August 27, 2021

Via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

To whom it may concern:

The following document constitutes Amgen Canada Inc.'s ("Amgen" or "we") comments on the Patented Medicine Prices Review Board's ("PMPRB") three proposed amendments to the new PMPRB Guidelines that were released for consultation on July 15, 2021.

The pandemic has exposed the fragility of our health care system and has had a durable impact on our economy. It also has revealed the importance of building resiliency in the Canadian healthcare system, driven by better adoption of innovative solutions like medicines, diagnostics, and devices.

We applaud the Government of Canada for its recently announced national Life Sciences Strategy (the "Life Sciences Strategy"), which has also been widely welcomed by industry, patients, and consumers alike. That said, we are concerned that the proposed reforms to the PMPRB are inconsistent with the Life Sciences Strategy, and detrimental to building a long-term resilient healthcare system in Canada. The reforms introduced by PMPRB will have a significant and direct impact on access to drugs and on the Life Sciences Industry for years to come.

We endorse the response to the draft Guidelines submitted by Innovative Medicines Canada and BIOTECanada, however, we would like to emphasize some important points on the proposal for the transition of grandfathered products and their line extensions:

1) **The proposal is at odds with PMPRB mandate of preventing excessive pricing as a result of patent abuse, and a proper justification is not presented for a proposal that will double the financial impact on grandfathered products.**

In the July 29, 2021 Federal Court of Appeal decision *in Alexion Pharmaceuticals Inc. v Canada (Attorney General)*, 2021 FCA 15, the Court states that PMPRB legal mandate is restricted to controlling against excessive pricing deriving from patent abuse, and not reasonable pricing, price-regulation or consumer protection at large. The decision also mentions that the Guidelines themselves are only non-binding guidance that must consistent with the law of the land.

The proposal of using the median of the current 7-country basket as the maximum list price for all grandfathered products is not consistent with this legal mandate to only control against excessive pricing. The potential result of this proposal is that it will push prices down beyond what would be expected from an excessive price control mandate. This observation is particularly relevant when we consider that the 2nd, 3rd or even the highest price in the international basket represent countries that were chosen as comparators by the Government of Canada.

PMPRB staff analysis shows that this proposal doubled the financial impact for the industry from 5% to 10% average price decreases. This is a significant departure from the previous guidance in which the PMPRB had already agreed that the general standard for pricing excessiveness for these existing products should be the highest price in the international reference basket. Such a significant and material change to the guidance should not be done without proper analysis and without a rationale that is consistent and in scope with PMPRB mandate.

2) **The proposal is at odds with Health Canada's delay of implementation of the new pricing Regulations.**

The last amendment the PMPRB guidelines published October 23, 2020 established a 12-month transition period for grandfathered products from the implementation date of the new Regulations. With the implementation date delayed to Jan 1, 2022, the new transition date should have been also delayed to January 1st, 2023; however, the proposal from PMPRB would require that price decreases on grandfathered products would be implemented by July 1st, 2022.

Given that the current state of economic and social uncertainty brought on by the COVID-19 pandemic, the Federal Government felt that it was justifiable to put in place another 6-month delay in the implementation of the new price Regulations. Additionally, knowing the new prices in October/November 2021 for implementation in June 2022 is very impractical because some cases might need a re-setting of NEAPs, and a lot of coordination is required between industry, public formularies and all the players in the pharmaceutical distribution chain for the actual implementation of the new list prices.

We respectfully submit that the transition date for price decreases on grandfathered products should also be delayed by an additional reporting period.

3) **The proposal is at odds with the objectives and goals of the Life Sciences Strategy. In particular, the proposal is inconsistent with Pillar Five of the Life Sciences Strategy, which calls for enabling innovation by ensuring world class regulation.**

Regulations and guidelines managed by the PMPRB are a critical part of the Life Sciences ecosystem in Canada. The proposed amendments to the PMPRB guidelines are wholly inconsistent with the intent of the Government to make Canada a more attractive destination for the Life Sciences sector.

According to a recent Statistics Canada Report, in 2018, the R&D pharmaceutical sector added almost $15 billion in value added (gross domestic product) to the Canadian economy and supported over 100,000 full time equivalent jobs (FTE) within Canada. Additionally, it spent between $1.5 and $2.0 billion on research and development. The sector spent $1 billion on in-house research and development in Canada, while also spending $950 million outsourcing research and development work both domestically and outside Canada. The innovative biopharmaceutical sector is important to the health of Canadians and the Canadian economy. It is hoped that further research will be able to build upon the findings contained within this study.

Based on research undertaken by Life Sciences Ontario in 2020, biopharmaceutical companies noted that the PMPRB regulatory changes will have negative impacts on the viability of Canada as a market for business, and the potential implications that would result in a reduced presence in Canada, including negative impacts on clinical trials, compassionate access programs, and product launches.

Conclusion

Canadians and the Life Sciences sector need a policy environment that promotes research and development, provides predictability for manufacturers, incentivizes technological advances and secures access to novel drugs so that we can keep people out of hospitals, have a healthier and productive workforce, and create resiliency by preventing and better managing chronic diseases.

For the reasons listed above, Amgen requests that PMPRB reconsider the proposed changes to the new PMPRB guidelines as follows:

- the highest international price remains the maximum list price for grandfathered products; and
- compliance timeline is set for January 2023, in order to remain consistent with the transition timeline of two reporting periods from the new date of implementation of the amended Regulations and the extra period granted to the industry by Health Canada.

Amgen appreciates the opportunity to provide feedback and remains open for dialogue and collaboration with the PMPRB in the goal of developing a more resilient healthcare system.

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