WYETH'S RESPONSE TO THE PATENTED MEDICINE PRICES REVIEW BOARD DISCUSSION PAPER "Options for Possible Changes to the *Patented Medicines Regulations, 1994 and the Excessive Price Guidelines"* DATED JANUARY 31, 2008

[A] Introduction

These are Wyeth's submissions responsive to the invitation of the Patented Medicine Prices Review Board ("PMPRB") concerning its discussion paper "Options for Possible Changes to the *Patented Medicines Regulations, 1994 and the Excessive Price Guidelines"* dated January 31, 2008.

Since the beginning of a consultation process in 2006 concerning the *Excessive Price Guidelines*, Wyeth has made several written submissions as well as had representation at the Bilateral Meeting held in Toronto on September 12, 2007. In addition, Wyeth has supported, and continues to support, the positions taken by Canada's Research-based Pharmaceutical Companies (Rx&D).

In Wyeth's view, the discussion paper reflects an inappropriate discounting of the concerns of the innovative pharmaceutical industry which have been repeated during the consultation process. The maximum impact of any amendments implemented by the PMPRB is felt by the innovative industry. Innovative industry is *the key stakeholder* in the excessive pricing regime of the *Patent Act*. Without innovation by the research-based industry, there are no patents and no new products. Without patents and products, the public interest is devastated and the PMPRB has no jurisdiction and no subject matter to regulate. As the PMPRB has so often repeated, it regulates factory gate prices within the limitations of its jurisdiction. It does not regulate consumer pricing, retail pricing or wholesale pricing.

Wyeth is concerned about the short turnaround time to submit a response to the discussion paper. There are many complex, interrelated issues or proposals included or advanced in the discussion paper, and a March 3, 2008 deadline does not allow adequate time to undertake due diligence in the formulation of a comprehensive response. While the PMPRB intimates that this latest document is building on prior consultations, many key issues raised during those earlier consultations remain unresolved and new issues have been raised adding yet another layer of complexity, while others are the subject of recently constituted working group assessments for which final reports have not been prepared or released. The fact that these discussions have been ongoing for almost two years with many of the issues remaining under discussion, attests to their complexity. It is not acceptable to move forward with the implementation of many of the proposed changes, especially as they relate to the "any market" and "re-setting the MNE price" issues, without the benefit of the additional information to be forthcoming from the working group activities. Wyeth urges the PMPRB to await the reports of working groups and thereupon allot additional time to undertake further discussions on these important issues, before implementing changes that could have a significant negative impact on many stakeholder groups, including a negative impact that may be unforeseen by the PMPRB.

[B] Principles which Inform Wyeth's Submissions

1. The jurisdiction of the PMPRB is limited to regulating a maximum non-excessive price for a given patented product.

2. The PMPRB does not have a mandate to ensure a low price, or a reasonable price, or even a high price. Parliament chose the word "excessive" very carefully.

3. The PMPRB does not have jurisdiction to control price fluctuations below the maximum non-excessive price. The reference to consumer price index as a factor (in paragraph 85(1)(d) of the *Patent Act*) is merely a permission to increase (or decrease) the maximum non-excessive ceiling price previously determined to account for inflation (or deflation).

4. As noted above, the PMPRB regulates ex-factory prices. It does not regulate prices at the wholesale or retail level. It does not control the price to the consumer. In a pricing matrix that is enormously complex and involves parties and inputs over which the PMPRB has no jurisdiction or control, attempts by the PMPRB to regulate ex-factory pricing taking into account those parties and inputs negatively distort the marketplace.

[C] "In any Market"

With respect to reviewing prices "in any market", the PMPRB has indicated its agreement with stakeholders that such reviews should be on a case-by-case basis. Yet, the proposals put forth in this latest discussion paper which would "trigger" a price review "in any market" suggest such reviews will become the norm *versus* the exception. Wyeth continues its contention, expressed in prior submissions, that the PMPRB *has not presented* a convincing policy rationale to support the need to make this change. Wyeth is also of the opinion that, if implemented, the proposed changes would add significant additional reporting and monitoring burden on patentees (not to mention the increased burden on the PMPRB), without creating any material benefit for any other stakeholder, including the Canadian consumer. This is contrary to the objectives of the Smart Regulation initiative, which aim to make regulation a source of competitive advantage not a counterproductive burden.

