East African Community

Establishment of a Regional Quality Infrastructure for the Pharmaceutical Sector
Objective
The implementation of the EAC Regional Pharmaceutical Manufacturing Plan of Action has made considerable progress in the work areas “Strengthening of the local capacity for the introduction of WHO-GMP standards” and “Strengthening of regulatory authorities”, owing to a quality infrastructure which has been adapted to 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) Quality Infrastructure services are equally needed by pharmaceutical manufacturers and by institutions which are in charge of regulating and controlling the pharmaceutical sector. Project activities are therefore aiming to strengthen the private as well as the public sector and to meet common challenges. These challenges are the insufficient availability of appropriate calibration services, affordable chemical reference substances, regular interlaboratory comparisons and reliable maintenance services for laboratory equipment.

Within the framework of the project laboratory intercomparisons will be introduced to the region enabling laboratories to compare their performance and take remedial action where necessary. Together with the National Metrology Institutes the scope of calibration services will be extended according to the needs of the pharmaceutical sector. In order to improve access to chemical reference material, EAC organs will be advised and accompanied in setting up a regional centre. Various custom-made training activities qualify staff from industry, regulatory authorities and Quality Infrastructure institutions on how to introduce quality management systems and to maintain laboratory equipment.

Impact
The improved access to Quality Infrastructure services for the pharmaceutical sector enables manufacturers and control authorities to better meet international accepted quality standards like the WHO prequalification or the ISO/IEC 17025 laboratory standard. This opens up new growth opportunities for manufacturers beyond their national borders and ensures better controls 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).

Financing
Federal Ministry for Economic Cooperation and Development, Germany (BMZ)

Term
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