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, we support the PMPRB's decision to defer implementation of the final guidelines by an additional six months. We also want to share our feedback regarding the most recent proposed three amendments to the new PMPRB Guidelines. Specifically, the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions.

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;

1. Definition of Gap Medicines

Proposed Changes: The definition of Gap medicines under the new Guidelines applies to medicines for which a DIN was assigned on or after August 21, 2019 and prior to July 1, 2021 and first sold in Canada prior to July 1, 2021. The PMPRB is proposing to extend the date on which the DIN was assigned and the date of first sale to the new coming-into-force date of January 1, 2022.

VIATRIS™ supports the PMPRB proposal to extend the date of the first sale of Gap medicines to the new coming into force date of January 1, 2022. However, we are concerned that this same deferral is, again, not being extended to patentees with respect to the compliance enforcement date. As per our submission of February 2021, we believe PMPRB should provide their previously proposed 18-month grace period prior to the compliance of the list price being enforced. We recommend that there be a fixed maximum annual price reduction limit (i.e. no more than 5% negative list pricing impact per twelve-month period under the new regime). In our view, the above recommendations will help manage the potential negative impact on patients, distributors, healthcare providers and provincial drug programs.

2. Comparator Countries

Proposed Changes: The comparator countries used under the new Guidelines are currently referred to as the "PMPRB11". The PMRPB is proposing to refer to the comparator countries more by reference to the Schedule set out in the Regulations as the "Schedule Countries".

VIATRIS™ is not in agreement with the selection of the comparator countries included in the actual definition of the PMPRB 11. We believe that the selection of countries should include those that have comparable economic markets to that of Canada.

Secondly, it is not clear what the rationale is for making this proposed change and, if the PMPRB is anticipating changes in the proposed "PMPRB 11" definition and/or its implementation, then this should be shared with stakeholders in advance of the consultation process. This highlights another example of how these reforms are generating uncertainty in the Canadian pharmaceutical industry.

3. International Price Tests for Grandfathered Medicines and their Line Extensions

Proposed Changes: The PMPRB is proposing that the MLP for Grandfathered and their Line Extensions be set by the lower of (1) the MIP for the Schedule Countries for which the patentee has provided information for the reporting period ending June 30, 2021 under the Regulations that are currently in effect (SOR/2008-70, s.6); or (2) the medicine's ceiling (e.g. the "NEAP") under the Guidelines as they were prior to the issuance of these Guidelines.

As mentioned previously, VIATRIS™ already has concerns regarding the negative financial impact generated by the countries selected for the constitution of the PMPRB 11.

The suggestion of using the MIP instead of the HIP will add considerable financial pressure to VIATRIS™ and will create additional hurdles to an already unpredictable environment. It is also important to consider that the contribution of VIATRIS™ within the Canadian economy will be negatively impacted since there is not a linear relationship between a decrease in the list price of a product and a decrease in the cost of goods. As a result, manufacturers may have to make difficult business decisions such as the layoffs for VIATRIS™ personnel, decreases in investments with key stakeholders (i.e. patient associations, medical clinics, hospitals, universities, pharmacies, etc.), along with the added pressure of the financial viability for current and future products.

In the last 18 months, we have observed the importance of securing and building a solid foundation toward a consistent and predictable supply of medications for Canadian patients. VIATRIS™ believes that this is a shared responsibility between manufacturers and Canadian regulatory bodies, such as the PMPRB. We also believe that price compression on multiple products will increase the risk of product discontinuations and US importation, adding unnecessary pressure to an already burdened supply of medications for Canadian patients.

As to the impact that the proposed changes will have on generic products, VIATRIS™ has expressed concern that, due to the Market Entrant Tiered Pricing Framework, any reduction in the originator price will correspondingly negatively impact the generic price. As generic pricing levels in Canada are already relatively low and internationally competitive, any reduction in originator pricing should not have a corresponding impact on the price of generic products. In recognition of the current five-year agreement between pCPA and CGPA, and of the agreed upon Market Entrant Tiered Pricing Framework, for the generic products already in the pipeline, we believe that there should be benchmark setting of the originator reference price for the next five years, which would be based on historical originator reference pricing.

There will be a significant number of grandfathered products facing a list price reduction, which will not only negatively impact manufacturers, but also all the other players involved in drug delivery to Canadians. Different government entities will have to increase the other components on the drug prices (i.e. wholesaler distribution, dispensing fees and pharmacy markup), which will reduce the expected financial savings from the PMPRB Guidelines reform as well as adding pressure to patients, public/private drug programs and relations during a time of a pandemic and Federal/Provincial elections. Most importantly, the focus will be directed on financials

as opposed to working on unmet health needs and a renewal of biopharmaceutical innovation, research, manufacturing, and patient access to medicines.

PMPRB's proposed change to use the MIP instead of HIP is not supported by a clear rationale and assessment of the resulting impact, raising real concerns about its substantive reasonableness. These last proposed changes are seen as an interim solution since they are impacting a majority of the products that were defined as grandfathered products. 'Grandfather' is defined as something or someone exempt of a new law or regulation, therefore our understanding was that the new guidelines will not impact grandfathered products. These proposed changes are also not relating to the delay of the coming-into-force date. Furthermore, they were published during the time that manufacturers were completing the reporting forms for the first semester of 2021 and refer to the definition of the scheduled countries that is not yet approved, creating a lot of confusion and misunderstanding on the reporting requirements and proposed changes.

VIATRIS™ remains concerned with respect to a number of issues raised in previous submissions. Of particular note is the inclusion of Biosimilars as complaints-based in the final PMPRB guidelines, however, with no corresponding criteria. As patented biosimilars will be classified as Category II drugs, we believe that the same conditions to trigger an investigation should apply to patented biosimilar medicines as would be applied to patented generics (i.e. complaints-based with criteria). 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,

Adam Coote

Head, Market Access & Pricing

VIATRIS™ Canada