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February 15th, 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: Notice and Comment – On the change to the definition of Gap medicines and the timeline for compliance (January 15, 2021)

Dear Dr. Levine:

Pfizer Canada ULC ("Pfizer") would like to offer our comments with respect to the current PMPRB Notice and Comment on changing the definition of "gap" medicines and the timeline for patentee compliance with the final Guidelines.

We are providing this submission further to our body of correspondence with the PMPRB on various matters related to the Guidelines development process. Consistent with those representations, Pfizer's submission is being made without prejudice to any ongoing litigation with respect to the PMPRB's regulatory framework and guidelines.

On this matter, Pfizer is fully supportive of the positions taken and specific submissions provided by our industry associations, notably Innovative Medicines Canada (IMC), BIOTECanada, and the Vaccine Industry Committee. We encourage the Board to consider carefully those recommendations with the goal of evolving a more effective and workable set of guidelines for all stakeholders.

Regarding the current Notice and Comment, Pfizer opposes the proposal to reduce the effective transition period following the coming into force of the amended *Patented Medicines Regulations* by half to six (6) months. This is a major and unanticipated change from the final Guidelines released in October 2020, which had set out a transition period of twelve (12) months for patentees to maintain compliance. The current Notice and Comment provides no rationale for this material change in timelines.

It is also important to recognize that due to the well-established filing procedures with the PMPRB itself, key compliance inputs will be unavailable to patentees until well within the six (6) month transition period (approximately mid-September 2021) that effectively reduces the transition further.

This operational reality will substantially further reduce the effective overall transition time available to come into compliance. A reduction in the transition period to a matter of weeks will impose a substantial and unanticipated administrative burden on patentees and Board Staff to reconcile legitimate technical matters of compliance. For example, patentees will be required to work through all relevant issues, including but not limited to contractual sales and adjustments, wholesalers, distributors, and pharmacies across the medicines supply chain.

Pfizer submits that a minimum twelve (12) month transition period is required to allow patentees to address the full suite of transitional requirements in support of ongoing compliance with the guidelines.

Thank you for your consideration of our feedback. Please do not hesitate to contact me directly should you have any additional questions for Pfizer Canada regarding this submission and the realities of transition measures and patentee compliance with the Guidelines.

Sincerely,

DocuSigned by:
Cole C. Pinnow
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Cole C. Pinnow
President, Pfizer Canada

cc: Douglas Clark, Executive Director, Patented Medicine Prices Review Board