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Secretary of the Board
Patented Medicine Prices Review Board
Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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RE: Discussion Paper: "Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines" – Lilly Canada Written Feedback

Secretary of the Board,

I am writing in regard to the Board's request for written feedback on the above discussion paper, released January 31, 2008. Eli Lilly Canada Inc. (Lilly) appreciates the opportunity to provide input to the Patented Medicine Prices Review Board (PMPRB) regarding its review of the *Patented Medicines Regulations, 1994* (the Regulations) and the Excessive Price Guidelines (the Guidelines).

Upon reviewing all the proposals and options presented in the discussion paper, Lilly, like many other stakeholders, finds it difficult to comment on each individual proposal, as many of these issues are interlinked and interdependent. Lilly would like to reiterate its concern that the large number of issues being reviewed by the Board has become a source of considerable uncertainty for patentees. Any investment decision must contemplate the attractiveness of the market where the investment will reside. The pricing regime is an important element in the comparative evaluation of competing investment locations for pharmaceutical companies. Lack of certainty with respect to pricing, and the possibility of further restrictions, acts to discourage investments in Canada.

It remains unclear what problems the current review exercise seeks to address. PMPRB data demonstrate that excessive pricing has not occurred – even by the PMPRB's own rigid definition of it. Since 1993, Canadian drug prices have, on average, remained below the international median. At the bilateral session on September 11, 2007, however, there was broad consensus concerning the existence of two problems: the number, length and expense of Board Hearings; and a fall in R&D investment by patentees. Further, it was agreed that most Hearings relate to disagreements over the application of the Board's Category 3 definition and its CPI methodology.

Lilly supports the submission to the Board of Canada's Research-Based Pharmaceutical Companies (Rx&D). Our positions on the key issues raised in the Discussion Paper are summarized as follows:

- **Any Market Price Review:** No Guideline revisions are required in this matter; the status quo should be maintained. The Board already has the authority to review sub-national markets based on the data filed by patentees and to order additional information when deemed necessary. Evidence and stakeholder feedback indicate that such reviews should continue to be undertaken on a case-by-case basis, where warranted.
- **Re-Setting the MNE Price:** No Guideline revisions are required in this matter; the status quo should be maintained. The new price re-setting criteria proposed by the Board may have unintended negative consequences for the Special Access Program. Further, they risk creating considerable commercial uncertainty for patentees – a situation that runs counter to the Board's mandate under the *Patent Act*.
- **Issues Arising from the FCC Decision:** Patentees should have the option to include or exclude a benefit (e.g. discount, free good, rebate, patient support service, etc.) in the Average Transaction Price (ATP) calculation, provided that the approach is consistent from one reporting period to the next. In other words, the current policy, enunciated in the April 2000 NEWSletter, should be retained. This does not require any changes to the Regulations. Lilly is supportive of any change to the CPI-adjustment methodology that improves upon the current system by de-linking the MNE from the ATP. Changes to the CPI-adjustment methodology should not be tied to mandatory inclusion of benefits into the ATP calculation; patentees should retain the option to include or exclude those benefits.

Overall Guidelines Review

A. Proposed Scenarios for Consultation (Discussion Paper pp. 4-7)

i) Any Market Price Review

With respect to reviews of "any market", the Board already has the power to examine sub-national data and to order additional data. Such reviews should be undertaken on a case-by-case basis only, where warranted. Lilly's position is that no Guideline revisions are required in this matter; the status quo should be maintained.

The evidence presented in the May 2006 Discussion Guide showed that prices for all drugs by class of customer, and by province and territory, were overwhelmingly within the range of 5% of the national maximum non-excessive (MNE) price or lower. The PMPRB's complaint mechanism is sufficient to capture the very few cases where a price in a particular market may appear inconsistent with the Guidelines. As noted in the PMPRB's May 2007 *Stakeholder Communiqué*, a review of submissions received by the Board on this subject shows that most stakeholders are opposed to moving away from the national market approach.

