

**VIA E-MAIL**

June 21st, 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 Proposed Guideline Monitoring and Evaluation Plan**

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 Guidelines Monitoring and Evaluation Plan.

Novartis, as a member of both Innovative Medicines Canada ("IMC") and BIOTECCanada, 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 recommendations:

- 1- Discontinue the regulatory changes until the pandemic has abated.
- 2- Due to two court rulings invalidating PMPRB access to confidential third-party rebates, PMPRB should clarify that its "maximum rebated price" concept will be discontinued.
- 3- Replace the PMPRB-led Guideline Monitoring and Evaluation Plan with an independent assessment by an objective third-party to conduct the analysis at arm's length.
- 4- Remove metrics which are beyond the PMPRB's jurisdiction.
- 5- Limit PMPRB's data reporting information sources to those derived from regulatory filings.
- 6- Replace or supplement PMPRB's 1987 definition of R&D with the more comprehensive and credible Statistics Canada assessment.



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,

A handwritten signature in blue ink, appearing to read "Christian Macher", with a long, sweeping flourish extending to the right.

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