AstraZeneca

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

October 6, 2008

Patented Medicine Prices Review Board (PMPRB)
Box L 40
Standard Life Centre
333 Laurier Avenue West
14th Floor
Ottawa, Ontario
K1P 1C1

Attention: Secretary of the Board

Dear Madame Dupont and Board Members,

RE: Consultation on the Board's Draft Revised Excessive Price Guidelines released August 20, 2008

On August 20, 2008, the Patented Medicine Prices Review Board (PMPRB) posted a Notice and Comment regarding the Draft Revised Excessive Price Guidelines ("Guidelines") and invited comments from stakeholders.

AstraZeneca 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.

AstraZeneca is particularly concerned that if the Guidelines are finalized in their current form, the PMPRB will be exceeding its mandate (and its jurisdiction) to ensure that the prices of patented medicines are not excessive. As more completely expressed in the attached technical appendix, the currently proposed Guidelines: (1) create disincentives to offering various forms of benefits as a result of the proposed de-linking model; (2) are a significant intervention into a competitive market; and (3) create confusion, not only for patentees but also all other stakeholders.

The Guidelines do not recognize the complexity of the pharmaceutical marketplace in Canada nor the role of Canadian businesses as part of broader global organizations.

PMPRB has received comprehensive guidance from its multi-stakeholder working groups and significant input from many stakeholders over the last 18 – 24 months. While, the

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PMPRB accepted the CGPA-PMPRB working group recommendations, with very little change, the recommendations of the other working groups were largely disregarded. AstraZeneca actively participated in a number of the other working groups; therefore it is hard for us to understand why the PMPRB has chosen to disregard the strong unanimous recommendations from these working groups. Disregarding such a significant body of work needs to be supported by a detailed rationale.

The framework in the proposed Guidelines could result in fewer new medicines reaching Canadian patients as early as they have in the past; could limit access to new medicines available from provincial formularies and could jeopardize valuable patient access programs supported and offered by the Canadian research-based pharmaceutical industry. As such, the proposed Guidelines interfere with patient and physician choice.

AstraZeneca believes that the most important change that should be made to the proposed Guidelines is to accept the recommendations of the Working Group on Price Tests to de-link the maximum non-excessive price from the average transaction price.

Finally, AstraZeneca stresses that, although the Guidelines as currently proposed need to be changed, it is willing to continue to participate in discussions with the PMPRB to resolve these issues. However, given the uncertainty and complexity of these issues, we request that the introduction of the Guidelines be suspended until an acceptable alternative is reached.

Sincerely,

Mark Jones

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AstraZeneca Canada Inc.

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Appendix: AstraZeneca Canada Inc. Technical Submission to PMPRB

AstraZeneca Canada Inc. ("AstraZeneca") seeks to provide technical submissions in support of its comments. These comments are in addition to or to highlight particular examples or concerns made in the Rx&D technical submission.

This submission is organized in accordance with the PMPRB's Notice and Comment package on the draft revised Excessive Price Guidelines released on August 20, 2008. In addition, we have identified other issues that have come to light as a result of a review of the draft Guidelines.

Levels of Therapeutic Improvement

The time constraints and accessibility of HDAP for advisory assistance raise significant concerns for AstraZeneca. To allow for appropriate considerations of price within the global business planning cycle, particularly in view of the changing guidelines and the associated uncertainty of the interpretation of these new guidelines by HDAP, four one-day meetings per year by the HDAP committee are unlikely to allow sufficient time for due consideration and assessment of each product.

One of the unanimous recommendations by the Working Group on Therapeutic Improvement was to give the patient perspective its appropriate weight in the assessment of the level of therapeutic improvement; it explicitly included the reference to patient convenience/preference in its recommendations. (Section 4.3 of the Working Group on Therapeutic Improvement final report). We urge the PMPRB to reconsider its position to exclude patient preferences in favour of considering patient convenience only if it leads to therapeutic improvement. Such a narrow approach does not give full consideration to the patient's perspective.

For example, cancer patients in remote areas, or even just a few hours travel away from a cancer treatment facility, will see a significant improvement in their quality of life, if they can access oral treatment options locally versus making regular and frequent trips to cancer treatment facilities for administration of an IV treatment. In this case, patient convenience and preference should be considered in any assessment of the product.

Introductory Price Tests

As a member of the Price Test Working Group, AstraZeneca is concerned about the omission of key price tests in the proposed Guidelines when compared to the current Guidelines. It was explicitly discussed and captured in the recommendations by the working group under the heading "Reasonable Relationship (RR) Test", that unless specifically requested by a patentee in a formal submission to the PMPRB, the existing three tests would be preserved and used in the future. These tests have worked well in the past and offered clear direction for patentees on the pricing of line extensions.

In addition, the PMPRB has created further uncertainty for patentees by removing alternate price tests should the reasonable relationship test not be applicable. These alternatives were either the Therapeutic Class Comparison (TCC) test, the International Price Comparison (IPC) test or a test specifically addressing the pricing requirements for modified release formulations.

