Via Online Submission

August 19, 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 Notice and Comment, published on July 15, 2021 ("Notice & Comment"). We are opposed to the proposal to change the International Price Test for Grandfathered Medicines and their Line Extensions ("Grandfathered Medicines"). We are also dismayed that the PMPRB may implement Guideline changes prior to the implementation of the Amended Patented Medicines Regulations ("Regulations").

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.

***PMPRB Proposal**: The PMPRB is proposing that the MLP for Grandfathered and their Line Extensions be set by the lower of (1) the MIP for the Schedule Countries for which the patentee has provided information for the reporting period ending June 30, 2021 under the Regulations that are currently in effect (SOR/2008-70, s.6); or (2) the medicine's ceiling (e.g. the "NEAP") under the Guidelines as they were prior to the issuance of these Guidelines. For Grandfathered and their Line Extension medicines first filed with the PMPRB for the reporting period(s) ending in December 31, 2021, or later, the MLP is set by the HIP for the Schedule Countries set out in the Regulations for which the patentee has provided information.*

We are greatly concerned that the PMPRB has proposed to change the MLP calculation for Grandfathered Medicines. The PMPRB has previously consulted and rejected the use of the median of the PMPRB11 and decided that the highest of the PMPRB11 was appropriate. We are perplexed as to why the PMPRB is revisiting the median of the Schedule Countries. In most instances, there will be an immaterial difference between the median of the PMPRB7 and the median of the PMPRB11 which means that the PMPRB is seeking to effectively revert to a price test that was consulted upon and ultimately rejected. Changing the MLP price

[1] This written submission reflects Bayer Inc.'s position in respect to select elements of the 2020 Draft Guidelines and July 15 Notice & Comment 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.

test for Grandfathered Medicines without a clear rationale seems punitive and if implemented, undermines the entire consultation process.

Lack of Appropriate Consultation

We are greatly disappointed after learning that the changes recommended in this Notice & Comment may be executed irrespective of the implementation of the Regulations. The proposed Guidelines were always contextualized to begin in lockstep with the Regulations. To deviate at this point is misguided and discounts all the discussions that were held in the past five years.

Any price change should be allotted a twelve-month period to implement following the implementation of the Regulations. We find it disconcerting that the PMPRB is shortening this timeframe to six months from the start of the Regulations despite conceding that twelve months was appropriate following the outcome from the January 15, 2021 Notice & Comment. The constant revisiting of decisions undermines confidence and predictability of the patented medicine regulatory environment and suggests that implications from these changes are not being adequately contemplated.

Conclusion

While we applaud the federal government's decision to delay the implementation of the Regulations by six months to allow stakeholders to battle the Covid-19 pandemic, we are concerned that the PMPRB has decided to rush changes to the Guidelines that could be decoupled from the Regulations. The extra time provided by Health Canada in recognition of the need of industry and other stakeholders to focus on the Covid-19 pandemic has been nullified by the unexpected changes included in this Notice & Comment.

Clear rationale needs to be forthcoming from the PMPRB to explain why it is revisiting the median of Schedule Countries when it was previously rejected in a consultation of the Draft Guidelines.

We ask that the this Notice & Comment be withdrawn and that the PMPRB work with stakeholders to implement a pricing regulatory environment that is conducive to access and sustainability while remaining consistent with PMPRB's mandate. This Notice & Comment does not achieve either. We thank you for this opportunity to voice our concerns.

Yours sincerely,

Dale Toki
Director, Strategic Pricing & Contracts
Bayer Inc.