MSF Submission – (Note that submission corresponds to the format of the consultation document)

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?

MSF Canada submits that Canada can play an important role in global pandemic preparedness. One key element on this mandate would be to develop affordable, accessible tools (e.g. vaccines, therapeutics, diagnostic tests) to respond to public health emergencies. More specifically, we suggest that Canada consider a focus on health or disease areas for which there is a market failure for which private for-profit companies are unlikely to provide a suitable response. Pandemic preparedness is one such area with high-need and, absent a global pandemic, little prospect of financial return. However, there are other areas of high-need, low-profitability where public health priorities are disconnected from profit-oriented solutions: neglected tropical diseases (e.g. Ebola, Lassa Fever, etc.), antimicrobial resistance (e.g. the development of new antibiotics, widely recognized as a significant public health threat yet a market failure), and others.

As one example, in the early 2000s, Canadian scientists developed an effective Ebola virus vaccine (rVSV-ZEBOV) at the National Microbiology Laboratory in Winnipeg. Much of the pre-clinical development work (and a significant amount of work thereafter) was conducted by Canadian government scientists. However, the lab lacks the ability to produce sufficient quantities of quality-assured vaccine and the requisite expertise required to conduct clinical trials. Therefore, the vaccine was licensed to an American company for subsequent development. This development, however, did not proceed and outsourcing the latter stages of development allowed this important vaccine to languish for years. The consequence was that it was not ready at the time of the 2014-2015 Ebola virus outbreak in West Africa.

Had Canada carried out the end-to-end development of this vaccine, it would almost certainly have been ready earlier, and lives would have been saved.

Today, Canada has promising vaccine candidates for other diseases whose value for global health outweighs their commercial value. This includes vaccines developed at the National Microbiology Laboratory against viral hemorrhagic fevers such as Marburg virus disease and for Lassa fever. Lassa fever in particular poses a serious public health threat in parts of West Africa where it is endemic. Despite hundreds of thousands of cases and thousands of deaths each year, at this time, there is no vaccine that has completed clinical trials and received regulatory approval. Supporting the development of the Lassa vaccine candidate discovered at the National Microbiology Laboratory could be an excellent application of a Canadian biologics and innovation initiative and, if successful, could represent a significant achievement of a Canadian biomanufacturing strategy, to manufacture a vaccine for which there is a high public health need and little to no commercial interest.

Such an initiative would help to advance Canada's innovation in this area. It would help to ensure Canada's publicly funded production facilities, whether at the National Research Council of Canada (NRC) facilities or elsewhere, are used to create a vital product Canadians (both scientists and the general public alike) can be proud of. Indeed, this element of job satisfaction in developing and producing a product the world needs should not be overlooked in attracting and retaining top talent in Canada.

It would also help ensure that those facilities – which maintain Canada's standing capacity – are used to their fullest extent, rather than left sitting idle when not being used for other products (e.g., COVID-19 vaccine). Furthermore, producing such a product for the global market would burnish Canada's reputation. Canada already spends money to ensure access to vaccines and Essential Medicines in other countries, through its support of mechanisms like Gavi and the Global Drug Facility (GDF). Producing its own drugs would support Canadians, while also underscoring Canada's role at the forefront of global health and the global community.

To conclude, the mandate of this initiative should be to provide a pathway to take Canadian innovation on important global health concerns from basic research to production of a patient-ready product, particularly (though not exclusively) for drugs, vaccines, diagnostic tests, and other health technologies for which a

market failure exists. Using examples of the (existing) Ebola virus vaccine and the (in development) Lassa fever vaccine, it can be seen how Canada could make full use of its research, development, and biomanufacturing capacity rather than let it sit idle, while at the same time filling an important niche, with important global public health impacts, by producing accessible, affordable vaccines (and treatments) for conditions that are frequently neglected by commercial pharmaceutical companies, regardless of the public health necessity and urgency of developing them.

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?

The scope for this initiative should be to focus on innovation to respond to public health priorities and unmet needs, and we specifically recommend that these objectives be delinked from, and not dependent on, commercial prospects or profit motivations, which have shown themselves to be out-of-step with public health needs. Supporting end-to-end development and production of crucial health technologies is a role Canada is well-prepared to play. This role also provides Canada flexibility in innovating new niche products, supporting novel Canadian ideas, and innovation.

Such operations should also be designed to be flexible in adapting to the production of different products. This both provides flexibility for innovators to experiment, and for Canada to make optimal use of such facilities when necessary (e.g., in a future pandemic).

As for the question of capacity, this initiative could be designed in such a way as to accommodate multiple innovators in the development and moderate scale production of a range of products. This would allow flexibility in developing, in total, sufficient capacity that could be converted to a future pandemic response, without relying on the production of a single large-capacity product to maintain Canada's overall capacity in non-pandemic periods.

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?

Forming close partnerships with Canadian experts, particularly in academia, and providing facilities to explore important innovations from end to end, is an important element of integration. The potential to see innovations from start to finish may offer a further incentive for attracting and retaining expertise in Canada. As such, use of these facilities for innovation as well as production is important.

This is also an area where the approach to intellectual property management deserves serious examination, including consideration of adopting an open science approach to foster knowledge building within Canada and in international collaborations.

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

As discussed in previous responses, utilizing this production capacity to both develop and produce the products of Canadian innovation (such as Ebola virus and Lassa fever vaccines), and to specifically focus on the manufacturing of technologies for which there are market failures, would be an effective way of sustaining these operations. Beyond a focus exclusively on Canadian-developed technologies, Canadian biomanufacturing capacity could also be used to support the production of medicines, vaccines, biologics, and other health technologies that already exist but for which there is no commercial market to support their continued manufacturing. For example, diphtheria antitoxin was developed in the late 19th century and remains essential for the treatment of diphtheria when cases occur. However, with the declining incidence of the disease (a success of increased use of an effective vaccine), the market for diphtheria antitoxin collapsed and there is no manufacturer producing it on a regular basis. There are other medicines – for example, various penicillins and snakebite antivenoms – that have suffered a similar fate of being in high-need, low-volume.

By filling niches of this kind, Canada plays an important role as a global citizen, while also not distorting market forces.

Promoting the development and production – a balance of research and commercial production – of multiple such projects is the best way of maximizing use of the facilities, including for the purposes of attracting and retaining expertise, and training the next generation of Canadian experts. By contrast, subletting these premises for a single commercial product leaves them too vulnerable to that specific product/partner, and also offers considerably less diversity with which to promote training and attract a variety of experts.

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

Whatever governance model is ultimately used, it should incorporate a broad spectrum of expertise, including in areas such as global health and humanitarianism. It should not be populated or driven exclusively by commercial considerations. The end goal should be innovation that responds to public health needs, rather than a focus solely on commercial or profit-making prospects.