What We Heard: Considering the Creation of New Biomanufacturing Capacity for Canada

Consultation Summary

May 2021

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Innovation, Sciences et Développement économique Canada
Canada

Table of Contents

Executive Summary

From the outset of the COVID-19 pandemic, the Government of Canada has demonstrated its commitment to use every tool available to combat the virus and mitigate its economic and health impacts. The Government of Canada has taken, and continues to take, strong and decisive action to protect the health of Canadians as well as support Canadian workers and businesses.

The Government of Canada is equally resolved to ensure that Canada is well-positioned to respond to future health emergencies and, to this end, has taken decisive action to promote the long-term sustainable growth in Canada's biomanufacturing sector. Budget 2021 illustrates the Government of Canada's deep commitment to investing in Canada's biomanufacturing and life sciences sector, by investing a total of $2.2 billion over seven years towards growing a vibrant domestic life sciences sector. These foundational investments will help build Canada's talent pipeline and research system, and support the growth of Canada life sciences firms.

As a part of the Government of Canada's overall strategy to strengthen and expand domestic biomanufacturing capacity, in February and March 2021, Innovation, Science and Economic Development Canada (ISED), in collaboration with Health Canada and the Public Health Agency of Canada, and with the assistance of the COVID-19 Vaccine Task Force, engaged expert stakeholders in a series of virtual roundtables as well as by soliciting written submission on the long-term and enduring elements of a robust domestic biomanufacturing sector. A detailed consultation paper entitled, *Considering the Creation of New Biomanufacturing Capacity for Canada*, laid out a series of considerations and key questions in the following areas:

- mission and mandate of such an initiative or interconnected initiatives;
- scope of operations;
- function of capacity within the existing landscape along the value chain (from research to commercialization to at-scale production);
- commercial sustainability of a biologics manufacturing platform; and
- governance models for such an initiative.

Overall, we heard very strong support for the proposed mandate of the initiative. Participants stressed the importance of ensuring connectivity amongst all those contributing to the life sciences ecosystem, including research institutions, private sector companies/industry, and government. Some participants noted that a large-scale, national innovation and manufacturing centre could serve as a critical anchor, connecting and leveraging assets across the country, and would directly support pandemic preparedness and economic development across the country.

It was generally recommended that the scope of operations for such an initiative build on areas where Canada already excels in the life sciences sector. The initiative is widely seen as needing to be collaborative, strategic, and built for the long term, and the consensus was that there should be a focus on ensuring sustainability outside of public health crises. It was suggested that a coordinated ecosystem of assets, anchored around a new centre, connect with multiple sites or networks to build capacity across the country and leverage existing investments and talent. These assets include research and academic institutes and facilities, small- and medium-sized enterprises, multinational enterprises, preclinical and clinical trial capacities, risk capital, and digital and physical infrastructure.

Participants agreed that stronger linkages between academia and industry are needed, including investing in translational research and seeking ways to build up the number of highly qualified personnel to work in the sector. It was noted that there is a role for government to help coordinate and align efforts between academia and industry, in addition to aligning policies and regulations to support the goals of the initiative.

The sustainability of this initiative should strike a balance between ensuring timely emergency responses and contributing to long-term economic success. Most participants agreed that public-private partnerships that leverage the innovation and entrepreneurship of industry with long-term sustainable and stable government funding for the organizations involved would be required for the initiative to be sustainable. The approach to ensuring sustainability should include ongoing support for research, and sustaining the ecosystem by leveraging the new capacity for commercial activities by academia or small- and medium-sized enterprises in between public health emergencies. While recognizing that the governance model for this initiative would need to ensure it can achieve multiple objectives, including pandemic preparedness and responsiveness, skills development, research, and industrial innovation, and would differ during a pandemic situation, many participants were of the opinion that Canada can draw on examples from other countries, including the United States, the United Kingdom, Ireland, and Australia.

ISED and its partner departments would like to thank everyone who took time to submit their feedback and ideas to this consultation. Feedback received from participants through this consultation will be carefully considered as the Government of Canada examines ways in which to build the next generation of biologics manufacturing and life sciences ecosystem in Canada.

