Via Online Submission

December 18, 2023

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 in response to the November 10 publication of the Patented Medicine Prices Review Board ("PMPRB") Scoping Paper for the consultation of the Board's Guidelines ("Scoping Paper")[1]. In this brief letter, we would like to highlight our top-line key messages. For an in-depth read, we refer you to the written submission by Fasken which contain the collective thoughts of the "Industry Coalition", including those of Bayer.

PMPRB's Mandate

As delineated in the Quebec Court of Appeal's decision in *Merck Canada c Canada*, 2022 QCCA 240 ("QCCA") and reiterated throughout the PMPRB roundtable discussion, any Guidelines issued by the PMPRB must adhere to its constitutional mandate, rooted in the Patent Act, to ensure that the prices of patented medicines are not excessive. The QCCA decision judiciously defines an excessive price as one that "without justification, exceeds the price of other medicines in the same therapeutic class or that otherwise exceeds the price for the same medicine in countries reasonably comparable to Canada"[2]. It is therefore essential to emphasize that the PMPRB should refrain from applying multiple price tests to secure price reductions below the excessive price threshold which would be effectively price control. Thus, a constitutional approach demands a higher than highest perspective, which also negates the viability of a median price threshold.

Predictability

If a price for a patented medicine is, or has been, deemed non-excessive, there should be no re-benchmarking of its price utilizing any of the Guidelines' price tests and its list price only assessed for increases that exceeds the CPI. This was a theme repeated throughout the roundtable discussion in that the drug ecosystem requires that there is predictability throughout the lifecycle of a medicine. Compliant existing medicines must be grandfathered into the new regime, ensuring continuity and regulatory stability. This proposed approach, rooted in the QCCA decision, promises enhanced predictability, reduced complexity, minimized duplication, and heightened efficiency in PMPRB's pricing regulations.

[1] This written submission reflects Bayer Inc.'s position in respect to select elements of the 2023 Scoping Paper for the Consultation of the Board's Guidelines published November 10, 2023, and should not be taken as Bayer's acceptance of the PMPRB's mandate and operations, including the New PMPRB Framework. Bayer reserves its rights otherwise.
[2] *Merck Canada c Canada*, 2022 QCCA 240 ¶49 (translation).

Lack of Policy Context

The questions presented by the PMPRB in its Scoping Paper demonstrated an unexpected level of specificity and detail concerning various aspects of the Guidelines. However, they lacked an accompanying policy context, rendering several questions challenging to address. The responses to these queries could significantly vary based on different sets of assumptions. Many of the questions raised in the Scoping Paper do not have a singular, universally applicable answer. Instead, the appropriateness of the response is contingent upon the specific framework presented. As an example, the PMPRB's suggestion of an expedited price review would require further background before meaningful commentary could be provided. This underscores the importance of establishing a clear policy context to provide a foundation for more precise and contextually relevant answers to the questions at hand.

Conclusion

As a fundamental principle, the PMPRB must ensure that the Final Guidelines accurately reflect its mandate to monitor instances of patent abuse and excessive pricing. To develop, refine, and implement a viable set of Final Guidelines, it is imperative to engage in intensive consultation early and foster stakeholder involvement through the prompt establishment of working groups as we have seen that many of the past Guidelines being recommended by the PMPRB, which were published without prior meaningful consultation, could not be operationalized by industry. Establishing working groups was a repeated theme throughout the roundtable discussion from multiple stakeholders and Bayer believes that increased collaboration and transparency will go a long way to help prevent these past missteps from being repeated.

Bayer commends the PMPRB's commitment to have an open mind and consider all feedback. For additional details on our thoughts, we refer you to Fasken's submission. We appreciate this opportunity to express our feedback and concerns.

Yours sincerely,

Dale Toki
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Bayer Inc.