MSF-USA Position on mRNA Manufacturing Scale-Up and Tech Transfer

**THE ISSUE:** Vastly inequitable distribution of COVID-19 vaccines. More than 80% of the world’s COVID-19 vaccines have gone to people in high income countries, with just 1% going to people in low-income countries. While immediately sharing COVID-19 vaccine doses is critically important, as the US has secured enough doses to protect its entire population of 330 million people and still has more than half a billion surplus vaccines left over, it isn’t enough. That’s why the US government must support policies to ramp up COVID-19 vaccine manufacturing and production in developing countries in order to address these stark inequities in access. Ensuring global vaccine equity is critical to all of us as the longer people worldwide are unvaccinated the more likely it is that new COVID-19 variants could take hold.

**WHAT MSF IS CALLING FOR:** The US government should ensure that the technology and know-how to produce at least one authorized mRNA vaccine is shared with the World Health Organization’s newly announced mRNA technology transfer hub in South Africa. COVID-19 cases are surging on the African continent, but there is currently limited vaccine manufacturing to meet the desperate and growing need. MSF applauds the Biden-Harris administration’s decision to support waiving intellectual property protections for COVID-19 vaccines, which could allow other manufacturers to legally make more COVID-19 vaccines. However, the waiver alone isn’t the solution to increasing access to vaccines worldwide. The US government must now pressure pharmaceutical companies to accelerate mRNA technology transfers to developing countries, including those in Africa. While mRNA manufacturers have transferred technology to a limited number of contracted partners in order to increase production, neither of the two companies with authorized vaccines have targeted qualified manufacturers in developing countries, where there is urgent need for expanded capacity.

**Why mRNA Manufacturing Scale-Up**

The novel mRNA technology is a game-changer in the COVID-19 vaccine story and will be a critical technology for future medical applications. COVID-19 mRNA vaccines (i.e. Moderna and Pfizer-BioNTech) demonstrate the greatest effectiveness at preventing infection, are easy to modify, and they are likely the most effective against emerging variants. While the current mRNA vaccines require special cold chain handling conditions that make them more difficult to use in low-resource settings, these challenges are not insurmountable as countries are prepared to store and administer these types of vaccines. The Moderna vaccine’s cold storage requirements, in particular, makes it more suitable for transport and storage in low-resource settings. The vaccine can be refrigerated for one month, and Moderna said it has data to support refrigeration for three months.

Additionally, mRNA vaccines are less time consuming to produce than traditional vaccines, and setting up mRNA manufacturing facilities requires less capital investment. The manufacturing is easier to scale as it does not rely on living cells. The agility of the technology makes adaptation to new COVID-19 variants very simple and the lead time from adaptation to manufacturing short (seven-week production cycle). Moreover, existing manufacturing facilities can be repurposed without prior experience in vaccine production or even the production of...
biologicals. For example, it took only six months for BioNTech to turn a cancer antibody factory into an mRNA vaccine factory, complete with regulatory approval.

For these reasons, mRNA platforms are easier to transfer to capable manufacturers with no previous expertise in vaccine manufacturing. The technology can also be adapted to target other pathogens—including those common in low-resource settings like HIV/AIDS—meaning the same platform can be “switched” to produce different vaccines, thereby offering enduring regional public health benefits.

Why Africa

To date, only approximately 1.1% of the 1.3 billion people living in Africa have been fully vaccinated against COVID-19. The continent is fully dependent on imports for COVID-19 and other vaccines. In the context of a pandemic and vaccine shortages, this means little or extremely delayed access. At the Virtual Conference: Expanding Africa’s Vaccine Manufacturing on April 13, 2021, African nations expressed a commitment at the highest level to create mRNA vaccine production capacity. The majority of MSF’s medical operations are located in Africa.

