ACTELION

2007 NOV 21 PM2:02

November 19, 2007

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

Dear Dr Benoit,

On behalf of Actelion Pharmaceuticals Canada Inc. I want to thank you for the invitation to participate at the bilateral meeting of last September which gave us an opportunity to discuss with members of the PMPRB. As per your suggestion we are pleased to send you our written comments regarding the Board's review of the Excessive Price Guidelines.

As a member of Rx&D, Actelion endorses the position this association made to the Board. There are numerous pricing policy issues that have been raised by the Board; these coupled with the current reimbursement issues create an increased level of uncertainty. In such a context we are concerned that the current PMPRB initiatives will bring more restrictive policies and make the Canadian environment less attractive for companies like ours who are competing at the global level. Ultimately it will result in negative implications for Canadian patients and the health care system. We also consider that many of these issues are beyond the scope of PMPRB's mandate. The mandate, as set out in the Patent Act, is to ensure that prices charged by patentees for patented medicines are not excessive. To date we have not seen any convincing reason to justify the proposed changes in the Excessive Price Guidelines.

*Categories*

We have reservations with the current categories mainly because they do not recognize innovation. For example, there are cases where Health Canada granted a priority review to a new drug and PMPRB did not categorize such drug as a breakthrough or even a substantial improvement. Furthermore, categories and price tests are too closely linked and we support Rx&D's position that if the Board adopts an appropriate excessive price test there is no need for categories.

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*International Therapeutic Class Comparison*
It is our opinion that the Board has all the latitude it needs with the current legislation and guidelines to conduct a therapeutic class comparison. There is no need to further expand this area as it is currently appropriately resolved on a case by case basis when required.

*Price Tests*
The Board indicated it is reserving comment on price tests in general and their use. In our opinion the price tests are inextricably linked to all the other issues and questions raised in the Guidelines. Consequently it will be difficult to comment on any of the proposed guidelines for each issue without knowing the price tests.

*Price Increases*
The Board will draft language to permit some flexibility in applying the existing CPI methodology for comment by stakeholders. I would like to propose that language is modified to allow CPI to be applied each year rather than the lower of the ATP and the MNE price. We look forward to seeing the proposed changes and the opportunity to comment.

*Other*
I would like to take this opportunity to again raise our serious concerns about the Board's statements regarding the Dovobet case as published in the April 2007 Newsletter which might push manufacturers to eliminate their current compassionate use programs. We welcomed the Board Communiqué released last October as it stated that the Board's priorities include the maintenance of compassionate access to needed medicines by consumers as long as the program parameters remain consistent with the law. We are confident it will be possible to maintain these programs to the benefits of many Canadians.

Actelion Pharmaceuticals Canada Inc. appreciates the opportunity to comment on the proposed Excessive Price Guidelines and is committed to continuing collaboration with PMPRB to ensure the Patent Act objectives are met as well as the government's commitment to foster innovation.

Respectfully yours,

William C. Fairey, Jr.
President

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