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SENT VIA E-MAIL (sdupont@pmprb-cepmb.gc.ca)

October 6, 2008

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

Subject : Sanofi-aventis Comments on *PMPRB Draft Revised Compendium of Policies, Guidelines and Procedures* published on August 20, 2008

Dear Ms. Dupont,

Thank you for this opportunity to provide comments on the draft revised PMPRB Compendium of Policies, Guidelines and Procedures. Please note that sanofi-aventis, as a member of Canada's Research-Based Pharmaceutical Companies association, endorses Rx&D position and comments in this matter as expressed in its answer letter dated September 30, 2008.

As a company focused on innovation, sanofi-aventis relies on pricing procedures able to support through fair pricing policies research and innovative medicine. In that respect, sanofi-aventis expected that the proposed revised Compendium were to result in increased transparency, clarity, simplicity and fairness of the Policies, Guidelines and Procedures.

We fear that the revised Policies, Guidelines and Procedures add complexity and decrease transparency and fairness in the application of pricing procedures. The following points are a non-exhaustive list of examples of what we consider lacks of clarity or unnecessary complexity.

1. De-linking Procedure

We welcome the concept of de-linking MNE from ATP since it provides companies with the ability to offer customers with benefits responding to their needs while also taking into consideration commercial realities. We strongly advocate that in the context of de-linking, prices of patented drugs should always be allowed to return to their introductory national Maximum Non Excessive Price (MNEP) adjusted with Consumer Price Index (CPI). The fact that initial pricing (during the benchmark period) is sometimes below the introductory MNE should never constitute an impediment for returning to a price level that was already approved in the past.

Paragraphs 4.2 and 4.3 at page 18 of the proposed revised Compendium appear to support the general principle mentioned previously: *"4.2 An exception to 4.1 is when the ATP of a drug product declines from a previous year due to the provision of a benefit(s) and if once the benefit ends the patentee provides evidence to demonstrate that the price increase was due solely to the*

termination of the benefit. In this case, the MNE price will be the lower of the previous highest non-excessive ATP (i.e., the De-Linking Methodology in Schedule 8) and the HIPC test." and *" 4.3 In addition, when a patentee can demonstrate that a national increase in the ATP is due solely to a sales-mix shift and none of the prices for each class of customer and in each province/territory exceed the MNE price as determined by the CPI-Adjustment Methodology, the ATP will be considered to not be excessive."*

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Although we appreciate the inclusion of this methodology, we believe that complexity has been unnecessarily added and that, as an accepted rule, the national introductory MNE adjusted with CPI should remain the ultimate reference throughout the entire patented life of a drug. Any rebound of a patented drug national average transaction price (ATP) should be compared with the introductory national CPI-adjusted MNE. As a result, the concept of a "Gap" should be included and an appropriate method for being able to increase the price back to the level of the CPI-adjusted introductory MNE should be developed. In regards to the transitory period of reporting, we strongly recommend that CPI-adjusted introductory MNE should constitute the MNE of reference for existing products.

2. Inclusion of Benefits

Since 2000, the Board adopted a policy leaving to the discretion of the patentees the choice for inclusion or exclusion of certain benefits from the reporting of the ATP as long as consistent reporting is maintained.

In its August 18, 2008 communiqué, the Board is reverting to a very strict position i.e. *"the Average Price must include any benefits listed in sub-section 4(4) of the Regulations that are connected to sales: rebates (including rebates / payments to third party); discounts; free goods; free services; gifts; and other benefits of a like nature."*.

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We question necessity and the pertinence of this change in direction (from discretionary to mandatory reporting of benefits). Because reported benefits *have to be connected to sales transactions*, we question even further the logics for inclusion of benefits not linked to direct sales (e.g. compassionate use program, indigent programs, etc). As a conclusion, we believe that reporting of benefits should be left to the discretion of the patentee (with the condition that it has to remain consistent in each report). On the other hand, if the mandatory reporting of benefits is maintained, clarity is much needed in the definition of benefits to be reported as well as a clear communication on how the first period of reporting, i.e. January to June 2009, will be treated. In the event that reporting of all benefits becomes mandatory, it cannot be conceived outside of the de-linking methodology, to ensure that Canadians continue to be offered benefits.

3. Any Market Review

The new proposed revised Compendium is departing from the previous general approach of conducting an "any market review" on a case-by-case basis to a more formal statement of conducting it at the introduction of a new drug (in this particular case only for the distribution channels) and, as presented by the Board Staff at the September 9 meeting, whenever the national ATP appears to be higher than the MNE. It is important to note that the current wording in the proposed revised guidelines is rather vague on this last issue and that clarity is required.

Complexity and Cumbersome Application
As a result, the patentees will now have to run numerous analyses in order to be ready to provide an "any market review". In fact, considering that the currently PMPRB proposed de-linking methodology and the mandatory inclusion of all benefits will certainly result in frequent rebounds of the national ATP, these analyses will become quite frequent.

The net effect of including all the benefits, of applying a complex de-linking methodology and of having to run numerous analyses in order to demonstrate the appropriateness of the ATP in the different markets is not expected to positively impact the companies' ability to propose beneficial commercial conditions to their customers. They will more likely lean toward sustaining the introductory MNE as the unique price for the drug.

Consequently, we recommend narrowing the "any market review" to very special cases where there is a high suspicion that markets' ATP are over the introductory MNE. In the case where a market's ATP were to be found higher than the introductory MNE, we recommend that excessive revenue continues to be calculated based on a national basis as is currently done for investigation purposes.

4. Addition of one Level of Therapeutic Improvement

The suggestion to create a category for moderate improvement products, with an appropriate price test, would represent a slight improvement versus the existing clinical categories.

In terms of elimination of unnecessary replication of clinical review, we recommend that HDAP review be more in line with Health Canada review. As an example, whenever Health Canada grants a priority review to a patented drug, this should result in a status of either a *breakthrough* or a *substantial improvement* from HDAP reviewers as the terms of reference are of similar nature in both status.

This summarizes sanofi-aventis main comments. We are looking forward to their consideration to jointly improve pricing establishment and control in a simple, transparent and equitable way for innovative pharmaceutical companies, regulators, payers and patients in Canada. This could and should be achieved without the burden of a cumbersome and complex administrative environment.

We appreciate and thank you for the opportunity that was given to us to comment on the draft revised PMPRB Compendium of Policies, Guidelines and Procedures.

Sincerely,

Jérôme Silvestre
President & CEO