January 28, 2016

Guillaume Couillard
Director, Board Secretariat, Communications and Strategic Planning
Patented Medicine Prices Review Board
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Dear Mr. Gouillard,

I am writing to provide the views of Bayer Inc. on the PMPRB's proposed amendments to the *Compendium of Policies, Guidelines and Procedures* released on December 4, 2015. We appreciate the PMPRB's continued efforts to increase dialogue between the Board and its key stakeholders.

Two amendments were proposed; namely, t*he Reasonable Relationship Test Amendment and List Price to Maximum Average Potential Price (MAPP) Verification Amendment.*

The two amendments are effective for all drugs introduced after January 1, 2016 whereas the deadline to respond to the Notice and Comment is January 29, 2016. We are concerned about the sincerity of the consultative process when the amendments are implemented before key stakeholders have had a chance to comment. In addition, given the tight timeline which spanned the holiday season, potential unintended consequences could arise owing to the lack of understanding and/or lack of due diligence performed on the proposed changes.

The Reasonable Relationship Test Amendment *- if the new drug and the comparable drug product(s) are both patented and owned by the same patentee, that Board Staff would use the non-excessive National Average Transaction Price of the comparable drug product(s) when establishing the Maximum Average Potential price for the new strength of the patented drug product. If the new drug and the comparable drug product(s) are owned by different patentees, then Board Staff*

would apply the current practice of using the lowest of the six publicly available sources to establish the Maximum Average Potential Price.

As stated in the notice to comment, the proposed approach is essentially a return to that taken in the pre-2010 Guidelines. The proposed amendment suggests using two different approaches to perform the Reasonable Relationship Test, depending upon whether or not the new drug and the comparable drug(s) are owned by the same patentee. We are concerned about the proposed amendment as it could potentially create an uneven playing field for the two parties. In addition, this proposal can be a disincentive for the patentee of the comparable drug to offer benefits to patients. We are apprehensive to revert back to the previous guideline, especially given the fact that only 2014 data and impacts were analyzed in the crafting of this amendment. We, as a stakeholder, would need to conduct more thorough studies and analysis, consult with the PMPRB Board Staff and eventually be certain that the intended purpose and consequence of the approach is fully understood, properly evaluated and fair to all parties before being implemented.

List Price to Maximum Average Potential Price (MAPP) Verification Amendment – *That an addition be made to section C.11 "Review of Prices of New Patented Drug Products at Introduction" requiring patentees to ensure that domestic list prices for* ***new*** *drugs are below the Maximum Average Potential Price.*

We are not clear why the PMPRB is concerned with implementing this Amendment and also question on whether it is even within PMPRB's mandate to regulate list pricing. In addition, in cases where the Average Transaction Prices are not excessive, it is unclear to us how the PMPRB would be able to claim excessive pricing claims against the patentee. Quite clearly, the rationale and the impact of this change needs to be fully evaluated before it is implemented. An additional regulatory burden that in most all cases would be inconsequential would also be contrary to PMPRB's objectives of simplifying and modernizing its Guidelines.

Bayer HealthCare

Recommendation

To summarize, the timeline given for comments is not sufficient enough to assess the impacts and consequences of the proposed amendments. For both amendments, we propose to allow further analysis and to keep the consultation process open with the targeted implementation date on January 1, 2017 after due diligence can be performed by all parties to ensure that there are no unintended consequences of any changes to the Guidelines. We would also like to have access to the analysis performed by the PMPRB and to have open dialogue with Board Staff in order to further understand its objectives in recommending these two amendments.

Bayer Inc. supports the PMPRB's commitment to a framework that is relevant, responsive, and appropriate as long as the consumer is protected and the benefits of patented medicines are recognized.

We would like to thank you for the opportunity to provide feedback on the proposed changes and we look forward to continuing to work with the Board on refining the PMPRB's processes and guidelines.

Yours sincerely,

Dale Toki

Dale Toki
Director, Pricing and Contracts
Bayer Inc.