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## **Novartis Submission to PMPRB Phase 2 Consultation on the Board's New Guidelines**

Via: [Consultation Submission Portal](#)

On behalf of Novartis Pharmaceuticals Canada Inc. ("Novartis"), we would like to share with you our feedback regarding the Patented Medicine Prices Review Board's ("PMPRB") Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines, issued June 2024.

Novartis is a focused innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide. In Canada, we employ about 600 associates from coast to coast and invest over \$30 million annually in research and development to improve patients' lives.

We are at the forefront of bringing innovative medicines to patients throughout Canada. We are a company of firsts with our groundbreaking innovations we were first to launch: CAR-T cancer therapy; gene therapy for spinal muscular atrophy and vision loss due to inherited retinal dystrophy; as well as the first pharmaceutical company to bring radioligand treatments, a new pillar in cancer care treatment, to Canadians. As a leader in advancing medical innovations like these, we continue to have concerns that the new Guidelines will create additional barriers for patients to access breakthrough therapies in Canada in addition to an already burdensome and lengthy time to patient versus international peer countries.

We appreciate PMPRB's continued engagement with stakeholders who will be impacted by the proposed changes, and for this opportunity to provide input into the consultation on key themes for the draft Guidelines. The recent amendments made to the PMPRB Regulations represent progress, but we continue to have concerns with the options included in the topics for consultation.

To that end, as a member of both Innovative Medicines Canada "IMC" and BIOTECanada, we are aligned with our trade associations' recent submissions to this consultation process.

Specifically, Novartis would like to re-iterate:

The final Guidelines need to be clear and predictable and provide enough time to manufacturers to adjust to any changes, particularly given global supply chain challenges and to allow for adjustments in our business model in Canada.

We provide the following response to the topics issued for consultation:

- Topic 1: Given the new Regulations have removed the US and Switzerland from the basket which has already constrained prices, the **Highest International Price** within the range of the new PMPRB11 **should be considered compliant**.
- Topic 2: **Existing medicines** that were reviewed and were not excessive prior to new Guidelines, **should not be subject to any additional price reviews** (e.g. it should be explicitly clarified that there will be no retroactive reviews – Guidelines should be forward looking only).
- Topic 3: **CPI should remain the standard tool** for pharmaceutical companies **to take price increases** as it is an objective measurement reflecting the current relevant economic landscape in Canada.
- Topic 4: **Complaints process must be further clarified**, if permitted, the process must be transparent in the methods and criteria used to evaluate compliance, should specify, and limit, the categories of stakeholders who may file a complaint under this process taking into consideration principles of interest, legitimacy and reasonableness and finally in alignment with fairness and legitimate expectation that punitive measures should be capped in the event of a finding of non-compliance or variance.

As the PMPRB Board's mandate is to ensure that prices are not excessive, now that the new Regulations are in place, no further price constraints are warranted.

Thank you for the opportunity to provide input during this Guidelines consultation process. As a leading innovative company, we trust our comments are useful in this process as we believe that we all share the common goal, of improved and timely access to new innovations for Canadians to improve their lives and that this will remain the number one priority.

We welcome the opportunity to meet to discuss further and are available to answer any questions.

Sincerely,

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Mark Vineis

Country President

Novartis Pharmaceuticals Canada Inc.