December 2, 2022

Dr. Mélanie Bourassa Forcier
Interim Chair
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Re: Consultation on the 2022 proposed updates to the PMPRB Guidelines

Dear Dr. Bourassa Forcier,

Gilead Sciences Canada, Inc. ("Gilead") appreciates the opportunity to provide feedback on the 2022 proposed updates to the PMPRB Guidelines. We believe the proposed Guidelines greatly reduce certainty and clarity for Canada's pharmaceutical industry and will negatively impact the ability of Canadians to access innovative patented medicines. We are calling for additional meaningful consultation to address the issues with the current proposal.

The proposed PMPRB Guidelines increase business uncertainty and reduce the ability to efficiently achieve patient access

For more than 30 years, the PMPRB has provided companies in the pharmaceutical industry with guidance that has enabled them to establish launch and post-launch prices for patented medicines. The current proposed updates remove this level of certainty, leaving companies without any guidance on pricing medicines at what the PMPRB defines as a non-excessive price in Canada. As such, under the proposed framework, companies must set their prices and sell their medicines with the ever-present risk of being found to have excessive prices. In doing so, the Guidelines have created a scenario in which the establishment of a non-excessive price to the PMPRB is accomplished **only** on a case-by-case basis, thereby imposing an inordinate and unnecessary amount of uncertainty on the pharmaceutical industry which, in turn, will create a barrier to access to innovative medicines for Canadians.

New approach disincentivizes industry to bring new medicines to market and invest in future indications

The business challenges created by the proposed Guidelines are further exacerbated by the introduction of the potential reassessment of list prices with the launch of new indications. The PMPRB's introduction of this new approach, without establishing clear guidance on how list prices will be assessed following the introduction of new indications, creates a disincentive for companies to bring innovative medicines to Canadians or to invest in expanding these medicines into new indications. This added uncertainty does not support the Government of Canada's priority of building a strong life sciences sector and a more resilient healthcare system.

Proposed Guidelines disproportionately impact innovative medicines

With the proposed Guidelines, the PMPRB will no longer consider the value innovative therapies bring to patients and our society in its assessment. Previous iterations of the PMPRB Guidelines

have recognized that the selection of comparators cannot be accomplished without also considering the level of therapeutic improvement offered by each comparator. The approach that has been adopted in these Guidelines disincentivizes the launch of medicines that offer the largest benefit to Canadians, as they are the most likely to have comparators that are inexpensive but significantly less effective. In these situations, companies can expect to dedicate time and resources addressing investigations with Board Staff, entering into expensive Undertakings, or engaging in long and uncertain Hearings. None of this supports efforts to provide Canadians with timely access to the world's most innovative medicines.

The proposed Guidelines exceed the agency's mandate of ensuring no abuse of a patent monopoly by no longer assessing prices to determine if they exceed international comparative price thresholds

The PMPRB's mandate is to ensure the prices of patented medicines are not excessive [1]. This has been confirmed by both the Federal Court of Appeal and the Quebec Court of Appeal; the mandate of the PMPRB is not to regulate prices through determining "reasonable" pricing nor is it to act as a consumer protection agency. [2,3] Any Guidelines put forward by the PMPRB should be designed to clearly demonstrate its adherence to this mandate. The proposed Guidelines do not meet this standard; instead, they establish an opaque system that is grounded in negotiations between companies and Board Staff as well as the arbitrary evaluation of "excessive" prices by the Panel of the PMPRB. Such a system not only contravenes the PMPRB's mandate but will act as a barrier on the ability of pharmaceutical manufacturers in Canada to bring innovative medicines to the Canadian market. It also leaves pricing decisions open to significant swings in individual opinion and judgment, further increasing risk and a severe lack of certainty to the industry.

Next steps

In summary, Gilead firmly believes the 2022 proposed updates to the PMPRB Guidelines will negatively impact the access of Canadian patients to innovative medicines and should not proceed. This position is fully aligned with Innovative Medicines Canada and BIOTECanada.

Appropriate modernization of the PMPRB Guidelines can only be achieved through meaningful collaboration between the PMPRB and stakeholders, including patient groups and manufacturers of innovative medicines, such as Gilead.

Thank you once again for the opportunity to participate in this process, and we look forward to continuing to work with you and other stakeholders to develop Guidelines that benefit all Canadians.

Best regards,

Christophe Griolet
Vice-President and General Manager, Gilead Sciences Canada, Inc.

[1] Patented Medicine Prices Review Board, Compendium of Policies, Guidelines and Procedures – Updated February 2017, Last accessed July 15, 2022 at https://www.pmprb-cepmb.gc.ca/view.asp?ccid=492.

[2] Federal Court of Appeal, Federal Court of Appeal Decisions: Alexion Pharmaceuticals Inc. v. Canada (Attorney General), Last accessed July 15, 2022 at https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do.

[3] Merck Canada inc. c. Procureur général du Canada, 2022 QCCA 240 (CanLII), <https://canlii.ca/t/jmjbm>, consulté le 2022-07-15.