



SUB-SAHARAN AFRICA REGION - MAV+ Manufacturing and Access to Vaccines, medicines & health technology products in Africa

#GLOBALGATEWAY #TEAMEUROPE

TEAM EUROPE PROPOSAL



Enabling environment for local manufacturing:

- Market design and demand intelligence
- Regulatory strengthening
- Access to finance
- Technology and intellectual property
- R&D hubs and talent development
- Information management

Senegal (regional vaccine manufacturing site): New facility at the IPD¹, (DE, FR, EIB)

Rwanda (regional vaccine and biologicals manufacturing center) : laboratory of the RFDA², (BE, DE, FR)

South Africa (antiretroviral drugs production): Aspen's vaccine production (June 2021 - IFC, DFC, Proparco and DEG); Biovac's facility in Cape Town (EIB, DE, FR, BE); WHO - five technology transfer hubs (DE, FR, BE, KfW)

Ghana to develop its vaccines and medicines manufacturing capacity

INTPA (initial amount of EUR 40 million):

- Regulatory convergence & authorities
- Technology transfer and innovation for local production
- Strategic purchase, demand consolidation
- Coordination, visibility, programme governance

Support the Africa CDC³ and the AUDA-NEPAD Africa Medicine Regulation Harmonization (AMRH) strengthening NRAs, RECs and preparing for the emergence of the Africa Medicine Agency (AMA) – Germany, EUR 10 million.

Areas for collective support:

- Regulatory frameworks at the AU level
- Manufacturing capacity for regional demand, starting with Senegal and South Africa
- Local initiatives on local manufacturing
- Skills development, higher education, TVET
- (Digital) supply chain management
- Trade, customs, and excise/taxes (AfCFTA)
- Financing and de-risking investment (AfBD)
- Demand coordination. Development of health economic capacity at NAs involved
- Other areas - as the TEI emerges over time

MODALITIES/ TOOLS

Policy dialogue

Blending and guarantees

Technical assistance

Loans

Grants

TRANSFORMATIONAL POTENTIAL

- To support scaling up local manufacturing of pharmaceutical products in Africa in the short, medium and long terms as a measure to underpin human development at the nexus to industrial development without harming the environment
- To boost vaccine and pharmaceuticals production in Africa and finally join the global pharmaceutical supply chain

KEY DELIVERABLES

Priority countries

1. Senegal:

a) MADIBA vaccine production plant (COVID and others) at the Institut Pasteur in Dakar (work well advanced, part of the equipment already delivered). The vial plant is expected to be completed in the first quarter of 2023 (and will be able to bottle - vaccines manufactured elsewhere - in mid-2023) and the drug substance manufacturing plant is expected to be completed by the end of 2023 (and in able to produce the substance at the end of 2024). The objective is to produce 300 million doses of vaccines (substance + vial) at the end of the project.

2. Ghana:

a) Upgrade of 2 laboratory facilities (pharmaceutical microbiology and molecular biology) to be operational in 2023 at Good Manufacturing Practice standards.
 b) Institutional development plans for the Ghanaian FDA to reach WHO maturity level 4 (for pharmacological vigilance it already reached level 4).
 c) Private sector consortium DEK, is building a Fill & Finish plant for mRNA vaccine in collaboration with BioNTech, where the Active Principal Ingredient will come from Rwanda; Ghana's infrastructure and capacity to ensure the fill and

finish for the production of X 30M vials (~150-180M doses) of Covid and non-Covid vaccines million vaccines by Q2 2024 and many other essential medicines.

3. Rwanda:

Delivery of key equipment (e.g. mobile containers by BioNTech) benefiting from EU support to the business environment.

4. South Africa:

Expansion of multi-vaccine manufacturing at Biovac's facility (dates TBC). See also TEI South Africa A just and green recovery

5. Regional/continental:

a) Regulatory strengthening via EMA, WHO and AUDA-NEPAD (the latter in charge of the main harmonization initiative). Particular attention to the African Medicines Agency (AMA), whose HQ were selected in July 2022 and will be operationalized in the coming months and years.
 b) Expanded know-how around the production of mRNA vaccines in low- and middle-income countries through WHO's mRNA hub in South Africa.
 c) EU-Africa pharma match-making events (DG GROW).
 d) GH-EDCTP3: Strengthening regulatory capacity to conduct clinical trials (RTD).

1 Institute Pasteur Dakar (IPD)

2 Rwandan Food and Drug Authority (RFDA)

3 Africa Centre of Disease Control and Prevention (Africa CDC)

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NATIONAL CONTEXT

Pharmaceutical systems are standing at the cross-over between economic and social policies

Ghana (2018) and Tanzania (2020):
Maturity Level 3 of WHO Global Benchmarking Tool (GBT).

Health care consumer market:

- Not integrated in the global vaccine and pharmaceutical industry supply chains
- Imports 99% of vaccines and 94% its medicines
- 600 pharmaceutical manufacturers in Africa, 80% in: Egypt, Algeria, Morocco, SA, Tunisia, Nigeria, Ghana, Kenya
- High growth - jumped to USD 28.5 billion in 2017
- 'Pharmerging' markets - Algeria, Egypt, Nigeria, South Africa (IQVIA Institute)

One vaccine comes from an African supplier - the yellow fever vaccine produced at the Institute Pasteur Dakar in Senegal

Less than 1% of local demand for vaccines are manufactured on the continent

COVID-19 has and is still exposing the challenges of global vaccine, medicine and health technology manufacturing

Beyond COVID-19, the need to secure access to essential medicines is enormous:

- Currently 1.3 billion people are health care consumers.

Regional policies:

- Treaty for the Africa Medicine Agency (AMA)
- Africa Continental Free Trade Agreement

GEOPOLITICAL CONTEXT AND RELEVANT SDGs

3 GOOD HEALTH AND WELL-BEING



Agenda 2030

African Union Agenda 2063

African Continental Free Trade Agreement (AfCFTA)

Partnership for African Vaccine Manufacturing (PAVM)

COVID-19 pandemic

**SDGs included based on a new JRC electronic text mining tool, which identifies SDGs (targets)