Submission for the Patented Medicine Prices Review Board on the Draft Guidelines

By Merck Canada Inc.

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On behalf of Merck Canada Inc. (Merck), thank you for the opportunity to provide comments on the Patented Medicine Prices Review Board's (PMPRB's) Draft Guidelines released in December 2024.

Our submission aims to complement those made by our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada.

Summary of Recommendations

1. Maintain the Highest International Price (HIP)
2. Conduct subsequent annual reviews based only on Consumer Price Index (CPI)
3. Implement full grandfathering of "existing medicines"
4. Implement a transition period for products launched in the interim period
5. Increase the predictability and transparency of in-depth reviews
6. Restrict the complaint mechanism to health ministers
7. Avoid retroactive revenue assessments
8. Allow for reasonable margins to address fluctuations in exchange rates
9. Implement a complaints-based approach for vaccines and Antimicrobial Resistance (AMR) medicines

Rationale for Recommendations

1. Maintain the Highest International Price (HIP)

Merck supports the PMPRB's proposal to anchor the new basket of countries (i.e., the PMPRB11) to the HIP and recommends this threshold be included in the Final Guidelines.

The HIP is the only international price comparison (IPC) threshold that aligns with the PMPRB's legal mandate, which the courts have confirmed is restricted to assessing whether drug prices are excessive due to patent abuse.[1] As further detailed in our September 2024 submission, IPC thresholds lower than HIP would fall outside of the PMPRB's jurisdiction and would be deemed unconstitutional based on court rulings.[2] A threshold that is lower than the HIP would be arbitrary and would significantly constrain drug pricing, effectively imposing price controls, which is inconsistent with the PMPRB's legal mandate.

Merck suggests, however, that the initial price review occur only when prices are available in at least five countries or three years have passed since the medicine's introduction on the market. Conducting the initial assessment based on the price from only one country, as proposed in the Draft Guidelines, would

[1] *Merck Canada Inc. et al v. Canada (Attorney General),* Quebec Court of Appeal, decision rendered Feb. 18, 2022: https://www.canlii.org/en/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?autocompleteStr=2022%20QCCA%20240%20&autocompletePos=1; *Alexion Pharmaceuticals v. Canada (Attorney General)*, 2021 FCA 157: https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do

[2] *Merck*, *Ibid* at paragraph 49.

lean towards price control, since the price in a single country could be an outlier for a number of reasons and would not be indicative of reasonable comparator pricing in the basket of countries. The proposed approach could have the effect of delaying the introduction of medicines in Canada. In this case, manufacturers could decide to wait to launch their products in Canada until more international pricing data is available.

2. Conduct subsequent annual reviews based only on the Consumer Price Index (CPI)

The PMPRB's proposal to require that annual price reviews be assessed against both the CPI and the HIP of the PMPRB 11 basket is inconsistent with the PMPRB's mandate. It will introduce significant uncertainty and impose an unreasonable administrative burden on the sector. There should only be an initial price review when PMPRB11 data is available in five countries or three years have passed, and prices should only be subsequently monitored against the CPI.

Price fluctuations in other countries, resulting from market conditions, regulatory changes, and exchange rate variations, are beyond the control of the rights holders and have nothing to do with whether a price is excessive as a result of an abuse of patent in Canada. Therefore, these factors should not be used to define excessive pricing, especially if the price of the medicine did not exceed the HIP during its initial price review. Continuously re-benching the prices of medicines against the HIP of the PMPRB11 would result in a gradual reduction of prices over time, effectively functioning as a form of price control, which is inconsistent with the PMPRB's mandate.[3]

Ensuring long-term price stability and predictability is essential for fostering a competitive and robust pharmaceutical market. However, reassessing prices against the HIP on an annual basis would create significant uncertainty for innovators as well as other key stakeholders in the pharmaceutical ecosystem. This could also involve continuous renegotiation or adjustments of product listing, distribution and dispensing agreements, imposing an excessive administrative burden on provincial governments, insurers, pharmacies and distributors.

Finally, conducting annual price reassessments against the HIP of the PMPRB11 would create a significant administrative burden for rights holders, requiring them to allocate additional resources to continuously monitor prices in the countries included in the new basket—an effort further complicated by frequent fluctuations in exchange rates.

3. Implement full grandfathering of "existing medicines"

The PMPRB is proposing only a one-year transition period for existing medicines (i.e., those first sold before July 1, 2022) before applying the new pricing regime. During previous consultations on the Discussion Guide, the vast majority of stakeholders—including organizations representing pharmaceutical companies, pharmacists and distributors—strongly advised against this approach.

