IMC Response to PMPRB Interim Approach Consultation

July 18, 2022

Submitted via the PMPRB Website: Consultation Submission Portal

This submission is made on behalf of Innovative Medicines Canada (IMC) in response to the PMPRB's June 30, 2022 Notice and Comment: PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations.[i] IMC is the national association of 49 biopharmaceutical and vaccine companies representing the majority of rights holders subject to the PMPRB's jurisdiction. IMC members are working steadfastly with Federal, Provincial and Territorial governments, to address the COVID-19 pandemic and bring a range of innovative therapies and vaccines to Canadians. Guided by a strict Code of Ethical Practices, we work with governments, insurance companies, healthcare professionals and other stakeholders to enhance the wellbeing of Canadians.

IMC's members continue to have significant concerns regarding changes to the PMPRB and future Guidelines that will implement the revised schedule of international reference countries. It should be noted that the June 30th proposal (the Interim Approach) does not fully reflect the "status quo" as stated in the Notice and Comment. Rather, it includes a proposal for a list price freeze for existing patented medicines during the interim period until the final publication of new Guidelines,[ii] and no guidance with respect to new patented medicines launched during the interim period.

The proposed Interim Approach requires rights holders to launch at risk with no visibility regarding how PMPRB will review new medicines for potentially excessive pricing. As such, PMPRB's proposal to not engage in investigation or enforcement of new patented medicines during the interim period[iii] is insufficient unless accompanied by a commitment not to seek the payment of revenues accrued between July 1, 2022 and the final publication of new Guidelines. The absence of such a commitment can be expected to have a chilling effect on patient access: companies may be forced to take a 'wait and see' approach to the introduction of new medicines.

IMC requests that the PMPRB consider the following recommendations:

1. **No retroactive payment of revenues during the interim period.** As discussed above, this is essential to ensure rights holders can, in absence of final Guidelines, continue to launch new medicines for the benefit of Canadian patients.
2. **Clarify which non-excessive average price (NEAP) applies.** PMPRB should clarify that the highest available NEAP will set the benchmark for the interim period. For patented sales first reported in the January-June 2022 reporting period, PMPRB should ensure that PMPRB7 pricing informs NEAPs that have not yet been established.

3. **A minimum twelve-month transition period will still be needed following the new Guidelines.** IMC notes that the twelve-month (two reporting period) transition period that PMPRB previously committed to (April 16, 2021) will still be needed following the finalization of new Guidelines. This period is necessary to allow rights holders and other pharmaceutical supply chain stakeholders (e.g., pharmacies, distributors and generics) to adjust their business plans. Because rights holders and others have no visibility into the new Guidelines, the interim period cannot reasonably be considered to be transitional in nature.
4. **Reflection of *Patent Act* Factors.** The Interim Approach and the new Guidelines must reflect PMPRB's legislative mandate and relevant case law. IMC notes that the Interim Approach would create significant disincentives to patentees taking list price increases, which in turn could result in de facto price reductions during the interim period. IMC also notes that "changes in the Consumer Price Index" is an explicit factor for assessing if a medicine is being sold at an excessive price in the *Patent Act* and should be reflected in the Guidelines.
5. **Anchor to an "excessive price" standard.** The Interim Approach and future Guidelines should reflect that the PMPRB's "excessive price" mandate is directed to monitoring for patent abuse. Specific price tests and adjustments proposed in future Guidelines should be clearly justified according to this excessive pricing mandate which precludes certain tests and price sources (e.g., "lower-of"-style price tests; "lowest among" international sources; and median-style tests).

Thank you for your consideration. We look forward to a fulsome and comprehensive consultation process when draft Guidelines are released for review and comment in the Fall of 2022.

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[i] IMC understands that the PMPRB intends to apply Guidelines within the framework of amendments to the 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, which remain, as of the date of this submission, under review by the Federal Court of Appeal in Court File No. A-215-20, the Guidelines, or the proposed interim approach. IMC reserves the right to oppose any aspect of the amended Regulations or Guidelines that exceed the jurisdiction of the Board. It should be noted the Current Notice and Comment seeks input on PMPRB policy for an "Interim Period" which is already under way in July 2022 at the time of the consultation and thus calls into question the meaningfulness of the interim consultation process. Finally, 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, and August 2021 submissions).

[ii] IMC notes that the PMPRB has not provided a rationale for the Interim Approach policies and enforcement proposals to ground them within the PMPRB's legislative mandate and relevant case law.

[iii] "The PMPRB will not conduct a price review of any new patented medicines or open any investigations in respect of them until the new guidelines come into effect." June 30, 2022, Notice and Comment.