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Domestic Biomanufacturing Capacity
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The pandemic revealed the many gaps in Canada's biomanufacturing landscape when we witnessed delays in vaccine arrivals and experienced other medical supply challenges. While industry, government, educational institutions and others worked diligently to respond to the emergence of COVID-19, it became clear that Canada should have been better prepared.

We have many of the constituent parts to a strong biomanufacturing sector: first-class academic institutions, a highly skilled labour force, access to a range of foreign markets and other financial incentives. Yet, we lack a coherent strategy to grow our domestic life sciences industry.

Having a life sciences strategy is critical to enabling the growth of our domestic biomanufacturing capacity. This involves a coherent — and publicly promoted — set of federal and provincial policies to support innovation rather than a series of ad hoc measures. A coherent approach to domestic life sciences will also play a vital role in the health outcomes of Canadians and strengthening the economy overall by supporting domestic production and the commercialization of R&D.

The manufacturing of life sciences products is a highly complex and controlled process that requires significant investment. Competition at the global level is substantial for investment capital as companies weigh competing policy frameworks and financial incentives offered by governments. Canada needs to be better positioned in this competition.

The government must take stock of where our capabilities can be most strongly developed since we will not be able to achieve full self-sufficiency. Canada should, in parallel, consider the important role medical technologies, such as PPE and ventilators, played in reducing the impact of the pandemic and take an ecosystems approach to developing a resilient biomanufacturing industry that supports the spectrum of life sciences R&D. Once our country carves out its niche, it should be promoted as an opportunity to attract private sector investment. This is critical to learn from the pandemic and build a resilient healthcare system that can withstand the shock of future crises.

Canada cannot maintain the status quo on its life sciences policies. We need to focus our approach to ensure we have a greater ability to address the needs of future health threats and pandemics. Creating a commercial and policy environment that promotes the life sciences sector and is integrated into global supply chains will drive a robust domestic production capacity.

The following actions will get us there.

RECOMMENDATIONS

Develop life sciences R&D infrastructure
The federal government should accelerate its investments in expanding, financing and producing R&D infrastructure in Canada. Accelerating investments in robust R&D infrastructure is crucial for supporting start-up and scale-up companies that perform early-stage research in new drugs, vaccines and medical technologies. Developing our life sciences R&D infrastructure should include boosting clinical trial capacity, supporting the commercialization of biopharmaceutical technologies through industry-academic research partnerships and enabling agile biomanufacturing infrastructure that can be used for different purposes.

This is particularly important given the unique requirements for life sciences facilities, such as those related to heating, ventilation and air conditioning (HVAC), electrical systems, plumbing, waste disposal, and facility and equipment management.

In addition to supporting the physical infrastructure for start-ups and scale-ups, the federal government should work with the provinces and initiate a review of the actions needed to help more SMEs grow in the life sciences sector, such as mentorship programs.

Create a national electronic health data system
Presently, organizations and provinces have their own systems for electronic medical records, leading to non-interoperability to the detriment of patients. To address this issue there should be a national electronic health record platform that aligns with industry and meets patient needs.

Towards this goal, the federal government should work with the provinces to create a national data system that will allow provinces, hospitals, clinicians, healthcare providers, and researchers to share and assess information quickly for decision-making. This information should include the evaluation of data, understanding patient outcomes, tracking outbreaks and healthcare human resource planning.

Invest in life sciences talent
The government should continue to invest in education to address the current shortage of science, technology, engineering and math (STEM) skills, invest in professional development for teachers working in STEM fields and work with innovators to identify the future needs of the life sciences sector. This will help the life sciences industry access highly skilled and technically trained workers, including masters and PhD students trained in AI, advanced manufacturing and industrial innovation, to meet industry R&D and manufacturing talent needs. At the graduate level, students can be provided with more knowledge in applied industry R&D and the commercialization of research.

Additionally, government should support the development of partnership programs between academic and manufacturing centres that can provide relevant on-the-job

training in R&D and product development, using state-of-the-art bioreactors, separation equipment and analytical instrumentation.

Build agile regulations and systems of patient access
Transforming the regulatory system is key to attracting investment and delivering high-quality vaccines, drugs and treatments to meet the health challenges of tomorrow. In order to develop a streamlined regulatory process, there should be a horizontal review of regulatory approaches to support biomanufacturing in Canada.

