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February 13, 2020

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Sirs/Mesdames,

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

On behalf of Vertex Pharmaceuticals (Canada) Incorporated (“Vertex”), thank you for the opportunity to provide input into the Patented Medicine Prices Review Board (PMPRB) revised guidelines that were posted for consultation on November 21, 2019. We also appreciated meeting with PMPRB staff on January 8, 2020, which allowed us to review several implications for how the draft guidelines might impact innovative patented medicines for unmet medical needs, especially among Canadians with rare disorders.

Our input herein 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).

Vertex recognizes and respects that the PMPRB has a mandate to deliver in accordance with the amended regulations. However, the current proposal creates significant long-term and far-reaching unintended consequences. These are likely to include the delay or the decision not to launch important new medicines in Canada.

Vertex has significant concerns about the use of a Health Technology Assessment plus market size adjustment to create a mandated and calculable ceiling price, the Maximum Rebated Price (“MRP”). As a result, Vertex would recommend the Maximum Rebated Price is removed from the PMPRB guidelines. There are two key reasons for this, outlined below:

1. Maximum Rebated Price creates an arbitrary maximum which cannot be negotiated

- By using the proposed Canadian HTA process as a basis to create a mandated MRP, the draft guidelines prevent any opportunity for dialogue and agreement on a rebated price that is viable for all parties, and common in all other HTA markets worldwide.
- All pharmacoeconomic models have highly variable outcomes depending on assumptions used. Small changes to the Canadian HTA assumptions, thresholds or methods in the models can have profound impact on QALY results and evaluation of the medicine. These changes could easily move a transformative medicine from being commercially viable to not commercially viable, despite the fact that the clinical benefit derived from that medicine is the same.
- In most other countries the HTA process is used to evaluate the clinical and cost-effectiveness of the medicine. Innovation is also recognized in some capacity through the process. Following

this evaluation, the final negotiated price is then agreed through private negotiations between the manufacturer and the government and is confidential.

2. Maximum Rebated Price is not confidential and could trigger global implications that will impact Canadian patients

- The mandated MRP would be visible and calculable both inside and outside of Canada. Countries would then be able to compare their confidentially agreed price and if higher than the calculated MRP in Canada, those countries would then request a price change.
- The global impact of the MRP poses a significant risk to any global pharmaceutical business and means that companies may have to refuse a publicly available price, preventing the availability of the medicine in Canada, when in fact a similar price may have been acceptable through confidential negotiations.

Given the significant concerns described above, we do not believe the guidelines should mandate the incorporation of economic factors to determine an MRP. Although Vertex has considerable concerns with the changes proposed by the PMPRB, we are committed to a continued dialogue to cultivate meaningful alternative solutions that will allow PMPRB to meet their mandate while not triggering the long-term and far-reaching consequences outlined above.

We welcome the opportunity to meet the PMPRB Executive to discuss other solutions that may allow all parties involved to achieve their goals and mandates – and most importantly, allow Canadian patients to continue to access innovative therapies in the future.

Sincerely, .



Michael Siau
Country Manager
Vertex Pharmaceuticals (Canada) Incorporated