Mr. Joël Lightbound, M.P. Chair Standing Committee on Industry and Technology House of Commons Ottawa, Ontario K1A 0A6

Dear Colleague:

Pursuant to House of Commons Standing Order 109, I am pleased to submit on behalf of the Government of Canada (the Government) the response to the fourteenth report by the Standing Committee on Industry and Technology (the Committee) titled *Domestic Manufacturing Capacity for a COVID-19 Vaccine – Prevention is Better Than Cure* (the Report), which was presented to the House of Commons on June 14, 2023.

The Government extends its gratitude to the members of the Committee for their work in developing the Report and preparing the recommendations, and to the witnesses who appeared before the Committee to provide evidence and share their advice. The Government supports the efforts of the Committee to examine the emergency situation involving the domestic manufacturing capacity for a COVID-19 vaccine.

COVID-19 has caused vast human and economic damage across Canada and the world. As of early August 2023, the World Health Organization (WHO) reported nearly 7 million COVID-19 deaths globally, which may be a significant underestimate. Over 4.7 million cases of COVID-19 have been reported in Canada with 53,246 deaths attributed to the disease (as of August 15, 2022), and the potential long-term health effects remain under investigation.

The COVID-19 pandemic has demonstrated the importance to national, health, social and economic security of growing and sustaining an innovative domestic life sciences and biomanufacturing sector. At the outset of the pandemic, Canada had few available facilities to produce vaccines and therapies and none that was equipped to work with emerging technologies at scales that would rapidly meet the needs of the population. In part, this was due to years of divestment by pharmaceutical companies and their consolidation of production in other countries



Despite this, Canada's advance purchase agreements (APAs) with vaccine companies, based on the advice of the COVID-19 Vaccine Task Force (VTF), resulted in the largest vaccination campaign in Canadian history with 98.4 million COVID-19 vaccines administered (as of August 4, 2023). Despite the initial lag in vaccine deliveries, by July 26, 2021, a sufficient supply of COVID-19 vaccines was available to achieve 100% coverage for first and second doses for those 12 years of age and older.

At the same time, the Government moved quickly to invest in, and commit significant longer-term funding towards, the revitalization of Canada's biomanufacturing sector, in particular through Canada's Biomanufacturing and Life Sciences Strategy (BLSS). Since 2020, the Government has invested over \$2.1 billion in 36 projects to support biomanufacturing facilities, vaccine development, and therapeutic development. Canada's Strategic Innovation Fund (SIF) has been the chief funding instrument, though federal funding for some of these projects has also been provided through the National Research Council (NRC) and its Industrial Research Assistance Program (IRAP), regional development agencies, and the Next Generation Manufacturing Canada Supercluster, among others. Investments in biomanufacturing facilities have covered a wide range of manufacturing technology platforms (e.g., mRNA, cell culture, viral vaccines, fill and finish), which will provide flexible, diverse, end-toend response capabilities that could be leveraged in a future health emergency or pandemic. Some of the prominent projects include funding AbCellera's COVID-19 antibody therapy and manufacturing facility, Sanofi Pasteur's end-to-end influenza vaccine manufacturing facility at its campus in Toronto, and the Biologics Manufacturing Centre located at the NRC Royalmount campus in Montréal. The Government has also reached a definitive agreement with Moderna to build an mRNA manufacturing facility in Laval that will be a strategic asset for future pandemic response. While the Government contributes to rebuilding the sector, there are also signs of growing momentum for the Canadian life sciences through other non-government investments and initiatives such as AstraZeneca's major expansion of its Global Research and Development Hub in Mississauga.

Through Budget 2021, \$2.2 billion was devoted to programs that became the foundational support of the BLSS, which was launched in June 2021 with an aim to providing integrated supports spanning the biopharmaceutical value chain from research to clinical trials to production capacity. This included the following:

- Strategic Innovation Fund (SIF), \$1 billion over seven years targeted toward promising domestic life sciences and bio-manufacturing firms;
- Canada Foundation for Innovation (CFI), \$500 million over four years, to support the bioscience capital and infrastructure needs of post-secondary institutions and research hospitals. This was the basis for the Biosciences Research Infrastructure Fund (BRIF);

- Canada Biomedical Research Fund (CBRF), \$250 million over four years, to support a new fund;
- Canadian Institutes of Health Research (CIHR) Clinical Trial Fund (CTF),
 \$250 million over three years to increase clinical research capacity;
- adMare, \$92 million over four years to support company creation, scale up, and training activities in the life sciences sector; and
- Stem Cell Network, \$45 million over three years to support stem cell and regenerative medicine research.

The BLSS has two overarching objectives: ensuring preparedness for pandemics and other health threats; and supporting the growth of a competitive domestic life sciences sector. In particular, the BLSS focuses on providing end-to-end support to the sector by taking a comprehensive approach to rebuilding and growing the sector under five pillars: (1) a strong and coordinated governance and effective collaboration with stakeholders in government agencies, industry and academia; (2) strengthening research systems and talent pipelines through investments in post-secondary institutions and research hospitals; (3) building domestic capabilities in biomanufacturing and life sciences through investments in existing and emerging areas of Canadian strength; (4) building public capacity, including at the Biologics Manufacturing Centre at the NRC; and (5) continuing work to modernize regulations and ensure Canada has a best-in-class clinical trials ecosystem. Further details on how funding has been distributed can be found in the responses to the Committee's recommendations that follow.

