



## 2018 Pre-Budget Submission

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**Submitted by:**

AstraZeneca Canada

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House of Commons Standing Committee on Finance  
Parliament of Canada

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## Introduction

AstraZeneca Canada is pleased to contribute to the federal government's pre-budget consultation process of the House of Commons Standing Committee on Finance for the 2018 Federal Budget. AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of innovative medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases, and Respiratory. AstraZeneca operates in more than 100 countries and its innovative medicines are used by millions of patients worldwide. In Canada, we employ more than 720 employees across the country and our AstraZeneca Canada headquarters is located in Mississauga, Ontario.

AstraZeneca is committed to working with the Government of Canada and Parliament to establish a strong innovation-based economy that enables rapid development of new technologies, taps into a highly skilled workforce, and provides a favourable research and development (R&D) and reimbursement environment. We believe the Government of Canada, working with Parliamentarians, has the potential to build a world-leading health/bio-sciences sector through a policy environment that supports innovation, ensuring Canadians benefit from the latest health research through access to the best possible treatments.

The health/bio-sciences sector benefits the Canadian economy by creating high technology jobs and making valuable research investments that help to support a vibrant biopharmaceutical hub in Canada – including universities, contract research organizations, research institutes, biotechnology and biopharmaceutical companies.

The cost of innovative pharmaceuticals make up 6.5% of total health spending in Canada<sup>1</sup> and deliver a clearly demonstrated return on investment for the health and economy of Canadians.<sup>2</sup> New treatments prevent or cure disease, extend lives, relieve suffering and improve an individual's quality of life. Innovative medicines when used appropriately allow patients to reduce or eliminate other costlier services, such as emergency room visits, hospital stays and surgeries, and delay the need for long-term care.

From the discovery of insulin in Canada and HIV treatments, to the latest hepatitis C and oncology drugs, our industry and the research we conduct and fund are transforming care and turning what were once terminal diseases into chronic or curable ones. These advancements in science can only occur in a competitive environment that provides incentives for innovation and delivers much needed medicines to patients when they need them. We are encouraged that the federal government agrees.

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<sup>1</sup> *Canadian Health Policy Institute*, Spending on Patented Drugs in Canada 1990-2014, February 23, 2016.

<sup>2</sup> [Conference Board of Canada](#), Reducing the Health Care and Societal Costs of Disease: The Role of Pharmaceuticals., July 2013.

*1. What federal measures would help **Canadians** to be more productive?*

The recognition of the health/bio-sciences sector as an economic driver and area of high technology investment is essential to Canada's future economic growth. The health/bio-sciences sector helps Canadians to be more productive by creating high-value, knowledge-based jobs in the new economy.

AstraZeneca is proud to be one of Canada's top contributors to health sciences R&D, supporting world-class Canadian research that will advance our scientific knowledge and the care of patients in Canada and around the world. AstraZeneca Canada was recently designated a Global Clinical Trial Delivery site and is playing an integral role within our global organization leading more than 35 global clinical trials in oncology, immuno-oncology and respiratory, some involving up to 30 countries worldwide. Our Clinical Trial Delivery team has grown to more than 110 Canadian employees, more than doubling in size since 2013.

In 2016, AstraZeneca Canada invested \$82.4M in R&D initiatives in Canada, as defined by the OECD criteria for measuring research investments – more than 12% of the gross revenues for our innovative products, and nearly double what is captured through PMPRB's current R&D reporting criteria.

Indeed, global pharmaceutical R&D spending is forecast to grow by 2.8 percent annually to \$182 billion in 2022 from \$149.8 billion in 2015 (compared with CAGR of 1.7 percent between 2008 and 2015).<sup>3</sup>

**We would therefore recommend that the federal government prioritize policies and programs that support skills development in R&D – both discovery and clinical - and its subsequent commercialization.**

*2. What federal measures would help **Canadian businesses** to be more productive and competitive?*

The future success of Canada's health/bio-sciences sector depends on the creation of a policy environment that supports and follows science, research and innovation across all related government ministries: including health, finance, innovation, economic development, science and technology. For Canadian businesses in the health/bio-sciences sector, the policy ecosystem must be integrated so that economic policy and health policy are complementary rather than contradictory.

