

July 18, 2022

Novartis Submission to PMPRB Interim Consultation

By Email: [Consultation Submission Portal](#)

On behalf of Novartis Pharmaceuticals Canada Inc. (“Novartis”), we are pleased to have this opportunity to provide our input into the interim consultation on the PMPRB reforms which were issued on June 30, 2022*.

Novartis is one of the leading healthcare companies in Canada employing approximately 1,000 Canadians from coast to coast 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 Canadians and were the first company to launch CAR-T cancer therapy as well as the first gene therapies in Canada for spinal muscular atrophy and vision loss due to inherited retinal dystrophy.

As a leader in developing innovative medicines we appreciate the work of the Government of Canada in addressing the issues of 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’s input to the guidelines to ensure Canadians have access to the medicines they need in a timely manner.

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. To re-enforce, Novartis firmly believes that:

A minimum of a 12-month transition period would be required following the implementation of new Guidelines in order to adjust and mitigate negative implications to our business model.

- **There should be no payment of excessive revenues** for sales during the interim period and until final guidelines are implemented. We would maintain non-excessive prices with flexibility to allow for meaningful dialogue between manufacturer and regulators
- **We should have the ability to take list price increases** in relation to current economic factors while taking into consideration the volatility in the market

Thank you for the opportunity to provide input during this interim process. As we await the next phase of these reforms with the launch of the draft guidelines, we will continue to focus on our work of delivering innovative medicines to Canadians including managing supply chains to ensure timely delivery. We believe that we all share the common goal, as we move forward with this process, of improved access to timely innovations for Canadians and that this will remain the number one priority.

Sincerely,



Andrea Marazzi
Country President
Novartis Pharmaceuticals Canada Inc.

*Novartis Pharmaceuticals Canada Inc. understands that the PMPRB intends to apply Guidelines within the framework of amendments to the *Patented Medicines Regulations* (Regulations), which came into force on July 1, 2022. While Novartis Pharmaceuticals Canada Inc. is committed to constructive engagement with the PMPRB, Novartis Pharmaceuticals Canada Inc.'s engagement should not be interpreted as supporting the validity of the amended Regulations, which remain, as of the date of this submission, under review by the Federal Court of Appeal in Court File No. A-215-20. Novartis Pharmaceuticals Canada Inc. reserves the right to oppose any aspect of the amended Regulations, Guidelines, or other decision that exceeds the jurisdiction of the Board.