patentee is willing to forego the accumulated CPI during the period of benefit. The PMPRB must appreciate the even *within* a given market, customers may have various prices, some following CPI-allowed increases while others may have various levels of benefits negotiated, which may fluctuate (but not necessarily terminate) from period-to-period. To prevent substantial banked CPI price increases 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 could be limited to a yet to be determined multiple of that year's CPI. However, it is imperative that the PMPRB acknowledge that neither a discontinuation nor a fluctuation of a benefit should be construed as having taken a price increase.

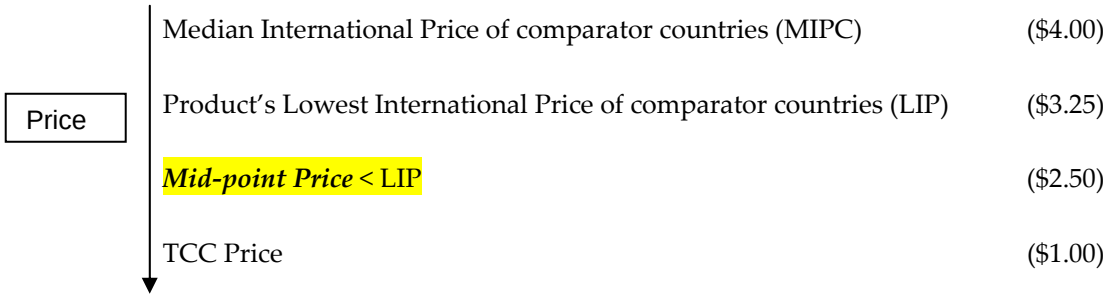
Any Market Reviews:

If the PMPRB adopts the above recommendations, it will also carry through with seeking to limit any market reviews to product introduction, when investigating excess revenues at a national level, and on complaint. However, by creating market-specific NEAPs and publishing "appears excessive" even when national excess revenues do not warrant investigation or are in fact compliant, the PMPRB is doing the exact opposite. Market-specific NEAPs only add to the regulatory burden that patentees face when contemplating offering a benefit, and create the potential for the appearance of excessiveness solely due to fluctuations in benefits. Publishing "appears excessive" creates a misassumption of guilt and may encourage complaint, when a price really does not generate excess revenues worthy of investigating or may actually in fact be compliant (but may appear excessive due to fluctuations in benefits). PMPRB

must appreciate that price *variability* does not equate to price *excessiveness*, especially if it is purely due to the offering of a benefit. Lilly recommends that the PMPRB adopt the de-linking guidelines proposed above, and only publish a product's price review status if it is truly under investigation (i.e. after consultation with the patentee to resolve any appearance of excessiveness due to fluctuations in benefits).

Levels of Therapeutic Improvement and Associated Price Tests:

Lilly believes that the price test associated with the new category of moderate improvement 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, representing 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*. Furthermore, Lilly recommends that the proposed capping of secondary benefits to upgrade the level of therapeutic improvement (one level) up to a maximum of "moderate", be rescinded. Lilly recommends that the HDAP should be allowed to review the importance of secondary factors to help determine the level of therapeutic improvement within the context of a particular drug's review, without being constrained by a policy decided a priori. Secondary factors identified such as success rate, and compliance leading to improved health outcomes could arguably be considered a *substantial* therapeutic improvement, depending on the context of the specific medicine and the disease/condition being treated. This new guideline was made without consultation with stakeholders, and is contrary to the recommendations of the Working Group on Therapeutics.

Other Comments:

- For the purposes of the ITCC, Lilly opposes the proposed guidelines for the inclusion of generics, as well as the use of the median price. Generics are not a relevant and fair comparator regardless of whether a company sells the same generic in Canada; the use of the median price of the therapeutic class is inconsistent with the domestic TCC test. Lilly believes that only patented products, and the highest price of the therapeutic class be used for benchmarking.
- For products judged to be in the "slight or no improvement" category, Lilly contends that the secondary price test of attempting to identify "superior" products for a TCC and using the lowest non-excessive price as the benchmark for MAPP, oversteps the spirit of the Patent Act. Nowhere in the Act does it state that the PMPRB should identify which products are superior or inferior, and the use of such terms may misrepresent what medicine works best for an individual patient. Lilly recommends that if the primary price test for this category of therapeutic improvement cannot be conducted, then the secondary test should be the median international price comparison.
- The PMPRB must be explicit in stating that if a previous price has been declared compliant, it cannot in a future period re-investigate its compliance and determine excessive revenues. Doing so would create perpetual price uncertainty for patentees and add to regulatory burden.
- The PMPRB has proposed that the offset of excess revenues by not taking allowable CPI increases is no longer acceptable, and patentees must decrease the price to below that of the previous year's NEAP. Lilly contends that this proposal is overly punitive, as the concept of foregoing CPI-allowed increases has always been a PMPRB-accepted option. Clearly, if the excess revenues can be offset in the following year by not taking the full CPI increase, the patentee should be allowed and entitled to take a partial CPI increase instead of being forced to a price below the previous year's NEAP.
- Lilly continues to oppose the re-setting of the MNE price due to new scientific evidence, even if no specific guideline is provided. Such an uncertainty only serves 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. Furthermore, restricting the latest guidelines to allowing the re-setting of the MNE at NOC to only the cost making and marketing still act to dissuade patentees from offering beneficial programs pre-NOC.

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 a detriment to the willingness of manufacturers to offer additional benefits in the marketplace. The real loser will be the patient's ability to access medicines.