AstraZeneca

Michael S. Cloutier
President and C.E.O.

April 15, 2005

PMPRB
Box L 40
Standard Life Centre
333 Laurier Avenue West, 14th Floor
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Attn: Secretary of the Board

RE: Proposed Amendments to the Patented Medicines Regulations

Dear Madame Dupont and Board Members,

In February 2005, the Patented Medicine Prices Review Board (PMPRB) issued a set of proposals to amend the Patented Medicines Regulations, 1994 (the Regulations), and invited comments from stakeholders ahead of the Canada Gazette process.

AstraZeneca Canada Inc. fully supports the position paper submitted by Rx&D regarding the proposed amendments.

In particular, we are concerned that the proposed amendments have the potential to lead to breaches of proprietary information relating to product monographs and pricing information significantly in advance of the information going public.

Additionally, the proposed regulatory changes will likely lead to delays in patient access to new and improved therapies in the Canadian market, as the proposals could lead to an instituted sixty day delay to market entry post-NOC. Please refer to section one of the Rx&D submission for a more detailed explanation of this point. AstraZeneca is firmly committed to providing patients with timely access to innovative medicines, and therefore we consider new delays to be unacceptable.

Furthermore, we would like to take this opportunity to make some comments on other issues related to the Board's operations.

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We believe that the PMPRB has been very successful in achieving its mandate of ensuring that prices for patented medicines are not excessive. Prices are at or below the international median.

However, we are concerned that the Board has been steadily growing its mandate over time. These proposed regulations are indicative to us of a slow shift from price review to price control. This in our view goes well beyond Parliament's intended mandate for the Board, and is a trend that causes our industry great concern. We believe that the Board already has sufficient powers outlined in the Patent Act to fulfill its role.

We also bring to your attention the fact that only a fraction of new medicines introduced in Canada are placed in Category II, which recognizes pharmaceutical innovation, despite the fact that significantly more medications are recognized within the medical community as breakthrough innovations. As well, the current guidelines for calculating the R&D-to-sales ratio do not reflect the true investment in research by AstraZeneca Canada Inc. and other Rx&D companies.

As a constructive suggestion, if PMPRB continues to monitor or regulate the prices of innovative medicines, we would strongly encourage it to consider the viability of the regulation of the prices of generic medicines (either at the federal or provincial level). Numerous recent studies have shown that Canadians pay significantly more than the international (or American) median for generic medicines.

AstraZeneca Canada Inc. encourages the PMPRB to reconsider the proposed amendments to the Patented Medicine Regulations as outlined in the Rx&D submission. In addition, we would urge the PMPRB to consider the comments above, in future discussions on the Board's role, function and mandate.

Sincerely,

Mike Cloutier
President & Chief Executive Officer
AstraZeneca Canada Inc.