Novo Nordisk Canada Inc.
2680 Skymark Avenue
3rd Floor
Mississauga, Ontario
L4W 5L6

(905) 629-4222
1-800-465-4334 (All Canada)
Telefax: (905) 629-8662

By Fax 613-952-7626

August 24, 2006

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

Dear Ms. Dupont:

Novo Nordisk Canada Inc. welcomes the opportunity to comment on the Discussion Guide for the Consultations on the Board's Excessive Price Guidelines. Novo Nordisk is pleased to provide our comments from a strategic top level perspective and in response to the three key issues the Board has identified. In addition, we look forward to a future opportunity to provide more feedback on the specific questions once the scope of change is clearly defined.

According to the Discussion Guide, the PMPRB mandate is to "protect consumers and contribute to Canadian health care by ensuring that prices charged in Canada by manufacturers for patented medicines are not excessive". However, according to the Patent Act, the Board has the mandate to review prices and to report on R&D expenditures and price trends. There is no mention of consumer protection or a role in health care. In fact the intention of the changes to the Patent Act in 1987 and in 1991 is to restore patent protection, encourage pharmaceutical R&D and to ensure Canadians have access to new medicines. Since the Patented Medicine Prices Review Board was a product of those changes, the mandate is generally protective and not one of a control agency and one that must give more weight to respective patent rights and encouraging R&D.

The Patented Medicine Prices Review Board was not intended to ensure prices of patented medicines are the lowest in the world. In fact the wording of the mandate restricts the Board's role to ensuring that prices are not "excessive". Novo Nordisk is of the position that the trend toward forcing prices down ever lower is not consistent with the original mandate of the Board and Parliament has not altered that original mandate.

The current PMPRB Guidelines are already very restrictive and do not adequately recognize the innovative nature of new drug products with additional therapeutic benefits. By forcing innovative products to price at the level of the older lower priced products, which are sometimes several decades old with lower development costs, the unintended consequence may be reduced investment in Canada. Regulatory and economic return constraints will often dictate most (bio-) pharmaceutic companies to seek to invest in countries with a more favourable operating climate. This will ultimately lead to fewer new products launched and less therapeutic options for Canadians.

Indeed, the latest PMPRB Annual Report indicates that R&D in Canada is dropping. It is interesting to note that this reduction coincides with increasing price control on the part of the PMPRB and payers with more restrictive Guidelines over the past decade.

The continued pressure on patented medicine prices not only restricts pharmaceutical patentees of the rights enjoyed by patentees of other technologies, it runs the substantial risk of depriving Canadians of the newest medicines. The Board no doubt recognizes that companies cannot have prices which are vastly different or lower than other developed countries. In order to remain consistent with its mandate, the PMPRB should ensure that restricting unnecessarily prices in Canada would not lead to fewer new innovative products being available to Canadians.

The Board has also identified 3 key issues and requested comments. Novo Nordisk's feedback is indicated below.

1. Is the current approach to the categorization of new patented medicines appropriate?

The categorization process appears to be a mechanism by which the Board recognizes innovation within the pharmaceutical industry. Novo Nordisk believes that the current Guidelines are inappropriately restrictive. It would appear, based on the data in the 2005 Annual Report, from 2003 to 2005, only two of the 59 new active substances have been classed as category 2. This is true despite the fact that Board Staff have failed to identify appropriate comparators for several of those agents that did not qualify for category 2.

Clearly, the criteria for category 2 fail to recognize much of the innovation that is taking place. When a classification system which is devised to segment products into multiple levels includes 97% of the products in question into a single class, the system is not working. The point of the classification system is to allow Board Staff to identify the appropriate price test for a particular new entry. Given that virtually all new chemicals are reviewed in a single class, this system is not distinguishing products at the category level. However, in many instances, including virtually all of the recent innovative diabetes products, have been reviewed using the category 2 price test, in recognition of the innovation and advance in therapy offered by these products despite the fact that they were not considered to qualify as category 2 drugs. From this perspective, the current categorization system appears to provide very limited value to the price review process.

