August 3, 2020

Dr. Mitchell Levine
Chairperson of the Board
Patented Medicine Prices Review Board
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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 offer our perspective with respect to the PMPRB Draft Guidelines released in June 2020. This current submission builds on our prior representations to the Board on this subject, the most recent one submitted in February 2020.

At the outset, we have taken careful note of the PMPRB's 2018 Annual Report (the latest edition currently available) as our point of reference for our assessment of the Guidelines. The 2018 report found that patented medicine sales declined in 2018 by 0.6% to below 60% of all medicine sales. Moreover, the PMPRB notes that, "In 2018, the increase in patented medicine prices was, on average, less than the rate of inflation, as measured by the Consumer Price Index (CPI), and therefore, did not contribute to sales growth."[1] The policy rationale often referenced to justify the changes to the PMPRB Guidelines is not well supported by recent Canadian market evidence as outlined in the 2018 Report.

Consistent with our prior correspondence to you, Pfizer's present submission is being made without prejudice to any ongoing litigation with respect to the PMPRB's regulatory framework. This is a highly relevant issue given the decision of Justice Manson at the Federal Court in June 2020 that certain aspects of the PMPRB's regulatory framework are *ultra vires* the *Patent Act.* Pfizer endorses the submissions from Innovative Medicines Canada, BIOTECanada, Biosimilars Forum and the Vaccine Industry Committee, especially as they relate to the implications of this specific issue for the future of the Guidelines. It is our view that not only does the Justice Manson decision undermine a key foundation of the PMPRB's proposed approach, namely the Maximum Rebated Price (MRP) concept, it reinforces the argument that a more fundamental reformulation of the Guidelines is urgently required. Policy impact should not be conflated with complexity. It is our view that a major reconstruction of the Guidelines is warranted in order to ensure consistency with the statute and to reflect customary

[1] PMPRB 2018 Annual Report, p. 38.

standards of regulatory efficiency, predictability, and overall compliance feasibility for all stakeholders, including Board staff.

Prior to offering our specific comments on certain aspects of the Guidelines, it is also important to take note of the broader policy and public health context in which we are all working. Canada's ongoing experience with the COVID-19 pandemic has underlined the challenges and vital importance of advancing innovative treatment options for human health, including novel vaccines and other therapeutics. All stakeholders – governments, citizens, healthcare providers – have rightly approached this problem with a primary focus on availability and access to treatment. At Pfizer, we are proud to have mobilized the full scale of our global resources to respond to this societal challenge, but we recognize that we cannot succeed in isolation. Collaboration and timely access to innovation will be critical to advancing and deploying treatments for COVID-19, in addition to ensuring that Canada is in the best possible state of preparedness for any future public health threats.

Despite the current public health challenge, it remains our sincere hope that Canada will continue to stand as a leading jurisdiction for private sector research and development, clinical trials and new product launches. Pfizer is concerned of the negative consequences the regulatory changes may have on Canada's life sciences and research investment ecosystem. Rewarding advancement in medicines is not just an urgent health imperative but also a key component of any eventual economy recovery and normalization of daily life.

Pfizer would like to highlight the following specific aspects of the current draft Guidelines, consistent with our previous submissions and recommendations to the PMPRB.

The Guidelines Do Not Reflect A Risk-Based Approach

Despite the overwhelming feedback and recommendations provided during the previous consultation period, we are disappointed that on balance the current iteration of the Guidelines do not align with the prior public comments made by the PMPRB with respect to a risk-based approach. Pfizer acknowledges and welcomes the proposals in the current draft to handle biosimilars and patented generics in a differential manner (complaints-basis only). This is a welcome and important recognition of risk-levels and market mechanisms already in place and functioning in Canada for those products. There is remaining opportunity to extend this approach to other, comparably differentiated product categories, in order to focus Board and patentee resources on compliance in the areas of greatest potential concern.

The separate acknowledgement by PMPRB elsewhere in the proposed Guidelines that both vaccines and blood plasma products face a structurally separate market context, notably the mandatory application of tendering for procurement and reimbursement purposes, is a very modest but warranted step. However, the application of the unique elements of these products falls well short of what would be appropriate given the characteristics already acknowledged by the PMPRB. It provides no meaningful purpose to limit the recognition of the circumstances for those products to only that Board staff "may" consider the existence of tendering in the context of an investigation. We submit that the discretionary nature of this recognition (which we address in more detail below) provides minimal comfort and predictability for vaccine and blood plasma product patentees, already challenged to navigate monopsonist purchasing structures for their products in Canada.

We are unclear on the source of hesitation and the disconnection of separately acknowledging the different circumstances for some product categories without providing details in the draft Guidelines to account for those differences. At an absolute minimum, both vaccines and blood plasma products should be limited to Category 2. Pfizer would recommend that the PMPRB consider going much further, as has already been established for biosimilars and patented generics, by explicitly directing those product categories to be addressed on a similar complaints-only basis.

Proposed Price Tests Inconsistent With "Grandfathering"

Contrary to feedback submitted during the prior round of consultations, the use of "lower of" price tests have been retained to impact all patented medicines including those that received Notice of Compliance (NOC) prior to August 2019. This basic element of the PMPRB's approach undermines any claim that "grandfathering" is being applied to any category of medicines in the draft Guidelines.

