April 14, 2005

PATENTED MEDICINE
PRICES REVIEW BOARD
By FAX 1-613-952-7626

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Sylvie Dupont
Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West Suite 1400
Ottawa, Ontario
K1P 1C1

CONSEIL D'EXAMEN DU PRIX DES MEDICAMENTS BREVETES

050408

3225-3-13

Dear Ms. Dupont:

**RE: PROPOSED REGULATORY CHANGES**

Novo Nordisk appreciates the opportunity to comment on the proposed regulatory changes contained in the January 2005 Notice and Comment document.

Novo Nordisk supports efforts to speed the price review process within the legislative framework and which will have a positive effect. However, after careful reading of the PMPRB proposed actions, it is very apparent that there needs to be substantially more analysis and planning before rushing to impose yet more regulation. We have provided below a summary of what Novo Nordisk believes to be critical shortcomings in the proposed approach.

**General Comments**

Novo Nordisk shares an interest in having prices of new drugs and price increases reviewed quickly. The Timelines Project, which has not yet completed its work, as well as comments from the Working Committee, has pointed out the need for speedier price reviews. While there is little question this would be beneficial to stakeholders, it is premature for the PMPRB to suggest Regulatory changes before the Timelines Project has finished and without addressing just where delays in the review process occur.

It would also be preferable for the PMPRB to provide a rationale for a regulatory solution including increasing the reporting burden placed on patentees. The PMPRB has had great success in reviewing prices with only 33 cases that have required a formal resolution in the form of a hearing or Voluntary Compliance Undertaking (VCU) in 15 years of the PMPRB's existence. This is out of many hundreds of new drugs or price increases over this time period. Regulations that require every patentee to file information on every new drug and price increase, no matter how small, in advance of implementation is far out of proportion when balanced with the extraordinarily small fraction of pricing issues that have arisen over 15 years.

The Notice and Comment document provides no evidence that demonstrates patentees have delayed responding to PMPRB requests. The absence of evidence and analysis is somewhat surprising given the increasing demands placed on industry by both provincial governments and federal regulators.

Evidence and a rationale for more regulations are important since the contemplated regulatory changes are not without significant costs to patentees. The PMPRB has not provided any estimate of the cost of meeting these new requirements.

**Novo Nordisk Canada Inc.**
2700 Matheson Blvd. East
3rd Floor, West Tower
Mississauga, Ontario
L4W 4V9

905-629-4222
1 800 465 4334
Fax 905 629 8662
www.novonordisk.com

In addition to no apparent justification for this approach, this initiative does not seem to fit with the Federal government's initiatives on "smart regulation" and efforts to streamline and coordinate the regulatory systems of the United States, Mexico and Canada.

**Specific Comments on the Proposed Changes**

Prices are often not determined until very close to the time the drug is introduced or the price is changed. As a result, patentees will face delaying launching new drugs until the regulated time has elapsed or the risk of serious penalties. The PMPRB will be faced with the increased burden of enforcing the regulations and holding hearings in the event patentees fail to meet the timeline.

The "Notification of proposed price" regulation is contrary to both the intent and wording of Sections 82 (1) and (4) of the Patent Act. Section 82 (2) gives the Board the authority "by order" to compel a patentee to provide price information. Section 82 (4) states that even where a Board order is issued, the information cannot be required more than 60 days before the intended date of first sale. If Parliament intended on extending the proposed regulatory authority to the PMPRB, neither Section 82(2) nor Section 82(4) would have been necessary.

The proposal to require notification of a proposed price increase is contrary to Sections 80(1)(b) and 80(2)(b) which both deal with instructing the Board to review prices which are or have been charged. There is nothing in the Act to suggest Parliament has authorized price controls or prices review in advance of sale. Furthermore, variance in reimbursement systems across the provincial jurisdictions makes such a change problematic and impractical.

The PMPRB provides no evidence nor does it suggest that patentees do not promptly comply with requests for information. Regulations requiring details on the calculation of net prices and revenues or the provision of product monographs are proposed without any justification or explanation of the implications for how prices will be reviewed.

In conclusion, Novo Nordisk does not believe the proposed regulations will serve the objectives stated by the PMPRB and that they will impose a significant regulatory burden on the Canadian pharmaceutical industry that is not balanced by any benefit to the public. The proposed regulations have not been justified with any evidence that would support the intention of speeding the price review process. Indeed, there is every reason to believe these will further tie up PMPRB resources in enforcing regulations that are outside the scope of the law, unnecessary and impractical.

Novo Nordisk takes great pride in the fact that it, like other patentees, complies with the PMPRB Guidelines and the intent of the Patent Act. While we have an interest in the speedy review of new product prices and price changes, the proposed regulations will do nothing to achieve this aim. We strongly suggest that the Timelines Review report on the reasons for delays in the price review process and that every effort be made to reduce the regulatory burden not to add to it.

We would of course, welcome the opportunity to participate in any public consultations concerning this initiative.

Sincerely,

Martin Fisher
Director, Diabetes Care Marketing