



Vertex Pharmaceuticals (Canada) Incorporated
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VIA ONLINE CONSULTATION PORTAL

August 4, 2020

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, L1P 1C1

Re: 2020 Guidelines to operationalize changes to the *Patented Medicines Regulations*

Dear Sirs/Mesdames:

On behalf of Vertex Pharmaceuticals (Canada) Incorporated (“Vertex”), thank you for the opportunity to provide input into the Patented Medicine Prices Review Board’s (“PMPRB”) revised Guidelines that were posted for consultation on June 19, 2020. Additionally, thank you for meeting with Vertex during the first consultation period to allow us to review the specific implications for how the draft Guidelines may impact innovative patented medicines for unmet needs, especially among Canadians with rare disorders.

Our input herein should be considered complementary and supportive to submissions from BIOTECanada, Innovative Medicines Canada and RAREi (the Canadian Forum for Rare Disease Innovators).

While we recognize that the PMPRB has taken steps to address some concerns raised in the initial Guidelines consultation, Vertex continues to believe that **the amendments to the *Patented Medicines Regulations* (“the *Regulations*”) and draft PMPRB Guidelines may delay or stop new innovative medicines from launching in Canada.** These changes will impact the availability of important medicines and leave Canadians at a significant disadvantage in contrast to comparable jurisdictions.

We are already seeing fewer drug launches in Canada compared to previous years¹ – this is tied directly to the uncertainty and dramatic price controls resulting from the amendments to the *Regulations* and the new PMPRB Guidelines.

Our primary concerns with the most recent draft Guidelines remain and are centered around arbitrary price reductions and confidentiality:

- **The method of how innovation will be measured, and the associated mandatory discounts, are arbitrary and will not be evaluated by an independent third party or medical experts trained in evaluating evidence-based clinical information.** This process will trigger mandatory discounts for products, contributing to high levels of uncertainty for manufacturers.
- **Mandated market size-related price reductions of up to 65% create an unfavourable and uncertain market for new drug launches in Canada.** Mandated reductions of this type and scale for new patented medicines may delay or altogether stop the launch of new innovative medicines in Canada due to the uncertainty related to net prices.

¹ Rawson, Nigel. “Fewer New Drug Approvals in Canada: Early Indication of Unintended Consequences from New PMPRB Regs?” Canadian Health Policy, March 2020. <https://www.canadianhealthpolicy.com/products/fewer-new-drug-approvals-in-canada--early-indication-of-unintended-consequences-from-new-pmprb-regs-.html>.

- **It remains possible under these draft Guidelines to calculate an approximate rebated price for new patented medicines.** The public nature of HTA assessment combined with market size (which may be known through public registry numbers) will provide a narrow range for the discount being mandated. This will disincentivise early launches in Canada, as these transparent prices may impact a manufacturer's global approach.

We continue to have substantial concerns around the impact of these Guidelines on future access to innovative medicines for rare diseases in Canada. **Vertex strongly urges the PMPRB to reconsider the factors as outlined above, to ensure that Canadians will continue to have access to future innovative medicines.**

Sincerely,

A handwritten signature in blue ink, appearing to read "Michael Siau", with a stylized flourish extending to the right.

Michael Siau
Country Manager
Vertex Pharmaceuticals (Canada) Incorporated