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October 6, 2008

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

Attn: Members of the Board

Re: Baxter Canada comments on the PMPRB Draft Revised Excessive Price Guidelines

On behalf of Baxter Canada, thank you for the opportunity to provide feedback on the Patented Medicines Prices Review Board (PMPRB) Notice and Comment, published August 20, 2008.

With respect to the Notice and Comment, as well as the August 18 Stakeholder Communiqué, Baxter Canada fully supports the comments and recommendations of our industry association, BIOTECanada. We share our association's concerns with respect to: (a) the proposed expansion of the Board's mandate as part of a new "underlying principles" section; (b) the selective application of the recommendations of the Board's working groups; (c) proposed changes to how the pricing tests will be calculated and applied; and important process and transparency issues.

However, Baxter Canada is most concerned with the Board's complex proposal to address average transaction price fluctuations by allowing only for limited de-linking of the Average Transaction Price (ATP) and the Maximum Non-Excessive Price (MNE).

Specifically, the proposed methodology for de-linking and its application to "any market" would:

1. Place the onus on patentees to provide the rationale and evidence for de-linking applicability in each particular case;

2. Impose severe limitations on the applicability of de-linking and, as such, fall far short in addressing normal average selling price fluctuations that can lead to the appearance of excessive pricing by:

    a. Separating the notion of "benefit" from a reduction in the list price to a particular market (e.g., a discounted price is not necessarily a "benefit" but rather a list price in a specific market);

    b. Requiring evidence that the price fluctuation is related only to the end of a benefit offered in a market (there is a reference to "a contract" as a form of evidence of a benefit, but

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this would require the release to the PMPRB of a confidential agreement or, more likely, many confidential agreements);

3. Apply an overly simplistic methodology that appears to assume that all benefits are the same for all customers within each market (e.g., that all hospitals have the benefit of the same contract price or that the same level of free goods, discounts, or rebates are offered to all customers);

4. Not allow application of the methodology in the case of new sales to a new class of customer;[1]

5. Not address long-standing issues relating to hospital contracting;[2] and

6. Lead to significant administrative challenges for both the Board and patentees (the examples of the de-linking methodology provided Board staff were highly complicated, citing cases on how the lowest price in Canada could be considered excessive under the proposed guidelines).

In sum, the proposed changes would have a major impact on allowable pricing, and do not appear to reflect the realities of the Canadian market for therapeutic products. Baxter Canada therefore urges the Board to undertake further consultation, and reconsider its draft approach on de-linking and "any market." In addition, any final changes to the guidelines need be subject to reasonable transitional measures, and the Board should support patentees in terms of flexibility and counsel in the application of any new reporting requirements.

Thank you for considering Baxter Canada's comments on the Board's proposed changes to the Guidelines. If you have any questions about our submission, please do not hesitate to contact me.

Sincerely,

Saurabh Popat
Director, Government Affairs and Public Policy, Baxter Canada Inc.

cc: Peter Brenders, President and CEO, BIOTECanada

[1] In other words, if sales begin in the wholesale class at the list price and subsequently to the hospital class at a discount, the hospital class price will not be allowed to bounce back to the list price in the event it needs to in future reporting periods. This would require patentees to make initial sales at the list price in each customer class during a product's introductory period to ensure the de-linking methodology is available (i.e., the methodology may discourage the offering of discounts to hospitals during the introductory period.)

[2] Hospital contracts are complicated: contracts can be won and lost; not all sales are tied to contract prices; one company's inability to supply product under a contract can result in another company supplying the product at list; the mix of sales volumes at contract prices and list prices can have a significant impact on average selling price; and often these issues have no bearing on the status of each of those prices in the context of excessive pricing.