Introduction

The COVID-19 pandemic has exposed significant limitations and gaps in Canada's capacity to produce life-saving vaccines and therapeutic drugs at sufficient scale to meet domestic needs. Serious consideration is being given to how best to ensure that Canada is well-positioned to respond to future health emergencies and how to promote the long-term growth of the Canadian life science sector. Since the outset of the pandemic, the Government of Canada has taken decisive action to ensure safe and secure access for Canadians to therapeutic products and is aggressively pursuing the rebuilding of Canada's biomanufacturing capacity. As it acts to deal decisively with the immediate crisis, the Government is seeking to lay a durable foundation for Canada's ability to respond to the current and future health emergencies.

To this end, the Government of Canada is exploring ways in which it can help promote long-term sustainable growth in Canada's biomanufacturing sector. ISED, in collaboration with other federal departments and agencies, including Health Canada and the Public Health Agency of Canada, and with the expertise, assistance, and oversight provided by members of the COVID-19 Vaccine Task Force, engaged with stakeholders on the long-term and enduring elements of a robust domestic biomanufacturing sector, including the prospective expansion of domestic biomanufacturing capacity and related enhancements to the life sciences ecosystem. These consultations were supported by a detailed consultation paper entitled, *Considering the Creation of New Biomanufacturing Capacity for Canada*, which laid out a series of considerations related to the creation of a potential biomanufacturing and innovation initiative through a new national centre for pandemic preparedness or a national network of pandemic preparedness hubs. Specifically, input was sought with respect to:

- the elements of Canada's biopharmaceutical sector in which Canada demonstrates strengths and possesses weaknesses, and the potential avenues for strengthening the biomanufacturing and related innovation ecosystem;
- the mandate and mission of a potential biomanufacturing and innovation initiative, such as a national centre for pandemic preparedness or a national network of pandemic preparedness hubs;
- the scope of operations for additional biomanufacturing capacity, in the context of both pandemic preparedness and long-term sustainability;
- methods for integrating any new capacity into the existing academic and life sciences landscape in Canada, and for ensuring continued strength in these areas; and
- consideration as to the most appropriate business models and governance structures.

From February 17 to March 12, 2021, written submissions were received through a widely accessible web submission form that was made available online through ISED's website. A total of 109 written submissions were received. In addition, from March 1 to March 12, 2021, seven

(7) roundtable discussions were held virtually via an online meeting platform. These targeted consultations sought input from biomanufacturing experts, industry leaders, thought leaders from universities, public health experts, leading international jurisdictions, connected sectors, and beyond.

The purpose of this report is to provide a summary of what was heard from participants through the online public consultation and the virtual roundtable discussions for each of the five elements outlined above.

What We Heard

MANDATE

What would be the appropriate mandate for a biologics manufacturing and innovation initiative in Canada in order to ensure long-term readiness for future pandemics and to realize economic development opportunities?

The consultation paper outlined the following as elements that the mandate of this initiative should include:

- ensuring standing capacity and capabilities to produce at scale to meet the needs of Canadians, and possibly larger quantities for export, across the main vaccine and therapeutic platforms, with biomanufacturing capacity readily available to the Government as a critical public health asset during an emergency (such as the current COVID-19 pandemic), or in response to domestic or global health initiatives;
- serving as a means within the Canadian life sciences ecosystem to connect small- and medium-sized enterprises, large global biopharmaceutical firms, academia, and researchers to accelerate health innovations and grow Canadian firms, including through making pilot-scale production capacity available to Canadian innovators;
- providing a venue and programs, or creating strong linkages and collaborative programs with existing venues, for the training of highly qualified personnel;
- ensuring alignment with and best use of existing assets to urgently expand capacity in response to the COVID-19 pandemic;
- developing and implementing efficiency-improving at-scale production processes;
- helping Canada contribute to international efforts aimed at ensuring fair and equitable access to biologics;
- ensuring that Canada retains and develops its biological intellectual property from research discoveries through commercialization; and,
- protecting Canadian researchers, scientists and companies from research and economic based threats to national security.

