



Amgen Canada Inc.
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Amgen Canada response to consultation on PMPRB Interim Rules released on June 20, 2023

The following document constitutes the response from Amgen Canada Inc. (“Amgen” or “we”) to the consultation issued by PMPRB on June 20, 2023: “Notice and Comment – Amendment to the Interim Guidance re: New Medicines”.

We support the responses to the draft Guidelines submitted by Innovative Medicines Canada and BIOTECanada. We will, however, make some supplementary comments on the current proposal.

- **In the interim period, price increases consistent with CPI are appropriate.**

Regarding existing products, the current proposal does not change the rule established in 2022 in which the 2022 NEAP (Non-Excessive Average Price) would be used to review the price of these products for the entire interim period. However, Section 85 of the Patent Act includes Consumer Price Index (CPI) as one of the factors to determine pricing excessiveness. As a result, there should be no excessive pricing penalties where price increases are taken in the interim period observing CPI.

Allowing increases restricted to CPI in the interim period, in observance of the Patent Act, may prevent unnecessary disputes between PMPRB and manufacturers.

- **Any price within the range of the new 11 reference countries should be considered compliant.**

The proposal of “considered reviewed” products with prices below the international median is presented with the goal of clearing a portion of the backlog of new drugs awaiting review. Though we understand the issue, the international median price should not be the standard to determine whether the price of a new drug is excessive. A price should not be considered excessive if it is a match to the many countries above the median that are considered references to Canada. Considering compliant any price within the range of the reference countries is better aligned with the PMPRB mandate given by the Patent Act. Further, we also note that with the removal of two higher-priced reference countries from the basket of reference in 2022, the price of new drugs will already be significantly restrained.



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PMPRB plays an important part in the life sciences environment. Industry, governments, stakeholders and Canadian patients need policies that promote predictability, incentivize technological advances and facilitate access to innovative drugs. We would welcome the opportunity to engage with PMPRB in collaborative discussions on the new Guidelines for future products. Thank you for the opportunity to provide our submission.

Sincerely,

DocuSigned by:

A handwritten signature in black ink that reads "John Snowden".

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John Snowden

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