

▶ BACKUP HEALTH

Improving framework conditions for local vaccine production in Africa

The challenges

Africa currently produces less than 1% of the vaccines the continent needs, with only a small number of African manufacturers involved. This makes the African continent critically dependent on international producers for vaccines across the spectrum, from immunisation for babies to important vaccines for adults. The COVID-19 pandemic has vividly illustrated the constraints that this dependency brings, as African countries struggled to rapidly source sufficient quantities of vaccines and other consumables. Expanding vaccine production in Africa is now a key objective on the international agenda. Most notably, the African Union has set the target of having 60% of vaccines produced locally by 2040.

Building sustainable vaccine production in Africa will entail not only massive investment in manufacturing facilities and infrastructure – challenges remain in the overall context. In most countries, regulatory processes and quality assurance are not yet at the level needed to comply with the exacting safety standards set for vaccine production. The marked shortage of skilled staff and high manufacturing costs are additional obstacles. The combined impact of these constraints on competitiveness makes vaccine manufacturing unattractive for private-sector actors who might otherwise be interested. Very few companies anywhere in Africa even fill and finish vaccines today, far less develop and manufacture vaccines. There is, however, a foundation to build on, and much potential for growth.



Project title	BACKUP Health
Objective	Improving framework conditions for local vaccine production in Africa
Commissioned by	German Federal Ministry for Economic Cooperation and Development (BMZ)
Project region	Africa / worldwide
Implementation partners	World Health Organization (WHO), Medicines Patent Pool (MPP), Partnership for African Vaccine Manufacturing (PAVM), African Union Development Agency AUDA-NEPAD – African Medicines Regulatory Harmonisation (AMRH) Initiative, University of Johannesburg, University of the Witwatersrand
Duration	April 2021 - August 2023

Our approach

The German Federal Ministry for Economic Cooperation and Development (BMZ) commissioned the GIZ BACKUP Health programme to establish a new project that is to **improve the framework conditions for sustainable vaccine production on the African continent**. The project is part of the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, medicines and health technology in Africa (MAV+). It focuses on three areas:



Pop-up vaccination site, community hall Pretoria, © GIZ/Nadia Said



Ndlovu Research Centre, Limpopo, © GIZ/Nadia Said



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Photo left: Bombo Hospital in Tanzania © GIZ/ Dirk Ostermeier

Photo right: Sequencing machine at Ndlovu Research Centre © GIZ / Nadia Said

1. Harmonising and strengthening the regulatory framework

Consistent, Africa-wide regulations aligned with international standards will ensure the consistent quality of vaccines and thus inspire trust in local production. Unless a stringent regulatory system is in place, local manufacturers will struggle to find buyers for vaccines made in Africa. Harmonising regulatory standards and processes across countries will also facilitate reciprocal recognition of such things as factory audits or streamlined product registrations. This in turn will help African manufacturers access a larger market, and enable them to develop and launch new products.

2. Improving conditions for technology transfer and developing local production capacities

Vaccine production is complex, even for existing pharmaceutical companies in Africa. If local actors are to successfully establish themselves in this branch they will need technology transfer, especially regarding mRNA and other recent vaccine platforms. The choice of technology depends in part on a complete understanding of the market opportunities, the intellectual property landscape and on the availability of the skills and capacities a company would need. And it is important to be aware that vaccine technologies adapted to the local environment as well as sustainable business models are vital if the product is to be manufactured and used in the long term.

3. Enhancing education and training to provide skilled workforce

It is paramount that the pool of skilled labour in Africa be expanded if sustainable vaccine production is to be developed. Companies and educational institutes need specialised engineers, industrial pharmacists and scientists to develop new products and innovate. Regulatory bodies and other government agencies also need staff with the appropriate skill sets to support and oversee vaccine manufacturing in many countries.

Partners and first steps

The project strongly embraces partnerships with multilateral and African institutions working in the areas set out above, to ensure a sustainable approach. The project supports the **Partnership for African Vaccine Manufacturing (PAVM)**, an initiative of the African Union, with its Framework for Action to establish local production and the enabling environment this entails. It also supports the work of several technical committees of the **African Medicines Regulatory Harmonization (AMRH)** Initiative on harmonising regulatory processes. Moreover, it delivers advisory services on organisational development to the emerging **African Medicines Agency**. Cooperation with Ghana's National Regulatory Authority is helping it on its way to becoming a flagship regulatory authority. Similarly, BACKUP Health supports the work of the **COVAX Manufacturing Task Force**. It has joined forces with the **World Health Organization (WHO)** to identify the capacity development needs of existing vaccine manufacturers, particularly in terms of compliance with international quality standards. Cooperation with the **Medicines Patent Pool (MPP)** focuses on mapping patents and licensing requirements for future technology transfers to bodies such as the newly established mRNA hub in South Africa. Together with the **University of Johannesburg**, the project initiates a research network to evaluate the innovation ecosystem for vaccine development and production in several countries.

In the field of education and training, the project works with the AMRH Initiative to set up regional centres of regulatory excellence and train national regulatory officers. The collaboration with the **University of the Witwatersrand** in South Africa is an example of support for Africa-wide training and education in the field of vaccinology, in the form of a short course and a master's degree.

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