Feedback was sought to gain a better understanding of the core functions that must be available across the country to ensure pandemic preparedness. In particular, participants were asked to identify what mandates would be required to support Canada's biomanufacturing security as well as long-term growth in the sector, without duplicating efforts. Participants were also to consider whether the proposed mandate is sufficient or lacking.

While the majority of participants agreed with the proposed mandate, they also identified a need for the Government of Canada to commit to the initiative over the long-term and suggested the implementation of a strategic plan with specific goals. Participants also agreed that there is a need for federal support to plan for and quickly respond to a pandemic, especially through investments to develop and retain talent, to provide funding for research, and to build end-to-end domestic vaccine and therapeutic production capacity. There was broad agreement amongst participants to focus readiness efforts on emerging infectious diseases, noting the importance of surveying the international landscape and building capacity through stakeholder engagement in order to be prepared to address potential threats.

In addition, several participants highlighted the following elements as being important for pandemic readiness: considering diverse vaccine platforms, creating redundancy in manufacturing capacity and enabling increased domestic production, ensuring integrated and forward-looking surveillance, strengthened supply chains, and ensuring enhanced genomics assets and capabilities are in place.

There was also consensus for considering mandates beyond pandemic preparedness that would support Canada's biomanufacturing security and promote long-term growth of the sector. For example, some participants suggested that the mandate be expanded to consider the health needs and well-being of Canadians during non-pandemic times. In addition to innovative medicines for emerging infectious diseases, some participants noted the need for therapeutics to address the existing burden of chronic diseases that affect Canadians, such as heart disease and cancers. Many participants felt that the benefits of an expanded mandate could include new economic opportunities for Canada and result in technological breakthroughs that would ultimately contribute to better health outcomes for Canadians.

Several participants indicated that any biomanufacturing intervention should include considerations beyond human health, such as a focus on animal vaccines and zoonoses. They indicated that vaccine research and production should not be solely focused on the needs of humans, given the close interplay between human population health and existing and emerging zoonotic diseases.

Many participants expressed their desire for the mandate to clearly include the assurance that Canada has a full development and manufacturing process and capability present in the country

– ranging from basic research and bench-scale discovery, to research and development (R&D), to commercialization with industrial scale production and distribution. In contrast, some participants believed that it would be more cost effective to identify gaps in the existing development and manufacturing process for new therapeutics and fund or add capacity to those areas. Some other participants advocated for leveraging Canada's unique technological strengths where the country has a significant global competitive advantage, such as precision medicine or cell and gene therapy, and adding biomanufacturing capacity accordingly.

Several participants agreed that ensuring the retention and development of biological intellectual property in Canada be included as part of the mandate and noted that while Canada supports a strong research ecosystem in world-class universities, it struggles to retain the value of innovations developed in these institutions, which are commercialized elsewhere. More funding and investment between discovery and commercialization in Canada was highly encouraged. Some participants also recommended taking a balanced approach that is geared to developing a large-scale commercial manufacturing presence in Canada and supporting both the retention of intellectual property and domestic talent.

In addition to vaccines and biologics, several participants indicated that Canada should consider national capacity for large and small molecules, monoclonal antibody and phage therapies, antibody gene transfer and bacteria and fungi, as well as address antimicrobial resistance (AMR). Some participants suggested including national capacity for active pharmaceutical ingredients, as producing them domestically would aid in supporting the supply chain for small and large molecules and could facilitate the export of product to other countries.

Some participants pointed to the benefits of creating a national-level facility or network of facilities for developing and manufacturing vaccines and therapeutics. They felt that this could be achieved through the creation of a new centre, with the goals of improving pandemic preparedness and building up and sustaining long-term life sciences innovation and competitive capabilities in Canada. Such a centre could be connected to regional nodes of developed and developing life sciences expertise.

Several participants advocated for the creation of a new, innovative, and integrated partnership model amongst industry, academia, and government that stresses collaboration and the ability to leverage expertise throughout the life sciences ecosystem. These participants believed that academic researchers and institutions can support talent development, contribute to the pipeline of new technologies, and support the translation of academic research into clinical studies and medicines, while industry can bring its commercial expertise in areas such as pricing, supply chain management, procurement, and project timelines.

