Patented Medicine Prices Review Board (PMPRB)
Standard Life Centre, Suite 1400
333 Laurier Ave.
Ottawa, ON
K1P 1C1

RE: VIATRIS™ Canada comments - On the change to the definition of Gap medicines and the timeline for compliance

Dear Mr. Clark,

On behalf of VIATRIS™ Canada, I would like to share with you our feedback regarding the most recent proposed amendments to the new PMPRB Guidelines. Specifically, the decision to delay the coming-into-force date of the *Regulations Amending the Patented Medicines Regulations* ("Regulations") by a further six months, from January 1, 2021 to July 1, 2021. In conjunction with the position put forth in this communication, Viatris is supportive of the position expressed by Canadian Generic Pharmaceutical Association (CGPA) and Biosimilars Canada.

Viatris is in a unique position of examining the PMPRB's proposed changes due to our broad portfolio, inclusive of brands, biosimilars, generics and over-the-counter medications. We hope that the following additional comments help highlight some of the concerns, issues and recommendations that are of importance to Viatris, namely;

<u>Definition of Gap Medicines</u>

Viatris supports the PMPRB proposal to extend the date of the first sale of Gap medicines to the new coming into force date of July 1, 2021.

<u>Compliance Timelines for Grandfathered and Gap Medicines</u>

We support the PMPRB's decision to defer implementation of the final Guidelines by an additional six months, however, we have concerns that this same deferral is not also being extended to patentees with respect to the compliance enforcement date currently set for December 31, 2021. Specifically, our concerns relate to the potential negative impacts and challenges this will present to patients, distributors, healthcare providers and provincial drug programs. Please find below our rationale:

- **Unrealistic timelines for compliance**
  As per the proposed final Guidelines, the PMPRB will only confirm the Maximum List Price(s) (MLPs) following the July 31, 2021 filing, resulting in unrealistic timelines for patentees to comply with the new MLPs. Since the initial expected implementation date of July 1, 2020, the PMPRB reduced its grace period from 18 months to 6 months without rational. This is in contradiction to the PMPRB's originally stated intention in providing patentees the required time to adjust to the new reporting requirements. The impact of this significant reduction to the grace period is made all the more challenging through the ongoing COVID-19 pandemic pressures.

- **Negative Impact on Stakeholders.**
  An implementation date of December 31st, 2021 for patentees, will create significant operational challenges in aligning the list prices within the respective provinces. It generally takes months for public payers to update their provincial formularies. The discrepancies between list price and formulary price will cause significant confusion for all stakeholders who are involved in the distribution and dispensing of the drug, and most importantly for patients. Additionally, it will create unnecessary operational and financial pressures on patentees, distributors and pharmacies who are already over-capacity, due to the COVID-19 pandemic. Viatris believe that securing supply and adapting processes and systems to improve responsiveness and resiliency to new and unfamiliar pandemic-driven operating demands are paramount and must continue to be prioritized

- **Lack of Fairness and Predictability**
  The PMPRB has deferred the implementation of the final Guidelines due to the COVID-19 pandemic, which is consistent with the Federal and Provincial governments approach in providing a number of relief measures, such as temporary financial deferrals, benefitting both Canadian citizens and businesses. While the PMPRB benefits from deferring its guideline implementation, they have not afforded patentees this same courtesy, even though patentees have also been significantly impacted by the COVID-19 pandemic.

In view of this, PMPRB should provide the previously proposed 18-month grace period before compliance is enforced, we suggest that there should be fixed maximum annual price reduction limits (e.g. no more than 5% negative list pricing impact per twelve-month period under the new regime).

In addition, PMPRB should close all existing investigations within current guidelines prior to the introduction of the new compliance measures as the finalized guidelines are more complex, unpredictable.

Viatris remains concerned as it relates to a number of issues that were included in previous submissions. The issues listed below have not yet been addressed or factored into the final Guidelines and we therefore ask that additional changes to be made prior to implementation of the finalized Guidelines:

- PMPRB should truly “grandfather” existing products and simply apply its international price ceiling threshold (highest for existing products) and use the current highest compliant list price rather than the current non-excessive average price (NEAP) as part of its “Lower-of” tests for grandfathered medicines. The NEAP is based on protected information and requiring a systematic request be filed, necessitating PMPRB staff to re-calculate a non-excessive benchmark ceiling, would be an inefficient use of both Viatris and the PMPRB staff resources.
- Potential Impact of PMPRB changes on price of generic medicines – Viatris has been concerned about the changes to the Patented Medicines Regulations and PMPRB framework for several years due to the reference-based pricing system for the generic medicines in Canada. Generic pricing levels in Canada are internationally competitive and any reduction in originator prices must not have a corresponding impact on generic prices. In recognition of the current five-year agreement between pCPA and CGPA, and of the agreed tiered pricing model, for the generic

products already in the pipeline, we believe that there should be benchmark setting of the brand reference price for the next five years, which would be based on historical brand reference pricing.

- Viatris remains concerned regarding the inclusion of patented generics and biosimilars in the final PMPRB guidelines. Nonetheless, since both patented generic medicines and patented biosimilars will only be categorized as a Category II drugs, we believe that the same conditions to trigger an investigation should apply to patented biosimilar medicines. The PMPRB should apply a fair and predicable process by including patented biosimilar medicines, under the Policy on Generic Medicines.

Again, on behalf of Viatris, I thank you for the opportunity to communicate our feedback for your consideration. Please do not hesitate to contact me directly should you have any additional questions for Viatris regarding this communication and the future evolution of the Guidelines.

Sincerely,

David Simpson

David Simpson
Country Manager, Viatris