IMC Response to the PMPRB's March 2025 Guidelines Consultation

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Submitted via the PMPRB Website: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines-pmprb-staff.html

This submission is made on behalf of Innovative Medicines Canada (IMC) in response to the proposed 2025 *Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation*.[1]

IMC is the national association of biopharmaceutical and vaccine companies representing the majority of rights holders subject to the Patented Medicine Prices Review Board's (PMPRB) jurisdiction. The association advocates for policies that enable the discovery, development, and delivery of innovative medicines and vaccines to improve the lives of all Canadians and supports the members' commitment to being a valued partner in the Canadian healthcare system. Collectively, our sector supports more than 107,000 high-value jobs, invests upwards of $3 billion in R&D annually, and contributes nearly $16 billion to Canada's knowledge-based economy.

Background and context

Changes to the PMPRB regime have been ongoing since 2017, including amendments to the *Patented Medicines Regulations*, judicial intervention invalidating significant elements of those amendments, interim guidance, and various iterations of the PMPRB's Guidelines. The current consultation marks what could be rights holders' last opportunity to provide formal comment, however, **significant collaboration will be required in the months and years ahead to ensure a functional and effective PMPRB regime.**

As proposed, the Guidelines would reflect a substantive change in direction for the operation of the PMPRB. The Guidelines would move the PMPRB from a regime that encourages high voluntary compliance through predictable benchmarks at the time of a medicine's launch, to a more open-ended regime where Guidelines are framed as review procedures for PMPRB staff. Under this regime, it appears that PMPRB staff would directly weigh the possible relevance of different excessive price factors in different product scenarios. The open-ended nature of the regime entails a lack of predictability for rights holders, unnecessary workload for the PMPRB, and a high potential for future file-specific disputes.

International price referencing

The PMPRB has anchored the International Price Comparison Test to the highest international price (HIP) of the revised PMPRB11 schedule of international comparators (the revised regulatory basket of comparators already reflects significant downward price revision due to the removal of the United States and Switzerland).

As previously discussed, of the IPC tests proposed by the Board for new products, we maintain that the HIP is PMPRB's only justifiable option to remain consistent with its mandate regarding the detection of patent abuse. As such, **maintaining the HIP of PMPRB11 for new medicines in the final Guideline is critical to ensuring predictability and stability.** See our September 2024 submission on this issue in relation to the PMPRB's mandate and relevant case law.[2]

Regarding procedure, IMC recommends aligning with the introductory price review timeline in the previous Guidelines (e.g. three years post-launch or once prices are available for five or more reference countries, whichever comes first).

Annual price reviews

As previously discussed, predictability over time is among the most important issues in the current Guidelines discussion for rights holders.[3] The PMPRB proposes annual reviews that could trigger in-depth reviews that includes all associated drug identification numbers (DINs) and an evolving mix of possible therapeutic comparators. Comparators may be different at the time of the in-depth review than those which existed when a rights holder made its initial investment decision at launch. This approach entails an ultimate lack of pricing predictability where rights holders may not be able to determine an allowable price at the time of product launch nor throughout the product life cycle. **Arbitrary price reductions are foreseeable under annual price reviews and would reflect inappropriate price control over time**.[4]

In IMC's view, PMPRB should validate if a patented medicine is priced non-excessively at introduction using, at minimum, the highest international price (HIP) of the PMPRB11 schedule, and then monitor compliance with that introductory price, plus consumer price index (CPI) over time (referred to as the 'HIP policy' hereafter).[5] This would allow the PMPRB to still routinely monitor and validate compliance with the CPI-adjusted price benchmark established at a medicine's introduction without arbitrarily revising prices on an annual basis.[6]

Full exemption for existing products

IMC is disappointed that the PMPRB has not incorporated an exemption for existing products. Existing products were already compliant and therefore non-excessive with the applicable legislation and Guidelines, given that the amended Regulations did not change the excessive price factors under the *Patent Act*. As communicated during the Fall 2024 Board Policy Hearings and in follow-up, there is precedent for the PMPRB to leverage the CPI factor to transition existing products' prices to a new Guideline. **The rationale for rejecting the industry position to leverage the *Patent Act* CPI factor to transition to a new Guideline has not been explicitly addressed by the PMPRB.**

Transition period for existing products

Among the various options identified in the 2024 consultation, the PMPRB has selected the minimum transition period of one year. A **three-year transition period would be more appropriate** and realistic for

the Canadian pharmaceutical supply chain (e.g., manufacturers, pharmacists, distributors, pharmacies and generic manufacturers) which is already struggling due to several Canadian cost control policies.