SCOPE OF OPERATIONS

What should be the scope of operations for an initiative that seeks to bolster long-term domestic pandemic preparedness and a robust and sustainable biomanufacturing sector?

Feedback was sought regarding general function and program requirements, including the minimum capabilities that Canada should have available to ensure pandemic preparedness, promote biosecurity, and maximize the growth potential of the sector. Participants were also asked to identify key considerations for site selection, including whether new biomanufacturing capacity should be consolidated at a single site or built up across multiple sites and which geographic location(s) would best support investments in biomanufacturing capacity.

The input received under this section was very broad in terms of its focus. At times, participants focused on the potential scope and coverage of the biomanufacturing initiative and ecosystem, while in other instances, participants' comments were associated with a potential facility or centre.

Many participants outlined elements that could foster better pandemic preparedness and realize the goals of new biomanufacturing capacity in Canada and they suggested placing an emphasis on investing in agile platforms, ensuring ongoing improvements are made to existing platforms, and working closely with public health and primary healthcare to assess and react to emerging health threats. They further expressed that focusing on domestic manufacturing alone is not sufficient to fully prepare Canada for the next pandemic or to sustain the broader health needs of Canadians, and suggested that the scope of operations should also include surveillance systems, a supply chain of active pharmaceutical ingredients, and effective distribution mechanisms.

Some participants also believed that to truly prepare for a pandemic, local ecosystems, where there are existing clusters of expertise, need to be built up. They pointed to elements that should be enabled within a local ecosystem, such as laboratories with the right biosecurity level (BSL2 or BSL3) and links to research hospitals to conduct clinical trials and to industry to ramp up production once a vaccine becomes viable.

Participants agreed with the elements of enhanced biosecurity outlined in the consultation paper, highlighting that speed in response is critical to a pandemic or public health crisis. Several participants indicated that in addition to end-to-end production capability, the scope of operations should include supply chain management. For example, they noted that it is critical to have fast access to and securing of raw materials, especially when there are spikes in worldwide demand, such as during a pandemic.

In addition to ensuring sufficiency in production with respect to vaccine manufacturing, several participants indicated that it is essential to ensure fill-and-finish capability in Canada. Some participants observed that there were no Canadian sites who were able to meet this need in response to the COVID-19 pandemic, and stated that the capacity and output levels were not sufficient to justify the necessary transfer of technology. As such, it was suggested to explore ways to avoid a bottleneck in the future at this stage of production. One example was to partner with a global fill-finish firm and have them scale up in Canada.

There was a general consensus amongst participants that in order for the initiative to be successful, any new biomanufacturing capacity must also include the identification, training, and retention of emerging talent, as well as the creation of flexible infrastructure to support this talent. It was noted that Canada has skilled talent to harness and it was strongly encouraged to strengthen this existing expertise and capacity with more specific training and targeted investments.

Participants were asked to consider the incorporation of good manufacturing practices (GMP) into new biomanufacturing capacity. Some participants encouraged investment in domestic GMP facilities, noting that minimal reliance on outsourcing would allow for greater control and adherence to GMP. However, participants identified a significant gap in training and developing expertise in domestic regulatory compliance with respect to GMP manufacturing in Canada.

Participants were also asked whether further investments through the proposed Canadian biologics manufacturing and innovation initiative in the context of pandemic preparedness should seek to consolidate any new biomanufacturing capacity at a single site or to continue to expand and strengthen capacity across multiple sites. Several participants agreed that focusing on one central site and one technology for the initiative, particularly as it relates to vaccine development and production, would be limiting, since there are a variety of technologies which can be used in the development of vaccines. Most participants believed that there are risks associated with a single facility and centralization, indicating a preference for multiple facilities or sites to mitigate risks and to ensure diversity in technology development.

