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Carlos G. Dourado
Président et directeur general
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Kirkland, October 6, 2008

BY EMAIL: sdupont@pmprb-cepmb.gc.ca
AND BY MAIL

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

Dear Dr. Benoit:

I am writing to you on behalf of Schering Plough Canada in response to the Patented Medicines Price Review Board's Notice and Comment package on the Draft Revised Excessive Price Guidelines released on August 20, 2008.

While I do appreciate that PMPRB has provided an additional opportunity for comment on the draft Guidelines before they are issued in November, I would like to express my disappointment that these proposed Guidelines fail to incorporate key recommendations that resulted from previous industry submissions as well as the report of the Working Group on Price Tests that was initiated by the Board. The draft Guidelines do not provide sufficient clarity and detail to assist patentees in understanding how these proposed changes would be implemented and what impact they would have on the reporting process required by patentees.

It is imperative that the Board understand that full implementation of these proposed Guideline changes will, from a company perspective, require significant changes to the internal reporting processes and a substantial increase in staff and technology resources. PMPRB has not provided a rationale why such an extensive change is required at this time and why companies should have to take on such additional costs, particularly since the Annual Reports to Parliament over the past few years have reported a decline of patented medicines prices and a high rate of compliance with the current Guidelines.

These proposed Guidelines represent an unprecedented intervention into the pharmaceutical market and will become an obstacle to attract research and development dollars to Canada. This is in direct contradiction to the mandate of the Board that was set out by Parliament which is to ensure that prices are not excessive while reporting on and encouraging the increase in investment in research and development in Canada. At a time when the Canadian economy is declining and the OECD is reporting that Canada has fallen to 11th place of OECD countries in terms of innovation, it is irresponsible of PMPRB to create barriers to attract investment.

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These proposed Guideline changes will also make it difficult to offer compassionate care programs to patients or reductions to consumers. The proposed delinking model is flawed and does not incorporate a true delinking of the average transactional price from the maximum non-excessive price. In a September 9th, 2008 briefing teleconference, it was clearly demonstrated to Board staff using their own models how the proposed delinking model would effectively institute a price freeze if a company offered a compassionate program or discount to a customer.

This is just one example of why the Board needs to delay implementation of these proposed Guidelines. This example demonstrates that despite the length of time that has been spent on the discussion of changes to the Guidelines, the implications of these changes has not been properly understood even by those who will be tasked with implementing them. I urge the PMPRB to recognize that these changes impact on the regulatory environment of our industry and consequently the long-term planning of corporations. They will have real and direct effect on the security and the well-being of corporations and their continued viability to provide jobs, create innovative medicines and invest in research and development in Canada.

The Rx and D Association have provided a comprehensive submission that includes substantial analysis of the flaws of these proposed Guidelines. I am in full support of the Rx and D position and I support their request to the Board to defer implementing the decision in the Communiqué of August 18th, and the proposed changes to the Guidelines, until the final outcome of the judicial review, and until appropriate and thorough further review and analysis is conducted.

Sincerely,

Carlos G. Dourado
President and General Manager

CGD/lv