Via Online Submission

September 10, 2024

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

RE: Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

Dear Sir or Madam:

Bayer Inc.
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Bayer Inc. ("Bayer") appreciates the opportunity to provide this written submission in response to the *Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines* ("DG")[1]. We recognize the efforts made by the PMPRB to solicit and reflect on input from all stakeholders, including from the December 2023 round-table discussion and scoping consultation.

Bayer fully endorses and supports the concurrent submissions made by our trade associations, Innovative Medicines Canada ("IMC") and BIOTECanada ("BTC"). We would also like to refer you to the written submission by Fasken which contain the collective thoughts of the "Industry Coalition", including those of Bayer.

We believe that the updated Guidelines should empower patentees to confidently assess, in advance, whether their prices are deemed non-excessive based on clearly defined price tests. This clarity will not only enhance compliance but also facilitate the timely launch of new products, ultimately benefiting Canadian patients and the healthcare system. We affirm our support for the Board's position that "transparent, predictable, and procedurally fair Guidelines provide an efficient way for rights-holders to manage risk."[2]

Importantly, 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.

PMPRB has indicated that the role of Guidelines is two-fold: (1) to enhance the Board's administrative efficiency, and (2) to provide transparency and predictability to Right Holders regarding the process typically engaged in by PMPRB staff ("Staff") in identifying patented medicines that may be at a greater risk for excessive pricing for an in-depth review or a potential hearing.

We are concerned that the DG outlines a framework that may envision providing Staff with wide procedural latitude and administrative discretion such that patentees would

[1] This written submission reflects Bayer Inc.'s position in respect to select elements of the 2024 Discussion Guide for PMPRB Phase 2 Consultation on New Guidelines 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] Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines - Canada.ca, p.4

lack sufficient predictability to assess compliance expectations and ultimately make sound product launch decisions for the Canadian market.

General Commentary

While the PMPRB has indicated that one of their goals is to develop transparent, predictable, and fair Guidelines, several key gaps remain, particularly with respect to the uncertainty associated with in-depth reviews:

- The international price comparison ("IPC") should adopt the highest international price threshold ("HIP"). Furthermore, Existing Medicines[3] that were compliant in the most recent compliance report should be grandfathered and exempt from in-depth reviews.
- For new products, IPC should be the initial test conducted. Further, one reporting grace period should be provided to give the rights holder the ability to adjust list prices. The IPC should be conducted with reasonable buffers (or ranges) such as allowing a 5% or $50,000 excess revenue allowance before advancing to an in-depth review. In most circumstances, prices should be available in at least 5 of 11 comparator countries before IPC is conducted or the passage of 3 years.
- PMPRB should broaden the list of low-risk products subject to complaint-based oversight and establish a clear set of triage measures that the Staff would utilize before initiating an in-depth review in response to complaints about these products.
- Finally, PMPRB should establish a Technical Working Group to address issues associated with managing Therapeutic Class Comparison ("TCC") comparators and to determine the role, if any, of the Human Drug Advisory Panel ("HDAP"). This collaborative approach has proven productive in the past and remains an effective way to navigate detailed technical issues. Clear guidelines are essential to ensure adequate transparency, fairness, and predictability in determining the TCC, assessing degrees of similarity, and applying procedural weighting. Throughout the roundtable discussion, multiple stakeholders emphasized the value of Technical Working Groups, and we believe that increased collaboration and transparency will help avoid the pitfalls encountered in previous attempts to establish the new framework.

We are pleased to provide the following detailed comments responding to the topics raised in the DG. We would also like to refer the PMPRB to our prior submissions, as they are still relevant and applicable in the context of the DG. [4]

[3] Patented medicines with a maximum average potential price (MAPP) or projected non-excessive average price (NEAP) as of July 1, 2022

[4] Bayer's previous recent submissions include the following: Bayer Inc. Scoping Paper response, Bayer Inc. 2022 Proposed Guidelines response, and Bayer Inc. 2020 PMPRB Draft Guidelines response

Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review.

Bayer recommends PMPRB adopt HIP for all new products; along with full grandfathering for Existing Medicines that were determined to be "Within Guidelines" in the most recent PMPRB price compliance report.

All current comparator countries in the PMPRB11 use national price containment measures for medicine prices[5]. Consequently, any price in the comparator countries has already faced external price controls, and therefore cannot be considered *prima facie* excessive. There is no justification that makes it appropriate to force maximum allowable prices below a known non-excessive price. The HIP comparison test is also consistent with recent Canadian jurisprudence in that factors set out in the *Patent Act* referencing the price of the same medicine in countries that are comparable to Canada[6].

Bayer supports the PMPRB's proposed high-level approach, where prices in the PMPRB11 comparator countries serve as the primary review mechanism. The HIP is the most predictable and knowable price test available for the patentee and is consistent with recent court rulings.

