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VIA ONLINE CONSULTATION PORTAL

December 5, 2022

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

Dear PMPRB Board Members,

Subject: Vertex Input on the 2022 Draft PMPRB Guidelines

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 posted for consultation on October 6, 2022. This submission should be considered supportive of those from BIOTECanada and RAREi (the Canadian Forum for Rare Disease Innovators), which we have contributed to.

Vertex recognizes that the PMPRB has a mandate to implement the amended *Patented Medicines Regulations*. However, we remain surprised and disappointed that, following years of feedback from industry, patients and the courts, the PMPRB continues to propose a regulatory framework that:

1. Lacks clear and predictable rules
2. Fails to recognize innovation
3. Is inconsistent with the PMPRB's mandate and key federal priorities
4. Is being expedited without adequate analysis and limited consultations

Given these important concerns, we strongly recommend a pause on the implementation of the Guidelines to develop an alternative approach that is clear, predictable and workable for healthcare system stakeholders across Canada. This will better ensure that our sector can commercialise its innovations in the Canadian market in a timely manner for the benefit of the patients who need them, our health system and economy. Below, we have outlined in more detail each of our key concerns with the new Guidelines.

1. Lacks clear and predictable rules

The proposed approach moves away from setting price ceilings to solely focusing on investigations of potential excessive pricing, with no clear criteria or tests to trigger investigations that will have unprecedented powers and discretion provided to the PMPRB staff. For instance, staff who may not have deep clinical expertise will be responsible for selecting medicines for the domestic therapeutic class comparison analysis. The result of this analysis, which cannot be challenged by the manufacturer or the patients it will impact, could lead to unreasonable price reductions, forcing manufacturers to reconsider or delay commercialising their medicines in this country.

These proposed guidelines, which will be based on a "case-by-case" approach for each new medicine, will undoubtedly lead to many more investigations, hearings and ultimately litigation. This further complicates an

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already long and complex commercialisation pathway for medicines in Canada, particularly medicines for rare diseases.

The uncertainty related to the new PMPRB Regulations and Guidelines has already led to less medicines being commercialised in Canada. Since 2016, the PMPRB has prevented and delayed new medicines from coming to Canada by proposing uncertain and restrictive new pricing rules. According to Life Sciences Ontario, the number of medicines launched globally that have been commercialised in Canada has declined every year since 2016, when the pricing reform was initiated.[1] Since 2019 when the regulations were finalized, more than half of all medicines approved by the United States Food and Drug Administration (USFDA) have not been submitted to Health Canada for approval.[2] **If these Guidelines are implemented, patients will experience reduced access to new innovative medicines in Canada.**

2. Fails to recognize innovation

The proposed approach unfairly targets the most innovative drug candidates, which are the ones that are most needed to address important unmet needs in the rare disease community. Specifically, comparing new breakthrough medicines to generic products devalues innovation as well as patents, which are intended to reward and promote innovation. This must be addressed in the final Guidelines to ensure clarity and predictability of appropriate comparator medicines for new innovative entries. **Comparing innovative medicines to generics will devalue new medicines and delay or altogether stop patient access to new medicines in Canada.**

3. Is not aligned with the PMPRB's mandate and key federal priorities

The new Guidelines clearly exceed the PMPRB's mandate, which the courts have said is limited to excessive pricing as a function of patent abuse. Triggering investigations based on "the lower of" calculations that could include comparisons with generic products goes well beyond ensuring prices are not excessive. **This is price regulation that impermissibly exceeds the court-approved mandate of the PMPRB.**

Additionally, this vague approach that continues to create uncertainty, coupled with potential steep and arbitrary price reductions will undermine efforts at the federal level to encourage innovation through a national rare disease and Biomanufacturing and Life Sciences Strategy.

4. Is being expedited through a new approach without adequate analysis and limited consultations

For such a fundamental change in approach, the PMPRB has not allotted enough time for the meaningful consideration of feedback to enable effective implementation of the Guidelines by the end of 2022. This new drastic approach has been characterized by the PMPRB as a "paradigm shift", and as such, requires much more robust consultation and regulatory impact analysis. The PMPRB has not provided any rationale for this major shift in approach to drug price control, nor has it shared any analysis or data qualifying the impact it will have on the health system and the life sciences industry.

[1] https://lifesciencesontario.ca/wp-content/uploads/2022/06/ENGLISH.pdf
[2] Health Canada Drug and Health Product Submissions Under Review (SUR); Health Canada Notice of Compliance Database; FDA Drug Approvals and Database

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To conclude, a vague “case-by-case” approach to price regulation creates significant uncertainty for the life sciences industry and impedes the development and delivery of innovative treatments for the patients who need them. We strongly urge the PMPRB to pause the implementation of the Guidelines. This will allow time to develop a clear and predictable approach that is consistent with the PMPRB’s legislated mandate and federal priorities, and that will enable breakthrough innovations to reach patients in a timely manner.

Sincerely,

Michael Siauw
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