sanofi aventis

Because health matters

April 15, 2005

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

3225-3-13

050410

SUBJECT: PROPOSED AMENDMENTS TO THE PATENTED MEDICINES REGULATIONS (1994)

Dear Ms Dupont,

Sanofi-aventis wishes to express its support to the concerns outlined in Rx&D's submission with respect to the proposed amendments, released by the PMPRB in February 2005, to the Patented Medicines Regulations (1994).

In our view, the amendments being considered may unnecessarily put the competitiveness of our products at risk and would do little, if anything, to improve the timeliness of current price review processes. We believe the proposed procedural changes will result in additional delays for patients awaiting access to new innovative therapies in Canada.

One of the amendments would require sanofi-aventis to submit proposed introductory prices of new medicines 60 days prior to the date of first sale. This will delay access to new medicines after they have been approved for use by Health Canada and add an unnecessary "pre-marketing" component to the current price review process for new, patented medicines. On a practical level, prices are often only established within a few days of first sale due to the various competitive factors that influence the pharmaceutical market in Canada.

A similar amendment would require a four-month advance notice of any price increases of our products. We currently provide comprehensive pricing information to the PMPRB at least twice annually and voluntarily provide additional information on

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price changes between reporting dates. As the PMPRB will not be using this information to pre-approve price increases, we question the necessity of adding this requirement. More importantly, there is a serious risk that prior knowledge of price increases, or decreases, could be used by wholesalers, pharmacies and other manufacturers to the detriment of Canadian consumers and the healthcare system as a whole.

Confidentiality is central to our concerns with regard to the proposed amendment that would require sanofi-aventis to file a draft monograph as part of its submission for a new, patented medicine that has not yet received its Notice of Compliance. The information these documents contain is proprietary and confidential; and, we have serious concerns about these draft documents being circulated as part of the price review process. Furthermore, by nature, the information in these draft documents is subject to change and any analysis based on their content may need to be redone. As a result, we believe that this may reveal to be an unnecessary step adding to the PMPRB's workload.

In all, the PMPRB has proposed six fundamental amendments to the Patented Medicines Regulations (1994). Rx&D has submitted a detailed commentary on each of them in its submission to the PMPRB. Sanofi-aventis strongly endorses Rx&D's position on the matter.

We commend the PMPRB's objective to streamline its price review processes but the amendments as proposed will only add inefficiencies to the current regime and negatively impact our competitiveness.

Thank you.

Michel Giroux
Head of Health Policy and Patient Access

MG/ml