By e-mail : sdupont@pmprb-cepmb.gc.ca

April 27, 2009

Dr. Brien Benoit, Chairperson
Patented Medicine Prices Review Board (PMPRB)

A/S Sylvie Dupont
Secretary of the Board
PMPRB
Box L40
Standard Life Centre
333 Laurier ave. West, Suite 1400
Ottawa, ON K1P 1C1

Dear Dr. Benoit,

Sanofi-aventis Canada Inc would like to thank the Board for the opportunity to comment on the draft revised excessive Price guidelines published on your website on March 25, 2009.

As a first general observation, we believe that Canadian prices used in pricing tests should always be based on available public sources. The use of non-excessive average prices (NEAP) of patented competitors is not an acceptable option. Not only would it create uncertainty (we don't know the NEAP of our competitors) but it would breach the confidentiality of the information provided to PMPRB. Even using a percentage range around the NEAP would inevitably result in disclosing competitive information on patented products. Confidentiality of the patentee's information has always been respected by PMPRB and using competitors NEAP in pricing tests would jeopardize it.

We are also concerned with the addition of unnecessary reporting complexity brought up by the proposed "any market" analyses and methodologies. On the long term we believe that, far from encouraging and fostering an innovative Canadian pharmaceutical environment, the new mandatory "any market" process would result in a diminution in the offering to Canadians. We strongly propose to revert to the initial guidelines where the "any market" analysis was considered an ad hoc process and seldom requested from patentees.

In addition to those two general observations, the following are specific s-a comments pertaining to selected proposed changes in the guidelines which we believe carry important consequences for the future.

1. Publication of available international prices of a patented drug
Based on the Board observation that the Form 2 block 5 information (i.e. Canadian and International ex-factory prices) is by definition required to be publicly available, it will no longer be considered privileged information.

Although Canadian and International ex-factory prices are not considered privileged information, this does not imply that it is not confidential. In many cases the information provided in Form 2 block 5 has only a selective distribution to some trade levels. If published by PMPRB on a regular basis without the patentee's consent, it will create frequent situations where competitive information is released. It would inevitably render the exercise of obtaining international prices much more difficult, if not impossible.

2. Publication of the CPI-Inflated Maximum Average Potential Price (CPI-I MAPP)
The Board is prepared to consider acting on the regular publication of the CPI-I MAPP. However, the Board made two important comments: the CPI-I MAPP could not be relied upon for regulatory purpose and, due to the confidentiality provisions of the Act, it may not always be possible for the PMPRB to find public prices suitable for reporting purposes.

Considering the uncertainty around establishing CPI-I MAPP for current patented products and the limitations noted above, Sanofi-aventis recommends that the CPI-I MAPP should not be disclosed.

3. Introductory Prices Tests
In the case of the Reasonable Relationship Test (RRT), the Board is proposing to revert back to the RRT test number three which means that it won't force different strengths to always rely on price per mg.

We agree with PMPRB that this flexibility is essential in certain cases and appreciate the availability of the RRT test number three.

4. International therapeutic class comparison (ITCC)
Use of generics in pricing tests for brand names
The Board mentioned that in cases where the ITCC test will be applied, in addition to finding comparable brand product, the Board will also include "those generic drug products that are being sold by a company that also sells the same generic drug product in Canada".

Having to add generics to brand names in order to perform an ITCC would inevitably skew the result of the test. Consequently, this could jeopardize the launch of new products / formulations in Canada.

It is also unclear if generics will be included whenever the test used to establish the maximum average potential price (MAPP) of new products will be "the lowest non-excessive price of the superior drug products identified for a new product *for which no comparable drugs have been identified*". As previously mentioned for the ITCC, introducing generics in the test will skew future pricing and this will negatively impact the attractiveness of Canada as a market for introducing new pharmaceutical products.

We recommend that generics should not be considered for inclusion in pricing tests for a brand name patented product.

5. Any Market price reviews

In the draft revised guidelines, the Board is now proposing that "the markets that will undergo ""any market"" review at introduction have been expanded to include: each province and territory in addition to each of the three classes of customers (hospital, pharmacy and wholesaler) and the national level".

It is our view that any benefits to PMPRB hypothetically generated by this new approach to reporting will be far exceeded by the unnecessary complexity of having to calculate and monitor numerous introductory benchmarks / NEAP / ATP for each specific market and for each strength of a patented drug product.

The methodology presented by the PMPRB staff also put in perspective that in the case of a retrospective ""any market"" investigation, a product introduced in the course of two or more years could generate different maximum potential prices. This again would add to the complexity of the pricing in Canada as well as this would increase the uncertainty around the future pricing of a drug in Canada.

Furthermore, if this new methodology is applied retrospectively to current patented products, it will generate unpredictable results. In general, all pricing trends were monitored nationally and very rarely with an ""any market"" perspective.

Finally, any product subjected to a Voluntary Compliance Undertaking (VCU) further to an ""any market"" investigation could result in the divulgation of highly confidential competitive information. (if Market specific NEAPs are published)

For all those reasons, we believe that it is in the interest of all Canadians that PMPRB reverts to a national review of the patented drug product and to reserve the ""any market"" review for rare special cases only.

6. Recognizing benefits ("DIP" methodology)

As an alternative to the consumer price index adjustment methodology (CPI – Adjustment Methodology), whenever an average transaction price (ATP) sudden increase is due to the termination or reduction of benefits offered to customers, the Board is proposing the application of what has come to be known as the "DIP Methodology". The proposed guidelines provide further clarification in the DIP methodology.