Importantly, the BLSS's foundational elements include prioritizing investments in life sciences innovation (including innovative medicines), supporting research and researchers in Canada, and job creation through education and training, which align well with the Committee's recommendation for a holistic approach to growing the life sciences ecosystem.

Extensive consultations in early 2021 informed the creation of the BLSS. These were collaboratively held by ISED, Health Canada, and the Public Health Agency of Canada (PHAC), culminating in the publication of the report titled *What We Heard: Considering the Creation of New Biomanufacturing Capacity for Canada*. Consultation participants provided valuable insights, which included an emphasis on sustainability in biomanufacturing investments, public-private partnerships, sustained government funding and coordination, and ongoing support for research. Participants also noted that stronger linkages between academia and industry were needed to support the sector. Other common suggestions included investing in translational research and seeking ways to build up the number of highly qualified personnel to work in the sector.

Noting that Annex A of the Committee's Report lists many of the Government's BLSS investments up to the time of its last hearing in April 2022, subsequent BLSS investments and policy priorities have significantly advanced the Government's work since then. These include the first \$131 million awarded to one consortium, seven training platforms, and 22 clinical trial projects under the CIHR CTF, \$127 million towards eight high-containment laboratory upgrades under the BRIF, and the first five pan-Canadian research hubs funded jointly by BRIF and CBRF. Additionally, further SIF and regional development agency contributions towards biomanufacturing capacity are ongoing.

Furthermore, recognizing the need to maintain momentum, the Government committed in Budget 2023 to explore new ways to be more efficient and effective in the development and production of the vaccines, therapies, and diagnostic tools that would be required for future health emergencies. As a first step, the Government is consulting experts on how to best organize our readiness efforts for years to come. The Government remains committed to growing the sector in order to ensure investments that were made and continue to be made are sustainable, resilient, and relevant to future health emergencies.

With this context in mind, please find below the Government's response to the Committee's recommendations. The response is a collaborative effort of all implicated departments including ISED, Health Canada, PHAC, the NRC, and Public Services and Procurement Canada (PSPC).

RECOMMENDATION 1: That the Government of Canada review the COVID-19 Task Force's work and publish its recommendations for improving advisory groups' transparency within one year.

The Government appreciates the Committee's recommendation and acknowledges that some of the testimony before the Committee was critical of the VTF's work and the management of conflicts of interest. The Government also appreciates that the Committee heard testimony directly from certain VTF members, who had the opportunity to explain their invaluable work and the robust conflict of interest guidelines that were put in place for that work and their resulting advice.

To start, the Government commends the VTF's invaluable contributions during the COVID-19 pandemic; these leading experts volunteered their time and expertise during an unprecedented emergency to help the Government protect Canadians. Their advice helped the Government to swiftly and effectively execute APAs with vaccine manufacturers that led to an unparalleled and successful vaccination campaign. Canada was one of the first countries to receive and administer vaccine doses for its population, including securing mRNA dosages from leading COVID-19 manufacturers, Pfizer and Moderna, at a time of great uncertainty and volatility. For these reasons, the VTF's work should be considered an immense success.

In order to receive the best advice, the Government needed experts with deep experience and knowledge in the relevant fields, which in the circumstances meant industry expertise and experience were critical. Given that this pool in Canada was small, naturally, some VTF members had connections to companies in their fields of expertise. To manage and mitigate the risks for potential conflicts of interest that could result, the Government implemented a robust conflict of interest protocol, informed by leading practices, which proactively managed both real and perceived conflicts. Every VTF member signed a Conflict of Interest and Confidentiality Agreement and disclosed activities and interests that could place them in a conflict of interest. They also committed to ensuring the integrity of the process and were expected to recuse themselves from providing advice on projects where there was a conflict.

To ensure utmost transparency, a registry of interests was also made available online and updated following all announcements by the Government that relied on the VTF's recommendations. The VTF members also signed Non-Disclosure Agreements (NDA) with several companies which were required prior to entering into strictly confidential discussions for the purpose of advancing the Government of Canada's response to the COVID-19 global health emergency. Information obtained while serving on the VTF was to be used only in the context of fulfilling the duties and mandate of the VTF. Because the VTF reviewed commercially confidential and sensitive information, discussions occurred in confidence and the recommendations by the VTF were not to be shared publicly. These processes were consistent with standard practices for individuals who are not public office holders and embody international best practices, including for similar task forces around the world.

In March 2023, recognizing the importance of evidence-based decisions, the Honourable François-Philippe Champagne, Minister of Innovation, Science and Industry, and the Honourable Jean-Yves Duclos, Minister of Health at the time, announced the creation of the Council of Expert Advisors (CEA), which is the longer-term expert advisory body for the BLSS, which continues and builds upon some of the VTF's invaluable work. In particular, the CEA provides expert advice on the implementation of the BLSS, helping to ensure that the Government's decisions and investments achieve maximum impact in the rebuilding of a strong and resilient Canadian biomanufacturing and life sciences sector.

