Alain Boisvert
Vice President
Health Policy and
Market Access

Novartis Pharmaceuticals Canada Inc.
385 Bouchard Boulevard
Dorval QC Canada H9S 1A9

Tel 1 (514) 828-4511
Fax 1 (514) 631-0307

Internet: alain.boisvert@novartis.com

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

Re: Response to the PMPRB Discussion Guide for Consultations on the Board's Excessive Price Guidelines

Dear Ms. Dupont,

The PMPRB's Discussion Guide marks the beginning of an extensive consultation on the appropriateness of the Excessive Price Guidelines upon which the PMPRB bases its price reviews of new medicines. In addition to supporting the submission of Rx&D in this matter, Novartis welcomes this opportunity to provide its own opinions on specific issues raised in the Discussion Guide.

As an opening comment, we would like to note that for several years now the PMPRB has reported that the prices of patented medicines have been, on average, below the median of international prices. That is to say that over 50% of medicines are priced lower in Canada than in other countries. In addition, because the Guidelines establish a ceiling on the prices of all patented medicines, their prices in Canada cannot be the highest among PMPRB-referenced countries. These facts point to the overall effectiveness of the PMPRB's current Guidelines. There are, nevertheless, particular issues that in our opinion are not adequately dealt with by the PMPRB's present Guidelines and/or by the present interpretation of criteria related to those Guidelines. These are discussed in the following responses to the PMPRB's specific questions relating to its Guidelines.

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

Question 1: *Are the new patented drug categories and their definitions appropriate?*

There is an inherent flaw in the PMPRB's new medicine classification system. The system was developed to reflect the concept that medicines offering substantial benefit should be afforded a wider degree of pricing flexibility. However, in practice this is rarely the case because, while the published criteria for category 2 have not changed since they were first

developed, there has been a significant change in the interpretation of those criteria over the years. This shift has resulted in a failure to recognize the beneficial contributions of many new medicines developed in important therapeutic areas over the last several years. In addition, the current criteria do not include consideration of quality of life benefits and patient reported outcomes, both of which are increasingly reported as being important factors in treatment decisions. Advances in drug delivery technology and/or the development of new easier-to-use dosage forms aimed at increasing patient compliance and better management of progressive diseases, are another important area ignored by the current criteria because these are viewed as merely patient convenience. Finally, Health Canada has a system that considers priority review status for medicines deemed to address an unmet medical need yet this status is not reflected in the PMPRB's criteria for category 2.

For these reasons, we support a review approach that would eliminate the categorization of new medicines in favour of a standard price review process for all new medicines that places increased emphasis on international pricing.

Question 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?

Question 3: If the answer to question 2 is yes, on what basis would a new medicine that offers "moderate therapeutic improvement" be distinguished from a new medicine that provides "little or no therapeutic improvement"?

These questions clearly demonstrate the problem associated with labeling medicines based on interpretation of therapeutic merit and the reason for our favouring an approach that would eliminate this practice. What criteria will be used to define "moderate" and how will the interpretation of those criteria evolve over time? As discussed under Question 1, an increasing number of new medicines are falling into the gap created by the shift in interpretation of the category 2 criteria. Past experience with the shifting interpretation of the term "substantial" in relation to category 2 suggests that, over time, the interpretation of the term "moderate" will also evolve to the extent that the PMPRB will at some point need to seek input into criteria to define medicines that, in its opinion, do not quite meet the "moderate" label.

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

Question 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?

While the current practice of comparing the price of a new medicine to prices of existing therapies is adequate in some instances, there are circumstances where other indicators suggest it is not.

a) Several of the foreign jurisdictions referenced by the PMPRB have rigorous price approval mechanisms in place and cases where a Canadian price is consistent with international pricing should be reflected in the Guidelines as acceptance of non-excessive pricing. In our opinion, a price test that forces the Canadian price of a new medicine to a level that is lower than its international range is not appropriate. In addition, a medicine that is priced lower in Canada than in the PMPRB's reference countries cannot be considered excessively priced.

b) New medicines representing the first new therapy to be introduced in a therapeutic area in several years should not be forced to a price equal to much older therapies in that market. Research and development costs have increased exponentially over time and limiting the price of a new medicine to much older therapies does not reflect the present day expenditures required to bring that new medicine to market. Again, international pricing of the new medicine should be the ultimate marker for excessive pricing under the Guidelines.

c) Under the current price review methodology, the price of a new medicine can be considered excessive even though it is priced at a level equal to or lower than a comparable medicine's maximum non-excessive price as established by the PMPRB. In our opinion, by definition, if a price level is not excessive for a comparable medicine it cannot be deemed excessive for the new medicine.

d) In its latest NEWSletter (July 2006), the PMPRB published a clarification to its price review practice relating to the reissue of existing DINs to a subsequent patentee.

