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,

I am writing to provide the Canadian Generic Pharmaceutical Association's (CGPA's) 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.

The CGPA is the national association representing Canada's generic pharmaceutical industry, a group of companies which specialize in the production and marketing of high quality, affordable generic drugs. For more than 50 years, Canada's generic pharmaceutical industry has played a vital role in the country's health-care system and its economy by providing safe, effective, proven alternatives to more expensive brand-name medications. Making prescription drugs more affordable and accessible is the key value proposition of Canada's generic pharmaceutical industry.

Generic medicines are used to fill 73 per cent of all prescriptions in Canada. Generic medicines are providing tremendous value and savings for Canadians, largely due to the work the CGPA has done with the pan-Canadian Pharmaceutical Alliance (pCPA). The pCPA and CGPA have had a 5-year generic drug pricing agreement ("5-Year Agreement") in place since April 1, 2018. This follows an earlier agreement, which resulted in substantial savings for Canadians.

The CGPA has been concerned about the changes to the *Patented Medicines Regulations* and PMPRB framework for several years because of the reference-based pricing system for generic medicines in Canada. Generic pricing levels in Canada are internationally competitive, and any reduction in originator prices must not have a corresponding impact on generic drug prices.

The 5-Year Agreement includes a tiered pricing model which has different pricing levels depending on the number of competitors in the market. These prices are fully transparent and apply to payers in both public and private markets. Prices of generic drugs are calculated and set by the pCPA as a percentage of the price of the reference originator product at the time the first version of that generic medicine seeks to be listed on provincial formularies.

Any subsequent change in the price of the originator product does not affect the price of a generic medicine already listed on provincial formularies under the Agreement. However, generic drug manufacturers begin development of new medicines several years prior to their launch on the market. Changes in the pricing of reference brand products currently on the market (for example as a result of the new international country price comparison tests) could negatively impact the pricing and market potential of the generic products under development, resulting in an increased risk of new generic medicines not launching in Canada.

The 5-Year Agreement includes a clause that requires the pCPA and CGPA to review the changes to the PMPRB framework and address potential impacts on generic drug prices. This clause was included to maintain the integrity of the agreement, ensure generic drug prices remain at sustainable levels, lower the potential risk of drug shortages for Canadians and maintain a viable generic medicines market in Canada.

However, the full impact of the changes on originator prices remains unclear and the topic of much debate, creating uncertainty about the impact of the changes on the 5-Year Agreement. The estimates of the impact of the *Patented Medicines Regulations* and PMPRB framework changes vary greatly.

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. The original 12-month transition period is likely a more realistic time period for patentees to bring the pricing of existing and “Gap” medicines into compliance with the new regime, and accordingly this would provide the CGPA members with more reliable pricing information in relation to the CGPA’s 5-Year Agreement with the pCPA.

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

Sincerely,

Jim Keon
President