

June 13, 2013

Ms. Michelle Boudreau
Executive Director
Patented Medicines Prices Review Board
Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Ms. Boudreau,

On behalf of the member companies of BIOTECCanada I would like to thank the Patented Medicine Prices Review Board (PMPRB) for the opportunity to provide comments on potential changes to the CPI Adjustment methodology and reduction of filing requirements.

BIOTECCanada members support the amendments to the Guidelines proposed and believe that it will provide predictability in the price increases process and reduce regulatory burden on patentees. Additionally, the members believe that it will make effective use of Board staff resources without adversely affecting its mandate to protect consumers. We do understand that further consultation will be undertaken on the proposed changes as well as on operational/transitional details, prior to final adoption and implementation, however at this point in time, BIOTECCanada members, would like to get further clarification on the following:

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

- What does PMPRB mean by "Actual lagged CPI"?
- How will the first transition year work?
- Will the existing three-year and one-year rule remain unchanged?

Reduction of Filing Requirements – Yearly Reporting

- How will this new measure impact the determination of the introductory benchmark price (IBP) for new DINs?
- How will PMPRB resolve situations where a product is sold in Canada at the introductory benchmark price (IBP) using an interim median as the international median price and the product is subsequently launched in comparator jurisdictions during the first year of sale.

Reduction of Filing Requirements – Form Changes

- When will patentees have to submit Form 2 and what information will be required?

BIOTECCanada and its member companies are fully committed to working cooperatively with PMPRB to continue to work to enrich the health of Canadians and provide for a sustainable health care system. Please do not hesitate to contact me should you or your staff have any questions or comments.

Sincerely,



Andrew Casey
President and CEO