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Ms. Sylvie Dupont
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Dear Ms. Dupont

Subject: Consultations on the Board's Excessive Price Guidelines

In May 2006, the Patented Medicine Prices Review Board (PMPRB) issued a discussion paper for the "Consultations on the Board's excessive price guidelines" and invited comments from stakeholders.

We thank you for the opportunity to comment on this paper. Merck Frosst Canada fully supports the Rx & D response to the discussion guide and would like to reiterate the following points.

As mentioned in the PMPRB 2005 Annual Report, the average ratio of Canadian to median international prices has remained below parity and is 8% below the median in 2005. In addition, the report reveals that the CPI has exceeded the average increase in patented drug prices almost every year since 1988. In 2005, the CPI exceeded the PMPI (Patented Medicine Price Index) by 1.3%. Therefore, there is no need for the PMPRB to consider even more restrictive pricing regulations that will have the effect of reducing prices even further.

We are also concerned that the PMPRB may be exceeding the scope of it's authority under the Patent Act and it's amendments by undermining the domestic price structure in favour of a structure which is heavily reliant on the International Median price which assumes equivalent market environments among the comparator countries.

We believe that manufacturers must be able to establish competitive pricing for innovative pharmaceutical treatments and take the allowable price increases. We are also concerned by further regulatory and administrative burdens which will result in longer price reviews and the delay of innovative treatments for the Canadian public.

The PMPRB has periodically introduced changes that have lowered the prices of Canadian drugs i.e. changes in the calculation of the CPI, the introduction of the discounted price of the US Dept. of Veterans Affairs in the calculation of the US price.

If this trend becomes the predominant way of regulating prices, the PMPRBB risks contributing to the very effect it aims to avoid (compliance issues). Any review of the PMPRB guidelines regarding price increases should take into consideration the entire pharmaceutical environment including patent protection, investments and research & development.

Although the questions in the discussion guide have been properly answered by the Rx & D submission we would like to add some additional comments in the attached document.

Gregg Szabo
Executive Director, Policy & Reimbursement
Merck Frosst Canada Ltd.

Merck Frosst Canada Ltd. Response to the discussion guide for Consultations on the Board's Excessive Price Guidelines.

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

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

- Category 2 criteria should recognize the value of new innovative therapies that are brought to the Canadian Health Care System (Since 2002, only 6 new medicines have been reviewed as Category 2). As stated in the Rx & D submission, Health Canada and the FDA have recognized more products as innovative.

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?

- There is no need for a system of categories. As per the Rx & D submission, medicine should only be considered to be priced excessively if it exceeds the prices in all other comparator countries and the CPI adjusted prices of all other drugs in the therapeutic class.

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 is amended to improve their appropriateness?

- As mentioned in Issue 1 Question 2, a medicine should only be considered excessive if it exceeds the prices in all other comparator countries and the CPI adjusted prices of all other drugs in the therapeutic class.

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?

- See 2.1 above

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?

- Comparable medicines should include medicines that treat the same indication regardless of the ATC classification.

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 is incorporated into the price tests for new medicines?

- In cases where the initial tests are not appropriate this approach can be considered.

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?

- There is no need to over regulate a process that is already cumbersome for patentees in terms of ensuring that the ATP remains within the guidelines. Reviewing the ATP within individual markets would make it difficult if not impossible to handle discounts and the ATP price with efficiency and without considerable reports and analysis.

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?

- The PMPRB can initiate a price review in exceptional cases if the data suggests that the price exceeds the guidelines. Prices are already well below the cumulative CPI and further breakdown and analysis of the prices would add substantial work on patentees and the PMPRB for no additional benefit.