Via Online Submission

March 14, 2025

The Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON,
K1P 1C1

RE: Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation

Dear Sir or Madam:

Bayer Inc.
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Bayer Inc. ("Bayer") appreciates the opportunity to submit our comments regarding the document titled "Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation" ("Draft Guidelines").

We fully endorse and support the concurrent submission made by our trade association, Innovative Medicines Canada. Additionally, we would like to draw your attention to the written submission from Fasken, which reflects the collective insights of the "Constitutional Coalition", including those of Bayer.

We believe that the updated Guidelines should empower rights holders to confidently assess, in advance, whether their patented medicine prices should be considered for a Hearing, based on clearly defined price tests. Providing clarity on this matter will not only enhance compliance but also facilitate the timely launch of new products, ultimately benefiting Canadian patients and the healthcare system.

We support the Board's assertion that "…it is our view that Guidelines which are clear, predictable, and procedurally fair provide an efficient way for rights-holders to manage risk."[1] Importantly, and as the Board itself has acknowledged, any Guidelines issued by the PMPRB must adhere to its constitutional mandate, grounded in the *Patent Act*, to ensure that the prices of patented medicines are not excessive.

Bayer agrees with the reliance on the clear and predictable Highest International Price ("HIP") test as the initial test, as it is the only international price threshold that aligns with the PMPRB's constitutional mandate. However, we are concerned that the additional proposed steps and processes outlined in the Draft Guidelines may introduce significant ambiguity, delays, and overall uncertainty for rights holders.

To address these concerns, our key recommendations for adjustments to the Draft Guidelines include:

[1] PMPRB NEWSletter – Special Edition - Guidelines Consultation Update - Canada.ca

- The Guidelines should incorporate clear, "bright-line" tests to establish transparent and measurable criteria for all parties, thereby minimizing subjective interpretation. Enhanced clarity and stability will enable rights holders to assess their compliance with reasonable confidence, while also reducing the need for unnecessary In-Depth Reviews and Hearings.
- New Medicines should be evaluated solely against the HIP during the Initial Review. For subsequent Annual Reviews, any increases in the list price of New Medicines should only be assessed against the Consumer Price Index ("CPI"). Additionally, we recommend implementing upfront gating criteria, such as a reasonable pricing buffer or margin, to account for situations where the list price only slightly exceeds the HIP.
- Existing Medicines that have been deemed compliant in the most recent compliance report should retain that status and be exempt from In-Depth Reviews unless list price increases surpass the CPI.
- The *Patent Act* does not include a complaints mechanism; however, any admissible complaints should be directed solely to the Federal Minister of Health or their Provincial or Territorial counterparts.
- Complaint-only based oversight for certain categories of medicines should be expanded to include other patented products that have demonstrated a low risk of excessive pricing due to purchasing models or other market mechanisms. This includes blood products and branded patented medicines that have lost exclusivity.
- Recognizing that individual patented medicines may be approved for different dosage strengths, dosage forms and release formulations, a single Drug Identification Number ("DIN") meeting the criteria for an In-Depth Review should not automatically trigger a comprehensive review for all Associated DINs[2].
- The proposed In-Depth Review process is expected to be resource- and time-intensive for all parties and excessively subjective. Most concerning is that the In-Depth Review process lacks adequate clarity, certainty, and transparency for rights holders. This current approach could create an unacceptable level of uncertainty surrounding a given patented medicine for many years.
- The PMPRB should only consider forwarding an In-Depth Review for a Hearing if the list price exceeds BOTH the HIP and the highest of the Therapeutic Cost Comparison ("TCC"), and only if the excessiveness is material.

We are pleased to provide the following detailed comments on the Draft Guidelines. We would also like to refer the PMPRB to our prior submissions, as they are still relevant and applicable in the context of the Draft Guidelines.[3]

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[2] "Associated DINs" includes all other dosage strengths and may include alternate dosage forms and prolonged release products but does not include combination products. [Draft Guidelines for PMPRB Staff - Canada.ca]

[3] Bayer's previous recent submissions include the following: Bayer Inc. Scoping Paper response, Bayer Inc. 2022 proposed Guidelines Response, Bayer Inc. 2020 PMPRB Draft Guidelines response, and Bayer Inc. Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

Role of Guidelines: A predictable, common and objective standard is necessary

The PMPRB has stated that the purpose of the Guidelines is to enhance the Board's administrative efficiency while providing transparency and predictability to rights holders regarding the review process typically conducted by PMPRB staff ("Staff"). This process aims to identify patented medicines that may be at a higher risk of excessive pricing, warranting an In-Depth Review or a potential Hearing.

To support timely launch decisions and related investments in Canada, it is essential to establish much greater clarity on the triggers that would result in a recommendation of a Hearing. The absence of "bright lines" complicates the decision-making process for investing in Canada. As countries compete for global resources, pricing uncertainty can significantly impact the Canadian business case, potentially resulting in delayed or even abandoned launches of new medicines.

