August 16, 2023

Thomas J. Digby
Chairperson
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Submitted By Email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Notice and Comment - Amendment to the Interim Guidance re: New Medicines (June 2023)

Bayer Inc.
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Dear Mr. Digby:

Further to the PMPRB's recent Notice and Comment - Amendment to the Interim Guidance re: New Medicines ("Notice and Comment"), we welcome the opportunity to provide you with the feedback of Bayer Inc. ("Bayer") on the relevant policy issues and proposed guidance for interim price reviews released for stakeholder input.

At the outset, Bayer affirms its full alignment with the concurrent submissions being made under this Notice and Comment by our trade associations, Innovative Medicines Canada (IMC) and BIOTECanada (BTC).

Our experience with the overall PMPRB reform process in recent years has been challenging, and we anticipate that other stakeholders will share these same sentiments. There is a clear imperative on all sides to return to normal interactions and advance workable policies for all. Accordingly, and with all policy developments considered to date, we wish to signal up front our strong and sincere interest in re-establishing an appropriate professional working relationship and communication channel with the PMPRB - including with you in your capacity as Chairperson, your Board colleagues, and Board Staff at all levels.

The natural and necessary companion of a renewed and stronger working relationship is active stakeholder consultation and engagement. Reflecting on the content of the current Notice and Comment, we encourage the Board and PMPRB Staff to continue to strive for early, transparent, and open dialogue with stakeholders on Board objectives, timelines, and policy intent to minimize any misunderstandings and promote improved compliance predictability and stability, while allowing for stakeholders to provide relevant and actionable feedback. We highly recommend that the PMPRB engage in pre-consultation meetings with IMC, BTC, patentee subject matter experts, and other stakeholders to collaboratively build the new Guidelines as a collective. The PMPRB's past practice of

publishing draft Guidelines without prior stakeholder input revealed that many of the proposals made by the PMPRB were not implementable and would, if implemented, have created significant uncertainty that would likely have jeopardized Canadian's access to future innovations.

Bayer welcomes the PMPRB's intent to offer patentees greater clarity on its Interim Guidance given the lack of updated permanent Guidelines. However, as the practical effect of the Notice and Comment may not adequately deliver on this intent, Bayer offers some specific comments in this respect below.

Necessarily, the guidance proposed in the Notice and Comment can and should be placed in its appropriate public policy and legal context. The Notice and Comment would benefit from a more robust recognition and explanation as to where the Interim Guidance would fit against prior Guidelines, recent public policy direction from the Government of Canada, and all relevant legal precedents. Ultimately, we join with our colleagues in industry, as well as many other stakeholders, in seeking to work with the PMPRB to promote a much more workable, stable, predictable, and efficient set of Guidelines that will enable patentees to make informed business decisions.

We note that the recent regulatory changes, namely the changes to the basket of international price reference countries, are already having a tangible and substantial impact on Canadian patented medicine prices in aggregate[1]. Absent any other policy change or specific Guidelines, this trend will continue and accelerate in the coming years. This is important context in any consideration of the Board's mandate with respect to non-excessive price regulation and related compliance activities.

<u>Notice and Comment – Specific Comments</u>

Re: Use of Median Price Test

The Notice and Comment proposes the use of a median price test for new medicines without an established Maximum Average Potential Price (MAPP) or Non-Excessive Average Price (NEAP).

Bayer reiterates its longstanding position, aligned with that of our associations and many other stakeholders, that the proposed application of the median price test is inappropriate in this context. Consistent with the Board's established statutory mandate to regulate excessive pricing, any price within the full basket of comparator countries, including the highest international price, should be accounted for in making any price comparison for new price reviews as the full range of prices within the basket are deemed non-excessive. Again, we highlight the material impact that the recent changes to the basket of reference countries have made when determining the highest international price.

Even within this median approach, there are substantial questions as to how the Board might operationalize this proposed Interim Guidance. There is no apparent detail as to

[1] PDCI webinar Oct 17, 2022

which specific median price might be established or referenced, given that different medians would be calculable within the current Interim Period. As currently construed, this would generate substantial uncertainty for patentees and, we submit, Board staff as well.

The Notice and Comment references the concept of “reviewed” for medicines found to be below the median international price. However, this concept is not explained in sufficient detail, particularly as to whether and when a given medicine could be re-reviewed, and how being deemed “reviewed” during the Interim Period may impact future compliance requirements under future Guidelines. It is unclear what the purpose of being “reviewed” is for a given medicine under an Interim Guidance where no retrospective excessive revenues would be calculated. For this Interim Period, any new medicine that is below its Highest International Price should be deemed “reviewed” and that PMPRB Staff would not re-assess the product provided that the list price does not increase beyond the Consumer Price Index (CPI). In addition, having the benefit of reference to final Guidelines is a critical requirement to allow for a proper assessment of the utility and impacts of the Interim Guidance proposed in the Notice and Comment.

Re: Permissible List Price Increases

The Notice and Comment contains language indicating that the August 2022 Interim Guidance will continue to apply with respect to price increases. In August 2022, the Board specified that no investigations would be triggered if prices did not increase beyond the CPI adjustment factor from the first filing period in 2022.

Section 85(1) of the *Patent Act* specifically provides that changes in the CPI shall be considered with respect to whether a medicine is or has been sold at an excessive price. The PMPRB should remove ambiguity of any CPI adjustments going forward by clearly stating the allowability of CPI pricing adjustments in both the Interim and Final Guidelines for the benefit of stakeholders, including Board Staff responsible for screening and compliance enforcement activities.

Next Steps

We sincerely appreciate the Board’s consideration of these and other stakeholder comments. There is a mutual opportunity and benefit to shaping an effective price compliance guidance for this Interim Period in parallel with the development of future Guidelines.

The foundation of this effort must be constructive communication and engagement at all stages of the process. We reiterate our support for efforts to rebuild working relationships based on respect, dialogue, and clear objectives consistent with legal and operational realities.

As the Board continues in these efforts, please do not hesitate to reach out to me directly with any questions on the content of this submission or any related matters of question or concern.

Yours sincerely,

Dale Toki
Director, Strategic Pricing & Contracts
Bayer Inc.