



The BMJ

madlen.davies@bmj.com

Cite this as: *BMJ* 2022;376:e304<http://dx.doi.org/10.1136/bmj.o304>

Published: 09 February 2022

INVESTIGATION

Covid-19: WHO efforts to bring vaccine manufacturing to Africa are undermined by the drug industry, documents show

The World Health Organization aims to help African companies make covid vaccines. Why did BioNTech's representative tell governments that the project was doomed? **Madlen Davies** reports

Madlen Davies *investigations editor*

A foundation representing the vaccine maker BioNTech has been accused of seeking to undermine the World Health Organization's initiative to bring covid vaccine manufacturing to the African continent, *The BMJ* can reveal.

The kENUP Foundation, a consultancy hired by BioNTech, has claimed that WHO's hub, which is creating a covid-19 mRNA vaccine that African companies can make, is unlikely to be successful and will infringe on patents, documents obtained by *The BMJ* have shown. Instead, they show kENUP promoting BioNTech's proposal to ship mRNA factories housed in sea containers from Europe to Africa, initially staffed with BioNTech workers, and a proposed new regulatory pathway to approve the vaccines made in these factories. The novel pathway has been described as paternalistic and unworkable by some experts, as it seems to bypass local regulators.

The move threatens the pan-African venture backed by WHO that seeks to scale up African production of lifesaving vaccines from 1% to 60% by 2040.¹ The documents, published for the first time, reveal new details of the proposal from kENUP and BioNTech and their criticism of the WHO venture.

The public approach

WHO's technology transfer hub, launched in June 2021 and based in South Africa, uses publicly available information to recreate Moderna's vaccine, to teach companies and scientists across the continent how to use mRNA technology. It will then develop a comparable vaccine, which, if successful in clinical trials and approved by regulators, it will manufacture industrially.

Two South African companies, Afrigen Biologics and the Biovac Institute, have joined a consortium to develop and manufacture the mRNA vaccine, with guidance from organisations including WHO, the Medicines Patent Pool, the South Africa Medical Research Council, and the Africa Centres for Disease Control (Africa CDC). This is part of the wider Partners for African Vaccine Manufacturing project coordinated by Africa CDC, launched in April 2021.

In a document sent to South African government officials after a visit to the country on 11-14 August last year, the kENUP Foundation said that the hub's

activity should be stopped. kENUP's *Mission Report to South Africa* (see supplementary materials in "Related content") said, "The WHO Vaccine Technology Transfer Hub's project of copying the manufacturing process of Moderna's COVID-19 vaccine should be terminated immediately. This is to prevent damage to Afrigen, BioVac, and Moderna ..."

"Provided that the release from patent cover will be granted by Moderna only during the pandemic, the sustainability outlook for this project of the WHO Vaccine Technology Transfer Hub is not favourable."

The Medicines Patent Pool, which supports the WHO hub, responded in November to claims that this would infringe patents.² "Unfounded rumours have been circulating that the mRNA vaccine technology transfer hub being established in South Africa intends to infringe patents," said a press release. "The Medicines Patent Pool, which is responsible for the intellectual property and licensing elements of the hub, wishes to make it clear that this is not the case."

South African law contains a provision authorising scientists and manufacturers to carry out research and development regardless of patent protection, meaning that the hub's reverse engineering of Moderna's vaccine is legal, it added. Moderna has also publicly promised not to enforce its covid-19 related patents during the pandemic and said that it was willing to license its intellectual property after that period. The hub is in talks with Moderna to obtain such a license.

Charles Gore, executive director of the Medicines Patents Pool, told *The BMJ* that the rumours were "ridiculous." He said, "Clearly, somebody has been going around Africa saying that we're going to infringe patents, which is extremely unfortunate since it's completely untrue."

Petro Terblanche, managing director of Afrigen Biologics and Vaccines, a biotech company developing the vaccine for the hub, said that kENUP's activities meant she had to defend her company's work to the South African government, funders, and the media. "I don't understand why kENUP, actively and in many forums, tries to undermine Afrigen's work," she said. "It drains energy that I could have spent making a vaccine."

