AstraZeneca

Mark S. Jones
President and C.E.O.

March 3, 2008

Patented Medicine Prices Review Board
Box L 40
Standard Life Centre
333 Laurier Avenue West
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Ottawa, Ontario
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RE: **"Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines" Discussion Paper**

Attention: Secretary of the Board

Dear Madame Dupont and Board Members,

On January 31, 2008 the Patented Medicine Prices Review Board (PMPRB) presented its latest Discussion Paper in the consultation process on the Board's Excessive Price Guidelines and the implications of the Federal Court Decision in *LEO Pharma*.

AstraZeneca Canada fully supports the position paper submitted by Canada's Research-Based Pharmaceutical Companies (Rx&D) to the PMPRB Board on this matter. We would, however, like to emphasize the following points with the Board.

We have significant concerns regarding the lack of detail and clarity of the proposals outlined in the Discussion Paper. As an industry member and stakeholder subject to the Board's regulatory oversight, we feel that the proposals provided in the Discussion Paper do not address the complexity and inter-relatedness of the issues. It is difficult, if not impossible in some cases, to assess the implications of the proposals outlined in the Discussion Paper while significant parts of the process are still under development or have not been given appropriate consideration.

"Any Market" Price Review

AstraZeneca Canada echoes Rx&D's concern that the Board's current proposal is inconsistent with its previous position, restated in the Discussion Paper, that reviews conducted at the level of any market should be undertaken on a case-by-case basis. In its May 2007 Stakeholder Communiqué, the Board said: "…, stakeholders expressed the view that if reviews are conducted at the level of any market, they should be undertaken where warranted, on a case-by-case basis. **The Board agrees with this approach**…." [Emphasis added] The proposed amendments in the Discussion Paper could lead to mandatory sub-market price reviews for each DIN.

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Not only is such a proposal unwarranted and unnecessary, it creates significant increased demands on both the Board and industry members. The rationale and benefits of moving away from a national Average Transaction Price ("ATP") towards a need to examine prices in 56 sub-markets per DIN have not been documented, making it difficult to understand or support the need for a proposal with such an increased administrative burden.

"Resetting the MNE Price"

In AstraZeneca Canada's view, the PMPRB should postpone further consultation on this matter until a detailed proposal, which considers the potential impact on the introduction of innovative medicines in the future and to the early access to new products provided by the Special Access Program (SAP), can be provided to stakeholders. This is particularly true given the lack of detail in the current proposal and its dependence on such undefined issues as the "costs of making and marketing" and the Progressive Licensing Framework.

According to the PMPRB's own criteria, any proposed changes should be clear, transparent and not overly burdensome to either the PMPRB or the patentee. Based on *the current proposal, it cannot be determined if the outlined changes meet these criteria.*

Furthermore, it is not within the PMPRB's mandate or expertise to "recognize the real value of the medicine", an assessment that is, in any event, complex, multifaceted and redundant in view of the assessments undertaken by other authorities. This clearly reaches beyond the stated mandate of the Board as established by the *Patent Act*.

FCC Decision – *LEO Pharma*

In AstraZeneca Canada's view, the Federal Court decision in *LEO Pharma* does not require the Board to make the policy change announced in the April 2007 NEWSletter and explored in the Discussion Paper.

In general, AstraZeneca Canada welcomes changes that would remove or reduce the disincentives in the Board's guidelines to offer programs or other benefits that have the effect of providing access to medicines or lowering prices for stakeholders. Therefore, some of the options presented by the Board may have merit.

In particular, the proposal to explicitly exclude third party payer agreements from reporting and from the calculation of the ATP is consistent with the *Patented Medicines Regulations*.

Of the two guidelines options presented by the PMPRB, Option 2 offers a greater potential for development, as it would help to mitigate some of the negative impact of the current CPI – Adjustment Methodology. However, we have concerns about the fact that it does not fully "de-link" the ATP from the maximum non-excessive price ("MNE") and that it is still not assured that patentees are not penalized for offering products and programs free of charge or at reduced prices to its stakeholders.

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Updates on other issues

As the other proposals are still under review, it is not possible to comment on these matters. However, AstraZeneca Canada would like to emphasize again that we do not believe that there is a need for medicines to be categorized for the purposes of determining the MNE, as the PMPRB can fulfill its mandate of ensuring non-excessive prices without such categories. We look forward to the opportunity to provide comments when the proposals are finalized.

Additional comments:

No part of the Discussion Paper addresses how the approximately 1100 existing DINs under the PMPRB's jurisdiction, would be "transitioned" to the new reporting requirements, once the proposed changes, in whatever form they ultimately take, are implemented. Given the significant changes proposed, this matter must be carefully considered and input from industry must be taken into consideration.

In addition to the regulatory amendments proposed by the PMPRB, AstraZeneca Canada would like to suggest that the reporting requirements for patented products that have seen the entry of a generic alternative into the market be changed. A patentee's monopoly is removed at this time, as it no longer enjoys market exclusivity. These products create a significant reporting and monitoring burden for patentees and for the PMPRB, with no apparent benefit to stakeholders, who can choose to purchase the generic alternative. One option is that these products are dealt with in a similar fashion as patented veterinary products.

Finally, it is of great concern to AstraZeneca Canada that pricing measures and controls do not lead to a reduction of treatment choices available to Canadian physicians and patients. We believe it is critical to ensure that patients have access to the best available treatments and that physicians are able to effectively treat their patients - practicing best medicine and not approximate medicine.

Thank you for the opportunity to comment on these important questions. Please do not hesitate to contact the undersigned for further clarification or perspective regarding the above.

Sincerely,

Mark S. Jones
President & Chief Executive Officer
AstraZeneca Canada Inc.