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

Montreal, October 6th, 2008

Ms. Sylvie Dupont
Secretary of the Board
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

RE: Comments on "PMPRB Notice and Comment: Draft Revised Excessive Price Guidelines" (Published August 20, 2008)

Dear Ms. Dupont,

We are writing to provide comments on the above-noted Draft Revised Excessive Price Guidelines, which are due on or before October 6, 2008 (the "Draft Guidelines"). Please note that as a member of Canada's Research-Based Pharmaceutical Companies (Rx&D), Abbott also supports, and is in agreement, with the comments and recommendations submitted by Rx&D in response to this matter.

In reviewing the Draft Guidelines, there are a number of issues that remain of great concern to Abbott.

First, it is Abbott's position that procedural fairness is lacking in the agenda and consultation process set by the PMPRB. It is apparent to Abbott from discussions with Board staff (i.e., more particularly the teleconference with the Executive Director and Director of Compliance of the PMPRB on September 12, 2008), that the Draft Guidelines lack sufficient clarity for consistent interpretation and implementation. Abbott is extremely concerned that the hasty timeline proposed by the Board is unrealistic to appropriately address and provide effective consideration of all the issues raised in the consultation process before the scheduled implementation of the final version of the Guidelines as of January 2009.

In addition, Abbott has serious concerns relating to:

(a) the de-linking methodology and impact on the offering of benefits;
(b) the methodology for calculating excess revenue arising from excessive price in any market (i.e., the any market review, including price tests); and
(c) the administrative impact of both (a) and (b) on the day to day operations of the PMPRB and on the day to day operations of a pharmaceutical company.

Abbott's comments and recommendations regarding the above concerns are addressed in more detail below.

COMMENTS AND RECOMMENDATIONS

AGENDA/CONSULTATION PROCESS

1) PMPRB's Agenda does not allow sufficient time to assess and correct flaws in the proposed Draft Guidelines.

   PMPRB's Agenda allows the Board only 11 working days to go through all stakeholder responses and to make decisions based thereon. Furthermore, only 15 working days are provided to the Board to develop and write the final Guidelines and the transition methodology (see August 18, 2008 Communiqué). Abbott is very concerned that, under these circumstances, certain issues will be overlooked which will, in turn, cause the risk of misinterpretations.

2) The timeline proposed by PMPRB in its August 18, 2008 Communiqué does not provide any transition time for patentees to adapt their internal systems to the Guidelines, once finalized.

   New guidelines will have a significant impact on internal accounting/financial systems, which will require more than 25 working days to adapt (i.e., November 17, 2008 to January 1, 2009). Even if the first report to PMPRB is not delivered until July, the data needs to be properly collected as of January 1, 2009. These time constraints highly compromise the accuracy of the data that will be reported. **Abbott asks that PMPRB provide patentees with a full calendar year to adapt to the new Guidelines.** This would also provide sufficient time to work out the details on unintentional consequences brought about by the new Guidelines, thereby reducing the number of potential investigations and, in turn, relieving some of the administrative burden on PMPRB staff.

3) Without any forewarning, the Reasonable Relationship (RR) - Different Strength Test has been completely changed. This was done against the recommendation of the Working Group's consensus to leave the test as is and against the recommendations of the stakeholders. It was implemented without notice or provision of any justification. Further, it was changed even though at page 4, of the August 20, 2008 Notice and Comment document (" 4. Issue-Introductory Price Tests"), the Board states, "the Board accepts the price tests proposed by the Working Group", and "also agreed to maintain the RR test for line extensions…".

   Abbott believes that transparency should be a principal mandate of the PMPRB. Such a non-transparent action conflicts with the core mandate of PMPRB and undermines the role of stakeholders in the decision-making process for future Guidelines. As stated by Dr. Benoit, the Chairperson of the PMPRB, in his statement to the Standing Committee on Health on March 28, 2007, the Guidelines, are to "provide clear, predictable and transparent information on how the prices of patented medicines will be reviewed".

   Abbott asks that PMPRB correct this situation and re-establish the Guidelines the way they were originally written. The "ratio approach" proposed by the Board does not represent the reality of our industry in that a drug's cost is not proportional to the number of mg (or amount of active ingredient per dosage form), i.e., a 15mg tablet production cost is not half the cost of a 30mg tablet.

