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Novartis Submission to PMPRB Consultation on the Board's Draft 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") draft Guidelines, issued December 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 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 access 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 for the draft Guidelines.

The recent amendments made to the PMPRB Regulations represent progress, but we continue to have concerns with some elements present in the draft Guidelines 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:

Consistency and predictability are at the core of our regulatory framework. Unfortunately, the final Guidelines lack clarity and congruity creating unclear anticipated outcomes for manufacturers. Given the current economic fragility and context (namely, increasing pressure on global manufacturers, and the instability on prices given the current USA-Canada commercial disputes) highlights even more the significance of these principles for manufacturers to be able to administer appropriately their

business models. We agree with IMC, that further engagement between all stakeholders is warranted during this unprecedented time before the Guidelines can be finalized.

We provide the following comments regarding the proposed draft Guidelines for consultation:

Grandfathering Existing Products:
Medicines that have been deemed compliant under previous Guidelines should not be subject to additional price reviews as their introductory price was set accordingly.

Implementation Timeline:
A phased implementation over 24 months after the implementation of new Guidelines would allow for smoother adaptation for existing medicines.

International Price Comparison (IPC):
A holistic approach considering real-world market fluctuations and local economic factors affecting the HIP should be considered when engaging in an in-depth review. Again, given the unprecedented impact of the current commercial dispute on prices and on exchange rates, it is required that more time and flexibility be afforded to manufacturers for the implementation of any new Guidelines.

Complaint Process:
More clarity on the criteria that deem a complaint eligible to be received by the PMPRB is needed.

Finally, 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 are pleased to see some progress and collaboration in this process of drafting new Guidelines and welcome the opportunity to meet to discuss further and are available to answer any questions.

Sincerely,

DocuSigned by:
Mark Vineis
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Mark Vineis

Country President

Novartis Pharmaceuticals Canada Inc.