> In the Board staff's view, in a situation where a subsequent patentee can demonstrate, to Board Staff's satisfaction, that it was provided with access to the price and sales information of the previous patentee, it is appropriate to allow the application of the same CPI-adjustment methodology to which the original patentee would have been entitled. Board Staff will therefore apply the Guidelines in this manner for the subsequent patentee of a DIN where the subsequent patentee demonstrates it has access to the relevant historical price and sales information of the previous patentee.

There are similar circumstances in which this approach should also apply. A new DIN representing a new formulation of a medicine that is replacing an existing DIN of a comparable dosage form of the medicine sold by the same patentee should be afforded the same treatment under the Guidelines as a DIN being transferred to another patentee. If the Board staff considers it appropriate to allow a subsequent patentee the same methodology to which another patentee would have been entitled, it should also consider it appropriate to allow a replacement DIN the same methodology to which the original DIN would have been entitled. In our opinion, to do otherwise represents an inconsistent application of the Guidelines.

e) The PMPRB's international price guideline, which establishes a ceiling on the prices of all patented medicines in Canada, can create an onerous operational issue. Fluctuations in exchange rates can create situations where a medicine priced at a level that was not

previously considered excessive can over time be deemed excessive even though the Canadian price and the price in the critical comparator country have not changed. In our opinion, the expectation that companies can continuously adjust their average selling price in order to comply with what becomes a moving target under the Guidelines is unrealistic from a business operations perspective. In this regard, we note the recent VCU published in relation to Hextend in which the PMPRB accepted the concept of freezing a product's maximum non-excessive price until such time as the price in the critical country changed in real terms rather than require continuous adjustments to the Canadian price based on applicable exchange rates. In our opinion, this more realistic approach should be accepted as a general rule under the Guidelines rather than applied on an exception basis.

Question 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 discussed under Issue 1, we support a standard price review methodology for all new medicines rather than an approach that labels new medicines based on the Board's interpretation of their therapeutic merit.

Question 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?*

In our opinion, comparable medicines considered in the price review of new medicines should reflect the market in which a product is sold rather than a limited selection based solely on ATC classification. These would include medicines considered alternatives to the new medicine in clinical practice.

Question 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?*

In our opinion, the prices of comparable medicines in other countries have a role in the PMPRB's price review in cases where the price of a new medicine in Canada would, in the application of other price tests, otherwise be forced to a level that is inconsistent with the new medicine's prices in the reference countries. The approach used to consider the prices of comparable medicines in other countries could reflect the foreign price ratio approach already used by the PMPRB in a few previous cases.

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

Question 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?*

Question 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?*

The PMPRB's analysis of average transaction prices in relation to MNE levels by province and by class of customer provides compelling evidence of the appropriateness of the PMPRB's current practice of reviewing average transaction prices at the national level. In our opinion, given the results of this analysis, instituting a process that would require the review of average transaction prices of all patented medicines by province and/or by class of customer for the sake of a few cases represents a significant undertaking with little or no impact on current results. The PMPRB's current processes include the potential for a by-province or class of customer review in instances where it is deemed necessary. These include cases where the top-level analysis suggests that the average transaction price exceeds the Guidelines or where the PMPRB receives complaints relating to the price of a medicine. In our opinion, the PMPRB's current approach in this regard is adequate and appropriate.

In summary, it is our opinion that international pricing should be given increased consideration in cases where the application of other price tests would force a Canadian price to a level that is inconsistent with international levels. Just as the Guidelines consider a medicine's price excessive if it exceeds its highest international price, it should consider a medicine non-excessive if it is priced below the international price range. The system whereby new medicines are labeled based on an interpretation of therapeutic merit is subjective and unnecessary and should be eliminated in favour of a standard review process for all new medicines. The PMPRB's Guidelines should reflect a consistency from one medicine to another in terms of what is considered a maximum non-excessive price.

Sincerely,

Alain Boisvert