June 21st, 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 Comments on PMPRB Guidelines Modernization and Evaluation Plan (GMEP)

Dear Dr. Levine,

On behalf of SANOFI Canada ("SANOFI"), I am providing comments in respect of the PMPRB's current consultation on a proposed Guidelines Modernization and Evaluation Plan (GMEP).

SANOFI is strongly supportive of the submissions provided by our trade associations for this consultation, notably Innovative Medicines Canada and BIOTECanada. It is notable that stakeholder concerns with the proposed changes remain undiminished. SANOFI reiterates its previously highlighted positions and recommendations regarding both the content and timing of the new regulations and Guidelines for the purposes of this submission.

Specifically, given both the ongoing COVID-19 pandemic and the implications of ongoing litigation for the PMPRB's proposed approach as of July 1st, the most urgent recommendation to the Government of Canada and the PMPRB itself is **to discontinue the proposed changes and explore alternate, more effective and predictable means to modernize the PMPRB's regulatory framework for all parties.**

That important context aside, the proposed GMEP scope and approach proposes to address several policy elements which fall well outside the PMPRB's mandate and expertise. It is inappropriate to conduct what would be an essentially "in-house" evaluation of the impact of the proposed reforms on much broader elements of the Canadian medicines access and reimbursement system. Initial focus should remain on those aspects of PMPRB functions and operations including list price information, international price comparisons, investigations, and other clearly established compliance activities.

Any evaluation of PMPRB operations must be fully independent and conducted by a third-party external to the PMPRB with the appropriate competencies. Assessment must be conducted only on matters within the direct purview of the PMPRB against transparent and agreed metrics and reliable, regulatory-grade sources of in-scope information. Broader public policy impacts, as suggested in the draft GMEP plan, exceed the PMPRB's mandate and quasi-judicial status and are more appropriately conducted by other agencies of government at both the federal and provincial levels.

SANOFI remains interested in pursuing such a broader engagement with all life sciences stakeholders, including public agencies and levels of government, to align on common pan-Canadian objectives for the sector including access to medicines, industry investments, and biomedical research. This should be supported by a competitive, agile and aligned regulatory framework. The PMPRB is but a single aspect of a much larger conversation which is urgently required in order to ensure Canada's long-term health and economic goals are fully realized.

Thank you for your consideration of this submission. SANOFI would welcome the opportunity to elaborate on a more appropriate approach to PMPRB's future regulatory framework including the scope and measurement of its operations and performance.

Sincerely,

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