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Amgen Canada response to Scoping Paper for the Consultations on the Board's Guidelines

The following document constitutes the response from Amgen Canada Inc. ("Amgen" or "we") to the consultation issued by PMPRB in November 2023: "Scoping Paper for the Consultations on the Board's Guidelines".

We support the responses to the Scoping Paper submitted by Innovative Medicines Canada and BIOTECanada. We will, however, make some supplementary comments on the questions posed by the Scoping Paper.

Under the old 2010 Guidelines, PMPRB was very clear in the principles under which it operated: fairness, transparency, openness, and predictability. The previous rules also aimed at achieving voluntary compliance from manufacturers, which avoided lengthy and resource-intensive legal disputes. Amgen encourages PMPRB to reinstate these important principles into its operational framework with the addition of one more principle that Amgen considers fundamental: sustainability. Amgen considers it fundamental to the operational success of PMPRB and industry's ability to comply with PMPRB requirements that PMPRB operate with predictability and sustainability in mind, and our response to this consultation focuses on these two important principles. Amgen's primary concern relates to the potential for uncertainty that would result from pricing reassessments for new indications and changes in therapeutic class, and the impact of that uncertainty on Canadian patients.

Sustainable and Efficient Monitoring of Prices

After years of instability and different complex versions of proposed Guidelines and consultations, Amgen welcomes the concept of efficient monitoring as proposed by PMPRB. Using the highest international price as the standard for monitoring pricing excessiveness is aligned with PMPRB's mandate, desired administrative efficiency, and the government's commitment to the National Strategy for Drugs for Rare Diseases and the Biomanufacturing and Life Sciences Strategies.

Rules that result in artificially low list prices would make Canada an unattractive destination for pharmaceutical investment, since the reimbursement conditions and process, as well as time to listing of new drugs are all less than ideal and different than in other jurisdictions.

Artificially low Canadian list prices can also negatively impact launch timing in Canada given that sixteen countries directly reference the Canadian list price and most of these countries do it periodically, not only at launch. This reference to Canadian pricing by other countries is a

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consideration for companies in the launch and life cycle management of pharmaceuticals in Canada.

Price reviews during the product lifecycle and the need for predictability

In the Scoping Paper PMPRB points out that "It is common in many countries for the list prices to decrease over time". Price renegotiations conducted by payers can happen in these countries, as it is also done in Canada. These pricing reassessments are directly connected to affordability, growth in market size, and budgetary control. Amgen is of the view that these considerations are not within the scope of PMPRB's mandate.

A regulator with legal powers to forcefully reduce prices by conducting duplicative reassessments would generate a very unstable pharmaceutical environment and jeopardize access to innovation by creating uncertainty. Forced price reductions could lead to market distortions, including selective delays in launching new indications or new products to coordinate timing with when the best clinical data became available. This would be a disservice to the health system and, more importantly, to Canadian patients.

It is also worth noting that at the December 5th roundtable discussions there was mention of list prices increasing or decreasing due to re-assessments that PMPRB could conduct when better data becomes available (for the products approved by Health Canada with Phase 2 data due to high unmet need, for example). Though we appreciate the goodwill of the Board in raising this possibility, the pricing policies of most provincial payers limit annual list price increases to inflation. Even if PMPRB allowed meaningful list price increases when higher-quality scientific evidence became available, this proposal could not be operationalized by manufacturers.

We would welcome the opportunity to engage with PMPRB in collaborative discussions, preferably technical working groups, on the future Guidelines. Thank you for the opportunity to provide our submission.

Sincerely,

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