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Pfizer Canada Inc.

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VIA EMAIL (pmprb.consultations.cepmb@pmprb-cepmb.gc.ca)

Mr. Douglas Clark, Executive Director
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

***SUBMISSION TO THE PMPRB – Rethinking the Guidelines* Consultation**

Dear Mr. Clark,

Thank you for the opportunity to contribute to the consultation on the proposed modernization of the Patented Medicine Prices Review Board (PMPRB or "the Board") Compendium of Policies, Guidelines and Procedures. Given that the PMPRB was established nearly 30 years ago, we welcome this consultation initiative, which we trust will lead to a modernized quasi-judicial tribunal that supports the best interests of Canadians.

As a leading biopharmaceutical company with a wide-ranging portfolio of innovative medicines, consumer products, vaccines and multi-source products, Pfizer Canada ("Pfizer") has extensive experience in the Canadian health care sector. In addition to this submission, Pfizer has contributed to and supports the submissions of our industry associations[1].

The Board's consultation process is aligned with the priorities set forth by the federal government. It is the first phase of a public policy dialogue where timely patient access, value of medicines and pricing of patented medicines and vaccines is being reviewed and modernized. While timely, the issues raised in the Guidelines modernization discussion paper are beyond the reach of any single agency with a number of intersecting interests at play[2]. We believe that if the Guidelines modernization framework overreaches, the Board's application of its mandate may be questioned, risking its ability to successfully regulate (and define a "bright line") non-excessive pricing in Canada.

The dialogue on Guidelines modernization was advanced and clarified significantly on September 30, 2016, at the Board's industry outreach session. Based on our understanding from this session, specific insights regarding the modernization initiative include:

1. ***The policy challenges and objectives need to be clearly understood and communicated****:* The Board is making an effort to determine the problem and objectives that will help guide the development of

[1] Include Innovative Medicines Canada, BIOTECanada, and BIOTECanada's Vaccines Industry Committee (VIC)
[2] Patented Medicines Price Review Board, *PMPRB Guidelines Modernization – Discussion Paper* – June 2016, Rethinking the guidelines, 2016 See LINK.

policy options to address specific challenges. The Board wants to be guided by an important purpose and have tools that are relevant and pragmatic so that it can achieve this purpose.

2. ***The Board is seeking to define its role in a broader policy context****:* The Board wants to determine its specific role in reviewing patented medicine prices to contribute to the affordability and access challenges faced by health system stakeholders; this means not duplicating the roles of other agencies, such as Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH), the pan-Canadian Pharmaceutical Alliance (PCPA) and other drug evaluation organizations and agencies.

3. ***There are no pre-determined solutions****:* The Board appears to be considering increasing its regulatory oversight of high-cost, specialty drugs, and reducing the regulatory burden on all other medicines that represent a significant proportion of the DINs reported to the Board.

4. ***Guidelines modernization could help streamline the price review process in part by making it more flexible****:* The Board wants to change how it reviews prices to determine whether they are excessive by developing less formulaic guidelines (e.g., increase staff and Board flexibility and only apply a regulatory approach to areas of significant concern from a consumer protection perspective using a pragmatic "bright line" principle to define non-excessive pricing).

5. ***Consultations will be broad in scope and outreach****:* This is an open consultation to discuss all possible options, and the discussion will include a wide range of stakeholders.

In this context, Pfizer is pleased to provide additional comments to the input provided by our industry associations:

1. ***Reduce the regulatory burden, duplication and oversight for products at low risk of monopoly power***:

    a. We agree with the Board that it should decrease its regulatory and remedial oversight for medicines that have a low risk of abuse of monopoly, for a number of reasons:

        i. this approach is aligned with the federal government's objective to improve the ease of doing business in Canada;

        ii. patented medicine reimbursement in Canada has evolved since the creation of the PMPRB. The pan-Canadian Pharmaceutical Alliance (pCPA) already acts as the gatekeeper of the affordability of medicines. Specifically, the pCPA has monopsony power and negotiates on behalf of public payers, resulting in confidential value transfer to provinces, whose beneficiaries include vulnerable patients.

        iii. In particular, we believe that a reduced pricing regulatory review could be applied to products such as multi-source products, blood products and vaccines that are already subject to constraining procurement policies and, therefore, pose a reduced risk of excessive pricing.

2. ***Predictable market and commercialization pathways****:*

    a. While Pfizer welcomes a more flexible and "risk-based" system with mutually agreed upon parameters, patentees require market certainty and predictability with respect to non-excessive pricing throughout a product's lifecycle. We support the Board's pragmatic "bright line" approach to non-excessive pricing, as was shared with participants of the September 30 industry outreach.

    b. Pfizer believes that a market-based lens should be applied to any proposed revisions or changes to the Guidelines, with a number of core objectives:

        i. encouraging competition within therapeutic classes;

        ii. incentivize patentees to launch new products in areas of high unmet medical need (Canada should aim to be an early adopter of promising innovations; after regulatory

approval, it is currently lagging behind in time to reimbursement by an estimated 449 days, on average, compared to a basket of 20 OECD countries)[3];

iii. appropriately rewarding incremental innovation, which builds towards long-term improved health outcomes;

iv. applying global best practices to pricing policy related to orphan drugs (these medicines already face several important hurdles for development and commercialization in Canada; applying a more restrictive price ceiling may add an additional barrier); and

v. applying modernized Guidelines to patented medicines that are currently within guidelines should not result in products being deemed excessive, in order to provide reasonable business certainty to patentees.

3. ***Create a supportive pricing platform for innovative reimbursement approaches****:* The Guidelines should be adaptable to emerging new technologies as well as a fast-evolving pharmaceutical and payer regulatory environment, in which price is just one element. For example, reimbursement models are becoming increasingly focused on paying for outcomes or coverage with evidence development.

4. ***Enhance development and adoption of health information technology (IT)****:* Global best practices for health information IT related to prescription medicine expenditures, utilization and impact should be considered.

5. ***Analyze more specific policy options before draft Guidelines are developed****:* Pfizer believes a series of industry working sessions with Board staff should be held in the short term before any proposed changes to the Guidelines are submitted for approval. Collectively, we can identify pragmatic and effective solutions that can serve as a stepping stone to ensure a continued high level of compliance, consistent with what was achieved throughout the Board's history.

6. ***Continue consulting broadly through multi-stakeholder forums****:* Given that the issues raised in the discussion paper are beyond the reach of any single agency, we are encouraged by the Board's commitment to consult with a full range of stakeholders. We believe that this approach will achieve the Board's objective to remain relevant and contribute to improve patient outcomes while limiting duplication in our healthcare system.

Thank you for providing Pfizer with the opportunity to make a submission on how Canada can modernize the non-excessive pricing review process for patented medicines. This is a timely initiative that offers interested stakeholders the opportunity to input on the Board's ability to continue fulfilling its mandate to Canadians, while also supporting a sustainable biopharmaceutical and innovation economy.

Pfizer looks forward to working with you and other stakeholders to ensure that the Guidelines modernization leads to optimal outcomes for Canadians.

Sincerely,

John Helou
President
Pfizer Canada Inc.

[3] Innovative Medicines Canada, *Access to new medicines in public drug plans: Canada and Comparable Countries*, 2016 Annual report See: LINK.