

# Submission for Pre-Budget Consultations in Advance of the 2022 Federal Budget

By: Life Sciences Ontario

## Recommendations:

1. That the federal government implement the Biomanufacturing and Life Sciences Strategy announced July 28 in order to create a globally competitive policy and business environment for life sciences companies.
2. That the federal government ensure that the Patented Medicine Prices Review Board changes do not create barriers for medicines for Canadians (reaffirming recommendation 12 from the Standing Committee on Finance's 2021 pre-budget report), in the context of unrefuted third-party and academic evidence that demonstrates the proposed price controls have already negatively affected patients, Canadian researchers, our healthcare systems and the economy.

As part of its pre-budget consultations in advance of the 2022 Budget, the Standing Committee on Finance (FINA) is interested in ideas about “measures the federal government could take to restart the Canadian economy, as it recovers from the COVID-19 pandemic.”

As one of the most innovative sectors in our economy, the life sciences sector has not only played a pivotal role in our country’s response to the COVID-19 crisis, but also holds the key to our economic recovery and resilience to future health crises. Since the start of the pandemic, organizations across the life sciences ecosystem have acted with unparalleled speed and coordination to develop the tools needed to fight COVID-19—from developing innovative health solutions during a time of unprecedented demand to leading global efforts to develop new vaccines and treatments.

The speed with which vaccines for COVID-19 were developed is a testament to the decades of non-COVID related research and scientific discoveries, including in Canada, that provided insights and new methods that drove the development of effective treatments and saved countless lives during the pandemic. If there is a lesson to be learned from this pandemic, it’s that today’s discoveries cure and prevent tomorrow’s diseases.

And we are just barely scratching the surface of what is an exciting new era of medical innovation. We are on the cusp of new medical breakthroughs and revolutionary new treatments for some of our most serious illnesses such as cancer, cystic fibrosis, and Alzheimer’s disease, among many others. Canada has an important opportunity to be a leader in this new era.

It also important to note that our sector’s contributions are not limited to health. The life sciences truly hold the key to addressing some of society’s most pressing challenges, including climate change and food security.

At a time when the importance of the life science sector is more apparent than ever, we must seize this moment to empower a truly integrated life sciences ecosystem that unlocks the globally competitive potential of our sector in support of our economic recovery and future prosperity.

The good news is that we’re not starting from square one. Canada already has a well-established life sciences sector that serves as an engine for economic growth. For example, Ontario’s life sciences sector alone contributes \$58 billion to Ontario and Canada’s GDP and supports over 190,000 direct and indirect jobs. About 1-in-13 jobs in Ontario are in life sciences or supported by its activity. Job wages in the sector are almost 25% higher than the provincial average.<sup>1</sup>

While life sciences is a crucial pillar of our economy, there is widespread consensus that the sector is not achieving its full potential. We need a more attractive commercial environment for

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<sup>1</sup> Deloitte. Accelerating Prosperity: The Life Sciences Sector in Ontario. February 2019. [https://lifesciencesontario.ca/wp-content/uploads/2019/03/LSO-Economic-Study\\_Final-Report\\_28FEB2019.pdf](https://lifesciencesontario.ca/wp-content/uploads/2019/03/LSO-Economic-Study_Final-Report_28FEB2019.pdf)

companies—one that encourages investment, drives innovation, and ensures that new health technologies are able to reach hospitals, clinics, and patients.

Earlier this year, Life Sciences Ontario helped develop and lead an effort across Canadian health technology developers, business and research leaders to ask the federal government to develop and adopt a coherent life sciences strategy. We asked specifically for more collaboration to solve for the pandemic today and future health challenges, and less uncertain and complex regulations that are blocking our ability to move at the speed of science.<sup>2</sup>

The government responded with important new investments in Budget 2021. Even more important than new financing, the government recently announced its plan to implement a coherent and coordinated Biomanufacturing and Life Sciences Strategy.

The Strategy has the right ingredients for success. There is a commitment to look beyond the short-term to create the right policy and business environment for life sciences companies. Pillar 1 of the strategy calls for coordinated action between all levels of government and policy alignment across multiple ministries, with both the health and innovation ministers signing off on the plan. There are calls for stronger public-private collaboration, talent development, augmenting supply chains, leveraging our strong academic centres and building on Canada’s strengths in artificial intelligence and other enabling sectors. The plan also calls for the continuation of the Health and Biosciences Economic Table which will provide leaders with access to private-sector expertise and oversight on the Strategy’s implementation.

