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VIA E-MAIL

August 26th, 2021

Dr. Mitchell Levine
Chairperson
Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON
K1P 1C1

Subject: Novartis Pharmaceuticals Canada Inc. Response to the PMPRB Consultation on the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extension

Dear Dr. Levine:

On behalf of Novartis Pharmaceuticals Canada Inc. ("Novartis"), an affiliate of Novartis AG, I appreciate the opportunity to share with you our comments and concerns regarding the Patented Medicine Prices Review Board's ("PMPRB") proposed changes to the Guidelines.

Novartis, as a member of both Innovative Medicines Canada ("IMC") and BIOTECanada, continues to be in full agreement with, and fully supports, the two responses submitted by our industry associations. More specifically, I want to reiterate the following key concerns:

- **The proposed changes to price tests are arbitrary and without a rationale rooted in an excessive pricing standard:** The PMPRB, as a national price ceiling regulator, is an independent quasi-judicial body mandated to ensure that prices charged by patentees for patented medicines sold in Canada *are not excessive*. Since all these Grandfathered medicines were previously deemed non-excessive by the PMPRB several years ago (at least prior to 2019), changing the international price tests (from the Highest International Price to the Median International Price) for Grandfathered medicines and their line extension is clearly an arbitrary decision and, more importantly, a decision that is outside the PMPRB's mandate.

- **Halving the Guidelines transition period undermines the stated objective of the most recent regulatory delay:** We are deeply concerned and opposed to the proposed reduction of the timeline for compliance for the Grandfathered and Gap medicines. As clearly stated in the Guidelines published in October 2020 and further reiterated in a communication from the PMPRB on April 16th 2021, the compliance with the Maximum List Price (MLP) for these medicines would be assessed after **two filing periods**. Accordingly, with the expected coming into force of the Amendments to the

Patented Medicines Regulations on January 1, 2022, the operative date for assessing compliance with the MLP should be January 1, 2023.

Again, on behalf of Novartis, I thank you for the opportunity to participate in this consultation.

Sincerely yours,

Christian Macher
Country President and Oncology General Manager Canada
Novartis Pharmaceuticals Canada Inc.