Bayer Inc.

April 27, 2009

Dr. Brien G. Benoit
Chairperson, Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Philip Blake
President and CEO

Bayer Inc.
77 Belfield Road
Toronto, ON M9W 1G6

Tel. (416) 248-3000
Fax (416) 248-6768
philip.blake.b@bayer.com

Dear Dr. Benoit:

I am writing to provide the views of Bayer Inc. on the PMPRB's Notice and Comment package on the Draft Revised Excessive Price Guidelines released on March 25, 2009. Bayer supports Canada's Research Based Pharmaceutical Companies (Rx&D)'s submission on this package and we are providing this letter with our specific comments.

I would like to begin by expressing our appreciation for PMPRB's efforts to increase the level of dialogue between the Board and its key stakeholders. After personally participating in the recent series of meetings with representatives from the Rx&D and PMPRB Boards, I can clearly say that these meetings and discussions have been very helpful in increasing the understanding of the fundamental objectives and principles which should form the basis of the Guidelines.

While we do appreciate the Board's willingness to engage in dialogue, we are disappointed that PMPRB has chosen to move forward with publication of this latest version of the Draft Guidelines, which continues to remain challenging in a number of areas. We recognize that the PMPRB has conducted a lengthy consultation exercise on the Draft Guidelines and there is a desire from both the PMPRB and some stakeholders to complete this work, we would however urge the Board to allow for adequate time to complete this final stage. The fruitful dialogue that has taken place demonstrates that solutions are possible and should not be sacrificed due to a desire to expeditiously conclude this partial process. As demonstrated by the 2007 proposed Guideline changes, there is a real danger in moving forward with the implementation of new Guidelines without fully understanding the potential unintended consequences.

More specifically, our primary concerns are the following:

Therapeutic Class Comparison Test (TCC) and the Reasonable Relationship Test (RRT)

These remain unclear as they are defined in the Guidelines. The application of these tests appears inconsistent and there is no adequate basis of certainty for patentees attempting to establish their prices. We are particularly concerned with the use of language in the document describing "superior" and "inferior" products for price tests for slight to no improvement products without direct comparators. The deeming of products as "inferior" and "superior" is outside the scope of the PMPRB or the HDAP committee which has been charged with identifying comparable drug products. We are disconcerted to see PMPRB proposing to evaluate products on this basis.

Furthermore, in Schedule 3 Section 2, we are concerned that the Board Staff could use a public price that is sufficiently close to the National Non-Excessive Average Price (NNEAP) of a patented drug product for comparison purposes. Given that the NNEAP could contain benefit(s) that would be removed by the DIP methodology, by using this NNEAP the new patented product would be penalized by the artificially low price of the comparator, thus resulting in a lower benchmark price. As such, we propose that the Maximum Average Potential Price with allowable CPI increases be used as an alternative.

Any Market Price Reviews

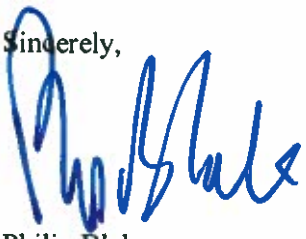
We are troubled with the language in the Draft Guidelines around how these reviews will be initiated and undertaken as it appears to be inconsistent with our recent bilateral discussions. The wording in the Guidelines continues to be vague for existing drugs and this raises even greater concern as it impacts the ongoing monitoring by patentees to ensure compliance with the guidelines. While the actual reporting requirements and format do not change, patentees will have to move from monitoring one national ATP and MNE to 17 NEAPs. With the new regulations Patentees will be required to track and extract information to explain various market variances, thereby greatly increasing the workload and burden to the patentee and PMPRB staff.

Criteria for Commencing an Investigation

We note that in the draft revised guidelines the threshold of $25,000 or more for cumulative excess revenues has been removed. For some older products with low sales special circumstances such as returns could cause the ATP to jump by more than 5%, however excess revenues may be in the order of a few hundred dollars. It would appear to be a poor use of PMPRB and patentee resources to pursue investigations of minor variances, and thus we would recommend that the threshold be retained. We also note that one of the criteria for commencing an investigation has changed from "complaints with significant evidence" to "PMPRB receives a complaint that a price is excessive". We would recommend retaining the current language in recognition that significant evidence should be required to launch an investigation.

Bayer has and continues to see a strong role for the PMPRB within its legislative mandate of guarding against excessive pricing and reporting on sales and R&D expenditures. We look forward to continuing to work with the Board on refining the PMPRB's processes and Guidelines to ensure the effective fulfilment of that mandate.

Sincerely,



Philip Blake
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