We were also very encouraged by the Strategy’s commitment to “enable innovation by ensuring world class regulation” as a Pillar 5 of the plan. Building on the learnings from Health Canada’s regulatory response to the COVID-19 pandemic, many of the interim orders adopted by the government, such as rolling and harmonized reviews, should now become permanent features of an agile regulatory system.

However, the biggest regulatory obstacle to the life sciences sector remains the government’s reforms to the Patented Medicine Prices Review Board (PMPRB). These regulations have been delayed three times in the context of the pandemic, but are still slated to come into effect on January 1, 2022. They remain a cloud of regulatory uncertainty that is a major brake on the sector’s ability to invest in and launch new vaccines and medicines in Canada. This challenge was recognized by the government during the pandemic when it exempted COVID therapies and vaccines from the reforms. The Federal Court of Appeal also cast a shadow over Health Canada’s regulations by affirming the PMPRB cannot engage in regulating “reasonable” pricing, just “excessive pricing” related to abuse of monopoly power, and that the PMPRB does not have the “consumer protection” mandate it claims to support its expansion.<sup>3</sup>

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<sup>2</sup> The open letter can be found in English at <https://www.lifesciencescan.ca> and in French at <https://www.sciencesdelaviecanada.ca>

<sup>3</sup> *Alexion Pharmaceuticals Inc. v Canada (Attorney General)* [2021] FCA 157.

As well, the PMPRB's recent behaviour is indicative of a major systemic issue in how our sector is regulated in Canada. PMPRB initiatives just this year include engaging in advocacy against stakeholders concerned about the reforms<sup>4</sup> and undertaking an abrupt consultation on new punitive rules that place significant additional burden on companies.<sup>5</sup>

Efforts to implement the Biomanufacturing and Life Sciences Strategy will never be successful if the PMPRB changes are left unaddressed. Without access to new medicines, we can build the infrastructure and the labs, but we won't have anything to put in the vials or capsules. We need to start valuing the new innovations that are brought to or developed in Canada, and this must start with a reconsideration of the PMPRB changes. This will signal to the industry that Canada is willing to forge a new relationship with the sector.

**For these reasons, Life Sciences Ontario strongly recommends that the government use Budget 2022 as an opportunity to grow the life sciences sector by adopting the following two recommendations:**

1. That the federal government implement the *Biomanufacturing and Life Sciences Strategy* announced July 28 in order to create a globally competitive policy and business environment for life sciences companies.
2. That the federal government ensure that the Patented Medicine Prices Review Board changes do not create barriers for medicines for Canadians (reaffirming recommendation 12 from the Standing Committee on Finance's 2021 pre-budget report), in the context of unrefuted third-party and academic evidence that demonstrates the proposed price controls have already negatively affected patients, Canadian researchers, our healthcare systems and the economy.

In sum, the life sciences sector holds significant potential to contribute to Canada's economic recovery, while tackling some of society's biggest challenges. We believe that through bold action, sustained efforts, and a more comprehensive and coordinated life sciences vision and strategy, we can help unlock this potential and drive significant economic growth.

Thank you for the opportunity to provide input.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jason Field', is positioned above the typed name.

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<sup>4</sup> <https://www.dropbox.com/s/eusxuabcq26uqt9/PMPRB%20ATIP%20Disclosure.pdf?dl=0>

<sup>5</sup> <https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-references-comparator-countries.html>

### ***About Life Sciences Ontario***

Life Sciences Ontario (LSO) is a not-for-profit organization that represents and promotes Ontario's vibrant and diverse life sciences sector. Members of LSO include life sciences companies, entrepreneurs, members of academia, and service providers from many different areas of the life sciences ecosystem, including biopharmaceuticals, agriculture, agri-food, the bioeconomy, medical devices, animal health, environmental technologies, and more. Ultimately, our mission is to encourage commercial success throughout this diverse sector by collaborating with governments, academia, industry and other life sciences organizations in Ontario and across Canada.