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April 27, 2009

Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board
Box L40, Standard Life Centre
333 Laurier Ave. West, Ste. 1400
Ottawa, Ontario, K1P 1C1

RE: Baxter Canada Comments on the Draft Revised Excessive Price Guidelines (March 2009)

On behalf of Baxter Canada, thank you for the opportunity to comment on the Patented Medicines Prices Review Board (PMPRB) Notice and Comment of the Draft Revised Excessive Price Guidelines, published for comment in March 2009.

In regards to this most recent version of the Guidelines, Baxter Canada fully supports the comments and recommendations submitted by BIOTECanada, particularly in context of a) any market price reviews, b) recognizing benefits (DIP methodology) c) offsetting of excess revenues and d) transition and implementation timelines. There continues to be an overall lack of transparency in several areas including the price source to be used for comparators when reviewing a new medicine's price and recognition of the complex and unique issues relating to the hospital market, contract pricing and sales to a single customer.

1. CPI-adjusted Methodology & Unique Customer Contracts:

The guidelines are not flexible enough to reflect the unique and complex pricing and contract models used in the hospital sector. These contracts are already negotiated to provide the best price to the hospital customers and often they are long-term in nature, thus unable to take advantage of various elements of the guidelines including CPI-adjusted methodology.

In addition, the guidelines do not adapt well to other models unique to the biologics' industry. For example, the guidelines do not address the issue of markets for which there is only one customer. This would include products sold exclusively to the Canadian Blood Service, Héma Québec (e.g. blood products) and to government agencies (e.g. vaccines). These products are sold under long term contracts at prices that have been negotiated and agreed to by both parties. In these cases, the guidelines should not interfere with the negotiation process by imposing the CPI-adjustment methodology into the equation. The guidelines should instead contemplate the review of these products only in the context of international pricing and, as long as the negotiated price does not

exceed the international price range for the product, should be considered not excessive. Furthermore, we recommend a specific exemption of vaccine products, particularly for Federally contracted vaccines for use among the Canadian population or for specialty use (e.g., Department of National Defence)

2. Recognizing Benefits - DIP Methodology:

While it is intended to address benefits that would lower the average selling price in a market for a period of time, the DIP methodology continues to ignore the realities of the hospital contract market. There can be several contracts running simultaneously with overlapping contract periods and there are also sales within the hospital market occurring outside of a contract (i.e., at the list price). With multiple overlapping contracts, the point at which the average selling price will be allowed to readjust becomes unclear as does the interpretation of what constitutes the highest average selling prior to a particular benefit (i.e., contract).

In addition, the methodology effectively freezes the price to non-contract customers over the period the contracts are in place, which is likely several years, by only allowing the bounce back to a previous highest level without consideration of the change in CPI over the contract period. With several contracts overlapping over the years, it is possible in fact that no CPI adjustment would ever be allowed in markets where contracts are an ongoing basis of sales.

3. Repayment of cumulative excess revenues after three years

The current guidelines allowed up to $50K in cumulative excess revenues to be carried indefinitely to allow flexibility as a result of minor fluctuations in average selling price.

However, the revised guidelines require companies to repay any excess revenues that fall below the criteria for investigation (i.e., < $50K cumulative) and that have lingered for three years. In addition, there is no lower limit on the amount in excess and there is no rationale included for what appears to be a very punitive measure. Given that a product priced as little as $0.0001 above its maximum non excessive price generates excess revenues, this new requirement assumes that a product's average selling price can be forecasted and managed to the "n"th degree which is particularly difficult with multiple contracts.

Coupled with this change is the PMPRB's intension to publish on its website an ongoing list of products with cumulative excess revenues not meeting the investigation criteria (i.e. under $50K in excess) under the status "Appears Excessive". This represents a significant departure on the PMPRB's previous view of these products. In fact, these products were considered to be within the guidelines. Portraying them as "Appears Excessive" is a misrepresentation of their status. At most these products should be listed as "under review".

4. Resetting the (Benchmark) Non-Excessive Average Price

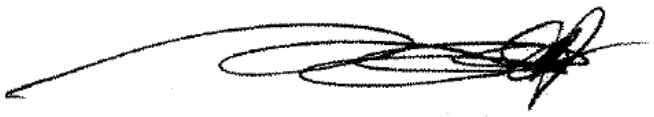
The guidelines appear to contemplate only one situation where the original benchmark price established for a product can be reset – that being the case of a product sold pre-NOC and for which the price during that period does not cover the cost of making and marketing the product.

This application is severely limiting as it does not allow the staff of the PMPRB to consider any other relevant issue and would require a public hearing to do so. In this way, it acts as a disincentive to the industry to offer products under special access at anything less than the highest price possible or to not provide the products prior to NOC at all.

Baxter Canada urges the Board to review and consider these issues and the recommendations submitted by BIOTECanada, before finalizing the Excessive Price Guidelines. Although it is important to complete the consultations and the process to revise the guidelines after many years in the making, it is more critical to ensure that the guidelines reflect the realities of the Canadian marketplace and the dynamic health care system. Furthermore, any final changes to the guidelines must be subject to reasonable transitional measures and implementation given the overall complexity and broadened scope of the guidelines and procedures. It is not reasonable to impose a July 1, 2009 implementation timeframe in context of both, the Federal Judicial Review and the time required for patentees to adjust internal processes to prepare for the full-scale changes.

Thank you for consideration of Baxter Canada's comments on the Draft Revised Excessive Price Guidelines. If you have any questions, please do not hesitate to contact me.

Sincerely,



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Cc: Peter Brenders, President and CEO, BIOTECanada