Amgen Canada Inc.
6775 Financial Drive, Ste. 300
Mississauga, Ontario
Canada L5N 0A4

Amgen Canada Response to the Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

The following document constitutes the response from Amgen Canada Inc. ("Amgen" or "we") to the "Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines ("consultation document") issued by PMPRB in June 2024.

We support the responses to the consultation document submitted by Innovative Medicines Canada and BIOTECanada. We will, however, make some supplementary comments on the pricing framework proposed in the consultation document.

New guidelines need to be predictable and aligned with PMPRB mandate

The guidelines should be designed from the perspective of PMPRB's mandate regarding excessive prices and the detection of specific instances of patent abuse. Application of highest international price (HIP) as the international price comparison (IPC) threshold is the proposed rule that is most aligned with said mandate. The application of International Median Price (MIP) or mid-point between HIP and MIP is inappropriate for fulfilling the mandate of monitoring for excessive pricing.

This same principle is applicable to other sections of the guidelines. The consultation document mentions that in the in-depth review there might be some variability on the results of the therapeutic class comparison test (TCC) based on the strength of the test (number of comparators and how many comparators are at the price level of the drug under review). This should not be a consideration in the new guidelines. Allowing the drug under review parity with the highest-priced comparator is the only rule aligned with the PMPRB mandate. Doing anything different would also mean adding significant uncertainty to the reviews.

The consultation document also establishes that any drug could go through an in-depth review many times throughout its lifecycle, where a new TCC could be conducted. Therefore, it is implied that the TCC could be an ever-changing price test, incorporating new occurrences and changes in the therapeutic class that are unpredictable for manufacturers. Launching new indications could also be very challenging in the context of this ever-changing TCC. This is not conducive to a stable business environment, where manufacturers need to make long-term launch and investment decisions. Additionally, re-assessments of therapeutic classes are commonly done by payers managing tight budgets, so they seem to be beyond the mandate of

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monitoring excessive pricing. For these reasons, PMPRB should not apply TCCs in in-depth reviews conducted in the post-initial review phase.

Manufacturers should be given some time to comply with the IPC prior to triggering an in-depth review

Manufacturers might not be able to predict the IPC accurately prior to launch or in later reporting periods due to many circumstances including, but not limited to, the following:

- For drugs sold by other manufacturers in the PMPRB11, public pricing information of other manufacturers might not be available as timely and efficiently as desired (if any).
- The new basket of countries has at least one country with negotiated prices which are hard to predict.

The issues mentioned above become more acute if the chosen rule for the IPC is MIP or mid-point between HIP and MIP, as these calculations are more complex and unpredictable, depending on all 11 countries in the reference basket. Unpredictable pricing results in a challenging environment for pharmaceutical companies to launch innovative products and new indications, which could impact the access of Canadian patients to new therapies.

CPI methodology should be used to adjust the IPC over time

Consumer Price Index (CPI) is one of the factors listed in Section 85 of the Patent Act to determine pricing excessiveness. CPI should be used to adjust the IPC over time. Allowing fair application of CPI would ensure companies can adapt to Canadian economic conditions and avoid unnecessary disputes between manufacturers and PMPRB.

We support expanding the list of products subjected to in-depth review only after a complaint

Besides vaccines and biosimilars, as proposed by PMPRB, we support the inclusion of originator products that have other sources (e.g., biosimilars or generics) but for which there are still reported relevant patents in the list of products that would be subjected to an in-depth review only if there is a complaint. Once other versions of the same molecule compete in the Canadian market, there is no possibility for patent abuse or excessive pricing by the originator. This criterion is easily verifiable by Board Staff, would increase administrative efficiency for Board Staff and manufacturers, and should not be detrimental to the interests of Canadians.

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The role of complaints

Complaints should be made by or streamlined through the Federal Minister of Health or any of his/her Provincial or Territorial counterparts. Additionally, only complaints that are substantive and clearly linked to the PMPRB mandate should trigger reviews.

Though the guidelines provide procedural guidance to Board Staff operations, they also need to provide clarity to manufacturers on excessive pricing standards for new launches and throughout a product's lifecycle. With the limited information in the consultation document, the results of the in-depth review would be unpredictable to companies like Amgen.

Thank you for the opportunity to provide our submission. As we approach a more advanced phase of consultation, when all the details and complexities will need to be worked out, we urge PMPRB to allow an opportunity for working groups and collaborative discussions.

Sincerely,

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