August 23, 2006

Ms. Sylvie Dupont
Patented Medicine Prices Review Board
Secretary of the Board
Box L40
Standard Life Centre
333 Laurier Avenue West
Ottawa, ON K1P 1C1

Dear Ms. Dupont:

Amgen Canada Inc. offers the following comments with respect to the Discussion Guide for the consultation on the Board's excessive price guidelines.

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

Question 1.1: Are the new patented drug categories and their definitions appropriate?

Amgen Canada is of the view that there is no need for different categories of drugs. A single definition of excessive pricing should apply to all new patented medicines; therefore, the current categories for new patented medicines and their definitions are inappropriate.

In addition, in the event the current categories are maintained, Amgen is of the view that they do not recognize improvements offered by new, state-of-the-art medicines, and in particular, biologics. Over the last several years, many biologic therapies have been introduced in Canada that represent improvements over previously existing therapies ranging from improvements in dosing regimens, to improving patient outcomes when used in conjunction with existing therapies (e.g., Avastin®)[1]. The innovation that these biologics represent has not been recognized under the current system of categorization.

If a system of classification for new medicines is maintained, it needs to recognize improvements in therapy such as those noted in the examples above. Ultimately, a clearly articulated definition of excessive pricing should be applied to all patented medicines.

[1] Hurwitz et al., Bevacizumab plus Irinotecan, Fluorouracil, and Leucovorin for Metastatic Colorectal Cancer. NEJM 2004; 350:2336-2342.

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Question 1.2: Is it important to distinguish a medicine that offers "moderate therapeutic improvement" from a medicine that provides "little or no therapeutic improvement?" If yes, why is it important? If not, why not?

As mentioned above, it is our view that a clearly articulated definition of excessive pricing should be applied to all new patented medicines whether the medicine is considered of "little therapeutic improvement" or a "moderate therapeutic improvement". A system should be adopted that reflects a standard of excessive pricing so as to equate it with an abuse of patent rights, as the PMPRB's function was intended by Parliament, which created the Board in 1987.

In the event that the current regime is maintained, it is unlikely that adding further categories will assist in recognizing moderate improvements. Nevertheless it is important to recognize these improvements, since it is through moderate improvements over time that substantial innovation often occurs. Too many products are relegated by the Board to so-called "me-too" status, compared using inappropriate comparators—sometimes old and even off-patent medicines being used as the basis upon which to conduct a therapeutic class comparison test. Greater rewards for "moderate" improvement must be made through recognition in the Guidelines, by permitting these products to be priced at the international median.

<u>Issue 2.</u> Is the current approach used to review the introductory prices of new patented medicines appropriate?

Question 2.1: Are the price tests currently used to review the prices of new medicines in the various categories appropriate for that category? Why? Why not? If not, how could these tests be amended to improve their appropriateness?

The current price tests are not appropriate. There is no need for new medicine categories. A single standard meaning to "excessive" can be applied to all new patented medicines. Amgen believes that the current system of categories and price tests goes well beyond Parliament's original intent with respect to the characterization of excessive prices. An appropriate price test that takes into consideration all other countries and the CPI adjusted Canadian prices of all other drugs in the therapeutic class, subject to other considerations, such as whether Canada is the first to introduce a product, is far more reasonable than current practices under the Guidelines and in Amgen's view, is consistent with current law.

It is important to note that the standard of "excessive" as it is used in the Act was meant to represent a price limit to ensure patent rights are not abused—it does not, under the statute, equate with a price that merely exceeds the price established by the Guidelines. The power of competitive pressures on the price of patented medicines in Canada is, in our view, sufficient to ensure appropriate pricing in Canada. If more than one treatment option exists, the determination of price will be driven by competitive pressures more than by any regulatory framework. If a product truly is a so-called "me-too" product, the market will determine the price. In our view, there is no need to regulate these prices; if they really do not constitute a significant enough improvement so as to justify a higher price, the market will contain their prices.

