

August 21, 2023

Novartis Submission to PMPRB Interim Guidance Consultation

By Email: Consultation Submission Portal

On behalf of Novartis Pharmaceuticals Canada Inc. (“Novartis”), we would like to share with you significant concerns we have regarding the Patented Medicine Prices Review Board (“PMPRB”) Draft Interim Guidance issued on June 20th, 2023.

Novartis is one of the leading healthcare companies in Canada employing approximately 1,000 people 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 patients 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. We remain concerned that the draft guidelines will create additional barriers for breakthrough therapies to be launched in our Country in the future.

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 upcoming guidelines to ensure people 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:

The Interim Guidance needs to be more clear and predictable in order to adjust and mitigate negative implications to our business model:

- Given the new Regulations that have removed the US and Switzerland from the basket which has already constrained prices, any price within the range of the new PMPRB11 should be considered compliant.
- CPI should remain the standard tool for Pharmaceutical companies to take as it is an objective measurement in line with the current economic environment in Canada.

As the PMPRB Board's mandate is to ensure that prices are not excessive, we are in alignment with these recommendations and that no further price constraints are warranted.

Thank you for the opportunity to provide input during this interim 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,



Andrea Marazzi
Country President
Novartis Pharmaceuticals Canada Inc.