



# VaccRelease

Regulatory capacity building in the field of vaccines: Training and scientific advice to establish official lot release

## Context

Vaccines remain the most effective tool for preventing infectious diseases and for improving global health. As only 1% of the vaccines needed in Africa are currently produced in Africa, the continent needs a robust vaccine industry. The COVID-19 pandemic, in particular, has highlighted the need for supranational structures to ensure access to vital drugs, vaccines and health technologies. This requires a strong regulatory framework for vaccines, including the ability to test and release locally produced vaccines through an official national control laboratory (NCL). To this end, the project works with regulators and laboratory personnel involved in the official lot release of vaccines at the national regulatory authorities (NRAs) and NCLs of Ghana, Senegal, Rwanda and South Africa. The project strengthens their expertise and the capacity of the NRAs and NCLs to perform official NCL lot release, in particular, for vaccines produced locally. It also promotes cooperation with NRAs and NCLs based in sub-Saharan Africa and with the AUDA-NEPAD AMRH initiative, AMQF and other partner organisations to support the development of a pan-African NCL network for vaccine lot release and to foster the establishment of a reliance system. The strengthening of NCLs and NRAs will ensure the provision of quality-assured, safe and efficacious vaccines for the African population and contribute to the development of a sustainable vaccine manufacturing industry. These efforts will strengthen the quality infrastructure in Africa and build confidence in locally produced vaccines.

## Objective

Strengthening the capacities of NRAs and NCLs for the official lot release of vaccines to improve access to quality-assured, safe and efficacious vaccines in African countries.

## Thematic focus

Marketing authorisation and safety of medicinal products

## Key facts

### Duration

1 January 2023 to 31 December 2025

### Budget

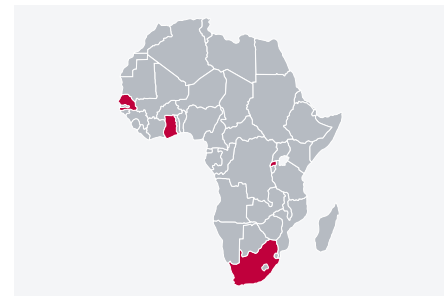
~ EUR 1.7 million

### Partner countries

Ghana, Senegal, Rwanda, South Africa

### Region

Western, Eastern and Southern Africa



### Implemented by

Paul-Ehrlich-Institut (PEI)

### Commissioning party

German Federal Ministry of Health  
(BMG)

## Activities



### STAFF DEPLOYMENT AND EXCHANGE

Training on lot release processes and related laboratory techniques



### CAPACITY DEVELOPMENT

Supporting NRAs and NCLs in establishing the official lot release function for vaccines by developing and supporting the implementation of lot release standards and processes; establishing the governance structures for vaccine lot release; developing an information system and standard procedures for complaints, quality issues and vaccine lot recalls



### NETWORKING AND COOPERATION

Collaborating with NRAs and NCLs based in sub-Saharan Africa and with the AUDA-NEPAD AMRH initiative, AMQF and regional organisations to support the development of a pan-African NCL network for vaccine lot release and to foster a reliance system specifically for locally produced vaccines

## In cooperation with

- Food and Drugs Authority (FDA), Ghana
- Rwanda Food and Drugs Authority (FDA), Rwanda
- Agence sénégalaise de Réglementation pharmaceutique (ARP), Senegal
- South African Health Products Regulatory Authority (SAHPRA), South Africa
- South African National Control Laboratory for Biological Products (SANCLBP), South Africa
- African Union Development Agency, New Partnership for Africa's Development (AUDA-NEPAD) African Medicines Regulatory Harmonization (AMRH) initiative
- African Medicines Quality Forum (AMQF)
- National Metrology Institute (PTB), Germany
- GIZ (local representatives in Ghana, Senegal, Rwanda and South Africa)

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Paul-Ehrlich-Institut   
Federal Institute for Vaccines  
and Biomedicines

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