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April 27, 2009

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

Subject: Novartis Canada's Response to the PMPRB's Notice and Comment on the Draft Revised Excessive Price Guidelines

Dear Ms. Dupont:

We appreciate the opportunity to respond to the Patented Medicine Prices Review Board (PMPRB) Notice & Comment to its proposed draft revised Excessive Price Guidelines issued on March 26, 2009. Novartis Canada (Novartis) fully endorses the formal submission of Canada's Research-Based Pharmaceutical Companies (Rx&D) on the proposed draft Guidelines and also takes this opportunity to highlight a number of specific concerns with the recently released draft Guidelines.

The Board is to be commended for addressing several of the concerns raised by industry in the previous round of consultations. We recognize that there have been a number of positive developments from the previously released draft Guidelines. However, Novartis continues to have reservations with regard to some aspects of the proposed Guidelines.

Exclusion of Non-Patented Drugs

Novartis is concerned with the proposed PMPRB policy that states that "Board Staff may exclude from the price tests any drug product identified for comparison purposes, both patented and non-patented, if it has reason to believe it is being sold at an excessive price."[1] First, the draft Guidelines do not adequately explain what criteria the PMPRB will use to determine if a non-patented drug is excessive. Second, and more importantly, by proposing to determine the price status of non-patented drugs in the context of the Guidelines, this policy is inconsistent with the PMPRB's jurisdiction. It is also incongruent with the Board's July 2008 hearing decision in the matter of Adderall XR. In that ruling, the Board considered the price of Dexedrine and stated that the premise of excessive price is not applicable to a medicine to which no patent pertains. In fact, the Board found no justification to support

[1] http://www.pmprb-cepmb.gc.ca/cmfiles/Notice_and_Comment-Draft_Revised_Guidelines-Mar2609.pdf Accessed on April 20, 2009

excluding Dexedrine's highest domestic price in the price test. Thus, the policy being proposed is not only lacking in implementation details but is in direct conflict with a previous Board ruling and inconsistent with the PMPRB's jurisdiction. In our opinion, the Guidelines should not contemplate making a determination on the exclusion/inclusion of a non-patented comparator medicine in new medicine reviews on the basis of price.

"Any Market" Price Review

Novartis continues to be concerned by the PMPRB's decision to pursue "any market" reviews for all new medicines, and the expansion of the review to also include all provinces. This approach potentially adds significant regulatory burden on patentees without a clear rationale for doing so since, according the PMPRB "... in the majority of cases (i.e., between 74% and 89% of cases) the prices charged at the provincial or territorial level are in the range of plus or minus 5% of the MNE price."[2] We also believe that the method being proposed for the calculation of excess revenues in the case of an "any market" review has the potential to misrepresent the level of apparent excess revenues. According to the proposed approach, the total quantity sold in Canada will form the basis of that calculation even though, in concept, only those quantities relevant to the market in question would have been the subject of an apparent excessive price. While there may be instances where the total quantity sold may be relevant, the quantity sold in the market in question must also be considered, and a case-by-case determination made as to which is appropriate in a particular case.

Repayment of Excess Revenue

We have issues with the changes proposed by the PMPRB with respect to the management of excess revenue. Novartis is unable to ascertain the necessity for the provision where patentees would be required to repay excess revenues that are below the criteria for investigation simply because they persist for three years. We believe that the existing Guidelines, by including the provision of a $50,000 limit on cumulative revenue, correctly focuses on ensuring that PMPRB resources are targeted on the most important cases while providing companies with a certain degree of flexibility with respect to managing their average selling price within the Guidelines.

DIP Methodology

Novartis is appreciative of the PMPRB's efforts to clarify the DIP methodology. We recognize that the proposed methodology is meant to provide pricing flexibility by allowing an average selling price that is impacted by benefits to "bounce back" to pre-benefit levels. Nevertheless, we remain concerned with the assumption that prices for other non-benefit customers within the market remain fixed during the period in which the benefit is offered. The proposed DIP methodology essentially freeze prices in a market at the pre-benefit level during the period in which the benefit is in effect rather than allow the price to "bounce back" to the pre-benefit price plus CPI. By restricting the "bounce back" to the previous highest

[2] http://www.pmprb-cepmb.gc.ca/english/view.asp?x=653&mid=571 Accessed on April 20, 2009

non-excessive average selling price, the PMPRB is creating significant uncertainty when it comes to non-benefit pricing within a benefit market. The deleterious impact of this methodology is that it will inhibit manufacturers from pursuing special programs that benefit patients. We urge the PMPRB to apply its existing CPI-adjustment methodology to the pre-benefit price to allow prices to fully "bounce back" to a level that would make it consistent with all customers within a market.

Determination of a "Superior" Product

As it pertains to new medicines classified as "slight or no improvement" for which there is no direct comparable existing medicine identified, Novartis is concerned with the PMPRB's approach when it comes to identifying a "superior" product. The failure to specify how the PMPRB will categorize a drug as "superior" creates a great deal of uncertainty for patentees. We believe that this new approach will result in added pressure being placed on the Human Drug Advisory Panel by creating the potential for more disagreement between parties with regards to the comparability of a particular product. Either a product is comparable to a new medicine or it is not and introducing new concepts with little explanation on their application raises more questions than answers. While the PMPRB strongly espouses the principle of transparency, there are a number of elements in the proposed draft Guidelines, including the lack of clarity on how "superior" will be interpreted, that undermine the Board's ability to adhere to its principle. In our opinion, as is the case currently, if there are no "comparable" drug products identified for price review purposes, the median international price should be relied upon as the fallback test.

Selection of Public Prices for Patented Comparators

PMPRB's proposal to choose public prices closest to the average selling price of comparator products creates significant uncertainty and is lacking in transparency. It is extremely important for the PMPRB to specify which public price source will be used as a general rule in the price review of new medicines. Absent this general guideline, companies are at a loss to know if the price being established for their new medicine will be considered excessive or not. In addition, this approach has the potential to only consider the lowest price in Canada valid for price review purposes since a comparator product's average selling price is impacted by benefits that must be reported in all cases, according to the PMPRB's new policy. As such, the new medicine's price in other parts of Canada will in all likelihood appear to be out of line as a result of the new "any market" review. We feel strongly that the current approach to comparator prices, whereby the ODB price is referenced in the first instance when available followed by consideration of other published sources if necessary, offers stability and predictability in the regulatory process. In our opinion, there is very little predictability or transparency in the new approach being proposed by the PMPRB.

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Implementation of Guidelines

Finally, there remain questions about how the upcoming judicial review regarding the inclusion of all benefits will impact the Guidelines. A decision on the matter is expected after July 1, 2009 – post implementation of the proposed Guidelines. As a result, we have serious concerns with the overall implementation of the proposed Guidelines. Given the broad scope and depth of the changes proposed, and the fact that judicial review is likely to impact the Guidelines, we urge the PMPRB to provide adequate transition provision and postpone the implementation of the Guidelines to January 1, 2010.

Novartis is grateful for this opportunity to provide feedback into this important endeavour and hope that our comments, along with those provided by our industry Association Rx&D, provide some meaningful insight to help improve the Guidelines in the interests of all stakeholders.

Yours sincerely,

Regards,

Martin Barbeau