

Executive Summary

Merck Canada (“Merck”) is pleased to contribute to the pre-budget consultation process of the House of Commons Standing Committee on Finance for the 2017 Federal Budget.

Merck is committed to addressing the significant unmet medical needs of Canadians. In Canada, Merck markets more than 250 vaccines and pharmaceutical and animal health products and is a leader in a broad range of therapeutic areas, including cardiology, infectious diseases, respiratory conditions, oncology, diabetes, virology and women’s health.

Merck employs approximately 975 Canadians across the country and our spending on R&D in Canada totaled **\$39.2 million** in 2014. We have maintained a leading position among major investors in R&D in Canada for 20 years and will continue honouring this commitment in the future.

Through this year’s pre-budget consultations, the government is seeking input on what federal actions would assist Canadian businesses to meet their expansion, innovation and prosperity goals, thereby contributing to the economic growth of our country. Merck is uniquely positioned to provide input in this area as we are a leader in Canadian R&D, in part by shifting our research focus from vertically integrated in-house research towards partnerships and risk-sharing agreements with universities, hospitals and Canadian biotechnology companies.

However, in order to achieve successful innovation in the healthcare field that will benefit Canadians, a robust and expanding life sciences ecosystem depends on a competitive Canadian regulatory environment. This includes supportive government policies on intellectual property protection and addressing impediments to access to medicines and vaccines for patients.

Importance of the Innovative Life Sciences Ecosystem to Canada

Keeping the Canadian workforce and population healthy is vital to our economy. Workforce productivity is a key competitive driver and fundamental to Canada’s economic performance. Avoidable illnesses and conditions compromise the ability of the system to deliver world-class healthcare in a sustainable manner over the long term. Innovative medicines are allowing for better management and prevention of chronic disease. In addition, the innovative life sciences industry plays a significant economic component in Canada by supporting 34,000 high quality jobs and invests over one billion dollars in research and development each year. This contributes over three billion dollars to the Canadian economy.

At Merck we are committed to building upon our history of advancing scientific knowledge that will lead to major improvements in health. For instance, we discovered the first vaccines for measles, mumps and HPV and developed ground-breaking medicines for heart disease, osteoporosis, diabetes, tuberculosis, HIV and melanoma.

Today, we are developing and bringing forward solutions to address some of the most urgent health challenges, including 30 different cancers, hepatitis C, Alzheimer’s disease, Ebola, antibiotic-resistant superbugs and cardio-metabolic disease.

Merck’s Commitment to Innovation

The constant in our work at Merck is our focus on the patient and improving their lives through better health. Merck is always cognizant of the need to optimize the use of novel therapies and

vaccines in an effort to find solutions that respond to real unmet medical needs. As a prime component of our commitment to building a better healthcare system, we have augmented our R&D vision to meet this goal.

In addition to the original research that is conducted at Merck, our company knows that the next great discovery in medicine may come from outside Merck laboratories. This is why we invest significant efforts in establishing strategic partnerships, which can help turn breakthrough science into novel medicines that improve patients' lives. Therefore, we have shifted our approach from conducting in-house vertically integrated research to forming partnerships with Canadian universities, hospitals, and biotech businesses. Our new model's objective is to make sure R&D spending yields innovations that improve the health of patients. That innovation also has a significant economic component – especially as we look to invest and partner with other organizations to develop and commercialize new therapies.

Our R&D collaborations in Canada are far-reaching and include venture capital investments, university research centres, clinical trials, and multi-national enterprises. We have formed partnerships throughout Canada and have been able to invest in every region of the country including the Alberta Diabetes Initiative and funding commitments in British Columbia for cardiovascular, dementia, and oncology research.

From 2010-2015 Merck spent \$100 million on R&D in Quebec through funds such as the Merck Lumira Biosciences Fund, AmorChem Venture Fund, Québec Consortium for Drug Discovery (CQDM), Québec – Clinical Research Organization in Cancer (Q-CROC), Fonds de recherche du Québec – Santé (FRQS), and Montréal University and hospital-affiliated research centres.

In 2015 in Ontario, a \$7.5 million grant to the Structural Genomics Consortium in Toronto was provided to contribute to the development of a basic understanding of the genomic underpinning of cancer as well as innovative medication discovery targets, in an 'open-source' format.

In 2013, in collaboration with MaRS Innovation and the Centre for Drug Research and Development (CDRD), Merck invested \$4 million in the Institute for Research in Immunology and Cancer – Commercialization of Research (IRICoR) for corridor projects. These projects are being developed in collaboration with two other Canadian Centres of Excellence for Commercialization and Research (CECRs) based in Ontario and in British Columbia. IRICoR works to identify, develop and commercialize technologies in healthcare.

These are just a few examples of Merck's major commitment to growing the critical mass of financing in our sector. We are often able to assist the most vulnerable firms struggling to translate promising research into commercial application. Merck is also able to provide the benefits of our experience and guidance to investment recipients as a result.

What Federal Actions Would Support Innovation in the Life Science Sector?

While Merck is eager to highlight our successful partnership model and showcase our breakthroughs in the innovation field, this area is not without its challenges. Canada is competing with other nations for investments. In our industry, where product development is increasingly complex and difficult, we look for a business environment that appropriately rewards innovation.