In establishing the CEA, the Government has taken steps to ensure robust transparency, in line with best practices from comparable jurisdictions and international peers. Similar to the VTF, the CEA's membership and mandate have been made public.² There are also measures in place to allow online publication of CEA meeting summaries, as appropriate. The Government has

¹ https://ised-isde.canada.ca/site/biomanufacturing/en/covid-19-vaccine-task-force/covid-19-vaccine-task-force-registry-interests

² https://ised-isde.canada.ca/site/biomanufacturing/en/council-expert-advisors).

also implemented a strong Conflict of Interest protocol. The CEA Secretariat tracks and records real and perceived conflicts, ensuring appropriate actions are taken in the particular circumstances, which include recusals from discussions and provision of advice when there is a real or perceived conflict of interest. Information on these is to be published on the CEA website following announcements by the Government that relied upon the CEA's advice.

The Government is committed to continuing to apply rigorous conflict of interest and transparency policies to the advisory groups it constitutes to assist in its important work on behalf of Canadians.

RECOMMENDATION 2: That the Government of Canada assess the current state of development of the country's biomanufacturing capacity to determine whether it meets its needs for a future health crisis and publicly disclose the status of this work within one year.

RECOMMENDATION 3: That the Government of Canada create a five-year domestic biomanufacturing capacity review process. This process could include consideration of pharmaceutical companies operating in Canada, the scope of their work and the vaccine manufacturing capacity of production facilities.

The Government's actions to date align with the Recommendations 2 and 3. Assessment of Canada's biomanufacturing capacity to ensure preparedness is part of the BLSS and it is an ongoing exercise as new investments are made and previous investments come online. However, Canada is still in the process of rebuilding the sector. As the Committee heard, establishing resilient capacity can take "years or even decades." Building and commissioning a single biomanufacturing facility can take in the range of three to six years. Therefore, assessing whether sectoral capacity can respond to ever-evolving health threats would not yield satisfactory results within one year. Rather, it requires a continual process of evaluation.

That said, as a matter of course, ISED tracks the industry and maintains up-to-date, publicly available information on the biomanufacturing and life sciences sector that can be found on its website.³ For example, profiles on the Canadian pharmaceutical industry and medical devices, as well as key information on Canadian life science, clinical research, and manufacturing capabilities are available. ISED also reports on progress for the BLSS via the Departmental Results Report available online.⁴

In the context of the Government's initial evaluation of the Canadian sector at the outset of the pandemic, ISED commissioned a study in 2020 that found that there was insufficient capacity to pivot to produce, at population scale, the leading

³ https://ised-isde.canada.ca/site/canadian-life-science-industries/en

 $^{^4\} https://ised-isde.canada.ca/site/planning-performance-reporting/en/departmental-results-reports/2021-22-departmental-results-report$

COVID-19 vaccines under development. This bore itself out as the Government attempted to negotiate with vaccine companies to manufacture in Canada, which they declined to do because there were not facilities that could produce at the scale needed to respond to a global pandemic.

Since then, preparing for future pandemics and health emergencies has remained a top priority. Conducting lessons-learned activities, as well as understanding remaining gaps, challenges, evolving evidence, potential health threats, emerging technologies, and changing market conditions are ongoing activities that inform strategic domestic biomanufacturing investments and engagements.

The Government is making investments across priority manufacturing technologies that would make the sector more robust and agile, support quick mobilization for vaccinating the Canadian population in future health crises, and meet the health needs of Canadians. This is consistent with testimony heard by the Committee on the importance of investing in a range of technology platforms in order to have a diversified base to respond to unknown, future threats. Recognizing that a future pandemic or other health emergency is likely to look entirely different from the COVID-19 pandemic, Canada must be prepared with capacity to develop and produce medical countermeasures to respond to a range of health threats.

The Government is making significant progress to achieve this. The \$1 billion of support through the SIF that was targeted in Budget 2021 to contribute to promising domestic life sciences and biomanufacturing projects builds upon the \$792 million invested in vaccine and biomanufacturing projects under the Plan to Mobilize Science launched in 2020. To date, the Government has made contributions towards, or agreements with, three large-scale mRNA facilities, at least five cell culture facilities that can produce either antibodies, protein-based vaccines, or viral vectors at a commercial scale or for later-stage clinical trials, two influenza facilities, and seven facilities with medium-to-large-scale fill and finish capacity.

While the Biologics Manufacturing Centre has received its Drug Establishment License and the Vaccine and Infectious Disease Organization (VIDO) pilot manufacturing facility in Saskatoon was completed in 2022, most of the other facilities that have received funding to date are expected to come online over the next few years. A list of biomanufacturing investments can be found on ISED's website.⁵

Looking to the future, as part of the Government's initiatives in Budget 2023, it is engaging with Canadian and international experts, and considering how to best organize readiness efforts and support a strong industrial and innovation base in

⁵ https://ised-isde.canada.ca/site/biomanufacturing/en/backgrounder-government-canada-investments-biomanufacturing-vaccine-and-therapeutics-ecosystem

life sciences for positive health outcomes. Charting a path on which Canada is better equipped to respond to the real, pressing threats of the future requires an ongoing monitoring of the sector's capacity, needs, and promising medical countermeasures under development.