As a final thought on this issue, the PMPRB sees its mandate as being to protect the interests of Canadian consumers by ensuring prices of patented medicines are not excessive; yet, should it move forward with implementing the proposals which would trigger price reviews "in any market", such actions may be to the detriment of Canadian consumers, as manufacturers of patented medicines may be discouraged from offering price discounts or compassionate drug programs. It is Wyeth's opinion that the existing methodology of determining ATP at an aggregate level (all classes of customers in all market segments) is working, and that the PMPRB is already effectively safeguarding any public interest against excessively ex-factory priced patented medicines.

The discussion paper omits reference to the fact that the 25% variance over MNE in some markets cited by the PMPRB occurred in less than 5% of all regulated products. The PMPRB always has the jurisdiction to inquire into "any market" in the context of a public hearing; to introduce an enormous regulatory burden into the reporting and compliance equation is, in Wyeth's view, unwarranted and detrimental.

[D] Re-setting the MNE Price

Wyeth continues to be of the opinion that the PMPRB still has not produced evidence to support the necessity for the changes proposed in the discussion paper. Wyeth believes that the existing criteria for so-called "re-benching" the MNE are adequate, and that the PMPRB's proposed changes would add significant and inherent price uncertainty for the patentee. This is especially the case with reference to extending the allowable time during which a review could be initiated, as well as allowing the PMPRB to initiate a review based upon scientific information or evidence not available at the time of launch. In this latter instance, it would appear that the PMPRB is moving away from its role of monitoring excessive pricing and into the realm of determining value for money, which is the purview of other agencies, such as CDR and provincial review bodies.

Wyeth is also concerned that the proposed changes to "trigger" a price review for the purpose of re-setting the MNE price may be a further discouragement to manufacturers from supplying drugs under the Special Access Programme.

It is Wyeth's position that, if any alteration is to be made to the criteria for "re-benching", the alteration should be that such re-benching is restricted to requests by a patentee to increase the MNE on a given product, due to changed market circumstances.

[E] "Other Issues": Categories of Medicines/International TCC/Price Tests/Costs of Making and Marketing

Each of the above noted issues are very much interrelated, and cannot be effectively reviewed and assessed in isolation; any decision made with respect to one of the issues will have, in some instances, significant ripple effect on other issues. While Wyeth applauds the PMPRB's initiative of establishing multi-stakeholder working groups to address these issues, setting mandates for each working group which restricts their focus to the single issue assigned will not encourage the kind of integrated assessment that is necessary. Wyeth urges the PMPRB to reconsider this review process by having these working groups work together to address these issues.

It should also be pointed out that any changes made in respect of the first three issues, as a result of the recommendations of the three working groups, will very likely have a significant impact on the "in any market" and "re-setting the MNE price" proposals.

Until the results of the various working groups constituted by the PMPRB are made public, it is impractical to offer complete and informed commentary on these issues at this time.

[F] Options to Address the *Leo Pharma*/Dovobet Federal Court of Canada Decision

Preliminary Comments

Wyeth observes that, among the options presented by the PMPRB, the option of maintaining the policy set out in the PMPRB's April 2000 newsletter does not appear. It is presumed that this absence stems from a view on the part of the PMPRB that it is prohibited from doing so by virtue of the *Leo Pharma* decision.

Apart from the fact that this could easily be remedied by an amendment to the *Patented Medicines Regulations, 1994* providing that any enumerated reduction may or may not be taken into account in calculating the average transaction price ("ATP") at the election of the patentee, Wyeth's position continues to be that the PMPRB's broad interpretation of the *Leo Pharma* decision is incorrect.

The PMPRB's interpretation of *Leo Pharma* is that the accepted methodology for calculating the Average Transaction Price (ATP), as set out in the April 2000 newsletter, can no longer be employed, and that *all deductions* must be included in the determination of the ATP.