In terms of economic policy, the federal government's Innovation Superclusters Initiative, along with the recognition of the health/bio-sciences sector as an economic driver and area of high technology investment, is essential to Canada's future growth.

AstraZeneca is actively participating in what we hope will be a new innovative health/bio-sciences supercluster, to help attract global investment in science and clinical trials. However, as we outlined in our submission on Health Canada's proposed amendments to the Patented Medicines Regulations, the Patented Medicine Prices Review Board (PMPRB) proposals, as written, introduce substantial uncertainty into the Canadian biopharmaceutical marketplace that risks being counter-productive to this policy goal.

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<sup>3</sup> [EvaluatePharma: World Preview 2016. Outlook to 2022](#), September 2016.

We are working with other industry partners, academic and research institutions, and Canadian small and medium-sized enterprises within the framework of the supercluster initiative and are hopeful that this collaborative approach will help to illustrate some of the policy and program gaps identified in the annual Conference Board of Canada's Report Card on Innovation.

An integral part of ensuring growth in the health/bio-sciences sector is providing innovators with a robust and predictable intellectual property (IP) regime in line with Canada's major trading partners. A recent Supreme Court of Canada ruling helped clarify a key issue for Canadian innovators because it removes ambiguity created by a uniquely Canadian and unusually stringent interpretation of patent law, known as the "promise doctrine." Globally, this decision helps bring Canada back in line with the international norm of other modern economies regarding patent utility.

Importantly, this decision boosts the federal government's efforts to position Canada as a good place to invest in health/bio-sciences and we encourage the Government of Canada to send similar signals to global investors through the practical application of the IP provisions agreed to through the Canada-EU Comprehensive and Economic Trade Agreement (CETA), including an equal and effective right of appeal for innovators and patent term restoration.

Overall, we believe that any new economic strategy should be fully aligned with the objectives of the health/bio-sciences supercluster initiative to enable Canadian businesses to reach their full competitive potential.

**We therefore recommend that the federal government ensure that the review, approval and execution of a health/bio-sciences supercluster be made a priority, and that any new IP policies ensure the highest possible standards to encourage innovation.**

With regard to health policy, it is critically important that it is aligned with the objectives of the supercluster initiative and the Innovation Agenda. Fast and predictable regulatory, pricing, health technology assessment and reimbursement approval systems should not frustrate or be counter to economic policy objectives, but rather must enhance Canadian productivity and competitiveness.

Canadians would also benefit from Health Canada modernizing its review process to better align with those of Canada's major trading partners, in keeping with Health Canada's life-cycle approach to regulatory approvals. We believe both Health Canada and patients would benefit from opportunities to consider external advice and new data, both of which are critically important to ensure that regulatory decisions keep pace with advances in science and medicine.

**AstraZeneca recommends that Health Canada: 1) accept external scientific advice as a standard within the submission review process; 2) permit the introduction of new data during the regulatory review to ensure that the best, most currently available scientific information is considered; and, 3) allow structured communication with industry mid-review to increase both the predictability and the opportunity to interact within the Canadian regulatory review process.**

Innovation in the context of healthcare is the process of taking a medical discovery or advance – whether it is a new biopharmaceutical product, a medical device or diagnostic, or a different medical procedure – to the point that it is being readily utilized, improving patient care and delivering value in the healthcare system.

**We therefore recommend that the federal government adopt a ‘whole of government’ approach coordinated by the Ministers of Finance, Health, and Innovation, Science & Economic Development to address some of the gaps in Canadian biopharmaceutical policy to ensure the success of a fully-integrated health/bio-sciences supercluster initiative within an innovation-based economy.**

## **Conclusion**

AstraZeneca has a relentless commitment to innovation and Canadian health sciences leadership. We are committed to working with the Government of Canada and other stakeholders to establish a strong innovation-based economy that enables rapid development of new technologies, and provides a favourable R&D and reimbursement environment. We believe that a constructive, productive and internationally competitive policy environment that includes Canadian regulators, pricing authorities, health technology assessment agencies and payors is a key part of enhancing Canada’s productivity and competitiveness. We believe that together we can foster a world-leading healthcare system through an innovative, predictable and stable biopharmaceutical economy. We would therefore encourage all Parliamentarians to engage with the health/bio-sciences sector with a view to partnership for the benefit of all Canadians.