Implementing "bright line" tests promotes fairness, transparency and consistency in regulation by holding all rights holders to a common objective standard. This approach greatly reduces the risk of biased or arbitrary enforcement of the Guidelines. Additionally, it minimizes the need for legal consultations and regulatory interpretations, ultimately saving both the Board and rights holders considerable costs and reducing the time spent on assessments and disputes.

Grandfathering is Vital for Existing Medicines

We would like to reaffirm our position that Existing Medicines deemed compliant in the most recent compliance report should be grandfathered and exempt from In-Depth Reviews, as they have already been found to meet PMPRB's own criteria for not being excessive in price.

Revisiting the status of Existing Medicines under the new Guidelines would be unfair to both rights holders and patients, particularly given the significant investments made based on prior compliance and established pricing frameworks. Specifically, medicines assessed as 'Within PMPRB Guidelines' for the January to December 2022 period should continue to be regarded as non-excessive in price under the new Guidelines. An In-Depth Review of an Existing Medicine should only be triggered if list price increases exceed the CPI.

Furthermore, we strongly recommend extending complaint-only based oversight to other products that clearly present a low risk of excessive pricing, such as blood products and branded patented medicines that have lost market exclusivity. This approach aligns with PMPRB's stated risk-based strategy and its objective to allocate resources in the most efficient and effective manner possible.

Initial Reviews: Reasonable and proportionate refinements would improve Initial Reviews

Bayer supports the PMPRB's proposed approach of using prices from the PMPRB11 comparator countries as the primary mechanism for review, along with the decision to adopt the HIP threshold for the initial International Price Comparison ("IPC"). The HIP

represents the most predictable and transparent price test available for rights holders and aligns with the Board's legally established mandate.

However, we do not support the proposal that a single DIN meeting the criteria for an In-Depth Review would automatically trigger a comprehensive review for all Associated DINs. Variations in dosage strengths and forms, extended-release formulations, and pediatric line extensions often involve distinct market considerations and often involve different patents. Subjecting all Associated DINs to an In-Depth Review could disincentivize launches of new dosage forms and line extensions, ultimately limiting treatment options for patients and denying access to improved versions of existing products or new formulations tailored for special patient populations with distinct needs. We recommend that the PMPRB continue to evaluate each DIN independently, as has been its historical practice.

We also believe that implementing reasonable gating criteria prior to In-Depth Reviews is warranted. For example, establishing an appropriate price buffer or 'margin of error' would accommodate instances where the highest domestic list price marginally or temporarily exceeds the HIP. In such cases, at a minimum, the rights holder should be given the opportunity to adjust the list price in the subsequent reporting period before an In-Depth Review is initiated.

It is important to note that during the early phase of a global drug launch, there can be significant variability in the HIP. This variability may be beyond the full control of the rights holder due to differences in regulatory review and market authorization timelines across jurisdictions. Considering these global realities, Bayer recommends a more measured approach to Board reviews during this initial period. The PMPRB should conduct an Initial or Annual Review only when pricing data from at least five comparator countries is available, or a minimum of three years has elapsed from its first sale in Canada. This nuanced and agile approach to enforcement would help prevent Canada from being at a disadvantage in accessing innovative drugs, as premature pricing reviews could deter manufacturers from introducing new medicines early into the Canadian market.

Additionally, there is a pressing need for greater clarity regarding how Staff will assess patented medicines that lack a published list price. These medicines should only undergo an In-Depth Review if a valid complaint is lodged, thereby preventing unnecessary regulatory intervention and resource allocation in cases where no pricing concerns have been raised.

With these reasonable and proportionate refinements, the PMPRB can maintain a balanced regulatory framework that fulfills its mandate while fostering pharmaceutical innovation and enhancing market accessibility.

Complaints: Clearly defined price-tests should eliminate the need for Complaints

The Patent Act does not provide for a complaints mechanism, and the implementation of clearly defined price tests in the Guidelines should ideally render such complaints unnecessary. However, if a complaints mechanism is to be established, any admissible complaints should be directed exclusively to the Federal Minister of Health or their Provincial or Territorial counterparts. Bayer does not support the Board's proposal to accept complaints from an expanded list of approved individuals or organizations.

Medicine pricing is an inherently complex and multifaceted process, impacted by a sophisticated system of downstream reviews, negotiations, and scrutiny within Canada's drug reimbursement framework. The payers' mandate is to ensure safe, effective and affordable drugs are made available to its constituents and is disparate with PMPRB's constitutional mandate. Against this reality, the complaint process should be restricted to the Federal Minister of Health and their Provincial or Territorial counterparts. Members of the public who have concerns about the price ceiling of a patented medicine have recourse by reaching out to their elected officials. It is important to note that publicly funded drug plans are ultimately accountable to, and can escalate their complaint to, the Ministry of Health in their respective jurisdictions. This approach ensures that only substantive issues, which cannot be fully addressed within existing tools and processes at the jurisdictional or pan-Canadian level, are elevated to the PMPRB.

