Via Online Submission

February 12, 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.
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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 Notice and Comment, published on January 14, 2021 ("Notice & Comment"). We are opposed to the proposal to change the compliance timelines for Grandfathered and Gap medicines. Additionally, we continue to oppose the inclusion of the NEAP in derivation of the MLP.

Bayer aligned with Innovative Medicines Canada ("IMC")

Bayer's position is aligned with the written submission presented by IMC in respect to this Notice & Comment.

Proposed Consequential Amendments to the January 1, 2021 Guidelines

1) Compliance Timelines for Grandfathered and Gap Medicines

PMPRB Proposal: Reduce compliance with the MLP for Grandfathered and Gap medicines to one filing period so that January 1, 2022 would remain the operative date for assessing compliance.

We are opposed to PMPRB's proposal to reduce the MLP compliance timeline to one filing period for Grandfathered and Gap medicines. The ambiguous process and unpredictable outcomes of MLP adjustment requests do not leave enough time for patentees to implement the price reduction within one filing period. While one filing period is six months, the effective time that is given to patentees is significantly less. Sales reporting, evaluation of the MLP, submission of the MLP adjustment request and the subsequent ruling by the PMPRB will effectively leave only one to two months for the patentee to implement the price reduction. Subsequent global approval and communication to external stakeholders by patentees would be required. Lowering the list price is a process which involves

[1] This written submission reflects Bayer Inc.'s position in respect to select elements of the 2020 Draft Guidelines and 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.

many third-party partners including Group Purchasing Organizations, hospitals, wholesalers and drug formularies. Additionally, the price decrease will need to be reflected in some Product Listing Agreements and commercial contracts. As this would be conducted during the holiday season where partners operate with limited staffing, this would not be feasible in the time frame proposed by the PMPRB.

Even two filing periods to come into MLP compliance could pose a challenge for certain patented medicines, especially in the circumstance where the patentee does not agree with PMPRB's ruling on the MLP adjustment. Removing the NEAP in the derivation of the MLP for Grandfathered and Gap medicines would significantly simplify the process, provide greater predictability and fairness for patentees, and allow price reductions to be implemented within two filing periods as originally proposed.

2) Definition of Gap Medicines:

PMPRB Proposal: The PMPRB is proposing to extend the date of first sale to the new coming-into-force date of July 1, 2021.

The PMPRB's proposal to change the definition of Gap medicines does not go far enough. Bayer continues to oppose the inclusion of NEAP in determining the MLP. Although the PMPRB has built in a provision that would allow the patentee to negotiate an MLP adjustment, it adds significant uncertainty and unpredictability. The NEAP is a figure that is derived from the information patentees provide in their Form 2 Block 4 submissions, the confidentiality of which is protected by the Patent Act. As such, the NEAP should not be used to determine the MLP as this would undermine the confidentiality of sales reporting by the patentee. Although the PMPRB indicated that the MLP would remain confidential[2], the price reduction of a patented product below the Highest or Median[3] of the PMPRB11 will signal that the patentee has provided benefits that were not accepted in the MLP adjustment. We see this as a punitive measure against patentees and is clearly contrary to PMPRB's previous intent not to punish patentees from offering benefits by virtue of the creation of the DIP methodology in the current PMPRB Guidelines.

Conclusion

While we applaud the federal government's decision to delay the implementation of the new PMPRB Regulations by six months to allow stakeholders to battle the Covid-19 pandemic, we are concerned with the proposal to reduce compliance with the MLP to one filing period. Patentees will now have to struggle to come into compliance with ambiguous Guidelines under significantly compressed timelines which effectively negates the federal government's intent to allow stakeholders to focus on the pandemic. The uncertainty arising from the MLP adjustment will result in needless investigations and greater uncertainty for all stakeholders. We ask that the timeline to comply with the MLP for Grandfathered and Gap products be maintained at two filing periods. To further simplify matters

[2] July 21, 2020 meeting between PMPRB and IMC and BTC members
[3] Highest for Grandfathered and Line Extension products and Median for Gap products

for all stakeholders and to confer predictability and fairness for patentees, we request that the NEAP no longer be considered in determining the MLP for Grandfathered and Gap medicines. We thank you for giving us the opportunity to provide feedback to the Notice & Comment.

Yours sincerely,

Dale Toki
Director, Strategic Pricing & Contracts
Bayer Inc.