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Thursday, June 13th, 2013

Ms. Sylvie Dupont
Secretary, Patented Medicine Prices Review Board
Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
K1P 1C1

**Re: PMPRB Notice & Comment May 2013 - Proposed Amendments to the Regulations -
Regulatory Burden Reduction Initiative**

Dear Ms. Dupont,

Thank you for the opportunity to review and provide comments on the regulatory burden reduction initiatives.

Warner Chilcott Canada Co. recognizes the ongoing efforts made by the Board and its staff to identify ways to reduce the regulatory burden on patentees while making effective use of Board staff resources without adversely affecting its mandate to protect consumers.

We fully agree with the Board's intent to simplify the regulatory burden by reducing the regulatory filing requirements. The replacement of the semi-annual regulatory filing of Form 2-Information on the identity and prices of the medicine by an annual filing, as well as the elimination of the requirement to submit Form 2 information for the first day of sales 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 would reduce the regulatory burden of patentees without compromising Board Staff's ability to determine whether a price is excessive or not at introduction.

It is Warner Chilcott's position however that additional information should be provided to patentees to fully understand how the Board intends to implement the proposed changes to eliminate the use of the Forecast CPI and to transition to the use of the Actual CPI as part of the CPI Adjustment Methodology.

The Board staff may have found little difference between the forecast and actual CPI rates in the current low inflation environment. However, the current methodology reduces uncertainty and provides stability to the overall framework even when inflation rates are stable and low because the Forecast CPI is released to manufacturers early in the year and can then be used within the internal planning processes. As a result, this aspect of the current methodology improves



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predictability and reduces uncertainty, which are both key to better planning, especially for manufacturers operating within complex global supply chains. This feature of the current methodology would become even more important if there were to be increased volatility in the rate of inflation in future years.

The current Forecast CPI methodology is both responsive to expected changes in inflation rates and provides some planning certainty for current year pricing changes. Perhaps the Board could provide an illustration that shows which Actual CPI rates would be used for what period and when they would be communicated to manufacturers.

We hope that these comments will assist the Board in reaching a decision on the proposed changes prior to final adoption and implementation of the amendments to the Regulations.

Sincerely,

Tim Hendrickson
Director
Warner Chilcott Canada Co.