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August 31, 2021

Dr. Mitchell Levine
Chairperson of the Board
Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario K1P 1C1

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

RE: Feedback on Notice and Comment - Proposed Amendments to the PMPRB Guidelines

Dear Dr. Levine:

Pfizer Canada ULC ("Pfizer") would like to offer our perspective with respect to the Notice and Comment on proposed amendments to the updated PMPRB Guidelines as released on July 15, 2021. This submission is further to and builds upon our prior representations to the Board on this subject. We would also emphasise at the outset that this submission is provided without prejudice to ongoing or future litigation impacting both the relevant regulations and Guidelines.

Pfizer would like to note our full support and alignment with the submissions being made by our industry associations, notably Innovative Medicines Canada, BIOTECanada, and the Vaccine Industry Committee on this matter.

Pfizer strongly opposes the proposed Guideline amendments in respect of "grandfathered" medicines and the reversion to a six-month transition period for patentee compliance. The proposed shift in calculating a Maximum List Price (MLP) based on the Median International Price (in place of Highest International Price) for grandfathered medicines first filed prior to June 2021 is highly unexpected and conflicts with the Board's role to regulate excessive prices.

It is particularly concerning that the breadth of proposed changes – and the intent to proceed with them irrespective of any coming-into-force of the amended regulations – have not been explained in a transparent manner and are being proposed without any stated rationale or supporting analysis. We further note that there was no prior discussion of such a major change in the treatment of grandfathered medicines at the time of the last adjustment to the coming-into-force of the new regulations.

Additionally, the proposed transition period had only just been established by the PMPRB at twelve months (two filing periods) given the complexity of potential changes required for patentees to ensure compliance with the new Guidelines. There has been no further information provided in the current Notice and Comment as to why the PMPRB has reverted to a six-month transition, which as previously communicated will represent a substantial compliance burden on patentees in a relatively compressed time frame.

Fundamental Change in Established PMPRB Convention & Ways of Working

There have been various updates to the PMPRB Guidelines since the Board's inception in 1987, but never have changes of such major impact for patentees been made with such haste and in the absence of a corresponding regulatory amendment and supporting rationale. These changes represent a regressive and stark shift in the PMPRB's established mandate as a quasi-judicial body, moving away from its longstanding voluntary-compliance approach when working with patentees in favour of a proactive, market intervention approach targeting previously compliant products. Indeed, through these proposed amendments to its Guidelines, the PMPRB would directly and inappropriately insert itself into the policy-making process and move far beyond its established mandate of addressing patent abuse in the form of excessive prices.

Drastic Impact to Industry, Public-Private Collaboration

The Government of Canada's rationale when announcing the most recent delay to the coming-into-force of the PMPRB regulatory amendments was clear: to avoid placing undue stress and distraction on the pharmaceutical industry during COVID-19.

> ***The Government of Canada is mindful that the COVID-19 pandemic continues to challenge all stakeholders, especially in consideration of the unexpected impact of the third wave. For this reason, the coming-into-force date of the Amendments to the Patented Medicines Regulations has been delayed by an additional six months, to January 1, 2022. This delay provides industry with additional time to prepare for and comply with the changes introduced in the amendments.***

In contrast, the proposed amendments to the Guidelines will exacerbate the very stress and distraction on patentees that the most recent regulatory delay was intended to mitigate. This fundamental disconnect is incoherent in both policy and operational terms. Despite the major impacts flowing from these proposals, it is unusual and regrettable that there has been no rationale provided or impact assessment offered to analyze the effects that these proposed Guidelines amendments will have on patentees.

The unexpected manner in which the proposed Guidelines have been brought forward lies in stark contrast to the collaborative relationships that have been fostered between our industry with various Government of Canada Ministries throughout the COVID-19 pandemic. Canada's experience during the last number of months has highlighted the critical need for government and industry to work collaboratively to address health care challenges with major policy implications together. The current Guidelines proposals would greatly undermine that work and send an unjustified and negative signal to our industry on the global stage. Questions will be raised with respect to the real purpose and motivation for this last-minute change, and whether non-policy related factors explain such an unusual staff decision from a quasi-judicial agency.

Conclusion – Collaboration Required for Sustainable Solutions

This haphazard and erratic approach to amending the Guidelines is generating additional uncertainty for all stakeholders. This approach also falls well short of the established standards for policy development and consultation by the Government of Canada for any sector of the economy. The Notice and Comment represents a drastic departure from both prior PMPRB practice and the evolving approach in the proposed new Guidelines as set out as recently as October 2020. Policy reversals of this magnitude simply cannot be introduced in this manner. These proposals would bring about significant disruption for an industry that continues to act as a central pillar of Canada's healthcare system during this period of unprecedented uncertainty for public health, our economy and society as a whole.

We remain steadfast in our opinion that optimal pricing reform is achieved through collaboration aimed at finding sustainable solutions for all stakeholders. As such, and at a minimum, we strongly encourage the PMPRB to reconsider its approach to its Guidelines and not proceed with the proposed changes in respect of the calculation of the MLP and restore the previously established twelve-month transition period for patentees. As an alternative, Pfizer's preference would be to extend the pricing regulatory practices of the past that were established on the principle of collaboration between regulators and the patentees, which would allow for a co-creation approach of rules that are sustainable for all parties and stakeholders.

Sincerely,

DocuSigned by:
Cole Pinnow
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Cole Pinnow
President
Pfizer Canada ULC