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

Subject: Notice and Comment, August 2008 – Draft Revised Excessive Price Guidelines

Dear Ms. Dupont,

As a member of BIOTECanada, Novo Nordisk Canada Inc. (NNCI) supports the Association's position and concerns put forward in its response to the PMPRB's Notice and Comment document, published in August of this year. NNCI also has additional concerns, presented herein.

While the proposed guidelines include some warranted and required additions, they also contain unnecessary changes as well as omissions from the current guidelines.

The complexity, number and scope of the revisions render the guidelines less than transparent and extremely confusing, potentially leading to numerous disagreements between the Board staff and patentees in relation to intention, interpretation and/or applicability of certain provisions of the guidelines in particular cases. Some of the proposed changes will create significant additional work for patentees, requiring additional resources (time and human capital) to ensure compliance and addressing the increased reporting with the revised *Guidelines*.

Categorization of New Medicines:
The proposed addition of the *new* moderate improvement category for new medicines is welcomed. It addresses the longstanding and significant gap between the previous category 2 and category 3 new medicines required level of justification/ evidence of little to no versus substantial improvement. The associated price testing methodology created for the new moderate improvement category provides recognition of the benefits these medicines offer over existing drugs used for the same indication.

Regulations Regarding Reporting Requirements:
In relation to the Board's interpretation and resultant position of the findings in the Federal Court Case (FCC) on Dovobet® relating to the required inclusion of all benefits, and specifically payments provided to third parties pursuant to confidential negotiated agreements, has been and continues to be a source of debate.

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Similar to the position of other relevant stakeholders, NNCI disagrees with the PMPRB's interpretation of these payments as benefits associated with a sales transaction, particularly one that deals with a "customer", as referred to in the *Patented Medicines Regulations* (the *Regulations*) and as further addressed in the Patentees' Guide to Reporting. The *Regulations* do not define a "benefit" in the form in which the Board has taken their liberal interpretation, which interpretation flies in the face of prior statements from that Board staff made in their meetings with industry that "the Board staff and the Board are not in a position to interpret the *Regulations* beyond what has been strictly written".

The *Guidelines* also lack specificity with regards to a clear definition of a benefit, as it pertains to reporting. While the PMPRB Board Staff have noted in verbal consultation with patentees that these must be "connected to a sales transaction", this guidance is subject to various (mis)interpretations. For example, while free goods are included one could argue that, since they are free, these goods cannot be considered related to a sales transaction. In addition, the term "goods" in this context is not defined (e.g. samples, promotional items, etc.). Free services are also included as being required to be reported but without direction as to what type of services might be envisaged (e.g. funding of continuing education programs, patient support programs, infusion clinics, nursing support, etc.). Additionally, if the linkage is drawn to the "sale" of a product, then for companies that provide such services that cover a number of products and potentially some outside of their basket of patented medicines versus a company that has only one related or relevant molecule manufactured and sold in the market, there is the issue of fairness/ equity in reporting requirements if the cost of that service could be spread over many products for one manufacturers, but only one for another. Clearly, reporting of this nature cannot be within the intent or the spirit of the *Regulations*. For transparency and to promote consistency in reporting, the guidelines should provide specific examples of benefits, free goods and free services that must be reported.

Finally, if a patentee owns the compound that is the comparator for new compound which it also owns, then the impact of that reporting or not reporting would be systemic and also inequitable, in that the ATP for the older compound lowered by in market activities is the MNE/ benchmark price for that new compound. If the patentee doesn't own the comparator compound, then the benchmark price is set on the publicly available list price.

De-Linking:

We applaud the PMPRB for proposing and including the concept of de-linking in the context of the revised *Guidelines*. However, the proposed de-linking methodology (and related any market review) has the express potential to address issues relating to average selling price fluctuations, which are more likely to occur now given the new reporting requirement. As was clearly apparent from the examples presented in the PMPRB's industry information sessions, the methodology has the potential to create unusual results that are in conflict with the expressly stated and underlying intent of the *Patent Act*. A methodology that envisages the price in a specific market as being excessive even though that price is consistently below a previously established non-excessive level and lower than prices in all other markets (i.e. other provinces or classes of customer), must be considered seriously flawed. NNCI respectfully submits that a

price cannot be considered excessive when it remains below a level previously deemed by the PMPRB to be non-excessive in any market in Canada. As outlined in the issues noted below, the overly complex nature of the methodology, its potential to produce conflicting results and uncertainty as to its applicability in any given case, combine to create an environment that is not conducive to offering benefits of any kind, no matter how they may be defined.

