



June 16, 2021

Amgen Canada response to consultation on Guideline Monitoring and Evaluation Plan (GMEP)

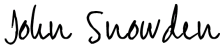
The following submission outlines Amgen Canada Inc.'s ("Amgen" or "we") response to the proposed GMEP.

Amgen fully endorses the responses to this consultation submitted by Innovative Medicines Canada and BIOTECanada, and we would like to re-emphasize a few points:

- The monitoring and evaluation plan should be conducted by an independent third party. PMPRB monitored previous changes in the Guidelines, however this time there are also important changes in the Regulations that resulted in a complete transformation of the pricing framework for patented drugs in Canada. The changes are controversial, and any monitoring plan will only be considered credible if conducted by an unbiased third party, with input from various stakeholders over what parameters should be monitored and how.
- The effects of this pricing reform on clinical trials, availability of innovative drugs in Canada and access conditions go beyond the PMPRB reporting mandate. This reinforces the point above on the need for an independent third party conducting this evaluation.
- The negative effects of the changes in pricing policy are already being felt in Canada, and likely started with the publication of the new Regulations in August 2019. Any evaluation plan should use years prior to 2019 as baseline.

We would also like to make it clear that these recommendations for GMEP should not be construed as Amgen's endorsement of the changes in pricing policy being implemented. Given the strong controversy among various stakeholders on the new pricing policies, ongoing litigation over key points of the new Regulations, and COVID-19 challenges/priorities, we urge the federal government to pause the implementation of the new pricing policies and move forward with a more collaborative approach to finding solutions for the sustainability of the Canadian healthcare system.

Sincerely,

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John Snowden
Executive Director, Value, Access & Policy
Amgen Canada Inc.