Question 2.2: If you think that medicines that offer "moderate therapeutic improvement" should be distinguished from medicines that provide "little or no therapeutic improvement" what would the appropriate new price test be?

As noted in our response to question 2.1, the only price test that should apply (as a preliminary indicator of whether a price is excessive) is that a patented medicine would be presumed to be excessive if it exceeds the prices in all other countries and the CPI adjusted Canadian prices of all other drugs in the therapeutic class, subject to other considerations if the finding is resisted at a Board hearing.

In the event the current regime is maintained, there clearly needs to be more flexibility available in determining what constitutes an improvement over other products in the same therapeutic class. For example, there are many situations where older products are not appropriate "comparators". In such cases, the Guidelines should provide more flexibility to Board Staff to disregard older, off-patent or otherwise inappropriate comparators and to assess the price of the product in comparison to the international median, at minimum.

Question 2.3: For price review purposes, "comparable medicines" are medicines that are clinically equivalent. Do you have any suggestions as to principles or criteria that should be used in determining how to identify "comparable medicines" for the purpose of inclusion in the above price tests?

A comparable medicine should have an indication to treat the same condition as the primary indication of the new medicine in question. In the absence of an approved indication, the Board should look to actual clinical practice. If a drug is used extensively 'off-label' by physicians for a specific condition, then it is artificial in the extreme to 'disqualify' that drug as an appropriate comparator and completely ignore the reality of clinical practice.

Question 2.4: Under the current Guidelines, Board Staff compares the Canadian average transaction price of the new medicine to the prices of the same medicine sold in the seven countries listed in the Regulations. However, Section 85(1) of the Patent Act states that the Board should take into consideration "the prices of other comparable medicines in other countries". Should the Guidelines address this factor? If so, how could this factor be incorporated into the price tests for new medicines?

Amgen supports an application of subsection 85(1) of the Patent Act as required. The international price comparison is particularly important to any consideration of whether a price is or is not excessive. It is our view that the policy was enacted to ensure that Canada is not out of step with other countries. For example, if the Canadian price is higher than the range of international prices and the range of prices in the therapeutic class, but the Canadian ratio of the price of the new product to a key comparator whose price is compliant is in line with comparable international ratios, this is evidence under the current regime that the Canadian price is not excessive. This approach was taken by the Board in the *Humalog* and *Viread* cases to demonstrate that their respective prices were not considered excessive.

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

Question 3.1: Given the price variations by provinces/territories and class of customer illustrated in the previous figures, is it appropriate for the Board to only consider an ATP calculated based on the total revenues from the sales for all provinces/territories and all classes of customer? Why? Why not?

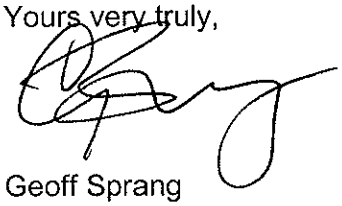
In the event that the current structure of the Guidelines remains, it would be appropriate for the Board to review ATP on an aggregate basis *only* given that the vast majority of DINs are currently below the MNE when the data is broken down by province (Figure 9 of the Discussion Guide), or by customer type (Figure 10 of the Discussion Guide). As a result compliance is not an issue. For the Board to consider the ATP for each province and class of customer would introduce tremendous delays and inefficiencies into the price review process and would yield only marginal benefit.

Question 3.2: If the current ATP calculation is not appropriate, should the Board review the prices to the different classes of customers and/or the different provinces and territories for all DINs? Or should this level of review be done on a case-by-base basis, where there is a significant variation in the prices charged?

As noted in the response to question 3.1, no change in the scope of the price review process is necessary due to the high level of compliance with the Guidelines when considering the province and customer class.

I look forward to further in-person consultations in the Fall. If you have any questions regarding the responses above, please do not hesitate to contact me.

Yours very truly,



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