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

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Doug Clark
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 Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations - Canada.ca

RE: Notice and Comment – PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulation

Dear Mr. Clark:

Pfizer Canada ULC ("Pfizer") welcomes the opportunity to provide our feedback with respect to the Notice and Comment released by the PMPRB on June 30th, 2022. To preface our submission, let us reiterate that Pfizer is supportive of the feedback provided to the PMPRB by Innovative Medicines Canada and BIOTECanada. As the relevant amendments to the *Patented Medicines Regulations* have now been published and are in effect as of July 1st, 2022, Pfizer and other patentees have an interest in understanding compliance obligations and expectations for the coming weeks and months prior to the PMPRB consulting on and eventually adopting new Guidelines.

Regarding the Board's proposed approach to price reviews, Pfizer is supportive of the approach as it relates to existing patented medicines. Consistent with our prior submissions to both Health Canada and the Board on the subject of existing products, for reasons of efficiency and fairness we recommend defining the proposed approach to price tests for existing medicines moving forward as including all medicines with a Health Canada Notice of Compliance (NOC) prior to July 1st, 2022. Currently marketed patented medicines have already been subject to PMPRB jurisdiction since their introduction and as such are not excessively priced. Any *post hoc* adjustments may introduce unnecessary disruptions for patentees and the wider medicines supply chain, including generic manufacturers, wholesalers, distributors, and pharmacy.

The current Notice and Comment, however, does 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. 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. Also, there should be no retroactive payment of revenues during the interim period. Finally, due to the inherently high uncertainty around price compliance of these products, 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
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Karine Grand'Maison
Vice President, Access & Government Relations