This shift away from "excessive price" to something different, including the application of multiple price tests in Category 1, lacks any explanation or adequate foundation and is a major contributor to the overall complexity and impracticality of the proposed approach to the Guidelines offered to date.

Guidelines Will Disproportionately Impact Innovative Therapies

The disproportionate impact on the products addressing the most urgent health needs, for example rare diseases with limited or no treatment options, remains a serious shortcoming in the Board's proposed approach. This has been consistently identified by stakeholder as a concern from the outset of this process and was a specific focus of the last round of consultation feedback from Pfizer and many others. While we note that PMPRB has made certain minor adjustments in the current draft Guidelines (e.g. to the specified thresholds for new price tests and other similar elements), the larger concern remains valid.

The PMPRB's recognition of the differential clinical and market context for different types of products is welcomed, but the relatively small changes in the current draft do not go far enough in properly recognizing and accounting for these differences. Pfizer would recommend that additional work is urgently required in this area, which would benefit from a collaborative approach to policy development with patentees and other stakeholders to ensure the unique elements of those products are adequately reflected in the Guidelines.

The PMPRB has acknowledged that the prior draft would have resulted in a very large percentage of all new products falling under Category 1, and that some adjustments have been made to decrease this share in the current draft. This recognition is important in that it supports our ongoing contention that the use of these tools, in the manner contemplated by the PMPRB, is extraordinary for a quasi-judicial body and is fraught with operational challenges. Moreover, the consequence of the application of these tools will be of significant concern for all stakeholders as increased complexity and uncertainty for new product launch calculations negatively impact Canada's designation as a tier one country for access to innovation.

The current draft Guidelines contain some adjustments to the proposed application of pharmacoeconomic tools (e.g. the increase in certain thresholds). Pfizer reiterates that the rigid application of these calculations is not appropriate in a regulatory context independent of budget-holders and other broader public policy and societal perspectives (and accountabilities). These tools are

not used in the manner proposed by the PMPRB in any jurisdiction in the world, with good reason: these tools and methods were never designed for regulatory, price-setting activities, but rather to inform and provide helpful context for policy decision-making by budget-holders.

Guidelines Remain Highly Complex with Questionable Operational Feasibility

Rather than streamline and simplify its proposed approach, we are concerned about the movement to introduce increasing layers of complex calculations at different time frames. The PMPRB has not established the necessity of pursuing such a complex approach, and Pfizer (and others in our industry) have been challenged to assess the full impact of the PMPRB proposals on our current portfolios and product pipelines. This is a challenge given the limited time frame before the new regulations take effect.

We are also concerned at the notable increase in Board staff discretion being inserted into the Guidelines and the overall compliance process. Increased discretion for Board staff – especially in subject areas beyond their mandate or competence (such as scientific and clinical determinations of levels of therapeutic improvement) - requires further consultation with all stakeholders. This increase in staff discretion is inconsistent with a regulatory approach to commercial decision-making for patentees and will not contribute to predictability and greater compliance. It also confuses and calls into question the future role and relevance of the existing expert Human Drug Advisory Panel (HDAP).

Combined with a substantially higher burden on compliance being placed upon patentees, and the continuing absence of key information such as filing requirements, submission portals and related specifications, we question the benefit and necessity of designing a process which increases complexity and uncertainty with unresolved questions about implementation and expectations for patentees.

As an agency of the Government of Canada, we would encourage PMPRB to take greater note of the ongoing Government-wide efforts, principally directed by the Treasury Board Secretariat, to modernize and streamline regulations.[2] Indeed, the approach being proposed by PMPRB not only increases compliance complexity and burden on patentees by many orders of magnitude, it fails to offset these changes with any commensurate and appropriate reductions elsewhere within the compliance framework. An updated cost-benefit analysis outlining the burden of implementation for patentees has not been provided in the context of the draft Guidelines.

[2] See for example, "*Canada revamps its Directive on Regulations - more agile, transparent, and responsive so businesses can thrive*" (News Release, September 7, 2018). https://www.canada.ca/en/treasury-board-secretariat/news/2018/09/canada-revamps-its-directive-on-regulations---more-agile-transparent-and-responsive-so-businesses-can-thrive.html

Finalization of Guidelines Must Be Deferred

Apart from specific content, we would encourage the PMPRB to approach the modernization of its Guidelines from the perspective of prioritizing predictability, simplicity, and operational feasibility. There has been limited recognition of the viability and utility of adjusting the application of Guidelines to different product categories and market conditions, but far more movement is required in this regard.

Against the backdrop of questions raised regarding the legal foundation for the PMPRB's proposed approach to its Guidelines, Pfizer respectfully submits that a more fundamental redesign is warranted. For all products, the PMRPB should seek to anchor to principles that establish a predictable and reasonable pricing floor.

Accordingly, Pfizer reiterates our previous request that the PMPRB defer the adoption of the Draft Guidelines until appropriately inclusive working groups are established to quantify impacts of possible changes to the Guidelines while ensuring operational clarity and compliance predictability. The Board would retain its 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:
Cole C. Pinnow
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Cole Pinnow
President, Pfizer Canada

cc: Douglas Clark, Executive Director, Patented Medicine Prices Review Board