

SUBMISSION TO HOUSE OF COMMONS STANDING COMMITTEE ON INDUSTRY, SCIENCE & TECHNOLOGY (INDU)

THE CANADIAN RESPONSE TO THE COVID-19 PANDEMIC

SUBMITTED BY INNOVATIVE MEDICINES CANADA

Innovative Medicines Canada is requesting an opportunity to appear before the House of Commons Standing Committee on Industry, Science & Technology (INDU) to provide Committee members with information on the innovative pharmaceutical sector's contribution to the fight against COVID-19, and on the challenges ahead for industry.

ABOUT INNOVATIVE MEDICINES CANADA

Innovative Medicines Canada represents Canada's innovative pharmaceutical industry. We help our members discover, develop, and deliver innovative medicines and vaccines.

Our membership consists of 40 companies, from established organizations to startups, committed to revolutionizing healthcare through the discovery and development of new medicines and vaccines.

Guided by a strict Code of Ethical Practices, we work with governments, insurance companies, healthcare professionals, patient groups researchers, universities, and others to make discoveries that will help enhance the health and well-being of Canadians. We are committed to being valued partners in Canada's healthcare system.

We form effective alliances, support policies that encourage innovation, advocate for improvements to Canada's regulatory environment, widen access to innovative medicines, and ensure the effective protection of intellectual property.

We believe that Canadians should have access to the innovative treatments they need and that our activities are fundamental to safeguarding our healthcare systems for future generations. Our work allows our members to focus on what matters: delivering better healthcare to Canadians.

BRIEF PREPARED BY INNOVATIVE MEDICINES CANADA

On behalf of Pamela Fralick, President
55 Metcalfe Street, Suite 1220
Ottawa, ON K1P 6L5
pfralick@imc-mnc.ca



BACKGROUND

An unprecedented public health crisis demands an unprecedented global response.

That is why, in the short time since COVID-19 emerged, the biopharmaceutical industry is collaborating like never before, with governments, researchers, as well as with the private and philanthropic sectors to discover, develop and deliver medicines to treat those infected by the virus, tests to diagnose, and vaccines to stop its spread. Never before has the industry collaborated to the degree that it has in the face of COVID-19.

That is because no one company, research effort or approach will be enough to defeat COVID-19.

Partnerships are key to speeding up the research and development process. We are focused on:

- Collaborations between governments, academia, the private and philanthropic sectors to discover, develop and deliver new medicines to treat those affected by the virus, tests to diagnose, and vaccines to stop its spread;
- Providing financial support and in-kind donations to organisations on the ground in Canada and around the world;
- Maintaining patient support and compassionate care programs put in place by industry to help keep Canadians out of hospitals and reduce the burden on Canada's health systems, and ensure that patients don't lose drug coverage in the event of COVID-related unemployment;
- Working with government and other stakeholders to help ensure that patients, doctors and hospitals continue to have access to the medicines and therapies they need;
- Exploring other opportunities to support patients and governments in our collective fight against COVID-19.

Specific efforts include:

Nationally, several of our members' therapies are being explored as part of CATCO, the Canadian Arm of the World Health Organization's SOLIDARITY trial, which is supported by the Canadian Institutes of Health Research (CIHR). These trials are happening in hospitals across Canada, coordinated by Toronto's Sunnybrook Hospital.

Our member Hoffman-La **Roche Canada** – that the Committee met with on June 5, 2020 - is also funding research proposals from Canada's scientific community through its COVID-19 Innovation Challenge, a funding program of \$900 000 to bring forward innovative ideas to address the pandemic.

In Quebec, **Medicago** is rapidly moving forward on clinical trials to assess the safety and efficacy of their vaccine candidate and scaling up production.

In Atlantic Canada, **BioVectra** is manufacturing critical raw materials for COVID-19 diagnostic testing kits and collaborating with multiple Canadian biopharmaceutical companies and academia on COVID-19 therapeutic products.



In **British Columbia (BC)**, **AbCellera** is partnering with **Eli Lilly** to co-develop antibody products for the treatment and prevention of COVID-19. This same company just received \$175 million from the federal government to increase manufacturing capabilities.

Also in B.C., our member **Amgen** is building on 20 years of experience in the field of therapeutic antibodies and is actively engaged in anti-COVID-19 therapeutic antibody discovery efforts.

In **Ontario**, **Bayer Canada** is partnering with Hamilton's Population Health Research Institute and Shopify founder Tobi Lutke's Thistledown Foundation to test a promising combination of two drugs — the antibiotic azithromycin taken with malaria medication chloroquine or a similar drug, hydroxychloroquine. Across Canada, 25 sites are expected to take part. Researchers will recruit at least 500 COVID-19 patients in hospital and 1,000 at home.

In the **Prairies**, the anti-malarial drug hydroxychloroquine, which is made by member companies including **Novartis** and **Sanofi**, is being tested in a number of other clinical trials, including by the University of Alberta.

Fifteen of Innovative Medicines Canada's member companies have opened up their libraries of molecular compounds that already have some degree of safety and activity data to share with the global scientific community for coordinated study through the Bill & Melinda Gates Foundations' COVID-19 Therapeutics Accelerator.

