June 13, 2013

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Ms. Sylvie Dupont
Director, Board Secretariat
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, 14th Floor
Ottawa, Ontario
K1P 1C1

Re: Notice & Comment

Dear Ms. Dupont,

GlaxoSmithKline is pleased to respond to the PMPRB's Notice and Comment on the Regulatory Burden Reduction Initiative.

Please see the following responses to the 2 initiatives listed in the Notice and Comment.

Initiative #1: Eliminate the Use of Forecast CPI and Transition to the use of Actual Lagged CPI as part of the CPI Adjustment Methodology

Proposal or 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.

- GlaxoSmithKline is in favor of using actual CPI in calculating the CPI Adjustment Factor for the forecast period. The use of actual CPI rather than forecast will enable better consistency and predictability.

Initiative #2: Reduction of Regulatory Filing Requirements

Proposal for Consideration – 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 annual filing

- As discussed in the Notice and Comment, the January – June information has been used as an early warning system to notify patentees when prices appear to exceed the Guidelines and give an opportunity to take action before the end of the year. Although this is useful for analysis, we recognize that annual regulatory filing of Form 2 information would allow for better use of patentees and Board Staff resources. We are in favor of replacing the semi-annual regulatory filing of Form 2 however, if any issues are

identified at the end of the reporting period, companies should be given up to the following year to resolve these issues without investigation.

Proposal for Consideration – 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 publically available ex-factory price in Canada on the date of first sale.

- GlaxoSmithKline is in favor of eliminating the requirement to submit Form 2 information for the first day of sales of a patented drug product. Patentees will still be required to file the January-June and July-December reporting for all new product launches to establish the Introductory Benchmark Price. As discussed in the Notice and Comment the introductory benchmark price is established from the first sale to the end of the six-month regulatory reporting period.

GlaxoSmithKline wishes to thank the Board for the opportunity to comment on these proposals.

Sincerely,

Cindy Roll
Vice-President
GlaxoSmithKline