Abbott Laboratories, Limited
Laboratoires Abbott, Limitée
P.O. Box/C.P 6150
Station/Succursale Centre-Ville
Montréal (Québec) H3C 3K6

Tel. / Tél. : 514.832.7000
Fax / Téléc. : 514.832.7800

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

Subject: Written comments following September 10th, 2007 Excessive Prices Guidelines Bilateral Meeting

Dear Dr. Benoit,

Since the beginning of the Excessive Prices Guidelines Consultation process in May 2006, Abbott Laboratories Limited (Abbott) has been an active participant at each step to identify key issues and to suggest constructive solutions. Following our participation at the Excessive Prices Guidelines Bilateral Meeting held on September 10th, 2007, Abbott is pleased to provide our written comments on this session. Abbott welcomes this additional and unprecedented opportunity, along with other stakeholders, to meet face to face with Board members, and we hope this dialogue will continue.

As a member of Canada's Research-Based Pharmaceutical Companies (Rx & D), we support their submission of Oct 31, 2007. In addition, Abbott has submitted comments in our letter dated August 2006 in response to the PMPRB's Board Discussion Guide of May 2006.

The Sept 10th Meeting
The absence of formality (no formal agenda, no moderator, no minutes, etc.) and the absence of a clear purpose raised certain doubts regarding the actual follow-up intended by the Board following this meeting. With 6 different stakeholder meetings held between Sept 10-12, it is not clear what issue(s) the Board is attempting to address. Abbott questions what the impact of these discussions will be to any decisions that will be made on these issues.

While the number of issues increased significantly from 3 to 8, as well as in complexity (most are interconnected i.e., categories and price tests) since May 2006, it makes it imperative that PMPRB develop as soon as possible for its stakeholders a clear and transparent timetable.

Issues discussed at the meeting
Although 8 issues were identified at the meeting, only 3 were focussed on during the 2-hour meeting: categories, price tests, and international therapeutic class comparison.

Abbott was pleased to discuss these issues with the Board and stakeholders present. However, we did not feel anything new was raised during this meeting that would change our position on these three issues. We therefore refer the Board to our August 6th 2006 letter and continue to support our position in regards to those key issues:

Categories
Abbott believes that Category 2 criteria need to be revisited and revised to reflect Health Canada's criteria for "priority review" medicines. It should be noted that there are presently enough tools at the Board's disposal to recognize "moderate therapeutic improvement". Creating additional categories would simply increase the complexity of the review process and the number of sources of disagreement.

Price tests and International Therapeutic Class Comparison
Abbott does not believe that the price tests currently used to review the prices of new medicines in the various categories are appropriate. We believe that all new drug products should be subject to their respective price tests, but if their primary price test forces the price in an inconsistent way with its international pricing then it should be compared to its comparators in other countries. Board staff has the responsibility to look at the international prices of a new drug product. This ensures that the new drug product is not being excessively priced.

As such, Abbott would support the use of international price ratios for new products on a case-by-case basis, as has been used for several products in the past few years to recognize their price as non-excessive.

Conclusion
Overall, Abbott is concerned about the direction taken by this consultation process as well as the continuing expansion of the number of issues. Whether the PMPRB's mandate will be expanded beyond the Act's original intentions, whether there will be an increasing inflexibility and reliance on the hearing process to solve patentee pricing issues, and whether the reporting requirements will be further increased to an onerous burden, all this creates an uncertain environment where innovation is stymied, the introduction of new drugs is delayed, and value-added patient support programs may not be encouraged. In an era of global R & D competition within companies, the ongoing pricing policy uncertainty will continue to prevent Canada from becoming a bigger player in attracting R&D investment.

Abbott encourages the PMPRB to establish a transparent process for dealing with the current issues and a more flexible approach to the resolution of these issues. As such, Abbott will continue to be an active participant in PMPRB's consultation process and will welcome further opportunities for dialogue.

Sincerely,
Abbott Laboratories, Limited

Laurie Dotto

Laurie Dotto
Director, Government and External Affairs