



**WRITTEN SUBMISSION FOR THE PRE-BUDGET
CONSULTATIONS IN ADVANCE OF THE 2019 BUDGET**

Innovative Medicines Canada



RECOMMENDATIONS

- **Recommendation 1:**
Support an innovation ecosystem by recognizing the value of innovative medicines and ensuring the sector's international competitiveness (safeguarding Canada's pharmaceutical Tier 1 status globally).
- **Recommendation 2:**
Work with the innovative pharmaceutical industry to ensure that patients receive the best standard of care and have access to necessary medicines and treatments through a productive and viable national pharmacare program.
- **Recommendation 3:**
Recognize changes in investment patterns in the life sciences industry and adapt investment policy to reflect these changes.
- **Recommendation 4:**
Promote intellectual property and artificial intelligence as competitive drivers in the life sciences sector.



Innovative Medicines Canada (IMC) is the national voice of Canada’s innovative pharmaceutical industry. We are committed to working with the federal government to ensure Canadian patients have access to the best innovative medicines and vaccines in the world, and to contributing to the long-term sustainability of Canada’s healthcare system.

The Life Sciences Innovation Ecosystem

As an industry, we live to innovate; it’s our driving force. Today’s pharmaceutical discoveries are leading to improved health outcomes through personalized medicine, with diagnoses, practices and treatments increasingly tailored to individual patients. For decades, Canadians have benefited from these discoveries—cutting-edge treatments that can turn chronic, debilitating and sometimes life-threatening illnesses into a thing of the past. In just one generation we have shifted HIV from a death sentence to a manageable chronic illness while research continues towards finding a cure. Our innovations provide Canadians with value — value to patients and their families, value to our healthcare system and value to Canada’s economy.

Discovering new pharmaceutical solutions is a time-consuming, costly and complex process that is constantly changing as new technologies emerge. It involves private sector and university-based researchers, life science companies, significant capital investments, government regulators and patients—all working collaboratively to increase and improve treatment options. Canada’s life sciences sector supports over 34,000 high-quality jobs, many of which are skilled science, technology, engineering and mathematics (STEM) positions. Currently, over 1,400 innovative products are in the development pipeline, thanks to clinical trial capabilities built up over 30 years.

Canada competes on a global stage. We need to work together – government and industry – to ensure Canada stays competitive as a Tier 1 country for new investments, clinical trials and delivering innovative medicines for patients.

In the highly competitive, globalized world of innovative biopharmaceutical development, there are key factors that encourage – or discourage – new investments and the latest product launches coming to a specific market (or country):

- Internationally recognized scientific institutions and high-quality scientific research talent.
- Reliable, cost-competitive and nimble clinical trial infrastructure.
- A system which embraces and recognizes significant research and development investments made by our global companies.
- Strong intellectual property and data protection provisions.
- A clear and efficient regulatory review pathway for marketing authorization.
- A stable and predictable market access environment characterized by rapid public access to new medicines.
- Positive political attitudes towards promoting the future viability of the life sciences sector.



These criteria are critical factors that global pharmaceutical executives consider when making decisions about locating clinical trials, R&D investments and prioritizing new product launches.

Following these priorities with supportive public policies will keep Canada aligned with other Tier 1 markets (i.e. United States, Germany, Japan, United Kingdom, European Union and Switzerland).

How We Innovate

Innovative models in the pharmaceutical sector are changing, and as a result, our industry has adapted and evolved. The old “blockbuster” discovery model is giving way to more personalized medicines that enable a focus on smaller disease populations and more specific conditions. Biologics are increasingly utilized to treat previously untreatable medical conditions and new genetic discoveries are being leveraged to enable the targeting of medicines and treatments on rare and hard-to-treat diseases.

These innovations provide a greater value-add to physicians; they also enable our industry to partner with governments in ensuring the sustainability of the healthcare system. New medicines not only improve patient outcomes through life-saving therapies, they also lead to healthier, happier and longer lives, and increased productivity for the Canadian economy. Moreover, they free up scarce healthcare dollars for reinvestment by reducing the number of formerly necessary surgeries and expensive hospitalizations.

How We Invest

Our industry is moving towards newer types of investment models, such as targeted financing and virtual research and open innovation models. By partnering with academic/clinical research institutes, commercialization centres and virtual research centres, our industry is expanding its capacity to conduct R&D work across Canada.

According to a recent EY Report, IMC member companies generate \$19-billion in economic activity, invest \$1.2-billion annually (9.97 per cent of revenues) into R&D, and support 30,000 high-value jobs in Canada.

For example, in Ontario, the sector supports over 7,000 direct and 12,000 indirect jobs and generates an economic impact of \$1.35-billion. In Quebec, the economic impact of the industry is estimated to \$1.2-billion while supporting more than 10,000 indirect jobs and more than 5,000 direct jobs.

Investing in Canada

The last federal budget echoed the findings of a report, published by the Finance Minister’s Advisory Council on Economic Growth. The Council, headed up by Dominic Barton, recommended Ottawa pursue a deliberate strategy to “unlock the untapped potential” of the health and bioscience sector through “carefully selected policy actions...to remove obstacles and seize opportunities.”

For our industry, this growing network of partnerships and collaboration represents tens of thousands of jobs and significant investments, including \$2.5-billion in hospitals and universities, over the past two decades. Our members play a catalytic role in innovation through partnerships with smaller biotechnology companies and publicly funded institutions.