The PMPRB has acknowledged that conducting in-depth reviews on all Drug Identification Numbers ("DINs") is neither feasible nor reasonable, and Bayer concurs. The use of a straight-forward, bright-line compliance test benefits both rights holders and the PMPRB. If the IPC identification criterion is set below the HIP, the number of in-depth reviews will increase by a substantial margin, but not automatically result in more findings of excessive pricing. Or put a different way – a much higher regulatory burden on all parties without any increase in regulatory effectiveness.

Any measure other than the HIP would introduce uncertainty and lead to a substantial rise in in-depth reviews. The PMPRB should also consider that the HIP has itself changed dramatically by eliminating two high-priced countries, the US and Switzerland, and the addition of six lower priced countries. The PMPRB11 now consists of countries that have similar economies, market conditions and drug regulatory frameworks as Canada. A single list price change in a reference country could have a dramatic effect on the MIP and the mid-point of the MIP and HIP. Both measures are expected to fluctuate significantly since they would be constantly evolving as the drug is launched in various PMPRB11 countries over time. The median or mid-point is arbitrary and aligns more closely with price control than with an excessive pricing standard.

Figure 1 of the DG highlights that of the 852 DINs under the PMPRB's current purview, 32% of DINs or roughly 270 DINs have a list price higher than the HIP[7]. A significant proportion of these DINs no longer have market exclusivity and pose a demonstrably low risk of excessive pricing despite remaining under Board jurisdiction due to the presence of residual patents. For these DINs, in-depth reviews would provide marginal benefit but would consume significant Board and patentee resources. Consequently, Bayer

[5] Canada Gazette, Part I, Volume 151, Number 48: Regulations Amending the Patented Medicines Regulations, December 2, 2017

[6] Alexion Pharmaceuticals Inc. v. Canada (Attorney General) - Federal Court of Appeal (fca-caf.gc.ca)

[7] Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines - Canada.ca, p17-18

recommends that no in-depth reviews be conducted on Existing Medicines that have received a “Within Guidelines” status in the last compliance report.

Bayer recommends that the PMPRB establish compliance bands before an in-depth review is triggered. For example, if the list price exceeds the IPC measure by 5%, and $50,000 excess revenue is accrued based on the Average Transaction Price, then the threshold would be met to trigger the in-depth review. We also recommend that the PMPRB grant one reporting period to allow rights holders the opportunity to adjust their list prices lower.

Finally, regardless of the trigger used for reviews, the initial price review should only be conducted when there are at least 5 countries’ prices available or after 3 years has passed, whichever is sooner. This approach would help mitigate wild fluctuations in the IPC. In addition, the price of the medicine should only be assessed against the IPC during the Initial Review and any subsequent review(s) should only be done to ensure that list price increases adhere to the allowable CPI increase.

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criteria for an Existing Medicine is met.

Given the investments made by rights holders based on the laws and regulations in effect at the time of launch, Existing Medicines should be exempt from the IPC identification criteria if their DIN was classified as “Within Guidelines” in the most recent compliance report.

For greater clarity, the price of an Existing Medicine, including any allowable CPI increase, should be considered the ceiling price, regardless of the prices in the PMPRB11.

Additionally, new medicines that were initially sold between January 1, 2022, and the publication of the Final PMPRB Guidelines should be afforded special consideration, as they were launched without any guidance from the PMPRB. These products should be granted the maximum possible timeframe to achieve compliance.

Topic 3: In depth review based on CPI increase criteria.

Bayer recommends implementation of both options under consideration.

The two proposals from the PMPRB are akin to the 1-year and 3-year CPI methodologies used in the previous iteration of the Guidelines and should be implemented together.

In some provincial jurisdictions, price increases are limited to align with their fiscal year, which typically begins on April 1st. In these cases, provinces require that any price changes be communicated late in the preceding year or early in the current calendar year. Since the full-year CPI rate will not be available at that time, it is essential for the PMPRB to adopt a lagging CPI method. This approach will provide patentees with clarity regarding the actual CPI rate that will be applied in their evaluations. During the PMPRB Webinar held on August 13, 2024, it was noted that the PMPRB intends to utilize the actual CPI rate for the year.

Topic 4: The individuals/groups permitted to submit a complaint.

Bayer recommends that complaints should be limited to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts.

Pricing is an inherently complex and multifaceted process, supported by a sophisticated system of downstream reviews and scrutiny within Canada's drug reimbursement framework. Therefore, we believe that 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 can reach out to their elected officials, as outlined in the DG. Additionally, any payer can escalate their complaint to the Ministry of Health in their respective jurisdiction. This approach ensures that only substantive issues, which cannot be fully addressed within a given jurisdiction, are elevated to the PMPRB.

In-depth reviews demand significant resources from both the manufacturer and the PMPRB. Consequently, even if a complaint is filed, it is essential for the PMPRB to implement careful triage to filter out frivolous complaints. Furthermore, it is important for the PMPRB to communicate these triage measures to the public to maintain transparency. Given the anticipated workload for the PMPRB, any complaint that is not reviewed within a year of submission should 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.

Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines.

Bayer recommends that complaint-based oversight of medicines be extended to blood products and branded patented medicines that have lost exclusivity. As Bayer does not currently market any biosimilars nor vaccines, we refer the PMPRB to IMC's and BTC's submissions on the appropriate treatment of biosimilars and vaccines.

It is essential for the PMPRB to allocate resources to products that pose the highest risk of excessive pricing. Conversely, it is equally important to adjust the level of scrutiny for products with minimal market power and a correspondingly low risk of excessive pricing. Low-risk product categories should include those procured through tendering processes and those facing generic competition.

Blood products are acquired through a structured process where the contract price is negotiated with the Canadian Blood Services and Héma-Québec through RFP/RFQ processes. Additionally, as previously mentioned, many DINs currently under PMPRB jurisdiction no longer enjoy market exclusivity and are subject to generic competition. Both of these categories of drugs have a low likelihood of excessive pricing and should not be scrutinized at the same level as other patented medicines. These differentiated categories should only undergo an in-depth review when a complaint is received, and the established triage measures are exceeded.

Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC.

Bayer recommends that a Technical Working Group be formed. From this group, the goal would be to provide clear, predictable, and replicable evaluations of the TCC.

We have significant concern that Staff, with or without input from HDAP, would have absolute discretion to assign similarity and weightings on s85(1) factors. Consensus is often elusive, even among medical and patient communities—experts with practical and lived experience—when it comes to determining relative similarity within drug classes. It is difficult to envision how Staff could efficiently and effectively conduct this analysis while still achieving the PMPRB's stated objective of providing a predictable framework for rights holders. Even if it could be done, the aforementioned concern would remain.

At this stage, we are unable to offer a comprehensive response to the Board's proposals, as it remains unclear how the PMPRB will select comparators, assess degrees of similarity, and assign weightings to each of the s85(1) factors. It is also unclear how the PMPRB will use the TCC in determining the list price ceiling. This lack of clarity grants Staff considerable discretion in their analyses, which undermines the predictability and fairness essential for rights holders.

Both options presented in the DG, despite their ambiguity regarding the degree of similarity, have significant drawbacks. Option 1 groups entire categories of comparators together, creating a blanket, non-specific threshold for comparison with new treatments. Option 2 would likely require the PMPRB to undertake more extensive individual analyses of comparators. However, without further details on the nature of these analyses, it is challenging to provide meaningful feedback.

Both options imply that the highest TCC is no longer being considered by the PMPRB for pricing comparators. In line with the Québec Court of Appeal's decision (Merck Canada) ("QCCA Decision"), 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 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."[8] Thus, a constitutionally valid approach demands a higher than highest perspective, which negates the viability of the use or reference to a median or midpoint price threshold or prices of comparator products that is not the highest in its therapeutic class.

From our understanding of the DG, the PMPRB will conduct a TCC analysis when the list price exceeds the IPC in the post-initial periods. This will involve regenerating a new TCC each time due to new entrants, product discontinuations, or innovation. Such scenarios would significantly complicate and introduce uncertainty into the TCC process during an in-depth review. Therefore, we recommend that a TCC should only be conducted in the initial period and only be considered if the list price of a patented medicine exceeds its IPC to justify a list price that is higher than the IPC.

Finally, additional clarity is needed regarding the practical application of the international Therapeutic Class Comparison ("iTCC") concept. Each country may have a different set of comparators and may vary in approved product indications or other criteria established by their regulatory bodies. This adds a substantial layer of complexity in determining the

[8] Merck Canada c Canada, 2022 QCCA 240 49 (translation)

TCC. We recommend that the iTCC be used sparingly and only on exceptional occasions when no domestic comparators are available.

Given the complex and interrelated issues associated with TCC, we believe that establishing a Technical Working Group is the most effective way to develop a viable solution.

Topic 7: Future role of HDAP

Bayer recommends PMPRB determine the future of HDAP based on output of the Technical Working Group considering the TCC. Without further details on how the TCC would function, it is difficult to provide meaningful feedback on whether HDAP should play a role in the TCC evaluation.

Conclusion

Bayer reiterates its appreciation for the opportunity to provide feedback on the DG. Working with stakeholders and grounded in the Board's statutory mandate, the future Guidelines should enable patentees to manage their product portfolios while planning for Canadian launches in a predictable and compliant manner. This approach would have the mutual benefit of encouraging higher rates of compliance while also allowing both Staff and patentees to allocate resources to the areas of greatest need.

We understand that the Board did not facilitate any face-to-face meetings with stakeholders as part of this consultation. This decision contrasts with the collaborative approach previously expressed and desired by all parties. We emphasize the importance of carefully constructing the Guidelines to avoid any unintended consequences for the Canadian healthcare system.

As the Board continues in its efforts, please feel free to reach out to me directly with any questions regarding this submission or any related concerns.

Yours sincerely,

Dale Toki
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Bayer Inc.