It is Wyeth's opinion that the *Leo Pharma* decision *does not* preclude the continued use of the April 2000 methodology. The Federal Court in *Leo Pharma* was addressing the primary point of whether the PMPRB had jurisdiction to determine whether a particular compassionate program was "genuine" and whether Leo Pharma, *having chosen to elect to deduct the value of the goods*, could do so. The Federal Court held that the PMPRB did not have such jurisdiction. The PMPRB has broadened this narrow finding, containing as it does permissive language supporting the April 2000 methodology, to encompass situations such as where a patentee may choose not to deduct a particular reduction, situations that were never before the Federal Court or envisaged in its decision.

Wyeth is concerned that the PMPRB's narrow interpretation could have a detrimental impact on Canadian consumers, in the event that manufacturers no longer find that engaging in compassionate drug programs or other price-reduction programs is a viable option due to pricing implications. The proper interpretation of *Leo Pharma* avoids consideration of the complicated options set out on pages 11 to 15 of the discussion paper.

Wyeth strongly opposes the proposal that the PMPRB be given discretion to determine whether a given reduction in price is "genuine". This would introduce a huge element of uncertainty in compliance, based on a factor (intention of the patentee) the consideration of which was determined by the Federal Court to be irrelevant to the intention of Parliament.

Wyeth reaffirms its position, stated in earlier submissions, that public and third party drug plan payers are not a class of customer, and any payments to them with respect to listing or cost-sharing agreements do not, and should not, fall within the *Patented Medicines Regulations* or otherwise under the jurisdiction of the PMPRB. Regulation in this area, even if it were appropriate within the statutory framework of the *Patent Act*, will negatively impact on such programs or agreements.

Possible Changes to the CPI-Adjustment Methodology for Determining the MNE Price

Wyeth supports the PMPRB's initiative to review the CPI methodology currently used to determine the MNE price. Wyeth is also encouraged by the PMPRB's acknowledgement that a price deemed non-excessive in a prior reporting period should, intuitively, not be considered excessive in a subsequent period.

As an *initial starting point for discussions*, the options proposed by the PMPRB in the discussion paper, especially option (ii), provide a basic framework upon which a new methodology can be built. While option (ii) provides a methodology that would help to address some of the negative

impact of the current CPI methodology, it does not address the more fundamental flaw in current CPI-adjustment methodology of basing the MNE on the ATP of the prior period(s). In addition, this option (ii) does not build in a CPI-increase mechanism to increase the original MNE, and only applies if the ATP is reduced in a given year.

As noted, the current CPI-adjustment methodology is fundamentally flawed. It ignores that the PMPRB has jurisdiction only to set a maximum non-excessive price ("MNE") with an allowance to have that MNE adjusted by increases (or decreases) in CPI. That MNE cannot logically change because a patentee chooses to benefit the public by reducing its price in a given year. The current methodology acts as a punishment for exactly the kind of program or policy that the Government sought to encourage by the permissive reduction provisions of the *Patented Medicines Regulations, 1994*. The PMPRB itself has stated and restated that its policy is to encourage (not regulate) lower prices. The CPI-adjustment methodology achieves exactly the opposite result. As a cornerstone for future discussions on this issue, Wyeth advocates serious consideration be given to developing a new CPI-adjustment methodology that would effectively "de-link" ATP and MNE. Such a methodology would result in subsequent MNE prices based upon current MNE prices adjusted by the CPI rate.

Wyeth recognizes that, as noted in the discussion paper, a possible result of changing the CPI-adjustment methodology is that a significant single year price increase could be initiated; i.e., a price increase in excess of the CPI rate which would still result in the ATP being below the MNE. While Wyeth would encourage a thorough discussion of possible alternatives to address these situations, we would also remind the PMPRB that their mandate is to ensure prices of patented medicines are not excessive, not to control any price increase or discourage any price decrease in these drugs. Wyeth also notes that isolated examples of dramatic price increases in industry are rare exceptions and do not warrant complex and flawed regulation.

Wyeth appreciates the opportunity to continue to be engaged in these discussions examining options for possible changes to the *Patented Medicines Regulations, 1994*, as well as review of the *Excessive Price Guidelines*. Wyeth encourages the PMPRB to continue full discussions with all stakeholders to ensure that any changes implemented are rational, fair and equitable and achieve the policy objectives of the excessive pricing regime.