



# Share mRNA Technologies, Save Lives

*Why sharing mRNA vaccine technologies with manufacturers in countries in Africa can help overcome this pandemic and prepare for future ones*

## Summary

The COVID-19 pandemic race to develop new vaccines has brought with it the introduction of revolutionary new technology: mRNA-based vaccines. Where available, mRNA-based COVID-19 vaccines are one type of new tool that can save lives and slow transmission, but too many people are being left behind waiting for access.

The World Health Organization (WHO) and many countries are already considering how to scale up mRNA and other vaccine manufacturing with existing vaccine manufacturers (e.g., BioVac and Institut Pasteur Dakar) through initiatives like the WHO COVID-19 mRNA Vaccine Technology Transfer Hub.<sup>1,2</sup> In addition to existing vaccine manufacturers, quality-assured injectable medicines manufacturers can be another potentially important source to increase mRNA vaccine production capacity, including for vaccine active pharmaceutical ingredients. For example, establishing mRNA vaccine production at an existing manufacturing site in at least one African country could create an annual production capacity of up to 100 million COVID-19 vaccine doses within 10 months in one of the regions most affected by vaccine shortages. Manufacturers, governments and WHO should work to ensure the Hub's success and utilise the additional production capacity injectable medicines manufacturers could offer to help deliver doses of mRNA vaccines still urgently needed to help protect millions of people from COVID-19.

## mRNA vaccines are a revolutionary new medical technology

The novel mRNA technology is a game changer in the COVID-19 vaccine story and will likely be an important technology for future medical applications. For a number of reasons, increasing access to these vaccines has the potential to improve our ability to protect people against COVID-19.

### 1. mRNA vaccines are effective and easy to modify

The two WHO-listed COVID-19 mRNA vaccines (by BioNTech-Pfizer and Moderna) demonstrate the greatest effectiveness at preventing infection, are easy to modify for new variants and are likely the most effective against emerging variants.<sup>3</sup> The agility of mRNA technology makes adaptation to new COVID-19 variants relatively simple, and the lead time from adaptation to manufacturing is relatively short. For example, it took Moderna about 30 days to develop an adapted version of their mRNA vaccine for a new COVID-19 variant and have it ready to be used in a Phase 1 clinical trial.<sup>4</sup> In contrast, the shortest time to adapt an adenoviral platform vaccine for a COVID-19 variant has been five months.<sup>5,6,7</sup>

The mRNA technology can also be adapted to target other pathogens, meaning the same platform can be 'switched' to produce different vaccines or even therapeutics.<sup>8</sup> Thus, in the longer term, building capacity to produce mRNA vaccines within a region may offer benefits for regional public health beyond supplying COVID-19 vaccines.

## **2. mRNA vaccines are simpler, faster and cheaper to manufacture than traditional vaccines<sup>9</sup>**

Production of mRNA vaccines is a relatively simple, cell-free process more akin to biochemical synthesis than traditional cell-based production of vaccines, which relies on living cells in the production process, adding complexity and variability. Manufacturing of mRNA vaccines is also relatively easier to scale up, as it relies on chemical not biological processes. The relative simplicity and robustness of the process of manufacturing mRNA vaccines makes it easier to standardise and therefore to transfer to more facilities in short timeframes. Pfizer can produce a batch of active pharmaceutical ingredient in three to seven days (plus additional time for fill, finish and quality control), whereas even the most rapid adenoviral vaccine production platforms like AstraZeneca's take two months to produce a batch of active pharmaceutical ingredient.<sup>10</sup>

Moreover, existing manufacturing facilities can likely be repurposed to produce mRNA vaccines without having prior experience in vaccine production or even the production of biologicals. For example, BioNTech turned a cancer antibody factory into an mRNA vaccine factory in only six months, complete with regulatory approval.<sup>11</sup> Rovi, a Spanish manufacturer of injectable, non-biologic medicines, will soon be producing Moderna's vaccine active pharmaceutical ingredient.<sup>12</sup>

A number of contract development and manufacturing organisations (CDMOs) and pharmaceutical companies operating under CDMO contracts are currently producing or expected to produce the active pharmaceutical ingredient for BioNTech-Pfizer and Moderna. The experiences of these CDMOs similarly indicate that mRNA vaccines can be produced more simply than traditional vaccines, for the following reasons:

- Most of these CDMOs had not produced any vaccines previously.
- Some have expertise in producing biological medicines (e.g., Lonza), but some only produce injectable, non-biological medicines (e.g., Rovi).<sup>13</sup>
- Observed or expected timelines between manufacturing deal announcements and first batches are within nine months (Annex 1).

