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Patented Medicine Prices Review Board (PMPRB)
Standard Life Centre, Suite 1400
333 Laurier Ave.
Ottawa, ON
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Attention: Ms. Anie Perrault, Acting Chairperson

RE: Response to December 2024 Draft Guidelines for PMPRB Staff – Third Phase of Consultation.

Dear Ms. Perrault,

On behalf of Viatris,[1] please find enclosed our response to the latest draft guidelines published by the PMPRB. We appreciate the opportunity to provide feedback in this latest round of consultation and acknowledge the updates made in response to previous stakeholder input. While some of our key positions have been addressed in this draft, others remain outstanding. Below, we outline our position accordingly.

Acknowledgment of Updates

1. **Highest International Price (HIP) for Price Review**: We acknowledge and appreciate the PMPRB's decision to use the Highest International Price (HIP) from PMPRB11 as a threshold for initial and post-initial price reviews. This aligns with our previous recommendation and supports Canada's global competitiveness. Ensuring that Canadian prices are benchmarked against the highest international prices allows for continued investment in innovative treatments and provides greater predictability for pharmaceutical companies considering product launches in Canada. By maintaining this approach, the PMPRB ensures that Canadian patients have access to the latest therapies without unnecessary delays that could result from lower pricing benchmarks.

2. **Complaint Process Restricted to Eligible Stakeholders**: The limitation of complaints to the Federal Minister of Health, Provincial/Territorial Health Ministers, and select payors

[1] Viatris is the business name for Mylan Pharmaceuticals ULC, BGP Pharma ULC, and Upjohn Canada ULC.

(public and private) is a welcomed change. This approach aligns with our previous feedback advocating for reduced complaint volume to ensure that only pertinent pricing concerns are raised, reducing unnecessary administrative burdens. By streamlining the complaint process, the PMPRB can focus its resources on reviewing and addressing legitimate concerns while preventing undue influence from parties that may not have a direct stake in the public healthcare system.

3. **Ad Hoc Use of the Human Drug Advisory Panel (HDAP)**: We support the decision to use HDAP on an ad hoc basis when deemed necessary by Staff. This will allow for a more efficient review process while preserving independent expertise for complex cases. We appreciate that this feedback was considered in the draft guidelines, as it reduces unnecessary delays in the pricing review process. The flexibility in HDAP utilization ensures that its expertise is reserved for situations where additional scientific and clinical input is truly required, rather than being a mandatory part of every review, which could create inefficiencies.

Remaining Areas of Concern

1. **Length of Time for IPC Identification Criteria (Three-Year Adjustment Period)**: Viatris Canada continues to support a three-year period for price adjustments to meet International Price Comparison (IPC) identification criteria. A three-year transition is necessary to allow companies to navigate complex pricing regulations, maintain financial stability, and align with global market strategies. Given the complexities of drug pricing, including regulatory approvals, reimbursement negotiations, and global reference pricing considerations, a shorter adjustment period may create disruptions that could impact patient access to medications. Allowing for a three-year adjustment period provides companies with sufficient time to make necessary adjustments while maintaining product availability in the Canadian market.

2. **Criteria for CPI-Based In-Depth Review**: We note that PMPRB has incorporated a cumulative two-year CPI approach ***only in cases where there was no price increase in the first year.*** While this is a step in the right direction, we continue to support a more consistent application of a cumulative two-year approach for all price reviews. A two-year cumulative measure allows for greater flexibility in pricing adjustments while mitigating short-term volatility. In the pharmaceutical industry, cost increases are often not linear, and a single-year assessment could result in misleading conclusions about pricing trends. A more standardized two-year cumulative review would better capture economic realities and allow companies to adjust pricing in a responsible manner, ensuring that medicines remain available without creating undue administrative burden or financial risk.

3. **Expansion of Complaint-Based Review to Biosimilars and Vaccines**: We note that the draft guidelines have entirely removed the section addressing the treatment of

biosimilars and vaccines. Previously, there was a discussion on whether these products should be subject to routine reviews or only be reviewed in response to complaints. The omission of this section in the draft guidelines creates uncertainty regarding the regulatory approach for these products. It is unclear whether biosimilars and vaccines will now be treated like all other patented medicines, subject to routine reviews, or whether PMPRB intends to address them separately in a future policy document.

We encourage PMPRB to provide clarity on this matter. If biosimilars and vaccines are now subject to the same price review process as all other patented medicines, this could have unintended consequences for market access and pricing stability. Given the distinct market dynamics of these products, we continue to support a complaint-based review process for biosimilars and vaccines, ensuring that regulatory oversight is applied only when specific concerns arise. We request PMPRB to confirm its intended approach and provide transparency on any future consultations related to these product categories.

4. **Use of Clinical Evidence for Therapeutic Class Comparison (TCC)**: While we acknowledge the inclusion of different levels of similarity for comparators, we emphasize that this process must ensure fairness and reflect real-world clinical and market dynamics. We continue to support Option 2, allowing for nuanced comparator assessments based on clinical evidence. A rigid approach that does not adequately differentiate between therapeutic alternatives could lead to inappropriate pricing benchmarks and inaccurate comparisons. We recommend that the PMPRB incorporate flexibility in defining comparator products to ensure that pricing assessments reflect the actual clinical landscape and patient treatment options.

5. **Product Life Cycle Changes:** As set out in our December 2023 response to the PMPRB's Scoping Paper, Viatris Canada believes that PMPRB's mandate to monitor pricing should be (a) limited to patents embodied in the marketed medicine, and (b) extinguished upon loss of exclusivity by the patented brand medicine.

    a. **Scope:** Patents with subject matter not reflected in the marketed brand product do not confer market exclusivity and should not fall within the PMPRB's jurisdiction. For example, in a recent decision of the Federal Court of Appeal,[2] the Court found that a patent covering the use of a particular concentration of active ingredient (0.3%) could not justify the PMPRB's jurisdiction over the marketed brand product that used a different, unpatented concentration of the same active ingredient (0.1%).
    b. **Generic competition:** Once a generic version of a patented product enters the market, there is no longer a need for regulatory oversight of the patented

[2] Galderma Canada Inc. v. Attorney General of Canada, 2024 FCA 208, para. 13.

medicine pricing. The price of a patented medicine does not increase in the face of generic competition; either the net price of the patented medicine drops, or the market share shifts even more forcefully to the generic alternative.

The above adjustments during a patented product's lifecycle would strike a balance that allows for ongoing price monitoring, without the undue administrative burden on patentees and the PMPRB for products with irrelevant patents and/or products already facing generic competition.

In conclusion, Viatris Canada remains committed to working with the PMPRB to establish a fair and balanced regulatory framework. We appreciate the improvements made in the draft guidelines and request further consideration of our outstanding concerns to ensure sustainable access to medicines for Canadian patients. In particular, we strongly advocate for a three-year adjustment period for price alignment, a two-year cumulative CPI review, and a clear and objective approach to complaint-based reviews for biosimilars and vaccines. These measures are essential to maintaining a robust pharmaceutical market in Canada while ensuring that patients continue to have access to high-quality medications.

We look forward to continued engagement on these matters and remain available for further discussions.

Sincerely,

Jeffrey Long

Jeffrey Long
Country Manager
Viatris Canada