1) The de-linking methodology incorrectly assumes that all customers within a market are offered or would be able to be offered a benefit. It ignores the fact that the price to non-benefit customers within the class and in other classes may be increasing pursuant to the CPI-adjustment methodology during the benefit period. By only allowing a price to bounce back to the previous highest non-excessive ATP in that specific class of customer regardless of how long ago the medicine was sold at that price, the methodology indirectly imposes an intended and deliberate price freeze in that market for the period during which the benefit is offered. This approach presents patentees with a significant disincentive to offer any form of benefit to customers in any market. In our opinion, the price rebound must, at the very least, take into consideration changes in the CPI from the period in which the highest non-excessive ATP was established.

2) The PMPRB proposes to apply the methodology only on an exception basis, which suggests that benefits are only offered from time to time. In reality, various benefits can overlap from one year to the next and, given the scope of the term "benefit", are relevant in one form or another to a majority of medicines sold in Canada. Therefore, since the methodology's limitation criteria place the onus on patentees to provide "sufficient evidence to support its application in each case", the proposed exception-based approach will necessitate ongoing case-by-case reviews by the staff of the PMPRB – a resource intensive initiative for both patentees and the Board staff.

3) According to the PMPRB's proposed new *Guidelines*, the de-linking methodology will only be applied when the average price increase is related to the termination of a benefit and then only if the patentee can provide evidence that the benefit existed and, according to suggestions by the PMPRB's staff, of the customer's knowledge that it was receiving a benefit. In our opinion, if a price at which the medicine is sold to a customer is below the published list price of the medicine, this should be sufficient evidence that the benefit existed and that the customer was aware that it was receiving a benefit. There should be no need to demonstrate that the customer is aware it is receiving a benefit.

4) The methodology will not be applied in cases where the average price fluctuation is the result of "new sales to a new class of customer at a lower price". This limitation is confusing since no reasoning for it is provided in the *Guidelines* and since it appears to run counter to examples supplied during the information sessions provided to manufacturers for the purposes of aiding comprehension. Taken literally, this limitation could inadvertently be triggered by a delay in orders received from a particular market

sector, possibly resulting from the timing of supply contracts (e.g. hospitals). In our opinion, this limitation is unnecessary, arbitrary and causes undue uncertainty in terms of the potential eligibility of the de-linking option.

In-Any-Market:
Although the PMPRB's proposed any market review will only be applied at introduction and, thereafter only in the context of an investigation, it creates an excessive burden for patentees. The mere possibility of a review in any market creates the requirement for a company to continually monitor the average selling prices of all of its patented medicines in all provinces and in all customer classes. In fact, ongoing monitoring at the customer account level may be required in some instances. As a result, additional resource expenditures to specifically address this requirement will be needed to ensure that any price does not inadvertently rise above the non-excessive level. In our opinion, given that the PMPRB's own analyses concluded that the majority of prices in any given market are not excessive, this represents an unnecessary and grossly undue additional financial and time intensive burden on patentees. In looking across other international models, it is difficult to find a similar example of the proposed level of price regulation and scrutiny.

Changes Not Addressed in Notice and Comment:
There are changes in the proposed guidelines as they relate to new medicine review processes and price tests. These were not contemplated in any of the consultation documents, not addressed in the price test working group's report and are not mentioned in the present Notice and Comment discussion document accompanying the revised *Guidelines*. Their potential impact on allowable pricing during the introduction period is significant and, in our opinion, should have been available for discussion during the consultation process.

1) The revised *Guidelines* as they relate to the price review of new medicines do not contemplate the median international price in cases where a therapeutic class comparison test would generally apply but cannot be conducted for various reasons. Under the current *Guidelines*, the median international price represents the final default test for new medicines in any category. This omission from the proposed *Guidelines* creates uncertainty as to process in these cases.

