sanofi pasteur
The vaccines business of sanofi-aventis Group

OFFICE OF THE PRESIDENT

Ms. Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board
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333 Laurier Avenue West
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Ottawa, ON
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August 25, 2006

Dear Ms Dupont,

Re: Discussion Guide for the Consultations on the Boards' Excessive Price Guidelines Discussion Paper

This letter is the Sanofi Pasteur Limited response to the **Discussion Guide for the Consultations on the Board's Excessive Price Guidelines**. Sanofi pasteur is a member of BIOTECanada and fully supports the position paper submitted by BIOTECanada dated August 25, 2006. In addition, sanofi pasteur appreciates the opportunity to provide some additional comments and feedback, set out below, on the issues raised by the PMPRB.

Sanofi pasteur is Canada's largest vaccine company with a proud heritage and commitment to public health. Sanofi pasteur is the vaccines business of the sanofi-aventis Group, the third largest pharmaceutical company in the world. We are committed to the protection and improvement of health for Canadians by providing important and superior vaccines for the prevention and treatment of infectious diseases, common illnesses and cancers. Sanofi pasteur continues a proud legacy as a cornerstone of Canada's unique public health system. Based on close partnerships with the provincial and federal governments, it is a legacy that has protected Canadians from disease through the development and delivery of essential biological products. Since its founding in 1914 in a backyard stable, the company, founded as Connaught Laboratories, has also been a key partner in the global control of many diseases, particularly diabetes, diphtheria, pertussis, polio and smallpox.

The business of vaccine products differ significantly from traditional pharmaceutical products in all aspects of research & development, manufacturing, distribution and usage in the medical community. Vaccines are generally more costly to develop and to make than pharmaceuticals. They carry higher costs associated with heightened regulatory scrutiny (each lot must be tested by both the manufacturer and the regulatory authority), increased complexity in researching, greater difficulty in developing (scaling up from vial in the lab to the huge bioreactor or fermenter for commercial production), more labour-intensive manufacturing of the purified-component and genetically-engineered vaccines, and the more stringent requirements of the cold chain for vaccine delivery and storage.

Moreover, vaccines are significantly distinct from pharmaceuticals. Vaccines have the ability to prevent disease; pharmaceuticals primarily alleviate symptoms of a disease or correct unbalanced body functions. Vaccines are overwhelmingly prophylactic, pharmaceuticals are primarily therapeutic. Vaccines generally have two to five dose dosage regimes; pharmaceuticals often require long-term even life-long usage. The recognition of these differentiating facts would suggest that the price evaluation of vaccines should be treated differently than traditional pharmaceutical products.

The *Patent Act (*Subsection 85(1)) establishes the responsibility for the PMPRB to ensure that patented medicines are not sold at an excessive price. The majority of vaccines sold in Canada are under long-term contracts that are negotiated between the vaccine manufacturer and the Provinces/Territories and Public Works & Government Services Canada (PWGSC). The Provinces/Territories and PWGSC are sophisticated and knowledgeable purchasers and are able to use their purchasing power and competitive bidding process to negotiate contracts that provide an optimal arrangement of price, quality, supply, and market investment. In addition, the difficulty and complexity of manufacturing vaccines limits the global supply of product and thus, the procurement of product is often managed by the economics of international supply and demand.

It is the position of Sanofi Pasteur Limited that current PMPRB Excessive Price Guidelines cannot be effectively applied to vaccine products due to their uniqueness and costs encountered by vaccine manufacturers in the research, development and manufacture of vaccines.

In response to the first issue raised by the Board "**is the current approach to the categorization of new patented medicines appropriate?"**, it is our position that the current approach is not adequate in that it does not recognize the value of innovation. In addition, in subsection 85(1) of the Patent Act, there is no reference to the categorization of patented medicines for the purposes of price evaluation.

The Board's definitions and application of these definitions to new entities is reflected in the low number of "category 2" products. The introduction of a new vaccine and the significant benefit it provides to the Canadian population is often hard to distinguish since the recipients of the vaccine may never show any symptoms of the organism against which the vaccine has been administered. By definition, pharmaceuticals provide relief of symptoms and thus, their effect is much more overtly dramatic than the prevention of the disease in the first place by vaccines. Thus, establishing the therapeutic value of a vaccine would be extremely difficult and extending this to a categorization of a new vaccine which is used to evaluate the price

for the vaccine is not appropriate. We would suggest that the categorization of new patented vaccines be determined by the comparison to prices established in the international market.

The second issue on which the Board has asked for consultation is: **"is the current approach used to review the introductory prices of new medicines appropriate?"**. The Board's mandate is to determine if prices for patented medicines are "excessive", and thus the automatic application of tests such as the Therapeutic Class Comparison (TCC) are contrary to the intent of the Patent Act amendment in 1987 which was to create an environment which stimulated the investment in research and development of medicines in Canada. If these types of tests are applied blindly, it does not create a stimulative environment since the comparative pricing is versus older products that may not have taken allowable price increases over their product lifecycle. Thus, in this situation, the innovation is not adequately recognized under the current approach for the review of introductory prices.

The last question posed by the Board is: **"should the Board's Guidelines address the direction in the Patent Act to consider "any market".** The current practice of the Board to consider the average transaction price (ATP) from all Provinces/Territories and all customers is adequate for the overall price evaluation of a patented medicine, and the review should not drill down to individual customer classes and/or different Provinces and Territories. As stated before, the majority of vaccines are purchased by the Provinces/Territories and PWGSC through long-term contracts. These contracts tend to equalize pricing on a national level among this particular customer base; however, inherent in the Provinces/Territories having significant purchasing power is the potential for this to create some price variations with other customer classes. It is possible, and entirely reasonable, that the company might sell the same product to other smaller volume customers at a higher price. Furthermore, the PMPRB should not be evaluating the individual market segment prices for patented products, and related elements such as value added components, including the nature or mode of delivery and timing, which could vary among the customer base due to the nature of the business relationship between manufacturer and customer and each customer's specific needs.

In conclusion, we urge the PMPRB to consider the differentiating factors that face vaccine manufacturers in Canada and adjust policies and guidelines to ensure that the long-term interests of the Canadian public are considered.

Sincerely,

J. Mark Lievonen
President
Sanofi Pasteur Limited