Innovative Medicines Canada member **GlaxoSmithKline (GSK)** is collaborating with the Coalition for Epidemic Preparedness Innovations (CEPI) by sharing their pandemic vaccine adjuvant platform technology to enhance the development of an effective vaccine. An adjuvant is an additive used in some vaccines to enhance the body's immune response, thereby creating a stronger and longer lasting immunity against infections than the vaccine alone. The use of an adjuvant is of particular importance in a pandemic situation since it can reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced, and therefore contributing to the protection of more people.

Others such as Janssen and Boehringer Ingelheim have begun landmark partnerships with governments in the US and Germany to discover and develop new treatments and vaccines.

This crisis has, without a doubt, highlighted the importance of a strong life-sciences ecosystem to the health and well-being of Canadians. It has also shown that strong health systems depend on high-quality health researchers, research and manufacturing infrastructure and capacity, and effective collaboration among all parts of the system, including governments, academia, the public and the private sectors. It is only by working together that we will achieve the goal of a vibrant, effective and efficient life-sciences sector.

It is through the combined and coordinated efforts of all these partners that economic recovery will be possible for Canada and the world. Innovative Medicines Canada believes there are great opportunities for accelerating innovation in Canada and moving us from the middle of the pack to the upper tiers of international competitiveness in the life-sciences sector. Government has an important role to play in promoting the growth of this vital sector at home and abroad.



CHALLENGES AHEAD FOR CANADA'S BIOPHARMACEUTICAL INDUSTRY & RECOMMENDATIONS

Innovative Medicines Canada was pleased with the recommendations of the Health Bioscience Economic Strategic Table (HBEST) report; however, the goals and objectives should be revised to acknowledge the need for continued pandemic research and to accommodate other policy decisions that could have detrimental impact on investment targets in the medium term.

Our manufacturing capabilities are holding up well, but we always need to pay close attention to other challenges to supply chains. It is important for Canada to protect our international supply chain and to maintain open borders. We applaud the federal government's public statements on the importance of preserving the integrity of international supply chains and the avoidance of tariffs and other barriers on essential goods, especially medical supplies, during the pandemic.

Once the pandemic is less acute, we hope that we can continue to work together to create a regulatory environment that will foster economic growth for Canadian life-sciences companies and encourage foreign direct investment in this country.

There are a few key areas that will also need to be addressed not just to achieve the objective of building a vibrant life-sciences sector that contributes to Canada's economic growth, but also to build resilience in the sector.

Smart regulations support smart investing

One area of great concern not only for our members, but for the millions of patients that are being impacted, are the changes to *Patented Medicines Regulations*. These changes will limit access to new medicines and will discourage investment in the life-sciences sector.

While we are pleased that the July 01, 2020 deadline for the implementation of amendments to the Patented Medicines Regulations has been adjusted to January 01, 2021, it remains our position that implementing these amendments will discourage future investments in research, infrastructure, and delay the launch of new therapies in our country. This is particularly concerning patients who are worried about their ability to access new treatments and therapies.

A third-party review of the initial Guidelines released by the PMPRB estimates that our industry's economic footprint will be reduced by more than \$41 Billion (Net Present Value) over the next 10 years due to Health Canada's new regulations on Canada's drug pricing system (in contrast to Health Canada's assessment of \$8.4B). This impact is dramatic and will impact our industry's capacity, and incentive, to invest in R & D and clinical trials in Canada.

R&D Capture

Our members have met their commitment to Canadians. Over the past 24 years, we have invested an average 10% of annual sales per year in research and innovation, one of the best industry records in Canada.



That said, as recent PMPRB reports show, the level of investment in the earlier primary pharmaceutical R&D tool in Canada (SR&ED) is decreasing. Why? The model for life-sciences research and innovation in the twenty-first century has changed. We are investing in new, more collaborative initiatives with Canadian universities, hospitals, centres of excellence, early-stage biopharmaceutical companies, and health charities. Yet, these often multi-million-dollar investments do not qualify under the 28-year-old criteria used by the PMPRB and that serves to distort the sizeable investments the sector is making in Canada.

For example, funds used to support a researcher working within a pharmaceutical company's laboratory, conducting discovery research, would be counted as an R&D expenditure. On the other hand, clinical trial research, carried out by a contract research organization but funded by the same pharmaceutical company, would not be counted as an R&D expenditure. Both types of R&D are company-funded and create jobs in Canada, yet only one is counted as R&D. This disparity hurts Canada's ability to attract global investment, which undermines our competitiveness as a country. The government's acknowledgement of industry investment would help inspire confidence in global investors.

We encourage ISED and INDU to consider an updated and modernized definition of R&D.

IN CLOSING

Despite these challenges, the CEOs of our member companies are strong global advocates for increased R&D in Canada. We have the same goals as the federal government and the INDU Committee in seeking more foreign investment in Canada, but it is critical we can demonstrate to our global research offices that this country offers a competitive environment in which to invest, particularly as we move toward recovery. As the Canadian representatives of a global industry, we have a huge stake in Canada presenting a highly competitive face to the world, and in gaining a larger share of these investments.