AstraZeneca

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

October 22, 2007

Ms. Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Re: Regulations Amending the Patented Medicines Regulations, 1994

Dear Ms. Dupont:

On behalf of *AstraZeneca Canada Inc.*, I am writing to you with respect to the proposed amendments (Amendments) to the Patented Medicines Regulations, 1994 announced by the Patented Medicine Prices Review Board (PMPRB) in the Canada Gazette (Part I) on October 6th, 2007.

AstraZeneca Canada supports the submission made 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 the Board.

While we appreciate that changes have been made from the original package, we are concerned that the current version of the Amendments will still result in an increased regulatory and administrative burden to patentees, and no convincing public policy rationale has been provided to justify the increased regulatory burden.

Patentee provision of draft product monographs

"...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."

AstraZeneca is concerned about the lack of clarity in the proposed Amendments in terms of the submission requirements if no NOC has been issued. It would be beneficial if the PMPRB could clearly articulate what would be considered "information similar to that contained in a draft monograph". Documentation relating to future product monograph content is highly confidential information that is generally not disseminated prior to launch; hence the distribution of such information prior to the issuance of a NOC for a product would raise significant confidentiality concerns.

In addition it should be noted that any information provided to the PMPRB prior to the issuance of a NOC, will likely be amended during the review process by Health Canada, therefore any recommendations and decisions made by the PMPRB based on this preliminary information will likely be subject to re-assessment at the time of launch.

AstraZeneca Canada Inc.
1004 Middlegate Road
Mississauga, Ontario
Canada L4Y 1M4
www.astrazeneca.ca

TEL 905-804-6840
FAX 905-275-0494

AstraZeneca

Reduction in reporting timelines

It is the hope of AstraZeneca that the reduced reporting timelines set out in the Amendments will actually lead to a more timely review of patentee submissions and compliance reports,. Otherwise, the increased time pressures and greater administrative requirements may not offer any benefits to AstraZeneca.

Average Price Calculation

"...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."

This proposed change represents the most serious issue for AstraZeneca with respect to the Amendments. The detailed information sought by the PMPRB through these Amendments is rarely needed for the PMPRB price review process. In the unusual case that it is required, patentees provide it on request from the PMPRB. In the event that this information is not provided voluntarily, the Board can issue an order under section 81 of the Act that will compel the patentee to provide the required information.

It does not appear that the PMPRB has considered carefully the incremental cost this type of reporting creates. Additional costs to AstraZeneca would be incurred not only from the initial creation, testing and validating of the reports in complex accounting systems, but also from the on-going monitoring and administration required to meet the increased reporting requirements.

We question the value and need for this level of detail and urge the PMPRB to reconsider its position and to drop this reporting requirement from the proposed amendments.

Veterinary Drugs, and Over-the-Counter Drugs for Human Use

AstraZeneca supports the amendment respecting non-prescription and veterinary drugs. This positive amendment should be expanded to include patented drugs subject to generic competition.

AstraZeneca would suggest a further amendment to the regulations, so that patented prescription drugs subject to generic competition would also be included in the definition in subsection 3.

Once generics enter the market, the price of the patented version of a drug is irrelevant given that there is mandatory substitution in all provinces to the lowest cost alternative. Moreover, the underlying premise of regulating drug prices through the 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 price regulation is highly questionable.

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

Sincerely,

Mark S. Jones
President and Chief Executive Officer