As such, several ideas were brought forth, with participants highlighting crucial elements to consider in choosing sites and agreeing that the approach should be commercially oriented and globally competitive. Some participants advocated for a multi-site approach which would leverage innovations and investments of major universities and their talent in a nationally coordinated way, while others recommended building up existing technology-specific sites across Canada, where talent, expertise, and excellence is present. Others still suggested that there could be a coordinated ecosystem of facilities with multiple sites or networks. It might be fully decentralized or a “hub and spoke” model. The “hub” would take on a central planning role in strategically assigning capacity and focus areas to the “spokes.” It was felt that this approach

would build capacity in a regional manner, leverage existing investments and areas of expertise, and build start-up communities.

There were diverse views regarding the geographic locations that would be best to support any proposed biomanufacturing expansions.

- Some participants felt it would be wise to consider emphasis on locations with existing infrastructure, facilities, and organizations in large metropolitan centres, such as Vancouver, Toronto, or Montreal.
- Other participants thought the aim should be to leverage academia to draw on highly qualified personnel and build production capacity and R&D opportunities around academic institutions, such as those located in Vancouver, Edmonton, Toronto, Montreal, and the Atlantic provinces.
- Others advocated for a regional approach that would see a distributed model, based on leveraging existing centres of current expertise which are not solely concentrated in major metropolitan centres, such as Atlantic Canada, Manitoba, and Saskatchewan.

ROLE WITHIN THE BIOLOGICS RESEARCH AND MANUFACTURING ECOSYSTEM

How can we ensure that any additional capacity is well-connected with Canada's research community and well-integrated into Canada's life sciences ecosystem?

Feedback was sought on how best to align the domestic biomanufacturing sector and academia, as well as to identify the gaps in Canada's research landscape. Participants were also asked how Canada could achieve an appropriate balance between developing highly qualified biomanufacturing personnel and sourcing expertise from abroad, support the growth of small- and medium-sized enterprises, and foster an environment that is more conducive to biologics research and manufacturing.

Several participants concurred with the consultation paper's recognition of opportunities for the Government of Canada to increase its attention to the life sciences sector in order to address public health crises, such as the current pandemic, and foster a vibrant ecosystem. Some participants indicated a desire for Canada to have a bold vision that promotes Canadian research and existing expertise and incentivizes investments in Canada in a more coordinated way.

Participants brought forward several ideas to leverage existing strengths in Canada. For example, to foster closer links and alignment between academia and industry, some participants suggested enabling small- and medium- sized enterprises to partner with academic institutions and utilize their testing facilities and laboratories, as the enterprises often do not have the

capital or access to these types of facilities. The participants also indicated that the capacity to make these types of partnerships happen exist. Alternatively, other participants suggested making connections with representatives of provincial/territorial biotechnology incubators to leverage their rich knowledge of local bio-accelerators.

Many participants expressed support for leveraging and promoting technologies where Canada already has expertise and potential to scale up, where there is an identified need in the sector, or both. Suggested technology areas of excellence for Canada included monoclonal antibodies, cell and gene therapy (CGT), messenger ribonucleic acid (mRNA) technologies, and liposome and lipid nanoparticle (LNP) technologies. mRNA was mentioned as a key area of excellence by a number of participants due to its use in rapidly developing a COVID-19 vaccine; they believed that ongoing development and trials may be worth pursuing for other applications beyond vaccines. Canada's strong expertise in this area could be further supported to solidify global leadership in this emerging technology area.

In addition, to maximize the benefits of public investment in the life sciences sector, some participants suggested that alignment of policies amongst all federal departments should be a federal priority. In particular, they noted that the federal government can play a role by helping to coordinate and align efforts between academia and industry, considering policies that create corporate incentives and foster a competitive and predictable intellectual property regime, and ensuring a responsive and enabling regulatory system that facilitates the uptake and adoption of innovation in Canada. Further, one suggestion was that a body be established by the government to convene stakeholders to discuss priorities and encourage the coordination of policies and strategies related to biomanufacturing.

