Novartis Pharmaceuticals Canada Inc.
385 Bouchard blvd.
Dorval, Quebec
Canada, H9S 1A9

Telephone 514 631-6775

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Novartis Submission to PMPRB Proposed Guidelines

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 Guidelines issued on October 6th, 2022.

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 are 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 guidelines to ensure people have access to the medicines they need in a timely manner.

As mentioned by many stakeholders, on several occasions, the Pricing Reforms will have unintended consequences and detrimental impacts on the predictability of the Canadian pharmaceutical market, innovation, and ultimately, patient access to innovative medicines.

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 Guidelines do not recognize innovation. In the past, significant therapeutic advancements were factored into the PMPRB process, enabling manufacturers like Novartis to bring new innovations to Canada earlier than other G7 countries. However, the elimination of this component removes any incentive for manufacturers to launch

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break through, transformative therapies in Canada first, and in fact, will create more barriers for new innovative therapies to be made available.

The Guidelines need to be clear and predictable. The current draft wording of the guidelines creates a high level of ambiguity: they do not provide predictability on the applicable compliance frameworks and criteria moreover, they make it very difficult for manufacturers to forecast and plan for future product launches. The draft guidelines in essence create more questions then answers for manufacturers in how to introduce a new innovative therapy in Canada going forward. If they remain unaltered, these guidelines will create further barriers and time delays to access for patients.

Additionally, the draft guidelines create uncertainty in particular in light of the expended scope of the staff discretion and the lack of clarity on elements which are likely to trigger a complaint in the future.

The Guidelines implementation should be postponed and provide appropriate time for patentees to prepare. Novartis, together with our industry partners is again reiterating the importance for the PMPRB to postpone the implementation and take appropriate time required to conduct a “meaningful consultation” with knowledgeable and impacted stakeholders to ensure that a thorough analysis of all the unintended consequences of the proposed changes are made and all questions/concerns have been addressed.

In conclusion, we recommend that the PMPRB will only make the appropriate changes to the Guidelines to align with its current mandate which is to ensure that drug prices are not excessive. The guidelines should support the revised regulations, but not be counterintuitive to them.

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.

Sincerely,

Andrea Marazzi
Country President
Novartis Pharmaceuticals Canada Inc.