October 31, 2016

Patented Medicines Prices Review Board
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RE: Amgen Canada response to PMPRB Guidelines Modernization Discussion Paper (Rethinking the Guidelines)

Thank you for the opportunity to provide comments on the Guidelines Modernization Discussion Paper. Overall Amgen's position is highly aligned with that of Innovative Medicines Canada (IMC) and BIOTECanada as captured in their parallel responses on this discussion paper and we have therefore limited our response to addressing the broader issues and implications associated with changes to the current price regulatory framework.

Fundamentally, we believe that an objective review of the data does not support the underlying premise of the discussion paper that the existing price regulatory framework in Canada has not been effective in protecting Canadians from the abuse of monopoly pricing power afforded by patent protection. On the contrary the PMPRB has been highly effective in protecting Canadians as is clear from the following observations:

- while there have been year over year fluctuations in Canada's ranking within the PMPRB7 reference countries, Canada currently is currently tied for 3rd and 4th position out of the 7 comparators which is essentially the "middle of the pack".
- the prices of patented drugs which have no generic equivalent (those for which true monopoly power exists) are even lower and for this subset of products Canada ranks 6th out of the 7 comparators.
- the rate of price increases for patented medicines has consistently been lower than the CPI such that prices have fallen in real terms
- the ex-factory price of medicines which is monitored and regulated by PMPRB does not capture the impact many other factors which further reduce prices including discounts, rebates, financial assistance and even free or compassionate goods which are provided by the industry.

We also agree strongly with the IMC position that expanding PMPRB's mandate to include considerations of "affordability" and "value for money" would encroach on the mandate and jurisdiction of other existing decision makers within the healthcare system resulting in duplication and confusion. In particular, Canada already has a robust health technology assessment framework that provides guidance to payers on the cost-effectiveness of medicines to assist in listing and pricing decisions. The determination of affordability is complicated by the nature of Canada's mix of public and private funding for prescription drugs under which no single assessment of affordability is possible.

We recognize that PMPRB intends to modernize its Guidelines and we understand that the current consultations are likely to prompt change. While we appreciate the process of consultation that PMPRB has undertaken here, we know from experience that even modest changes in the PMPRB's guidelines

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can have far reaching and often unanticipated implications which may be counter-productive. Therefore, in addition to the current consultation, we strongly encourage the PMPRB to establish a process of ongoing dialogue through a working group with industry and other stakeholders to evaluate potential changes thoroughly prior to implementation in order to reduce the likelihood of unintended consequences and disruption.

Lastly, while we recognize and respect the role of PMPRB to ensure that Canadians are not subject to excessive prices, we continue to believe that the best path forward to the Canadian healthcare system is to move away from a singular focus on individual budget siloes and control of system input costs towards an integrated approach to resource allocation, the focus of which is achieving the best outcomes for patients.

Many countries are moving in the direction of Value Base Health Care (VBHC) whereby the objective is to derive the best patient outcomes for a given level of investment. In such a model, medicines are viewed as part of an integrated healthcare model and financing decisions are made on the basis of value as opposed to price or cost. It is Amgen's aspiration that Canada follows the lead of other jurisdictions in this respect. Encouragingly, we have already seen some examples emerge here. However, in order to facilitate experimentation and to pilot these novel approaches, the access and pricing policies in Canada, including the PMPRB's policies, need to provide a degree of flexibility and a forward looking perspective. We are deeply concerned that the outcome of the current change process will in fact be less flexible than the current framework (which itself is problematic) and is likely to limit the ability of stakeholders, including but not limited to the industry, to move in the direction of VBHC.

We understand and respect that PMPRB's current mandate may limit its ability to directly address some of these broader issues. However, we urge the PMPRB to take a forward looking and longer term perspective in revising its policies in order not to impose rigid frameworks that will inhibit the ability of manufacturers to engage in innovative value-based reimbursement schemes such as risk-sharing agreements or pay-for- performance models.

We appreciate the opportunity to participate in your consultation and would be pleased to provide any additional information or clarification as required.

Sincerely,

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