	UNITED REPUBLIC OF TANZANIA **MINISTRY OF HEALTH** **TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**	TMDA Tanzania Medicines & Medical Devices Authority

OPENING REMARKS BY THE DIRECTOR OF MEDICAL DEVICES AND DIAGNOSTICS CONTROL - TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA) DURING THE CAPACITY BUILDING WORKSHOP ON MNCH MDs ASSESSMENT OF TECHNICAL FILES
DELTA HOTEL MARIOTT, DAR ES SALAAM
31ST OCTOBER 2023

- ✓ **Representatives from WHO,**
- ✓ **Representatives from AUDA-NEPAD**
- ✓ **Representative from MTaPs**
- ✓ **Chair and vice-chair of AMDF**
- ✓ **Representative from USFDA**
- ✓ **Distinguished guests,**
- ✓ **Esteemed colleagues,**
- ✓ **and participants,**
- ✓ **Ladies and Gentlemen,**

GOOD MORNING! Habari za asubuhi!

I am honoured to welcome you all to this capacity-building workshop on the assessment of Maternal, Newborn, and Child Health (MNCH) medical devices technical files for regulators. I would like to give a special heartfelt welcome to all participants and representatives coming from outside Tanzania; please welcome to Tanzania especially in this Business city, Dar es Salaam. Special thanks goes to the organizer of this workshop, Medicines, Technologies, and Pharmaceutical Services (MTaPS) in collaborated with AMDF, WHO, AUDA-NEPAD I highly appreciate your support and time dedicated for preparation and attending this workshop. In addition by selecting Tanzania to be the host of this workshop.

I would like to thank all 11 National Regulatory Authority (NRAs) in your respective countries for allowing you to attend this workshop.

South Africa, Zambia, Botswana, Kenya, Rwanda, Uganda, Tanzania, Ethiopia, Ghana, Nigeria, Senegal

Ladies and Gentlemen,

Many African countries face considerable challenges in ensuring quality, safety and performance of medical devices circulating on the market due to lack of expertise to assess these Medical Devices including those for MNCH in the continent.

So convening this workshop is a major milestone in overcoming this challenge as the training will produce a pool of experts for assessing the medical devices before been authorized for marketing.

Ladies and Gentlemen,

I am sure you all know that the first line of defence of any National Regulatory Authority (NRAs) for a medical product to enter into the market is to conduct assessment for quality, safety and performance (MDs). These are very important registration criteria.

Regulators play a pivotal role in ensuring that these medical devices meet the highest standards, providing a crucial safeguard for patients and healthcare providers. It is with this reason that we gather here today to empower our regulators with the knowledge and skills needed to effectively assess technical

files, ultimately making a profound impact on healthcare outcomes.

So in these 3 days that you are going to be here, you will be looking at the requirements as per guidelines and ISO standards and be learning how to assess submitted data and use that information to make an informed decision regarding registration of a particular devices.

You will also have the opportunity to engage with experts in the field, exchange valuable insights, and gain practical knowledge that will fortify your ability to evaluate these critical medical technologies. The outcomes of this training will not only bolster the regulatory framework but also pave the way for safer and more effective MNCH medical devices.

Ladies and Gentlemen,

This is the first workshop of its kind to be conducted here in Tanzania. We are all committed to enhance the quality, safety and performance of medical devices critical to the health and well-being of mothers, newborns, and children.

I encourage you to actively participate, engage in constructive discussions, and leverage this platform to learn, share, and network. By working together, we can further the cause of better healthcare for mothers, newborns, and children, advancing our collective mission of saving lives and improving the quality of care.

Ladies and Gentlemen,

It is therefore my hope that through this workshop all the participants will become good assessors of MNCH MDs and for sustainability, you will be able to train others in your respective workplaces.

With these few remarks, I wish you a productive and enlightening workshop.

It is my exceptional honor to declare this training is officially opened.

ASANTENI AND KARIBUNI SANA!!

This in person training for regulators from different NRAs of the regional economic communities of the continent will enable the medical devices assessors to strengthen technical skills and assessment knowledge of different types of health technologies, to enable them conduct regulatory activities in an effective way and reinforce product registration function.

This will also facilitate the development of a pool of well-trained assessors on medical devices including those for MNCH, who will also participate in different regional and international joint review of medical devices and in vitro diagnostics. These assessments will contribute to strengthening the assessment process and in turn enhancing access to suitable medical devices, increasing safety and performance of medical devices and support quality of care and support health care systems at national and regional level.

The purpose of the course is to provide capacity building for assessment of medical device technical file for medical device assessors. The capacity building sessions are aimed at increasing skills and knowledge of product registration personnel by:

Enhancing the capacity of assessing scientific assessment reports on data submitted on applications for registration of medical devices in accordance with established regulatory Standards, Regulations and Guidelines, as well as the considerations for regulating MNCH medical devices