February 12, 2021

Doug Clark
Executive Director
Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario K1P 1C1

Submitted electronically: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: SANOFI Canada feedback regarding the change to the definition of Gap medicines and the timeline for compliance (Notice and Comment - January 15, 2021)

Dear Mr. Clark:
SANOFI Canada (SANOFI) would like to offer our perspective on the current PMPRB consultation with respect to the definition of Gap medicines and the proposed timeline for compliance. This submission is further to our previously submitted comments to the PMPRB during the Guidelines development process.

SANOFI strongly opposes the reduction of the transition period for the new guidelines to six months. This change represents a substantial and unanticipated reduction from the twelve-month transition specified as part of the final Guidelines made available in October 2020. The proposed six-month period is insufficient and unrealistic for coming into compliance with the new Guidelines.

Implementing these changes requires adequate time in which to make important adjustments to our processes and the significant number of contractual arrangements with our suppliers and customers. This compressed timeframe for compliance transition will create a significant administrative burden and distraction for SANOFI and our supply chain partners at a time when we remain focused on addressing the ongoing COVID-19 pandemic. It was the continued imperative to focus on our collective efforts against the pandemic which was cited by the Government of Canada in making the December 2020 announcement to defer the coming-into-force of the amended *Patented Medicines Regulations* to July 2021 in the first place. In contrast, the proposed reduction of transition time for Guidelines compliance has not been offered in the current consultation with any associated rationale, explanation or further justification.

The PMPRB's established administration and notification procedures currently allow for important information for compliance purposes to be known to patentees after the passage of a period of time (typically a number of weeks) following the filing of certain key information. In practical terms, under the proposed transition window this reality of PMPRB practices will result in the intended six-month transition period being curtailed, negatively impacting the ability of patentees to come into compliance and causing an unnecessary distraction to the company's efforts to fight the pandemic and expedite Canada's economic recovery.

SANOFI strongly recommends that the PMPRB reconsider its approach with respect to transition and revert to the October 2020 state of allowing for a full twelve-month transition period for patentee compliance with the new Guidelines.

SANOFI fully endorses the submissions of our trade association on this matter, including Innovative Medicines Canada, BIOTECanada, Rare Disease Innovators (RAREi), and the Vaccine Industry Committee (VIC). In particular, we believe that twelve months is the minimum reasonable period for patentees to file and receive the required information, make any internal adjustments, and manage any external customer or supply chain issues arising from the new compliance requirements.

We appreciate your consideration of these comments. Should you have any questions or wish to explore these matters further, please do not hesitate to reach out to me directly.

Yours truly,

Marissa Poole
Country Lead, SANOFI Canada
General Manager, SANOFI Genzyme