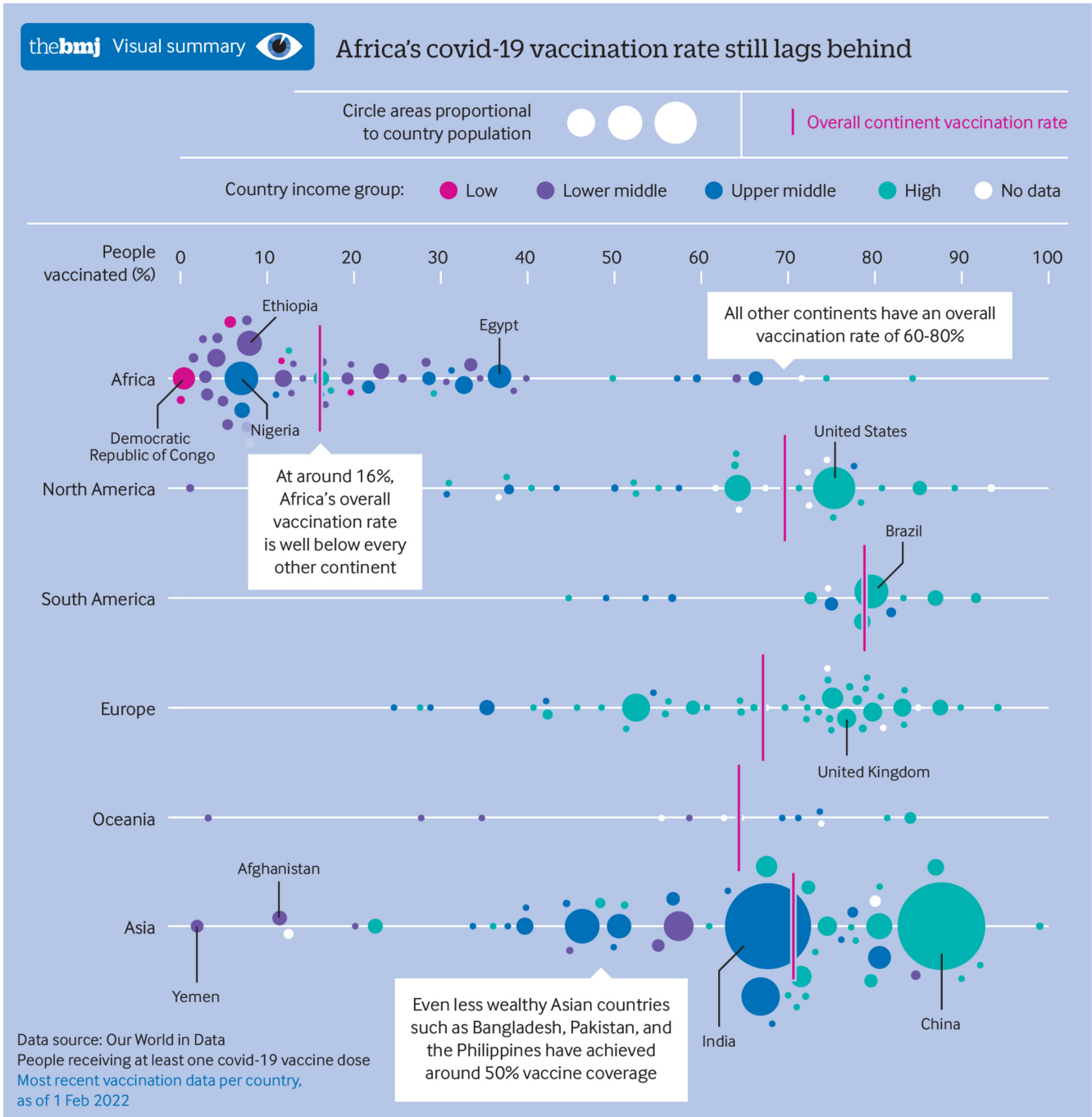


Fig 1 | Visual summary

In January, Afrigen successfully reproduced Moderna's full vaccine, both the mRNA and the formulation—the final vaccine that introduces the active ingredient into the body. It will now experiment with other formulations that are cheaper to produce and don't need to be frozen in storage—a necessity if it's to be given out in many African settings. Afrigen is in talks with two biotech companies to help scale up manufacturing, and it hopes to begin clinical trials in November 2022, Terblanche said.

