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RE: Amgen Canada response to consultation on PMPRB Draft Guidelines

The following document constitutes the response from Amgen Canada Inc. ("Amgen" or "we") to the proposed draft Guidelines released for consultation on November 21, 2019.

We request that the PMPRB immediately pause or delay implementation of the amended PMPRB regulations and reengage industry stakeholders in a new round of consultations.

While we support and endorse the response to the draft Guidelines submitted by Innovative Medicines Canada, we have addressed several points that we feel should be emphasized. We would also like to express our disappointment and frustration that despite dedicating significant time and effort to participating in a Technical Working Group where many of these issues were raised, we were advised that such issues were out of scope. The overwhelming majority of our considered input appears to have been ignored from a reading of the final regulations which remained almost unchanged with respect to the areas of concern we identified. We now find ourselves reiterating the same issues, including many that call into question the feasibility of implementation.

Therefore, a new round of consultations is necessary to consider the legitimate and substantive concerns from drug manufacturers regarding access to innovative treatments for Canadian patients, as well as the many significant feasibility issues relating to the implementation of the amended PMPRB regulations and Guidelines, as detailed below in this document.

The determination of a Pharmaco-Economic Price (PEP) will delay launch

As we have repeatedly stated in comments provided directly to the PMPRB, as well as through the Technical Working Group and Steering Committee, the use of Health Technology Assessment ("HTA") as a price regulatory factor presents a major challenge for manufacturers. Leaving aside the theoretical inappropriateness of applying a single public health system perspective to establishing value in a heterogeneous payer market, the use of a health economic assessment in a deterministic manner to establish a PEP ignores the fundamental limitations of HTA that arise from the inherent uncertainty around many of the assumptions used to construct and apply health economic models. In our experience, CADTH HTA reviews recognize this uncertainty which is reflected in a probabilistic rather than a deterministic assessment framework and the establishment of a range of incremental cost effectiveness ratios rather than a single point estimate.

Where significant uncertainty exists, which is often the case with innovative products, CADTH HTAs typically tend to adopt the most conservative (worst-case) assumptions which reduce the modelled cost-effectiveness. Recognizing these limitations, CADTH's cost-effectiveness assessments have historically been used, alongside other considerations, to inform public payers when entering into pricing and access negotiations, allowing flexibility to consider these uncertainties in the context of the unique market characteristics of each new product.

Given the wide range of possible outcomes and the subjectivity of the choice of assumptions used to inform HTA, and knowing that these assumptions will ultimately translate in a highly prescriptive manner to a specific point estimate of cost-effectiveness that will determine a PEP, manufacturers will have to deal with much higher levels of uncertainty in forecasting net prices of new products than was the case under the previous regulations and guidelines. They will also be faced with the reality that their PEP will be fixed at a point in time when uncertainty is highest (and PEP will be low) and if new data reduces the initial uncertainty and results in a more favourable cost-effectiveness assessment, there is no provision in PMPRB's new framework to adjust prices upwards. This uncertainty coupled with the inability to adjust a PEP upward in response to new data, will inevitably lead to decisions to delay, and in some cases abandon altogether, the launch of new products in Canada.

Use of the Therapeutic Class Comparison (TCC) test to new products is inconsistent with policy goals.

The new proposed Guidelines remove the therapeutic improvement classification for new molecules and leave the choice of appropriate comparator products entirely at the discretion of Board Staff. In addition to the inherent uncertainty arising from the lack of defined criteria around choice of TCC comparators (which adds to the challenges already facing a manufacturer), the application of this measure will result in very low prices for products in therapeutic areas dominated by older genericized products and provides no defined mechanism to account for relative improvement in treatment brought by the new molecule. This impact is compounded by PMPRB's proposal to use the median of the TCC comparator prices as opposed to the highest priced comparator. More often than not, this will result in a Canadian list price aligned with the lowest price within the new international reference group.

