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

Tel. / Tél. : 514.832.7126
Fax / Téléc. : 514.832.7858

August 25th, 2006

Patented Medicine Prices Review Board
Sylvie Dupont
Secretary of the Board
Box L40
333 Laurier Ave W
Suite 333
Ottawa, On
K1P 1C1

Dear Secretary of the Board,

Following the issue in May 2006 of the "Discussion Guide for the Consultation on the Board's Excessive Price Guidelines", Abbott Laboratories would like to provide its position on the issues and specific questions identified.

Issue 1: Is the current approach to the categorization of new patented medicines appropriate?

Question 1.1: Are the new patented drug categories and their definitions appropriate?

No, the categories and their definitions only recognize breakthrough or major advances in patient treatment, not "moderate" ones. According to the PMPRB's 2005 annual report, only 6 New Active Substances (NAS) were classified as category 2 out of 59 NAS introduced from 2003 to 2005. This means that the remaining 53 products (90% of total NAS evaluated) were classified as category 3. In the last few years there has been a tightening of the application of the categories and some inconsistencies where NAS introduced in Canada were not recognized to the extent that they would have been in the past, even with the categories and their definitions not changing. When compared Health Canada and the FDA, it is clear that PMPRB is not being consistent with the designation of new breakthrough products. From 2000 to 2004, there were 18 Category 2 products by PMPRB while there was 68 Priority reviews by Health Canada and 81 by the FDA, a 4 to 5 fold difference. Abbott believes that Category 2 criteria need to be revisited and revised to reflect Health Canada's criteria.

Question 1.2 Is it important to distinguish a medicine that offers "moderate therapeutic improvement" from a medicine that provides "little or no therapeutic improvement"?

There is no need to distinguish "moderate therapeutic improvement" from "little or no therapeutic improvement" in the categorization process by creating additional categories. This would create a heavier review mechanism that could eventually complicate further the whole review process requiring more comparison tests and would not serve the purpose of the Canadian government to ensure that prices of patented medicines are not excessive.

There are presently enough tools at the Board's disposal to recognize "moderate therapeutic improvement" within the Guidelines. Abbott Laboratories would encourage a more frequent application

of those tools in the excessive price review than to create a confusing 4-tiered system of classifying NAS. (see answer to question 2.2)

It is important that innovation, even a "moderate" one, be recognized in the excessive price test process. It is essential for the advancement of the care to the Canadian population that innovations, even "moderate" ones, continue to be introduced in Canada to build on each other and cumulatively have a "significant" impact on therapeutic improvements. Presently, the application of the Guidelines by the PMPRB does not encourage such innovative steps forward.

Issue 2: Is the current approach used to review the introductory prices of new patented medicines appropriate?

Question 2.1 Are the price tests currently used to review the prices of new medicines in the various categories appropriate for that category?

No, all NAS 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 (see answer to question 2.4). Board staff has the responsibility to look at the international prices of a NAS. This ensures that the NAS is not being excessively priced.

Those tests should be consistent with the tests applied to any existing medicines throughout the life of the product under PMPRB's jurisdiction, namely the IPC test. The Guidelines allow Board staff the flexibility to use alternative tests when the primary price test is inappropriate, therefore a more flexible application of the Guidelines should be adopted.

Question 2.2 If you think that medicines that offer "moderate therapeutic improvement" should be distinguished from medicines that provide "little or no therapeutic improvement" what would be the appropriate new price test be?

As stated in our response to question 2.1, the IPC test is the most relevant price test for a NAS during its introductory period with the addition of CPI for subsequent reporting periods.

The IPC test takes into account the innovation that the international community recognizes for each product introduced to market.

In section 8.6 of the Guidelines, Board Staff can use an alternate price test to determine if the introductory price of a product that offers "moderate therapeutic improvement" is excessive.

"When it is inappropriate or impossible to conduct a Therapeutic Class Comparison Test, Board Staff will give primary weight to the median of the International Price Comparison Test to determine if the introductory price of the new DIN is excessive."

Presently, Board Staff is not regularly using this tool at its disposal with the subsequent effect of potentially delaying the introduction of such products or even possibly denying them to the Canadian market.

Question 2.3 For price review purposes, "comparable medicines" are medicines that are clinically equivalent. Do you have any suggestions as to principles or criteria that should be used in determining how to identify "comparable medicines" for the purpose of inclusion in the above price tests?

The criteria used to determine "comparable medicines" should not be restricted to the ATC class but should also include medicines with an approved indication that is the same as the primary indication of the new medicine and/or evidence that the medicine is used in clinical practice to treat that indication. Any medicine that is used as an alternative to the new medicine in clinical practice should be included in the "comparable medicines" group of comparators.

Question 2.4 Under the current Guidelines, Board Staff compares the Canadian average transaction price of the new medicine to the prices of the same medicine sold in the seven countries listed in the Regulations. However, Section 85(1) of the Patent Act states that the Board should take into consideration "the prices of other comparable medicines in other countries". Should the Guidelines address this factor? If so, how could this factor be incorporated into the price tests for new medicines?

Abbott would support this in cases where the standard price test currently used forces the Canadian price of a NAS in a way that is inconsistent with the prices in the other comparable countries, then it would be appropriate to compare the relation between this medicine and the international prices of its comparators (comparative ratios). A Canadian price with a similar or lower ratio would then be deemed not excessive to the Canadian market. Therefore, 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.

Issue 3: Should the Board's Guidelines address the direction in the Patent Act to consider "any market"?

Question 3.1 Given the price variations by provinces/territories and class of customer illustrated in the previous figures, is it appropriate for the Board to only consider an ATP calculated based on the total revenues from the sales for all provinces/territories and all class of customer?

Yes. Looking at ATP price review figures it is clear that the vast majority of the products are within the Guidelines. Therefore it is appropriate to consider an ATP based on total revenues and on an exceptional basis to review the provinces/territories and all class of customer sales data to determine if a specific DIN is excessively priced. The ATP review system looks at a national average so it is to be expected that slight variations between regions or type of customers would exist. The figures provided by PMPRB clearly show that those variations are minimal and that they are not discriminatory.

The ATP's review process and criteria were created for this National average evaluation. The figures clearly show that almost all products are within a 5% range when looked at by provinces/territories and class of customer. Therefore, the amount of resources and time necessary for such a detailed analysis would only lead to inefficiencies and increased burden that could not be justified by the PMPRB.

Given the current system is doing its job there is no need to bring more resources and time to an already heavy burden of reporting. This would only bring additional inefficiencies to the current system for patentees.

Question 3.2 <u>If the current ATP calculation is not appropriate, should the Board review the prices to the different classes of customers and/or the different provinces/territories for all DINs? Or should this level of review be done on a case-by-case basis, where there is a significant variation in the prices?</u>

If the current ATP calculation is not appropriate a review should only be done for that DIN on a case-by-case basis. This further review should ensure that no class of customer or Province/Territory has received a price increase greater than CPI taking into account volume shifts in the global ATP calculation.

As stated in the response to question 3.1, the burden of time and resources from such a review to PMPRB and patentees should only be done on a case-by-case basis.

We appreciate the opportunity to respond to the PMPRB's discussion guide on these issues.

Sincerely,

Abbott Laboratories

Laurie Dotto

Laurie Dotto, Director, Government and External Affairs