We appreciate the inclusion of a methodology that positively addresses the rebound of a Market Specific ATP (MS-ATP) to a pre-benefit or reduced-benefit MS-ATP. Although the GAP methodology along with the DIP should have been retained, we appreciate the efforts put in these draft guidelines to clarify the DIP methodology.

However, certain points still remain to be clarified. Notably,

- the methodology that will be applied to current products for defining their introductory market specific Maximum Average Potential Price (MAPP). Will the MAPP be recalculated for each introductory period if a product is introduced in a market on year 1 and in another market in year 2?

- a list of examples of acceptable and non-acceptable benefits.

- a methodology for considering multi-factorial benefits impacting the ATP (e.g. in one province, the final MS-ATP might be the result of a multitude of factors i.e. different hospital contracts, different wholesalers agreements and different general benefits offered to the patients across the country but mainly used by patients in one province).

- A clarification of the methodology which should include a mechanism by which all MS-NEAPs may rebound to the highest initial benchmark (considering all markets) adjusted with CPI as long as it is demonstrated that benefits where terminated or reduced. The year of the MS-NEAP resetting should also reset the MS-benchmark year in order to eliminate the possible lowering effect of the 3-year CPI-Adjustment methodology.

7. Use of patented and non-patented drug products in the price tests

It is the current practice of the Board Staff to examine the price of all pivotal comparator drug products, both patented and non-patented. The Board Staff is considering looking at the NEAP of patented pivotal comparators.

Four very important issues are associated with this proposal.

a) It brings a lot of uncertainties in the task of forecasting the potential maximum price of a new product as this implies that the price of our future new patented drugs may end up being based not on public pricing but rather on information that is not available to us (NEAP of patented pivotal comparators are confidential information only known from PMPRB)
b) It raises confidentiality issue around our product's NEAP if our patented products serve as pivotal comparators for new patented products. Even using a range of plus or minus 10% of the NEAP would result in the disclosing of competitive information regarding the extend of benefits being given on a competitive patented product.
c) Setting a comparison on a NEAP rather than the public price (e.g. the Ontario formulary listed price) would also mean looking at a price of a patented pivotal comparator that might be including many benefits. This would set our new product price to a price level that might not be achievable for a new product entrant with no market shares yet: this would be unfair for the new product entrant.
d) Furthermore, in certain cases this would create unfair market conditions. The comparator would be allowed to rebound to a higher initial market-specific benchmark (if the comparator was first sold without benefits) whenever the new introduced product with a pricing based on the comparator's NEAP of a subsequent year would never be able to rebound to the same comparator's initial benchmark if the comparator's NEAP were to include benefits.

Consequently, we suggest that PMPRB continues to use public sources (like the Ontario formulary) for examining the price of pivotal patented comparators. PMPRB staff should never rely on NEAPs of pivotal patented comparators as it not only brings a lot of uncertainties and unfairness to the process, but it also raises an important issue around strict confidentiality of NEAPs for patented products.

8. Offset of excess revenues

The Board is proposing that "excess revenue balances below the amount sufficient to trigger the investigation criteria that are carried for six consecutive six-month reporting periods (3 years) will be expected to be offset through a Voluntary Compliance Undertaking. Failing this, Board Staff will refer the matter to the chairperson."

This approach contravenes the legal principle of *de minimis non curat lex*, i.e. the law does not concern itself with trifles. If an ATP is considered excessive to the point where it triggers an investigation, the PMPRB should investigate it. If the ATP is so small not to justify investigation, then it should be left alone, not aggregated with other minimal infractions to achieve a result indirectly, that the PMPRB does not wish to address directly.

As long as a product's ATP doesn't meet the criteria which trigger an investigation[1], we recommend that the product should be considered as within guidelines.

CONCLUSION

Sanofi-aventis would like to stress the importance of keeping a fair balance between maintaining non-excessive prices for patented medicines and the maintenance of an environment which encourages and fosters pharmaceutical innovations.

We anticipate that the new proposed guidelines will create an environment where there is more uncertainty (NEAP of comparable pivotal competitors introduced in pricing tests) and potential breach of confidentiality (disclosing ex-factory prices; basing pricing tests on NEAP instead of the public price of comparable pivotal comparators). The inclusion of generics in pricing tests for brand names would skew pricing towards discounted generic pricing which, as a result, would act as a deterrent for the introduction of new pharmaceutical products on the Canadian market. Finally, the establishment of introductory NEAPs both at the national level and at the level of all provincial markets and trade levels appears excessive and should be reserved for very special cases.

The application of the proposed guidelines will not benefit Canadians nor the Canadian health care system. It may result in the availability of less drug products and less convenient new strengths on the Canadian market as well as a reduction of all benefits offered with these products.

We hope that you will give serious consideration to our concerns. Should you wish to further discuss them with us, we remain available to do so at your convenience.

Sincerely,

Jacinte Morel
Senior Manager, Pricing Strategies
sanofi-aventis Canada Inc.

[1] Criteria for commencing an investigation

1. The National Average Transaction Price or any Market-Specific Average Transaction Price of a new drug product exceeds the Maximum Average Potential Price during the introductory period by more than 5%.
2. The National Average Transaction Price of an existing drug product exceeds the National Non-Excessive Average Price by more than 5%.
3. Excess revenues for a new or existing drug product are $50,000 or more.
4. PMPRB receives a complaint that a price is excessive.