We were therefore surprised to see the PMPRB not only disregard stakeholders' recommendations to fully grandfather existing medicines but also adopt the shortest transition period proposed in the Discussion

[3] See paragraph 146 of *Merck Canada Inc. et al v. Canada (Attorney General)*, Quebec Court of Appeal, decision rendered Feb. 18, 2022: https://www.canlii.org/en/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?autocompleteStr=2022%20QCCA%20240%20&autocompletePos=1

Guide. This decision dismisses industry concerns without providing a rationale and imposes an unnecessarily abrupt shift in the pricing framework, which will create disruption.

We continue to emphasize that existing medicines should be grandfathered and subject to review only if their prices exceed the allowable CPI increase. The proposed approach is not only disruptive but also raises serious constitutional concerns.

Medicines that were not considered excessively priced under the previous pricing framework should not suddenly be deemed excessive. Once a product has been evaluated for excessive pricing, no further adjustments are necessary unless the manufacturer raises the price above the allowable CPI increase. Changing the pricing thresholds for existing medicines solely because of the introduction of a new framework would be arbitrary and amount to price control.[4]

Pharmaceutical companies reasonably expected that prices previously deemed non-excessive would only be reviewed for CPI compliance. Business plans, financial forecasts and product listing, distribution and dispensing agreements were developed on the existing framework at the time of launch. Constant regulatory changes make long-term planning and effective operation unfeasible. Altering price thresholds for existing medicines would also disrupt the entire pharmaceutical ecosystem. Companies, governments, insurers, pharmacies, and distributors would be forced to implement widespread price adjustments within a short timeframe, creating operational challenges and potentially disrupting medicine procurement and distribution.

If the PMPRB ultimately decides against grandfathering existing medicines despite the reasons outlined above, we strongly urge the implementation of a longer transition period of at least three years. This would provide the Canadian pharmaceutical supply chain with more time to adapt to the new pricing rules.

4. Implement a transition period for products launched in the interim period

The Final Guidelines should allow for a one-year transition period for products launched between July 1, 2022, and the coming into force of these new guidelines. This transition is essential to allow rights holders sufficient time to make necessary adjustments and ensure compliance, as these products were introduced without clarity on the new pricing framework.

Once the Final Guidelines take effect, the PMPRB should not calculate any potential excess revenues for these products based on sales made during the interim period. Applying the Final Guidelines retroactively would be procedurally unfair, as rights holders would have had no opportunity to comply with them before their publication.

5. Increase the predictability and transparency of in-depth reviews

Merck continues to be very concerned about the in-depth review process, which remains opaque, unpredictable, highly discretionary, and lengthy (12 to 28 months). The proposed approach lacks clear pricing benchmarks, leaving rights holders without sufficient guidance on how to appropriately price their

[4] See paragraph 146 of Merck Canada Inc. et al v. Canada (Attorney General) et al, Quebec Court of Appeal, decision rendered Feb. 18, 2022: https://www.canlii.org/en/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?autocompleteStr=2022%20QCCA%20240%20&autocompletePos=1

medicines. Under the Draft Guidelines, PMPRB staff have extremely broad discretion to assess all indications and comparators and to weigh Section 85 factors at their discretion when determining whether to recommend a hearing, further exacerbating uncertainty.

As such, and as emphasized in our previous submissions to the PMPRB, we continue to call for the establishment of technical working groups to address the in-depth review process, including comparator similarity in the Therapeutic Class Comparison (TCC). As suggested by IMC, the PMPRB could move forward with implementing the HIP policy while pausing the in-depth review process until these important issues have been examined within the working groups, allowing for the development of a more practical and effective approach.

Finally, if the PMPRB decides not to establish these working groups and instead proceeds with the proposed in-depth review process, we recommend the following changes to help mitigate uncertainty:

- These reviews should not result in establishing price thresholds below the HIP, with CPI adjustments. To be clear, the TCC cannot be used to further drive down prices below this level, as this would constitute price control, which falls outside of the PMPRB's mandate. However, the TCC may be used to justify a price higher than HIP.
- Enhance transparency by providing rights holders with the scientific report and the price review report, reducing the risk of misunderstandings that could lead to unnecessary hearings.

6. Restrict the complaint mechanism to health ministers

Under the Draft Guidelines, complaints automatically trigger in-depth reviews, which can extend up to 28 months. Given the lengthy and uncertain nature of these reviews, the criteria for accepting complaints that trigger an in-depth review should be restricted to prevent unnecessary or arbitrary investigations.

