August 24, 2006

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

PMPRB Discussion Guide

Dear Ms. Dupont,

Sanofi-aventis welcomes the opportunity to comment on the issues and questions outlined in the PMPRB's Discussion Guide.

Sanofi-aventis Canada Inc. is the Canadian affiliate of the European based sanofi-aventis organization, the world's third largest pharmaceutical company. Headquartered in Laval, Quebec, sanofi-aventis Canada employs 1,140 people across the country and is home to a world-class manufacturing facility. The sanofi-aventis Group is also represented in Canada by Sanofi Pasteur Limited in Toronto, the largest producer of vaccines in Canada employing a further 1,100 people.

As a leading healthcare partner, we provide, and are developing, innovative medicines for treatments in several therapeutic areas: cardiology, thrombosis, the central nervous system, oncology, metabolic disorders and internal medicine. We also play a role by investing in activities that improve health and quality of life in our communities.

Sanofi-aventis is a member of Canada's Research-Based Pharmaceutical Companies (Rx&D) and we support the positions outlined by Rx&D in their submission to the PMPRB. Moreover, we believe the current consultations offer the PMPRB a unique opportunity to redress a persisting imbalance in the Board's Excessive Price Guidelines.

Issue 1: Is the current approach to the categorization of new patented medicines appropriate?

Question 1: *Are the new patented drug categories and their definitions appropriate?*

The categories as applied by the Human Drug Advisory Panel (HDAP) fail to recognize innovation. The threshold for "substantial improvement" is so severe that almost no new medicine can achieve the standard. As a result the PMPRB has fallen out of step with both Canadian and international standards that recognize innovation. We support a price review system that would not rely on categorization of new medicines, or, if the current system is to be maintained it must recognize the advances offered by so many new therapies.

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Question 2: *Is it important to distinguish a medicine that offers "moderate therapeutic improvement" from a medicine that provides "little or no therapeutic improvement?" If yes, why is it important? If not, why not?*

The issue is not the number of categories but rather the definitions of "improvement" applied by the HDAP. The current definitions ignore technological advances, patient preferences and insist on clinical trial evidence that is often impractical or unethical to assemble. We are concerned that the same inherent flaw would apply to a "moderate improvement" category.

Question 3: *If the answer to question 2 is yes, on what basis would a new medicine that offers "moderate therapeutic improvement" be distinguished from a new medicine that provides "little or no therapeutic improvement"?*

Any product that offers physicians and patient a new treatment alternative (e.g., a new active substance, new dosage form, modified release formulations) should be considered moderate improvements unless there is further evidence to support substantial improvement. Generics are the only products that offer no therapeutic improvement.

Issue 2: Is the current approach used to review the introductory prices of new patented medicines appropriate?

Question 1: *Are the price tests currently used to review the prices of new medicines in the various categories appropriate for that category? Why? Why not? If not, how could these tests be amended to improve their appropriateness?*

The current guidelines are too limiting. The PMPRB Annual Report for 2005 indicated that the prices of patented medicines have increased slower than inflation (as measured by the Consumer Price Index or CPI) and have remained below international prices, a trend that has persisted for many years. This is evidence that, not only are Canadian prices falling in "real" terms, they have also fallen below international standards. The price of a patented medicine should only be considered excessive if it exceeds the therapeutic class comparison (TCC) test and the highest international price test. The consumer price index should be taken into account for adjusting the prices of comparators in a TCC test.

Question 2: *If you think that medicines that offer "moderate therapeutic improvement" should be distinguished from medicines that provide "little or no therapeutic improvement", what would the appropriate new price test be?*

The price of a patented medicine (irrespective of category) should only be considered excessive it exceeds the therapeutic class comparison (TCC) test and the highest international price test. The consumer price index should be taken into account for adjusting the prices of comparators in a TCC test.

Question 3: *For price review purposes, "comparable medicines" are medicines that are clinically equivalent. Do you have any suggestions as to principles or criteria that should be used in determining how to identify "comparable medicines" for the purpose of inclusion in the above price tests?*

In our opinion, comparable medicines should include any medicine that could reasonably be considered an alternative to the new patented medicine. The selection should not be limited to the ATC class.

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Question 4: *Under the current Guidelines, Board Staff compares the Canadian average transaction price of the new medicine to the prices of the same medicine sold in the seven countries listed in the Regulations. However, Section 85(1) of the* Patent Act *states that the Board should take into consideration "the prices of other comparable medicines in other countries". Should the Guidelines address this factor? If so, how could this factor be incorporated into the price tests for new medicines?*

In the event that initial price tests suggest that the price of a patented medicine may be outside the Guidelines because it exceeds both the TCC and IPC tests, it may be appropriate to take into account the relationship of the new medicine to its comparators in other countries. If a price premium exists in other countries, this would serve as evidence that a price premium in Canada is not excessive.

Issue 3: Should the Board's Guidelines address the direction in the Patent Act to consider "any market"?

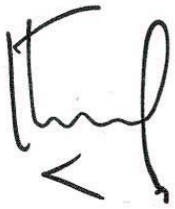
Question 1: *Given the price variations by provinces/territories and class of customer illustrated in the previous figures, is it appropriate for the Board to only consider an ATP calculated based on the total revenues from the sales for all provinces/territories and all classes of customer? Why? Why not?*

Question 2: *If the current ATP calculation is not appropriate, should the Board review the prices to the different classes of customers and/or the different provinces and territories for all DINs? Or should this level of review be done on a case-by-base basis, where there is a significant variation in the prices charged?*

The PMPRB's price review should focus on the average transaction prices aggregated to the Canada total. Only if a price appears to be outside the Guidelines should the PMPRB consider sub-analyses as prices to sub-markets may be consistent with the guidelines and it is only the "averaging" that has resulted in the appearance of pricing above guideline thresholds.

In summary, we welcome the opportunity to contribute to the current consultations and in particular would encourage the Board to improve its guidelines such that they more reasonably reflect the level of innovation offered by the new therapies developed and introduced by research-based companies like sanofi-aventis.

Yours truly



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