Ellen 't Hoen, a lawyer and public health advocate, said that BioNTech should be accountable for kENUP's actions. "If you run a not-for-profit foundation and you go around trying to stop people from developing lifesaving vaccines, then I don't know what your

agenda is but it smells really bad," she said. "If kENUP is on the BioNTech payroll, then BioNTech should be held accountable for this kind of behaviour."

The kENUP Foundation did not directly address the allegations or answer *The BMJ's* questions, but it said in a statement that it was "committed to global collaboration in the fight against infectious diseases." It added that it "has always coordinated with important intergovernmental organisations, such as WHO and Africa CDC."

BioNTech also said in a statement that its plans to establish mRNA based vaccine manufacturing on the African continent "will be done

in close alignment with the WHO, the African Union, and the African CDC.”

Refusal to share

These initiatives were launched owing to vast global inequities in covid vaccine distribution. By the end of last month 10 billion doses were administered around the world, but only 346 million had been given out in African countries.³ Booster programmes are under way in Europe and North America despite WHO’s pleas for first doses to be prioritised.

It was hoped that Pfizer-BioNTech or Moderna would share technology and know-how with the hub, which could go on to teach African companies, and hubs in other countries, how to make the vaccines. So far both companies have refused, although the hub is in discussions with Moderna over some form of collaboration—probably a voluntary licence, an authorisation given to companies to allow them to produce Moderna’s vaccine in exchange for a royalty. In a statement, a Moderna spokesperson said that trying to accelerate technology transfers could “put at risk” the delivery of its current production lines, with “negative efficiency, safety, and quality consequences.”

Ellen ’t Hoen said, “These companies are so reluctant to share the technology because their eye is on the big ship of gold for cancer and other diseases that are very prevalent in high income countries.” Both Pfizer and BioNTech disagreed with this characterisation, arguing that sharing the technology would not lead to increased vaccine supplies in the short term and could take the raw ingredients needed away from established manufacturers.

The process of making a covid vaccine would have taken a year with the help of the companies, but without them it will take three, said Martin Friede, coordinator of the Initiative for Vaccine Research at WHO, which is supporting the hub’s work. Afrigen and Biovac can manufacture as many as 500 million doses a year, although capacity will increase once other companies throughout the continent learn to make the vaccine. Friede anticipates bottlenecks from shortages of reagents, glass vials, and trained staff.

In October 2021, five months after the hub was formally announced, both Moderna and BioNTech announced their own initiatives. Moderna announced that it would spend as much as \$500m (£370m; €437m) to build its vaccine plant in Africa, aiming to make 500 million doses of mRNA vaccines each year.⁴ It said that it planned to begin filling doses there in 2023 and hoped to make other mRNA products at the facility too.

That same month, BioNTech announced that it had signed memorandums of understanding with the governments of Rwanda and Senegal to build mRNA production facilities, with construction beginning in mid-2022.⁵ BioNTech said that the factories would make around 50 million doses of vaccine a year once fully operational, with further factories added until several hundreds of millions of doses could be made.

Sea containers

kENUP’s *Mission Report to South Africa*, sent to the South African government last August, describes BioNTech’s initiative. It proposes exporting fully equipped mRNA production lines in a series of sea containers. Made in Europe and staffed initially by BioNTech workers, these sea container factories would create the mRNA, the active ingredient of the vaccine, which would need to be put into vials by another company (a process known as “fill and finish”). The document proposes such a set-up in South Africa.

