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Government and Economic Affairs

October 22, 2007

Secretary of the Board
Patented Medicine Prices Review Board
Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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RE: Updated Proposed Amendments to the *Patented Medicines Regulations, 1994*

Secretary of the Board,

I am writing with respect to the updated proposed amendments to the *Patented Medicines Regulations*, as published in the *Canada Gazette*, Part I on October 6, 2007.

Eli Lilly Canada Inc. (Lilly Canada) wishes to express its views on the substantive elements of the updated proposed amendments. Our views are anchored in the belief that changes to the current regulations should add value to Canadians by accelerating the review process, or by eliminating activities that do not add value, allowing for optimal resource utilization by the PMPRB and patentees. Moreover, any changes should reflect the practical aspects of their implementation.

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Form 2 Data Requirements

... patentees would be required to report the types of benefits deducted in the average price calculation, but not the amounts of each benefit. To further lessen the burden of implementation on patentees, the regulatory amendment respecting identification of specific types of benefits has been changed so that it would come into force on July 1, 2008, and not immediately following publication in the Canada Gazette, Part II.

With this proposed amendment, 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.

Lilly Canada believes that the current *Regulations* provide sufficient clarity on what variables should be included in determining average selling price. When one considers the volume of data that is currently provided in terms of net sales, quantity, international data, first 30 days of sales and a variety of forms, we feel the PMPRB has ample data available to determine if prices comply with 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 PMPRB reviewers.

If the PMPRB requires further clarity in how the average selling price was determined, 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 currently has the authority to seek further information on a case-by-case basis.

Timeline for Provision of Information re: First Sales of the Medicine
The PMPRB will still request data for the first day of sales only, but it is now proposed that the deadline for filing remain at the current 30 days after the day on which the medicine is first sold in Canada.

With respect to the provision of price and sales information for the first day of sales, the practical utility of this proposal is unclear. It is common practice among manufacturers to put in place rebates, discounts and trial prescription programs for the benefit of Canadian patients. Such programs are unlikely to be in place on the day after the date of first sale and, therefore, will not yet be reflected in the average selling price.

This proposed timeline modification significantly shortens the time period available to patentees to provide price and sales information respecting first sales. The *Regulations* currently allow for this information to be provided 60 days after the date of first sale.

From a practical perspective, this reduction in timeframe for reporting will be onerous to patentees, as data for filings must be gathered from a variety sources, including the parent corporation. At the same time, it is not clear that the reduced timeframe will achieve the streamlining of reviews that appears to be the purpose of the change.

Timeline for Provision of Information re: Identity of the Medicine
The PMPRB has notified Rx&D it is now proposed that the timeline for provision of this information be changed to the earlier of seven days after the date of issuance of the first NOC in respect of the medicine, or seven days after the date on which the medicine is first offered for sale in Canada.

This proposed modification significantly shortens the time period available to patentees to provide their medicine identification information. The *Regulations* currently allow for this information to be provided within the earlier of 30 days after the date of NOC and 30 days after the date of first sale.

From a practical perspective, this drastic reduction in the timeframe for reporting will be onerous to patentees. At the same time, it is not clear that it will achieve the streamlining of reviews that appears to be the purpose of the change.

Provision of Draft or Final Product Monograph
... patentees will still be required to submit, if an NOC has not been issued in respect of the medicine, information similar to that contained in a product monograph. The

proposed requirement that a product monograph be provided in cases where a NOC has been issued has not changed.

Lilly Canada understands that the PMPRB uses the product monograph in the scientific review process of the price review.

Our primary concern is with the mandatory submission of a draft monograph (or information similar to that contained in a draft monograph), which could potentially change before the 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 a duplication of effort.

The use of draft product monographs (or similar information) raises additional confidentiality concerns, as the PMPRB may share this document with external reviewers.

We trust that Lilly Canada 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 price reviews. Given that the product monograph has long been identified as a requirement in Schedule 8 of the PMPRB's *Compendium of Guidelines, Policies and Procedures*, the PMPRB must already be receiving the document voluntarily from most companies. In the likely few cases where it is not, the *Patent Act* provides the PMPRB with the power to order its production. Thus, we question the need to formally incorporate the provision of the product monograph into the *Regulations*.

Complaints-Based Regulation for OTC and Veterinary Drugs

...would be regulated on a complaints-based approach. Patentees will be required to provide price and sales information to the Board within 30 days after the date on which the Board sends a request in response to a complaint respecting the price of a medicine.

Lilly proposes that this positive amendment be expanded to include patented prescription drugs 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 PMPRB could realize further efficiencies and patentees would benefit from a reduced reporting burden if genericized prescription drug products were treated in the same manner as PMPRB intends to treat veterinary and non-prescription drugs.

Lilly Canada trusts that the PMRPB will take our input into consideration and will seek amendments that support efficiencies, while at the same time being mindful of the regulatory burden faced by patentees. It is our hope that the Board will pursue solutions that make the best use of the resources at their disposal to the benefit of Canadian taxpayers.

Sincerely,

Lauren Fischer
Sr. Manager, Government & Economic Affairs