The proposal in the Discussion Paper is not consistent with a case-by-case approach supported by most stakeholders; it would impose a *de facto* full sub-market price review. The Board has provided neither any evidence to suggest this approach is warranted, nor any analysis of the

implications of this proposal on the workload of the Board and patentees. Furthermore, the PMPRB has not been clear in outlining how their proposed changes in relation to "any market" would be implemented and operationalized. This lack of clarity causes difficulty for stakeholders to provide constructive commentary. However implemented, it is likely that the proposal would lead to unnecessary delays in price review. Lilly would not support this type of added regulatory burden, especially when PMPRB has not demonstrated that there is a need.

ii) Re-Setting the MNE Price

We share Rx&D's concern that the new specific criteria proposed by the Board may limit the circumstances under which it may be prepared to re-set the price in some cases, but expand them in other cases in an unpredictable way. Lilly's position is that no Guideline revisions are required in this matter; the status quo should be maintained.

The current Guidelines provide that the price of a drug sold under the Special Access Program (SAP) may be re-set when the drug receives its Notice of Compliance. The proposed criteria to re-set the MNE price in these circumstances create an extremely high threshold. The effect of this proposal would be to discourage manufacturers from supplying drugs under SAP at prices lower than the price that they would intend to sell at when the drug receives its Notice of Compliance. Uncertainty about the PMPRB's pricing policies may discourage manufacturers from supplying drugs to Canadians under the SAP at all. Lilly believes that the most fair and logical way of solving this issue is through the de-linking of the ATP from the MNE at product introduction. The approved introductory MNE should be the benchmark price for future periods, and not a lower ATP that resulted from a price reduction under the SAP or other benefit program. De-linking the introductory ATP from the MNE allows patentees to continue providing lower prices under SAP and other introductory period benefit programs while ensuring price certainty, thereby increasing the greater public good.

We are also opposed to the proposal to re-set the MNE price based on new "scientific information/evidence." The proposed circumstances are vague and could open the door to frequent debate. This, in turn, would create considerable commercial uncertainty for patentees, adding to the existing barriers to bringing products to market in Canada. This runs counter to Parliament's intent in creating the Bill C-22 amendments to the *Patent Act*, which was to provide regulatory certainty for patentees. Although the PMPRB positions this change as a potential benefit to patentees in that it would allow recognition of the true benefits of a medicine once there is sufficient evidence, in practice, a patentee would unlikely benefit from this provision. There are too many market barriers and controls that would prevent a price from rising significantly, even if the PMPRB ruled that new evidence supported a higher MNE.

B. Updates on Other issues Under Guidelines Review (Discussion Paper pp. 8-10)

i) Principles

Lilly does not consider that the proposed revision to the preamble of the Guidelines is necessary. The PMPRB's mandate under the *Patent Act* is clear; it is based on a balance of "five pillars":
1. intellectual property protection;

2. industrial benefits;
3. international trade policies;
4. health care; and
5. consumer protection.

Additional language in the Guidelines related to the protection of consumer interests is unnecessary. Further, it risks reinforcing the existing imbalance in the PMPRB's application of the "five pillars", to the detriment of patentees.

ii) Categories of Medicines and
iv) Price Tests

With respect to the issue of categories, the statutory standard of "excessive" and the factors in the *Patent Act* does not require the categorization of new medicines. When Canada's Parliament created the PMPRB, its intention was to ensure that there was not excessive pricing of patented medicines as a result of *Patent Act* amendments that restricted the issuance of compulsory licenses. The PMPRB Guidelines and their application deviate significantly from Parliament's original intent. The Guidelines would better reflect that intent if excessive pricing were defined as pricing that exceeds the range of prices in other countries and the CPI-adjusted prices of all other drugs in the therapeutic class.

iii) International Therapeutic Class Comparison and
v) Costs of Making and Marketing a Medicine

As in the case of any market reviews and MNE price re-setting, the Board has not demonstrated any need to pursue the issue of examining the costs of making and marketing or the routine use of international therapeutic class comparisons. No changes to the Guidelines pertaining to these issues are required.

