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Government & Economic Affairs

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Secretary of the Board
Box L40, Standard Life Centre
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Secretary of the Board,

RE: Response to PMPRB "Price Increases for Patented Medicines: Discussion Paper"

The following is Eli Lilly Canada's input on the three hypothetical regulatory frameworks presented in the Discussion Paper, followed by the five specific questions with regards to PMPRB's Guidelines.

Lilly's general view is that the current guidelines provide adequate means for controlling price increases and the Board has clear guidelines in place to make it known how it will deal with those that have priced excessively. Based on the past ten years, the level of price increases has been substantially below the level of CPI allowed by the Board. Lilly's cumulative price increases over the last ten years have not kept up with inflation and furthermore, Lilly's largest selling drug Zyprexa has not seen a price increase since launch. Under this backdrop of limited if any price increases, any means of further restricting price increases that would otherwise been allowed under current PMPRB guidelines, would seem inappropriate.

The PMPRB must recognize that the pharmaceutical industry is a critical component to the economic growth of Canada. Significant investments in research and development are made through broad collaborations with universities, hospitals and other centres that add to the overall growth of our economy and research and development presence. Lilly trusts that any review of pricing regulations will take into account a much broader review of the industry policies relating to intellectual protection, investment, research and development, health care funding and other environmental factors. A proper review of the overall system will allow for an optimal solution to be established.

Consideration of the Three Frameworks Representing Different Regulatory Systems

1. *Current system where patentees are allowed to take an automatic price increase in a given period up to a predetermined maximum, with price reviews taking place after the fact.*
2. *Patentees would be required to apply to the PMPRB in advance of any price increase, allowing a review of the proposed price increase before it is implemented to ensure that the new price is within the Guidelines.*
3. *Patentees would be required to apply in advance for a price increase and would also be required to provide justification for the proposed increase and the extent of the increase. The PMPRB would make a determination on both the appropriateness of the increase and on the extent of the increase up to a non-excessive maximum.*

It is Lilly's view that of the three frameworks, the first one represents the best means of ensuring the Board's mandate by providing clear guidelines that are not overly restrictive and inefficient in their implementation.

Under framework # 1, all parties are clear on the allowable price increase of a medicine through clear guidelines (CPI and not exceeding International maximum price). Those that have clearly violated these guidelines would be dealt with via the compliance and enforcement guidelines. Based on the historical number of price increases and considering Lilly's own practice of taking no or minimal price increases, a further restrictive approach will simply create non-value added work for both the manufacturer as well as the PMPRB. It would seem to make more sense to deal with outliers than apply a broad brush to the entire industry.

Requesting all manufacturers to submit price increases in advance for prior approval when the guidelines clearly state the methodology would add an additional layer of bureaucracy would not add value to the overall system. Furthermore, if some price increases have been taken, as has been the case with Lilly, this has been on a few select drugs with the overall weighted increase being well below the allowable levels.

Within the discussion paper, the PMPRB has raised various themes which include "price stability", reference to European countries limiting price increases or reversing price increases. Lilly finds this "cherry picking" approach to containing prices concerning, as it does not address the broader differences between the Canadian and European models. Many European negotiations around price will include a broader discussion on access and reimbursement levels, which are totally ignored by the proposed framework. Other European countries allow for free pricing and for much faster access and reimbursement for innovative technology.

We trust the PMPRB will broaden its framework for discussion to achieve an optimal solution.

Lilly's response to the five questions raised in the Discussion Paper:

1. Should the PMPRB's Guidelines continue to allow automatic (ie. without prior approval) price increases?

As previously stated in Lilly's response to the April 15th letter, Lilly's view is that any proposed changes to the regulations should either improved efficiency or effectiveness of the price increase process once the regulations have been established. Therefore, with clearly established price increase regulations, manufacturers should continue to be allowed to take increases within the current guidelines. Modifying this process will simply introduce new steps that would create unnecessary reviews resulting in further inefficiencies and wasted productivity by the PMPRB. Lilly's price increases over the years have been negligible from a portfolio standpoint and have been substantially below the allowable CPI increases. Based on this level of pricing activity, additional reviews seem inappropriate in light of larger review issues faced by the PMPRB.

A further concern with gaining prior approval is centred on confidentiality. Lilly will typically inform its wholesalers with very little lead time when a price increase will be taken to avoid any inappropriate stocking by wholesalers. Informing the PMPRB of a potential price increase could create further risks in the distribution channel for arbitrage. Manufacturers should not have to carry this undue risk. As the PMPRB is focused on ASP and manufacturers report ASP, seeking prior approval creates further complexities with the reporting of list prices, which are published versus ASP, which are for PMPRB purposes.

2. Are there considerations other than or in addition to the CPI that should be used to review price increases?

Based on the amendments to the CPI guidelines in January 1994, coupled with the current level of controls through Section 7.1 of the Guidelines which prohibit Canadian prices exceeding maximum international prices, the PMPRB has strong controls in place. Any further tightening of these controls would place undue pressure on the industry and force Lilly to re-evaluate its broader environmental strategies.

3. How often should price increases occur? (eg. Every year, once every 3 - 5 years, only after a certain introductory period, when justified)

Lilly does not see the need to establish a time frame when price increases can occur. The current regulations clearly state what level of price increases would be allowed based on CPI and other factors; they do not state when these increases need to be taken. Any violation of these guidelines would be dealt with by the PMPRB.
Thus, with the level of allowable increase established, a control is self evident in terms of what potential price increase could be taken. Imposing timing limits when an established price can be taken, would only add further complexity and

inefficiencies that resolve very little in terms of what is fundamentally approved based on the regulations (ie. the level of price increase allowed).

4. If justification is required, what criteria should be considered?

As previously stated, Lilly's position is that justification of price increases should only be required after the fact, as Lilly is perfectly clear on the allowable price increase based on approved PMPRB guidelines. Furthermore, Lilly's reporting of ASP on a bi-annual basis provides further evidence that we are within compliance. Any manufacturer out of compliance can be dealt with appropriately based on the compliance and enforcement guidelines established by the PMPRB.

5. Given that the CPI is established in the Patent Act as a factor to be considered by the PMPRB, do you have any comments on its appropriate application in future Guidelines?

The CPI should continue to serve as a means to determine price increases in the future. Many major industries rely on CPI to keep track with inflationary costs. The PMPRB could look to modify its approach in establishing comparison prices when conducting a Therapeutic Class Comparison by adjusting the price of old medicines by CPI to determine an appropriate price point for new medications, rather than utilizing medicines that are 10-15 years old which were developed with an old cost structure. This could prevent the need for older medications to take price increases and allow for an overall benefit to the Health Care system and fair pricing for newer medications.

Conclusion

Eli Lilly trusts that any potential modification to the current regulations will involve a broader discussion on other environmental factors related to health care. In a globally competitive environment, a move to further limit pricing without addressing the access and reimbursement component could create an ill-fated outcome. If the PMPRB is to focus their efforts on constraining forces and exclude the enabling forces such as providing appropriate health care investments and access for Canadians, industry may be forced to re-evaluate many of its economic and environmental contributions. We trust any final review of price controls will be reviewed within a broader context.

Sincerely,

Tim Oreskovic
Associate Director, Government & Economic Affairs

cc: Terry McCool
Vice-President, Corporate Affairs