Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines
Response from Gilead Sciences Canada, Inc.

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Submitted via the PMPRB Consultation Portal (https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/discussion-guide-phase2.html)

Re: Discussion Guide and Phase 2 Consultations on New Guidelines

Gilead Sciences Canada, Inc. ("Gilead") appreciates the opportunity to provide feedback on the *Discussion Guide and Phase 2 Consultations on New Guidelines*. Gilead is a member of both Innovative Medicines Canada (IMC) and BIOTECanada, and fully supports each organization's submission to this consultation.

There are two topics that Gilead wishes to comment on, for the Board's consideration:

1. Price level within the PMPRB11 to be used in the initial and post-initial price review.
2. Predictability.

Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review.

Gilead believes that many proposed approaches in the *Discussion Guide* go beyond the mandate of the PMPRB, which is to ensure the prices of patented medicines are not excessive. For setting a price level in the initial and post-initial price review, the *Discussion Guide* states that "The Board is considering the following options:"

- **Option 1:** Median International Price (MIP)
- **Option 2:** Highest International Price (HIP)
- **Option 3:** the midpoint between the MIP and HIP

In the creation of the PMPRB11, two higher-priced countries (Switzerland and the United States) were already 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. This will ultimately limit patient access to innovative therapies.

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 new Guidelines. Setting prices at a newly created "midpoint" between the MIP and HIP is similarly arbitrary. Both MIP and Midpoint options look like price control, which is neither consistent with the PMPRB's mandate nor supported by recent legal decisions.

Of the proposed options, Gilead reinforces its belief that the only appropriate price point is Option 2, at the HIP.

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Topic 2: Predictability.

Manufacturers of innovative medicines expect that maximum non-excessive price points will be predictable over the life cycle of a product, subject to applicable Consumer Price Index (CPI) adjustments. Predictability itself is one of the most impactful components of any proposed new Guidelines.

Elements of the *Discussion Guide* portend complex re-benchmarking of prices through proposed annual price reviews and potential in-depth reviews, leading to the potential for arbitrary price reductions. These re-benchmarking elements introduce an inherent lack of predictability for manufacturers. Moreover, these elements could be viewed as price control measures, which exceeds the PMPRB's mandate.

Next steps

Patient access to innovative medicines in Canada already lags peer countries. The impact of new Guidelines on the ability of pharmaceutical manufacturers to bring to market innovative medicines that benefit Canadian patients must be considered. To ensure the appropriate modernization of the PMPRB Guidelines, Gilead encourages the PMPRB to engage in active, collaborative, and fulsome consultation with all impacted stakeholders, including Patient Groups and manufacturers of innovative medicines.

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

Sincerely,

Scott Spencer
Interim General Manager and Executive Director, Finance
Gilead Sciences Canada, Inc.