DE-LINKING METHODOLOGY AND IMPACT ON THE OFFERING OF BENEFITS

DE-LINKING METHODOLOGY

4) Abbott is pleased that the Board recognizes that ATP variations are sometimes due to factors other than price increases and intends to implement a "de-linking" of the ATP from the MNE price to palliate such variations. However, **Abbott is concerned that the proposed methodology does not, in fact, truly de-link the ATP from the MNE and continues to bring major disincentives to patentees in providing programs of significant benefit to patients.** What follows are three examples:

   a) The Draft Guidelines will force patentees to implement a price freeze in respect of any trade class customers to which they offer benefits. The Draft Guidelines do not recognize that (1) patentees do not offer the same benefits to all customers from one class, and (2) customers who receive benefits are also subject to price increases. For example, if a customer is offered a 20% rebate on $10.00, and the price is subsequently increased to $10.30 through a CPI adjustment, the customer will receive 20% off of the increased price of $10.30. If the rebate program ends, the customer is well aware that the price will be $10.30 and not $10.00. However, according to the de-linking methodology, the $10.30 patentee would be considered excessive as it would be above the prior maximum ATP for the medicine prior to the rebate. Because variations of benefits are highly unpredictable, the patentee has no choice but to suspend any price increases to the whole class of customers.

   b) The methodology proposed by the PMPRB in Schedule 8 of the Draft Guidelines suggests that the previous highest non-excessive ATP/MNE would become the MNE price should an ATP become lower due to increasing benefits. In the examples provided by PMPRB on their September 12, 2008 teleconference, there were numerous cases where an ATP for a particular customer class became excessive even though it was lower than the MNE and ATPs for other customer classes. (See also examples provided in the Rx&D submissions). Not only does this demonstrate that the MNE is still closely linked to the ATP variations, it also stresses the added complexity of the model since MNEs are now established for each customer class. If an ATP is below the MNE, then it is not excessive and the PMPRB has fulfilled its mandate. In summary, the Draft Guidelines arguably suggest the establishment of multiple MNEs for a medicine. They further lack clarity as to what would be considered a "market". This creates added complexity for implementation for both the Board and for the stakeholders and merits further consideration.

   c) The GAP methodology proposed by the Price Tests Working Group was completely disregarded. However, it is when a product is introduced on the market that the offering of compassionate programs and support programs are the most needed and critical. Should the PMPRB establish an MNE price of $5.00 to a drug that finishes its benchmark period with an ATP of $2.00 because of such programs, it does not make sense that the PMPRB should then force the patentee to an MNE price of $2.00. <u>This possibility will certainly discourage companies in providing any of these programs and, eventually, could even jeopardize the introduction of new drugs in the Canadian market</u>.

5) **Abbott, therefore, considers that the proposed de-linking methodology would greatly benefit from additional deliberations with the industry and should not be implemented without further consultation.** Abbott has established a strong reputation for its support towards patients, healthcare providers and the healthcare community and would regret having to eliminate programs because of hasty implementation of a flawed methodology in order for PMPRB to meet the arbitrary deadlines imposed by its Agenda.

IMPACT ON BENEFITS

6) The Draft Guidelines provide significant disincentives for patentees to provide any benefits to patients and customers.

For example, (1) the De-linking methodology as outlined in Schedule 4(3) and 8 of the Draft Guidelines forces the patentee to "freeze" its price on any class of customer to which it offers benefits (see discussion above in paragraph 4(a)); (2) the absence of a "Gap" methodology and the dismissal of the Working Group's recommendation for same will compromise the offering of any compassionate programs for drugs introduced in Canada as no patentee would want to offer a drug prior to the end of the introductory period at a reduced cost or free basis as this would reduce the ATP for the relevant determination period and may result in a reduced initial MNE being established for the medicine (see discussion above in paragraph 4(c); (3) the risk for an Any Market review will compromise the offering of any short-term benefits provided to a wholesaler/hospital/pharmacy (see discussion above in paragraphs 4 (a) and (b); (4) the prospect of having to share confidential information with PMRPB (i.e., contracts/agreements need to be produced to justify ATP variations) to prove that change in ATP was "solely" due to termination of a benefit will decrease the interest for both parties to enter into any such agreements. Further, the use of the term "solely" creates an evidentiary burden that depending on how it is implemented, may, from a day to day practical operations perspective, be an impossible one to meet and/or administer. It is requested that "solely" be amended to "related to" or "arising from". Evidence showing the termination or implementation of a benefit and subsequent variation of ATP should, it is submitted, be deemed sufficient to meet the evidentiary test.

7) PMPRB is going beyond its mandate to ensure non-excessive pricing in Canada by attempting to regulate price fluctuations (as opposed to excessive pricing) through the "Any Market" review and the "De-linking" methodologies.

In all of the "Any Market" and "De-linking" examples provided by PMPRB in preparation for their teleconference on September 12, 2008, PMPRB deemed excessive ATPs that are either below the MNE and/or lower than other non-excessive market-specific ATPs. Common sense dictates that if a certain price is deemed non-excessive, then anything below <u>is not</u>, by definition, excessive. For example, if a stakeholder has priced a drug at the non-excessive price of $10.00, then PMPRB should not be concerned about prices below that threshold, nor for any variations of prices therein. The PMPRB's mandate, as stated in Sections 83 to 85 of the *Patent Act* is to simply determine whether a price is excessive for the medicine. Once determined it contravenes common sense that the sale of a medicine at a lower price should be of concern to the PMPRB. Further, please see paragraphs 4 (a) and (b) above.

