

INNOVATIVE  
MEDICINES  
CANADA



MÉDICAMENTS  
NOVATEURS  
CANADA

**MAKING CANADA  
AN INTERNATIONAL  
LIFE SCIENCES  
LEADER | MARCH 2021**

## MAKING CANADA AN INTERNATIONAL LIFE SCIENCES LEADER

Canada's innovative biopharmaceutical industry is committed to collaborating with federal and provincial governments to build a thriving life sciences sector, one which will protect Canadian patients' access to the newest, most innovative medicines, that will attract investment to Canada, foster innovation, and contribute to domestic manufacturing capacity. Achieving this goal will require two shared conceptions:

### A COMMITMENT TO WORK TOGETHER

- 1 First, there must be a commitment from all stakeholders to work together. The collaboration that has taken place over the last year during the COVID-19 pandemic – between industry, governments, researchers, and patients – has fueled the discovery, development, approval, and delivery of vaccines and treatments in near record time. That model of collaboration must now become the standard for how we move forward; and

### A COMPREHENSIVE STRATEGY

- 2 Secondly, we must recognize that building a thriving life sciences sector requires a comprehensive strategy. The report from Canada's Health and Biosciences Economic Strategy Table recognized that building a thriving life sciences sector requires us to have an "whole-of-government" approach, an approach that considers not just what bio-manufacturing strategies are needed, but one that considers Canada's policy and regulatory environment in a holistic way.

This document outlines the industry's recommendations for a comprehensive and integrated approach to building a thriving life sciences sector in Canada.

## THE OPPORTUNITY

The COVID-19 pandemic has graphically demonstrated the need for a better life sciences environment in Canada.

The innovative biopharmaceutical industry supports over 100,000 FTEs in Canada, added almost \$15B to GDP, and spends nearly \$2B/year on R&D (StatsCan, 2018), and can make important contributions to Canada's health and life sciences environment:

- Access to capital;
- Expertise in R&D, commercialization and manufacturing;
- Partnerships with universities, colleges, life sciences clusters, VCs, CDMOs and start ups;
- Assistance with post-pandemic health system challenges including future pandemics; and
- Long term vision and perspective.

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*While the industry is only one component of the life sciences sector, the experience of other leading life sciences jurisdictions demonstrates the contributions it can make to national health and wealth.*

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## CANADIAN STRENGTHS

Canada has important life sciences strengths and assets that can be better leveraged, including:

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*Canada's strengths are recognized internationally, and a collaborative effort can fully unleash its life sciences potential.*

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- Universities and Colleges with recognized medical, and biomedical and software and computer engineering faculties;
- Clinical trial expertise and quality;
- Public healthcare system infrastructure;
- Existing industry concentrations in several regions, notably in MTL and the GTA;
- Emerging innovation clusters in regenerative medicine, oncology, infectious diseases, metabolic diseases, neurodegeneration, genomics and personalized medicine; and
- World leader in key sectors such as AI and stem cell therapy/regenerative medicine.



## THE PATH FORWARD - FOUR STEPS TOWARDS INTERNATIONAL LIFE SCIENCES LEADERSHIP

By adopting the following four proposals, Canada would signal that it is determined to be a life sciences leader by creating an environment that leverages our strengths, encourages domestic commercialization and greater manufacturing and participation in global supply chains, and supports health and economic resilience.