RECOMMENDATION 4: That the Government of Canada establish a follow-up mechanism for funding awarded through the various research support programs, including, but not limited to, the Canadian Institutes of Health Research (CIHR), the Social Sciences and Humanities Research Council (SSHRC) and the Natural Sciences and Engineering Research Council (NSERC), in order to consider other funding options for research organizations awarded funding through the networks of centres of excellence program so they do not suffer a funding shortfall after 31 March 2023, and are able to continue their activities through another source such as the strategic science fund, as of 1 April 2023.

The Government's current course of action aligns with the Committee's recommendation. The Government has created a number of funding streams that provide research organizations with the opportunity to secure continuous funding and drive impactful research after March 31, 2023.

Additional opportunities are provided by the federal granting agencies and the CFI. The Canada First Research Excellence Fund supports priority research areas in post-secondary institutions, and the Canada Excellence Research Chairs program attracts top researchers to Canadian universities. The New Frontiers in Research Fund's (NFRF) Transformation Stream backs large interdisciplinary projects, especially in public health and medicine. CIHR's flagship program, the Project Grant, funds investigator-initiated research and knowledge mobilization in all areas of health. This includes large, interdisciplinary, and network-based projects led by academic researchers in partnership with industry, government, and not-for-profit organizations. CIHR's priority-driven research initiatives also offer additional funding opportunities for research networks to secure new or additional funding to address health issues of strategic importance to Canada. Moreover, new opportunities include the CBRF and BRIF, as part of the Government's investments made under the BLSS. In regard to the Strategic Science Fund, which supports third party science and research organizations, an announcement of successful recipients for the program's inaugural competition will be made this year. Finally, as part of the work related to the Budget 2023 commitment, the Government is considering how to best position Government support for health emergency readiness objectives moving forward.

RECOMMENDATION 5: That the Government of Canada consider ways to improve its funding structure at the interface between academic research and the pharmaceutical industry to both support research at universities and stimulate investment by pharmaceutical companies.

The Government agrees with the Committee's recommendation, and it has already undertaken several actions to address bridging the gap between academic research and commercialization. The Government is focused on making investments in new commercial biomanufacturing capacity that will be sustainable, and integrated with expanded research and innovation capacity at Canada's universities and in the life-science ecosystems, so academics can contribute to the pipeline of new technologies and bring their products to clinical studies.

Funds dedicated to CIHR, BRIF, CBRF, and adMare under the \$2.2-billion investment announced in Budget 2021 aim to support the creation of deeper partnerships between industry and academia at the intersection of applied research and manufacturing, as well as research infrastructure, clinical trials, and talent development.

A \$570-million joint BRIF/CBRF program was launched to catalyze academic-industry partnerships by establishing five pan-Canadian research hubs across the country. Those Stage 1 funding recipients announced in March 2023 are:

- University of British Columbia Immuno-Engineering and Biomanufacturing Hub:
- University of Alberta's PRAIRIE Hub for Pandemic Preparedness;
- University of Ottawa / McMaster University Canadian Pandemic Preparedness Hub;
- University of Toronto Canadian Hub for Health Intelligence and Innovation in Infectious Diseases; and
- The Université de Montréal Eastern Canadian Pandemic Preparedness Hub.

The hubs will play a vital role in advancing the development of next-generation vaccines and therapeutics, supporting the development of products aiding Canada's pandemic readiness, and nurturing the talent necessary for a thriving biomanufacturing sector in Canada. By combining the expertise of academia with the scalability of the pharmaceutical industry, the research hubs are poised to accelerate innovation and facilitate the translation of groundbreaking discoveries from clinical trials to commercialization. Moreover, the Government's strategic investments are expected to establish lasting networks across public and private sectors, further amplifying the impact of these initiatives. The five hubs have collectively established partnerships with well over a dozen private sector companies, public research institutions, and non-profits. Details can be found on

the Stage 1 recipient's website. Through this collaborative approach, Canada is well positioned to solidify its position as a global leader in biomedical research and biomanufacturing while nurturing its growing pharmaceutical industry. Call for proposals for Stage 2 funding for the Pan Canadian research hubs was launched on March 2, 2023, and will support research, talent development, and infrastructure.

Providing biosciences researchers with advanced tools, cutting-edge research spaces, and biocontainment facilities will also aid the transition of their ideas from discovery to development and commercialization. Results of a first round of the BRIF competition to upgrade eight Canadian biocontainment facilities, for a total award value of \$127 million, were announced in November 2022. The results of the second round, which will provide up to \$360 million for the specialized infrastructure and equipment needs of five pan-Canadian research hubs, will be announced in March 2024

Additionally, as part of its overall mandate, CIHR is also committed to facilitating the commercialization of health research in Canada. CIHR's Project Grant program, therefore, encourages commercialization projects and offers a dedicated commercialization peer review committee to evaluate these proposals. As previously noted, the Government continues to consider how it could improve even further the enhanced approaches taken to date to support this work.

