**Pfizer Canada**
17300, autoroute Transcanadienne, Kirkland (Québec) H9J 2M5
17300 Trans-Canada Highway, Kirkland, QC H9J 2M5

August 16, 2023

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

*Submitted electronically: Notice and Comment - PMPRB consults on new proposed Interim Guidance*

**RE: Amendment to the Interim Guidance regarding New Medicines**

Dear Mr. Couillard:

Pfizer Canada ULC ("Pfizer") welcomes the opportunity to provide feedback with respect to the Notice and Comment released by the PMPRB on June 20th, 2023. To preface our submission, let us reiterate that Pfizer is supportive of the responses and comments provided to the PMPRB by Innovative Medicines Canada and BIOTECanada. The present letter further emphasizes key elements that Pfizer Canada wishes to bring to the PMPRB for consideration.

**Pfizer Canada's 2022 interim guidance consultation response is still valid.**

In our response to the PMPRB's initial consultation on the Interim Guidance, Pfizer Canada raised that the proposed guidance did not provide sufficient clarification as to the compliance expectations for medicines receiving a Health Canada NOC from July 1st, 2022. In the absence of any clear direction from the Board, patentees with medicines in this situation are faced with potential launch considerations "at risk" for the coming period up to the adoption of updated Board Guidelines. The lack of clarity created a volatile pricing ecosystem with limited predictability and stability of current and future drug prices in Canada, which can jeopardize international prices stability given that Canada is referenced by several other countries.

Pfizer encourages the Board to provide adequate clarification for patentees as to their compliance obligations for all products moving forward as future Guidelines are developed. Specifically, Pfizer would strongly encourage the Board to reflect the clear policy direction and intent from Health Canada, as well as recent jurisprudence, as to the appropriate focus for future price reviews on non-excessive pricing. Therefore, we continue to support an approach that limits disruption of ongoing practices and reduces administrative burden based on temporary rules.

**The updated Interim Guidance and New Guidelines should clarify rules governing price increases aligned with the Consumer Price Index.**

Section 85 (1) of the Patent Act continues to apply and the Board shall take into consideration changes in the Consumer Price Index (CPI) for possible price adjustments. From that perspective, we strongly believe that price increases in line with CPI should be considered compliant and not automatically trigger investigations. This creates confusion as to the future interpretation of guidelines, but also creates unnecessary administrative burden with the need to produce answers to all new investigations. In addition, the PMPRB has not issued 2024 CPI-based price adjustment factors for patented drugs nor revisited its decision to use the 2022 NEAP throughout the interim period as it was committed in its August 2022 decision following the initial interim period guidance consultation.

Pfizer expects that the Interim Guidance and new PMPRB Guidelines will reflect the PMPRB's mandate under the Patent Act to remedy instances of excessive pricing of patented medicines. The proposed 2023 amendment to the Interim Guidance intends to provide early guidance and greater predictability for new medicines if the List price is lower than the median of the PMPRB11. This proposal is opening the discussion on the appropriateness of using the median of the new PMPRB11 basket of countries as the reference point for excessive pricing. Under an excessive pricing mandate, Pfizer strongly believes that any price within the range of the new PMPRB11 (i.e., countries that have been selected for comparison purposes because they do not have excessive prices) should be considered non-excessive. Hence Maximum List Prices should reflect the Highest International prices of the comparator countries.

Pfizer is supportive of the principle of providing greater predictability, but the proposed interim guidance fails to reach this objective since there remains a lack of clarity on what "considered as reviewed" means for the future price assessment of new medicines once the new guidelines come into force. As well, more clarity on the mechanical aspects of price tests (e.g., timing of the maximum price calculation, which periods are to be considered, and how frequent a new medicine would be subject to a price test) is required. Finally, due to the inherently high uncertainty around price compliance of new medicines, we reiterate that a minimum of two (2) full reporting periods would be required to minimize any potential disruptions to the medicines supply chain and allow for sufficient time for any compliance-related adjustments.

Pfizer would be pleased to elaborate on any aspects of this submission. We welcome and appreciate the Board's consideration of stakeholder feedback as it shifts to managing price reviews during the interim period while also working to develop updated Guidelines.

Yours sincerely,

DocuSigned by:
Karine Grand'Maison
25487A5203E94AB...

Karine Grand'Maison
Vice President, Access & Government Relations