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October 22, 2007

Ms. Sylvie Dupont,  
Secretary,  
Patented Medicine Prices Review Board  
Box L40, Standard Life Centre  
333 Laurier Avenue West, Suite 1400  
Ottawa, Ontario  
K1P 1C1

**Re: Proposed Amendments to the Patented Medicines Regulations**

Dear Ms. Dupont,

Procter & Gamble Pharmaceuticals Canada, Inc. (P&G) welcomes the opportunity to comment on the PMPRB's proposed amendments to the Patented Medicines Regulations that were published in the Canada Gazette on October 6, 2007.

Overall, P&G fully supports Rx&D and the comments it provided in its letter dated October 22<sup>nd</sup>, 2007 regarding these proposed amendments. In addition, P&G desires to highlight the reporting of types of benefits as a primary concern regarding the proposed amendments.

**Reporting of Types of Benefits**

Under the current Regulations, a patentee, when calculating the net revenue from sales or the average price per package of medicine, may include any reduction in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature. The proposed amendment requires "each reduction used in the calculation" to be "identified by its type." PMPRB is currently assessing its policy relating to these reductions in light of the *Leo Pharma* decision of the Federal Court in Canada. Until that review process is completed, it is premature to enact such regulatory amendments. Further, P&G and other patentees are unable to substantively comment on the effects of the proposed change without knowledge of the "types" of benefits that will need to be identified.

Given the issues identified above, P&G recommends that this requirement be removed from the proposed amendments to the Regulations.

If you or other PMPRB staff members have any questions, or wish to discuss these issues, please feel free to contact me at 416-730-4539.

Sincerely,

Andy McClenaghan  
General Manager  
Procter & Gamble Pharmaceuticals Canada Inc.