

Chris Halyk
President

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Ref: CH-BF-Gen-066

June 13, 2013

Ms. Sylvie Dupont
Director, Board Secretariat
Patented Medicine Prices Review Board
Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Ms. Dupont:

Thank you for the opportunity to comment on the proposed changes to the Compendium on Policies, Guidelines and Procedures, outlined in the Notice and Comment published on May 16th, 2013.

Janssen Inc. supports the proposed changes, and congratulates the PMPRB on their ongoing efforts to reduce the regulatory burden for both Board Staff and industry. Eliminating the use of forecast CPI in favour of an actual lagged CPI would provide predictability and certainty to business planning, which would be highly valuable to patentees. The second proposal to reduce the filing requirements for both new and existing patented drugs represents a significant reduction in regulatory burden. Moving from a semi-annual to an annual filing would indeed allow for more efficient use of both PMPRB and patentee resources. The proposed changes for new patented drugs provide a more efficient reporting mechanism without compromising the Board Staff's ability to assess prices at introduction.

We encourage the PMPRB to continue collaborative efforts to streamline the Guidelines and regulatory processes. We look forward to the opportunity for further consultation regarding operational/transitional details prior to the final adoption and implementation of the proposed changes.

Sincerely,

A handwritten signature in blue ink, appearing to read "CH Halyk".

Chris Halyk
President

cc: Barbara Favaro, Director, Strategic Pricing