



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

Submitted by:

AstraZeneca Canada

Submitted to:

House of Commons Standing Committee on Finance
Parliament of Canada

August 3, 2018

Recommendation 1: To ensure Canada's competitiveness in the biopharmaceutical sector, the Government of Canada should postpone implementation of the proposed amendments to the Patented Medicines Regulations until a full economic analysis, modelled in the context of the Canadian health system and innovative life sciences ecosystem, is undertaken and considered.

Recommendation 2: Representatives of Canada's biopharmaceutical companies should be formally invited to join the Advisory Council on the Implementation of National Pharmacare to ensure that future drug coverage for Canadians is value-based and supports optimal health outcomes by providing the right medicines to the right patients at the right time.

Recommendation 3: The Government of Canada should delay Health Canada's planned cost recovery for drug submissions until such time that the transformational changes resulting from the Regulatory Reform of Drugs and Devices (R2D2) initiative can be accounted for in the new fee proposal.

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 2019 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 – Cardiovascular, Renal & Metabolism; Oncology; Respiratory, Inflammation and Autoimmunity. AstraZeneca operates in more than 100 countries and its innovative medicines are used by millions of patients worldwide. In Canada, we employ more than 800 employees across the country and our headquarters is located in Mississauga, Ontario.

In the highly competitive, globalized world of innovative biopharmaceutical development, there are key factors that encourage – or discourage – new investments and the latest innovations coming to a particular market, including a stable and predictable market access environment characterized by rapid public access, opportunities to implement patient support programs, and national pricing regimes compatible with company global pricing policies.

The health/bio-sciences sector benefits the Canadian economy by supporting more than 30,000 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. 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.

According to the Canadian Institutes of Health Information (CIHI), patented medicines represented just 6.7% of total healthcare spending in 2016.¹ And innovative medicines when used appropriately also 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.

We believe it is an ideal time to improve Canada's competitiveness in the health/bio-sciences sector as global businesses like ours seek opportunities to partner with government and academic institutions to transform the future of medicine. For example, AstraZeneca and our global biologics research and development arm, MedImmune, are collaborating with partners in Finland, the United Kingdom and the United States as part of an integrated genomics strategy. In doing so, we aim to provide new insights into the biology of diseases, and to allow patients to be matched with treatments more likely to benefit them using the power of next generation sequencing and increasingly sophisticated data analysis utilized in the international genomics community.

Recommendation 1:

¹ Canadian Institutes of Health Information, [National Health Expenditures](#), 1975-2017

The future success of Canada's health/bio-sciences sector depends on the creation of a policy environment that is integrated and supports 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.

Unfortunately, the changes introduced to the Patented Medicine Prices Review Board (PMPRB) by Health Canada introduce substantial uncertainty into the Canadian biopharmaceutical marketplace and would be counter to the Government's goal of increasing Canada's competitiveness. If implemented as written, the proposed sweeping changes will result in fewer new medicines and indications being launched in Canada and delayed launches of new medicines, to the detriment of clinical trial investments and the health of Canadians.

The PMPRB's narrow and outdated R&D definition is also significantly out-of-step with our G7 partners and other Organization for Economic Cooperation & Development (OECD) modernized economies. In order to more successfully attract biopharmaceutical foreign direct investment, we ask all related federal departments to measure biopharmaceutical R&D in a way that is more consistent with the OECD definition of R&D, which is already utilized by Statistics Canada.

AstraZeneca is among Canada's leading R&D contributors across all industries, investing more than \$90 million in 2017, including partnerships with Canadian universities, hospitals, centres of excellence, early stage biopharmaceutical companies and health charities. This R&D represents 13.9% of our revenues, but the PMPRB still only captures the type of R&D that was dominant when it was established 30 years ago.

To ensure Canada's competitiveness in the biopharmaceutical sector, the Government of Canada should postpone implementation of the proposed amendments to the Patented Medicines Regulations until a full economic analysis, modelled in the context of the Canadian health system and innovative life sciences ecosystem, is undertaken and considered.