Additionally, the small dosages and volumes of materials required for producing mRNA vaccines result in considerably lower manufacturing capacity requirements compared to other production platforms, while producing the same number of doses. This in turn means lower upfront capital investments and the possibility of retrofitting parts of existing injectable medicines production facilities to produce mRNA-based vaccines, while continuing the facilities' regular production activities.<sup>14</sup>

## **3. Future versions of mRNA vaccines may be more thermostable**

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.

BioNTech-Pfizer and Moderna have been generating data to support longer storage at 2-8°C for their mRNA vaccines. These companies, along with others, are also working on more thermostable second-generation mRNA vaccines. Thus, mRNA vaccines should not be discounted as not feasible in low-resources settings based solely on current cold-chain requirements, as these may change soon.

## Existing manufacturers in countries in Africa can make mRNA vaccines

African countries are currently almost entirely dependent on imports for COVID-19 and other vaccines.<sup>15</sup> In the context of a pandemic and vaccine shortages, this means limited and extremely delayed access. At the Africa Centres for Disease Control and Prevention's *Virtual Conference: Expanding Africa's Vaccine Manufacturing* on 13 April 2021, the African Union committed to creating vaccine manufacturing capacity to reduce dependency on imports.<sup>16</sup>

While creating new capacity for cell-based vaccine manufacturing platforms will take years, mRNA technology can offer a faster way of establishing new production capacity, including for active pharmaceutical ingredients, by leveraging existing manufacturing sites currently producing injectable medicines.

At least seven manufacturers actively producing sterile injectable medical products and based in African countries meet two basic prerequisites indicating the quality-assured manufacturing capacity necessary to produce COVID-19 mRNA vaccines, based on Médecins Sans Frontières' (MSF) analysis (Annex 2). These prerequisites include:<sup>a</sup>

- Accreditation from a stringent regulatory authority or WHO for the manufacturing of sterile pharmaceutical products.
- Operations based in a country where the national regulatory authority is a Pharmaceutical Inspection Co-operation Scheme (PIC/S) member or has achieved or is likely to achieve WHO's Maturity Level 3 accreditation for vaccines within the next 12 months.<sup>17</sup> Maturity Level 3 accreditation is a necessary condition for WHO prequalification eligibility for the vaccines produced in the country.

Setting up the capacity to produce up to 100 million doses annually is possible for manufacturers based in countries in Africa within a 10-month timeframe, based on observed timelines for similar manufacturing deals (Annex 1). Manufacturers would need to have full access to mRNA vaccine materials from the same suppliers as the companies that launched the vaccines first. Manufacturers would also need to leverage existing infrastructure (e.g., facilities, water for injection production) and their pre-existing know-how in quality-assurance management of aseptic processes.

Based on an analysis by Imperial College of London commissioned by MSF, the estimated total cost needed for starting up mRNA vaccine manufacturing in an existing manufacturing site

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<sup>a</sup> These prerequisites are needed, but not necessarily sufficient. Manufacturers' actual capacity to begin producing mRNA vaccines will depend upon a case-by-case gap analysis and an evaluation of necessary actions to address any identified gaps.

and producing 100 million doses could be as little as US\$127 million for BioNTech-Pfizer's vaccine and \$270 million for Moderna's vaccine.<sup>b,10</sup>

A pilot project to support mRNA production development could be initiated and, if successful, replicated in other countries and regions with no vaccine production capacity. This could create a geographically distributed network of manufacturers, diversifying production and leading to autonomy of supply for future pandemics, minimising the supply shortages that currently result in nationalistic hoarding.

## Recommendations

Increasing and diversifying production and supply of mRNA vaccines through additional manufacturers, beginning with those based in countries in Africa, offers an opportunity to deliver urgently needed additional mRNA vaccine supplies where they are lacking most.