The importance of available return on capital should not be underestimated, and there are a growing number of competing jurisdictions available beyond Canada. The federal government

can help strengthen Canada's position globally which will bring economic benefit and support health sustainability.

Financing and Business Expertise

The “commercialization gap” in Canada has been identified as a persistent challenge – including in the life sciences sector. Canada's health system and research institutions are world-class, but we lack the critical mass of financing and business expertise to bring many of these ideas to market domestically, especially at the early stages of development.

A federal policy framework to address this gap should include a willingness and ability to act as a commercial partner and/or leverage other public and private sources of funds (e.g. universities, foundations, research institutions, pension funds, and multi-national investors.)

Business Climate & Regulatory Issues

Intellectual property and regulatory considerations are also necessary ingredients to capitalize on the promising life sciences work already underway within Canada. A healthy and growing life sciences ecosystem depends on a competitive Canadian regulatory environment, including a competitive, stable, and predictable intellectual property protections to attract capital.

The Canada and European Union (EU) Comprehensive Economic and Trade Agreement (CETA) represents a significant step in bringing Canada's intellectual property standards in line with those of the EU and will allow us to be better equipped to compete for global investments in the life sciences sector, as well as the whole innovation economy. We ask the government for quick passage and rapid implementation of CETA.

The previous Federal Government committed to address so-called “dual litigation” in the context of CETA implementation, even though this notion was not part of the formal negotiations. As this issue was not included in the agreement, this issue should not be examined as part of CETA implementation. Time and resources allocated to a non-CETA item has the potential to undermine the achievements within CETA and detract from Canada's position as an increasingly competitive destination for life sciences investments.

As a business competitiveness issue, Merck strongly encourages the government to consider the concept of rolling regulatory submissions at Health Canada. Moving to this model would allow regulators to have the benefit of the latest scientific data to help them make appropriate decisions on behalf of Canadians and facilitate timely access to beneficial therapies. This advance would also send a strong and positive signal that Canada is receptive and responsive to innovation.

Going hand in hand with timely access to medicines is the issue of coverage and affordability. The federal Patented Medicine Prices Review Board (PMPRB), sets and maintains a price ceiling for each patented medicine sold in Canada, based on an independent assessment of the treatment's therapeutic value versus alternatives, and by referencing prices of Canadian patented medicines to prices for the same medications in other countries.

The PMPRB is one of several tools and processes in place in Canada to ensure that innovative medicines are priced at levels that are not excessive for payers and individual consumers, and that Canadians are getting good value from these medicines. The PMPRB has had a successful

record on their defined mandate of ensuring non-excessive pricing of patented medicines. **However, any proposed change to the PMPRB mandate to address affordability or coverage, a responsibility that lies with public and private payers, would be misplaced and unlikely to meaningfully address issues of access to medicines for Canadians.**

Another area in which innovation can bring sustainability to the health care system is regarding biosimilars (also known as subsequent entry biologics.) Biosimilars are similar versions of approved originator biological products. They are a cost-effective treatment option that can help improve patient access to lifesaving medicines.

In order to receive regulatory authorization for sale in Canada, biosimilars must demonstrate that there are no clinically meaningful differences when compared with originator biologics in terms of safety, purity and potency.

For Canadians to have access to these lifesaving medicines, a competitive regulatory approval system, one that reflects patients' safety and health outcomes, must first exist. **Merck encourages the Canadian Agency for Drugs and Technologies in Health (CADTH) to conduct a priority or expedited review of a biosimilar when this is supported by strong scientific/clinical evidence and a high economic benefit.**

Vaccines are basic preventive interventions that have proven to be effective tools to prevent disease, alleviate suffering, and reduce healthcare costs. They also offer economic benefits through reduced hospitalization and decreased demand for other expensive treatments including visits to emergency rooms and physicians. Federal leadership in facilitating access to cost-effective immunizations would ensure that Canadians live longer, healthier and more productive lives.

Therefore, Merck recommends that the Federal Government work with the provinces toward establishing a permanent funding mechanism to ensure adoption of new, recommended vaccines in public health programs within six months of their approval by Health Canada.

Conclusion

Canadians are living longer, healthier, more productive lives today thanks, in part, to better healthcare and access to innovative medicines and vaccines. Medicines and vaccines can also benefit the overall health care system and society by reducing hospitalizations and other costly complications of disease.

Merck is a key contributor and partner to innovation and health in Canada in addressing the significant unmet medical needs of Canadians. We are evolving our research model and our strategic investments and partnerships support this commitment on an ongoing basis.

The key investments Merck has made across Canada, as part of our focus on innovation, have a significant health and economic component for our country. However, a robust and expanding life sciences ecosystem benefitting both patients and the economy, depends on a competitive Canadian regulatory environment. Merck is committed to working collaboratively with the federal government to discover, develop, and implement health solutions that improve patient outcomes in a manner that is consistent with health system sustainability.

Merck appreciates the opportunity to share our unique perspective on innovation and partnerships especially as it relates to what federal actions would assist Canadian businesses to meet their expansion, innovation and prosperity goals. We ask that we be considered to appear as a witness at the pre-budget hearings of the Standing Committee on Finance to discuss our recommendations and respond to any questions the Committee may have.