February 29, 2008

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

Re: Response to Discussion Paper Released January 31, 2008

Dear Ms. Dupont:

I am writing to you regarding PMPRB's Discussion Paper released on January 31, 2008. As the matters addressed in the Discussion Paper are of great importance to stakeholders, particularly the biotechnology industry, AMGEN Canada Inc. ("AMGEN") appreciates the opportunity to provide comment on these matters and looks forward to further consultation. Each issue will be addressed individually:

"Any" Market Price Review

The Discussion Paper proposes several options under which a price review in any market in Canada may be undertaken. AMGEN is concerned with these proposals as they may introduce a significant monitoring and reporting regulatory burden for industry while generating little benefit with respect to the PMPRB fulfilling its mandate. The Discussion Paper states that prices of some drugs are 25% above the MNE in some markets according to the analysis presented in the PMPRB's Discussion Guide released in May 2006. When looking at the proportion of drugs that are priced 25% above the MNE, these are clearly exceptions, as the vast majority of drugs are priced within 5% of the MNE within each market. This indicates there is not an issue with excessive pricing under the PMPRB's current policies when looking at "any market". As noted above, any deviation from the current policy would result in an increased regulatory burden for industry patentees and PMPRB staff, without helping the PMPRB to fulfill its mandate. AMGEN's position is that the current policy of the PMPRB is sufficient with respect to reviewing prices in "any market", as there does not appear to be excessive pricing when prices are reviewed in this manner.

AMGEN Canada Inc., 6775 Financial Drive, Ste. 100, Mississauga, Ont. L5N 0A4
Telephone: (905) 285-3000...Fax: 1-866-912-6436

Re-Setting of the MNE

Section III.A.ii of the Discussion Paper outlines scenarios to consider for re-setting the MNE. As with price reviews in "any market", AMGEN has concerns with the proposed changes to the Guidelines, in that the rationale for one of the proposals expands the PMPRB's jurisdiction beyond its stated mandate. This occurs specifically in the proposal to re-set the MNE based upon new scientific evidence. The Discussion Paper states,

> "additional clinical trials and/or post market surveillance may provide new evidence to better determine the relative category of therapeutic improvement of the medicine. Re-setting the MNE price would recognize the real **value** of the medicine."(emphasis added).

AMGEN notes that the mandate of the PMPRB is not to determine the value of medicines. According the PMPRB website, its mandate is as follows:

> "To protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not **excessive**." (emphasis added).

There is no mention in its mandate that the PMPRB's role is to determine the value of medicines. Determining a medicine's value is the jurisdiction of expert bodies such as the Canadian Agency for Drugs and Technologies in Health ("CADTH"), the Common Drug Review (CDR), Joint Oncology Drug Review (JODR) and payers, both public and private. These entities are well equipped to deal with changes in the value of any medicine based on emerging scientific evidence through their own methodologies. The proposed change would clearly expand the jurisdiction of the PMPRB and create an overlap with the responsibility of CADTH, CDR, JODR, and payers. Therefore, this change would give rise to redundancies and is unnecessary, as it is beyond the PMPRB's mandate.

In addition, implementation of such a Guideline change would introduce great uncertainty into the commercial environment if the MNE price re-setting can be initiated by the PMPRB or a third party. Any mechanism for re-setting the MNE must be triggered only by the request of a patentee.

Finally, it is unclear what would constitute the appropriate level of evidence, as well as changes in clinical efficacy/safety required to necessitate re-setting the MNE of any particular medicine.

AMGEN recommends that the Board retain its current case-by-case approach to re-setting the MNE.

Regulatory Options to Address the Federal Court of Canada (FCC) Decision

The Discussion Paper outlines several options to address the Federal Court of Canada decision in LEO Pharma/Dovobet, each will be addressed individually.

Respect PMPRB's Legal Interpretation of FCC decision

AMGEN does not believe this option is workable for patentees, and may be detrimental to patients, publicly funded hospitals, and drug plans for several reasons:

1. *Inclusion of all benefits will lead to fluctuations in ATPs and may lead to non-compliance with the MNE due to factors out of a patentee's control.*

   A requirement to include the value of the programs that patentees provide that benefit publicly funded institutions and patients in the calculation of ATPs will produce arbitrary and artificial fluctuations in ATPs, which will clearly put compliance at risk. For example, if a tender to a hospital is lost to a competitor it may result in a higher ATP due to shift in customer mix, and may lead to non-compliance. These naturally occurring market driven forces are out of any patentee's control. Being held accountable for "non-compliance" due to the circumstances described defies reason and is a significant risk.

