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SENT VIA E-MAIL (sdupont@pmprb-cepmb.gc.ca)

June 13, 2013

Ms. Sylvie Dupont
Secretary to the Board of PMPRB
Box L40
Standard Life Centre
333 Laurier Avenue West Suite 1400
Ottawa, Ontario, K1P 1C1

Dear Ms. Dupont:

The purpose of this document is to provide the views and recommendations of Merck Canada Inc. on PMPRB's Notice & Comment: *Regulatory Burden Reduction Initiative*, released on May 17, 2013. We would also like to highlight our support of Canada's Research-Based Pharmaceutical Companies (Rx&D) submission to the PMPRB Board.

Merck Canada, through participation in Rx&D activities, has been actively engaged in the consultation regarding these PMPRB proposed changes on regulatory burden reduction. Ongoing discussions are essential in ensuring that the Guidelines remain relevant and uphold the principle of fairness, transparency, openness and predictability. We would also like to thank the Board Staff for being available to answer questions regarding the proposed changes.

We are in agreement with the Board's proposed amendments and provide commentary on each proposal below as stated in the consultation document.

Consumer Price Index (CPI) Adjustment Methodology

> *PMPRB Proposal for Consideration:* "Maintain current CPI Adjustment Methodology for existing drug products, except replace the use of the forecast CPI with actual CPI in calculating the CPI Adjustment Factor for the forecast period."

The unpredictability and administrative burden that resulted from the use of a forecast CPI in 2009 clearly illustrates the benefits of moving to an actual CPI. Particularly given that this situation is expected again in 2012-2013, Merck Canada is aligned with Rx&D in supporting this measure. An actual CPI provides certainty and will streamline work for both patentees and Board staff.

Reduction of Filing Requirements – Yearly Reporting

> *PMPRB Proposal for Existing Patented Drugs:* "For existing drug products, to replace the semi-annual regulatory filing of Form 2-Information on the identity and prices of the medicine by an annual filing."

The July filing period is an unnecessary regulatory requirement given that PMPRB Staff only use full-year data (i.e. January-December) to determine whether an existing product is within guidelines. Merck is aligned with Rx&D in supporting this proposal. Merck Canada is fully committed to monitoring its compliance throughout the year. We would ask that the PMPRB provide along with the annual compliance report, the forecasted non-excessive average price (NEAP) for the upcoming year for all DINs monitored. This is an important check for patentees to ensure their calculations reconcile with those of the PMPRB.

Merck Canada supports the position that the PMPRB continue to use the existing six months reporting requirement for determining an Introductory Benchmark Price (IBP).

Reduction of Filing Requirements – Form Changes

> *PMPRB Proposal for New Patented Drugs:* "To eliminate the requirement to submit Form 2 information for the first day of sales of a patented drug product in Canada and to add a section in the Form 1-Medicine Identification Sheet to report the publicly available ex-factory price in Canada on the date of first sale."

Merck is aligned with Rx&D in supporting this change.

Conclusion

In closing, Merck Canada would like to thank the PMPRB for the opportunity to comment on its proposal to reduce regulatory burden. Merck Canada endorses the recommendations of Rx&D in their submission document and looks forward to actively participating in future consultations between Rx&D and the PMPRB.

Yours truly,

Tama Donoahue-Walker
Vice President, Patient Access