February 29, 2008

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

RE: Comments regarding the "PMPRB Discussion Paper: Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines" dated January 31, 2008.

Dear Ms. Dupont;

We are pleased to have the opportunity to comment on the Patented Medicine Prices Review Board's (PMPRB) Discussion Paper of January 31, 2008, the most recent stage of the public consultations on the Excessive Price Guidelines and the implications of the March 2007 *LEO Pharma* Federal Court decision.

As an active member of Canada's Research-Based Pharmaceutical Companies (Rx&D) we have been fully involved as the consultations have proceeded, by presenting extensive submissions and being responsive to each stage of the process. However, we are dismayed to note that despite our efforts, the Discussion Paper largely failed to take into account the submissions and recommendations from us, our individual patent-holders or, indeed, from Rx&D itself. This is unfortunate since pharmaceutical patentees must be viewed as the principal stakeholders in this process; as the only stakeholders subject to the Board's regulatory oversight we are best placed to comment on the impact of the Board's proposals on the Canadian pharmaceutical industry.

In response to our thorough review of the Discussion Paper, we would like to submit the following comments and suggestions to the Board for consideration and implementation.

"Any Market" Price Review

The detailed proposal in the Discussion Paper regarding price review is not consistent with the Board's historical "case-by-case" approach to the ongoing monitoring and review of prices on the basis of an Average Price in Canada. The Discussion Paper proposes a submarket price review for **all** new patented drugs, as well as those in the remit of Voluntary Compliance Undertakings and Board Orders. This change seems to indicate that the Board has a new policy objective: that of ensuring prices in all submarkets should not exceed the national MNE price. If this is the intent, such a change would, in our opinion, be premature, especially since the appropriate definition of MNE price and the calculation of the Average Price are still unresolved and subject to study and debate in other reviews of Board policy, for example in the case of *LEO Pharma*.

EMD Serono Canada Inc.
2695 North Sheridan Way, Suite 200
Mississauga, ON L5K 2N6
Phone 905-919-0200
Fax 905-919-0299
www.emdserono.ca

Furthermore, such a move would shift the current one-market Average Price in Canada model to an unwieldy 56-submarket model, since a submarket price review would be triggered whenever the national Average Price appears to exceed the MNE price. Since patent holders continually run the risk of inadvertently pricing their products slightly above the MNE, for example, as sales mixes shift, they will need to constantly monitor their compliance in all submarkets to avoid regulatory action.

The Discussion Paper also provides no analysis of the impact of this change on incentives to offer discounts or rebates within the framework of the current CPI-Adjusted Methodology. The increase in the workload of the Board is also not considered: the Board now has to review prices in 56 markets rather than one. The regulatory burden for patentees will become similarly onerous.

Finally, and most significantly, the Board has not justified the need for this proposal. It has not stated that its current methodologies and practices are inadequate or explained why they need to change. Neither have we been presented with evidence that change is required, or an analysis of the rare instances where prices exceeded the MNE prices in submarkets by a significant amount.

Re-setting the MNE Price

We share the concern of Rx&D that the new criteria proposed by the Board may have the effect of re-setting prices in a nontransparent and unpredictable manner. We urge the board to remain with the current criteria for re-setting the MNE price and, when justified, to continue to re-set prices case-by-case.

The implications of the proposal for the Special Access Program (SAP), in particular, give us grave concern. The current guidelines allow for a price to be re-set on Notice of Compliance, but the proposal's criteria for re-setting the MNE price at NOC will result in an unrealistically high threshold. As a result, manufacturers are likely to be discouraged from supplying SAP drugs at reduced prices or, indeed, supplying any drugs to Canadians under Special Access at all.

The proposal to re-set the MNE price based on new "scientific information/evidence" also gives cause for concern, since the circumstances in which this would happen are not specified and we face the prospect of frequent debates every time a new scientific paper comes out. Quite apart from the beaurocratic effort involved, we have reservations about any proposal that adds barriers to bringing products to market here and thus makes the Canadian market relatively unfavourable internationally. Finally, we feel that weighing new scientific evidence is outside the mandate of the board, which is that of price-setting, and that existing mechanisms at the provincial level ensure that new scientific evidence is taken into consideration during considerations of coverage and reimbursement.

.../3

FCC Decision – *LEO Pharma*

As discussed in the legal opinion previously submitted by Rx&D, the Federal Court decision in the *LEO Pharma* case does not require the Board to make the policy change announced in the April 2007 NEWSletter. However, we understand the Board has received different legal advice (although it has not shared that advice with us) and as a result has identified a range of options to address its concerns about this issue. We would urge the board to include two further options in their considerations:

- The status quo. This would involve maintaining the April 2000 policy, along with the flexibility to include or exclude compassionate and other special pricing programs in the Average Price.
- De-linking the MNE price and the Average Price in the CPI-Adjustment Methodology. We share Rx&D's opinion that this approach would be a significant step towards addressing the *LEO Pharma* concerns and would certainly clarify and solidify the price review process in the future.

We also share Rx&D's qualms about regulatory options that appear to be inconsistent with the *LEO Pharma* decision, since they will certainly discourage manufacturers from offering special pricing programs in general and compassionate use in particular.

Although several of the guidelines options, Option 2 in particular, are a step in the right direction since they partially offset the negative impact of the current CPI-Adjustment Methodology, they do not go far enough. Basing the MNE price on a previous net Average Price creates a disincentive to offer lower prices, special rebates or incentives.

"De-linking" the Average Price and MNE price will remove this disincentive – by which we mean, instead of basing the MNE prices on the net Average Price, as it is today, basing it on the MNE price in the introductory year, adjusted for changes in the Consumer Price Index.

Moving Forward

We appreciate and value the opportunity to be involved in the consultation process but we are disquieted that the Board appears to have taken little account of our past contributions in its proposals and options. We trust that the suggestions contained herein meet with your approval and we look forward to a positive response.

Deborah Brown
General Manager
EMD Serono Canada Inc.