Governments should use the lessons learned from the pandemic to create a flexible and accountable process for the regulatory approval of life sciences products. Rolling submissions should become the norm to help expedite the regulatory process during non-pandemic periods.

Beyond regulatory approvals of vaccines, drugs and devices, the other bodies involved in creating the drug listing process and bringing health technologies to Canadians must coordinate to ensure review processes are predictable and streamlined. This means that CADTH/INESSS, the pan-Canadian Pharmaceutical Alliance (pCPA), the new Canadian Drug Agency (CDA) and the provinces need to work together seamlessly and efficiently to improve patient access to medicines. While governments will also need to use their procurement practices to ensure value for money, processes should also work to leverage procurement as a tool to supporting domestic production and R&D.

Improve tax treatment
To support financially viable operations, companies need to ensure tax treatment incentivizes investment through globally competitive cost structures. The government should explore measures that will help life sciences and collaborate with the provinces on improving tax treatment.

This includes investment tax credits, accelerated depreciation, and improvements to R&D tax credits. When reviewing tax policy tools, the government should benchmark Canada's rates against international competitors to ensure Canada's approach is competitive.

Strengthen Canada's trade systems
Regulatory cooperation and border initiatives can be enhanced to ensure ease of movement of inputs and finished products across borders. Given Canada will not be able to produce all of its needs domestically, it is important to ensure integration into global supply chains. This helps to attract investment and enable resilience in times of crisis and shortage given the inherent complexity in supply chains to produce life sciences products.

Canada should take a lead role in the World Trade Organization (WTO) Trade & Health discussions to ensure countries do not resort to export restrictions but instead focus on trade facilitation measures and regulatory processes. The government should also ensure discussions at the WTO remain focused on tools that will lead to a demonstrable

change in vaccine production and distribution rather than sweeping changes to IP rules.

At the bilateral level, the government should ensure non-tariff barriers do not block the integration of Canada into global supply chains. This includes using regulatory cooperation forums, such as the Regulatory Cooperation Council with the United States and Regulatory Cooperation Forum with the European Union, to advance regulatory convergence. Customs officials should also continue to explore how expedited clearance measures can ensure borders remain seamless to enable the movement of life science products.

Uphold strong intellectual property protection
Maintaining domestic intellectual property protections are vital to incentivizing the development of innovative technologies. Canada needs to keep pace with its competitor jurisdictions on intellectual property standards, including robust data protection and comparable patent term restoration.

Regulatory initiatives that affect intellectual property should be robustly evaluated to ensure the considerations of various stakeholders are understood. The federal government should commit to undertaking an impact assessment one year after the planned Patented Medicine Prices Review Board (PMPRB) changes enter into force.

Promote agile manufacturing
Given the complexity of manufacturing life sciences products, it requires inputs from a wide range of sources. However, it would not be viable for certain suppliers to only produce these inputs for life sciences. As a result, it is important for the government to think holistically about the life sciences value chain and help agile manufacturing to support more suppliers in making the inputs needed for various steps of the production process.

Encourage data and digital technology
In a digital economy, companies need to leverage the power of data to accelerate innovation of biomanufacturing products. Health Canada should enable the continuation of electronic file submission for Certificates of Pharmaceutical Products and Good Manufacturing Practices. Additionally, regulatory agencies should ramp up the virtualization of clinical trials through digital health technologies and extend the use of digital technologies for virtual regulatory inspections, such as Good Clinical Practice and pharmacovigilance (corrective actions and recalls) inspections.

To ensure remote communities can participate in biomanufacturing supply chains, the government needs to improve coordination with the provinces and accelerate digital infrastructure across the country. Expanding broadband investment through increasing funding, expediting product selection under the Universal Broadband Fund and bringing forward rural 5G investments will assist remote communities in their efforts to attract business investment.

Facilitate a green and sustainable biomanufacturing sector

The adoption of further biomanufacturing capacity in Canada should not come at the cost of the environment, and it is important for the life sciences industry to play its part in helping Canada achieve its net-zero 2050 goals. Many in the life sciences sector have adopted aggressive net-zero goals, which will support the Government of Canada's net-zero objectives while building its resilience to address future health threats. The government should contribute to assisting the industry in the deployment of sustainable production practices, such as through energy efficiency.