Several participants expressed support for increasing federal assistance towards small- and medium- sized enterprises, such as biomanufacturing start-ups. To help these businesses grow in Canada, participants expressed the importance of providing diverse types of government support for research (such as funding for academia, investment in clinical trials and clinical trial infrastructure), pursuing domestic procurement opportunities for products coming through the research and development (R&D) pipeline, and providing technical and regulatory support. In addition, better distribution of funding for these smaller companies, including start-ups and research networks, and not just larger, established organizations, was suggested. Recognizing that there are existing resources and platforms of national funding agencies and granting councils, some participants noted that there is an opportunity to improve communications amongst federal departments and agencies and provincial and territorial governments to ensure alignment between jurisdictions on biomanufacturing priorities and funding initiatives.

Several participants identified a need to broaden sources of investment as a means to enable the domestic life sciences sector. For example, they indicated that both public and private

investments in academic innovation could help advance disruptive research and discoveries, including accelerating research translation and enhancing clinical trial capacity in Canada. Furthermore, they noted that addressing underinvestment in venture capital funding would assist in bridging academia and the biomanufacturing industry, noting that investment at scale in domestic companies would help retain and grow the ecosystem and the talent pool of expertise.

There was consensus from participants that talent is a critical component of the life sciences ecosystem and is essential to fostering innovation and scientific breakthroughs. The majority of participants observed that Canada is lacking sufficient supply of talented and skilled individuals who have the practical experience necessary to build and run a biomanufacturing facility.

Many participants identified issues preventing the development of a broader talent pool in Canada, such as a lack of industry-specific training, insufficient linkages between academia and industry, and barriers to recruiting from overseas. However, participants also offered solutions to developing the talent pool, such as implementing specialized training programs through Canadian universities and colleges, helping researchers and academics translate their research into commercial products, and enabling the recruitment of highly qualified personnel from other countries. Several participants indicated that skills and talent development programs should be focused on research, entrepreneurial and industrial skills, and manufacturing/operations.

Some participants noted the benefits of providing practical training for young scientists, calling for more collaboration between colleges and universities and industry to provide programs that would help developing talent obtain the necessary skills to excel in the life sciences sector. To this end, participants recommended developing more apprenticeship and mentorship programs and offering hands-on training and experiential learning at emerging biomanufacturing facilities or centres.

SUSTAINABILITY

Outside of a pandemic scenario, how would such an initiative best sustain its operations?

Feedback was sought on how to ensure the sustainability of the proposed biologics manufacturing and innovation initiative. Participants were asked to identify activities and potential operating approaches for sustainable operations and to consider factors that would facilitate pivoting between supporting a public health emergency response and commercial operations.

At times participants focused on the biomanufacturing initiative and ecosystem and its sustainability, while in other instances, the discussion on sustainability was associated with the operation of a potential facility or centre.

Participants agreed that the sustainability of the initiative must include considerations for non-pandemic times. In particular, several participants highlighted the risks of building a "white elephant" facility that will sit unused until the next public health crisis. Many participants emphasized that the sustainability of the initiative requires a flexible approach of manufacturing a portfolio of products, stating that facilities must have the ability to pivot rapidly to producing therapeutic products that are relevant outside of a public health emergency, as well as the capacity to support the development and production of these products.

To achieve this, participants recommended focusing on a diverse array of technologies and considering technological platforms that could be used for multiple applications and scaled for different capacities. For example, some participants suggested that viral vectors have the potential to be quickly pivoted; they are commonly used for vaccines, but are being tested for other applications, including gene and cancer therapies. Some participants also pointed to generics and biosimilars as a potential opportunity for sustainable manufacturing in Canada in periods between public health crises, noting Canada's existing generics expertise represents an important area of strength where additional investments could address a shortage of generic drug production capacity.

Many participants also highlighted that in order for this initiative to be sustainable, Canada's domestic capacity must be of sufficient scale, such that the country can also participate in strategic international partnerships and alliances. Ensuring that the Canadian life sciences sector is competitive internationally was mentioned as a secondary, but significant, consideration in supporting the sustainability and success of the sector.