Recommendation 2:

The Advisory Council on the Implementation of National Pharmacare as announced in Budget 2018 has begun its consultations with Canadians. AstraZeneca Canada supports the implementation of drug coverage for Canadians who currently do not have access to the medicines they need; we must work together to ensure that any national pharmacare model does not unintentionally result in more restrictive access to medicines or poorer health outcomes for Canadians.

It should be noted that only about 60% of the innovative medicines launched in key global markets around the world are available in Canada today. In order to increase our ability to compete for global

research investments, we must ensure that regulatory and/or policy proposals do not create unpredictability, further delays, or significant pricing pressures that would act as barriers to bringing new products to Canada.

The potential magnitude of a national pharmacare initiative necessitates the meaningful involvement of all affected public and private stakeholders, including patient groups, to ensure that any changes are evidence-based, encourage innovation, and improve patient access to new medicines. We believe that any national pharmacare initiative should therefore be designed collectively to improve health care for Canadians, while also ensuring that Canada remains competitive in attracting the R&D investments for future treatments that are newly emerging or are still to be discovered.

Representatives of Canada's biopharmaceutical companies should be formally invited to join the Advisory Council on the Implementation of National Pharmacare to ensure that future drug coverage for Canadians is value-based and supports optimal health outcomes by providing the right medicines to the right patients at the right time.

Recommendation 3:

AstraZeneca Canada is one of the largest global biopharmaceutical companies operating in Canada, and is proud to have been recently designated a Clinical Trial Delivery Hub within our global organization, doubling in size since 2013. The Canadian Hub, one of only three such AstraZeneca hubs globally, has grown to more than 140 Canadian employees who are leading roughly 37 global clinical trials in oncology, immuno-oncology and respiratory disease areas.

Currently, Canada has been able to attract between four and six percent of AstraZeneca's global clinical trials; however, Canada only accounts for two percent of AstraZeneca's global sales. In order to offset the small market size as compared to other G7 and OECD countries, Canada must be competitive in attempting to attract R&D investments and innovative products to the Canadian market, as well as ensuring it is a Tier 1 or early-to-market country for the launch of new medicines.

Within this context, we are concerned about many elements of Health Canada's Cost Recovery Renewal Initiative for drugs and medical devices, especially when they are coupled with the proposed amendments to the Patented Medicines Regulations.

As we have shared with Health Canada, we consider these increased fees to be excessively high; moreover, the proposed simultaneous implementation of these changes less than a year from now increases the negative impact to the biopharmaceutical industry exponentially, jeopardizing Canada's competitiveness both in its regulatory submission timelines and in its ability to attract clinical trial investments.

In addition, these increased fees have been proposed prior to Health Canada's implementation of the Regulatory Reform of Drugs and Devices (R2D2) initiative, whose objective is, "to establish an agile regulatory system that supports better access to therapeutic products based on healthcare system needs."

The Government of Canada should delay Health Canada's planned cost recovery for drug submissions until such time that the transformational changes resulting from the R2D2 initiative can be accounted for in the new fee proposal.

Conclusion

AstraZeneca is driven by a belief that scientific innovation is critical to addressing the unmet medical needs of Canadians. We believe the best way to transform the lives of patients is to focus on breakthrough science to discover these mechanisms and develop novel, targeted therapies that interact with them; indeed approximately 90% of our innovative medicines in development utilize are personalized medicines. Our industry-leading innovation is raising the bar on what science can do and making the impossible possible.

We are committed to working with the Government of Canada and other stakeholders to establish a globally competitive 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 would therefore encourage Parliamentarians to engage with the health/bio-sciences industry to ensure Canada remains competitive and considered a Tier 1 country for new investments, clinical trials and delivering innovative medicines for patients by our global pharmaceutical executives for the benefit of all Canadians.