By removing these alternatives the PMPRB has eliminated another avenue for patentees and Board staff to engage in constructive and reasonable discussions to resolve pricing issues, prior to resorting to resource-intensive investigations or hearings. (Sections 8.3 and 8.6 of the current guidelines)

Modified Guidelines for Certain Patented Generic Drug Products

AstraZeneca would urge the PMPRB to establish consistent reporting requirements for any patented product sold in Canada in a multi-source environment.

Impact of Reporting Benefits (De-linking of the ATP from the MNE Price)

AstraZeneca would like to stress the importance of the de-linking mechanism.

By establishing a de-linking methodology as proposed by Rx&D and the Working Group on Price Tests (WG-PT), the PMPRB creates a stable and predictable pricing environment in Canada that will benefit all stakeholders. In fact, it could be viewed as a positive step and be a motivating factor for parent companies to consider Canada as an investment opportunity. It would remove disincentives for offering rebates, discounts, free goods, free services, gifts and other benefits of like nature created that is by linking the MNE to an ATP that includes all benefits, thereby eroding the MNE.

Robust de-linking removes a strong disincentive for companies to provide benefits and access programs to the obvious benefit of patients and other stakeholders. However, the proposed de-linking model put forward by PMPRB is not feasible. It does not account for the complexity in the Canadian pharmaceutical environment, the number of (overlapping) programs in place at any one time and the multitude of stakeholders that can be involved. The monitoring, reporting and analysis needed on both the part of the patentee and the PMPRB would be extensive and likely not feasible without increased resource requirements on the part of patentees. This is in contravention to the directive by the federal government to reduce the administrative burden for Canadian industry (*Cabinet Directive on Streamlining Regulations, April 1, 2007*).

Even in the simple model put forward by the PMPRB (enclosed in the Rx&D submission for reference), that only looks at a few customers as opposed to the potential 56 in play in the current system (13 provinces and territories each with potentially four classes of customers), it is apparent that the complexity of scenarios would be overwhelming.

Perhaps of even more concern is that in each of the eight examples of various pricing scenarios set out, the PMPRB would trigger an investigation at one point during the first few years on the market in each one of them. Considering the simplified set up (limited number of customers and reporting factors) the number of investigations triggered by the PMPRB in the actual reporting environment would likely be much higher. This is an unnecessary investment in time and effort for both parties because these investigations are triggered by product prices *below* the national MNE set out by the PMPRB.

By de-linking the MNE from the average transaction price ("ATP"), the PMPRB would address a number of stakeholder concerns that have been expressed in previous consultations. In addition, the unanimous endorsement of the de-linking methodology put forward by the WG-PT is further indication that this proposal would be a positive evolution of the PMPRB for all parties involved. PMPRB's proposal outlined in the Guidelines is unnecessarily complicated, not reflective of actual business processes and practices, it is unduly cumbersome to monitor and report on and will likely result in further confusion for all stakeholders on this matter.

There is an urgency to address the de-linking issue as quickly as possible. AstraZeneca supports Rx&D proposal that the Board establish a small committee with Rx&D to identify some interim reporting and assessment measures pending a more thorough review.

Any Market Price Reviews

The PMPRB's proposed any market price reviews only add a further level of complexity and confusion to the pricing and reporting of patented pharmaceuticals. The proposed approach in conjunction with the outlined de-linking methodology is not reflective of business practices and overly cumbersome.

In May 2007 the Board indicated in its own summary of stakeholder feedback:

> "Through the Board's consultations, 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 and will be identifying circumstances where it may be appropriate to review prices in any market."

The proposed guidelines are in contrast to this conclusion, by introducing a formal review of products at the introductory stage as well as in case of an investigation or disagreement with a patentee.

AstraZeneca recommends to the Board to more clearly define and highlight the issue that needs to be addressed through further any market review guidelines. Once that has been done, the Board should re-evaluate the need for further Guidelines beyond the approach taken to date.

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Re-setting the MNE Price and Exchange Rates

AstraZeneca is fully supportive of the issues and concerns raised by Rx&D with respect to the proposed changes to resetting the MNE and the view on price adjustments due to exchange rates. It is not acceptable or feasible to hold a Canadian business entity accountable for pricing decisions made by another company or that are influenced by the policy decision of a foreign government.

Transition

Finally, it is not clearly expressed in the proposed PMPRB guidelines how these proposals would apply to existing patented products under the PMPRB's jurisdiction.
The draft Guidelines fail to outline a clear transition process, period or criteria, nor do they provide any insight on how these rules are to be applied to existing DINs going forward. This leaves a tremendous amount of uncertainty for patentees and other stakeholders. Without addressing this aspect of the draft Guidelines in its plans and communications to stakeholders, it does not appear to be prudent for the PMPRB to proceed with its current proposals. Further thought and analysis to ensure that the Guidelines do not create unintended negative implications is required.