Interim period as it relates to new medicines

IMC recommends a minimum 1-year transition from entry into force of Guidelines for new medicines that were launched in the Interim Period. We also take this opportunity to reiterate the PMPRB's commitment that "once new Guidelines are in place, no potential excess revenues will be calculated by staff retrospectively for any New Medicines for sales made during the interim period." [7]

We are aware of some recent direct communications from PMPRB staff to rights holders that have caused confusion regarding this point. For greater certainty, our view is that the interim period is in effect until the Guidelines are finalized in 2025 or 2026. Therefore, **rights holders expect no financial impacts for sales made during the interim period, up to the date when the Guidelines are finalized plus an appropriate transition period.**

Common sense file resolution and tariff adjustment mechanisms needed

Given the current state of heightened trade tensions and resulting uncertainty, IMC wishes to engage directly with the PMPRB on the issue of possible tariffs and the need for appropriate flexibility and shared risk mitigation to resolve such issues that are outside of a rights holder's control. If Canada imprudently imposes tariffs on pharmaceutical imports, the PMPRB must pause Guidelines implementation to ensure appropriate adjustment measures can be thoroughly discussed.

As previously suggested, the draft Guidelines should also include some reasonable buffers or tolerance factors (e.g. +/- 10% fluctuation against the PMPRB11 benchmark price) to ensure that minor price fluctuations, for example due to changes in exchange rates, do not result in in-depth reviews when domestic prices are otherwise stable. This is similar to previously proposed measures. This and other possible common sense file resolution mechanisms[8] are critical for smaller biotech companies who do not have the resources of large and specialized teams to manage PMPRB pricing dynamics.[9]

No retroactive revenue assessments

PMPRB should provide written clarity to staff and rights holders that, in the event of a hearing (e.g. due to a complaint or in-depth review, post marketing), any possible excess revenue calculations will not be retroactive to the time of product launch; rather, these will only apply to the period in which a hearing is initiated. This clarity is essential. Market dynamics change continuously and impact the mix of possible therapeutic comparators. Companies cannot be held to a different set of comparators and pricing years after the date of their first sale, than existed at time of first sale. Under the current proposals, there is no way for a rights holder to predict the outcome of an in-depth review. This **absence of clarity on the scope of potential retroactive liability will impact corporate decisions regarding the introduction of new medicines in Canada**.

Different price standards for complaints are inappropriate

The PMPRB proposes to apply a different pricing standard to patented products, solely on the basis of a complaint (e.g. international reference price test for products with no complaints, and automatic in-depth review and associated price tests for products with a complaint).

It is inappropriate to automatically apply an in-depth review and associated price tests simply on the basis that a complaint has been made. This would create aberrant incentives for arbitrary complaints and could lead to significant additional complaint volume, political contention, and unnecessary burden for both PMPRB staff and manufacturers.

The PMPRB must avoid automatic in-depth reviews and establish a reasonable complaints resolution mechanism. Namely, **the PMPRB should validate complaints against the HIP standard and close complaints (without in-depth review) where pricing is consistent with the HIP**.[10] Section 73 of the Guidelines should be revised to note that prices below the HIP are considered non-excessive.

Complaints eligibility

In general, eligibility for complaints should be narrow, transparent, consistent with s. 86(2) of the *Patent Act,* and restricted to Federal, Provincial and Territorial Ministers of Health. **It is inappropriate and not justified to grant for-profit commercial insurance companies and their associations special status for complaints.**

Complaints-only processes

As previously iterated, IMC is in favour of all tendered products (including vaccines and blood products) being considered on a complaints-only basis.[11] Tendered products are already subject to competitive contracting and complex commercial pathways that make them at low risk of excessive pricing.

