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Amgen Canada Response to the Draft Guidelines for PMPRB Staff - Phase 3 Consultations

The following document constitutes the response from Amgen Canada Inc. ("Amgen" or "we") to the consultation version of the "Draft Guidelines for PMPRB Staff" ("consultation document") issued by PMPRB in December 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 proposals in the consultation document.

Manufacturers should be given some time to adjust prices in response to reductions in the highest international price (HIP) prior to initiating an in-depth review (IDR)

This suggestion was included in our Phase 2 consultation submission however we would like to reiterate it. Manufacturers do not always have knowledge of future international prices arising out of re-negotiations in the PMPRB11 countries and/or licensing agreements with other manufacturers in some reference countries. Giving manufacturers at least one reporting period to comply with a change in HIP could save PMPRB and manufacturers from unnecessary in-depth reviews in cases where manufacturers intend to maintain list prices below HIP. We request that the Guidelines be revised accordingly.

Biosimilars should be reviewed by PMPRB only when a complaint is received

Biosimilars are brought to the Canadian market to bring savings and have consistently been launched at a significantly lower list price than the originator product. Subjecting these products to international price comparisons is inefficient because the international prices depend on factors such as how long biosimilars have been present in the PMPRB11 countries and policies that do not allow confidential contractual prices (which makes the international price a poor comparator for the Canadian list price). In order to avoid unnecessary disputes with manufacturers over products that are unlikely to have excessive pricing, the Guidelines should be revised to state that PMPRB will review these products only when there is a complaint, a policy that would be similar to the one currently applied to generics.

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There should be no retroactivity on the calculation of excess revenues after an in-depth review

The consultation document is unclear regarding what years will be in discussion once an IDR is initiated. There seems to be no limitation to the number of years PMPRB could retroactively require re-payment of excess revenues on any medicines that undergo an in-depth review. This would result in significant financial uncertainty for any sector to bear, especially one that requires long term investment like the pharmaceutical industry. Excess revenues should only be calculated starting from the time that an in-depth review is initiated.

We also request that the Guidelines clarify that there will be no financial liability for manufacturers with respect to prices over the interim period (i.e. July 1, 2022 to the coming into force of the final Guidelines) as a result of application of the final Guidelines. Potentially requiring re-payment based on retroactive application of new Guidelines to sales that occurred during the interim period would mean holding manufacturers to rules that were completely unknown when these sales occurred.

Associated DINs should not be included for the in-depth review

The current proposal states that once an in-depth review is triggered by one DIN, all other DINs of that product would also be subjected to the review. Taking DINs with low chance for excessive pricing to an in-depth review is unreasonable and over-taxing since these products would have already been found to be in compliance with the Guidelines through three different measurements (application of HIP, consideration of CPI changes and absence of complaints). We request that the Guidelines be revised to clarify that associated DINs will only be subjected to an in-depth review if they independently trigger a review.

Consistent policy regarding decision rules for in-depth review price tests is required

We appreciate PMPRB providing case studies in the consultation document. Some of these cases brought to light the fact that using different rules, depending on factors like the range of prices within an international price comparison (IPC) or within a therapeutic class comparison (TCC), will result in excessive subjectivity. It will be impossible for a manufacturer to know what price level would trigger a recommendation for a hearing once an in-depth review is initiated.

It is our view that using the highest price as a rule in each of the IPC and TCC price tests is the only result compatible with the stated goal of the Guidelines per the consultation document, to: “provide a transparent, predictable, and procedurally fair process around price review for

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those who sell drugs in Canada". To require a hearing for situations like Case Study 6, where the list price is below HIP and below some TCC comparators, would not be consistent with the stated goal. We request that the Guidelines be revised accordingly.

There needs to be clarity over the therapeutic class comparisons conducted for different indications in an in-depth review

The current proposal states that therapeutic class comparisons will be carried out for each indication, however there is no information on how PMPRB will determine which therapeutic class comparison will be used for the in-depth review or whether multiple comparisons will be used and assigned different weights. We request more clarity in the Guidelines as to how the therapeutic class comparisons conducted for different indications will be used to determine potential pricing excessiveness.

Considering that most of the items listed above, as well as many other questions, pertain to in-depth reviews, at this point it would be impossible for a manufacturer to predict the results of these reviews. Amgen would support a phased implementation of new Guidelines, where the HIP and CPI tests could be implemented prior to finalizing the process for in-depth reviews, to allow for better development and understanding of the rules and procedures applicable to in-depth reviews and inclusion of related clarifications in the 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.