SOLVAY PHARMA

April 14, 2005

The Secretary of the Board
Patented Medicines Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, 14th floor
Ottawa, ON
K1P 1C1

3225-3-13

050415

Via Fax – (613) 952 7626

To Whom It May Concern:

RE: PROPOSED AMENDMENTS TO THE PATENTED MEDICINES REGULATIONS

Further to the Patented Medicines Prices Review Board (PMPRB) "Notice and Comment" newsletter of January 2005, I would like to comment on the proposed amendments to the Patented Medicines Regulations on behalf of Solvay Pharma Inc.

1) Notification of Proposed Price

We do not agree with the proposed addition to the regulations that a patentee shall provide the price at which a medicine will first be offered for sale 60 days in advance of first sale. We believe that this constitutes an unnecessary additional step in the regulatory process and further delay entry on new products into the market, thereby limiting patient and prescriber choice. Furthermore, as a competitive company, we need to be able to set our prices according to the current market environment into which we are launching a product, not the market 60 days in advance of a launch.

2) Notification of a Proposed Price Increase

We do not agree with the proposed addition to the regulations that a patentee shall provide 120 days advanced notification to the Board of an intended price increase. Again, as noted earlier, as a competitive company we need to be able to set our prices according to market conditions as they exist at the time, not as we presuppose them to exist 120 hence. Furthermore, given the supply chain system in which we operate, through the supply of our product to our customers via third party distributors, such notification of any price increases could potentially create an artificial demand for the product through arbitrage opportunities. This would have ramifications in terms of manufacturing capabilities and the ability to continue to supply the market on a sustainable basis.

Furthermore, as a patentee is limited to price increases within the CPI, as communicated by the PMPRB annually, we do not understand why this additional notification is necessary.

3. Draft product monographs

The proposed regulation that would require patentees to provide draft product monographs of a new patented medicine to the Board for review is of concern. Firstly, draft monographs are just that, draft. They are subject to change and amendment and for the Board to use them as a tool towards determining a non-excessive price would potentially add prejudicial information to the determination process. The Board should use approved, final monographs for its review process. Furthermore, given the competitive nature of our industry, the review of such proprietary information gives rise to confidentiality concerns.

Thank you for providing us with an opportunity to comment on the proposed amendments. Should you have any questions or comments, or require any clarification, please do not hesitate to contact me.

Yours sincerely,

L. J. Downey

Laurence J. Downey, MB, ChB, FFPM
President & Chief Executive Officer
SOLVAY PHARMA INC.