Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

February 12, 2021

Douglas Clark, Executive Director
Patented Medicines Prices Review Board
Attention: PMPRB Guideline Consultations
Box L40 Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

* *Submitted via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca*

Re: Notice and Comment issued January 15, 2021 with respect to change in the definition of Gap medicines and the timeline for compliance

Dear Mr. Clark,

On behalf of Biosimilars Canada, the biosimilars medicines division of the Canadian Generic Pharmaceutical Association, I am writing to provide a response to the PMPRB's invitation for stakeholders to comment on two proposed consequential amendments to the new PMPRB Guidelines resulting from the decision to delay the coming-into-force date of the *Regulations Amending the Patented Medicines Regulations* ("Regulations") a further six months, from January 1, 2021 to July 1, 2021. The PMPRB proposes to change the definition of Gap medicines and the timeline for compliance with the Maximum List Price (MLP) ceiling for Grandfathered and "Gap" medicines.

Biosimilars Canada is a national association representing the biosimilar medicines industry in Canada. Its member companies are at the forefront of the global development and marketing of biosimilar medicines. Biosimilar medicines are approved by Health Canada as being as safe and efficacious as their reference biologic drugs, and are developed to the same quality standards. Biosimilar medicines present a significant opportunity to embrace cutting-edge therapies while addressing the cost-effectiveness demands on healthcare systems in Canada.

Biosimilars Canada was disappointed that the Final PMPRB Guidelines did not establish conditions for the launch of an investigation into a patented biosimilar medicine as a safeguard

to prevent misuse/abuse of the complaints-based process. Such safeguards are in place for patented generic medicines.

Biosimilars Canada also remains concerned about the application of price tests for patented originator medicines to investigations of patented biosimilars, which does not take into account the market realities and other important considerations for biosimilar medicines. A separate test for biosimilars that is focused on the domestic market is needed for investigations into patented biosimilar medicines.

In addition, Biosimilars Canada remains concerned about the uncertainty and potential impact of changes to the PMPRB Framework on originator medicines prices and corresponding negative impacts on biologic drug competition that could result from such changes.

With respect to the specific consultation questions, we note that the PMPRB Guidelines finalized on October 23, 2020 provided a 12-month transition period for patentees to bring the pricing of existing and “Gap” medicines into compliance with the new regime. The PMPRB proposes shortening the period to six months, but does not provide a rationale for this change. Biosimilars Canada continues to favour the adoption of a 12-month transition period as originally planned as this would provide patentees with two reporting periods to facilitate a smooth transition to the new reporting regime.

Thank you once again for the opportunity to provide feedback on the PMPRB’s latest consultation. Biosimilars Canada would be pleased to answer any questions you may have.

Sincerely,

Jim Keon
President