Both public and private drug plans actively negotiate reimbursement criteria and prices for medicines. Allowing complaints from these parties to automatically trigger In-Depth Reviews risks inappropriate use of the system and unnecessary use of resources. This could create potential conflicts of interest, particularly for private payers, who represent for-profit interests and may be incentivized to leverage the PMPRB's complaint process as a negotiation tactic. There is no justification for including trade associations in the list of allowed complainants, as they have no stake in negotiating medicine reimbursement and no direct interest in the outcome. Allowing complaints from trade associations increases the likelihood of spurious complaints that are disconnected from market realities or customary commercial practices.

We emphasize that the prospect of In-Depth Reviews requires significant resources from both the rights holder and the PMPRB. Therefore, when a complaint is filed, it is essential for the PMPRB to conduct comprehensive triage to filter out non-valid or unfounded complaints. Additionally, it is important for the PMPRB to clearly communicate these triage measures in the Final Guidelines to the public to maintain transparency.

Finally, given the anticipated future workload for the PMPRB, any complaint that is not reviewed within one year of submission should expire and no longer be subject to an In-Depth Review. Establishing timely, transparent, and quantitative triage measures will facilitate the prompt assessment of complaints, ensuring they are meritorious and appropriate for Staff and Board scrutiny. At a minimum, basic metrics should be utilized to validate complaints (e.g., if the list price is found to be below the HIP, an In-Depth Review should not be initiated).

In-Depth Review: Objective measures are needed

As noted above, the proposed In-Depth Review process will be resource-intensive, excessively subjective, and far too time-consuming for all parties. It does not provide adequate clarity, certainty, nor transparency to rights holders. As currently proposed, this process could create an unacceptable level of uncertainty surrounding a given patented medicine for years.

One of the major concerns with the proposed In-Depth Review process is its prolonged timeline. The Draft Guidelines suggest that individual reviews may be deferred multiple times to manage Staff resources, and only then taking up to a subsequent 28 months to

arrive at a Staff recommendation. Potential "excess revenues" are accumulated throughout this entire period. This review period would raise an unacceptable level of uncertainty and potential risk, making it difficult to develop competitive business cases, discouraging investment and delaying the launch of innovative medicines in the Canadian market.

To mitigate these unintended consequences, we recommend establishing a maximum of one deferral period, or six months, to ensure a prompt initiation of the review process. If the PMPRB cannot initiate an In-Depth Review within this timeframe, the matter should be closed with no further action taken. Additionally, to enhance efficiency and certainty, we propose that the total duration of an In-Depth Review, including the deferral period, should not exceed 24 months, with any failure to meet this deadline resulting in automatic closure of the review. Furthermore, a ceiling timeframe should be applied on the assessment of excess revenues to a period of one year. This cap will promote timely reviews and limit the risk and costs for companies associated with delays or internal resource challenges faced by the PMPRB.

Other major issues with the proposed In-Depth Review framework are the subjectivity of selecting comparators, determining comparability, and an overall lack of clear guidance for the weighing of the Section 85(1) factors. We also object to the proposed inclusion of generic and biosimilar comparators in the TCC. These products, which will have the same Anatomical Therapeutic Chemical ("ATC") classification and have the highest comparability, would receive undue weighting in the TCC. We urge the PMPRB to ensure that all aspects of the Guidelines are established to achieve its mandate to only assess patent abuse.

As currently constructed, the Draft Guidelines provide Staff with excessive discretion, potentially leading to inconsistent or distorted pricing outcomes. To ensure a fairer and more transparent process and one that adheres to the Quebec Court of Appeal's decision in *Merck Canada c Canada*, 2022 QCCA 240 ("QCCA"), the TCC should utilize the highest-priced comparator for a similar indication or use, regardless of its ATC classification or degree of comparability. This will also serve the purpose of significantly shortening the time to conduct an In-Depth Review while concomitantly increasing the predictability of the outcome. In addition, given the complexity of utilizing an international TCC, we recommend that it should only be used in exceptional cases when domestic comparators are unavailable.

The QCCA decision articulated that "The *Patent Act* does not define an excessive price, but it can be understood from the factors set out in the *Act* that it is a price 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."[4] In light of PMPRB's mandate to prevent patent abuse, a patented medicine, in order for it to be recommended for a Hearing, should materially exceed <u>BOTH</u> the HIP and the highest of the TCC.

[4] Translation of *Merck Canada c Canada*, 2022 QCCA 240 ¶49

Conclusion

Bayer would like to express its appreciation for the opportunity to provide feedback on the Draft Guidelines. It is essential that the future Guidelines, developed in collaboration with stakeholders and aligned with the Board's statutory mandate, enable rights holders to manage their product portfolios effectively while planning for Canadian launches in a predictable manner.

We were disappointed that the Board did not facilitate face-to-face meetings nor leverage Technical Work Groups during this consultation process, which contrasts with the collaborative approach previously expressed and desired by all parties. We would like to emphasize the importance of carefully constructing the Guidelines to prevent any unintended consequences for the Canadian healthcare system.

As the Board continues its efforts, please feel free to reach out to me directly with any questions regarding this submission. Thank you for your attention to this matter.

Yours sincerely,

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Bayer Inc.