Kirkland, February 14, 2020

Dr. Mitchell Levine
Chairperson of the Board
Patented Medicine Prices Review Board
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Ottawa, Ontario K1P 1C1

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

RE: Feedback on PMPRB Draft Guidelines

Dear Dr. Levine:

Pfizer Canada ULC ("Pfizer") would like to provide a series of formal comments with respect to the PMPRB's Draft Guidelines as part of the current consultation process. Our perspective on the Draft Guidelines is informed by our accumulated experience in the Canadian patented pharmaceutical market, including our longstanding compliance with the PMPRB's filing requirements and Guidelines since the Board's creation in 1987. Pfizer is one of the largest patentees in Canada.

At the outset, it is important to highlight key points of context regarding this submission. First, Pfizer's comments are offered without prejudice to its position in any litigation to which Pfizer is a party, including in relation to the recently amended *Patented Medicines Regulations*. Secondly, Pfizer would like to affirm our endorsement of the submissions offered by our industry associations on this matter, specifically Innovative Medicines Canada, BIOTECanada, the Vaccines Industry Committee, and the Biosimilars Forum. Lastly, the purpose of this submission is to highlight and emphasize certain aspects of the above-mentioned association submissions for the Board's consideration as it finalizes its Draft Guidelines.

Pfizer is providing PMPRB these comments against the backdrop of the experience of stakeholders during the pricing policy development process of the past number of years. Despite the large volume of stakeholder concerns and constructive proposals regarding regulatory and policy reforms for the PMPRB, we have seen essentially no meaningful incorporation of this feedback by either Health Canada or the PMPRB itself. This is extremely disappointing for stakeholders who have invested considerable time to participate in these processes in good faith with a constructive and collaborative mindset. Going forward, Pfizer requests that the PMPRB demonstrates transparently and explicitly how it has assessed and incorporated stakeholder feedback as the Draft Guidelines are revised or why PMPRB is rejecting stakeholders' feedback.

Our submission focusses on 8 specific areas of concern:

1- Draft Guidelines Fail to Reflect A Risk-Based Approach to Regulation

Although the PMPRB has referred to pursuing a "risk-based" approach to implementing the amended regulations, we believe the Draft Guidelines fall short of achieving this vision. Rather than accounting for the degree of market power possessed by a patentee or level of product innovation and clinical value for patients, the Draft Guidelines outline an approach based exclusively on cost, as expressed by anticipated revenues or price levels. This places PMPRB squarely in the realm of affordability considerations which currently fall under the purview of budget-holders making resource allocation decisions. This also results in pricing regulation substantially moving away from recognizing therapeutic innovation that encourages and fosters access to new innovative medicines. Pfizer remains deeply concerned by the negative implication of pricing reform as it currently stands and its impact on timely access to innovative medicines and vaccines for Canadian patients.

2- Median Price Tests Are Inappropriate and Do Not Support 'Grandfathering'

The proposed application of a median international price test for all drugs and a median therapeutic class test are both inconsistent with the well-established "excessive" price threshold as set out in the *Patent Act.* It is inappropriate to adopt a standard that presumes that all prices above the median of foreign prices or the median of existing drugs that treat a given condition are "excessive."

In the context of the Draft Guidelines, the reference to the concept of "grandfathering" is a misnomer. Under the Draft Guidelines, all patented medicines will be subject to a downward price adjustment with the change in the international price threshold from "highest" to "median." Moreover, the PMPRB has not provided clear evidence nor any comprehensive impact assessment in relation to this change.

3- Draft Guidelines Will Disproportionately Impact Innovative Therapies

Historically, the PMRPB has sought to promote compliance and certainty for all stakeholders using "bright line" guidelines. In contrast, the Draft Guidelines depart from this established approach. A patentee will no longer be able to calculate an allowable, compliant price with any degree of certainty prior to making the product available in the market. While the existing Guidelines allow for greater price flexibility for innovative products, the Draft Guidelines move in the opposite direction.

As proposed, the newest and most significant innovations to treat and cure diseases will be subject to a much higher degree of oversight and far more stringent price limitations. Pfizer Canada shares the deep concern expressed by our industry associations, other patentees and stakeholder groups that the lack of predictability and increased compliance burden on the most innovative therapies will directly contribute to delayed launches, or worse, inability to launch in Canada.

4- Many Patented Drugs Do Not Present Risk of Excessive Pricing to Canadian Consumers

As an example, tendered patented products (e.g. vaccines and blood products), are being included in the amended regulations. Pfizer would strongly encourage the PMPRB to pursue a truly risk-based approach appropriate to the level of market share and the realities of the current Canadian pricing and reimbursement system for these medicines. The existence of well-established, tender-based procurement systems is a more than adequate rationale to warrant either a complete exemption from the requirements contemplated in the Draft Guidelines or a wholly separate approach appropriate to their materially lower level of excessive pricing risk.

Another example of a low risk category is Biosimilars, as described in detail in the Canadian Biosimilars Forum's submission. Biosimilars with patents should be exempted from the proposed Draft Guidelines and be dealt with on a complaint basis, similar to multi-source generic medicines with patents.