With respect to international therapeutic class comparisons, the Board should continue to apply this factor of the *Patent Act* case-by-case, in a flexible way, to assist in the resolution of disagreements with patentees.

vi) Price Increases (CPI Methodology)

Lilly's feedback is provided below.

<u>Options to Address Issues Arising from the Federal Court of Canada (FCC) Decision</u>
A. Regulatory Options (Discussion Paper pp. 11-15)

Lilly's Overall Position

Lilly supports Rx&D's position that the patentee should have a choice as to whether or not a benefit (e.g. discount, free good, rebate, patient support service, etc.) is included in the ATP calculation, as long as the inclusion or exclusion is done consistently from period-to-period. Thus, there is no need to alter the current Regulations so as to require "mandatory" reporting/inclusion. Lilly does not view the Dovobet/FCC decision as a matter of "mandatory" reporting/inclusion of benefits. Rather, Lilly views the FCC decision as a clarification to the effect that a patentee's intention in offering a benefit has no bearing on whether that benefit

should be excluded from the ATP calculation. The PMPRB challenged the inclusion of certain benefits offered by Leo Pharma, arguing they should be excluded because they represented an attempt to "manage" ATP. However, the FCC ruled that, if a benefit falls within the categories listed in the Regulations, it may be included in the ATP calculation regardless of the intent of the patentee. In other words, Leo Pharma had a choice as to whether it would include its benefit into the ATP calculation, and it exercised this choice. The FCC ruling appears to have upheld a patentee's ability to exercise this choice. Thus, Lilly views the extrapolation of this ruling to mean mandatory reporting or inclusion of benefits as inappropriate.

Currently, if an ATP that does not include any/all benefits is at or below the MNE, it is compliant. Forcing the inclusion of these benefits will not change the compliance status (i.e., it will still be compliant, but at a lower ATP). However, forcing a patentee to include such benefits could discourage the patentee from offering them in the first place, especially under the current rules for determining the subsequent period MNE. Disincentives to the offering of benefits would result in a decrease in the public good. Under the *Patent Act*, the PMPRB does not have jurisdiction over a patentee's net wholesale price (NWP), but rather the average transaction price. If a patentee chooses to include benefits in its ATP calculation - even if it is for the reason of ensuring compliance with the MNE - it should be entitled to exercise this option (a right the FCC decision appears to uphold). In neither of these situations, does there need to be a "mandatory" reporting/inclusion of benefits. The current policy of allowing the patentee the option to include or exclude benefits in the ATP calculation (so long as the patentee is consistent from period-to-period) is not the true problem at hand. The Guidelines and Regulations as they currently stand allow the PMPRB to meet its mandate of ensuring that average transaction prices are not excessive. To summarize, forced inclusion of benefits does not improve compliance—it only creates a disincentive to offer benefits in the first place.

Instead the focus of the PMPRB should be on changing the MNE calculation rules to remove any potential disincentive for patentees to offer benefits. The one reporting change that Lilly can support is one whereby, if a patentee chooses to include a benefit into the calculation of its ATP, it should disclose the existence of this benefit and, at the PMPRB's request, demonstrate that it has been consistent with the reporting of this benefit from period-to-period. However, it should be noted that any such disclosure would not be for the purpose of selection of which benefits should or should not be accepted, but rather to ensure that the PMPRB is informed of the benefits included in the ATP calculation. To summarize Lilly's position, the current policy allowing the patentee the option to include benefits in the ATP calculation, as long as the patentee is consistent in its reporting from period-to-period, should not be changed.

It is under the lens of the above position that Lilly evaluates each of the PMPRB's proposed regulatory options:

Option 2

There is no need to amend the regulations to exempt patentees from the requirement to report benefits provided to third-party payers, nor is there any need to compel patentees to report this type of benefit. The PMPRB has correctly identified that these third party-payers do not fall into the four specified classes of customers—so, if anything, these benefits should be excluded.

