August 31, 2021

Dr. Mitchell Levine
Chairperson of the Board
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 on PMPRB Guidelines Notice and Comment (August 2021)

Dear Dr. Levine:

On behalf of SANOFI Canada ("SANOFI"), I am providing comments in respect of the PMPRB's current Notice and Comment as issued on July 15th, 2021. This submission is provided further to SANOFI's past record of submissions to PMPRB on its Guidelines.

At the outset, SANOFI would like to signal our complete alignment with and support for the submissions provided by our trade associations on this matter, notably Innovative Medicines Canada and BIOTECanada.

SANOFI would identify a number of serious concerns with the current proposals. In particular, SANOFI strongly opposes the proposed changes to international price tests for existing patented medicines and their line extensions. These proposals are a clear departure from the established mandate regarding non-excessive prices and are offered without any rationale or impact assessment.

This proposal is an unanticipated and highly negative surprise for the entire patented medicines supply chain. It is being proposed despite the PMPRB itself having only just established a materially different approach following a recent and extensive set of stakeholder consultations. In addition to undermining the PMPRB's own previous consultation process to date on its Guidelines and these issues, this current proposal is an unnecessary, unwarranted and destabilizing signal at a time when Canada remains focused on pandemic recovery and ensuring continuity of care for patients. It is extraordinarily difficult to reconcile a set of policy announcements linked to consideration of the reality of a combined regulatory burden and managing the ongoing COVID-19 pandemic with the impact of the current Notice and Comment on patentees.

Our recommendation: that the Guidelines immediately revert to the prior approach to international price tests for existing medicines (highest international price test) as set out in the October 2020 Guidelines.

SANOFI is also opposed to the reversion to a six-month transition period for the coming-into-force of the new regulations. Again, this change is being proposed despite the PMPRB having only just established a twelve-month transition period in April 2021, also following substantial stakeholder consultation. As communicated by many stakeholders to PMPRB previously, a six-month transition period is insufficient. It will in practice function as a materially shorter window of time for patentees to receive the appropriate information from the PMPRB itself and establish required pricing adjustments both internally and for various supply chain participants. A twelve-month transition is far more appropriate, practical for compliance purposes, and aligns with the stated policy intent from Health Canada in respect of addressing the COVID-19 pandemic.

Our recommendation: that the Board immediately reverts to the twelve-month transition period for compliance as publicly confirmed by the Board itself in April 2021.

These types of sudden and arbitrary changes represent an unanticipated and challenging compliance burden on patentees who have been working to prepare for the future under an approach set out by PMPRB in October 2020 and just reconfirmed in April 2021. It also does a great disservice to the PMPRB as a federally mandated public agency and the basic expectations for due consultation process, consistency and predictability of operations, basic fairness, and ongoing commitments to “smart” approaches to regulation supported by a clear policy purpose and rationale.

The proposed approach stands in direct opposition to the stated policy intent provided by Health Canada with respect to the previously announced delays to the coming-into-force of the new regulations. They are also misaligned with the recently announced federal Biomanufacturing and Life Sciences Strategy which includes clear and welcome language with respect to enabling innovation through world-class regulation.

We are hopeful that the PMPRB will reflect carefully on stakeholder submissions and fundamentally reconsider the approach proposed in the current Notice and Comment. SANOFI would welcome the opportunity to elaborate on our perspective related to the compliance burden on patentees related to the coming-into-force of the new regulations.

Sincerely,

Carrie McElroy
Interim Country Lead, SANOFI Canada