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Douglas Clark
Executive Director
Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
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Ottawa, Ontario K1P 1C1

Submitted electronically: *PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca*

**RE: Feedback on Draft PMPRB Guidelines (Version October 2022)**

Dear Mr. Clark:

Pfizer Canada ULC ("Pfizer") would like to offer our perspective with respect to the draft PMPRB Guidelines as released for stakeholder comment in October 2022. This submission is further to and builds upon our prior representations to the Board on this subject. We also emphasize at the outset that this submission is provided without prejudice to ongoing or any future litigation impacting both the relevant regulations and Guidelines.

Pfizer would underscore our full alignment with the concurrent submissions on this matter by our trade associations, notably Innovative Medicines Canada (IMC), BIOTECanada, and the Vaccine Industry Committee (VIC). Building on those submissions, Pfizer would like to highlight a number of key comments and recommendations for the PMPRB ahead of the potential implementation of new Guidelines in early 2023.

Overall, the draft Guidelines are highly problematic and warrant a substantial reconsideration. They are unduly destabilizing, complex in their application, and would certainly lead to any number of unintended consequences for both currently marketed and future medicines not yet launched in Canada.

The draft approach appears based on a fundamental misunderstanding of the limits on the Board's statutory authority and role. In addition to being operationally unworkable, these draft Guidelines stand in stark dissonance with the overall policy direction of the Government of Canada in support of health system resilience and the role of the life sciences sector in contributing to economic growth.

On a constructive note, Pfizer is supportive of the proposed treatment of vaccines and patented biosimilars on a complaints-only basis and would welcome the implementation of this approach. We would further encourage the Board to take a reasoned and proportionate approach to other structurally low-risk or highly managed product categories, including blood-derived products.

**On balance, and for the additional reasons provided below, Pfizer strongly recommends that the current draft Guidelines are set aside and reconstituted only following the appointment of the new Board Chair.**

Departure From Bright-Line Compliance

As currently construed, the draft approach represents a substantial and unwarranted departure from the PMPRB's established mandate and practices, as well as a rupture with the foundational guiding principles of the Board. Very early on, the Board recognized that the "most effective and efficient way to protect the public from excessive prices and achieve maximum compliance" was achieved by providing "clear, understandable guidelines that provide, to the maximum extent possible, certainty and predictability for patentees in the definition of excessive prices". In place of a "bright-line" compliance system which promotes voluntary compliance for both rights holders and Board staff, the current draft would introduce an unworkable, discretionary and needlessly adversarial approach. The operation of the Board's Guidelines cannot be entirely open-ended or situational.

While the existing Guidelines are far from perfect, the historical record demonstrates a very high level of patentee compliance since the Board's inception. This was largely due to the availability of, or ability to calculate, known and predictable price ceilings prior to product launches. In stark contrast, the draft Guidelines remove many important aspects of regulatory predictability in favour of a subjective, discretionary staff-centered approach.

Risk Of Exceeding Mandate

It is clear to Pfizer that implementing the proposed approach will result in lower prices that fall well outside of the Board's clearly defined legal mandate of regulating only for excessive pricing that rises to the level of patent abuse, as clarified by recent jurisprudence. The PMPRB is not empowered or authorized to act as a price negotiator or expenditure manager – but this will be the effective impact of the current draft.

The approach in the draft Guidelines is a clear regulatory over-reach and would risk violating the legal standard related to excessive pricing. Proposed operational concepts of "lower of" step well beyond the concept of "non-excessive." The effective result of the draft Guidelines as proposed would be an unpredictable and ongoing attempt to reduce prices arbitrarily. This is illustrated in the draft approach by removing the concept of innovation from any consideration by Board staff and by engaging in therapeutic class referencing, including against generic (multi-source) prices in certain instances.

Problematic Use Of dTCC Test

As proposed in the current draft, products priced above the domestic therapeutic class comparison (dTCC) test, irrespective of level of innovation or therapeutic benefit, can be subject to an automatic investigation. Paradoxically, even dTCC prices which fall under the lowest international price (LIP) threshold, that is the lowest known price compared to all other countries set in the regulation, could also end up being investigated by staff under the proposed approach. The dTCC is proposed to stand as part of the principal "Investigation Criteria," but can only ever be used to drive prices lower, including in circumstances where the dTCC falls well under the LIP.

There are further implications under the proposed use of the dTCC. Generic medicine prices in Canada are currently managed by the pan-Canadian Pharmaceutical Alliance (pCPA) through a different process which sets a Tiered Pricing Framework at the national level, reflecting prices often 75% to 90% lower than originator brand prices. Under the draft Guidelines, a new innovative drug

price could be investigated and possibly deemed excessive against a dTCC standard which includes very low generic prices. Using the dTCC in this way to lower the prices of new and innovative medicines is unrelated to regulating for excessive prices of patented medicines.

Lack of Impact Assessment And Policy Misalignments

The challenges with the proposed approach are compounded by the lack of any meaningful impact assessment to give the necessary context to the Board's proposals. The implications of these proposals for patient care, the medicines supply chain, the overall health system, and Canada's medical research establishment remain unassessed. The absence of this key information further undermines Pfizer's ability to support the draft Guidelines.

Further, the draft Guidelines fail to reflect, and may in fact damage, the Government of Canada's expressed policy intent to advance modern and agile regulatory frameworks and support a world-class biomanufacturing and life sciences sector.

The proposed Guidelines will also destabilize any ongoing work to develop and implement a national Drugs for Rare Diseases (DRD) policy by impairing the launch prospects for new DRDs. The positive potential and opportunity of a rare disease strategy will be more than outweighed by severe pricing measures that adversely impact the business case to launch such products in Canada. The draft Guidelines would advance an approach to price regulation which would leave Canada isolated and less competitive than other jurisdictions offering adapted or differentiated approaches to managing DRD access within their pricing and reimbursement systems.

Recommendation

**Consistent with the policy direction provided by the Government of Canada in 2022 surrounding the regulatory amendments pertaining to the PMPRB, as well as the clear direction of the Courts, Pfizer strongly recommends that the PMPRB immediately set aside the current draft and redevelop a new package of draft Guidelines that meet the existing policy objectives and operative legal framework. In addition to being consistent with the Board's limited mandate to regulate excessive price, the approach should be efficient, predictable and clear for all parties. A new set of draft Guidelines should be prepared only once a new Board Chair is appointed.**

Please do not hesitate to reach out to me directly should the PMPRB have any questions regarding the content of this submission. We look forward to the Board's timely reflections on the risks and limitations of the current approach to its Guidelines and the provision of much greater clarity for patentees prior to January 2023.

Sincerely,

DocuSigned by:
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