Other Private Sector Partnerships

The Government's efforts to attract foreign investment to the sector are also catalyzing research spending from industry. For example, Moderna has committed to funding R&D activities and establishing other partnerships in Canada. The company has already announced several research projects at Canadian universities. As part of its agreement with the Government for its FLUZONE facility currently under construction, Sanofi Pasteur has committed to invest at least \$79 million per year in Canadian R&D. Sanofi continues to support emerging talent at universities by leveraging government funding to invest in new research and discovery projects. The Government of Canada has also committed over \$3.8 million to 20 NSERC research projects in partnership with Sanofi between fiscal years 2016–2017 and 2021–2022.

Innovation Symposium

Finally, the Government is taking other active steps to foster cross-pollination and collaboration within the sector. ISED, in conjunction with Health Canada, SSHRC and NRC, organized the virtual Biomanufacturing and Life Sciences Innovation Symposium on June 28, 2023. The Symposium brought together over

 $^{^6}$ https://www.sshrc-crsh.gc.ca/funding-financement/cbrf-frbc/stage1-etape1/award_recipients-titulaires_subvention-eng.aspx

400 stakeholders from the life sciences ecosystem to showcase innovation and capacity-building activities across the country and provide a venue to foster greater collaboration and stronger partnerships in Canada. Attendees included the five CBRF/BRIF pan-Canadian research hubs, Canadian researchers, public institutions, and private sector companies, with representation from North America, Europe, and Asia. Key themes and takeaways emerged, reflecting significant areas of interest including advancing collaboration, coordination, and partnerships, enhancing preparedness and response, developing a robust and diverse ecosystem, investing in talent development and recruitment, fostering a responsive regulatory environment, and attracting and sustaining investments.

RECOMMENDATION 6: That the Government of Canada carry out a review of lessons learned during the pandemic as regards vaccine procurement and development and publish its findings within one year. The review could include, but is not limited to:

- The work done by scientific experts to advise the government during this period;
- The investments in research infrastructure and vaccine production and the status of that work:
- The investments in organizations that developed a COVID-19 vaccine and the status of their work;
- The costs of the large-scale vaccine procurement strategy and the timelines for vaccinating all Canadians;
- Government of Canada contracts with pharmaceutical companies for COVID-19 vaccines procurement.

The Government has been transparent on the development and procurement of vaccines, its investments in manufacturing facilities, and investments in vaccine development. It agrees with the importance of reviewing lessons learned during the pandemic. Reviews have already been conducted, while others are in the process of being conducted on the effectiveness of Canada's overall COVID-19 procurement strategy and vaccine rollout, including the relative cost of the procurement strategy, and contracts with pharmaceutical companies for COVID-19 vaccines.

For example, the 2022 Report 9 (*COVID-19 Vaccines*) of the Office of the Auditor General (OAG) detailed actions performed by PHAC and Health Canada, supported by PSPC, to respond to the pandemic by securing sufficient COVID-19 vaccine doses to vaccinate all Canadians. The report found that PSPC provided efficient procurement support and secured a sufficient supply of vaccine doses

for Canada by putting in place seven advance purchase agreements for up to 414 million potential doses by January 2021. PHAC was successfully able to distribute vaccine doses, reporting about 82% of people who were eligible to be vaccinated at the time had received at least two doses. The report also outlined lessons learned from the pandemic which relate to vaccine wastage and data sharing.

In fact, PHAC has developed Management Response Action Plans to respond to the findings and recommendations of four reports from the OAG: Pandemic Preparedness, Surveillance, and Border Control Measures; Securing Personal Protective Equipment and Medical Devices; Enforcement of Quarantine and COVID-19 Testing Orders; and COVID 19 Vaccines. PHAC has also appeared before the Standing Committee on Public Accounts (PACP) on February 6, 2023, to respond to inquiries regarding COVID-19 vaccine procurement and distribution, CanSino, the Pan-Canadian Health Data Strategy, vaccine wastage and expiry, COVID-19 vaccine donations, vaccination rates, and vaccine authorization and approval. In April 2023, the PACP passed a motion to view all COVID-19 vaccine contracts signed with suppliers. PSPC provided the committee the unredacted versions of the contracts. PHAC will also be developing a Government Response to the report by the PACP committee regarding OAG Report 9. PHAC has also appeared before the Standing Committee on Health (HESA) on the Supplementary Estimates C 2022–2023 (March 2023) to discuss COVID-19 vaccine doses and on the Supplementary Estimates A 2023–2024 (June 2023). Further, PSPC has appeared five times at various parliamentary committees and has participated in six studies during the 43rd and 44th Parliaments to discuss procurement processes related to the COVID pandemic, including HESA's study on Recent COVID-19 Developments (January 2022), HESA's study on the Emergency Situation Facing Canadians in Light of the COVID-19 Pandemic (September 2020–August 2021), HESA's Briefing on the Canadian Response to the Outbreak of the Coronavirus (July 2020), the studies of the Standing Committee on Government Operations and Estimates (OGGO) on the Government's Response to the COVID-19 Pandemic (during the 1st and 2nd Sessions of the 43rd Parliament), and PACP's Report on COVID-19 Vaccines.

