



August 4, 2020

Dr. Mitchell Levine, Chairperson
Patented Medicine Prices Review Board (PMPRB)
333 Laurier Ave. Suite 1400
Ottawa, ON K1P 1C1

RE: Amgen Canada response to consultation on PMPRB Draft Guidelines issued June 19, 2020

The following document constitutes the response from Amgen Canada Inc. (“Amgen” or “we”) to the PMPRB’s proposed draft Guidelines released for consultation on June 19, 2020.

We endorse the response to the draft Guidelines submitted by Innovative Medicines Canada. Most importantly, we believe that as a consequence of the recent Federal Court of Canada ruling that confidential third-party payments are *ultra vires* the *Patent Act*, any reference to the regulation of a Maximum Rebated Price should be excluded from the Guidelines. However, we recognize this consultation is about receiving feedback on the draft Guidelines as proposed on June 19, 2020, prior to that ruling, and therefore we will make comments on the current proposal.

Drugs launched early, or given Priority Review at Health Canada, would require deep mandated rebates by PMPRB, leading manufacturers to either delay or cancel product launches.

Given the strict definition of what will be required for a product to qualify for Therapeutic Criteria Level (TCL) I or II, promising innovative products that are approved early in Canada with Phase II data, or Phase III results with surrogate end points like Progression Free Survival, will be classified as TCL III or IV. For high cost drugs this classification will now impose a mandatory rebate floor of up to 50% on all sales above \$12 million which may rise as far as 67.5% with growth in sales. These inflexible mandatory prescribed rebate requirements effectively preclude the establishment of innovative payment models including outcomes-based agreements or coverage with evidence development. In the case where the MRP of an early launch product is re-assessed upwards several years later, when more mature scientific data is available on the product, there is no reason to believe that manufacturers will be able to benefit when deep levels of rebates have already been established. Such a framework is very likely to discourage companies from introducing promising innovative products in Canada until more robust data is available, to the detriment of Canadian patients.

Current MRP proposal disincentives competition

Under the proposed guidelines, the first entrant in a class could be classified as an innovative product TCL I or II, and so it would bear a lower level of mandated rebate than following entrants classified as a TCL IV (no improvement over the first entrant). This could lead to fewer entrants in a class and disincentive competition. Nowadays a later entrant with similar efficacy is assessed against the public list price of that first entrant and can match this price. This basic fairness is absent in these proposed Guidelines, representing a disincentive to the launch of more competitors in the class.

The unprecedented amount of power and discretion given to Board Staff in the June 2020 guidelines proposal

In this June 2020 guidelines proposal, HDAP becomes secondary in the price review process. Board Staff, rather than clinical experts, will do the therapeutic categorization of the product. Board Staff also seem not to be bound by the guidelines in any shape or form, especially in investigations, where the categorization of products could be changed, or applicable price tests be made more stringent (e.g., the median of TCC could be used in an investigation in cases where the guidelines spell out the highest should be used). As a result, a patentee could trigger an investigation due to a 5% difference in price but be “charged” with a 50% excess, for example, once the investigation starts. The resulting level of unpredictability and the extent to which Board discretion will enter such determinations represents a major obstacle for manufacturers and is very likely to delay or discourage new product launches in Canada

Concerns not addressed by the proposal

In our previous submission we pointed out important implementation barriers attached to the MRP:

- 1) The Canadian market is not uniform in its capacity to accept confidential rebates from manufacturers. Not all payers in the country are able or willing to accept rebates. Retail products also have a considerable share of cash payers, who pay list price.
- 2) Complex PLA structures, misalignment between contract periods which determine rebates and the PMPRB reporting periods, and delays in the availability of accurate data introduce unmanageable complexity to the process of tracking and reporting third-party rebates to PMPRB.

The current guidelines proposal makes substantive changes in the way the MRP is calculated but does not propose any solution to the important issues related above.

Given the recent Federal Court decision and the complex issues raised above, we recommend that PMPRB leave the concept of MRP out of the final guidelines published in the Fall 2020. We also



recommend that PMPRB maintain current boundaries on Board Staff discretion on investigations against patentees. This would demonstrate respect for the principles of predictability and fairness in the price review process and avoid future unnecessary litigation between PMPRB and patentees.

Sincerely,

A handwritten signature in black ink, appearing to read "Geoff Sprang", is positioned below the word "Sincerely,".

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