

Consortium sparks debate over intellectual property of mRNA vaccines manufactured in SA

By  Katja Hamilton

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The mRNA technology transfer programme reached new heights this week when more than 200 members from around the world landed in Cape Town to celebrate the official launch of the programme's hub at Afrigen.



Source: [Pexels](#)

Afrigen is a South African biotechnology startup [working with](#) the WHO to develop mRNA vaccines, not only Covid vaccines, but mRNA vaccines for HIV, TB, malaria, vaso [sickle cell disease], dengue fever, and Ebola.

This milestone kickstarted a five-day meeting that is reviewing the progress of the mRNA technology transfer programme since WHO and Medicines Patent Pool (MPP) set it up in June 2021. Participants are [discussing](#) intellectual-property issues and regulatory aspects surrounding mRNA technologies linked to HIV and tuberculosis.

"The entire Afrigen team is thrilled to reach this important milestone with the completion of the mRNA technology platform," Petro Terblanche, executive director of Afrigen said in a [statement](#). "This platform is housed within the end-to-end mRNA vaccine development and production facility where the mRNA hub Covid 19 vaccine candidate AfriVac 2121 is currently in scale-up phase."

The vaccine candidate [will be tested](#) on humans in early 2024. Its launch is [estimated](#) to be released by May next year.

WHO's director general in attendance

The inauguration of the hub took place at a ribbon cutting ceremony at Afrigen on 20 April, and was attended by World Health Organization (WHO) Director General, Tedros Adhanom Ghebreyesus, Minister of Health Joe Phaahla, and Minister of Trade and Industry, Ebrahim Patel together with high-level officials from funding countries.

“I am delighted to be here in Cape Town with our partners to support a sustainable model for mRNA technology transfer to give low- and middle-income countries equitable access to vaccines and other lifesaving health products,” said Ghebreyesus. “I am immensely proud of the achievement of all those involved in this project. In less than two years we have shown that when we work collaboratively, we succeed collectively.”

WHO [announced](#) on 21 June 2021 that the consortium, Afrigen Medical Research and Biovac will be the technology transfer hosts of the mRNA technology transfer programme: Afrigen the hub, Biovac the first spoke, with the Medical Research Council managing the clinical trials and the R&D programme.



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It was [planned](#) that Afrigen would develop a Covid-19 vaccine and the know-how transferred to at least 15 production facilities in low-and middle-income countries across the world.

“There are spokes in five African countries [Kenya, Nigeria, Senegal, Egypt and Tunisia] but Afrigen is running parallel with the Eastern and South American companies; and the 15 companies - depending on the readiness of each company - will get on-stream for production almost parallel depending on capacity,” Terblanche [said](#).

The participants of the five-day meeting that are reviewing the progress of the mRNA technology transfer programme include the biomanufacturing partners, leading experts, industry, civil-society representatives, and funders.

Focus on intellectual property issues and regulation

During the meeting, the participants will share progress and discuss critical enablers for the sustainability of the programme such as intellectual-property issues and regulatory aspects, as well as the science of mRNA technologies and key applications relevant to LMICs in other disease areas such as HIV and tuberculosis.

“ Delighted to be in Cape Town,  to support a sustainable model for mRNA technology transfer to give low- & middle-income countries equitable access to lifesaving health products: <https://t.co/Aqv17SnJY5>
Proud of such initiatives with lasting impact for generations ahead. [#WHO75](#) pic.twitter.com/ZGGHEu4AyH— Tedros Adhanom Ghebreyesus (@DrTedros) [April 20, 2023](#) ”

In a media [statement](#) released by the WHO, the Covid-19 pandemic has underscored that gross inequity exists in access to health products, especially vaccines. “As of March 2023, more than three years after WHO declared Covid-19 a public health emergency of international concern (PHEIC), 69.7% of the global population had received at least one dose of a Covid-19 vaccine. Notably, this proportion still remains below 30% in low-income countries (LICs),” it said.

“This programme aims to contribute to equitable access to mRNA vaccines by increasing the distribution of sustainable manufacturing capacity across LMICs, enhancing regional and inter-regional collaborations, and developing and empowering a local workforce through tailored and inclusive training and expert support.

"What is unique in the mRNA technology transfer model is the multilateral process that allows sharing of technologies to multiple recipients so that, through local and regional production, those in need can be reached rapidly."

Afrigen in the history books

Over the last 18 months, Afrigen has undergone an incredible transformation with the support of a network of partners and mentors enabled by the mRNA technology transfer programme.

"We have grown our capability and capacity to meet the highest quality standards of mRNA vaccine development, serving the objective to build sustainable capacity in LMICs to produce mRNA vaccines," Terblanche said.

"Afrigen has successfully established a Covid-19 vaccine manufacturing process at a laboratory scale and is currently scaling up that process to a level suitable for manufacturing vaccine batches to be used in Phase I/ II clinical trials to good manufacturing practice (GMP) standards. In a parallel process, Afrigen will continue to carry out training and technology transfer to the network partners."



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The funders play a crucial role in supporting the mRNA technology transfer programme with total funding to date at \$117m and France being the first to fund the mRNA technology transfer work.

Present at the inauguration were representatives from the European Commission, Belgium, Germany, as well as Norway, Canada, African Union, South Africa, and the Elma Foundation.

Caroline Delany, GlobalAffairs Canada's director general for southern and eastern Africa said: "Canada reaffirms its continued support of the mRNA technology transfer programme and we are delighted to announce a further contribution of 15m Canadian dollars.

“ The [@CityofCT](#)'s Mayoral Committee has approved the transfer of land in Ndabeni & Maitland to the Biologicals & Vaccines Institute of SA for the possible expansion of the Cape Health Technology Park which comprises of offices, research labs, and manufacturing plants (1/3)— [PropertyWheel \(@PropertyWheel\) February 22, 2023](#) ”

"This brings Canada's total contribution to the programme up to 45m Canadian dollars. These funds support the running of the hub in South Africa as well as network partners around the world. We firmly believe in the importance of building capacity at local and regional level."

Martin Seychell, deputy executive director of the European Commission (EC), said: "The EC has already contributed €40m to the establishment of the mRNA technology transfer hub and has recently signed another grant with the European Investment Bank EIB for €15,5m to facilitate the expansion of vaccines manufacturing capacity.

"This is part of the overall investment under the EU Global Gateway strategy, where more than €1bn has been mobilised under the Team Europe Initiative on manufacturing health products. It is now particularly important to also address possible regulatory and demand bottlenecks, to ensure not only production of vaccines of the highest standard in all regions of the world, but also rapid and equitable access to those vaccines."

ABOUT KATJA HAMILTON

Katja is the Finance, Property and Healthcare Editor at Bizcommunity.

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