AstraZeneca

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

April 27, 2009

Patented Medicine Prices Review Board (PMPRB)
Box L 40
Standard Life Centre
333 Laurier Avenue West
14th Floor
Ottawa, Ontario
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Attention: Secretary of the Board

Dear Madame Dupont and Board Members,

RE: Consultation on the PMPRB's Draft Revised Excessive Price Guidelines (March 2009)

On March 26, 2009, the Patented Medicine Prices Review Board (PMPRB) released the Draft Revised Excessive Price Guidelines (Draft Guidelines) and invited comments from stakeholders. AstraZeneca Canada would like to take this opportunity to provide recommendations as part of the PMPRB's consultative process. We also encourage the PMPRB to consider the comments submitted by Canada's Research-Based Pharmaceutical Companies (Rx&D), as we are generally supportive of their suggestions.

AstraZeneca Canada appreciates the progress that has been made to the Draft Guidelines, however, the current draft does not address a number of fundamental concerns raised by AstraZeneca Canada as well as Rx&D in previous submissions. There continue to be considerable gaps in the areas of new product introductions, price predictability and confidentiality of information (consult Appendix).

We are also concerned with the lack of clarity surrounding the PMPRB's decision-making process on which recommendations would be incorporated in the Draft Guidelines and which would not. AstraZeneca Canada was an active participant in a number of working groups convened by the PMPRB during the 2008 consultation process. We have observed that recommendations that received unanimous consent by all working group participants, including PMPRB staff, were not included in the proposed Draft Guidelines.

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AstraZeneca Canada recognizes that there is a desire to conclude this consultation expeditiously; however, due to the level of complexity and practical implications of the Guidelines, we strongly suggest that all stakeholders collaborate on the final draft. We also believe that we should initiate training sessions in the next 7 months to educate all PMPRB staff as well as patentees on the impact of the implementation of the Guidelines. This would provide an effective forum for all stakeholders to discuss the implementation timelines as well as address any additional questions or concerns.

Please find attached with this letter, a technical Appendix that provides further commentary, examples and potential solutions for the PMPRB to consider prior to finalizing and implementing the Guidelines.

Moreover, the Appendix encompasses additional points for future consideration of the PMPRB. In the spirit of updating reporting guidelines, we encourage the PMPRB to consider reviewing the annual reporting of patentees' Research & Development (R&D) investments in Canada to include all research mandated by the Canadian government and not only R&D investments that are based on the Scientific Research and Experimental Development (SR&ED) definition included in the *Income Tax Act.* We also encourage the PMPRB to revise the reporting requirements for patented products sold in a multi-source environment, similarly to those regulatory changes introduced for veterinary and OTC products.

AstraZeneca Canada appreciates the extensive effort that has been undertaken by all stakeholders involved to date; however, we strongly believe that further collaboration is required as we move forward in finalizing and implementing the Guidelines. We thank you for the opportunity to provide our suggestions and we would be delighted to meet with you to discuss our comments and recommendations further.

Sincerely,

Mark Jones.

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