Shire Canada Inc.
2250 Alfred-Nobel Blvd., Suite 500
Saint-Laurent, Québec H4S 2C9 Canada
Tel. 514 787 2300 Fax 514 787 2427
www.shire.com

Claude Perron
Vice President and General Manager
Direct Line: (514) 787-2345
Fax: (514) 787-2428
E-mail: cperron@shire.com

Via E-mail: sdupont@PMPRB-CEPMB.gc.ca

October 17, 2007

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

Subject: **Review of the Board's Excessive Price Guidelines**

Dear Dr. Benoit,

Further to the review of the PMPRB's Excessive Price Guidelines and the Stakeholder Communiqué of May 31, 2007, Shire Canada Inc. ("**Shire**") is pleased to provide its comments on the issues raised in the Stakeholder Communiqué:

1. Categories

With respect to Category 3, Shire's position is that there should be a distinction between drugs that show limited improvement versus incremental improvement. Otherwise, a patented medicine which shows incremental improvement would not be recognized as it should and would be compared in some cases to off-patented drugs to determine the benchmark price.

Comparison with other products in the market in Canada is only one of the factors to be considered in determining whether there has been excessive pricing. Some categories within the Board's Guidelines do not allow or do not have equal weight to the International Price Comparison.

2. International Therapeutic Class Comparison

Section 85(1)(c) of the *Patent Act* clearly states that the Board shall take into consideration the following factor when determining whether or not a medicine is being or has been sold at an excessive price in any market in Canada: the prices at which the

medicine and other medicines in the same therapeutic class have been sold in countries other than Canada. Therefore, no matter what category Board Staff applies to a medicine, it must always perform an International Therapeutic Class Comparison. The Board shall always do the International Therapeutic Class Comparison anyway. It is mandatory by law.

3. **Price Tests**

The Price Tests are more restrictive than the *Patent Act* itself. The *Patent Act* does not make such distinction between categories of medicines. It has set out some factors to be considered in determining whether or not a price is excessive. The Board shall always apply the same factors for all patented medicines.

4. **Costs of Making and Marketing**

When appropriate, adding the costs of developing, making and marketing a drug should be considered, as an example: biotech products.

5. **Price Increases**

In some exceptional situations, a mechanism could be implemented to recognize supply costs increases that would allow a Manufacturer to increase price beyond the CPI.

6. **Adjustment the Benchmark Price (Re-benching)**

No comments to provide. This was barely discussed.

7. **Any Market**

No comments to provide. This was barely discussed.

We trust the foregoing is satisfactory. Should you have any questions, please do not hesitate to contact me.

Sincerely yours,

Claude Perron
Vice President and General Manager

/des