



# PharmTrain2

## Building regulatory capacities and infrastructure: Marketing authorisation of medicinal products

### Context

Global health crises are on the rise, especially those caused by infectious disease outbreaks, and pose a serious threat to health and well-being. WHO estimates that up to 10 million lives could be saved every year if access to safe and effective medicines and vaccines were improved. As a World Health Assembly resolution on this subject highlights, stable, well-functioning health care systems are urgently needed to ensure timely access to quality medical products, which will help countries prevent and respond effectively to health crises. Despite considerable advances in recent years, the capacity to improve access to essential medical products through regulation is still limited in many regions, including sub-Saharan Africa. The project therefore aims to strengthen regulatory infrastructure and the capacity of partnering authorities to evaluate the pharmaceutical quality, efficacy and safety of medicinal products. This will improve the quality, consistency and efficiency of regulatory decision-making. PharmTrain2 also strongly promotes medicines regulation harmonisation in Africa. The activities build on the achievements of the RegTrain-PharmTrain project and involve working with staff from the medicines regulatory authorities in the seven partner countries and supporting AUDA-NEPAD in operationalising the African Medicines Agency (AMA).

### Objective

Strengthening the institutional development of selected African medicines regulatory authorities in the field of marketing authorisation of medicinal products.

### Key facts

**Duration**

1 January 2023 to 31 December 2025

**Budget**

~ EUR 1.8 million

**Partner countries**

The Gambia, Ghana, Liberia, Sierra Leone, South Africa, Tanzania, Zimbabwe

**Region**

Western and Southern Africa

**Implemented by**

German Federal Institute for Drugs and Medical Devices (BfArM)

**Commissioning party**

German Federal Ministry of Health (BMG)

### Thematic focus

Strengthening of public health systems

Marketing authorisation and safety of medicinal products

Resolutions and international agreements

## Activities



### TRAINING AND COMPETENCE DEVELOPMENT

Training staff from national medicines regulatory authorities to become trainers in drug evaluation for marketing authorisation and related procedures, with a focus on biosimilars and the clinical assessment of pharmaceuticals



### CAPACITY DEVELOPMENT

Strengthening regulatory frameworks by developing structural documents (e.g. guidelines and standard operating procedures); supporting regulatory authorities in developing harmonised regulatory guidelines and procedures



### NETWORKING AND COOPERATION

Fostering harmonisation initiatives and the scale-up of guidelines from the regional to the continental level; for example, supporting the Technical Committees on Evaluation of Medical Products and Regulatory Capacity Building of the African Union Development Agency, the New Partnership for Africa's Development (AUDA-NEPAD), and thereby contributing to the operationalisation of AMA

## In cooperation with

- African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD)
- Food and Drugs Authority (FDA), Ghana
- Liberia Medicines and Health Products Regulatory Authority (LMHRA), Liberia
- Medicines Control Agency (MCA), The Gambia
- Medicines Control Authority of Zimbabwe (MCAZ), Zimbabwe
- Pharmacy Board of Sierra Leone (PBSL), Sierra Leone
- South African Health Products Regulatory Authority (SAHPRA), South Africa
- Tanzania Medicines and Medical Devices Authority (TMDA), Tanzania
- World Health Organization (WHO), Switzerland

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**GHPP, the Global Health Protection Programme** of the German Federal Ministry of Health, promotes networking, exchange and cooperation between specialized German and international public health actors. By reducing health risks and strengthening health systems at the national, regional and international level, in particular relating to pandemic and epidemic preparedness and response, the GHPP fosters public health protection – worldwide.



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