

Ronnie Miller
President and C.E.O.



October 19, 2007

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

Attention: Sylvie Dupont

Subject: Proposed amendments to the Patented Medicines Regulations, 1994 –
Update – Canada Gazette Part 1

Dear Dr. Benoit,

Hoffmann-La Roche Limited (Roche), a member of the innovative pharmaceutical industry, fully supports the position put forward by Rx&D in its submission to the proposed amendments to the *Patented Medicines Regulations* that were posted on Canada Gazette Part 1 dated October 6th, 2007.

Of particular concern are the proposed amendments to the Average Transaction Price. Roche remains strongly opposed to this amendment because it will create an onerous reporting burden without creating any material benefits for the PMPRB or more importantly for customers in Canada. This proposed new requirement will have the affect of creating more regulatory burden and possibly hindering programs that help ease the Canadian health care system and are of significant benefit to Canadian patients. Further, it is unclear how this new proposed regulation will be coordinated with any possible changes coming in the next year as a result of the Dovobet case.

In addition, Roche is very concerned by the increasing activities that are taking place at the PMPRB which do not seem to be integrated into an overarching approach to optimize industrial and health policy for Canadians. From new proposed regulations, to a variety of proposed new guidelines, Roche is concerned that all of these activities are taking place in silos. At a time when the federal government has just released its Speech from the Throne emphasizing that it will “*support Canadian researchers and innovators in developing new ideas and bringing them to the marketplace through Canada’s Science and Technology Strategy*”, Roche submits that these continuous changes by the PMPRB do affect the stability and predictability of the innovative pharmaceutical industry’s working environment in Canada.

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Page 2.

We remain optimistic that the PMPRB will work to address the increasing number of new targeted therapies, biologics and innovative delivery technologies being developed now and into the future, in such a way that a greater degree of pricing certainty is provided to members of the innovative pharmaceutical industry.

Thank you for your attention to this letter.

Yours sincerely,

Hoffmann-La Roche Limited

A handwritten signature in black ink, appearing to read 'Ronnie Miller', is written over the printed name and title.

Ronnie Miller
President and C.E.O.

cc: The Honourable Tony Clement, P.C., M.P.
The Honourable Jim Prentice, P.C., M.P.