Overall, Canada's national immunization campaign has been highly successful, but it is still ongoing. Federal, provincial, and territorial partners continue to support the vaccine rollout and ensure all Canadians have access to scientific evidence and information to make informed decisions about future doses. According to the latest data, over 166 million doses of vaccines have been delivered into Canada with 121 million doses distributed to provinces, territories, overseas Department of National Defence bases, and Canadian diplomats posted across the world. Over 98 million doses have been administered,

including 10 million fourth doses. It is important to note a key aspect of the strategy was to overbuy, given uncertainties about which vaccines would be successful, and that provinces and territories were responsible for elements of the strategy.

While there has been significant work done to produce public-facing information that could be leveraged to support the review of lessons learned, certain contract details, particularly financial terms (such as price per dose) cannot be shared publicly due to strict confidentiality terms included in the contracts with vaccine companies. Information that can be shared will be to the greatest extent possible.

In terms of the costs to vaccinate Canadians during the pandemic, to date, the majority of costs were allocated towards doses of vaccines for Canadians; that said, the overall strategy included a number of other costs paid by the Government that would need to be considered carefully in a review involving multiple agencies. Details of these other supply needs (e.g., syringes, needles, freezers, dry ice) can be found online. As the Government reviews lessons learned and considers future pandemic readiness supply security, flexible and nimble response to infectious disease threats, consideration of a diverse portfolio of vaccine platforms, and innovative procurement approaches will be key elements of future strategic procurement initiatives.

The ongoing work announced in Budget 2023 will also yield lessons learned and conclusions on what may be required to more effectively and efficiently support critical actions to ensure health emergency preparedness. The Government will continue to consider how best to support a portfolio of vaccine platforms, accelerate lead time to development, production, and availability, as well as optimize presentation and packaging of vaccines to more efficiently distribute and administer them.

RECOMMENDATION 7: That the Government of Canada increase investment in university research and fundamental sciences, bringing it in line with other advanced OECD nations in the world.

The Government's actions align with the Committee's recommendation. The Government acknowledges the significance of investing in science and research to drive innovative breakthroughs with social, health, and economic benefits for Canada and the world. Since 2016, the federal government has committed more than \$16 billion of additional funding to support research and science across Canada. The COVID-19 pandemic highlighted the value of such investments in fundamental research, underscoring the crucial role of science and technology in addressing challenges like climate change, green energy transition, and sustainable growth.

⁷ https://www.canada.ca/en/public-services-procurement/services/procuring-vaccines-covid19.html

For its primary support to Canada's research enterprise, the Government funds the three federal research granting agencies: CIHR, Natural Sciences and Engineering Research Council of Canada (NSERC), and Social Sciences and Humanities Research Council of Canada (SSHRC), along with CFI. These organizations play a pivotal role in supporting research, training, and infrastructure in post-secondary institutions. The roughly \$4-billion annual federal investment fuels novel discoveries and skilled talent that drive innovation. Additionally, the government provides funding through various mechanisms and initiatives, supporting third-party science organizations.

In 2016, the Government initiated the Fundamental Science Review (FSR) to assess how to maintain Canada's world-class standing in research and ensure coherent, strategic, effective, and agile federal support for research. The independent panel's 2017 Naylor report paved the way for unprecedented investments in fundamental research. Budget 2018 responded by providing over \$1.7 billion over five years to support Canadian researchers and research institutes plus \$2.4 billion for CFI and the granting agencies. This included the largest-ever investment in fundamental research in Canada and increased funding for established programs like Canada Research Chairs and the College and Community Innovation Program, as well as the creation of the NFRF for international, interdisciplinary, fast-breaking, and high-risk research. More than \$500 million was provided in Budget 2019 in additional support to third-party science and research organizations, in addition to the creation of the Strategic Science Fund. Budget 2021 invested in bio-innovation research, talent development, and research infrastructure, and committed \$1.2 billion for pan-Canadian strategies on artificial intelligence, quantum science, and genomics. Budget 2022 continued to support various research themes, including research on the long-term effects of COVID-19, dementia and brain health, and technologies for net-zero emission agriculture.

Recognizing the evolving nature of research, the Government aims to enhance the federal research support system's cohesiveness, strategic coordination, and collaboration across funders. To achieve this, the Prime Minister mandated the Minister of Innovation, Science and Industry, in collaboration with the Minister of Health, to develop a plan for modernizing the research support system. To support this effort, the Advisory Panel on the Federal Research Support System was established in October 2022, providing independent expert advice to ministers. The government is carefully considering the panel's recommendations to ensure the research support system effectively addresses current and future challenges while building on the strengths and successes of Canada's granting agencies.

RECOMMENDATION 8: That the Government of Canada support the creation of high-value, well-paying positions in biomanufacturing and life sciences to attract and retain top talent and consider:

- increasing the value of graduate scholarships and the number of scholarships awarded at the master's, doctoral and postdoctoral levels;
- ensuring that scholarships are internationally competitive and increase with the cost of living;
- addressing the underinvestment in a generation of Canada's most promising young researchers;
- ensuring that graduates and workers have the skills Canada needs by increasing opportunities for lifelong learning and work-integrated learning; and
- encouraging the immigration of international talent to the country by strengthening Canada's position as a destination for global talent by reducing processing times for study and work permits for students and faculty.

The Government agrees with the Committee's recommendation. The Government has taken a number of strong actions to support the creation of high-value positions and to attract and retain top talent.

