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October 6, 2008

Ms. Sylvie Dupont
Secretary of the Board
Box L40
Standard Life centre
333 Laurier Avenue West
Suite1400
Ottawa, ON K1P 1C1

Dear Ms. Dupont:

Thank you for the opportunity to provide comments on the Draft Revised Excessive Price guidelines released on August 20, 2008.

Levels of Therapeutic Improvement

As we have previously indicated, we do not believe that categorization of new patented drugs is necessary. The therapeutic value of a new medicine is not one of the factors that the Patent Act directs the Board to take into consideration.

For the current categories, we do not believe that they recognize the value of incremental innovation and differences in the therapeutic profile, metabolism, adverse effects that may impact on the patient response/tolerability of the medication.

We acknowledge and agree in principle that the proposal to establish a "moderate improvement" category for price review purposes provides greater flexibility for the price review than with the currently used three category classifications. However, we do not see the requirement for the PMPRB to establish levels of therapeutic improvement and again recommend that the Board reassess the need for specific categorization of new patented drugs.

Introductory price tests criteria

We agree with the option to provide a therapeutic improvement case for line extensions and if this option is not used that a Reasonable Relationship Test (RRT) could be considered for the price assessment. However, for the RRT, we recommend that the price assessment should be based on the ex-factory price and not the ATP.

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

We are encouraged that the Board has considered an alternate model of price review that would involve de-linking the MNE price from the ATP.

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For the "gap" methodology there are still significant issues as outlined by the Working Group in having this methodology result in a timely way to address having the Maximum Allowable Price being similar to the MNE price and/or ultimately achieving the MNE level.

For the "dip" methodology, there were many issues raised in the September consultation session which suggest that this methodology would create significant regulatory and operational issues and require further evaluation before being considered for implementation. A further Working Group evaluation should be considered.

Any Market Price Reviews

We are concerned about the decision by the Board to expand use of the any market reviews. Certainly we, and many stakeholders, have already indicated that they do not believe that the Board should review prices in any market on a regular basis and further clarification of the problem that needs to be addressed and the extent of the problem is required.

We look forward to your consideration of these issues in further considering the implementation of changes to the Excessive Price Guidelines.

Sincerely,

Lance W. Payne, B.Sc.Phm., Pharm.D
Director, Federal & Provincial Regulatory Affairs