WRITTEN SUBMISSION FOR THE PRE-BUDGET CONSULTATIONS IN ADVANCE OF THE 2020 BUDGET

Innovative Medicines Canada

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RECOMMENDATIONS

- **Recommendation 1:**
  Support an innovation ecosystem by recognizing the value of innovative medicines and ensuring the sector's international competitiveness.
- **Recommendation 2**:
  Strike a balance between affordability and access to ensure that Canada maintains its status as an attractive destination for new innovative drug launches and research investments.
- **Recommendation 3**:
  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.

Recommendation 1: Support an innovation ecosystem by recognizing the value of innovative medicines and ensuring the sector's international competitiveness.

The Value of Innovative Medicines

IMC is proud to be an integral part of our country's world-class health systems. We work to ensure Canadian patients have the best access to innovative medicines and vaccines. Canada's innovative pharmaceutical companies are a critical part of the life sciences sector and are committed to providing value to patients, to our health systems and to the Canadian economy. Working with patient groups and governments alike, IMC advocates for better access to the ground-breaking new innovative medicines that help Canadians live longer and healthier lives. New therapies help Canadians avoid costly hospital stays, invasive surgical procedures, and what can sometimes be a lifetime of dealing with a chronic illness.

Our industry also plays an important role as a driver of innovation in Canada's life sciences sector. Investments made by our industry not only help scientists discover and develop new treatments and vaccines, they support over 30,000 high-quality jobs and contribute more than $19.2 billion to our economy. Approximately 10 per cent of industry gross patented medicines revenues is invested into R&D. (Source: EY, 2017).

Our investment in R&D ranges from collaborative initiatives with Canadian universities, hospitals, and centres of excellence, to funding for early stage biopharmaceutical companies and health charities. Globally and in Canada, we have also seen a move towards newer types of investment models, such as targeted financing and virtual research, and open innovation models.

How We Innovate

Innovation 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 greater value-add to physicians; they also enable our industry to partner with governments in ensuring the sustainability of the health systems. New medicines not only improve patient outcomes through life-saving therapies, but they also lead to healthier, happier and longer lives, and

increased productivity for the Canadian economy. In addition, they save scarce health care dollars by reducing the number of formerly necessary surgeries and expensive hospitalizations.

As an industry, we are learning to work in different ways to create new models for innovation within the emerging life sciences ecosystem. We also acknowledge that the challenges generated by climate change will have a huge impact on our health. The World Health Organization has stated that "…changes in infectious disease transmission patterns are a likely major consequence of climate change."

Climate change is also causing concern with respect to vector-borne diseases transmitted by ticks, mosquitoes, and other mobile insects which are affected by changing climate patterns. A shift in disease patterns may increase the frequency of some illnesses and how often they spread to new parts of the world. For example, transmission of the denge virus is increasing due to climate change.

It is a new and dynamic set of relationships that harness multiple discovery inputs through a diversity of partnerships—among multinationals and start-up companies, universities and hospitals, the public and private sectors—all focused on the continuum that discovers, nurtures and develops new products.

How We Invest

The global changes in how pharmaceutical companies innovate have caused significant changes in the pharmaceutical investment model over the past 25 years—moving from companies with internal research and development (R&D) infrastructure in multiple countries, to external financing and research partnerships through direct investments, venture capital funds and other mechanisms.

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 in Canada.

Canada's innovative pharmaceutical companies invest more than $1.2 billion every year into research and development to find new ways of treating and curing illnesses and diseases. We have some of the best researchers and scientists in the world, and a vibrant life sciences sector. The country has been the home to critical discoveries in diabetes, heart disease, HIV/AIDS, Alzheimer's, to name a few, and world-class research continues in the application of stem-cell technology, personalized medicine techniques, big data and artificial intelligence.

At present, there are more than 500 new products in development in Canada, including therapies focused on cancer treatments, infectious diseases and vaccines.

While we are working hard to continue medical research and development in our country, the reality is Canada only attracts approximately 1% of pharmaceutical research and development investment in the world. Canada has a significant opportunity to attract additional foreign investment and more clinical trials, however, as the government of Canada has noted, regulations need to be more agile, transparent and responsive.

Recommendation 2: Strike a balance between affordability and access to ensure that Canada maintains its status as an attractive destination for new innovative drug launches and research investments.

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, often expensive, 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.

Discovering new pharmaceutical solutions is a time-consuming, costly and complex process. It involves private sector and university-based researchers, life science companies, significant capital investment, government regulators and patients – all working collaboratively to increase and improve treatment options.

The Patented Medicines 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 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.

As part of that, IMC is committed to working with the federal government in the creation of a national strategy for high-cost drugs for rare diseases. The industry has been exploring a potential policy framework to make these high-cost drugs more affordable and accessible to Canadians suffering from rare diseases.

Clinical Trials: The Canadian Advantage

We have a distinctly Canadian advantage when it comes to clinical trials (CTs), a critical step in the drug approval process. Canada currently has the highest number of active CTs per capita among G7 nations. Our country is a very attractive place to conduct CTs given our world class infrastructure that produces high quality data with a commitment to high ethical standards.

The Institute for Health Economics (IHE) in Alberta completed an important report quantifying the research based pharmaceutical industry's clinical trial contribution to Canada's health systems. It was recently published in the online journal of Pharmaco Economics.

The report demonstrates that the 394 industry-sponsored clinical trials completed in Canada in 2016 offset $2.1 billion in costs to the Canadian healthcare system. There are currently 4,500 CTs underway in Canada. When a pharmaceutical company sponsors a CT, it covers the cost of the drug, as well as:

- Fees for ethics reviews;
- Management costs (such as start-up costs for labs and pharmacies, document archives); and
- Patient care costs (such as screening, procedures, consultations, treatments of adverse events, laboratory tests and imaging procedures).

Recommendation 3: Promote intellectual property and artificial intelligence as competitive drivers in the life sciences sector.

Investing in AI and Ensuring IP Protection

Several of our member companies have been investing in AI and machine learning with the goal of making the drug discovery process significantly more effective, faster and cost effective. From an industry perspective, the goal of AI is twofold: to improve care for patients, as well as to control costs and make healthcare sustainable for the future.

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 Canada to become a leader in this sector globally. Improved protection for intellectual property (IP) however, is critical to increasing investments into the research and development (R&D) in this sector.

Conclusion

To compete on a global scale, Canada must have regulatory frameworks that enable it to attract local and international capital investment and the required talent to compete with similar economies, all while ensuring that patients have access to innovative medicines. It is important that Canada continues to actively promote, support and invest in innovation in order to develop and maintain a vibrant R&D base, together with a highly competitive workforce. The innovative pharmaceutical industry has a considerable role to play in achieving the shared objective of equitable and affordable access to medicines everywhere in Canada and is committed to working with government in achieving this goal.