DIRECTOR UNITID AND CHIEF TECHNOLOGIST ATTENDS EAC REGIONAL HARMONISATION OF MEDICAL DEVICES IN DAR SALAAM

From R-L Director UNITID ,Prof Walter Mwanda and Fred Mose (far Left) and other Members from the Kenyan Republic during the Meeeting at New Africa Hotel at Dar Saaam.UNITID is participating in the Regional EAST AFRICAN COMMUNITY REGIONAL meeting ON THE STRENGTHENING AND HARMONIZATION OF THE REGULATION OF MEDICAL DEVICES AND DIAGNOSTICS.

The Institute is represented by Director UNITID and Chief Technologist .The EAC meeting is to strengthen and harmonise the regulation of the Medical devices among the EAC member countries .

London School of Tropical Medicine is one of the key informants of the EAC on harmonisation of the medical Devices .

East African Community (EAC) is a regional inter-governmental organization of the five Partner States, namely the Republic of Burundi, the Republic of Kenya, the Republic of Rwanda, the United Republic of Tanzania and the Republic of Uganda, with its headquarters located in Arusha, Tanzania.Access to medical devices and diagnostics for health in the EAC is limited by their availability and cost, and there is uncertainty as to the safety and effectiveness of some products. Regulatory control of medical devices and diagnostics is weak across the EAC with efforts to control the quality of imported products largely confined to national disease programs for pathogens such as Human Immunodeficiency Virus (HIV) and malaria. Weak regulation allows poor quality products to be marketed. Inefficient regulation delays access to beneficial new products and increases costs to manufacturers, inflating prices for consumers. Streamlining and harmonizing regulatory processes in EAC Partners States can reduce delay and unnecessary expense, and improve access to new products.

The primary aim of the *East African Community Regional Project Proposal on Strengthening and Harmonization of the Regulation of Medical Devices and Diagnostics* is to enhance the health of the population by improving access to diagnosis and treatment of communicable and non-communicable diseases by ensuring access to safe and effective medical devices and diagnostics though the enhancement of regulatory capacity and supporting the use of collaborative mechanisms for regulatory approval in the region in accordance with the mandate provided by Article 118 of the Treaty on the establishment of the EAC.

The project will be implemented by EAC Secretariatôs Health Department together with the National Medicines Regulatory Authorities (NMRAs). In undertaking this project a Project Coordination team operating within the EAC Secretariat will be responsible for the overall

management and implementation at regional level while national level activities will be undertaken by the technical staff of the NMRAsô.

It is envisaged that the project will run for five years with the following objectives:

i. To develop and implement regional harmonized regulatory and mutual recognition framework for regulation of medical devices and *in vitro* diagnostics
ii. To develop and implement Quality Management System in EAC Partner States NMRAôs for regulation of medical devices and in vitro diagnostics
iii. To build and improve human resource and infrastructural capacity for the regulation of medical devices and diagnostics in the EAC region
iv. To develop and implement a regional integrated Information Management System (IMS) for regulation of medical devices and in vitro diagnostics linked to all EAC Partner States and EAC Secretariat
v. To establish and strengthen platforms for sharing developments in research and innovations on medical devices and in-vitro diagnostics

The EAC harmonized regional medical devices and diagnostics regulation system will be sustained through the existing organisational and institutional framework of the EAC Secretariat and Partner StatesôNMRAs. Financial resources to be mobilized will be used to support the project for the five years of its duration. Subsequently, the cost of maintaining on-going project activities and personnel will be borne by the EAC Secretariat and the Partner StatesôNMRAs. The project staff at EAC Secretariat and at the NMRAs will be absorbed and retained as regular staff in order to institutionalize the harmonized regulatory systems.