However, benefits provided to third-parties do translate into a benefit for the end customer in the marketplace (e.g. in the form of enhanced access to medication). The PMPRB has also correctly identified that, if the ATP without these benefits is already in compliance with the MNE, it should not be concerned if a payment further reduces the ATP. Thus, it is Lilly's position that the current PMPRB policy should hold—i.e. that patentees should retain the option to include this type of benefit into the ATP calculation, so long as they disclose the existence of these benefits if they choose to include them, and, if so, report them consistently from period-to-period.

PMPRB Staff have raised the following concern: … if one jurisdiction enters into an arrangement, which reduces the price paid by the drug plan, other jurisdictions may pay higher prices to offset the lost revenue for the patentee….
Agreements patentees enter into often tie price levels to access and/or volume levels. In addition, provinces such as Ontario have declared they want to benefit from their size and purchasing power in price negotiations —this is one of the reasons behind the enactment of the TDSPA (2006). Such elements already work to provide a market-based control of the prices of medications. In addition, the PMPRB's *current* regulations, along with those of other agencies, already remove most of the discretionary pricing from the system. Often a jurisdiction that is paying a "higher" price is one that offers a lower level of access. Jurisdictions/payers have the power to determine their levels of access (and hence to a large extent volume) in response to a price, so there is already a check-and-balance in the market to keep prices in line. Furthermore, the notion of a "higher" price being excessive in the current MNE guidelines is a potential misnomer. Currently, the MNE decreases in step with a decreasing ATP, so the inclusion of a benefit depresses not only the current period ATP, but also the future MNE by which the PMPRB judges excessiveness—that "higher" price paid by one class of customer may well have been compliant if the MNE had not decreased due to the inclusion of a benefit for another customer. In addition, the current set of regulations allows a customer to file a complaint with the PMPRB if they feel a patentee is charging them an excessive price—i.e. above the MNE. This complaint mechanism works well and should be the only necessary check-and-balance employed by the PMPRB. The existence of this complaint mechanism (regardless of whether it is used frequently) acts as a strong and effective deterrent to prevent patentees from taking excessive price increases. Any additional PMPRB interference with the market price may have deleterious consequences, as the PMPRB is not a market-maker, neither in terms of volume nor in terms of access.

Option 3
i) The FCC decision does not give the PMPRB the mandate to exclude all free goods from the ATP calculation— in our view, that is a misinterpretation of the ruling. Lilly disagrees with the PMPRB's proposed interpretation that a free good does not fall under the definition of a "sale", and thus should be excluded from the ATP calculation. For accounting purposes, if the good is in saleable form, but is given away, it is booked as a zero dollar sale. (If the patentee were to sell that good for one cent per unit, would the PMPRB then count that as a sale and thus include it in the ATP calculation, even though it was effectively given away?) The PMPRB should focus on (as the FCC decision has) the benefit side of the ledger—did a customer benefit? If it was given away to someone in the marketplace, then the answer is yes. Lilly's position is consistent—the patentee should have the option to include free goods in its ATP calculation so long as the

patentee discloses the existence of this benefit, if it chooses to include it, and reports it consistently from period-to-period. If a patentee chooses to use free goods to ensure compliance with the MNE, then the current Regulations and Guidelines allow this (and the marketplace benefits from the free product). If a patentee does not choose to include free goods into its ATP calculation, it should not be forced to include them - particularly if doing so creates a disincentive for the patentee to offer these free goods. PMPRB should be concerned only with the consistency of the patentee's reporting; this can be achieved by the patentee disclosing the existence of such a free goods program, if it chooses to include it, and being able to document that it has been reporting it consistently, if requested to do so.

ii) Lilly's position is consistent for the reasons discussed above—the patentee should have the option to include free goods in its ATP calculation as long as the patentee discloses the existence of this benefit, if it chooses to include it, and reports it consistently from period-to-period.

iii) Lilly agrees that products which are in sample or non-saleable form should not be included in the ATP calculation.