2) Revisions to the *Guidelines* have also eliminated the therapeutic class comparison test as a default for the price review of new DINs of an existing medicine in a comparable dosage form (formerly category 1) when the Reasonable Relationship (RRT) methodology is not appropriate. The current *Guidelines* specify instances where some form of therapeutic class comparison test would be used, including material differences in dosage regimen or therapeutic use and in cases involving modified release formulations. The proposed new *Guidelines* appear to suggest that a submission providing evidence of therapeutic improvement would be required, which also necessitates review by the HDAP according to the new *Guidelines*, in order to justify moving beyond the RRT in such instances. In our opinion, this represents an unnecessary use of the HDAP's time, an increased workload for Board staff and the

HDAP and an additional burden for patentees. It would ultimately likely represent the need to have a second HDAP review, which would beg the question whether the same consistent decisions are being made across similar or same issue case files. Ultimately, it will lead to significant delays in the price review of previously routine reviews of simple line extensions.

3) The different strength test associated with the RRT methodology has been revised such that it now excludes the price test previously applicable to the subsequent introduction of a lower strength DIN. While these new DINs can be priced up to the unit price of the existing higher strength under the current *Guidelines*, they will now be restricted to the same per mg price of the existing DIN. The impact of this change is significant in the first instance because it imposes an important new restriction on the price of the lower strength, but then subsequently restricts all other new DINs of the medicine to that same per mg price because of the linear relationship test. This change has the potential to force companies to delay introduction of the first DIN of a medicine in Canada until a launch sequence that will allow a more traditional pricing relationship among the strengths of the medicine is available.

Other issues of express concern to NNCI include:

1) The required price reduction solely as a result of a decline in exchange rates (i.e. regardless of a constant local currency price) is inappropriate and reflects an inappropriate level of price regulation that is not mirrored in other markets. Given that there is little opportunity to re-adjust the price to its previous level once the exchange rates climb back up, this requirement imposes an unrealistically long-term restriction on a price based on factors well beyond a patentee's control.

2) The potential use of a comparator's previous highest average selling price, which would be published at the request of some patentees, in the price review of new medicines and the related issue of using the non-excessive average selling price in the case of a comparator sold by the same patentee as the new medicine under review represents an inconsistent application of the *Guidelines*. In the vast majority of cases, the price of a new medicine is reviewed against the list price of the identified comparators. Restricting some new medicines to the comparators' ATP merely because it happens to be sold by the same patentee or the manufacturer has chosen to allow publication of the ATP unfairly penalizes certain companies. Consistency and equitable treatment for all patentees requires that the list price of the identified comparators be used in all instances.

3) The PMPRB has not announced any transitional measures that will be required as the new *Guidelines* come into effect. Given the vast scope of the revisions being proposed, the nature of these transitional measures represents a very important part of the implementation process. As such, NNCI reserves the right to provide comments on these measures once they are announced.

In Summary:

The proposed new *Guidelines* have important gaps in information that impact on the transparency of the price review process going forward. The term "benefit" needs to be more precisely defined in the *Guidelines* by way of specific examples of what should and shouldn't be included. A specific description of the forms and levels of evidence expected of a patentee by the PMPRB in order to trigger application of the new de-linking methodology must also be prescriptively included. The very simplistic description of this latter methodology in the *Guidelines* versus the extremely complicated methodology presented during the PMPRB's information sessions has created a great deal of confusion and needs to be restated to ensure a complete and correct understanding of the methodology and the process by which it will be applied. The price review process as it applies to new medicine reviews must include the previous language relating to instances where the conduct of other established price review methodologies may be required.

Finally, we must reiterate our profound disagreement with the PMPRB's newly imposed requirement to report any form of payments made to third parties and our related concerns regarding the potential for disclosure of this information. In our view, only payments to customers, as referred to in the *Regulations*, need be reported. Third parties that are unrelated to the patentee's factory gate transaction clearly are not customers and as such, any payments to them need not be reported.

We trust that these opinions and the feedback provided will be taken into consideration in the process of further consultation with interested stakeholders.

Yours truly,

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Novo Nordisk Canada Inc.