Written Submission for the Pre-Budget Consultations in Advance of the 2019 Budget

By: Amgen Canada Inc.

List of Recommendations

- **Recommendation 1: Amgen recommends that the Federal Government maintain private insurance participation in the implementation of a National Pharmacare program to ensure early and broad adoption of new innovative products and a positive impact on productivity.**

- **Recommendation 2: Amgen recommends that the Federal Government take a balanced approach to the modernization of the Patented Medicines Review Board (PMPRB)'s regulatory powers given its correlation to investment in R&D and maintenance of the standard of care.**

- **Recommendation 3: As Canada seeks to become a leader in Big Data Analytics (BDA) and Artificial Intelligence (AI), Amgen encourages the Federal Government to signal its commitment to these investments by encouraging more public/private partnerships in big data infrastructure to help position us ahead of the curve and drive the next generation of medical advances to compete on a global level.**

Amgen applies science and innovation to help fight serious illness and dramatically improve people's lives. With Canadian headquarters located in Mississauga's vibrant biomedical cluster, and a research facility in British Columbia, Amgen's Canadian affiliate has been an important contributor to Canada's biotechnology sector since 1991.

Amgen Canada serves patients by delivering vital medicines and contributes to the development of new therapies or new uses for existing drugs in partnership with Canada's leading healthcare, academic, research, government and patient organizations. Tens of thousands of Canadians use Amgen medicines every year, and thousands more are enrolling in our clinical studies that deliver the next generation of innovation.

Amgen would like to thank the Federal Finance Committee for the opportunity to share our views on Canadian productivity and competitiveness. We would like to draw attention to two policy issues currently in development that could impact Canadian productivity (National Pharmacare and the PMPRB reform) and one area of focus to build a stronger life science sector in Canada (Big Data Analytics and Artificial Intelligence).

Recommendation 1: Amgen recommends that the Federal Government maintain private insurance participation in the implementation of a National Pharmacare program to ensure early and broad adoption of new innovative products and a positive impact on productivity.

Amgen supports the idea that no Canadian should be denied access to medication for financial reasons. To this end, proposed reforms to the system should ensure availability of multiple treatment options and respect the choice of patients and healthcare professionals. We are committed to the idea of a National Pharmacare program which provides Canadians with access to more, not less. However, a new system must consider the advantages of private insurance participation so as not to diminish existing coverage. When roughly 22.5 million Canadians are currently covered under a private drug plan[1], all-encompassing changes will not only be costly to the public, they may also divert funds which could potentially be re-invested to provide broader access. Since private insurers have traditionally listed products more rapidly than the public system, a structure which includes both types of payers will safeguard early adoption of innovative medicines and allow for the prioritization of productivity amongst those covered.

Delaying access to innovative medicines can have drastic results, including costly hospital visits, emergency pharmaceutical administration and even long-term care. Ultimately, costing the healthcare system more, not less. To illustrate this point, the Conference Board of Canada demonstrated in a 2013 study that new pharmaceutical innovations in asthma and rheumatoid arthritis would help reduce incremental health and societal benefits by over $2.9 billion between 2013 and 2030.[2] Additionally, during the same period, the study demonstrated that pharmaceutical innovation in prescription smoking cessation aids would result in preventing more than 4,400 cases of chronic diseases.[2]

Patients around the world are living longer, healthier and more productive lives, due in large part to access to medicines that prevent, treat and cure deadly diseases. Innovative medicines can reduce the need for emergency room visits and help manage disease complications and co-morbidities; both of which are associated with higher overall costs than the medicines themselves.[3] A healthcare system which supports innovation is the best way to improve productivity and reduce overall costs; keeping in mind that quality care is often less expensive in the long run. Evidence shows that the cost of pharmaceutical innovation is offset by reductions in healthcare resources and productivity losses

associated with disease: in 2012, the $1.22 billion spent on pharmaceutical treatment generated offsetting health and societal benefits of nearly $2.44 billion.[2]

Although many consider the National Pharmacare implementation program as an exercise in decreasing the price of pharmaceuticals, it is imperative to remember that these costs represent a small portion of total healthcare expenditures. A far bigger impact will come from changing demographics and the burden of chronic disease. For all drug classes studied by the Conference Board of Canada (cardiovascular disease, diabetes, asthma, rheumatoid arthritis and prescription smoking cessation aids) the ratio of health and societal benefits relative to the cost of treatment will be higher in 2030 than in 2012; moreover, they estimate that the combined benefits associated with the use of biologics will exceed the cost of treatment by 60% in 2030.[2] Therefore, we must be thoughtful and deliberative when proposing and implementing changes; mindful of the benefits for maintaining both a public and private structure. Improvements must emerge out of innovation and investment in novel treatments, giving patients quick access to medicines that will allow them to lead more productive lives.

