

# **MAV+ South Africa**

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Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+) is a comprehensive support package tackling barriers to manufacturing and access to health products and technologies in Africa. MAV+ is tightly aligned with African strategies and is supported by a broad and inclusive consortium of European actors.

South Africa is a regional and continental hub for mRNA vaccine technology transfer and is well positioned to be a leader in local production thanks to its active pharmaceutical sector and its relatively strong regulatory authority, which reached WHO Maturity Level 3. MAV+ focuses its support in South Africa on industrial development, research, regulatory strengthening, skills development and market shaping.

# **Key MAV+ collaborations and activities**

# Supporting local vaccine production through the WHO / MPP mRNA technology transfer hub and vaccine production line at Biovac

Team Europe played a key role in establishing the WHO / MPP mRNA technology transfer hub to increase local vaccine production in low- and middle-income countries. Afrigen leads mRNA technology development with South African Medical Research Council (SAMRC) providing research and Biovac serving as the first manufacturing "spoke."

South Africa
£697.14

million
5 projects\*

\*excludes multi-country projects

Team Europe also supports SAMRC in addressing gaps in fundamental pre-clinical research to promote sustainable vaccine manufacturing in South Africa.

Another highlight is Team Europe's role in strengthening Biovac's vaccine production capacities, which was achieved through a combination of blended finance and technical support to establish fill-and-finish capacity for Pfizer's COVID-19 vaccine in Africa. This initiative also aims to enable end-to-end production and accelerate the production of a cholera vaccine in South Africa. Biovac has already supplied over 15 million vaccine doses annually to South Africa and beyond. Team Europe provided strong support to Aspen Pharmacare's partnership with Johnson & Johnson to produce annual COVID-19 vaccine doses in South Africa. In response to low demand for these vaccines, a new agreement will expand production to include more commonly administered vaccines.

#### Contributing to the continental regulatory system strengthening

Team Europe enhances the quality of health products in South Africa through technical assistance and training. Fifteen South African Health Products Regulatory Authority (SAHPRA) staff members have been trained on vaccine and pharmaceutical sector regulations, while 180 others took part in online biomanufacturing training.

SAHPRA is a key player in regulatory harmonization across the continent, partnering with the Egyptian Drug Authority (EDA), Nigeria National Agency for Food and Drug Administration and Control (NAFDAC) Rwanda FDA, Ghana FDA and SADC regulators.

Through one multi-country project, SAHPRA developed regulatory capacities and structures for the marketing authorization of medical products. It leveraged a regional framework to implement a risk-based procedure for evaluating unapproved drugs across Southern Africa, specifically aimed at strengthening drug regulation during health crises.

Building on SAHPRA's success in achieving WHO Maturity Level 3 for official lot release of vaccines, MAV+ projects are supporting SAHPRA's efforts to reach WHO Maturity Level 4 in the fields of clinical trials and pharmacovigilance as well as SAHPRA's ambition to be regional center of excellence in partnership with AMA.

#### Special support for an enabling environment for regional production

The Special Measure 2023 aims to fill the gaps identified in national plan of South Africa through three key components:

- 1. Establish a Centre of Excellence for health product safety monitoring across Southern Africa through a collaboration of Institute of Tropical Medicine, Antwerp (ITM) and University of the Western Cape
- 2. Support the enabling environment for local pharmaceutical production, focusing on R&D skills, higher education, market shaping and regulatory strengthening
- 3. Strengthen the biomanufacturing capabilities in Southern Africa, with a focus on addressing skilled labour shortages and scaling up biomanufacturing processes for vaccines and pharmaceuticals hosted by the Council for Scientific and Industrial Research (CSIR)

In terms of training and workforce development, MAV+ partners are already working with the Department of Science, Technology and Innovation (DSTI) to put in place training courses with businesses, universities and state research institutes. The goal of these efforts is to build local capacities to develop and produce vaccines in South Africa.

### **Team Europe funders**

MAV+ actions in South Africa are primarily funded by the European Commission, Belgium, Germany and France. Germany also funds multi-country projects.





National partners include South African Health Products Regulatory Authority (SAHPRA); South African Department of Science, Technology and Innovation (DSTI); South African Department of Health; Afrigen, Biovac, and South African Medical Research Council (SAMRC) for the mRNA technology transfer program; University of the Western Cape; Aspen Pharmaceuticals; Siemens; Council for Scientific and Industrial Research (CSIR); and SMEs and the South African research community. SAHPRA and South African National Control Laboratory for Biological Products (SANCLBP) are partners on multi-country projects.

# Additional Team Europe and international stakeholders

Stakeholders for national projects include BIO (Belgian Investment Company for Developing Countries), DEG (German Investment Corporation), EIB (European Investment Bank), GIZ, IFC, Institute of Tropical Medicine, Antwerp (ITM), KfW, MPP, PROPARCO (French development finance institution) and WHO. The German Federal Insitute for Drugs and Medical Devices (BfArM) and Paul-Ehrlich-Institut (PEI) are stakeholders in multi-country projects that include South Africa.