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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 Draft Guidelines Consultation

Dear Mr. Couillard,

Pfizer Canada ULC ("Pfizer") would offer a number of comments in response to the current PMPRB (Phase 3) Draft Guidelines consultation. This submission builds on our prior response in September 2024, and representations to the Board on future Guidelines, including those provided 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) and BIOTECanada. 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 the final Guidelines in the coming weeks and months.

At the outset, we commended the PMPRB for its stated objective of pursuing a Guidelines development process grounded in transparency, and procedural fairness and consistency. 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 Draft guidelines itself do not provide sufficient detail and predictability on critical issues. There remain outstanding questions as to how the Board would envision operationalizing its own proposals to allow for considered feedback.

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 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. As such, it is of critical importance that the HIP is maintained in the final Guidelines.

- **In Depth Reviews:** The level of Board staff discretion apparent in the overall approach detailed in the Discussion Guide, particularly for the proposed "in-depth" reviews are of concern. Absent appropriate direction, the unpredictable use of transient or context-specific compliance interpretations would run counter to the stated objective of predictability. Under the current proposals, there is no clear sense to patentees to predict the outcome of an in-depth review and PMPRB should provide written clarity to staff and patentees.

  One critical clarification pertains to the calculations of excess revenue. The uncertainty surrounding potential retroactive liability may influence corporate decisions regarding the introduction of new medicines in Canada. Therefore, considering the market's evolution over time, patentees' potential excessive revenues should be calculated only from the period in which an in-depth review or a complaint is received.

  Finally, given the potential resource intensive nature of in-depth review, the final Guidelines should establish common sense file resolution mechanisms. It is important that the guidelines incorporate reasonable buffers or tolerance factors, thereby avoiding unnecessary regulatory burdens when domestic prices remain stable. This will ensure the efficient use of PMPRB staff and patentees' resources.

- **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 treating these types of products on a complaints-only basis, reflecting their unique market and consumer characteristics and corresponding lower risk of non-excessive pricing.

- **Complaints:** The current draft proposes an automatic in-depth review solely based on the filing of a complaint. This process lacks transparency (unknown price test, no information shared, etc.), is inconsistent with the Patent Act, and is inappropriate. Such a proposal could lead to unintended consequences, such as arbitrary complaints, resulting in a significant increase in complaint volume, contentions, and an unnecessary review burden. Additionally, it is inappropriate to grant for-profit commercial insurance companies and their associations special status for complaints, given the lack of clarity in the current proposed Guidelines.

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 encourages 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 Board's Guidelines. An extensive list of outstanding technical questions remains which merit much more in-depth consideration and external clarification.

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