PMPRB'S 2023 Interim Guidance Consultation

Response from Gilead Sciences Canada, Inc.

August 21, 2023

Submitted via the PMPRB Consultation Portal (https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-new-medicines.html)

Re: Consultation on the 2023 Proposed Amendment to the Interim Guidance on New Medicines

Gilead Sciences Canada, Inc. ("Gilead") appreciates the opportunity to provide feedback on the *2023 Proposed Amendment to the Interim Guidance re: New Medicines*.

Industry, as well as patients, advocacy groups, and the broader healthcare system in Canada, values certainty and stability. Gilead believes the extended reform process does just the opposite – it creates uncertainty that is disruptive to government and public health officials, patients, and industry in Canada. This uncertainty negatively impacts the ability of Canadians to access innovative patented medicines. Gilead respectfully calls on the PMPRB to engage in meaningful consultation to address ongoing issues with the reform process. Gilead respectfully calls on the PMPRB to engage in meaningful consultation to address ongoing issues with the reform process.

Gilead believes that the proposed amendment to the Interim Guidance goes beyond the mandate of the PMPRB, which is to ensure the prices of patented medicines are not excessive. In the creation of the PMPRB11, two higher-priced countries (Switzerland and the United States) have already been removed from the international schedule. Imposing the median price of the PMPRB11 countries will act as an additional barrier on the ability of pharmaceutical manufacturers to bring innovative medicines to patients in Canada, and ultimately limit patient access.

Additionally, the PMPRB's proposal to use the PMPRB11 median price is arbitrary. The proposed median price threshold unfairly puts manufacturers who have launched new medicines in Canada during the interim period at risk for excessive revenues following the implementation of the new Guidelines. Gilead therefore recommends the following solutions:

- The use of the PMPRB11 median to determine what drugs are subject to review **should not apply to drugs that have already launched** and have complied with the Interim Period Final Decision dated August 18, 2022.
- Active consultation with stakeholders to align on whether the median of the PMPRB11 should be used as a determining factor for price reviews.

Next steps

Gilead believes that the proposed amendment to Interim Guidance will unfairly and negatively impact the ability of pharmaceutical manufacturers to bring to market innovative medicines that will benefit Canadian patients. Active and collaborative consultation with all impacted stakeholders, including Patient Groups and manufacturers of innovative medicines, such as Gilead, is required to ensure the appropriate modernization of the PMPRB Guidelines. We strongly suggest that the PMPRB take this approach.

Thank you for the opportunity to provide feedback. Gilead looks forward to ongoing collaboration with the PMPRB and other stakeholders on the development of new Guidelines, to benefit patients in Canada.

Regards,

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