

Sub-Saharan Africa



East African Community

Establishment of a Regional Quality Infrastructure for the Pharmaceutical Sector

Objective The quality infrastructure in the EAC region will have developed in line with the needs of the pharmaceutical sector.

Approach To ensure availability of affordable and qualitatively good medicines on the EAC Market (Burundi, Kenya, Rwanda, Tanzania, Uganda, South Sudan) quality infrastructure services are equally needed by pharmaceutical manufacturers and by institutions which are in charge of regulating and controlling the pharmaceutical sector.

However, the lack of regionally available quality assurance services such as interlaboratory comparisons, calibrations and reference materials results in difficulties in the production of pharmaceutical products in East Africa that are in line with international standards. It also entails that sufficient regulation of pharmaceutical products and surveillance of the market cannot always be ensured.

For these reasons, the project is geared towards expanding the pool of human capital used for quality assurance and quality control within the scope of production, approval and market surveillance of pharmaceutical products. In addition, it supports the regional harmonization and coordination of market surveillance, the establishment of local providers of interlaboratory comparison measurements in accordance with international standards, the expansion of locally offered calibration services, and the improved availability of reference materials in the region.

Impact The improved access to quality infrastructure services for the pharmaceutical sector enables manufacturers and control authorities to meet international accepted quality standards like the WHO prequalification or the ISO/IEC 17025 laboratory standard more successfully. This opens up new growth opportunities for manufacturers beyond their national borders and ensures better control against substandard medicines by regulatory authorities. Hence, the accessibility of safe and affordable medicines for all EAC citizens improves.

Further development of the pharmaceutical sector is a strategic priority of the EAC Secretariat and through the project important framework conditions for this development are set.

Cooperation The project is an integral part of the German development program "Support to the EAC integration process" and cooperates closely with Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ).

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Contact EAC Secretariat, Arusha, Tanzania
George Ndira
+255 754 009 487
gndira@eachq.org

Physikalisch-Technische Bundesanstalt
Tobias Diergardt
+49 531 592-8228
tobias.diergardt@ptb.de

