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Kirkland, June 21st, 2021

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 Guidelines Modernization and Evaluation Plan (GMEP)

Dear Dr. Levine:

Pfizer Canada ULC ("Pfizer") would like to offer our perspective with respect to the PMPRB Guidelines Modernization and Evaluation Plan "GMEP" as released for comment in May 2021. This submission is further to and builds upon our prior representations to the Board on this subject. We would also emphasize at the outset that this submission is provided without prejudice to ongoing litigation impacting both the relevant regulations and Guidelines.

The revised Guidelines raise several serious concerns and questions for Pfizer. First, the Guidelines are excessively broad and fail to reflect an efficient, risk-based approach to the Board's operations. Pfizer and others have highlighted opportunities during the consultation process to frame the Guidelines in a much more proportional and efficient manner linked to risk and Canadian market realities, but unfortunately the final package fails to reflect adequately this approach. Stakeholder feedback throughout the policy development process has not been adequately incorporated into the final Guidelines package.

Pfizer also remains concerned that, as currently structured, the Guidelines will disproportionately impact and raise new compliance challenges for the most innovative treatments focused on unmet medical needs. With such a high degree of complexity, the Guidelines present a substantial regulatory burden on patentees while also raising issues of operational feasibility and consistency for Board staff. Accordingly, our position remains that both the regulations and Guidelines should be deferred pending substantial amendments to address these identified issues linked to clear public policy objectives for Canada.

GMEP Scope Recommendations

In respect of the proposed GMEP framework and forward plan, we are supportive of the concept of tracking and measurement in circumstances where a clearly defined target and objective has been established for all stakeholders. Unfortunately, the new regulations and Guidelines have yet to be connected to any evident policy objective or specific intended outcome.

The proposed scope of work within the GMEP is exceptionally broad with many aspects falling well outside of the Board's expertise. Pfizer would encourage the PMPRB to remain focused on and limited to

those subject areas and activities which have been clearly established and defined as its operational mandate. Broader horizontal policy questions and impacts are more appropriately within the purview of Health Canada or other public agencies with correspondingly relevant mandates and expertise.

Based on a close review of the proposal, Pfizer recommends that PMPRB concentrate its evaluation efforts to an assessment of list pricing linked to the implementation of the new Guidelines. Specifically, this work should address the application and impact of the revised list of international comparator jurisdictions. We would also be supportive of a transparent reporting of performance standards related to compliance activities.

The overall GMEP exercise will benefit from the involvement and contribution of other relevant pricing and reimbursement stakeholders, each with established mandates, capacity and recognized expertise. For instance, we would strongly encourage PMPRB to partner with acknowledged and independent expert agencies such as Statistics Canada, the Department of Innovation, Science and Economic Development (ISED), Health Technology Assessment bodies such as the Canadian Agency for Drugs and Technologies in Health (CADTH) and others to map existing tools and appropriate data sources for inclusion in any monitoring activities. Duplication or reinvention of pre-existing information and procedures should be avoided. Moreover, attempts to monitor and analyze impacts on the wider, multi-faceted Canadian reimbursement system and life sciences ecosystem should be avoided given they fall well outside of and beyond the PMPRB's role and expertise.

Key Measurement Principles

Given the absence of a clear policy objective, we would encourage the GMEP process to remain consistent with certain key principals already embedded within the revised Guidelines. Notably, we would emphasise the value of the GMEP focusing on the core issues of **Transparency** and **Predictability** for implementation purposes.

With respect to **Transparency**, the integrity and impartiality of the PMPRB as a quasi-judicial body should remain an essential basis of its entire process and operations, including in its public communications. The GMEP evaluation should clearly establish and monitor the performance of key basic operational elements of Board activities including products under jurisdiction by year, the content, frequency and utility of PMPRB Newsletters, and in ensuring that the PMPRB Annual Report is being prepared and provided to the Minister of Health in a timely fashion. Service standards with respect to the processing of information from patentees, managing investigations, and external correspondence and communications should also form part of this monitoring. These essential activities are an important area of focus for greater transparency given the observed performance variability in recent years.

With respect to **Predictability**, much greater clarity is required for patentees and other stakeholders in regard to the timing of various compliance process elements, the projected number of investigations, the management of questions or enquiries from patentees, the number, source and outcome of external complaints, and any other relevant or published performance standards.

Administrative Burden

The projected administrative burden on patentees to engage with and comply with the new Guidelines is considerable. As has been conveyed to the Board repeatedly during the consultation process, we question the purpose and value of the volume of information required for filing which is not of typical use

or priority to the Board. We would include in this category filing information for vaccines, biosimilars, low-cost patented medicines.

There remains a lack of risk-adjusted consideration in managing the required resources to prepare, submit, and assess these types of information for both patentees and Board staff alike. We are not aware of any intention to incorporate analysis of estimated maximum utilization or expenditure for many of these product categories, which would help define the scale of the situation and possible areas for a reduction in regulatory burden for all parties.

The GMEP should include a measurement of the compliance burden on patentees in addition to compliance performance in order to help determine whether certain activities will remain useful to the PMPRB in the future. Finally, we would be strongly supportive of directly linking the broader public sector efforts to establish agile and efficient regulations, as directed by the Treasury Board Secretariat, against the scope and findings of the GMEP. Clearly, the regulations and proposed guidelines have *not* aligned with these Government-wide objectives with respect to the importance of agile and evidence-based regulations in support of a fair and competitive economy.

Conclusion

The proposed GMEP would benefit from refocusing on relevant information and impact measurements in subject matter areas where the PMPRB has clear jurisdiction and expertise. Most immediately, these would include list price tracking and comparisons and price review processes.

Broader policy considerations which necessarily extend well beyond the PMPRB's role and mandate should be undertaken by other public agencies. The impact of the PMPRB regulatory changes and its associated Guidelines on the wider life sciences ecosystem is an important topic and one which demands the participation of other agencies of the federal and provincial governments, including Health Canada and Innovation, Science and Economic Development (ISED). These worthy activities will require an up-front alignment across stakeholders of the shared policy intent and objectives against which any public policy would be assessed.

We appreciate your consideration of this submission and would welcome any further questions or opportunities to elaborate on our recommendations directly with the Board and PMPRB staff.

Sincerely,

Cole C. Pinnow
President, Pfizer Canada