Via Online Submission

June 21, 2021

The Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON,
K1P 1C1

Dear Sir or Madam:

Bayer Inc.
2920 Matheson Blvd. East
Mississauga, Ontario
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We at Bayer Inc. ("Bayer") appreciate the opportunity to provide a written submission[1] in response to the Patented Medicine Prices Review Board ("PMPRB")'s invitation to comment on the proposed Guideline Monitoring & Evaluation Plan ("GMEP").

We agree that the impact of the proposed PMPRB Guidelines ("Guidelines") should be continuously evaluated and the Guidelines fine-tuned to ensure that patients continue to receive timely access to innovative medicines. However, we feel that it is critical that such an evaluation be conducted without bias and that conclusions **be formed by an independent third party**.

We also feel that commenting on a GMEP framework when the Guidelines are still ambiguous to stakeholders is premature. Comprehending how the Guidelines will be applied is a pre-requisite to providing fulsome feedback.

Bayer aligned with Innovative Medicines Canada ("IMC")

Bayer's position is aligned with the written submission presented by IMC with respect to GMEP.

Additional Measures to Capture

The list of metrics that are planned to be tracked and reported by the PMPRB is robust. Notwithstanding, we feel that the following additional measures should also be considered:

- Capturing time elapsed between regulatory approval and first commercial sale
- Capturing time elapsed between regulatory approval and the first provincial listing
- Compassionate and free-of-charge medicines provided to patients
- Widening the measure of R&D spend to be consistent with Statistics Canada's definition and including other costs such as joint ventures and investments in start-ups
- Capturing the time elapsed between the first commercial sale of a patented medicine and the PMPRB providing their pricing evaluation to the patentee

[1] This written submission should not be taken as Bayer's acceptance of the PMPRB's mandate and operations, including the New PMPRB Framework. Bayer Inc. is a named applicant in *Merck Canada Inc. et al v Canada (Attorney General)*, Quebec Superior Court file 500-17-109270-192.

- Tracking the number of complaints received by the PMPRB on excessive pricing claims and the number that proceed to an Investigation and/or Hearing

Conclusion

The PMPRB has twice delayed the implementation of these new Guidelines citing the global pandemic. As we are still amid this battle, it would be prudent for PMPRB to further delay the implementation. During this proposed hiatus, we urge the PMPRB, industry, patient groups and other stakeholders to find alternative solutions to the Guidelines through meaningful dialogue. It would be to the benefit of all stakeholders that workable Guidelines, in conjunction with a robust GMEP framework conducted by a third party, are ultimately implemented.

Bayer recognizes the importance of tracking the impact of PMPRB Guideline changes so that they can be quickly modified if they impede access to patented medicines. It is imperative that the data collection and subsequent conclusions drawn from the analyses are made promptly by an independent third party. Only independent conclusions developed at arm's length will create an environment whereby the PMPRB and stakeholders can work together with the collective goal of ensuring that innovative medicines continue to be available to Canadian patients on a timely basis.

Yours sincerely,

Dale Toki
Director, Strategic Pricing & Contracts
Bayer Inc.