

IMC Response to the PMPRB's 2023 Interim Guidance Consultation

August 21, 2023

Submitted via the PMPRB Website: [Consultation Submission Portal](#)

This submission is made on behalf of Innovative Medicines Canada (IMC) in response to [the 2023 Proposed Amendment to the Interim Guidance re: New Medicines](#) (the Draft Guidance).ⁱ

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 \$2.4 billion in R&D annually, and contributes nearly \$16 billion to Canada's knowledge-based economy.

Opportunity for Collaboration

IMC and its members are conscious of the current opportunity to collaborate with the PMPRB on an efficient and effective Guidelines that are consistent with the government's Biomanufacturing and Life Sciences Strategy and other initiatives. The continuing uncertainty caused by the extended reform process is not in the interest of industry, governments, or Canadian patients. In a period of unprecedented life sciences innovation, the need for a reasonable, predictable and stable maximum non-excessive pricing system to help launch new treatments in Canada has never been greater.

We look forward to engaging in a productive dialogue with the PMPRB on the Interim Guidance and, more importantly, with respect to the development of final Guidelines that are consistent with the Board's mandate while meeting the needs of the government, right holders, and other stakeholders. In this spirit, IMC offers the following recommendations:

- With respect to the final Guidelines, IMC recommends a change in approach from previous consultations. Rather than posting detailed draft Guidelines followed by a set period for stakeholder feedback, it would be preferable to engage in a higher level and principles-based dialogue with representatives of rights holders prior to the posting of any proposals.
- In addition, we recommend that, in advance of PMPRB publishing a draft Guideline, a working group with patentee technical experts be established to engage in a more iterative Guideline development process, as was the customary practice for Guidelines discussions prior to 2016-17.



- We would also make the offer that, once the PMPRB Board has been re-constituted with new members by the Governor in Council, a Board-to-Board dialogue should be established to share perspectives and proactively facilitate a productive relationship going forward.

Consistency with an Excessive Price Standard

While potentially a legacy from previous Guidelines proposals, IMC notes that the specific price point identified in the Draft Guidance - the median – is reflected without reference to the PMPRB’s mandate regarding excessive prices and the detection of specific instances of patent abuse.

Rather, the Draft Guidance may have the effect of encouraging rights holders to price their New Medicines below an inappropriate price point among the revised schedule of international reference countries.

In IMC’s view, this is inconsistent with an excessive price standard, and recent appellate court decisions that have constrained the role of the PMPRB within its constitutional and legislative limits.ⁱⁱ Rights holders should be considered compliant with the new basket (or “considered as reviewed”, to use the PMPRB’s terminology), provided their submitted Canadian prices are within the range of available prices of the revised PMPRB¹¹ schedule.

The government has already removed the two higher-priced countries (Switzerland and the United States) from the international schedule, which has the effect of constraining the ceiling price of New Medicines. The PMPRB should not further constrain prices by selecting the median as a reference point either for this Interim Guidance, or in future Guidelines.

With respect to current right holder pricing practices for new medicines, the draft guidance notes that “approximately 55% of New Medicines have list prices that are below the median of the new basket of comparator countries (PMPRB¹¹).” IMC has no position with respect to individual company pricing policies. However, we would observe that the issue is whether the median becomes a mandated standard, rather than whether or not individual products have been voluntarily priced below the median.

Finally, we note the language used in the consultation document (“[i]n order for the PMPRB to move forward with implementing the basket...”) is not entirely accurate. The revised schedule of PMPRB¹¹ countries is already a regulatory reporting requirement. The selection of the median is not required for its implementation, and alternatives more consistent with jurisprudence can and should be considered.

Predictability over time for “Reviewed” Medicines

There are inherent predictability issues related to the PMPRB’s legislative framework, but other predictability issues are within the PMPRB’s control. Regardless of the statement regarding no retrospective calculation of revenues during the interim period,ⁱⁱⁱ the measure to establish a “reviewed” and “under review” dichotomy cannot fully address predictability and risk for patentees.



We acknowledge PMPRB’s stated objective to provide rights holders with greater predictability. The PMPRB can help to do so by issuing a statement in the draft guidance and Guidelines that “once a product is determined to be “reviewed,” PMPRB Staff will not reassess or ‘re-benchmark’ the product, provided the rights holder does not increase its price by more than the consumer price index.”

Consumer Price Index Adjustments

The Consumer Price Index (CPI) is specifically referenced in the *Patent Act*. PMPRB’s proposed Guidance should be clarified to remove any doubt regarding the allowability of CPI adjustments under the guidance. Clarity can be provided that a price increase within the range of CPI for 2023 and ongoing, would not cause a product to be “under review.” As a practical matter, the PMPRB must continue to update its *CPI-Based Price-Adjustment Factors for Patented Drug Products* on an ongoing basis.^{iv}

Guidelines Next Steps

IMC looks forward to hearing from the PMPRB on the options for dialogue proposed above (pre-consultation, technical staff group, and Board-to-Board meetings). We sincerely believe that a reset will allow all parties and stakeholders to engage in a collaborative, first-principles discussion with respect to new final Guidelines. While the current consultation does not reference the policy direction for future Guidelines, we would [reiterate](#) that the Fall 2022 Proposed Guidelines were fundamentally flawed and should not be the starting point for future discussions.

Thank you for your consideration of our submission, and we look forward to collaborative discussions on this critical issue for our industry, governments, stakeholders, and Canadian patients.

ⁱ IMC understands that the PMPRB intends to apply Guidance following amendments to the Regulations which came into force July 1, 2022. While IMC is committed to constructive engagement with the PMPRB on the Interim Guidance and ultimate Guidelines, IMC’s engagement is not intended and should not be interpreted as supporting the amendments to the Regulations, the Guidelines, or the August 2022 [interim approach](#). IMC reserves the right to oppose any aspect of the amended Regulations, Guidance, or Guidelines that exceed the jurisdiction of the Board. 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 (please see IMC’s [February 2020](#), [August 2020](#), [February 2021](#), [August 2021](#), [July 2022](#) and [December 2022](#) submissions).

ⁱⁱ For example, the draft Guidance has not apparently taken into consideration rulings which confirm that *Patent Act* section 85 factors are to be applied solely when dealing with negative effects of excessive prices flowing from the patent monopoly.

ⁱⁱⁱ Quote from Guidance: “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.”

^{iv} We note that any price adjustments for 2023 would have already taken place in April 2023.