First, the Government's BLSS investments will help to build Canada's talent pipeline and research systems. The Government's foundational Investments in biomanufacturing will create and maintain high-quality positions that will not only increase Canada's resiliency, but also provide good opportunities for graduates from life sciences programs to remain in Canada long-term.

The Government's support for training within the sector will also help create a pool of skilled workers. Budget 2021 funds provided to adMare BioInnovations will drive company creation, scale-up, and training activities in Canada's life sciences sector. Training for Canadian scientists is being delivered through its BioInnovation Scientist Program while instruction for highly qualified personnel is delivered through its Executive Institute, postdoctoral fellowship, and undergraduate training programs. The Canadian Alliance for Skills Training in Life Sciences (CASTL), which has received support from adMare, will house its flagship training facility at the PEI BioAlliance BioAccelerator (supported by a \$25-million federal contribution from the Atlantic Canada Opportunities Agency). CASTL is addressing a critical need by providing training in the good manufacturing practices (GMP) required to work in biomanufacturing facilities. CASTL has also been identified as a training partner for most of the five Pan-Canadian Research Hubs detailed in the Government's response to Recommendation 5.

In early 2023, the CIHR CTF announced \$32 million for seven different clinical trials training platforms at Canadian universities which will prepare the next generation of clinical scientists and researchers to conduct high quality clinical trials. The Government also provided \$45 million in Budget 2021 to the Stem Cell Network, which will provide specialized training to ensure highly qualified personnel are well placed to compete in Canada's knowledge-based economy and equipped with the skills to work in regenerative medicine labs and biotechnology companies.

The Government also recognizes the significant, mutual benefits to be achieved by working with like-minded partners from other countries. For example, on June 8, 2023, ISED and the United Kingdom's Department of Science, Innovation and Technology announced the signing of a Memorandum of Cooperation (MOC) in relation to a Canada–UK Biomanufacturing Collaboration. Supported by a \$32-million fund jointly administered by the NRC in Canada and Innovate UK, this new partnership will advance collaborative science, R&D, and industrial development. There will be a specific funding stream for biomanufacturing training initiatives.

Second, to further strengthen lifelong learning opportunities, the Government also launched the Upskilling for Industry Initiative, a \$250-million program that will help more than 15,000 workers transition to new work opportunities in key high-growth sectors, including biomanufacturing. The program is being delivered in collaboration with a third-party organization, Palette Skills Inc. The Government is also investing in increasing opportunities for work-integrated learning in the sector, notably via Mitacs which facilitates partnerships between academia and industry to support innovation-focussed internships.

Third, as noted in the Government's response to Recommendation 7, it has taken significant action to support research at Canadian universities. However, the Government also recognizes that federal scholarships and fellowships play a role in the career progression of Canada's top talent, and it has taken measures to increase the number of scholarships, make research more affordable, and reduce the cost of living for students. Budget 2023 provided \$813.6 million in 2023–2024 to increase Canada Student Grants by 40 percent, raise the interest-free Canada Student Loan limit from \$210 to \$300 per week of study, and waive the requirement for mature students, aged 22 years or older, to undergo credit screening in order to qualify for federal student grants and loans for the first time. This builds upon 2020 initiatives that included \$291.6 million in income support for research trainees to offset the hardships of the global pandemic and \$323 million in wage support for approximately 32,000 research-related personnel at universities through the Canada Research Continuity Emergency Fund.

Budget 2019 provided \$114 million to the granting agencies to create 500 more master's level and 167 more doctoral scholarships annually, as well as \$9 million to Indspire to support additional bursaries and scholarships for First Nations,

Inuit and Métis students. Budget 2022 provided \$40.9 million to the granting agencies to support targeted scholarships and fellowships for Black researchers. Looking forward, to prepare a diverse population of students and postdoctoral fellows for careers in research across all sectors of society, the Government, through the work of the Canada Research Coordinating Committee, is developing a Tri-agency Training Strategy that aims to be trainee-centric, evidence-based, and transparent while upholding the principles of equity, diversity, and inclusion.

Fourth, the Government is committed to attracting and retaining top academic talent so that Canada continues to be a leader in world-class education, research, and innovation. Immigration, Refugees and Citizenship Canada (IRCC) launched new authorities to its Express Entry program to meet identified economic goals and its categories selected for 2023 include a focus on candidates with work experience in STEM occupations. IRCC plans to add additional pathways to attract and retain top academic talent, such as an open work permit stream for specialty occupations, an Innovation Stream under the International Mobility Program, and improvements to the Start-up Visa Program. IRCC continues to make great efforts to improve its processing times. Within the first three months of 2023, it processed over 1.7 million applications for temporary residence, permanent residence, and citizenship. This is over 700,000 more applications compared to the same period last year. As of June, processing times for study permits were 44 days, well within the 60-day service standard, and almost half the 86-day processing times during the same period last year.

RECOMMENDATION 9: That the Government of Canada help strengthen Canada's biomanufacturing ecosystem by funding diverse national expertise capable of withstanding future health crises, by taking a broad approach that includes research related not only to vaccine development but also to neuroscience, mental health, and immunotherapy, and protecting the patents and intellectual properties.

