Via Online Portal Submission

July 18, 2022

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.
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Bayer Inc. ("Bayer") appreciates the opportunity to provide a written submission[1] in response to the June 30, 2022, publication of the Patented Medicine Prices Review Board ("PMPRB")'s Notice and Comment on Interim Guidelines ("Interim Guidelines"). Bayer has made several recommendations to improve the Interim Guidelines that will enhance clarity, fairness, and predictability. These are described below.

**Interim Guidelines should be amended to account for a potential delay in the publication of the Final Guidelines beyond January 1, 2023**

In the event Final Guidelines are not published and implemented by year end, Bayer recommends that the Interim Guidelines provide an updated 2023 National Non-Excessive Average Price ("N-NEAP") based on the patentees' 2022 sales reporting and the current CPI Adjustment Methodology.

In addition, tools that are currently used in the current Guidelines such as the DIP methodology, Schedule 6.1.2 within the Highest International Price Comparison Test and adjusting the National Average Transaction Price ("N-ATP") due to, but not limited to, product returns, free goods, and market mix should continue to be applied in the Interim Period and clearly reflected in the final version of the Interim Guidelines.

**Clarity on the 2022 N-NEAP to be used in the Interim Guidelines**

The PMPRB has indicated that an existing patented medicine will not trigger an investigation if it's N-ATP remains at or below its most recent N-NEAP established under the existing Guidelines. To provide clarity, the PMPRB should confirm that the highest N-NEAP provided in the 2021 Compliance Status Report would be used.

[1] This written submission reflects Bayer Inc.'s position in respect to select elements of the 2022 Interim Guidelines in the June 30, 2022, Notice & Comment and should not be taken as Bayer's acceptance of the PMPRB's mandate and operations, including the New PMPRB Framework. Bayer reserves all of its rights otherwise

**Products without N-NEAP**

Clarity is required on products that do not have a N-NEAP because it has either not yet undergone PMPRB's regulatory scrutiny or had no commercial sales during the year. Given that PMPRB is not providing guidance on the price regulation of new products during this Interim Period, products whose N-ATP is below the high of the PMPRB11 should not be at risk of potential liability for any excessive revenues if the Final Guidelines subsequently determines that the launch price is 'excessive'.

## Conclusion

As a core principle, PMPRB must ensure that the Final Guidelines reflect its mandate to monitor for patent abuse and excessive pricing. Consequently, any price tests should avoid any measure that utilizes the lowest, mean, or median measures.

The development, refinement, and implementation of an effective set of Final Guidelines will require intense consultation and stakeholder engagement through working groups. These groups should be established immediately rather than waiting for the publication of the draft Final Guidelines in the fall. In addition, to minimize disruption and ensure that Canadian patients continue to have access to innovative medicines, the PMPRB should provide an adequate transition period of at least 18-months.

Bayer applauds PMPRB's desire to implement Interim Guidelines that are simple and practical for all parties. Bayer is of the view that the changes identified above will only serve to provide additional clarity for all stakeholders. We thank you for this opportunity to voice our feedback and concerns.

Yours sincerely,

Dale Toki
Director, Strategic Pricing & Contracts
Bayer Inc.