May 9, 2005

By Fax 1-613-952-7626

Sylvie Dupont
Patented Medicine Prices Review Board
Standard Life Centre
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Ottawa, Ontario
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Dear Ms. Dupont:

The comments contained in this letter constitute the response of Novo Nordisk to the March 2005 Notice and Comment document "Price Increases for Patented Medicines: Discussion Paper".

Although the PMPRB make a number of arguments supporting changes to the CPI Guidelines, Novo Nordisk can find no persuasive evidence a change is necessary.

The PMPRB document presents a series of leading questions and 3 frameworks within which to respond to these questions. In addition to the status quo, the two alternative frameworks presented by the Board both include pre-approval of prices. The concept of pre-approval is inconsistent with the fundamental principle of "price review" upon which the "Patented Medicine Prices Review Board" was founded. The prior-approval of price increases is contrary to both the intent and wording of Sections 83 (1) of the Patent Act. Section 83 (1) stipulate "Where the Board finds that a patentee of an invention... is selling the medicine in any market in Canada at a price that, in the Board's opinion is excessive, the Board may, **by order**, direct the patentee to cause the maximum price at which the patentee is selling the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order". Contemplating Guidelines, which are inconsistent with the Patent Act, is inappropriate.

Under the current PMPRB regulatory framework, the Guidelines are not binding on either the patentee or the Board. As a result, a patentee is permitted to sell a product at any price, subject to "review" by PMPRB at regular intervals. Implementation of a pre-approval system is additional but unnecessary bureaucratic burden that also precludes any price change without input from the Board. This introduces inappropriate uncertainty and potential delay into the management of the Canadian market with potential negative consequences for the patients.

The discussion paper repeats the concern over "price stability". The document implies that falling or constant prices constitute price stability. Novo Nordisk would challenge this concept. Modest price increases certainly constitute price stability if they are not out of line with generally rising price in the same order of magnitude.

Novo Nordisk would also contest the implication that rising drug prices are contrary to the public interest. As Parliament recognized in 1987, drug availability and research leading to new products is at least as an important public policy objective as is pricing. The Discussion Paper in fact makes reference to the need to have medications available to Canadians. It is our greatest hope that the PMPRB understands that a system which advocates generic price

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levels and virtually forbids modest price increases will certainly not be conducive to introduction of innovative medicines.

The discussion paper refers to concerns about the possibility of drug shortage in Canada and price hikes of Canadian price to the level of the US. However, it is not clear what relevance this part of the discussion paper has to the issue of controlling and further lowering Canadian prices relative to those in the US. Unduly constraining Canadian prices will do nothing to remove the threat of drug shortages.

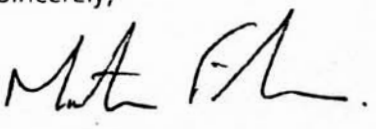
The Board has emphasized international price comparisons in the Discussion paper as a means of ensuring that Canadian prices are not excessive. Although, Novo Nordisk recognizes that international prices have a role to play in this determination, consistent with the Guidelines, these must be considered in context and not in isolation. As in other parts of the Discussion Paper, the evidence offered relative to international price comparisons explains only a small part of the issue. Comparing international prices is difficult at best. Comparing the role and rationale of policy is virtually impossible without a major dissertation on the full system under comparison. The UK has, for example, launched a major program of spending more on pharmaceuticals that moved away from control. There are efforts to improve prescribing and making more use of the latest drugs.

The outcome of international maximum price comparisons, international median price comparisons, and the comparison of annual price fluctuation all are affected by a number of non-price factors. Inflation is not the only factor affecting price fluctuation. Purchasing power, exchange rates, foreign policy decisions, and domestic policy are other factors and the Board must be cautious not to put undue emphasis on over-simplified international comparisons.

Taking into consideration the significance of the concerns noted by the Board, Novo Nordisk, nonetheless, believe that there is no reason for the PMPRB to stop allowing for automatic price increases. It is clear that drug spending and the likelihood of major price hikes by pharmaceutical drugs do not pose a major concern within the framework of the current Guidelines.

Novo Nordisk believes that the current Guidelines are overly restrictive and impose an inappropriate amount of price control, resulting in many cases, in Canadian prices that are unacceptably low. Adding to the current burden, to further restrict pricing will certainly result in undesirable effects on the health care system and Canadians which cannot be quantified by a simple cost equation. It is disappointing that, as provincial formularies realise that price freezes are not sustainable in the long term and are not in the best interest of constituents, the Federal government is considering instituting such policies at another level.

Sincerely,



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