February 9, 2021

Via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Amgen Canada response to consultation issued January 15, 2021 on proposed PMPRB guideline changes

To whom it may concern,

This document constitutes the response from Amgen Canada Inc. ("Amgen" or "we") to the PMPRB's invitation for consultation on its proposed changes to the PMPRB Guidelines published on October 23, 2020 ("Guidelines").

We endorse the responses to these changes that were submitted by Innovative Medicines Canada and BIOTECanada. We would like to add to these responses by presenting our concerns with the Guidelines' proposal to reduce the deadline for compliance of Grandfathered and Gap medicines from two to one reporting period.

Implementation of these new prices in a 6-month period will be extremely challenging

We believe six months is not enough time to calculate and implement price changes on a substantial number of DINs regulated by PMPRB due to the number the steps required to implement such price changes and the large number of stakeholders involved.

With industry filing the international prices for the new 11-country basket for the first time in July 2021, we will likely receive our new prices from PMPRB in September. PMPRB and patentees would then need to discuss the cases where NEAP re-setting is required, as predicted in paragraph 75 of the Guidelines. This process that will likely be initiated around mid-October and even if accomplished expeditiously, it would leave us mere weeks to execute the next steps required for compliance with the new list prices by December 31, 2021. The next steps entail the internal process to obtain approvals from their respective global head offices and communication of price changes to all payers (public and private), wholesalers, distributors, pharmacies and institutional accounts in the country. Further, contracts with these stakeholders will also need to be updated And depending on the magnitude of the price cuts required by PMPRB, portions of several contracts might have to be re-written, which would entail a few months of collaboration between the pricing, contracting and legal departments of the parties involved in such contracts.

This process further is complicated by the fact the PMPRB compliance date imposes simultaneous change for all manufacturers in a large number of DINs. All players mentioned above need reasonable timelines to act on the change, and some of them (especially public payers) have different timing requirements for price notifications and formulary updates.

Given these constraints, we believe it is not possible to execute the change with the speed PMPRB proposes.

The proposal is at odds with one of expressed reasons for delaying the coming-into-force of the new price Regulations.

One of the reasons expressed by Health Canada for this six-month delay in the coming-into-force date of the new PMPRB Regulations is to allow manufacturers and other heath partners to remain focused on responding to COVID-19. PMPRB proposal means that all the discussions and operational process mentioned above would have to take place in the second half of 2021. Unfortunately, the COVID-19 pandemic still seems far from abated in Canada. Setting the compliance deadline for at least two reporting periods after the coming-into-force of the Regulations seems to be a reasonable measure given the unique circumstances brought on by the pandemic.

The proposal does not reflect the Regulatory Impact Analysis Statement (RIAS)

The RIAS published on the Canada Gazette Part II of January 20, 2021 evaluates the impact of a six-month delay in the effects of the pricing reform and concludes that most of the savings brought in by the new Regulations will continue to occur as originally estimated.

Recommendation:
Given the reasons above, we believe it would be prudent for PMPRB to provide at least two reporting periods for the transitioning of grandfathered and gap medicines, making these price changes operationally feasible, while keeping coherence with the RIAS and the reasons given by Health Canada for the delay in the effects of the new pricing Regulations.

Sincerely,

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