2. Is the current approach used to review the introductory prices of new patented medicines appropriate?

The second issue addressed in the discussion guide relates to the application of price tests. This discussion can commence where the previous one ended. The purpose of the categorization system is no doubt to recognize innovation and provide a reward incentive to continue to bring innovative new products to Canada. Under the current system, the reward laid out to encourage the rapid introduction of innovative new products in Canada is to allow these products to price at the level of the international median, in other words, to price lower than many of the other countries. In fact, under the Guidelines, category 2 products that are introduced in Canada ahead of many of the countries in the PMPRB basket, can be forced to reduce their price, should some of the late entry countries reduce the international median. The implication is that there is absolutely no incentive to lead global development and bring an innovative product to the Canadian market in a timely fashion and in fact, if a company does, the price may be subsequently rolled back.

The data presented by the PMPRB in the Discussion Guide further demonstrate the failure of the current system to reward innovation. These data indicate that 65% of new drugs would not have achieved a premium by being classed as category 2 drugs. This conclusion clearly demonstrates that an alternative, less restrictive price test is required in order to provide the appropriate level of reward for innovation in the Canadian drug price landscape.

Section 85.1 of the Patent Act refers to the factors the Board should consider in determining whether a medicine is or has been sold at an excessive price in Canada. It is clear that the translation of those factors into Guidelines are restricting Canadian prices. For instance, Section 85.1 (d) of the Act states, "changes in the Consumer Price Index". In the Guidelines, this was translated into the CPI-adjustment methodology. This methodology restricts any change in the average transaction price (ATP) for one year and impacts this price in future years. Often, the restriction is beyond what is indicated in the Act as to consider CPI. Competing on the price

becomes discouraged when a price increase to the level of a previously allowed price cannot be possible.

As indicated in the 2005 PMPRB Annual Report, the ratio of Canadian prices to international median has been dropped to 0.92; Canadian prices are 8% below the international median.

3. Should the Board's Guidelines address the direction in the Patent Act to consider "any market"?

The Board was designed to ensure that within the context of a state supported monopoly created by a patent, prices were not excessive. However, in many cases, despite the presence of patent protection of one description or another, a monopoly does not exist. This may be true because multiple interchangeable products are available or in fact multiple copies of the same entity co-exist on the market. In the presence of such competition, it is non-productive for the Board to interfere with competitive forces by restricting competitive bidding, volume discounts or other programs which may result in price fluctuation. Patentees must be allowed the flexibility to operate their business without unnecessary intervention from government.

Furthermore, the Canadian pharmaceutical purchasing landscape, although it once consisted of virtually uniform pricing, is becoming increasingly segmented. Evaluating the causes and impact of this fragmentation is outside the scope of the current document. Novo Nordisk believes that it remains appropriate for the Board to consider an ATP at the national level. Different markets are dictating different levels of pricing restriction on companies. The introduction of Bill 102 in Ontario and Bill 130 in Quebec are setting market dynamics. PMPRB must not penalize patentees for changes imposed by other entities such as the F/P/T governments. The Board should not make any attempt to ensure that all prices are forced to the lowest common denominator.

As PMPRB and provincial governments introduce increasingly stringent price restrictions that are also at times conflicting, this creates confusion in the market place as to the agency that has true jurisdiction to ensure prices are not excessive. More recently, the Common Drug Review has also commented on whether product prices are excessive or justified, which would be deemed beyond its scope or mandate. Clearly, this blurred line requires further consultation with stakeholders including the pharmaceutical industry to better define price setting versus access and respective responsibilities.

Overall, we appreciate the opportunity to provide comments during the current consultation. The Board is to be commended for initiating a review of the current Guidelines and for revisiting the policies which are currently restricting pricing in Canada to an ever greater extent. It is time to consider alternative regulatory opportunities that would recognize and reward innovative products coming to market, ensure that prices are not excessive – instead of aiming for low pricing on a worldwide scale. We believe improved pricing policies could benefit all Canadians.

We would be pleased to discuss this further with you and look forward to providing further input as this evolves.

Sincerely,

Vince Lamanna
President

NOVO NORDISK CANADA