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Secretary of the Board
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Secretary of the Board,

In light of the recent request for comment on the proposed amendments to the Patented Medicines Regulations, 1994, Eli Lilly Canada Inc. (Lilly) wishes to express its views on the six proposed changes. Lilly's views are anchored in the belief that changes to current regulations should add value to Canadians by accelerating the review process or eliminating non-value activities allowing for optimal resource utilization by the PMPRB. Furthermore, any changes should reflect the practical nature of their implementation. Our response to each amendment will reflect these fundamental beliefs.

Questions of legality are clearly to be raised in the review of the proposed amendments but will not be discussed within the context of our response at this time.

1. Notification of proposed price

The PMPRB proposes to add a new section to the *Regulations*:

> 5. (1) In addition to the information referred to in paragraph 4(1) and for the purpose of section 82(1) of the Act, the patentee shall provide prior to the sixtieth day preceding the date on which the patentee first offers the medicine for sale, the price at which the medicine is intended to be sold.

The above stated amendment raises some concerns regarding the scope of the PMPRBs regulatory authority. Under Section 82 of the Act, manufacturers provide pricing information related to the price of medicines currently sold or that were sold in Canada and NOT those that plan on being sold.

From a practical standpoint it would be very difficult to ensure a price be provided 60 days prior to first sale. Various dynamic factors are at play that influences the end price, which include: International pricing and launch timing, competitor pricing and external market dynamics. The difficulties in providing a "timely" pre-submission of expected price would be as difficult as providing a notice of intent to sell at a fixed time frame versus the current practise of 'as soon as practicable after determining the date'. Since we would never know the exact date of launch (due to NOC unpredictability) any submissions would not provide value to the PMPRB or Canadians as they would always either fall out of the targeted 60 days thus creating a potential delay if NOC was received prior to the 60 days or if delayed then unnecessary reviews by the PMPRB on a price that may need to change due to revised NOC timing and external market changes. We believe the current process and regulations provide ample timing and clarity in determining an appropriate price and the mechanisms are in place to resolve any differences in a timely and efficient manner.

2. Notification of a proposed price increase

The PMPRB proposes to modify section 4 of the *Regulations*:

> (4) Notwithstanding subsection (2), any proposed increase to the price of the medicine, for any class of customers in any market in Canada, shall be communicated to the Board at least 120 days before the effective date of the intended price increase.

The PMPRB's rationale for this proposed amendment is to allow for prompt review of any price increases between reporting periods. This would allow the PMPRB to inform patentees if there were any pricing issues, but would not be a means to acquire prior approval for the price increase.

This particular amendment raises concerns on various fronts. Price increases are very sensitive information due to the fact that they can influence inappropriate purchasing patterns within the supply chain if information relating to potential price increases is disclosed. Many within the supply chain will speculate on potential price increase as a means to gain profit. Lilly does not support actions that would potentially increase the risk of inappropriate purchasing and profit taking. As this risk cannot be eliminated due to potential information leaks or miscommunications due to accidental disclosure, manufacturers should not be exposed to this negative practise which would create negative consequences affecting many.
As the guidelines for allowing price increases are clearly stated with the regulations and as the PMPRB is not looking for prior approval, there seems to be little additional value in manufacturers supplying a "potential" price increase 120 days prior. Due to the nature of the dynamic market many price increases would be influenced by competitor actions, reimbursement and other factors, which could result in last minute pricing decisions.

The PMPRBs mandate is to review current prices that are being sold or have been sold and not those that could be sold. As the current mechanisms are in place to achieve the PMPRBs mandate coupled with the lack of value and impracticality this amendment offers, Lilly sees no value to Canadians with this amendment as it would only further create additional resource drain with no incremental return.

3. Details on the calculation of net price and net revenues

The PMPRB proposes to add the following sentence to paragraph 4(4) and (5) of the *Regulations*:

> For the purpose of this paragraph, any amounts used in the calculation must be identified and reported on the appropriate form.

The PMPRB is seeking the further expansion of information provided in determining how patentees arrive at the average price per package for all reported medicines. The PMPRB wishes to utilize "appropriate" forms to help gain clarity on how calculations are performed in determining average prices.

Lilly believes that the current regulations provide clarity on what variables should be included in determining average selling price. We are unclear on what additional data the PMPRB would want to see submitted in an "appropriate" form. When one considers the volume of data that is currently provided in terms of net sales, quantity, international data, first 30 days sales and a variety of forms, we feel the PMPRB has ample data available to determine if prices are within current regulations. Any additional reporting volume would not change the determination of the average selling price but would generate a significant amount of additional non-value added work for both the manufacturer and the PMPRB reviews. If the PMPRB requires further clarity in how the average selling price was determine it can currently seek this information from the manufacturer on an as needed basis. We do not see the value of having all manufacturers provide additional information when the PMPRB has the current authority to seek further information on a case-by-case basis. We would hope the PMPRB would seek solutions that simplify the current process and add value versus additional administrative burden.

4. Product monograph / draft monograph

In section 3(1), which reads:

> 3. (1) For the purposes of paragraphs 80(1)(a) and 80(2)(a) of the Act, information identifying the medicine shall indicate

The PMPRB proposes to add:

> i) a product monograph, or draft monograph if a notice of compliance has not yet been issued;

Lilly understands the PMPRB utilizes the Product Monograph (or Draft) in its scientific review process of the price review. The PMPRB would seek to have a product monograph/draft automatically submitted for each new patented medicine.

Lilly's primary concern is with the mandatory submission of a draft product monograph could potentially change before NOC is granted. Depending on the magnitude of the changes the PMPRB may need to reassess its review which would result in wasted time and resources due to the duplication of efforts. The use of draft product monographs raises additional confidentiality concerns as the PMPRB may share this document with external reviewers. We trust that Lilly has filed its Product Monograph in a timely manner upon receipt of NOC and that the current process has met the needs of all parties in conducting the pricing review.

5. Recognition of electronic signatures

The PMPRB proposes to add the following new sections to the *Regulations*:

> 9. Any signature that is required by these Regulations to be shown on a record or document may be an electronic reproduction of the required signature.
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> 10. Any information that is required to be maintained or filed with the Board by these Regulations may be maintained or filed with the Board in any electronic format from which a printed copy of the record can be produced.

Lilly support this amendment as it clearly adds value and seeks to improve efficiencies in a practical manner.

6. Filing requirements for veterinary patentees

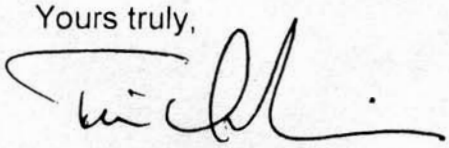
Propose adding new text to section 4(3) so that it reads as follows:

> 4. (3) The information referred to in subsection (2) shall be provided:
> (a) within 30 days after the end of each period referred to in that subsection where the medicine is for human use; and
> (b) within 30 days following receipt of a written request made by the Patented Medicine Prices Review Board where the medicine is for veterinary use.

Lilly supports this amendment.

We trust the Board will take our input into consideration and will seek amendments that clearly provide improved efficiencies that lead to faster approvals. Furthermore, we trust the Board will seek solutions that best utilize the resources at their disposal to the benefit of Canadian taxpayers.

Yours truly,



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