

THE UNITED REPUBLIC OF TANZANIA



MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER,
ELDERLY AND CHILDREN

OPENING REMARKS MADE BY DR. ZAINAB A CHAULA,
PERMANENT SECRETARY
AT THE TRAINING WORKSHOP ON GMP INSPECTION
FOR SADC REGULATORS

HARBOR VIEW HOTEL, DAR ES SALAAM
13th August 2019

- World Bank Representatives,
- SADC Representatives responsible for MRH Programme Coordination,
- TMDA Acting-Director General and other Directors,
- Training Facilitators,
- Dear Participants,
- Media Representatives.

Ladies and Gentlemen,

I feel incredibly honoured to be availed this opportunity to officiate this important regional elementary training workshop that has been agreed to be held right here in Tanzania at this hotel premises.

On behalf of the Ministry of Health, Community Development, Gender, Elderly and Children, I would like to welcome you to Tanzania and for those who are visiting for the first time this part of Africa, we say **karibuni sana** in our local language (meaning you are warmly welcome).

Let me also use the occasion to thank all those who took part in the build-up to this scheduled training. I know it is hectic, time-consuming and daunting experience to organize such regional trainings particularly from the perspective of ensuring that participants from other countries arrive safely and assemble for the intended purpose. You are indeed acknowledged and appreciated for your efforts and well planned coordination.

Ladies and Gentlemen

You will all agree with me that Governments all over Africa even around the globe strives to put measures that will protect public health by all means. The Sustainable Development Goals 2030, has set up goals that intends to achieve universal health coverage and access to safe, effective, quality and affordable essential medicines and vaccines for all.

It is from this standpoint that the Government of the United Republic of Tanzania through the Ministry I'm heading, has developed a Health Policy that aims at amongst others, to ensure that these goals are attained.

To be in tandem with this, the Tanzanian government had established the Tanzania Food and Drugs Authority (TFDA) which operated since 2003 and recently it has been switched to Tanzania Medicines and Medical Devices Authority or in short TMDA to regulate the quality, safety and efficacy of medicines, medical devices and diagnostics. The regulatory functions related to food and cosmetic products have now been shifted to Tanzania Bureau of Standards (TBS).

The TMDA just like the way it was TFDA was operating, has been working hard to set-up systems for regulation of medical products and I truly commend them for what they are doing. Through TMDA, we can now evaluate products to ascertain their quality, safety and efficacy, license premises, conduct Good Manufacturing Practices (GMP) inspection and do all other regulatory functions as recommended by the World Health Organization.

It is due to their efforts and sustained commitment that they have recently attained Maturity Level 3 status through the WHO benchmarking process which you are all aware and believe that you are also working hard towards the same milestone.

Ladies and Gentlemen

I know most of you here have also established regulatory agencies that unequivocally functions to protect public health. I also believe because of the complexities and technicalities involved in conducting GMP inspection of pharmaceutical manufactures and as alluded to by the Acting Director General of TMDA, that's why you have decided to organize this training programme.

I have also noted that this training is part of the efforts of SADC member countries towards imparting knowledge and skills to new Inspectors in the region to effectively conduct GMP inspections. This in-turn will allow products of good quality to be manufactured and marketed in our countries.

Nonetheless, despite the outcomes of this training, I still urge you to expedite approval processes of medicines in your countries to make them freely available. Should you prolong the review timelines, the same will result into delays in access to these essential medical products that also save lives.

By making them accessible, even the Medical Stores Department of Tanzania which has recently won the tender to supply medicines in the SADC region, through the pooled procurement process, will be able procure and supply registered products to all SADC countries.

Ladies and Gentlemen

Let me finally reiterate on the significance of forging partnerships, collaborations and cooperation amongst you as regulators. I have noted that there are around 30 Inspectors from 14 SADC member states including my country who will take part in this training workshop.

This is really fundamental and we should uphold the regional cooperation particularly on technical capacity building, information sharing and taking speedy regulatory actions. Should substandard or falsified medical products cross our borders, we should communicate for action to be taken immediately. It is my plea that we truly maintain this in the long run.

Ladies and Gentlemen

Before concluding my remarks and on an exceptional note, let me now take the opportunity to thank the World Bank for providing financial support to this scheduled training and the SADC Medicines Regulatory Harmonization Coordinating Team for the technical support in the harmonization process.

It is through these types of initiatives that technical requirements will be streamlined and a common platform established in regulation of medical products in the region.

Lastly, we at the Ministry, we pledge our full commitment and support towards the SADC harmonization initiative including other initiatives in Africa as alluded to by the Acting Director General in his introductory remarks. If I could also mention here, we are also in the process of ratifying the Treaty for establishment of the African Medicines Agency (AMA) through our country procedures and we will notify NEPAD and other concerned parties on the outcome within shortest possible time.

Ladies and Gentlemen

With these few remarks, I wish you all the best and I now have the honour to declare that this *SADC Elementary Good Manufacturing Practices Training for new GMP Inspectors* has officially been opened.

Thank you for your attention

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