GHP Programme

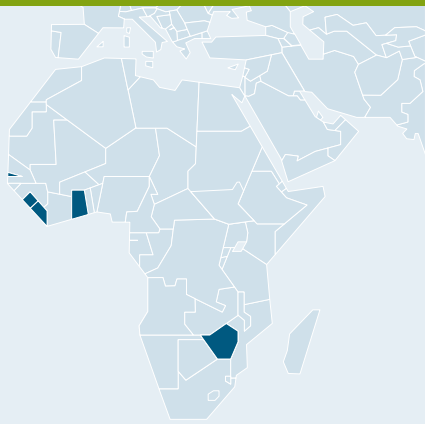
Regulatory Training and Advice in the Field of Pharmaceuticals

RegTrain-PharmTrain

Duration
2019–2021

Budget/year
approx. 390,000 EUR

Partner countries
Ghana
Liberia
Sierra Leone
The Gambia
Zimbabwe



Challenges addressed by the project

The availability of effective and safe medicines is a crucial pillar for the promotion and protection of human health. At present, however, the possibilities for regulation and control of the pharmaceutical market are very limited in most sub-Saharan African countries. In some cases, there is a lack of legal foundations or their implementation in practical work. Therefore, functional and reliable structures have to be built, standards established and training of available personnel strengthened. In particular, there is a clear need for training in the evaluation of marketing authorisation applications , which is addressed by the PharmTrain project.

Objectives

- Improving the functional capacity of medicines regulatory authorities in Africa
- Enhancing the professional competence and expertise of the African partner authorities' staff
- Improving the quality, efficacy and safety of medicinal products
- Strengthening regional and supra-regional cooperation between regulatory authorities in sub-Saharan Africa
- Preventing/controlling epidemics and combating antimicrobial resistance

Overview of activities

Evaluation of the regulatory authorities' functionality in Ghana and Zimbabwe and assistance in their further development

Based on the WHO Global Benchmarking Tool and in collaboration with WHO, the project team participates in the stocktaking process in these two Regional Centers for Regulatory Excellence (RCOREs) and supports the staff of partner agencies in recommending steps for further institutional development.

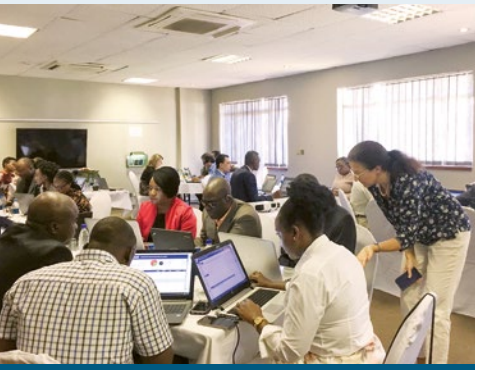
Consultations in The Gambia, Liberia and Sierra Leone on necessary structures

Based on the WHO Global Benchmarking Tool, colleagues from partner authorities, in cooperation with the PharmTrain project team at the Federal Institute for Drugs and Medical Devices (BfArM), assess their agencies' current status with regard to marketing authorisation of medicinal products. Based on successive analysis of strengths and weaknesses, an individual work plan is developed for each agency and its implementation subsequently monitored.

Supported by:

Federal Ministry of Health

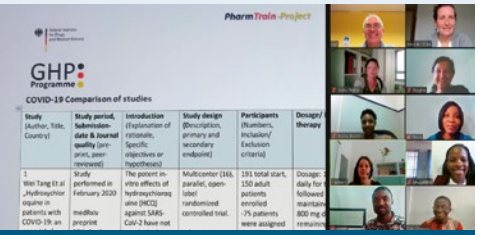
on the basis of a decision by the German Bundestag



The PharmTrain team assisting colleagues of the Medicines Control Authority Zimbabwe in their self-benchmarking, Mai 2019

PharmTrain fellows practising transfer of newly gained knowledge, November 2019

Workshop of the PharmTrain team with colleagues from the Liberia Medicines and Health Products Regulatory Authority, January 2020



Capacity building with PharmTrain fellows from Ghana and Zimbabwe accounting for the project partners' most burning training needs and adapted to the situation during the Corona pandemic, June 2020

(Photos ©PharmTrain)

Train-the-Trainer module

Colleagues from the partner authorities in Ghana and Zimbabwe are trained at the BfArM as trainers for the evaluation of marketing authorisation applications for medicinal products. The PharmTrain-project team supports these fellows in their initial trainings and in the development of "training modules" for regional and supra-regional harmonisation initiatives. This ensures sustainability via transfer of the newly acquired knowledge.

E-activities

Due to the Corona pandemic in 2020 major on-site activities are transferred temporarily to a purely virtual format. Regular video conference calls take place with the international project partners for each of the three streams mentioned above to ensure the uninterrupted collaboration and continued progress in each of these areas. Furthermore, concepts for e-learning are developed.

Information platform and international network

The PharmTrain team is in regular contact with WHO and NEPAD to coordinate work plans and contents of the project.

Partner institutions

National medicines regulatory authorities in the partner countries:

» Food and Drug Administration (FDA), Ghana
» Liberia Medicines and Health Products Regulatory Authority (LMHRA), Liberia
» Pharmacy Board Sierra Leone (PBSL), Sierra Leone
» Medicines Control Agency (MCA), The Gambia
» Medicines Control Authority of Zimbabwe (MCAZ), Zimbabwe
» Paul-Ehrlich-Institut (PEI), Germany

Supranational Partners

» World Health Organization (WHO), Switzerland
» New Partnership for Africa's Development Agency (NEPAD), South Africa

Supporting institution in Germany/Contact

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