5- Established Limitations with HTA Will Disproportionately Impact Rare Disease Medicines

With respect to drugs for rare diseases, the limitations of existing QALY-based HTA methodologies to assess value for money have been acknowledged in both Canada and at the international level.[1,2] The proposal to apply HTA principles, with only minor adjustments, fails to address the fundamental objections to the use of those tools. Without substantial revisions, the Draft Guidelines would unfortunately represent a major barrier to the availability of new drugs for rare diseases in Canada, which is counterproductive for Canadian patients.

Taken as a cumulative whole, the Draft Guidelines fail to provide the promised and required "bright line" guidance to patentees to allow for voluntary and sustainable compliance. It is unacceptable in our legal system to have a framework that lacks clarity on the expected conduct of patentees, and yet provide for quasi-penal consequences in cases of non-compliance. As evidenced by the level of concern and extent of stakeholder feedback provided to both Health Canada and the PMRPB since 2016, the lack of adequate and required clarity in these Guidelines will represent a major increase in regulatory burden for both patentees and PMPRB staff. This burden is due to the requirement for more frequent discussions and filing of additional information. This also suggests a related increase of the prevalence of lengthy and costly hearings which do not serve the interests of Canadian patients or other public agencies.

6- Draft Guidelines Lack Clarity and Operational Feasibility

Pfizer is very concerned with the Draft Guidelines lack of clarity, completeness, predictability, and the less than optimal operational feasibility of several key elements. To our knowledge, PMPRB has not yet provided detailed operational guidance using illustrative examples nor adequate clarity as to how patentees are expected to report newly required information. As a key example, the amended regulations mandate the filing of prices or revenues net of third-party rebates. However, many patentees, including Pfizer, do not typically know the actual rebate amounts until reimbursement agencies submit invoices. It is challenging – if not impossible – to file unavailable information. The invoicing process often occurs many months beyond the required filing date to the PMPRB, presenting a challenge to a patentee to provide accurate information which is not yet available. The burden of this requirement is amplified by the

[1] Nicod E, Annemans L, Bucsics A, Lee A, Upadhyaya S, Facey K. HTA programme response to the challenges of dealing with orphan medicinal products: process evaluation in selected European countries. Health Policy 123 (2019); 140-151

[2] Hyry HI, Stern AD, Cox TM, Roos JCP. Limits on the use of health economic assessments for rare diseases. Q J Med 2014; 107:241-245

practical necessity of adapting internal financial systems to collect, track, forecast, and report the required data. This later adaptation has been requiring expenditures that will continue to accrue over time and that exceed the unrealistic and narrow estimates made in the Health Canada Regulatory Impact Assessment Statement.

7- Draft Guidelines Represent Substantial Increases in Regulatory Burden and Uncertainty

The PMPRB's perceived reduction in regulatory burden on patentees related to this specific change is misleading due to the increased requirements contained in other aspects of the Draft Guidelines. We would further suggest that these new requirements are imprecise or misplaced and will result in an increase in resource intensive disputes for both patentees and Board staff. Examples of increases in regulatory burden for patentees include but are not limited to:

- The lack of clarity with respect to what to include as accurate information in filings related to net prices (as highlighted above);
- The addition of a median domestic and international therapeutic class price test and the need to align on appropriate comparator products and dosage regimens;
- The proposed calculation of a price point based on a health technology assessment (HTA), including how to resolve differing assumptions within the analysis and how to reconcile recommendations based on limited criteria or patient sub-populations; HTA is an exercise that is inherently characterized by tremendous uncertainty and has always served to guide decision making and not to establish definitive price points;
- The imprecise anticipation of market size and the onerous task of reconciling and re-submitting forecasts over a product life cycle fails to deliver on the promise of a more modernized, efficient approach in these proposed Draft Guidelines. For example, medicines and vaccines procured through the tender process, which could eventually outright win and/or lose a contract, would see their market size significantly impacted with no reassessment of Median Retail Price (MRP).

8- Additional Regulatory Burden Conflicting with Treasury's Guidelines

In addition, Pfizer submits that the additional burden on patentees created by the proposed reforms go against the Government of Canada Treasury Board Secretariat's new directives on regulations that aim to promote an agile regulatory system that is predictable, efficient, and consistent. Further, it also completely undermines the implementation of the recommendations from the Federal Government's *Bioscience Economic Strategy Table Report* (HBEST) with respect to regulatory modernization and the laudable aspiration to double the total annual amount of equity capital invested in the Canadian health and biosciences sector to $2 billion by 2025.

And to state once again: the implementation of the guidelines in their current state would inevitably cause product launch delays, or worse, inability to launch in Canada.

Our short term ask: Adoption of New Guidelines Should Be Deferred

Consistent with industry association submissions, Pfizer requests that the PMPRB defer the adoption of the Draft Guidelines until the PMPRB follows through on their commitment to create working groups until a better understanding of the impact is established and to ensure the operational ability of patentees to be compliant with a new regime. Considering these significant and unresolved issues, Pfizer Canada and relevant stakeholders recognise that in the interim, the Board retains powers under the existing regime to fulfill its mandate and address any specific product situations of concern.

Thank you for your consideration of our feedback. Please do not hesitate to contact me directly should you have any additional questions for Pfizer Canada regarding this submission and the future evolution of the Guidelines.

Sincerely,

DocuSigned by:
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C.C.:
Doug Clark, Executive Director