There was consensus from participants that the domestic production of a sustainable supply of products must primarily meet the needs of Canadians in times of crisis, prior to shipping resources globally as part of the global supply chain. However, some participants cautioned that focusing exclusively on the Canadian marketplace was unlikely to be successful or serve to sustain the initiative over the long-term. Participants felt that in order to be viable, the reach of the initiative would need to be global and cost competitive, and designed such that Canada could be an active participant in international biomanufacturing supply chains. Some felt that a large volume of product would need to be exported to other jurisdictions; otherwise, there would be a need for ongoing government funding and intervention to sustain operations, which would detract from the initiative's long-term commercial viability.

In order to ensure the sustainability of facilities, participants widely agreed that defined mandates and some form of partnership model between the public and private sectors are needed. Both the government and industry would have a role to play, with government leadership providing long term sustainable and stable funding, and private industry fostering innovation and entrepreneurship across a diverse array of technologies. Furthermore, participants viewed the concept of a public-private partnership model as a way to strengthen relationships within the life sciences sector.

Many participants believed that with closer collaboration through a public-private partnership, there is an opportunity for improved communication and knowledge transfer within the sector. In particular, some participants observed that industry could gain a greater understanding of academia's skillsets and R&D capabilities, and academia could be aware of industry's needs in terms of technologies, platforms, talent development, and areas of commercialization.

GOVERNANCE

When designing and implementing an initiative to strengthen domestic biomanufacturing and innovation, what governance model(s) would be most effective?

Feedback was sought on suitable governance models that would maximize public benefits and commercial success of the initiative. In particular, participants were asked to identify governance models that would ensure a fair competitive life sciences sector that is attractive to global partners and to consider key factors for determining the involvement of the public and private sectors in the governance of biomanufacturing assets.

The discussions on governance primarily revolved around the biomanufacturing initiative as a whole, with participants describing what it should achieve, and in some cases suggesting key stakeholder participants. For the most part, the discussions on governance did not speak specifically to governance and operational models for a centre of facility.

Participants discussed governance in two contexts: during pandemics and public health crises, where speed and agility would be essential in emergency response efforts; and during more stable, longer-term, and fiscally sustainable times. Specifically, many participants expressed that governance during public health emergencies needs to have the ability to respond rapidly to emerging information. It should ensure there is a pandemic preparedness network that includes public and private sector partners, include the capability to navigate complex supply chains, maintain partnerships with other countries that would allow researchers to collaborate and share data, and ensure that the Government of Canada has access to resources and products when

needed. Such a network could also have agreements in place regarding where clinical trials are conducted, identifying access points and technology transfers, and securing raw materials.

Participants advocated for building a governance model that promotes close collaboration throughout the life sciences sector. There were several key stakeholder groups identified by many participants as being part of the ideal model, including: academics, industry associations, small- and medium-sized enterprises, biomanufacturing experts, government, regulators, and patients and patient advocacy groups. Strong, collaborative leadership with the support of an advisory committee was also suggested by several participants. Many participants felt that to be effective, the governance structure would need to be lean and nimble with balanced representation from academia, industry, and the government. Other participants believed that the governance model should look largely to leadership from the private sector, given its expertise in securing financing and maintaining supply of biologics on a large scale.

Many participants pointed to some existing domestic and international models that could potentially be adapted to the Canadian context. The governance structure used by the Institute of Canadian Directors (ICD) was mentioned as an example of a lean and nimble model to emulate and draw ideas from. The U.S. Biomedical Advanced Research and Development Authority (BARDA) is an organization that can mobilize research, priorities and large investments with speed and impact to support the ecosystem before, during, and after pandemics and was noted as a potential model by a large number of participants. Other models referenced by participants included the United Kingdom's Vaccines Manufacturing and Innovation Centre (VMIC) and Australia's Commonwealth Serum Laboratories (CSL) as examples of national efforts to build state-of-the-art and global scale biomanufacturing facilities.

Conclusion

The Government of Canada would like to thank everyone who took time to submit their feedback and ideas to this consultation. Comments received are being taken into consideration by ISED, Health Canada, and the Public Health Agency of Canada with respect to the creation of new biomanufacturing capacity for Canada.