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June 12, 2013

VIA E-MAIL

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

Subject: Novartis Canada's Response to the PMPRB's Notice and Comment on the proposed changes to reduce the regulatory burden

Dear Ms. Dupont:

On behalf of Novartis Pharmaceuticals Canada Inc. ("Novartis"), we thank you for your commitment to reduce the regulatory burden on patentees and for the opportunity to provide feedback to the Patented Medicine Prices Review Board (PMPRB) regarding the Notice and Comment issued on May 16, 2013.

Novartis is pleased to take part in this discussion and offer our input after reviewing the draft consultation document. Our comments and suggestions pertaining to the proposed revision to the CPI Adjustment Methodology are as follows:

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

With respect to the CPI Adjustment Methodology, the proposed changes are lacking in detail. Specifically, the Notice and Comment refers to the "elimination of the forecast CPI and transition to the use of a lagged CPI." However, no specification is provided as to which "lagged CPI" will be used. We would like to request clarification on the timeframe that "lagged CPI" refers to in this context.

Internal price increase evaluation is a complex and lengthy process conducted many months prior to the effective date of the price increases. Provincial requirements for price increase submission are also an important aspect that determines the timing of the internal process. As such, the early publication of the actual lagged CPI factor is essential to ensure that this new

measure is successful in reaching its objective. Therefore, we propose using a lagged CPI based on an annual average ending June of the previous year. For example, the actual lagged CPI rate for 2015 would be based on the annual average CPI from July 2013 to June 2014. The CPI rate for the previous two years (2014 and 2013) would be based on the same time period (July to June). The PMPRB could publish the relevant lagged CPI rates in the July PMPRB Newsletter.

Another element to consider carefully is the implementation of an appropriate transition phase and measures to avoid situations where past price increase decisions in compliance with current CPI methodology could result in future apparent excess solely due to the change in methodology.

Again, we thank you for the opportunity to provide feedback on this important issue and hope that our comments provide some valuable insight to help improve the Guidelines in the interests of all stakeholders. Please feel free to contact me for any questions or clarifications regarding these comments.

Sincerely,



Trinh Luong
Director, Health Technology Assessment & Pricing Regulation