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October 6, 2008

Dr. Brien 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:

I am writing in response to the Stakeholder Communiqué released by the Patented Medicine Prices Review Board (PMPRB) on August 18, 2008 and the draft revised Excessive Price Guidelines (the "Guidelines") published for Notice and Comment on August 20, 2008. We have serious concerns with both of these communications.

Allergan Inc. is a healthcare company based in Markham, Ontario and is a subsidiary of Allergan, Inc., a global healthcare company based in Irvine, California that is traded on the New York Stock Exchange under the ticker symbol "AGN". Allergan supplies products for the eye care, neuromuscular, skin care, obesity intervention, urology, breast aesthetics and other specialty markets. Allergan has consistently worked to ensure full compliance with the *Patented Medicines Regulations* and with the existing Guidelines.

Allergan has followed the progress of the PMPRB's consultations on the Guidelines, including with respect to rebate reporting requirements. Allergan is not a member of the industry associations Rx&D and BIOTECanada, but Allergan is in substantial agreement with their submissions. Allergan is disappointed that your consultation package and Communiqué did not address many of the concerns raised by pharmaceutical patentees.

While Allergan sees many troubling aspects in the proposed Guidelines and the changes to rebate reporting requirements, for purposes of this submission I would like to focus on an area of particular concern – the consumer market for medicines that do not relate to medically necessary conditions and are not reimbursed by federal and provincial public drug programs or by private plans.

Allergan's understanding is that the PMPRB was created to ensure that prices for medically necessary medicines which benefit from market exclusivity are not excessive. The consumer market for non-reimbursed products is distinct from the market for most patented medicines, benefiting from competition from non-patented comparable products and from alternative products or treatments. These competing products and treatments are not subject to PMPRB oversight and do not face the restrictions on marketing practices inherent in the proposed Guidelines.

The PMPRB has previously recognized that it is not appropriate to use the same approach in different markets. For example, the PMPRB introduced a complaints-based process for patented veterinary medicines in 1999 and for over-the-counter (OTC) medicines in 2007. These policy changes have been reflected in amendments to the *Patented Medicines Regulations* and recognize that those markets are distinct from the traditional prescription drug market for medically necessary conditions.

The inappropriateness of applying the Guidelines and rebate reporting requirements to consumer products is reinforced by the changes which the PMPRB is proposing. Whatever the merits of amending the rebate reporting requirements for patented medicines in general, it is evident that increasing those requirements in the case of consumer products will limit any firm's ability to compete with products that are not subject to the same rules. It will add a tremendous burden on manufacturers and will introduce limitations on the types of benefits and promotions which may be offered, thereby discouraging firms from bringing such products to market and ultimately limiting consumer choice for these products. Presumably, this was a major factor behind the PMPRB's decision to relieve veterinary and OTC patented products from such reporting requirements.

We would appreciate an opportunity to meet with you and your staff at an early opportunity to explore this issue in more detail and develop concrete proposals to address the foregoing concerns.

Yours very truly,

Steve Van Wyck

Director Reimbursement / External Affairs

Allergan Inc.

c.c. Mary Catherine Lindberg, Vice Chairperson, PMPRB
Tim Armstrong, Member, PMPRB
Anthony Boardman, Member, PMPRB
Anne Warner La Forest, Member, PMPRB