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Baxter

March 3, 2008

Sylvie Dupont, Secretary of the Board
PMPRB
Box L40; Standard Life Centre
333 Laurier Avenue West; Suite 1400
Ottawa, ON. K1P 1C

Dear Ms. Dupont:

Baxter Canada is pleased to submit a response to the PMPRB Discussion Paper, "Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines" released on January 31, 2008. The paper is seeking comments on multiple proposals, but of particular concern to Baxter is the focus on reviewing prices in "Any Market", "Re-setting the MNE" and the Federal Court of Canada decision in the matter of the LEO Pharma Dovobet case.

1. Reviewing Prices in "Any Market":

Baxter Canada is a diverse health care company that provides critical therapies for people with life-threatening medical conditions including cancer, hemophilia, immune deficiencies, infectious diseases, kidney disease and trauma.

As a result, Baxter Canada supplies products through several channels including government agencies (including the Canadian Blood Services), hospitals, buying groups and group purchasing organizations, wholesalers and retail pharmacy. In addition to the PMPRB price reviews, the cost and value of these products are assessed by a wide range of organizations and processes including government tenders (for blood products and vaccines), hospital therapeutics committees and buying groups and provincial and federal drug benefit programs. Indeed, products sold in these sub-markets are subject to detailed scrutiny that focuses not just on price, but on value as well. Moreover, these reviews may take into account combinations of products or products and services (such as provincial listing or risk sharing agreements) that are difficult to disaggregate to the simple product level required by the PMPRB Guidelines.

Accordingly, when PMPRB attempts to regulate prices within these sub markets (i.e., "any market") there is an increased probability that the application of the PMPRB guidelines will conflict with the objectives of the specific programs and may create disincentives for manufacturers to offer discounts or value added programs.

We note that the PMPRB's "Any Market" proposal is described as reviewing prices in sub-markets on a case-by-case basis. However, the case-by-case criteria described in the proposal would include a review of all sub-markets for every new drug introduced in 2008 and beyond. This is clearly not a case-by-case approach. The market that is most important, should remain the overall Canadian market.

The "any market" proposal also raises practical concerns. In theory, a patented medicine could be sold in more than 50 sub-markets at any time. That raises the prospect of more than 50 price reviews and potentially more than 50 MNE prices for a single drug. In practice, most patented products are likely sold in 20 to 30 of the sub-markets (i.e., two or three classes of customer across ten provinces) but even that number of price reviews and MNEs is impractical (and unnecessary) from a PMPRB mandate perspective.

The current statutory provisions allow the Board to consider prices in any market. Moreover, the Board's enforcement policy allows the Board staff to commence an investigation when there are complaints with supporting evidence of excessive pricing in any market. The current Guidelines do not limit the Board Staff from referring a matter to the Board if there is evidence of excessive pricing in any market. Accordingly, the Board has the necessary tools to monitor and regulate prices in any market on a true case-by-case basis without changes to the Guidelines or its price review procedures. Therefore, Baxter opposes the proposed "Any Market" guideline as unnecessary and potentially detrimental to the sub-markets that it is ostensibly attempting to protect.

2. Re-setting the MNE:

With respect to the proposed "Re-setting the MNE" provision, the proposal is premature. Until such time as consultations are completed on the relationship of the average price to the MNE and the mechanism(s) for re-setting the MNE price are fully defined, it is not possible to make an informed assessment of the proposal. In particular, it will be important to define the price tests that would apply in each case. Moreover, an important consideration of resetting MNE prices is that prices should be allowed to increase (beyond CPI increases) to the same degree they might be required to decrease under the re-setting provisions.

Finally, re-setting MNE prices the potential for a domino effect. For example, if product "A" has its MNE price re-set what happens to the MNE prices of other products that used the original MNE price of product "A" as a reference. Will they too be allowed higher prices or be required to lower prices when "A" has its MNE price re-set?

3. LEO Pharma Dovobet FCC decision:

The LEO Pharma Dovobet Federal Court decision reflected the facts and circumstances of a particular case. The Board and Board staff have interpreted the decision as applying not only to cases before it in a hearing (as was the case with LEO Pharma) but

necessarily to all price reviews conducted by Board Staff under the Guidelines. This is unfortunate, and in our view, unnecessary. Moreover the need for careful and thoughtful consideration of the issues is highlighted by conflicting and uncertain policy direction that emerged from the Board in the months immediately following the Court's decision.

Nevertheless, the LEO Pharma case and the Board's reaction to the Court's ruling raised important issues regarding the treatment under the Guidelines of special access programs, compassionate programs, free goods and risk sharing/listing agreements with third parties (e.g., provincial drug benefit programs) and products purchased through government tender (e.g., vaccines and blood products).

These issues could be addressed by de-linking the average price from the MNE price such that an MNE price is established at introduction and adjusted by CPI each year such that average prices (aggregated to the national level) would be considered to be within the Guidelines if they remained at or below the MNE price.

We welcome the opportunity to contribute to ongoing consultations and we look forward to continuing our participation in the coming months to assist the Board with its deliberations.

Sincerely,

Saurabh Popat
Director, Government Affairs, Baxter Canada