Abbott recommends that these concepts be re-visited to ensure that no more disincentives remain in providing benefits to patients and customers.

THE METHODOLOGY FOR CALCULATING EXCESS REVENUE ARISING FROM EXCESSIVE PRICE IN ANY MARKET (I.E., THE ANY MARKET REVIEW, INCLUDING PRICE TESTS)

ANY MARKET - Excess Revenues Calculation Methodology

8) Since the MNE is calculated using the national ATP which, by definition, comprises the average of higher and lower ATPs from the different Canadian markets, it is mathematically illogical to use the ATP from one of these specific markets against the national ATP in order to calculate excess revenues. Indeed, this **implies that the Board is imposing pricing uniformity across all markets and/or customer classes**. This is highly unrealistic if one only takes into account the highly competitive hospital tendering market. If forced on the patentee, this concept could result in compromising the offering of current and future compassionate programs for patients.

   It is Abbott's recommendation that the Any Market review, as proposed by the Board, be used solely (1) to identify markets where an ATP is above MNE (and not to regulate price increases) and (2) within the context of an investigation or hearing process. **The Any Market Review should not have any impact on the current excess revenues calculation methodology, which should continue to be carried out on a national basis.**

PRICES TESTS

9) Please refer to paragraph 3, above, for Abbott's comment on the RR-Different Strength test. Abbott does believe that the price tests proposed in the Draft Guidelines are properly aligned with the different categories of drugs. However, contrary to the original Guidelines, no clear guidance has been provided as to when to depart from the primary test.

10) Abbott also recommends that the ITCC test be more explicit in terms of the selection of the calculation method (ratio *vs* mean) in specific circumstances.

11) Finally, Abbott recommends that in the TCC test, all drugs be compared according to the same standards, i.e. that the highest public/published price should always be used for all TCC tests, regardless of whether the drug is bioequivalent to a reference brand or is a licensed version of a patented brand name drug. The assessment of a drug's price should not be related to its owner but to the ongoing market price of its therapeutic comparators.

ADMINISTRATIVE IMPACT ON PATENTEES

12) Significant additional administrative burden is created by the Any Market review and De-linking methodology which forces patentees to manage and forecast ATPs for 17 markets.

a) The patentee & PMPRB will have to spend significant time and resources to track down the historical data and transactions to create a dossier to pinpoint the ending of benefits. Abbott invites the Board to consider the numerous benefits provided simultaneously to individual customers from a same trade class (which may number in the hundreds) **(e.g., Abbott has over 600 individual retailers, 300 hospitals and 25 wholesalers)**, and to multiply this across all trade class customers and markets (e.g. 13 provinces and 4 trade class customers), to fully understand the complexity of what is being proposed. **If the ATP in respect of all customers is below the MNE, further scrutiny of pricing is unnecessary.**

b) The increased administrative burden is not justified by the results obtained through application of the methodology, which may lead to nonsensical results. For instance, if a price increase is implemented for trade class #1 in province B while offering benefits to trade class #2 in province B, then an Any Market review could show an ATP increase for trade class #1 and an ATP decrease for province B. Should benefits end for trade class #2 at the next reporting period, the review will then show an ATP increase for trade class #2 that may surpass the CPI adjustment, while the corresponding ATP increase in province B could be minimal because of the blended sales from the other trade class customers.

13) Abbott is concerned about the additional delays and costs the new reporting methodology will create at the Board level

Abbott is concerned that the significant amount of scrutiny and the complex analyses required to review patentee's submissions will cause significant and additional delays to the review process done by PMPRB. Even without the increased burden, it currently takes PMPRB from 3 to 6 months to provide a simple compliance report based on a single national ATP and up to 1 full calendar year to complete a single product benchmark price investigation. Such delays create uncertainty for patentees.

REQUEST

In order to: (i) decrease the number of unintentional consequences created by any final Guidelines that are issued, (ii) to provide a clear interpretation of the final Guidelines (both for the patentees and the Board Staff), and (iii) to allow for a smooth transition and implementation of the final Guidelines, **Abbott requests that the present submissions and those of Rx&D be considered, revised Draft Guidelines be issued again for final comment before publishing any final Guidelines, and that these final Guidelines become applicable after a full calendar year to allow the administrative systems of the patentees to adjust to the new Guidelines.**

We thank you in advance for consideration of Abbott's comments and recommendations. Do not hesitate to contact the undersigned if you have any questions relating to this matter. We look forward to the PMPRB's considered response.

Sincerely,

Laurie Dotto
Director, Government & External Affairs
Abbott Laboratories Limited/Laboratoires Abbott, Limitée