Canada Innovation

Montreal, January 28, 2016

To whom it may concern,

This letter is written in response to the current PMPRB Notice and Comment, issued December 4, 2015 - Incremental Reforms to Compendium of Policies, Guidelines and Procedures. Comments on each of the proposed rules are provided below.

Initiative1. *The "Reasonable Relationship Test (Schedule 4)" price source change*
The proposed change appears to be a logical way to minimize the need for PMPRB staff to undertake significant investigations into the price of a line extension that is priced in line with existing, previously launched, DINs of the same chemical sold by the same patentee. However, it is imperative that the language of the rule not allow discounts, and other programs to diminish the allowable price of new line extensions and create new investigations.

Furthermore, the logic supporting the new rule for products subject to the reasonable relationship test, applies equally to products for which a same chemical therapeutic class comparison test will be applied, when both the new and existing DINs are sold by the same patentee.

Proposed Implementation Timelines: *"These changes would be effective for all drugs introduced in Canada after January 1, 2016."*
Teva Canada Innovation (TCI) respectfully suggests that an effective date that precedes the deadline for receipt of responses to a Notice and Comment invitation undermines the comment process and at best is inappropriate and at worst fails to comply with the requirements of the Patent Act under section 96 subsection 5. We propose that changes would be effective 10 business days after the closing of the comment process.

TCI appreciates the opportunity to provide input on these initiatives and would welcome the opportunity to participate in further discussions, should that be deemed appropriate.

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