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July 18, 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

Dear Dr. Bourassa Forcier,

Gilead Sciences Canada, Inc. ("Gilead") appreciates the opportunity to provide feedback on the PMPRB's proposed interim guidance through the Notice and Comment process. The interim guidance and the final guidelines will have a significant impact on patient access to patented medicines in the years to come and, as such, a substantial level of consultation is warranted.

Gilead fully supports the positions of both Innovative Medicines Canada and BIOTECanada regarding the existing proposal for price reviews during the Interim Period (i.e., the period between the coming into force of the new Patented Medicines Regulations and the final publication of a corresponding set of guidelines). In particular:

- All pricing guidance should be aligned with the PMPRB's mandate to prevent abusive pricing by "ensuring that the prices of patented medicines are not excessive"[i]; as noted by both the Federal Court of Appeal and the Quebec Court of Appeal, the mandate of the PMPRB is not to control prices through determining "reasonable" pricing.[ii,iii]
- The highest reported non-excessive average price (NEAP) for a given medicine should set the benchmark during the Interim Period.
- Products launched during the first half of 2022 should be found by the PMPRB to be compliant if pricing conforms to the Regulations and Guidelines in effect at time of launch.
- No payment of excessive revenues for sales during the Interim Period should be required for patentees willing to launch new medicines in the absence of clear guidelines.

Following the finalization of the new guidelines, patentees should have at least two full reporting periods (i.e., 12 months) to come into compliance. In addition, the new guidelines should align with the legislative mandate of the PMPRB, as clarified by the most recent commentary of the Federal Court of Appeal.

Thank you for the opportunity to provide feedback. We trust that the input received from Gilead and other stakeholders will receive the consideration commensurate to our commitment to bringing new medicines to Canadian patients.

Best regards,

Melissa Koomey
Vice President and General Manager, Gilead Sciences Canada, Inc.

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