

PTB in brief

A globalized international economy calls for globalized metrology. This is why the orientation and impact of PTB, the national metrology institute of Germany, is not restricted to the national borders.

PTB with its 2,000 staff members is rather a „global player“ in the world of metrology and faces the responsibility involved for society, economy and science.

The international tasks of PTB include cooperation in all kinds of metrological organizations (the Meter Convention being the most prominent example) and cooperation with national metrology institutes all over the world. Furthermore, the PTB International Technical Cooperation advises and supports the conceptual design and practical implementation in the establishment of the quality infrastructure in developing and transition countries.

The clients of the Technical Cooperation projects are above all the Federal Ministry for Economic Cooperation and Development (BMZ), which finances the majority of projects with PTB participation, but also the European Union, the World Bank and other organizations. For the implementation of projects a network of strategic partners is available.

All in all, the global networking of PTB has one major objective: the international harmonization of quality infrastructure and its mutual acceptance.

Project Data

Establishment of a regional Quality Infrastructure for the pharmaceutical sector

Source of finance

Federal Ministry for Economic Cooperation and Development, Germany

Commission value

1,500,000 EUR

Implementing agency

Physikalisch-Technische Bundesanstalt (PTB)
National Metrology Institute, Germany

Term

March 2013 until February 2016

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updated: 04/2013



Establishment of a regional
Quality Infrastructure for
the pharmaceutical sector
in the EAC

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Background

During the past few years, a pharmaceutical industry has developed in East Africa which produces generics and its own pharmaceutical products. The pharmaceutical sector thus contributes to improve the medical care for the population and to reduce imports of pharmaceutical products. Most pharmaceutical enterprises are only allowed to produce for their own domestic market. They are excluded from tendering for the large-scale orders of donors such as the WHO because they cannot prove that they will comply with the respective quality standards. For the approval and market surveillance of pharmaceuticals in the member states of the East African Community (EAC), special regulatory authorities and control laboratories are responsible.



The Quality Infrastructure in the region is not well adapted to the requirements of the pharmaceutical sector. There are shortcomings as regards the number of trained quality managers and service technicians, the calibration of laboratory equipment, the capacity to carry out comparison measurements and the availability of reference materials.

The EAC has an interest in supporting the pharmaceutical industry. This is reflected by the fact that the health ministers of the EAC states have approved the *EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA)*.

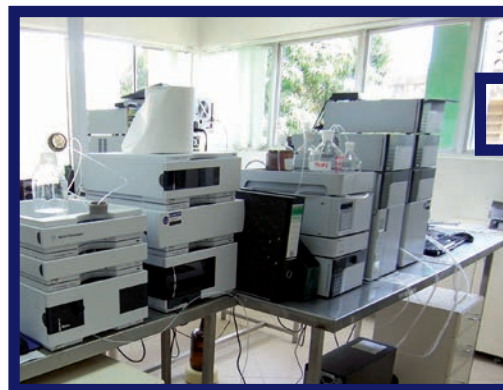
Objectives

The overall objective of the project is to contribute to the implementation of the RPMPOA and to improve quality infrastructure services (QI) in the region in such a way that they meet the demand of the pharmaceutical sector.

Components of support

The project focuses on the following areas:

- Strengthening of local producers' capacity to meet WHO-GMP and WHO prequalification standards (focus on calibration and validation)
- Developing the capacities of pharmaceutical control laboratories (through comparison measurements and provision of reference material)
- Supporting market surveillance in partner states in the prevention of inferior quality



HPLC for the analysis of pharmaceutical substances



Inspection of a pharmaceutical production site

Project Partners

The project is an integral part of the German development program "Support of the EAC Integration process".

It is implemented in cooperation with the EAC Secretariat, its *Health Department*, which is part of the *Directorate of Productive and Social Services*. Beneficiaries are the National Medicines Regulatory Agencies and their control laboratories as well as the local pharmaceutical manufacturers who are organized in the *Federation of East Africa Pharmaceutical Manufacturers*.

