



Vertex Pharmaceuticals (Canada) Incorporated
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VIA EMAIL: pmprb.consultations.cepmb@pmprb-cepmb.gc.ca

August 31, 2021

Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Feedback Regarding the Proposed Amendment to International Price Tests for Grandfathered Medicines and their Line Extensions - Vertex Pharmaceuticals (Canada) Incorporated

Dear Sirs/Mesdames,

On behalf of Vertex Pharmaceuticals (Canada) Incorporated (“Vertex”), thank you for the opportunity to provide feedback on the Patented Medicines Prices Review Board (PMPRB) proposed Guideline changes that was posted for consultation on July 15, 2021. This written submission should be considered complementary and supportive to other submissions that we have helped contribute to, specifically, submissions from BIOTECanada and RAREi (the Canadian Forum for Rare Disease Innovators).

Overall, the PMPRB reforms continue to create uncertainty for people living with rare diseases and the pharmaceutical industry. Specifically, there continues to be evidence that the reforms will negatively impact access to medicines, clinical trials, and research and development within Canada^{1,2}.

With regard to this consultation, **Vertex is concerned that the PMPRB’s proposed amendment to change the maximum list price (MLP) calculation for Grandfathered Medicines and their Line Extensions is creating further uncertainty to an already precarious Canadian pharmaceutical marketplace.** Industry has based business decisions on previous iterations of Guidelines that were publicized as *final*; these unexpected changes from the PMPRB only worsen the unpredictability of the reforms. This is the third such variation to the MLP for Grandfathered Medicines and their Line Extensions since 2019, and it has further challenged the industry’s ability to make predictable business decisions.

¹ Labrie, Yanick., *Is there evidence that regulating pharmaceutical prices negatively affects R&D and access to new medicines? A systematic literature review*, (Canadian Health Policy Journal, June 2020), <https://www.canadianhealthpolicy.com/products/evidence-that-regulating-pharmaceutical-prices-negatively-affects-r-d-and-access-to-new-medicines-.html>, Accessed August 8, 2021

² Rawson, Nigel., *Clinical Trials in Canada: Worrying Signs that PMPRB Changes will Impact Research Investment*, (Canadian Health Policy Journal, February 2021), <https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada--worrying-signs-that-pmprb-changes-will-impact-research-investment.html>, Accessed August 8, 2021



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Vertex believes that this additional and unnecessary revision to the Guidelines will create further commercial uncertainty for the industry. We hope the PMPRB will reconsider this change and we welcome the opportunity to meet with the PMPRB to discuss our concerns. Through meaningful collaboration we believe we can achieve everyone's goals and mandates – and most importantly, allow Canadians living with rare diseases to receive the treatments they need in a timely manner.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Siau".

Michael Siau
Country Manager
Vertex Pharmaceuticals (Canada) Incorporated
(647) 790-1600