March 18th, 2025

To the PMPRB

The following feedback is provided by BioCryst Canada ULC in response to the PMPRB Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation (Version for consultation, December 2024).

Source: Draft Guidelines for PMPRB Staff - Canada.ca

1. **Annual Review: Prices are to be compared against Consumer Price Index ("CPI") and subject to re-benching for HIP**
    - **Summary**: Prices will be reviewed annually against CPI increases as an identification criterion to prioritize medicines that warrant an In-Depth Review. Prices will also be reviewed annually against the HIP with the most recently filed domestic and international pricing data. This means that changes in the HIP could render the applicable threshold lower or higher in subsequent years than it was at introduction, depending on how the international landscape evolves and could result in medicines being subject to an In-Depth review even if considered compliant after the Initial Review. New and existing medicines will be subject to annual reviews.
    - ***Comments**: We are of the view that the price of a medicine after Initial Review should only subsequently be monitored against the allowable CPI increase, as this is consistent with the Quebec Court of Appeal's decision in Merck Canada c Canada, 2022 QCCA 240. In our view, re-benching medicines against the HIP due to changes in market conditions may arbitrarily drive prices down beyond acceptable (non-excessive) thresholds and result in regulation of the market itself.*

2. **In-Depth Review: Tests to be applied when assessing recommendation for a hearing**
    - **Summary:** Staff will consider all s. 85 factors at the in-depth review stage in determining whether a medicine should be recommended for a hearing. S. 85 factors will be considered individually and weighted against one another. The Appendices provide various scenarios whereby medicines are likely to be recommended for hearing. Notably, where pricing data are available for International Price Comparison (IPC) and Therapeutic Class Comparison (TCC), a medicine will be recommended for hearing when the price is above both. As well, where there are no TCC comparators, a hearing will be recommended if the list price is significantly above HIP, and if there are no IPC data, a hearing will be recommended if there is a significant differential between the list price and TCC. Conversely, the staff is unlikely to recommend a hearing where the list price is below both HIP and TCC, or where there is a de minimis

differential_between list price and either HIP or TCC if only one comparator is available.

- ***Comment**: The concern is that the Appendices are sufficiently broad that it remains unclear how PMPRB Staff would use and apply the factors in their analysis. We would, with respect, remind the PMPRB that the "highest of the high" is the only constitutionally valid approach, in light of Merck QCCA.*

3. **Deferral Letters**
   - **Summary**: The Guidelines allow for the possibility that in the event of resource constraints, the Staff shall prioritize medicines with list prices significantly above the HIP or whose list price increases are significantly above the CPI, while other medicines may receive deferral letters. It is possible that some medicines with list prices above the HIP may be deferred multiple times. Deferral letters do not provide relief from reimbursement of excess revenue gained during the period of deferral.
   - ***Comments**: Deferral letters may create unwanted uncertainty for patentees. We would advocate for increased certainty by stating in the final Guidelines that there be a maximum of 2 deferral letters after which time a medicine would be considered reviewed and released from the threat of reimbursement of excess revenue gained during the period of deferral. Also, it would be helpful for the final Guidelines to clarify whether advance ruling certificates are still available to patentees.*

4. **The Role of the Guidelines**
   - **Summary:** The Draft Guidelines stipulate that they are "not intended to suggest or set prices in Canada and are not intended to encourage "compliance" with any tests or price ceilings." The Guidelines "do not calculate "price ceilings", "non-excessive prices", or "potential excess revenues" either at introduction or at any subsequent point nor do they deem or presume any prices or price thresholds to be excessive or not excessive."
   - ***Comments**: It appears that the PMPRB is intending to leave flexibility in their application of the Guidelines once finalized. However, we would respectfully point out that the PMPRB is bound to follow the Federal Court of Appeal's decision in Alexion Pharmaceuticals Inc. v Canada (Attorney General), 2021 FCA 157, which provides that the PMPRB must provide clear reasons when departing from the Guidelines.*

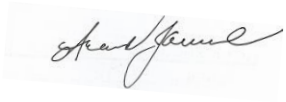
5. **PMPRB jurisdiction over patents that pertain to a medicine**
   - **Summary:** Section 31 of the Draft Guidelines cites the 2017 and 2019 Galderma decisions and says that the PMPRB may consider a rational connection and clinical similarities when determining whether a patent pertains to a given medicine, even if there was no active patent on that medicine (the "Slender Thread" test).

- ***Comments**: The Draft Guidelines do not take into account the most recent Galderma decision (2024 FCA 208) which clearly limited the PMPRB's jurisdiction to the question of whether a medicine is still protected by a patent, which will likely require a formal claim construction showing that a medicine falls within the scope of a patent. We respectfully submit that the PMPRB should take into account the Galderma decision of 2024 in the final version of the Guidelines.*

7. **Coming into force**
   - **Summary:** Section 55 provides that existing medicines will be reviewed starting one year from the date the Guidelines come into effect. New medicines will be reviewed immediately after the Guidelines come into effect.
   - ***Comments:** it is not clear if new medicines will be expected to immediately comply upon the coming into force or if there will be a transitional period for compliance. We kindly request clarification on this point.*

8. **Transition period**
   - **Summary:** The PMPRB has selected the minimum transition period of one year.
   - ***Comments:*** A longer transition (e.g. 3 to 4 years) would be more appropriate during this high period of uncertainty allowing the Canadian pharmaceutical value-chain to elastically respond to this and other pricing changes which may be unpredictable at best, currently. Additionally, we wish to re-iterate that, we respectfully hold the PMPRB to its commitment stated in Interim Guidance 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."

Respectfully submitted,



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