October 22nd, 2007

Ms Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West
14th Floor
Ottawa, ON
K1P 1C1

Dear Ms. Dupont,

Subject: Abbott Laboratories' response to proposed changes to the Patented Medicines Regulations, 1994 in the Canada Gazette 1 (Part I) on October 6th, 2007.

This is a response to PMPRB's publication of their proposed changes to the Patented Medicines Regulations, 1994 in the Canada Gazette Part I of October 6th, 2007.

Please note that, as the proposed changes are either the same or variations of the proposed changes published in The Canada Gazette Part I of January 1st 2006, you will find that our position is still very similar to the one expressed in our response letter dated January 30th, 2006. While Abbott Laboratories ("Abbott") is encouraged with certain revisions to the proposed changes, such as the removal of the requirement to notify PMPRB of proposed price increases, Abbott still has concerns with the proposed changes as outlined below.

Patentee Provision of Draft Product Monographs

Abbott is first concerned with the confidentiality of the information disseminated in such a document and second, is puzzled with the actual efficiency of using such information. Indeed, a draft monograph (or information similar to that contained in a draft product monograph) is highly likely to change or to be revised and as such, Abbott is concerned whether any decision based on an unofficial monograph would just be repeated again. If no decision is to be made until the official monograph is produced, then it is Abbott's view that the work of continually refiling any new/amended information is imposing on PMPRB and the patentee an unnecessary bureaucratic burden. Furthermore, Abbott would like to respectfully remind PMPRB that this approach appears to be at odds with the principles of Smart Regulation where Canadian regulations should be seen as a source of competitive advantage, not the opposite.

Reduction in Filing Timelines for Information Respecting the Identity of the Medicine
For changes in Form-1 reporting, Abbott maintains its position that reducing the deadline for reporting from 30 days to 7 days after receiving a NOC does not leave enough time to gather the relevant information and is just not realistic to complete due process in a large corporation. Abbott questions the rationale behind this new deadline and is not convinced it would increase efficiency and/or data accuracy.

Reduction in Filing Timelines for Price and Sales Information for the First Sales of the Medicine
Abbott does not believe that requiring reports within 30 days of the first day of sales (as compared to the current requirement for a report within 30 days after the first 30 days of sales) will provide PMPRB with a valid estimate of a newly launched product's ATP. Abbott is puzzled with respect to this amendment's rationale and does not believe it would provide any substantial benefit over current requirements. We suggest maintaining status quo here.

Average Price Calculation
Abbott strongly disagrees with the amendment that requires patentees to report the types of benefits deducted in the average price calculation. Since different types of benefits are already included in the ATP calculation, Abbott does not understand how identifying types of benefits will in any way increase PMPRB's efficiency in monitoring excessive pricing. Abbott believes this amendment will only result in discouraging the implementation of future discounts and patient programs. Furthermore, it is Abbott's view that the regulatory burden and additional stress this will add to the current reporting requirements and appears not justified in any way by any significant benefits to the PMPRB.

Abbott is committed to improving any process in the filing of information with PMPRB. However, we do not believe that the proposed changes to the Patented Medicines Regulations, 1994 published in the Canada Gazette Part I will achieve the goals of PMPRB to create a more efficient process, improve compliance and improve the precision of information included in the different filing forms.

Sincerely,

Laurie Dotto
Director, Government & External Affairs
Abbott Laboratories, Limited