MSF has identified a potential list of companies operating in Tunisia, Egypt, South Africa, and Morocco with manufacturing capacity to produce COVID-19 mRNA vaccines. Scoping is based on:

1. The capacity of the company to deal with aseptic processing of medical products and therefore to comply with Good Manufacturing Practices for sterile pharmaceutical products
2. Accreditation from a Stringent Regulatory Authority or the WHO for the manufacturing of sterile pharmaceutical products
3. The National Regulatory Authority in the country has achieved or is likely to achieve WHO’s Maturity Level 3 accreditation for vaccines, which is a necessary condition for eligibility of the vaccines produced in the country for WHO prequalification

Why a Pilot Program

A successful pilot project to support mRNA production development can be replicated in other African countries and globally, thereby creating a distributed network of manufacturers which would minimize concentration of means of production and resulting nationalistic hoarding.

The mRNA technology opens the possibility of democratizing and geographically diversifying vaccine production capacity at a speed that would be impossible with traditional cell-based platforms.

US Government Opportunities

The US government, with its long history of international health and humanitarian assistance, has an opportunity to help end the pandemic by stepping up action to ensure equitable global access to vaccines. The US has facilitated global vaccine manufacturing scale-up before. For example, between 2006-2014, the United States Department of Health and Human Services’ Biomedical Advanced Research and Development Authority (BARDA) administered a program to provide technical and financial support for influenza vaccine production to fourteen manufacturers in thirteen countries. While the US has taken extraordinary measures to help develop vaccines at record pace during the COVID-19 pandemic, the work is not over until everyone, everywhere is vaccinated.
The US government invested significant public funds into COVID-19 vaccine research and development. Moderna’s COVID-19 vaccine’s clinical development, for example, was almost entirely funded by the US government. This means the government should—and is in a strong position to—*immediately facilitate technology transfer*—essentially “share the recipe”—of the Moderna mRNA vaccine to the WHO’s *newly-announced* mRNA technology transfer hub in South Africa.

Possible mechanisms for technology transfer are quickly evolving. In March 2021, the WHO *called* for the establishment of one or more technology hubs to provide manufacturers in low- and middle-income countries with the financial, training, and logistical support needed to scale up mRNA vaccine manufacturing. In June 2021, the WHO *announced* plans to support the first such hub in South Africa—a development that MSF welcomes. However, technology transfer occurs, whether through hubs like this one or the WHO’s COVID-19 Technology Access Pool, MSF advocates that the selected mechanisms ensure that:

1. Technology used is either free of intellectual property constraints in low- and middle-income countries (LMICs) or that such rights are made available through non-exclusive licenses to produce, export, and distribute the COVID-19 vaccine in LMICs, including through the COVAX Facility
2. Rights to use the technology extend beyond COVID-19
3. Rights to export produced vaccines to the region/other LMICs are protected
4. Public markets are prioritized over private markets

The Biden-Harris administration has significant leverage to facilitate vaccine recipe transfers. First, the government can mandate that US-based companies share knowledge under the Defense Production Act (DPA), which contains a broad information disclosure obligation. The US can also use the DPA to shape and prioritize amongst contracts with industry in order to address broad national security issues such as the threat of virus variants. While the DPA’s broad reach was not fully utilized in the recent domestic Johnson & Johnson and Merck partnerships, the administration reportedly *leveraged* the Act to ensure that the companies cooperated with one another to scale up vaccine production. Moreover, the federal government has still other powers beyond DPA to use or share products it has funded and—in the case of several leading coronavirus vaccines—even *owns a patent* on a necessary vaccine technology component.

The US government is in a strong position to facilitate the rapid sharing of knowledge to scale up mRNA vaccine manufacturing where it is needed most around the world. MSF urges the US to begin by using this power and a modest investment of resources to equip qualified manufacturers on the African continent to start production of mRNA COVID-19 vaccines as soon as possible. According to Public Citizen, $25 billion of designated funding to BARDA would produce 8 billion additional vaccines—enough for LMICs. Just a fraction of this sum would generate enough doses for Africa, meeting a need that is becoming more *urgent* by the moment, with the continent in the midst of a devastating third wave of COVID-19 and vaccine delivery at a virtual standstill.