

Upgrading of Quality Infrastructure in the Pharmaceutical Sector in Africa

Assuring the quality of locally manufactured medicines and vaccines

Background

Currently, Africa imports more than 80 per cent of the medicines, vaccines, pharmaceutical ingredients and medical devices it needs. The early months of the Covid-19 pandemic and the resulting collapse of global supply chains put the impact of this import dependency in the spotlight – and made access to quality-assured medicines even more difficult. However, improving access to medicines and vaccines through local production based on international standards is an important measure not only in the context of pandemic situations, but also on the path to the sustainable development of African countries.

Our approach

The African pharmaceutical sector is striving to adapt the production and quality assurance of medicines, vaccines and medical devices to international standards, procedures and guidelines. However, the quality infrastructure for pharmaceuticals is partly lacking: there is a shortage of qualified personnel, especially in the areas of production and control, maintenance and servicing. Quality assurance services often cannot be sufficiently provided. The national medicines regulatory authorities (NMRAs), which are responsible for authorisation and supervision, and the national control laboratories



Operators maintaining a tablet press
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Project name	Upgrading of Quality Infrastructure in Africa
Commissioned by	Federal Ministry for Economic Cooperation and Development (BMZ)
Lead executing agency	Physikalisch-Technische Bundesanstalt (PTB)
Political partner	African Union Commission (AUC)
Implementation partners	African Medicines Regulatory Harmonization Initiative, regional and national medicines regulatory authorities
Budget	EUR 3.0 million (pharmaceutical component of the overall project)
Duration	9/2020 – 8/2024

are often unable to fulfil their tasks adequately due to a lack of equipment and the low number of qualified staff. The regulation of medicines, vaccines and medical devices has not yet been carried out in harmonised procedures at continental level; the African Medicines Agency (AMA) is still being established.

Through a multi-level approach, PTB supports the efforts of the African Union, its Member States, the African Regulatory Harmonization Initiative (AMRH), the African Medicines Quality Forum (AMQF), the African Organisation for Standardisation (ARSO) and other relevant partners in upgrading the quality infrastructure for the pharmaceutical sector. Special focus is placed on the support of control laboratories and their quality assurance capabilities. These are being improved, for example, through the introduction of quality management systems and through intercomparison measurements. The methodical approach is based on different concepts of capacity building including virtual and practical formats, study tours, organisational development and policy advice.

In cooperation with:

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY



AMRH
African Medicines Regulatory Harmonisation Programme

Quality aspects in the pharmaceutical value chain

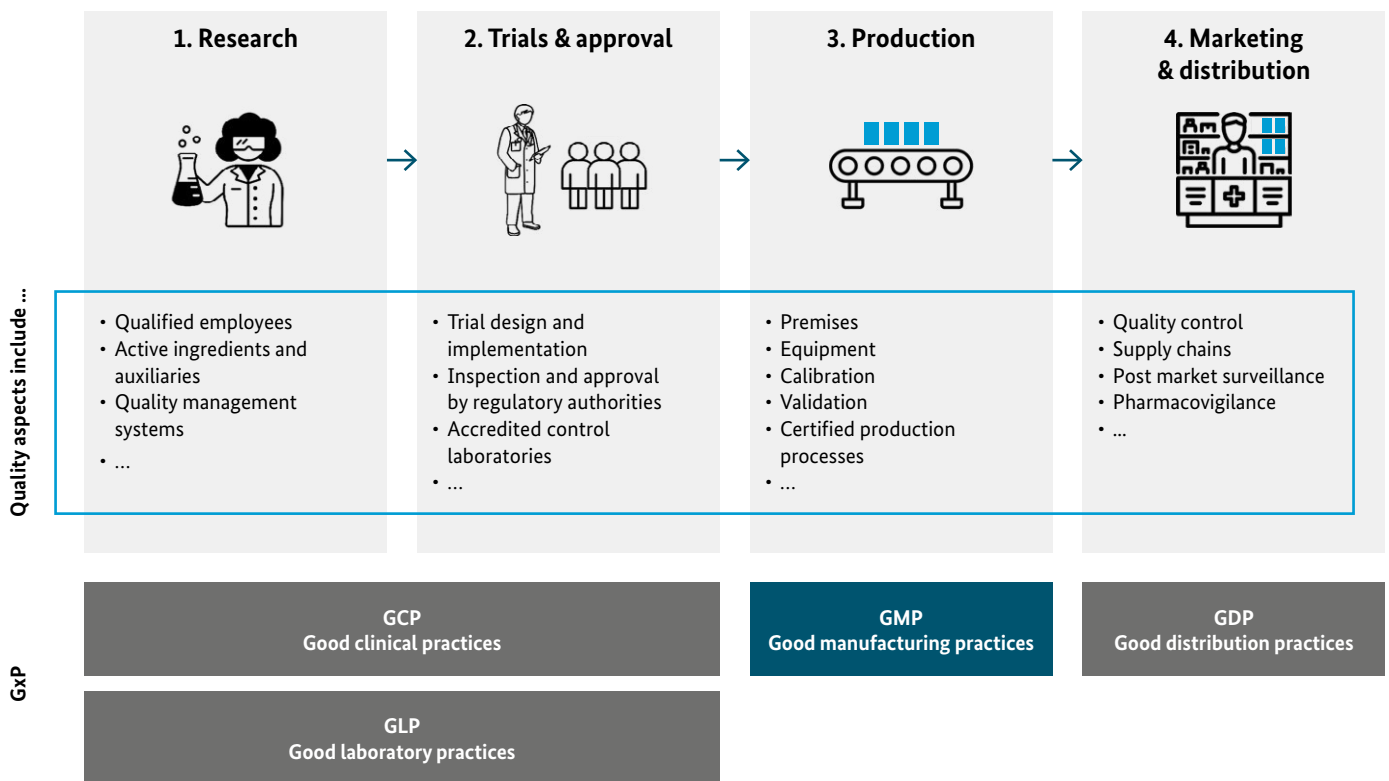


Figure 1: Quality aspects in the pharmaceutical value chain

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Objective and components

The aim of the PTB project is to strengthen the framework conditions for both the local manufacture of pharmaceutical products and the capacities of the regulatory authorities. The focus is on improving the quality assurance of pharmaceutical products in line with international standards (WHO, ISO, ICH, etc.), which includes locally manufactured and imported medicines, vaccines and medical devices. This implies capacity building at national regulatory authorities as well as at the future AMA in Kigali.

The project operates in a demand-driven logic and covers three main areas in this regard:

- Strengthening capacity and competences for regulation and quality assurance in manufacturing, quality control & inspection
- Supporting the harmonisation of standards and developing regulated procedures, guidelines and manuals and their implementation together with the competent institutions (ARSO, AMRH, AMA)
- Raising awareness and expanding quality services to the pharmaceutical sector through other institutions such as national metrology institutes and universities

Partner structure at the continental level

The political partner of the project is the African Union Commission (AUC). Support is coordinated by the development agency of the African Union, AUDA-NEPAD, as the main partner institution. The African Medicines Regulatory Harmonization Initiative (AMRH) is another key partner, of which the future African Medicines Agency (AMA) is a member. Special cooperation exists with the NMRAs in Senegal, Ghana, Rwanda and South Africa. Important implementation partners are the African Organisation for Standardisation (ARSO), as well as regional and national regulatory authorities and harmonisation initiatives and quality infrastructure institutions. Furthermore, the project is partnered with relevant international and sectoral institutions, such as the United States Pharmacopeia (USP), the Paul-Ehrlich-Institut (PEI) and the World Health Organization (WHO).

Key challenges

A well-developed quality infrastructure is a complex network. It must be developed based on the needs of industries, consumers and traders and be designed in an interlocking logic.

- Staff in regulatory authorities, quality infrastructure institutions and manufacturing facilities need profound technical knowledge, e.g., in the areas of production, quality control, testing, calibration, inspection and standardisation.
- Quality infrastructure institutions must be aware of the private sector's needs and systematically work towards meeting these.
- At the political level and in the relevant public institutions, awareness on the necessity and dimensions of quality infrastructure is needed, as to ensure adequate financing of the relevant bodies.

Key benefits

In this project, PTB is using its core competence – quality infrastructure – to help improve the availability of high-quality, locally produced medicines and vaccines in Africa. In particular, the project improves the conditions for compliance with international quality standards in the production and regulation of medicines and vaccines.

The project aims to increase the capacities of manufacturers of medicines and vaccines to meet international standards, particularly good manufacturing practices (GMP). It will also improve human resources for quality assurance in the areas of manufacturing, quality control, inspection and regulation. Overall, the quality infrastructure will be strengthened in terms of regulatory and control laboratory capacity and the provision of quality assurance services. Training programmes on quality assurance procedures of different formats offered to regulators, manufacturing companies, reference laboratories and quality control laboratories contribute to this. In addition to awareness-raising and educational measures, knowledge sharing, technology transfer and networking between manufacturers and national regulatory authorities are also promoted.

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