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Thomas J. Digby
Chairperson Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario K1P 7C1

Submitted electronically via the PMPRB portal.

RE: Pfizer Canada Submission – PMPRB Guidelines Scoping Paper

Dear Mr. Digby,

Pfizer Canada ULC ("Pfizer") welcomes the opportunity to offer our perspective in response to the current PMPRB consultation on the recently released Guidelines Scoping Paper (November 2023).

At the outset, Pfizer emphasises our full alignment with the concurrent submissions under this consultation by our trade associations, notably Innovative Medicines Canada (IMC) and BIOTECanada. Building on those submissions and our appearance before the PMPRB during its Policy Roundtable on December 6th, Pfizer would like to underscore several key aspects as the Board contemplates revised Guidelines in 2024.

As a general comment, there are a wide range of general issues and topics referenced in the Scoping Paper. However, in many instances it is challenging to provide specific feedback absent much more detail in the broader context: Raising a narrow question may elicit different responses contingent on the policy context and available information.

Overall, it is fundamentally important that Board Guidelines aim to promote a stable, predictable, and feasible compliance regime to the benefit of all parties. This is consistent with best practices for quasi-judicial agencies as well as ongoing efforts in support of regulatory modernization and agility at the federal level. This also reinforces the inherent value of early and ongoing stakeholder engagement in developing Guidelines, rather than a much later reactive, *post hoc* review of a close-to-final package.

Looking to the future, and with reference to the topic areas raised in the Scoping Paper, we would highlight the following priority considerations:

- **Board Mandate**. Pfizer encourages the Board to reaffirm and design future Guidelines based on its established mandate regarding excessive prices for patented medicines. This mandate is grounded in both the relevant legislation and the overall pricing and regulatory landscape in Canada. It has also been recently and unambiguously upheld by jurisprudence. Focusing and limiting future activities to this mandate will contribute to proper and effective allocation of Board resources while avoiding duplications of activities under the purview of different agencies and levels of government.

- ***Patent Act* factors**. Section 85 of the *Patent Act* prescribes specific factors for Board to consider in determining whether a given product price is non-excessive. Pfizer holds that each of the factors is important and should be considered to define introductory prices – different weighting between factors is not appropriate or supported by the Board's mandate.

  Within the list of factors, it is important to note that the Consumer Price Index (CPI) is included as a prescribed factor and should always be considered for the purposes of determining non-excessive prices. Future Guidelines should specify clear policies and rules with respect to price increases over time.

- **International Price Referencing**. The PMPRB has operationalized a regime of international price referencing and tests since its inception. The recent regulatory changes which came into force on July 1st, 2022, amended the list of countries to establish the current so-called "PMPRB11."

  Consistent with the Board's legal mandate, Pfizer strongly supports the use of the highest international price (HIP) test, which ensures consideration of the entire basket of reference countries. Therefore, any price which falls within the PMPRB11 should be deemed non-excessive given that the countries have been set out for that explicit purpose.

- **Transition Measures**. Pfizer recommends that patented medicines marketed prior to July 1st, 2022, that have already been subject to PMPRB jurisdiction since their introduction and that are not excessively priced according to the guidelines applicable at time of launch should be grandfathered from new Guideline requirements. The current interim measures could be extended into future guidelines: existing products could be determined as non-excessive, provided their national average transaction price (N-ATP) does not exceed the most recent non-excessive average price (NEAP), as adjusted by the CPI. Any post hoc adjustments may introduce unnecessary disruptions for patentees and the wider medicines supply chain, including generic manufacturers, wholesalers, distributors, and pharmacy.

- **Rebenching**. Price predictability and stability are important for all parties including but not limited to patentees. There are significant and highly consequential impacts downstream throughout the medicines supply chain when pricing is changed. Any rebenching exercise should be done infrequently by exception and only when significant variations are observed to minimize disruptions and any impacts on stakeholders.

- **Treatment of Unique Product Categories (Vaccines/Low-Risk/Rare Disease)**. There are well-defined and substantiated categories of patented products which are demonstrably lower risk from a non-excessive pricing perspective. These include vaccines, biosimilars, blood products, and patented medicines which have lost market exclusivity. In these cases, there are other well-characterized and highly effective market and reimbursement structures in place which substantively lower the risk of non-excessive pricing occurring. These include tendering, centralized procurement process and other competitive market mechanisms. Accordingly, and consistent with the PMPRB's excessive pricing mandate, Pfizer recommends that these categories of patented medicines are acknowledged in the future Guidelines and managed on a complaints-only basis for the purposes of investigations.

Further, the unique aspects of drugs for rare diseases should be recognized by the Board, as these medicines may typically feature unique clinical, evidentiary and market factors due to the pathology and levels of available expertise on certain conditions, health system capacity and heterogenous and much smaller patient populations. Future Guidelines should not negatively impact the Government of Canada's priorities and policy intent as reflected by the National Strategy on Rare Diseases.

Conclusions

As this Guidelines process evolves, Pfizer strongly encourages the PMPRB to ensure that its work is aligned with sustaining a modern and effective health system that aspires to offer the best possible health outcomes to Canadians. Canada is fortunate to offer many strengths within its overall life sciences ecosystem to sustain the critical innovation cycle spanning discovery, clinical trials, manufacturing and commercialization, product launches, and ongoing evaluation and reinvestment.

It is important to emphasise that timely and appropriate patient access to medicines is and must remain at the very centre of that ecosystem, particularly as ongoing and future research will depend on Canada offering access to the latest standard of treatment for many diseases.

Pfizer has been encouraged by the Government of Canada's adoption of its inaugural *Biomanufacturing and Life Sciences Strategy*. The Strategy recognizes that Canada is operating in a highly competitive global life sciences arena, and that there are substantial public benefits to fostering a world-class life sciences sector across both health and economic considerations.

Price predictability and market stability is a key consideration for Canada's ability to remain an early and compelling product launch country on the world stage. Once products are launched, pricing stability is a critical consideration to create incentives for manufacturers to invest further in research and additional indications.

Pfizer looks forward to future opportunities to contribute to a future PMPRB Guidelines approach that respects its mandate, promotes pricing predictability and ongoing compliance, and enables Canada's wider public policy goals with respect to the quality of care and the future growth of our life sciences sector.

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 and Value