In-depth reviews

IMC has ongoing concerns regarding in-depth reviews which have not been resolved in the draft Guideline. As proposed, there is no way for a rights holder to predict the outcome of an in-depth review, and this absence of clarity could influence corporate decisions on bringing new medicines to Canada. Please see our detailed previous commentary on in-depth reviews and the future role of the Human Drug Advisory Panel (HDAP).[12]

The discussion of therapeutic comparability tiers raises numerous issues and leaves room for subjective decision-making by PMPRB staff. The Guideline appendices on *Patent Act* Section 85 direct staff to consider over 30 broad and open-ended questions—many of which may extend beyond the scope of the *Patent Act*. However, the Guidelines offer little guidance on how to assess, prioritize, or resolve conflicting answers.[13] This lack of clarity creates foreseeable challenges for both the PMPRB and rights holders.

An analogy is a highway where neither driver nor highway patrol know the speed limit. The rules of the road are only determined 12- 24 months after the fact, according to the discretion of the individual highway patrol officers, based on the speed of other cars driving at that later date. To provide greater clarity, "Recommendations for Closure" should prominently include "International Price Comparison respecting the Highest International Price."

IMC suggests a fundamental reconsideration of the purpose and practicality of in-depth review proposals. Technical working groups with experts representing rights holders should be created to identify a path forward. **PMPRB can move forward with international referencing elements (HIP policy), pause implementation of specific in-depth review policies, and consider the application therapeutic considerations through further consultation.**

Next steps - Technical working groups

IMC reiterates its request to engage with the PMPRB in a more iterative manner including through technical working group(s) on issues such as file resolution mechanisms, exchange rate mitigations, consumer price index methodology, timeframes including validation of the introductory price and especially in-depth reviews (prior to inclusion of in-depth reviews in final Guidelines). As outlined, we remain deeply concerned about in-depth reviews. We again request direct dialogue that is consistent with previous successful practices (e.g. the collaborative DIP methodology technical working group discussions).[14]

Thank you for your consideration of our submission. For ease of reference, a summary of key points in provided below. IMC recognises the PMPRB's efforts, and we provide this commentary in the sprit of helping to build a practical and functional Canadian pricing regime for the future.

Appendix: Summary of Key Points

- Significant collaboration will be required in the months and years ahead to ensure a functional and effective PMPRB pricing regime.
- Maintaining the HIP of PMPRB11 for new medicines in the final Guideline is critical to ensuring predictability and stability.
- Arbitrary price reductions are foreseeable under annual price reviews and would reflect inappropriate price control over time.
- The rationale for rejecting the industry position to leverage the *Patent Act* CPI factor to transition to a new Guideline has not been explicitly addressed by the PMPRB.
- Rights holders expect no financial impacts for sales made up to the date when the Guidelines are finalized plus an appropriate transition period.
- Common-sense file resolution and tariff adjustment mechanisms are essential to avoid unnecessary disputes (e.g. to address exchange rate issues; dynamic tariff environment)
- The absence of clarity on the scope of potential retroactive liability will impact corporate decisions regarding the introduction of new medicines in Canada.
- Different price standards for complaints are inappropriate. The PMPRB should validate complaints against the HIP standard and close complaints (without in-depth review) where pricing is consistent with the HIP.
- Complaints eligibility should be restricted to Federal, Provincial and Territorial Ministers of Health.
- PMPRB can move forward with international referencing elements (HIP policy), pause implementation of specific in-depth review policies, and consider the application therapeutic considerations through further consultation.
- "Recommendations for Closure" should prominently include "International Price Comparison at or below the Highest International Price."
- Technical working groups would provide value for all parties in resolving key issues.

[1] IMC understands that the PMPRB has issued draft Guidelines following amendments to the Patented Medicines Regulations (Regulations) which came into force July 1, 2022. While IMC is committed to constructive engagement with the PMPRB on the Guidelines, IMC's engagement is not intended and should not be interpreted as supporting the amendments to the Regulations, the August 2022 interim approach, the September 2023 amended interim approach, or the draft or final Guidelines. IMC reserves the right to oppose any aspect of the amended Regulations, Guidance, or Guidelines that exceed the jurisdiction of the Board or are otherwise unlawful. There are a number of Guidelines-related issues that had been identified in previous IMC submissions that have not yet been addressed and which require future consultation with rights holders (please see IMC's February 2020, August 2020, February 2021, August 2021, July 2022, December 2022, August 2023, December 2023, and September 2024 submissions).

