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Schering-Plough

March 3, 2008

Dr. Brien G. Benoit
Chairman
Patented Medicines Price Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON
K1P 1C1

Dear Dr. Benoit,

RE: Response to Discussion Paper for Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines.

On behalf of Schering Plough Canada, I appreciate the opportunity to provide comment to the Discussion Paper issued by the Patented Medicine Price Review Board (PMPRB) on January 31, 2008. I would like to affirm that Schering Plough Canada is fully supportive of the submissions presented to the PMPRB by the Rx and D Association and BIOTECanada. I encourage the PMPRB to review both submissions carefully and taken together, they form a comprehensive and informative response to the Discussion Paper and are included as part of the Schering Plough submission.

This Discussion Paper is the latest in a series of activities that the PMPRB has undertaken since it first issued possible regulatory changes in 2005, subsequent Guideline consultation in 2006, new reporting requirements announced by newsletter in 2007 and further regulatory and guideline consultations in 2007. The cumulative effect of all these processes has been to create a real climate of uncertainty in the Canadian market. As well, the PMPRB has never presented a comprehensive plan or timetable on how all these parallel but inter-related processes are to be considered. I would strongly encourage the PMPRB to take the time now to review all of these initiatives and to develop a plan to share publicly that will outline how they are to be finalized.

I would also like to re-emphasize, as stated in our previous correspondence, that Schering Plough does not agree with PMPRB's interpretation of the Federal Court decision in *LEO Pharma-Dovobet* as expressed in the PMPRB Newsletter of May 2007. There is considerable legal evidence, including several legal opinions secured by Rx and D and BIOTECanada which make clear that the Board interpretation is incorrect and therefore it is imperative that the Board consider the implications of any action within the context of avoiding any future litigation.

As you are aware, there was an unprecedented level of dialogue that opened between the Board staff and the members of the Rx and D subcommittee through the fall of 2007. Schering Plough dedicated significant resources in good faith to that working group process in order to find a productive mechanism to resolve issues of concern. I am pleased that the PMPRB has identified the option not to include payments to third party

payers in the calculation of Average Price. As noted by BIOTECanada, this represents a clear statement by PMPRB that it will not proceed with any attempt to expand its jurisdiction in this regard.

I find it unacceptable that the PMPRB failed to include in this Discussion Paper the model of true delinking of the Maximum Non-Excessive Price (MNE) from the Average Transactional Price (ATP) that had been proposed in those sessions. The purpose to delink the MNE from the ATP is to ensure that manufacturers can offer reductions to Canadian patients in the form of compassionate care programs, or rebates and discounts without a consequential negative impact on the maximum non-excessive price established by the Board. The models proposed in the Discussion Paper do not remedy that situation and they create a disincentive for manufacturers to offer these benefits.

I am surprised by the inclusion in the Discussion Paper of proposals to reset the price and to review prices in any markets. Schering Plough has been an active participant in all of the previous consultations as well as in the working group sessions noted above. In all of these proceedings involving multiple stakeholders, these two proposals were not raised as issues of concern nor were they presented as priorities. I believe that the PMPRB has failed to present a rationale to support making these significant and burdensome changes to its processes.

Schering Plough has been providing innovative medicines to Canadians for over eighty years. It has recently reaffirmed that commitment with the investment of a new Head Office in Kirkland, Quebec, the launch of life-saving medicines such as Posaconazole for the treatment of invasive fungal infections, and with the recent acquisition of Organon BioScience in order to broaden the portfolio of therapeutic treatments it can offer. Any changes proposed by the PMPRB should be made within its statutory mandate and maintain the balance between supporting innovation in Canada while protecting Canadians from excessive pricing.

Yours sincerely,

Carlos Dourado,
President and General Manager

c.c. Mary Catherine Lindberg, BSP, Vice-Chairperson
Tim Armstrong, QC, O. Ont, member
Anthony Boardman, BA, PhD, member
Anne Warner LaForest, LLB, LLM, member