A second kENUP Foundation document, marked as confidential and sent to South African and European government officials in November, describes a framework to regulate such factories. This “white book” document (see supplementary materials in “Related content”) suggests that in order to quickly begin producing mRNA vaccines on the African continent, a new regulatory pathway should be agreed in which the sea container factories are licensed by the European Medicines Agency. It claims that this allows them to be fast tracked for WHO prequalification, the global mechanism for ensuring a medicine’s safety, efficacy, and quality. The document describes building up local regulatory capacity in the longer term.

But regulatory experts contacted by *The BMJ* said that this concept was flawed. Containers can be “useful innovations” for flexible manufacturing and distribution of vaccines, said Prashant Yadav, a senior fellow at the Center for Global Development. “However, they need to be approved by local regulatory bodies, and there should be a local quality responsible person from the country or site where such modular manufacturing is to be used,” he added.

Marie-Paule Kieny, who chairs the hub’s steering committee as chair of the Medicines Patent Pool and worked for decades on vaccines at WHO, said that it was “pure nonsense” to believe that a European Medicines Agency licence that was intended to authorise vaccines used in Europe would apply to those made on a different continent under such different circumstances. “Only somebody who doesn’t know how it works can say something like that,” she said.

Local regulators are needed to test vaccines before they are released to market, something that European regulators will not carry out for African countries, said Kieny. She described kENUP’s proposed regulatory approach as “paternalistic” and advocated more locally owned schemes.

Margareth Sigonda-Ndomondo, who is leading on regulation for Partners for African Vaccine Manufacturing, said that her department had had several interactions with kENUP about its white book and that it was “not well informed.” She rejects the idea that the African regulatory system doesn’t have capacity and that another route for approval is needed. “So, we have actually expressed our concern to say we do have existing systems on the continent,” she said. “We have explained to them that all they need to do is to work within the existing initiatives, structures, and systems.”

The African Medicines Agency was ratified in 2021 and will harmonise regulation across the continent. South Africa has a laboratory able to carry out the necessary tests, which has been inspected by WHO, hopefully allowing its regulator to approve vaccines by the end of the year, she said. Once it does, it could act as a centre for excellence, supporting other regulators.

Sigonda-Ndomondo added that kENUP and BioNTech could not expect to bring in mRNA factories and expect African regulatory agencies to “give the go ahead without having to go through the scientific review process.” However, she welcomed plans to build mRNA factories on the continent and said that she would continue engaging with kENUP to find a solution that would allow African people access to these vaccines.

Others are waiting with interest for more granular details on the kENUP and BioNTech proposal. “The real proof of the pudding is going to be, ‘Will this vaccine, made in Rwanda and approved through this novel regulatory process, be accepted in Europe?’” said Patrick Tippoo, executive director of the African Vaccine Manufacturing Initiative and head of science and innovation at Biovac. “And if the answer to that is yes, then I would say, maybe it could be accepted in Africa as well.”

What is the kENUP Foundation?

The kENUP Foundation is a public interest foundation, with offices “magnificently overlooking the Grand Harbour” in Kalkara, Malta, its website states. Its chief executive, Holm Keller, was previously chancellor of Leuphana University in Germany and a consultant at McKinsey. Often seen in a yellow scarf, Keller is shown on kENUP’s website and in documents meeting government officials and scientists throughout Africa over the past year. Keller has told *The BMJ* that kENUP’s work on bringing mRNA vaccines to the continent is funded by BioNTech.

The foundation makes money from its consultancy services and has an affiliated company that invests in healthcare. The EU Transparency Register states that in 2020 kENUP had a total budget of €3.2m (£2.7m; \$3.7m). Most of its revenue, €3m, came from consulting, and it estimated maximum costs of €1.25m.

kENUP has worked on projects across a wide range of issues, including science and healthcare, musicians’ digital rights, blockchain technology, financial technology, and education. One of its highest profile projects was founding the EU Malaria Fund, which aimed to connect biotech companies making vaccines, drugs, or tests for malaria that had not been pursued by the drug industry, with funders that could offer loans at preferential rates. It partnered with the European Investment Bank and Investitionsbank Berlin. After initial plans to create a fund of €500m, the fund gave out €70m and was closed in June 2020 after one year.