Option 4

Lilly supports the amending of the Regulations to include consideration for services that are either free or partially subsidized, as partially subsidized services have beneficial value to customers. Lilly assumes that the patentee's cost of providing either the free or subsidized service will be the amount that will be used for the ATP calculation. Lilly also maintains the patentee should have the option to include free or subsidized services in its ATP calculation as long as the patentee discloses the existence of this benefit, if it chooses to include it, and reports it consistently from period-to-period.

Option 5

Lilly supports the amending of the regulations to exclude "gifts" from the calculation of the ATP.

Option 6

The PMPRB should take into account the magnitude of the excessive revenues when evaluating the remedy that the patentee is offering to offset its excessive revenues. The PMPRB's notion of "dumping" of free goods is a misnomer—dumping in trade terms refers to an act of predatory pricing in a market foreign from the manufacturer, and is usually used as grounds for protectionist pricing policies (i.e., keeping a price high to protect local manufacturers). However, in the PMPRB's context of preventing excessive or so-called "high" prices, "dumping", especially large quantities of free or very inexpensive product, is a positive action in terms of driving average prices down. On the receiving end of the "dumped" product is a customer in the marketplace that has benefited from receiving that free product. If overall excessive revenues are relatively minor, we would argue the PMPRB should not be concerned about how targeted the remedy is. If, however, overall excessive revenues are significant, a manufacturer would have to "dump" a significant amount of free product in any case, which will either be not feasible (e.g., due to customer stocking limitations), or will have generalized market benefits. One could argue that this method of distributing benefit to offset excess revenues is

equivalent to or, even more beneficial to the marketplace than, writing a cheque to General Revenues to repay the excess revenues.

In addition, the approach being proposed by the PMPRB (i.e. excluding any benefits implemented after staff notification of an investigation) would impose significant restriction on patentees to implement any benefit that may have been in the planning stages long before the notification. It would also severely restrict a company's ability to offer patients any form of special program over the course of an often lengthy investigation not to mention a formal proceeding. Such an approach will have a detrimental effect on the implementation of programs benefiting patients.

Finally, the manner in which the PMPRB proposes to amend the regulations in this option appears to run counter to the FCC legal decision. Any amendment should be congruent with the FCC decision.

B. Guidelines Options: Possible Changes to the CPI-Adjustment Methodology for Determining the MNE Price (Discussion Paper pp. 16-17)

Lilly is supportive of any change to the CPI-adjustment methodology that improves upon the current system by de-linking the MNE from the ATP. If anything, patentees should be given an incentive to offer benefits that may decrease the ATP without the negative consequences associated with a corresponding drop in the MNE. The current system, in fact, creates an incentive for patentees to do the opposite - to maximize price increases (within CPI) so that the MNE continues to rise.

Of the two options presented, the second option is preferred; however a complete de-linking of the MNE from the ATP would be most appropriate in terms offering the proper incentives for patentees to provide benefits, and to decrease the regulatory burden for both patentees and the PMPRB. The PMPRB's price review methodology should not be applied in such a way as to consider a previously deemed non-excessive price to be excessive in a subsequent period. Lilly also maintains that changes to the CPI-adjustment methodology should not be tied to mandatory inclusion of benefits into the ATP calculation—patentees should always retain the option to include or exclude those benefits. Regardless of CPI-methodology changes, forced inclusion of benefits into the ATP calculation constitutes a disincentive for patentees to continue offering them.

The PMPRB should not expand its mandate beyond excessive pricing. Specifically, the PMPRB should not attempt to expand its jurisdiction to removal of benefits and the subsequent increase in ATP. This oversteps the mandate for the PMRPB set out by the *Patent Act*, and creates a disincentive for patentees to offer benefits in the first place.

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We trust that Lilly's comments will be given due consideration as the PMPRB proceeds with its review of the Regulations and the Guidelines. If the Board has questions, or requires additional information, please contact the undersigned at Tel.: 416-699-7446 or E-mail: fischer_lauren@lilly.com.

Sincerely,

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