Merck Frosst Canada Ltd.
P.O. Box 1005
Pointe-Claire - Dorval
Quebec, H9R 4P8
Telephone: (514) 428-2638
Facsimile: (514) 428-2662
www.merckfrosst.com

SENT VIA E-MAIL (sdupont@pmprb-cepmb.gc.ca)

March 3, 2008

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

Dear Ms. Dupont,

The purpose of this e-mail is to highlight Merck Frosst's support of Canada's Research-Based Pharmaceutical Companies (Rx&D) submission to the PMPRB Board re: the Discussion Paper – "*Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines".* We would also like to reiterate certain concerns expressed in the Rx&D response and provide our views that the process for this consultation is too short, should be aligned closer to on-going PMPRB Board assessment efforts, and should encompass previous input from primary stakeholders.

Merck Frosst, through participation in Rx&D activities, has been actively engaged in the consultation around the PMPRB. In fact, the recent working group activities with the PMPRB have led to the hopes that a closer working relationship has developed among the parties. Despite these efforts, it appears, as reflected in the Discussion Paper, that the proposals and options identified have not taken into account previous recommendations, discussions and submissions by Rx&D.

We endorse the recommendations by Rx&D in their submission document, including:

"Any Market" Price Review

PMPRB guidelines have provided for the ongoing monitoring and review of prices on the basis of an Average Price in Canada. Although the guidelines are based on a national Average Price, the Board always has the capacity to review prices “in any market in Canada” as provided by section 83 of the Act.

Merck Frosst is concerned by the potential for the proposal as outlined in the Discussion Paper to constrain the incentives to offer volume discounts or price incentives. We also feel that moving away from the current one-market Average Price in Canada model to a 56 sub-market model would add to the regulatory burden. Given the amount of uncertainty as a result of this proposed policy change, the outstanding questions around why a change is even needed, and the observation that the current approach is working, we encourage the Board to retain the status quo.

Re-Setting the MNE Price

The current criteria for re-setting the MNE price and the practice of re-setting the price when warranted on a case-by-case basis continue to be appropriate. We are concerned that the new specific criteria proposed by the Board may limit the circumstances under which it may be prepared to re-set the price in some cases but expand them in other cases in an unpredictable way.

The effect of the proposal could discourage patentees from supplying drugs under SAP at prices lower than the price that they would intend to sell at when the drug receives its Notice of Compliance. The notion of re-setting the MNE price based on new "scientific information/evidence" is vague and leads to greater uncertainty moving forward. Finally, several of the proposed criteria are not fully developed – "costs of making and marketing" and the Progressive Licensing Framework. Based on the above, we recommend that the Board retain its current criteria for re-setting the MNE price.

FCC Decision – LEO Pharma

Legal opinions given to both Merck Frosst and Rx&D confirm the view that the Federal Court decision does not require the proposed regulatory changes presented in the Discussion Paper. The current policy has worked and continues to be appropriate. Under the current policy, patentees can opt to include or exclude products supplied under compassionate release and other special programs from the calculation of the Average Price provided they do so on a consistent basis.

Regulatory Options

We support the option to exclude benefits to third-party payers from reporting and from calculation of the Average Price. In our view, such reporting is not required by the Regulations nor by the LEO Pharma decision.

Guidelines Options

Merck Frosst endorses the comments in the Rx&D submission around "*the guidelines options"*. In particular, we agree that it would be appropriate for the Board to revisit the CPI-Adjustment methodology and to look at the concept of a complete de-linking of the MNE Price and the Average Price. Merck Frosst urges the Board to consider this option as de-linking is consistent with the Board's excessive price mandate, is much less cumbersome

than the current methodology and the options presented in the paper, and would preserve incentives for offering benefits and compassionate programs.

It is our hope that the Board is cognizant as to why we consider many of the guideline proposals and options of concern, as outlined in the Discussion Paper. Many of these potential changes would in fact have a negative effect on patient access to new therapies and create potential uncertainty and new regulatory and administrative burden for patentees. The alternative suggestions as outlined in this letter and in further detail in the Rx&D submission highlight approaches that would be acceptable to our industry and minimize negative consequences to Canadians.

We look forward to further discussions with the Board on these important issues.

Sincerely,

Dawn Graham
President
Merck Frosst Canada Ltd.