

December 18th, 2007

Dr. Brien Benoit, BA, MD, MSc, FRCSC, FACS
Chairperson
Patented Medicine Prices Review Board
Box L40
Standard Life Center
333 Laurier Avenue West, Suite 1400
Ottawa, ON
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Re: Working Group on International Therapeutic Class Comparison and PMPRB Consultation Plan

Dear Dr. Benoit:

On behalf of *Canada's Research-Based Pharmaceutical Companies* (Rx&D), I am writing to you regarding the Working Group on the International Therapeutic Class Comparison (ITCC). The ITCC Working Group was initiated by the Patented Medicine Prices Review Board (PMPRB) as part of its ongoing review of the Excessive Price Guidelines (Guidelines).

The Working Group's first meeting took place by teleconference on December 14, 2007. At the meeting, it is my understanding that several Working Group members had questions about the underlying rationale and motivation for convening a group to discuss ITCC issues. Given some other aspects of the Guidelines may be in flux, it was also noted by several Working Group members that it will be challenging for them to provide meaningful conclusions or advice to the PMPRB Board on ITCC.

Rx&D previously expressed concern about the mandate of the ITCC Working Group. It is difficult to provide an opinion on comparisons when it is unclear how such a price test might apply, or whether there will be changes in categorization. Rx&D notes that a separate Working Group has been tasked with reviewing and making recommendations with respect to categorization.

Rx&D has never requested, nor encouraged the creation of, an ITCC Working Group. As noted in our recent submission on the Guidelines, while we are cognizant of the factor set out in Section 85(1)(c) of the *Patent Act*, we also believe that the rationale for this Working Group has never been clearly established. However, given that the PMPRB decided to proceed with this Working Group as part of the Guidelines consultation process, Rx&D agreed to participate.

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President's Office / Bureau du Président

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Rx&D believes that the present issues with the ITCC Working Group are symptomatic of a larger issue. Several of the PMPRB's present or anticipated consultation processes pertain to overlapping and related issues. Therefore it is in the interest of the PMPRB, patentees and other stakeholders that these processes should be approached in a cohesive, coordinated and transparent fashion. Accordingly, Rx&D would like to request again that all stakeholders be provided with the PMPRB's overall plan for the entire Guidelines consultation process, including how this process corresponds to the consultations initiated on the proposed changes articulated in the April 2007 NEWSletter, and with the Canada Gazette process underway pertaining to proposed amendments to the *Patented Medicines Regulations, 1994 (Regulations)*.

In conclusion, Rx&D strongly encourages PMPRB to revisit the mandate and timing of the ITCC Working Group. More broadly, we would encourage the PMPRB to share publicly its overall consultation plan related to the Guidelines.

I wish you and your family a happy holiday season, and please accept my best wishes for the New Year.

Sincerely,



Russell Williams
President

RW/dh

cc: Mary Catherine Lindberg, BSP, Vice Chairperson
Tim Armstrong, Q.C., O. Ont.
Anthony Boardman, BA, PhD
Anne Warner La Forest, LLB, LLM
Barbara Ouellet, Executive Director, PMPRB
Sylvie Dupont, Secretary to the Board, PMPRB
Rx&D PMPRB Sub-Committee