We recommend the following changes to the proposed complaint mechanism:

- Complaints should be assessed against the clear benchmarks outlined in the new Guidelines, such as the HIP with permitted CPI increases. Prices set below the HIP are already considered acceptable by the PMPRB's own criteria, and the complaint mechanism should not introduce an unconstitutional alternative standard that undermines this framework.
- Complainants should be limited to the federal/provincial/territorial health ministers, consistent with section 86(2) of the *Patent Act*. Allowing third parties, such as private payers, to file complaints would be inappropriate, as they represent private and for-profit interests rather than the broader public interest. Private payers operate within competitive markets and may have financial incentives to challenge drug prices for their own benefit, which could lead to frivolous or strategically motivated complaints, diverting resources away from the PMPRB to focus on necessary reviews.
- Complaints should be well-substantiated and supported by credible evidence to ensure they address legitimate concerns rather than being speculative or unfounded.
- The details related to complaints should be shared with the rights holders, including any supporting evidence, to allow an informed dialogue between rights holders and the PMPRB.

7. Avoid retroactive revenue assessments

Excess revenue calculations should not be applied retroactively to a product's launch but should only cover the period from when a complaint was received or an in-depth review was initiated. The Final Guidelines should explicitly clarify this to ensure predictability and regulatory consistency. Without this

clarification, the risk of retroactive liability could create uncertainty and discourage pharmaceutical companies from launching new products in Canada.

8. Allow for reasonable margins to address fluctuations in exchange rates

Under the proposed framework, even minor fluctuations in exchange rates – factors beyond the control of rights holders – could create an unnecessary administrative burden or, worse, trigger in-depth reviews, even when domestic drug prices remain stable. To mitigate this issue, the Final Guidelines should incorporate a 5-10% price margin against the PMPRB11 threshold, ensuring greater flexibility and reducing the risk of unwarranted reviews. For instance, the previous Guidelines allowed for a 5% margin at the initiation of investigations.[5]

9. Implement a complaints-based approach for vaccines and AMR medicines

As stated in our previous submissions, we strongly urge the PMPRB to adopt a complaints-based approach for vaccines and AMR medicines.

In the case of vaccines, these products are already subject to an established and well-functioning vaccine recommendation and reimbursement mechanism through the National Advisory Committee on Immunization (NACI) and centralized procurement via the federal government on behalf of the provinces and territories. Given this comprehensive public health procurement system and the very low risk of excessive pricing for vaccines, the PMPRB should only assess the prices of vaccines if a complaint has been filed. This would align with the PMPRB's vision to prioritize outliers, as articulated by its staff in recent presentations on the Draft Guidelines. Given the PMPRB's limited resources and the substantial number of initial reviews it must conduct, it would be appropriate to allocate fewer resources to areas where excessive pricing is unlikely to be an issue.

For antimicrobial resistance (AMR) medicines, a complaints-based approach is essential to create urgently needed incentives that strengthen the Canadian market and revitalize the development pipeline. Currently, very few new AMR medicines are being developed and commercialized in Canada, despite the growing public health threat. Merck is one of the few large pharmaceutical companies that continue to invest in R&D for treatments targeting bacterial infections. Given that resistance to first-line antimicrobials was approximately 26% in 2018 and is projected to rise to 40% by 2050, Canada should take all necessary measures to help address this escalating crisis.[6]

Conclusion

In recent presentations on the Draft Guidelines, PMPRB staff acknowledged that adjustments to the new pricing framework may be necessary to address unforeseen issues. While Merck appreciates this openness to adapt the pricing framework, we believe many of these challenges could be proactively identified, analyzed, and resolved before the implementation of the Final Guidelines through the establishment of technical working groups.

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[5] PMPRB, Compendium of Policies, Guidelines and Procedures – Updated February 2017: https://www.pmprb-cepmb.gc.ca/view.asp?ccid=492#1647

[6] Council of Canadian Academies, When Antibiotics Fail: The Expert Panel on the Potential Socio-Economic Impacts of Antimicrobial Resistance in Canada, Ottawa, 2019: https://cca-reports.ca/reports/the-potential-socio-economic-impacts-of-antimicrobial-resistance-in-canada/

Given the significant commercial implications of these issues, including the impact on launch decisions, we strongly urge the PMPRB to reconsider its consultation approach and facilitate more in-depth discussions with industry pricing experts. This proactive engagement would help anticipate and mitigate potential challenges, ensuring a smoother transition and more practical and workable guidelines. These working groups are particularly necessary to address key aspects of the in-depth review process, as mentioned above, as well as the CPI methodology.

We appreciate the opportunity to provide input on the Draft Guidelines and look forward to continued, substantive engagement with the PMPRB as the new Guidelines are finalized.