To get started, we need companies, governments and international organisations to step up and support these efforts:

- **Developers of WHO-listed mRNA vaccines**, BioNTech-Pfizer and Moderna, should urgently share their vaccine technologies via technology transfer to manufacturers with mRNA vaccine production capacity in countries in Africa. WHO's COVID-19 mRNA Vaccine Technology Transfer Hub, created to provide staff training, research and development support and facilitation of full technology transfer for the mRNA vaccine platform to diversify production capacity, should serve as a mechanism to facilitate this exchange.<sup>18</sup>
- **WHO's COVID-19 mRNA Vaccine Technology Transfer Hub** and all technology transfer partners should ensure that mRNA technology used is either free of intellectual property constraints at least in all low- and middle-income countries (LMICs) or that intellectual property rights are made available through transparent, non-exclusive licenses to produce, export and distribute the COVID-19 vaccine in all LMICs, including through the COVAX Facility. Additionally, the rights to use, further develop, produce and supply the technology should extend beyond COVID-19.
- **All governments** should utilise all legal, political and policy options to facilitate and diversify vaccine production and supply and overcome the refusal to share technologies and intellectual property by technology-holding companies. Governments should also provide financial and technical support to the WHO COVID-19 mRNA Vaccine Technology Transfer Hub.
- **Governments hosting manufacturers receiving mRNA technology** should work with WHO to ensure their national regulatory agency is eligible for WHO prequalification of vaccines (Maturity Level 3).
- **The US government, German government and European Commission** should ensure by all political, legal and financial means possible that WHO-listed mRNA vaccine developers based in their jurisdictions share their technologies with the Hub.

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<sup>b</sup> Investments needed for mRNA manufacturing are extremely sensitive to the [dose of mRNA](#) used in the vaccine. BioNTech-Pfizer's vaccine is 30 micrograms of mRNA per vaccine. Moderna's vaccine is 100 micrograms of mRNA per vaccine.

## Annex 1: Announced deals for the production of mRNA active pharmaceutical ingredients

Vaccine	Manufacturer	Country	Announced	Delivery of first batches	Timeline
Moderna	Lonza <sup>19</sup>	Switzerland/United States	May 2020	July 2020	3 months
Moderna	Rovi <sup>12</sup>	Spain	April 2020	September 2021 (estimated)	4-5 months
Moderna	Samsung Biologics <sup>20</sup>	Republic of Korea	June 2021	March 2022 (estimated)	6-8 months
BioNTech-Pfizer	BioNTech <sup>21</sup>	Germany	September 2020	February 2021	6 months
BioNTech-Pfizer	Pfizer <sup>22</sup>	United States	April 2020	November 2020	7 months
BioNTech-Pfizer	Rentschler Biopharma <sup>23,24</sup>	Germany	October 2020	December 2020	3 months
BioNTech-Pfizer	Fosun <sup>25</sup>	China	May 2021	August 2021	4 months

## Annex 2: Companies in countries in Africa with potential manufacturing capacity for mRNA vaccine production

Based on MSF's analysis of publicly available information, at least seven companies based in countries in Africa produce sterile injectable medical products and currently meet prerequisites to produce quality-assured COVID-19 mRNA vaccines (see "Existing manufacturers in countries in Africa can make mRNA vaccines"). This preliminary list needs to be further refined through direct contacts with these companies to establish a detailed gap analysis and determine the investments that would be needed for successful mRNA platform technology transfer.

Company	Site Address	Inspecting Regulatory Authority <sup>c</sup>
Aspen Pharmacare <sup>26</sup>	<b>South Africa</b> Port Elizabeth	United States, WHO
Egyptian International Pharmaceutical Industries Co. <sup>27</sup>	<b>Egypt</b> Industrial Aria B1, 10th of Ramadan City, P.O. BOX 149 - 10 <sup>th</sup>	Romania
EVA Pharma <sup>28</sup>	<b>Egypt</b> 176., El Sadat Str., Kafr El-Gabal, El-Haram, Giza	Hungary
Global Pharmaceutical Industries <sup>29</sup>	<b>Egypt</b> Part no.2A, 5th Industrial Zone, 6th of October City	Romania
Laboratoires UNIMED <sup>30</sup>	<b>Tunisia</b> Z.I. 4060, Kalaa Kebira, BP 38	France
Les Laboratoires Médis S.A. <sup>31</sup>	<b>Tunisia</b> Route de Tunis Km7 B.P., Nabeu-I Tunisie, 206 8000	Czech Republic
SOTHEMA <sup>32</sup>	<b>Morocco</b> BP N° 1, Bouskoura, 20180	Netherlands

<sup>c</sup> Sources for manufacturer accreditations: [Aspen website](#) for Aspen, EMA's [EudraGMDP database](#) for all others.

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