March 3, 2008

Sylvie Dupont
Secretary to the Board
Patented Medicines Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Original delivered by facsimile: (613) 952-7626

Subject: Response to "*Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines*"

Dear Ms. Dupont:

Novo Nordisk Canada Inc. ("NNCI") understands that BIOTECanada has already submitted comments on the Board's discussion paper entitled "*Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines*" (the "Paper") in a letter dated March 3, 2008. NNCI supports the views expressed in the BIOTECanada letter and wishes to make the following additional comments.

Preliminary Comments

All stakeholders, including manufacturers such as NNCI, are being given a limited period in which to comment on the extremely complex proposals that are included in the Paper. The task of commenting is further complicated, as noted in the letter of BIOTECanada, by the inherent inter-relationship between many of the issues being considered.

Further, the Paper highlights a fundamental disagreement among stakeholders over the mandate of the Board. Is it "to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive", suggested on page 8 of the Paper, or is it "to regulate the prices that patentees charge – the factory gate price – for prescription and non prescription patented drugs sold in Canada" suggested further on in the Paper, on page 18. The Paper indicates that the Board intends to address its mandate in revised language to the preamble to the Guidelines. For some time, members of the manufacturer community, including NNCI, have been expressing concern about what manufacturers see as a creeping expansion of the mandate and jurisdiction of the Board. In our opinion, it is not a responsibility of either stakeholders or, for that matter, the Board to redefine the jurisdiction of the Board. This is, in our opinion, an exclusive responsibility of government.

The issues that form part of the Board's consultations could have a significant impact on NNCI's ability to introduce new patented medicines in Canada. It is critical that the Board understand the relationship between new regulations that increase the level of regulation of the prices of patented medicines and create an environment that encourages the introduction of new patented medicines and the investment in research and development in Canada, which is in line with the original mandate.

Leo Pharma Federal Court Case Decision

NNCI wishes to add its voice to those expressing concern over the negative effect on patient access to important new therapies created by the continuing uncertainty about the impact of Leo Decision. The Paper outlines a number of options. However, it fails to propose the one obvious option that would have confirmed the continuation of the current guideline requirements – amend the regulations to make the regulations consistent with the current guidelines. The direction of the Board in the April 2000 Newsletter, allowing for the patentee to use its discretion in the decision to either include or exclude reporting of special programs with consistency, was a fair and appropriate approach to managing such special programs which served to benefit patients, and aligns with the mandate of the Board as defined in both the Act and the regulations. NNCI believes that this was an important omission and that is option needs to be part of further and necessary consultation.

Furthermore, it is our belief that the proposal that has been tabled previously by industry associations regarding de-linking of the calculation and imposition of the MNE from the ATP is a valid solution; however, it has not been included as an option within the Paper itself. As has been defined by other stakeholders at large, "de-linking" refers to establishing the MNE price at launch based on the appropriate excessive price tests and then adjusting it annually based on changes in the Consumer Price Index (CPI). It would eliminate adjusting the MNE price each year based on the average price in an earlier year. This model is fully consistent with the Board's mandate and is easier to manage and oversee than are any of the other options presented in the Paper.

Any Market Review

The Paper suggests that the Board is seeking to make transparent when the Board staff would undertaken an "any market" review. With respect, what appears to be proposed is a new requirement that both at the time of introduction and in any future period the ATP for each class of customer and each province/territory cannot exceed the MNE. NNCI believes that it is important to state that the fact that a price for one purchaser or in one market is lower than for others does not mean that the price for others is necessarily excessive. As we noted in our response of August 24, 2006, we continue to assert that an "any market" price review is unnecessarily restrictive and intrusive given that other market forces (e.g., hospital buying groups) that already limit prices with specific sub-markets.

Re-Setting the MNE Price

NNCI believes, as do the other members of BIOTECanada, that the current guidelines make adequate provision for the review of the original MNE price and the establishment of a new MNE price (re-benching) and should only be conducted on a case-by-case basis as may be warranted by the facts of the particular price review.

The Paper requests input on whether it would be appropriate to consider re-setting the MNE price when the median of the international price comparison is the pivotal test and the medicine is sold in too few countries at introduction. The current guidelines state that an interim price will be used when in cases a medicine is sold in fewer than 5 countries at the time of its introduction. The interim price may then be reviewed at the end of 3 years or when the medicine is sold in at least 5 countries, which ever comes first. NNCI believes that the current guidelines on re-benching are entirely appropriate. The use of 5 countries in such an assessment provides for more consistency and offers a more reflective median of the basket of seven comparator countries than if instead the test was 3 countries. The Board did not provide sufficient evidence and rationale in the Paper to change current provisions for adjusting the MNE price depending on the number of countries in which the drug is sold. NNCI inherently believes that re-benching would add to the issue of price instability and unpredictability rather than stability and predictability, which is the role of the Board.

We would be pleased to discuss the aforementioned issues further and look forward to additional opportunities to continue to provide input on the issues/ proposals included in the Paper. We are certain that all parties agree that there is a considerable amount of work to be done on the matters set out in the Paper to ensure that they reflect the best possible public policy outcomes.

Yours Truly,

Novo Nordisk Canada Inc.

Vince Lamanna,
President