Application of this methodology will result in Canadian list prices being the "lower of the lowest", especially in therapeutic classes where innovation is needed most. Such conditions for pricing in Canada are inconsistent with the PMPRB's stated policy intent of aligning Canadian prices with the OECD median and will unquestionably have an adverse impact the launch of new products and indications in Canada, which will in turn compromise the ability of Canadian patients to access recent treatment advances.

Implementation challenges have not been given sufficient consideration.

The PMPRB proposal to impose an MRP overlooks significant limitations in the Canadian prescription drug marketplace that make it difficult for manufacturers to comply.

Contracting Capabilities - The proposal assumes that the Canadian market is uniformly capable of engaging contractually with manufactures and accepting non-transparent rebates from them. While public plans do have this capacity and have a history of engaging in Product Listing Agreements for all new products or



indications, in our experience many private payers do not want, or do not have the technical capability, to engage in product listing agreements (PLAs) or to accept, process and repatriate to plan sponsors, rebates received from manufacturers. To complicate matters further, a significant share (19.9%¹) of prescription drug expenditure is attributed to cash paying customers. There is no reliable way for a manufacturer to accurately quantify these expenditures. How is a manufacturer to achieve an MRP under such circumstances?

Complex PLA Structures and Misalignment of Reporting Periods - Even for those payers that are operating under a PLA, the rebate amounts that accrue in a given reporting period may not be known for many months following that period as a result of complicated agreement structures that often include expenditure caps, tiered rebate thresholds, individual patient expenditure caps or performance measures. For any given product, PLA annual reporting periods vary across payers and will rarely if ever align with PMPRB's calendar year reporting period. Furthermore, the payment of rebate amounts will be "lumpy" with large reconciliation payments falling in PMPRB reporting periods that are not actually aligned with the expenditures on which the rebates have been calculated. Leaving aside the significant complexities and additional administrative burden associated with tracking and reporting to PMPRB under these circumstances, how will PMPRB assess compliance with the MRP when net prices fluctuate unpredictably year over year?

Availability of Reliable Market Data - As noted above, a significant proportion of prescription expenditures will be attributable to private payers unable or unwilling to engage in contracts with manufacturers or to cash paying customers with whom such agreements are not possible. Manufacturers do not sell directly to these entities. The overwhelming majority of retail prescription drug sales are to wholesaler intermediaries. As a consequence, it is not possible to accurately quantify sales beyond the ex-factory amounts sold to wholesalers. Data that is available from syndicated sources (e.g. IQVIA) is subject to significant limitations and is certainly not adequate for the purposes of calculating rebates.

These are just a few examples of the limitations that pose significant implementation barriers to reporting and compliance with an MRP.

Existing products need to be properly grandfathered

Historically the industry has had high levels of compliance with PMPRB guidelines and procedures. Existing PLAs, investments in patient assistance programs, facilities and staff in Canada related to the "old" products were all made based on business cases at existing price levels. The immediate application of the new price reference group and rules to existing products fundamentally alters the business cases and development and launch planning cycles for these products with no period of adjustment. This is likely to adversely impact not only on manufacturers and innovation in the Canadian life sciences sector, but also investments in programs made by healthcare stakeholders that benefit patients and providers. We believe that changes in regulations with such profound consequences should exclude existing molecules or at least allow for a much more gradual phase-in period.

Conclusions

In view of the significant issues outlined above, we believe the appropriate action is for PMPRB to immediately pause/delay implementation of the regulations and allow for a comprehensive and authentic consultation process through which manufacturers' legitimate concerns about the impact on access to innovative treatments as well as the many significant feasibility issues we have identified can be considered and thoughtfully addressed.

Sincerely,



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Amgen Canada Inc.

¹ Canadian Institute for Health Information. *Prescribed Drug Spending in Canada, 2019: A Focus on Public Drug Programs*. Ottawa, ON: CIHI; 2019.