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October 31st, 2007

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

Re: Response to October 6, 2007 Proposed Amendments to the Patented Medicines Regulations

Dear Ms. Dupont:

In response to the consultation process and on behalf of Schering-Plough Canada, I am bringing to the attention of the Patented Medicines Price Review Board (PMPRB) issues of concern that have been raised through the various processes that it has undertaken. In particular, I am referring to the proposed amendments to the *Patented Medicines Regulations, 1994* as published in the Canada Gazette of October 6, 2007, the follow up to the consultations on the *Guidelines* that took place on September 10, 2007 and the announced changes to the reporting requirements in the May 2007 Newsletter published by PMPRB.

The cumulative effect of these processes has been to create confusion and uncertainty in the Canadian marketplace. In the bi-lateral meeting between members of the PMPRB Board and the Rx and D Board, it was noted that a

direct consequence is that patentees are hesitating before initiating new products and programs. It has also led to a dampening effect on our ability to attract global investment into research and development. I encourage the PMPRB Board to take a comprehensive look at the processes, to determine a co-ordinated and clearly communicated plan of action and to resolve quickly the uncertainty that has been created.

In its deliberations, it is imperative that the PMPRB Board not consider the issues resulting from these parallel processes as distinct and separate from each other. They are not and any consideration of one must indeed be made within the context of the other processes underway. Given the complexity and diversity of issues raised by these numerous processes, I have not addressed all of them here. For the sake of clarity, I have focused on the major issues of concern as raised by the proposed amendments and the May 2007 Newsletter. I also would like to acknowledge my support of the positions that have been articulated separately in the submission of October 12, 2007 by Rx and D in response to the proposed amendments to *Patented Medicines Regulations.*

Proposed Changes to Regulation 4 (1) (f)

In two separate processes, the Newsletter and the proposed amendments, PMPRB has proposed changes to the same regulation. It has not however explained how these two proposed changes would be reconciled. Furthermore, the changes contemplated by these proposed amendments represent a significant expansion to the original mandate of the PMPRB.

Reporting of Provincial Listing Agreements

In the May 2007 Newsletter, the Board announced that it would now require that patentees include on the semi-annual reporting (Form 2) "any rebates or discounts required through provincial/territorial legislation, regulation or negotiated agreement (e.g., resulting from Ontario's Bill 102, Quebec's Bill 130, or other agreements with payers/customers)". This is clearly an expansion of the mandate. The current regulation 4. (1) (f) requires the reporting of "publicly available ex-factory price for each dosage form,

strength and package size of the medicine that was sold by the patentee or the former patentee to each class of customer in each province during the periods referred to in subsection (2). At no time, was a province nor a provincial government (or its agency), or a payer contemplated to be a customer as referred to in this regulation. Therefore, it is our position that there is no basis for PMPRB to require the reporting of any arrangements with a provincial/territorial government or payer or to otherwise broaden the mandate of the regulation. I would strongly ask that the PMPRB exclude payer including provincial/territorial government from any reporting requirement.

Reporting of Reduction by Type on Form 2

In the proposed amendments to *Patented Medicines Regulations, 1994*, as published in the Canada Gazette of October 6, 2007, the Board is proposing further change to the semi-annual reporting (Form 2) by altering the same regulation 4. (1) (f) to add the requirement that patentees report and identify reductions by type. This change in reporting requirement would add significant administrative burden for patentees without any evidence of benefit to the ability of PMPRB to achieve its mandate of ensuring that the prices of patented products are not excessive. Reductions by their very nature decrease prices and therefore provide ultimate benefit to customers and to Canadians. I would ask that PMPRB remove this proposed amendment to identify the type of reduction as it is not relevant and moreover, reporting will be unduly burdensome and complex. Furthermore, I believe that the mandate of the PMPRB is not now or should ever be to potentially risk a decrease in overall reductions that benefit Canadian patients by requiring patentees to undertake such an administrative burden, particularly when any additional benefit for such reporting is not clear.

In the Regulatory Impact Analysis Statement (RIAS), the PMPRB notes that the motivation for proposing these amendments to the *Regulations* is to modernize them and that they are in keeping with objective of Health Canada's Therapeutic Access Strategy of improved access for Canadians to affordable pharmaceuticals. I would encourage PMPRB to ensure that these regulations are also in concert with the Government's stated objectives as

articulated in the *Cabinet Directive on Streamlining Regulation* in that regulations **promote a fair and competitive market economy** that encourages entrepreneurship, investment, and innovation.

I do acknowledge that the Patented Medicines Price Review Board (PMPRB) has made certain changes to the proposed amendments as they were originally published in December 31, 2005. As well, I would like to recognize that the PMPRB recently announced an extension of the transition period for the implementation of the proposed changes articulated in the May 2007 Newsletter. I believe that these are important first steps and such, I encourage the PMPRB to continue its initiative of collaboration by taking careful consideration of my comments as well as those raised separately by Rx and D through its submission.

Yours sincerely,

Carlos G. Dourado
President and General Manager