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VIA E-MAIL

February 11, 2021

Dr. Mitchell Levine
Chairperson
Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON
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Subject: **Novartis Pharmaceuticals Canada Inc. Response to: Notice and Comment – Change to the definition of Gap medicines and the timeline for compliance (January 15, 2021)**

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 definition of GAP Medicine and the timeline for compliance.

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. We are deeply concerned and opposed to the proposed reduction of the timeline for compliance for the Grandfathered and Gap medicines.

The PMPRB's intention in the Guidelines, which were finalized less than four months ago on October 23, 2020, was to provide patentees with two reporting periods (corresponding to a 7-9 months transition period) from the date of the entering into force of the amended Patented Medicines Regulations (the "Regulations") to bring the pricing of Grandfathered and Gap medicines into compliance with the new regime. While Novartis still believes that more than two reporting periods should have been provided to bring all prices in compliance, the proposed change to only one reporting period (corresponding to less than 3 months) is unfair, unjustified and goes against the intent of the decision to delay the effective date of the Regulations by an additional 6 months.

The Health Minister justified the delay with the implementation of the Regulations in order to provide patentees with more time to prepare to the new regime while allowing patentees and health system partners to remain focused on responding to COVID-19. However, by reducing the timeline to only one reporting period, the PMPRB is actually providing patentees with 67% less time to prepare (going from 9 months to only 3 months) and be compliant with the new regime. This proposed change goes against the Government's intent with the delay of the Regulations.

In conclusion, we trust that the PMPRB will provide patentees with a reasonable transition period from the date on which the Regulations come into force. Novartis invites the PMPRB to consider a transition timeline of three reporting periods which would provide patentees with at least 15 months to adjust to these significant changes. We trust that the PMPRB will use this extra time to meet with patentees and provide answers to the many questions raised by both industry associations and several manufacturers since October 2020.

Furthermore, Novartis reiterates our industry's request for the PMPRB and the Federal Government to engage with the pharmaceutical industry and embark on an alternative path towards a fair and balanced approach for all parties committed to addressing drug affordability.

Again, on behalf of Novartis, I thank you for the opportunity to participate in this consultation and welcome an invitation to discuss with you these reforms in greater detail.

Sincerely yours,

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