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Ms. Sylvie Dupont,
Secretary,
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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Aug 25, 2006

Re: Discussion Guide for the Consultations – Board's Excessive Price Guidelines

Dear Ms. Dupont,

P&G Pharmaceuticals Canada Inc. (P&G) is pleased to take this opportunity to offer its input into the consultation process initiated by the Patented Medicine Prices Review Board (PMPRB) through the release of the May 2006 Discussion Guide on the Board's Excessive Price Guideline.

P&G supports the position and concepts put forward in Rx&D's response to the PMPRB's Discussion Guide. In addition to Rx&D's submission, we offer the following comments in relation to some of the areas of discussion.

As an overall comment, P&G is of the opinion that the PMPRB's Excessive Price Guidelines should reflect a flexibility to address circumstances in which medicines that are clearly not excessively priced from a common sense perspective can be considered excessive through a rigid application of the Guidelines. Related details are provided in our responses to specific questions posed in the Discussion Guide.

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?*

The current system categorizes medicines on a subjective basis. Under this system, the assignment of a particular category reflects the opinion of the reviewers, in this case the PMPRB's Human Drug Advisory Panel (HDAP). Recommendations by the HDAP are based on that panel's interpretation of the criteria set out in the Guidelines and just as membership in the HDAP changes over time, so does the HDAP's interpretation of that criteria. Over the last several years, the interpretation of category 2 criteria has narrowed to the point of becoming an almost insurmountable hurdle, as evidenced by the very few new medicines being recommended for category 2 (breakthrough or substantial improvement) in recent years. During the thirteen years from the PMPRB's creation in 1988 through to 2000, new medicines were classified category 2 at a rate of 4 per year, on average (range of 1-11). In the past five years this rate has dropped to just over one medicine per year (range of 0-3), with none achieving category 2 status in 2004 and only one in each of 2003 and 2005, this despite many innovative new medicines being introduced in important therapeutic areas during those years.

Eliminating the labeling of new medicines in favour of one general price review method for all new medicines would remove the subjectivity inherent in the current system.

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?" If yes, why is it important? If not, why not?*

Following up on our response to question 1.1 above, adding an additional category to distinguish "moderate" improvement medicines will merely add another layer of subjectivity to the process. What criteria would be used to define "moderate" and how would that criteria be interpreted now and over time?

If a system of categorization is deemed necessary, P&G believes that by expanding the current restrictive interpretation of category 2, many so called "moderate" improvement medicines would be more appropriately recognized for the benefits they offer without the need for additional categories. For example, any medicine granted priority review status by Health Canada should, by definition, be classified a category 2 new medicine. Additional similar objective rather than subjective category 2 criteria could also be established.

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? Why? Why not? If not, how could these tests be amended to improve their appropriateness?*

The current price tests force the vast majority of new medicines to a price consistent with much older medicines whose prices have been impacted by generic competition or to a price equal to the same medicine using much older technologies. This approach does not recognize the therapeutic benefits for the patient or the research and development expenditures associated with the new product. For example, a new medicine offering a technology that can be reasonably expected to improve patient compliance through a simplified dosage regimen, improved delivery system, etc., or that offers a more accurate and regulated delivery of an existing medicine should not be strictly limited to the prices of medicines to which these advances were aimed at improving.

P&G is of the opinion that the Guidelines should place greater weight on international pricing, particularly when the results of other tests that may be used are clearly inconsistent with the new medicine's international price range. In addition, the PMPRB's staff should be allowed some flexibility in the application of the Guidelines in cases where the new medicine obviously does not fit the standard mold for which the Guidelines were designed.

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 the appropriate new price test be?*

P&G does not support the addition of a 4th category for new medicine classification. In P&G's opinion, a standard review that places the main emphasis on the new medicine's international price range is appropriate for all new medicines.

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?

Selecting comparable medicines to a limited representation of the new medicine's market based on ATC classification does not always reflect the relevant market in which the medicine is sold. A system that excludes alternative existing therapies merely because they are classed in a different 4th level of the ATC index rather than considering the prices of all therapeutic alternatives sold in the relevant market is inconsistent with the factors set out in the Patent Act.

To properly reflect the market in which a new medicine is sold, comparable medicine selection should include all medicines with an approved indication and medicines for which there is evidence of use in an indication that is the same as the primary indication of the new medicine.

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?*

P&G is of the opinion that the factors set out in the Patent Act should be reflected in the Guidelines used to review the prices of patented medicines. Doing so could avoid lengthy and costly hearings and litigation. The PMPRB has in a few select cases in the past used the concept of international price ratios as an indicator of non-excessive pricing. P&G supports the consideration of international ratios of the prices of new products to those of their comparator products in the PMPRB referenced countries as a reasonable and logical means of reviewing new medicines that, under the current Guidelines, would appear to be excessively priced. Under these circumstances, the prices of new medicines in which the Canadian price ratio falls within the range of international price ratios should not be considered 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 classes of customer? Why? Why not?*

And

Question 3.2: *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 and territories for all DINs? Or should this level of review be done on a case-by-base basis, where there is a significant variation in the prices charged?*

Reviewing average transaction prices at the aggregate level represents the most efficient means of price review. As noted in the Discussion Guide, the prices of the vast majority of patented medicines fall within a range of ±5% of their MNE when viewed either by class of customer or by province. Under the PMPRB's investigation criteria,

prices that are less than 5% above the product's MNE level are considered to be within the Guidelines. In P&G's opinion, expanding the PMPRB's review to encompass examination of pricing by customer class and/or by province as a standard practice will create unnecessary and clearly unwarranted inefficiencies in the PMPRB's review process.

P&G is committed to ensuring that the prices of its patented medicines are not excessive. We appreciate this opportunity to provide comments on the issues raised in the PMPRB's Discussion Guide and look forward to participating in future discussions surrounding the PMPRB's review of its Excessive Price Guidelines. In the meantime, if you should require additional information, or have any questions, please contact me at (416)-730-4428

Sincerely,

Elaine Ng Chu

for Rebecca Yu, B.Sc.Phm.
Manager, External Relations
Procter & Gamble Pharmaceuticals Canada