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Mr. Guillaume Couillard
Director General
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: Pfizer Canada Submission – PMPRB Discussion Guide (Phase 2) Consultation

Dear Mr. Couillard,

Pfizer Canada ULC ("Pfizer") would offer a number of comments in response to the current PMPRB (Phase 2) Discussion Guide consultation. This submission builds on our prior representations to the Board on future Guidelines including at the December 2023 roundtable in Ottawa.

For the purposes of this consultation, Pfizer is strongly supportive of the concurrent submissions provided by our trade associations: Innovative Medicines Canada (IMC), BIOTECanada, and the Vaccine Industry Committee (VIC). Within the totality of overall feedback being provided in those submissions, there are a number of specific points of consideration to emphasize as the Board develops revised Guidelines in the coming weeks and months.

At the outset we commend the PMPRB for its stated objective of pursuing a Guidelines development process grounded in transparency and predictability. These are important foundational principles which must remain central to both the development and future implementation of the new Guidelines.

However, as an overall document, the Discussion Guide itself does not provide sufficient detail on critical issues such as the Board's intentions with respect to the use of price tests. There remain too many outstanding questions as to how the Board would envision operationalizing its own proposals to allow for considered feedback.

We also have concerns with the level of Board staff discretion apparent in the overall approach detailed in the Discussion Guide, particularly for the proposed "in-depth" reviews. Absent appropriate direction, the unpredictable use of transient or context-specific compliance interpretations would run counter to the stated objective of predictability.

Building on the appropriate principles of transparency and predictability, Pfizer would encourage the PMPRB to recommit to its prior focus on "bright line" Guidelines that support feasible and predictable compliance for rights holders. This sound approach would be fully consistent with best

practices for public and quasi-judicial organizations, including the ongoing focus on administrative modernization and regulatory agility. This approach would also enable the PMPRB to fulfill its statutory mandate while promoting increased alignment with other broad public policy considerations, including but not limited to the Government of Canada's Biomanufacturing and Life Sciences Strategy.

Given the extent of outstanding and unanswered practical questions, Pfizer would strongly support the design and tasking of joint working groups to explore options on various technical and operational matters that would be both effective and workable for all parties. This model has been used with great success in past instances and has enhanced the effectiveness of and patentee compliance with Board Guidelines.

Further, Pfizer would submit the following recommendations on the following issues:

- **Price Tests:** The most appropriate price test, for both existing and new medicines, should be the Highest International Price (HIP). This is the only price test consistent with and grounded in the Board's statutory mandate and affirmed by recent jurisprudence. Any price which falls within the PMPRB11 should be deemed non-excessive, given that the comparator countries have been set out for that reason. Other price tests may not be consistent with the Board's legal mandate of regulating non-excessive pricing and would be increasingly complex to administer.

- **Existing Products Transition:** Existing marketed products have already been compliant and should be transitioned as compliant going forward. The legislative basis of the PMPRB has not been amended, and the *Patent Act* non-excessive price factors remain identical as before. Consistent with the Board's approach to existing products including under its current "interim" measures, the HIP price test should continue to apply into the future in addition to the established Consumer Price Index (CPI) annual adjustment.

- **Treatment of Low-Risk Products:** There are a number of categories of products under the purview of the PMPRB, including patented vaccines, biosimilars, blood products, generics and over the counter (OTC) medicines, which warrant a differential and risk-adjusted compliance standard. Notably, the exclusive negotiation and purchasing regimes in place for vaccines and blood products, including tendering and joint contracting, greatly reduce the likelihood or possibility of an excessive price in the Canadian market. Pfizer supports the option identified in the Discussion Guide to treat these types of products on a complaints-only basis, reflecting their unique market and consumer characteristics and corresponding lower risk of non-excessive pricing.

As we have stressed throughout this process, the PMPRB should continue to strive towards a non-excessive pricing compliance regime which is efficient, effective and predictable for all system stakeholders, consistent with its mandate. Pfizer 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.

Continued stakeholder engagement is a critical success factor for the next iteration of the Board's Guidelines. We reiterate the extensive list of outstanding technical questions which merit much more in-depth consideration and external clarification (see for example the Appendix to the submission made by Innovative Medicines Canada).

Pfizer has sought to achieve and maintain complete compliance with all PMPRB regulations and Guidelines over time, and we would fully expect to continue that compliance on an ongoing basis. We are fully committed to working with the PMPRB to advance a workable and effective compliance regime that enables competitive market conditions in Canada for critical investments in medical innovation, clinical trials and new product launches for the benefit of all Canadians.

Please do not hesitate to contact me directly should you wish to discuss any aspects of this or future submissions.

Yours sincerely,

DocuSigned by:
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Karine Grand'Maison
Vice President, Access & Value