1 Establish a new and lasting partnership	2 Support the uptake and adoption of innovation	3 Implement agile, efficient and predictable regulatory systems	4 Enhance Canada's international attractiveness.
<p>Our governments should prioritize regular and strategic interactions with life sciences industries and stakeholders by: Establishing a Life Sciences Champion to coordinate efforts and track progress towards goals, and to Chair a national Life Sciences Council including senior Federal (DMs of Health, ISED, Finance and GAC), senior P/T officials, and key sector associations and CEOs.</p> <ul style="list-style-type: none"> <li>Regular and high level interactions between government and industry is a hallmark of first tier life sciences countries; and</li> <li>Examples include the UK and Denmark.</li> </ul>	<p>Our governments' policies should support the uptake and adoption of life sciences innovation: Regulatory, pricing, HTA and listing/reimbursement agencies should re-focus their mandates and performance metrics to make Canada a leader in the adoption of health technologies. Public health systems should make adopting innovation an objective in pricing negotiations and should act as real-world testbeds and beneficiaries for life sciences innovations.</p> <ul style="list-style-type: none"> <li>Value based procurement agreements should be adopted.</li> <li>A new or existing organization should be established as a health procurement innovation agency.</li> <li>Create Real World Evidence platforms to support timely access to innovation.</li> <li>Establish metrics to assess the timeliness of access and adoption of new technologies.</li> </ul>	<p>Our regulatory frameworks should:</p> <p><b>FIRST STEP:</b> Discontinue unpredictable and harmful regulatory changes (PMPRB)</p> <ul style="list-style-type: none"> <li>Be harmonized with the standards and approval timeframes of leading regulatory agencies (FDA and EMA) including greater use of joint and non-Canadian reviews and decisions. Expand regulatory efficiencies used to evaluate COVID-19 products to other biopharmaceutical approvals (rolling reviews).</li> <li>Regular third-party review of life sciences regulatory processes to ensure they remain relevant and do not impose undue costs or burden.</li> <li>Ensure a competitive fiscal framework within the G7 and provide a predictable tax regime.</li> <li>Address gaps with effective policies to promote innovation (DRD and AMR).</li> <li>Remedy coverage gaps for the uninsured and underinsured (Pharmacare).</li> <li>Ensure that all stakeholders are consulted with respect to new agencies (CDA).</li> </ul>	<p>Our trade policy and international positioning should support life sciences innovation at home and abroad through:</p> <p><b>FIRST STEP:</b> Support IP within international organizations (WTO and WHO).</p> <ul style="list-style-type: none"> <li>Promoting international regulatory harmonization.</li> <li>Countering protectionism and barriers to international supply chains (the Ottawa Group).</li> <li>Highlight and promote domestic strengths (AI and regenerative medicine).</li> <li>Leveraging life sciences exports through our extensive network of trade agreements (CUSMA, CETA, CTPP, and C-UK TCA).</li> </ul>
<p><i>Alignment may not always occur through interaction, but meaningful dialogue and the principle of no surprises should be the objective.</i></p>	<p><i>Supporting and adopting innovative technologies will improve healthcare outcomes for Canadian patients and encourage greater industry investment.</i></p>	<p><i>Efficient and predictable regulatory systems improve patient outcomes by accelerative access to new technologies, and provide the needed stability for industry investment.</i></p>	<p><i>Positive trade policy and international positioning sends a clear message that Canada is intent on international life sciences leadership.</i></p>
<p><b>IMPLEMENTING THESE PROPOSALS WILL TAKE A SUSTAINED AND MULTI-YEAR EFFORT BY INDUSTRY, GOVERNMENTS AND OTHER STAKEHOLDERS, BUT WILL PRODUCE HEALTH AND ECONOMIC BENEFITS TO CANADA FOR DECADES TO COME.</b></p>			

Canada's innovative biopharmaceutical sector recognizes it has the expertise, the experience, and the knowledge to help Canada build a thriving life sciences sector. We are committed to working with governments in Canada, and all stakeholders, to achieve this goal.

In this document we have outlined important pillars of a Canadian life sciences strategy, but we also recognize that other stakeholders will also have recommendations to share. An open and transparent exchange of ideas and perspectives is critical to the success of this shared endeavour.

Innovative Medicines Canada is an important resource for government, and we look forward to re-building, not just the life sciences sector in Canada, but the constructive working relationship between industry and government that is the hallmark of world-leading life sciences sectors around the world.