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December 20th, 2023

Novartis Submission to PMPRB Scoping Paper Consultation on the Board's 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 ("PMPRB") Scoping Paper Consultation on new Guidelines issued in November 2023.

Novartis is one of the leading healthcare companies in Canada and a subsidiary of Novartis AG, a leading global pharmaceutical company focused on addressing challenging and unmet healthcare needs of society. We are at the forefront of bringing innovative medicines to patients and were the first company to launch CAR-T cancer therapy and gene therapy for spinal muscular atrophy and vision loss due to inherited retinal dystrophy. We remain concerned that new guidelines will create additional barriers for breakthrough therapies to be launched in Canada in the future.

As a leader in developing innovative medicines we appreciate the work of the Government of Canada in addressing access to medicines to ensure sustainability of the health care system, and we have been an active participant in the numerous consultations throughout this pricing reform process. The recent amendments made to the PMPRB regulations represent progress, but we encourage further considerations be given to stakeholder input to the guidelines to ensure that Canadians have access to the medicines they need.

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 firmly believes that:

The new Guidelines need to be clear and predictable and enough time must be provided to manufacturers to adjust to any changes, particularly given global supply chain challenges and to allow for adjustments in our business model in Canada, pending the final guidelines. We recommend the following:

- 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.
- Existing medicines that were reviewed and were not excessive prior to new Guidelines, should be grandfathered and not subject to new Guidelines.
- CPI should remain the standard tool for Pharmaceutical companies to take price increases as it is an objective measurement in line with the current economic environment in Canada.


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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 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 people in Canada 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,

DocuSigned by:

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Pedro Miguel Ferreira
Country President (Ad-interim)
Novartis Pharmaceuticals Canada Inc.