Our industry has sponsored \$6.7-billion in research funding to academic and clinical research institutes, including the University of Toronto, McGill University and the University of British Columbia. IMC members Roche and Merck have both partnered with the Montreal Heart Institute to fund basic and translational research in cardiometabolic disease. Janssen and Pfizer, two other IMC members, have partnered with the Ontario Institute for Cancer Research (OICR) to fund innovation, technology and translational research. The OICR filed for 31 licences between 2009 and 2013.

In terms of commercialization, across the country, the NEOMED Institute (Montreal), MaRS Innovation (Toronto) and the Centre for Drug Research and Development (Vancouver) benefit from industry partnerships to work on commercializing new, potentially life-saving and life-changing therapies. Industry is also stimulating R&D through venture capital (VC) funds, allowing further access to innovative technologies and developing them while minimizing risk.

Striking the Right Balance

Medical advances have changed the lives of millions of Canadians, but they have also highlighted a public policy dilemma: ensuring equitable, timely and affordable access to medicines. This challenge is amplified by several factors such as the advent of new drugs for rare diseases and increased expectations for access to medicines, along with federal, provincial and territorial governments' desire to make healthcare budgets more sustainable.

The Patented Medicine Prices Review Board (PMPRB) has raised several public policy issues related to pricing and affordability of patented medicines in Canada. Our industry believes that all Canadians should have access to the medicines they require, regardless of their ability to pay. We are committed to working with the government to explore new collaborative models to meet access, affordability and budget sustainability, while finding greater regulatory efficiency that balances pharmaceutical policy with Canada's ability to attract R&D investments.

Similarly, the policy discussions on the proposed national pharmacare strategy have focused on striking a balance between the cost of drugs, ensuring patient access to necessary medicines, and exploring a variety of coverage programs while attracting R&D investments. This discussion contemplates one of the most significant changes to social policy in recent decades, and we have encouraged the government to explore models that involve true collaboration between the public and private sectors to address gaps in the system.

Clinical Trials

Finding the balance between affordability and access will be essential to ensuring that Canada maintains its status as an attractive destination for drug launches and clinical trial investments. Currently there are 4,500 clinical trials involving 24,000 Canadians across the country, developing the latest cutting-edge—and in some cases—lifesaving treatments. The economic and patient impacts are significant.

For example, the Institute of Health Economics (IHE) in Edmonton conducted a study on the economic value of industry sponsored clinical trials in Alberta. IHE identified that industry sponsored trials in Alberta were valued at almost \$100-million annually. This is the value that the government and private funders would have had to pay for the care that was provided through trials. Clinical trials also constitute the bulk of clinical research, and, therefore, it was determined that this amount was far greater than clinical research from all



other sources combined, including Alberta Innovates – Health Solutions (AIHS) (\$14-million) and Canadian Institute of Health Research (CIHR) (\$7-million).

We have had a distinctly Canadian advantage when it comes to clinical trials, and they are a critical step in the drug approval process. However, clinical trials require significant investments on the part of the drug developer over a period of time. It can take up to seven years to develop a drug, following which eight years are usually necessary for trial before it can access market. The importance of maintaining and growing these kinds of investments must be considered when undertaking any regulatory and pricing policy changes.

Intellectual Property (IP) and Artificial Intelligence (AI)

We were pleased to see the federal government take recent steps to unveil its IP strategy, acknowledging its commitment to developing an innovation economy and becoming a leader in the AI field.

Several of our member companies have been investing in AI and machine learning with the goal of making the drug discovery process significantly faster and more cost effective. From an industry perspective, the goal of AI is twofold: to improve care for patients, as well as to control costs and improve healthcare sustainability for the future. This year, following a bilateral agreement between Canada and France, both nations are collaborating in developing AI policy frameworks.

A primary attraction of AI in pharmaceutical research is its ability to quickly review vast amounts of scientific data. The speed of these technologies allows our member companies to develop better diagnostics or biomarkers to identify drug targets and to develop new and innovative medicines. AI in pharmaceutical research is still in its infancy in Canada, and there is ample opportunity for our country to become a leader in this sector globally. Continued protection for intellectual property is critical for increasing investments into the research and development in this sector. Strong IP policies drive job creation, economic growth and innovation and entice health innovators to invest.

We also applaud the support of Parliament and its commitment to the global trade agenda, and we were pleased to see Parliament move the Comprehensive Economic and Trade Agreement (CETA) through to a successful conclusion. International trade plays a critical role in aligning our IP protection regime with our key trading partners is a matter of competitiveness in Canada: the more Canada is aligned with other countries, the more we will compete effectively in the worldwide race for life sciences investments in R&D, clinical trials, biotechnology, genomics applications and the commercialization of innovative medicines.

Conclusion

To compete on a global scale, Canada needs a robust regulatory and IP regime that encourages the Canadian life sciences sector to innovate and grow. We also need to see greater collaboration between businesses and public sector R&D resources to help create a competitive regulatory environment that champions sound scientific data and evidence, all while ensuring that patients have access to innovative medicines.

The innovative pharmaceutical industry is a critical partner in achieving the shared objectives of equitable and affordable access to medicines across Canada. It is important that Canada actively promotes, supports



and invests in innovation to develop and maintain a vibrant R&D base together with a highly competitive workforce.