2. *Inclusion of all benefits in the ATP in any structured manner is not feasible due to the stringent reporting requirements of the PMPRB.*

   ATPs are calculated on a DIN level basis, and patentees are required to use the accrual method of accounting in their reporting. The reporting requirements of the PMPRB clearly do not contemplate capturing the various contractual arrangements that patentees may enter into with hospitals, group purchasing organizations, or provincial drug plans. These contracts may provide for rebates, discounts or other benefits for customers but may not be traceable at the DIN level. In such circumstances an ATP cannot be calculated taking into consideration these benefits. In addition, the realization of a rebate or similar benefit may not be known until weeks or months after the end of a reporting period, and in some cases there may not be an accurate way to account for these benefits. If the filing is based on an accrued benefit, an adjustment will need to be made once the actual value of the benefit is realized. This makes any initial assessment of an ATP being in compliance or not irrelevant until all the information is known. In these cases a patentee will not be in a position to report the data until it is known whether the conditions to trigger a rebate or benefit to a customer was eventually realized. Consequently, the reporting timelines can not be adhered to in any structured manner.

3. *Inclusion of benefits will discourage patentees from offering incentives or agreements benefiting publicly funded hospitals, drug plans and patients.*

   The requirement to include in ATP computations, the impact of programs that represent benefit to publicly-funded drug plans and hospitals, would act as a strong disincentive to continue offering these programs. Such a change in reporting requirements would introduce an unmanageable level of complexity into the conduct of business. Another concern is that, by further complicating the commercial landscape with these additional measures, the PMPRB is introducing distortions into

the market dynamics that have historically fostered open competition and clearly benefited the customer. At best this will reduce the level of healthy open competition and motivate participants to find less transparent modes of competition. At worst this will all but eliminate competition and dramatically reduce the benefits currently realized within the healthcare system.

This option, if considered in-conjunction with the an option to "de-link" the ATP from the calculation of the MNE may be acceptable, although further consultation will be required to elucidate how this approach could be implemented.

Exclude Expenditure Limitation Agreements with Third-Party Payers

We believe there are good grounds to dispute the PMPRB's authority to obtain information on any payments to "downstream" payers and require inclusion of such amounts in the calculation of ATP, based on the current Regulations, and given that the entire scheme of reporting is based on a "factory gate" system. However, for purposes of clarification, explicitly excluding such agreements from being reported and included in the calculation of ATP would relieve the uncertainty which could discourage patentees from offering such incentives or agreements. Therefore, AMGEN supports the option of excluding benefits to third-party payers from reporting requirements and from the calculation of ATP.

Exclusion of Free Goods from ATP Calculation

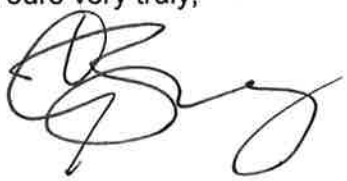
AMGEN is in support of this Regulation change; however, if free goods are excluded from the calculation of the ATP going forward, then a transition period must be implemented to re-set the MNE of medicines in which free goods were included in the ATP to ensure that patentees are not penalized for reporting practices that were compliant prior to the regulatory change. A better approach would be to maintain the PMPRB's current policy as articulated in its April 2000 newsletter which could be supplemented, if deemed necessary in light of the FCC decision, by a regulatory change which permits patentees to include or exclude free goods (or any benefit) at its option.

Changes to the CPI-Adjustment Methodology for Determining MNE Price

Two options were presented in the Discussion Paper to "de-link" the average price from the MNE price. Both are a positive step forward compared to the current CPI-adjustment methodology. However, AMGEN would support a true "de-linking" of the Average Price and MNE price. "De-linking" the Average Price and MNE price refers to a change in the CPI-Adjustment Methodology whereby MNE prices in years following introduction of a medicine would be based on the MNE price in a previous year, adjusted for changes in the Consumer Price Index, rather than the net Average Price, as is the case today. A price deemed non-excessive in a previous reporting period should, intuitively, not be considered excessive in a subsequent period. The de-linking methodology would continue to allow PMPRB to fulfill its mandate, while reducing the degree of uncertainty surrounding price reviews and compliance.

In conclusion, AMGEN believes many of the changes proposed will not be in the public interest, and go beyond the PMPRB's stated mandate to ensure the prices of prescription medicines are not excessive. I look forward to further consultation regarding these issues. If you have any questions regarding the responses above, please do not hesitate to contact me.

Yours very truly,



Geoff Sprang
Director, Corporate Affairs
AMGEN Canada Inc.