Three recipients contacted by *The BMJ* told of their surprise when the fund closed, as they had received only one tranche of money when they had expected funding for years. They said that they were all directly

approached by kENUP to participate in the fund and had spent a lot of time writing proposals for its scientific and investment review boards.

Andrew Tobin, of Keltic Pharma Therapeutics in Dublin, said that both boards had signed off on a €29m investment to help the company develop an antimalarial drug over five years. But it received only €5m before the fund closed. “The business case is really built on €29m,” said Tobin. “So, we were a little bit disappointed that did not come through. But we are highly optimistic of filling the gap in funding.”

Similarly, Stephen Hoffman of Sanaria Inc, based in Rockville, Maryland, received €12.9m to develop its own malaria vaccine, but it expected to receive similar amounts for another two years. “So, you go out on the line and you spend, and all of a sudden there’s no more funding,” he said. “That’s a pretty anxiety provoking position to put yourself in.”

Ernst Böhnlein and Michael Lanzer of Sumaya Biotech in Heidelberg, Germany, said that they had received €7.3m to fund a clinical trial of their adenovirus vectored malaria vaccine in an African country, expecting to receive funding for five years. They are grateful to kENUP but now have to search for more funding. “The big dream became a smaller dream. At least we got started, and many other smaller companies got started,” said Lanzer.

After the fund closed, kENUP launched the Eradicate Malaria project, which is supporting BioNTech in its aim of developing an mRNA malaria vaccine that will be manufactured end to end on the African continent. This project is funded by BioNTech.

The EU Malaria Fund said that it had fully complied with all contractual obligations and that “all companies were informed directly and in due time . . . about the end of its investment period.”



Fig 2 | Holm Keller

This article was funded by *The BMJ's* Investigations Unit. For more details go to <https://www.bmj.com/investigations>

Competing interests: See [bmj.com/about-bmj/editorial-staff](https://www.bmj.com/about-bmj/editorial-staff)

Provenance and peer review: Commissioned; externally peer reviewed.

- 1 Partnership for African Vaccine Manufacturing. Concept note. 7 Dec 2021. https://africacdc.org/wp-content/uploads/2021/11/ENGLISH_PAVM_Public-Stakeholder-Engagement_Concept-note_Final-version.pdf

- 2 Medicines Patent Pool. MPP position statement on patents with regards to the mRNA vaccine technology transfer hub. 16 Nov 2021. <https://medicinespatentpool.org/news-publications-post/mpp-position-statement-on-patents-with-regards-to-the-mrna-vaccine-technology-transfer-hub>
- 3 Our World in Data. 28 Jan 2022. <https://ourworldindata.org/grapher/cumulative-covid-vaccinations-continent?country=Africa~Asia~Europe~North+America~Oceania~South+America>
- 4 Moderna. Moderna to build state-of-the-art mRNA facility in Africa to manufacture up to 500 million doses per year. 7 Oct 2021. <https://investors.modernatx.com/news/news-details/2021/Moderna-to-Build-State-of-the-Art-mRNA-Facility-in-Africa-to-Manufacture-up-to-500-Million-Doses-Per-Year-10-07-2021/default.aspx>
- 5 BioNTech. BioNTech plans to initiate the construction of an mRNA vaccine manufacturing facility in Africa in mid-2022. 26 Oct 2021. <https://investors.biontech.de/news-releases/news-release-details/biontech-plans-initiate-construction-mrna-vaccine-manufacturing>

This article is made freely available for personal use in accordance with BMJ's website terms and conditions for the duration of the covid-19 pandemic or until otherwise determined by BMJ. You may download and print the article for any lawful, non-commercial purpose (including text and data mining) provided that all copyright notices and trade marks are retained.