



PharmTrain-Corona Global

Drug Regulation in Health Crises: Development of a Framework for the Regional Implementation of a Risk-based Procedure for the Evaluation of Unapproved Drugs (WHO-EUL) for Southern Africa

Duration

2021 – 2023

Budget

approx. 252,500 EUR

Partner countries

Angola
Botswana
Comoros
Democratic Republic of the Congo
Eswatini
Lesotho
Madagascar
Malawi
Mauritius
Mozambique
Namibia
Seychelles
South Africa
Tanzania
Zambia
Zimbabwe

Challenges addressed by the project

Particularly the COVID-19 pandemic highlighted the importance of efficient and robust structures in drug regulation to ensure healthy lives and well-being for all. Well-functioning regulatory systems ensure the quality, safety and efficacy of medicines and contribute to timely access to essential medical products. In turn, the absence of clearly established definitions of roles and responsibilities and defined procedures in regulatory systems pose a risk on the population's supply with safe and effective medicines in a public health emergency (PHE). Especially resource-constrained countries face a considerable burden due to often fragile systems with weak structures.

Objectives

- » Strengthen regulatory systems by the establishment of a framework for the regional implementation of the “World Health Organization Emergency Use Listing Procedure” (WHO-EUL)
- » Support the national medicines regulatory authorities of the partner countries in strengthening their preparedness for health emergencies
- » In the event of regional or global crises, the establishment of standardized procedures within the national medicines authorities of the Southern African Development Community (SADC) aims to accelerate the assessment of promising drug candidates
- » Regional harmonization of standards and procedures in the 16 African countries of SADC to reduce the workload of the already understaffed regulatory authorities due to work sharing activities
- » Improve the efficiency and effectiveness of regulatory systems in SADC region

Overview of activities

The project aims to strengthen the national medicines regulatory authorities in building structures and capacity in Southern Africa. The focus of the project lies on the establishment of a framework which facilitates harmonized procedures and standards for an accelerated assessment of drug candidates in PHEs. For this purpose, the “PharmTrain-Corona Global” team is collaborating with the national medicines regulatory authorities of SADC comprising 16 countries in the southern African region. With a population of about 300 million, it is the biggest economical region on the African continent. Moreover, it is considered to be the most peaceful and stable



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SADC Heads of Agencies Meeting 2019
(Photo ©SADC)



PharmTrain-CoronaGlobal Kickoff meeting,
September 2021; “Expanding the network”
(Photo ©BfArM)



PharmTrain-CoronaGlobal Kickoff meeting
September 2021; SADC - Technical working
group (Photo ©BfArM)

region in Africa. The project consists of two parts. The first part includes the analysis of the current situation of the 16 countries in the SADC region regarding existing structures and procedures for approving medicines in case of emergencies. Afterwards, a framework based on the WHO-EUL procedure with harmonized structures will be developed. For the second part, the partner institutions will implement the framework at national level assisted by the GHPP-PharmTrain-Corona Global project team. The project activities are going to take place in form of regular online meetings, a series of virtual workshops and face-to-face meetings if the pandemic situation allows. The overall goal is to support the partner institutions in building structures for well-functioning drug regulatory authorities which enable them to apply the necessary methods for ensuring drug safety. Establishing prerequisites for development and approval of specific drug therapies will also contribute to reinforce global health security. The existence of guidelines for drug registration in exceptional circumstances is one of the requirements of the WHO Global Benchmarking Tool and hence an important indicator for the agency’s maturity.

Partner institutions/Contact

- » Southern African Development Community (SADC)
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- » African Union Development Agency (AUDA-NEPAD)
- » World Health Organization (WHO)
- » National Medicines Regulatory Authorities of SADC region

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