The Government aligns with the Committee's recommendation. The BLSS seeks to not only establish and sustain sufficient vaccine and therapeutics manufacturing capacity to respond to a future pandemic or health emergency, but also build strength in emerging technology areas with high potential to solve current and future health challenges. Of the investments to date, there has been an emphasis on mRNA production—for its potential to accurately target a wide range of cancers and rare diseases plus building on existing Canadian expertise in RNA science and delivery technology—and cell culture manufacturing for antibodies, protein-based vaccines, and viral vectors and therapies that also they hold the potential to treat cancers, rare diseases, and chronic conditions. Other precision medicine platforms, including cell and gene therapies and artificial intelligence (AI) for drug discovery, were identified as important Canadian research strengths driving health innovation.

The broad applications and capabilities of these platforms have implications for improving the health of Canadians and ensuring the economic viability and sustainability of biomanufacturing investments. Contract development and manufacturing organizations (CDMO) will be available to fabricate cutting-edge medicines in development by small and medium-sized Canadian companies, thereby keeping those companies in Canada. As outlined in the BLSS, investment in foundational research, research infrastructure, and manufacturing will accelerate the development of products and processes that will be translated into new intellectual property.

In other BLSS programs that demonstrate the broad-based approach to health research, the initial CIHR CTF investments under the clinical trial stream cover an extensive range of therapies, diseases, pathogens, and surgical techniques. These include antimicrobial resistance studies, CAR-T cell therapies for cancer, ventilation techniques for patients with respiratory failure and critical illnesses, streptococcal vaccines, novel anesthetics, stem cell therapy, heart disease, and many others. Additionally, the Accelerating Clinical Trials (ACT) consortium will support and expand clinical trials networks in many clinical areas, in order to improve collaboration and efficiency in the broader clinical trials ecosystem.

RECOMMENDATION 10: That, as part of the implementation and evolution of the Biomanufacturing and Life Sciences Strategy, the government develop a holistic approach to supporting Canada's biomanufacturing industry and develop a framework for funding translational research organizations by supporting preclinical to clinical translation.

The Government agrees with the Committee's recommendation. As described throughout this response, the BLSS was conceived to support the continuum of pharmaceutical development from basic research through to manufacturing and commercialization of Canadian innovations. What follows reiterates how support across the ecosystem is implemented and brought together through BLSS initiatives to the greatest extent possible under the current frameworks in place.

Programs such as CBRF/BRIF pan-Canadian research hubs will accelerate the research and development of next-generation vaccines, therapeutics, and diagnostics and facilitate translation of promising research into commercially viable products and processes through cross-sectoral collaboration. Organizations such as the Stem Cell Network and CASTL will contribute to skills training for biomanufacturing workers and adMare will provide early-stage companies functional knowledge of business practices, pharmaceutical markets, and regulations.

The CIHR CTF will create a pipeline for medical innovation and research in complement to federal investments in domestic biomanufacturing capacity. Expected outcomes of CTF investments include improved coordination of clinical

research, support for research networks, and collaborations on clinical trials that may extend internationally. CIHR is currently consulting with a broad range of stakeholders on issues related to the Canadian clinical trials ecosystem and CIHR's role in funding clinical trials. This will contribute to developing of a long-term clinical trials strategy.

Biomanufacturing investments will provide Canadian pharmaceutical companies access to domestic CDMOs for clinical and commercial manufacturing, as well as attracting international clients. The presence of major pharmaceutical companies in Canada also offers opportunities for collaboration with innovative small and medium-sized Canadian companies. Investments in public institutions such as the NRC and VIDO establishes a clinical manufacturing base for early-stage companies to develop their products under the guidance of experts.

The Government also continues to modernize its regulatory system for health products, which will play a key role in growing Canada's biomanufacturing sector by facilitating access to cutting-edge, advanced treatments and products currently in development. Health innovation requires greater regulatory agility, while at the same time managing the risks, benefits, and uncertainties of more diverse and complex products.

Overseeing these efforts is a governance system that coordinates the Health Canada and ISED portfolios along with the advice of expert advisors and consultations with stakeholders from industry and academia in order to strategically direct investments towards filling gaps in the ecosystem, supporting emerging, innovative technologies, and addressing potential health threats. In summary, the Government has made significant progress, but recognizes that the work is not done and that future pandemic and health emergency preparedness will depend on success across a number of interrelated elements: Canadian universities and research institutions fostering disease research applied to vaccines, therapeutics, diagnostics, and other medical countermeasures, while training researchers in the practicalities of manufacturing and regulations: Canadian companies with a track record of commercialization and running clinical trials; healthcare systems communicating their needs to researchers and providing much of the infrastructure for clinical research and testing new technologies; Canadian CDMOs that can manufacture cutting-edge products from clinical to commercial scale; and the presence of globally relevant biopharmaceutical anchor firms to drive and support further innovation, while bringing knowledge and expertise to the Canadian ecosystem. The work that began with the formation of the BLSS will continue through the aforementioned Budget 2023 initiatives to grow a cohesive domestic life sciences sector, stimulate economic development, improve the lives of Canadians, and prepare for future health emergencies.

Sincerely,

The Honourable François-Philippe Champagne, P.C., M.P.