Recommendation 2: Amgen recommends that the Federal Government take a balanced approach to the modernization of the Patented Medicines Review Board (PMPRB)'s regulatory powers given its correlation to investment in R&D and maintenance of the standard of care.

Despite significant progress in medical discovery, new treatments are still needed for many chronic diseases. Clinical trial investment is therefore essential since it provides Canadians with early access to innovative, potentially life-saving therapies. This investment also increases the likelihood that healthcare providers and hospitals will adopt new medicines to provide better care for patients. Investment in clinical trials today, becomes the standard of care tomorrow.

Canada is the second largest clinical trial site for Amgen outside of the United States. Abundant, up-to-date comparator data is one main reason for this; another is an understanding that Amgen will commercialize products upon trial completion and adoption will be timely, especially for Canadians who are enrolled and wish to remain on the drug. Many of the current reforms being proposed by the PMPRB could have an impact on when, or even if, a drug will be launched in Canada; potentially influencing the decision to run clinical trials here at all. While seemingly divorced from Canada's productivity and competitiveness agenda, in fact, decisions which complicate the product-launch process inhibit our ability to advance R&D and ultimately, impedes development of the innovative medicines needed to address the complex diseases facing Canadians.

Consequently, PMPRB reform should be handled in a balanced manner, and while we recognize the need to modernize and adjust to the current healthcare ecosystem, new guidelines should not result in a detriment to the operating environment for innovative pharmaceutical companies. While Amgen has demonstrated a willingness to collaborate with Health Canada and PMPRB on their process modernization, continuously indicating a willingness to negotiate with payers, we believe the current scope of the proposed regulatory changes goes well beyond a reasonable reduction in ceiling prices. We would like to remind the committee that the challenges facing the healthcare system go beyond expenditure on patented drugs. In fact, of the 14% spent on prescription drugs in 2017[4], only a portion (6.8%) were patented.[5] Also noteworthy, PMPRB data on public drug program spending from 2012 to 2016 demonstrated that the price of patented drugs remained stable.[5,6] So, while the cost of pharmaceuticals is an easy target, addressing the challenges of healthcare budget sustainability requires a holistic, system-wide approach. Limiting the conversation to the price of prescription medication does not account for the big picture and will almost certainly cost the country more in the long-run.

Recommendation 3: As Canada seeks to become a leader in Big Data Analytics (BDA) and Artificial Intelligence (AI), Amgen encourages the Federal Government to signal its commitment to these investments by encouraging more public/private partnerships in big data infrastructure to help position us ahead of the curve and drive the next generation of medical advances to compete on a global level.

As Canada seeks to become a leader in AI and BDA, Amgen's investments in real world evidence, clinical trials and value partnerships, align with this goal. When Prime Minister Trudeau met with our global CEO, Bob Bradway, last February, the conversation centered around the potential Canada holds in this space. We would like to build on that conversation. As a company Amgen develops biologics; medicines that are more complex and therefore more expensive to produce. We believe that the value and impact our products have on patients can only be fully demonstrated if the outcome they produce, relative to other interventions, is measured. That is why we are strong supporters of data analytics in the context of a value-based healthcare system; one geared to delivering the best possible outcomes for patients.

New insights for patient management and outcomes will be driven by BDA and AI in the next generation of innovative prescription medicines. Traditionally relying on clinical judgement, those in the healthcare community are moving toward evidence-based medicine, relying instead on an automated, systematic review of all available clinical data before making decisions.[7] A study conducted by the McKinsey Global Institute predicts annual savings in the billions of dollars by utilizing BDA to modernize how clinical care is provided, through a comprehensive analysis of patient and outcome data and by comparing the effectiveness of various interventions.[7] Accordingly, personalized patient-care provides value while reducing the burden on clinicians and saving the healthcare system by delivering the right medicine at the right time; eliminating wasteful spending.

The use cases for BDA in healthcare are abundant, from finding causes of and treatment for diseases, to more quantifiable patient-centric examples such as active monitoring to avoid an adverse event, saving time by ordering fewer tests and conserving resources by only administering treatment to those who will benefit.[7] Combined, the return on investment is estimated to represent as much as five to six percent of the over $228 billion spent by the Canadian government on healthcare in 2016.[7,8] Furthermore, drug costs were better managed when BDA was utilized in pilot projects through derived efficiencies in clinical operations, formulary management and remote patient monitoring.[7] The benefits are simply too great to ignore.

All stakeholders, including governments, clinicians, patients and the innovative pharmaceutical industry should embrace new technologies using BDA and AI to help deliver personalized care. Amgen has always invested in innovation and as healthcare technology evolves, the conversation must include investments in private infrastructure to help grow capabilities within the system. Government support of public/private innovative partnership agreements would be highly impactful and signal that this is a priority; it would also help ensure that Canada remains competitive through this dynamic and complex shift to the next generation of healthcare.

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