[2] e.g., *Merck v Canada,* 2022 QCCA 240; *and Alexion v Canada,* 2021 FCA 157.

[3] There has been considerable feedback from rights holders and other interested parties that any form of re-benchmarking (either through application of the international schedule, or therapeutic referencing) would pose significant predictability concerns. The PMPRB has functioned for decades without re- benchmarking. Provincial product listing agreements and private payer agreements effectively control pricing over time. The PMPRB can address predictability concerns by including a statement in the Guidelines that "once a product is determined to be 'compliant' or 'reviewed,' the PMPRB will not reassess or 're-benchmark' the product, provided the rights holder does not increase its price by more than CPI."

[4] See PMPRB's analysis of price reviews during Product Life cycle 2023 Scoping document, Box 3, Pricing trends in Canada versus the PMPRB11. Based on this data, re-benchmarking would clearly reflect price control over time, which is inconsistent with an excessive pricing mandate.

[5] Monitoring prices over time does not require or enable the PMPRB to force prices downward over time. Unnecessary complexity, variability, and discretion will cause compliance challenges for rights holders, who have historically been highly compliant with PMPRB's Guidelines, and will also reduce regulatory transparency for all interested parties

[6] A product should be considered compliant over time provided it does not exceed its at-launch price (plus Consumer Price Index adjustments). A requirement that the ceiling price of patented medicine decrease over time on an annual basis, or other time-based reduction processes, are inconsistent with preventing patent abuse.

[7] https://www.canada.ca/en/patented-medicine-prices-review/services/legislation/interim-guidance.html

[8] For example, new manufacturers considering Canada and start ups have commented on the need to understand their price prior to making significant investment into infrastructure and have suggested a process to discuss or pre-confirm compliant pricing that manufacturers could opt into.

[9] Small companies have noted the challenges of holding a manufacturer to potentially significant exchange rate fluctuations that are outside of their (and Canada's) control and that this may impact the sequence of Canada in global launches and Canada as a viable, predictable market. The PMPRB should ensure that year-to-year changes and/or methodological considerations such as exchange rate fluctuations (notably but not exclusively) do not produce unnecessary regulatory burden for all parties negatively impacting the cost of marketing drugs in Canada.

[10] In general, the PMPRB should focus more on the substance of complaints and how to resolve them. If a price appears to exceed the ceiling set out by the price tests, then an investigation could be undertaken to determine if the test was appropriately applied in the circumstances. Under a HIP policy, complaints could be easily resolved with a check against the HIP.

[11] Provided the eligibility of complainants is in line with the recommendations in the previous paragraph, should be exempt from all initial, annual and in-depth review unless a complaint is made. The topic of vaccines being considered under a complaints-only based process should now be a settled matter. The PMPRB previously adopted this position in its 2020 Guidelines at paragraph 88: "Notwithstanding the above, in the case of Biosimilars, medicines for veterinary use, over the counter (OTC) medicines, and vaccines, an investigation will only be commenced by Staff if a complaint is received." https://www.canada.ca/content/dam/pmprb-cepmb/documents/legislation/guidelines/PMPRB-Guidelines-en.pdf

[12] Despite our previously iterated concerns and the judicial invalidation of the pharmacoeconomic value regulatory factor, ongoing reference to HTA bodies continues to reflect a concerning signal to PMPRB staff.

[13] Note: Section 92 of the draft Guidelines references information "collected by Staff that relates to factors in Section 85 of the Act, namely: … information relating to the TCC selection and analysis." This language causes ambiguity vis-à-vis the actual *Patent Act* Section 85 language " …other medicines in the same therapeutic class have been sold in the relevant market."

[14] PMPRB should eventually revisit plans for monitoring and evaluation as the previous 2021 Guidelines Monitoring and Evaluation Plan is now dated.