

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY



**WELCOMING REMARKS MADE BY MR. ADAM MITANGU
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AT THE REGIONAL TRAINING WORKSHOP ON GMP
INSPECTION FOR SADC REGULATORS**

HARBOR VIEW HOTEL, DAR ES SALAAM

13th August 2019

- Guest of Honor – The Permanent Secretary - Ministry for Health, Community Development, Gender, Elderly and Children,
- World Bank Representatives,
- SADC Representatives responsible for MRH Programme Coordination,
- TMDA Directors present here,
- Training Facilitators,
- Dear Participants,
- Media Representatives,
- Ladies and Gentlemen

Guest of Honor

Let me first and foremost begin by thanking you for accepting our invitation to officiate this important training workshop despite your busy schedule. The workshop has been organized by the SADC Medicines

Regulatory Harmonization Coordinating Team and Tanzania is the host country.

Guest of Honor

As you have heard from the introductions, before you are participants from SADC member states who have convened here for the purpose of being trained on matters related to good manufacturing practices (GMP) inspection of pharmaceutical manufactures.

We welcome all of you in Tanzania and for those whom this is your first time to visit this part of East Africa, please find some time to explore the beauty of Dar es Salaam - our commercial city.

Guest of Honor

Tanzania is a member of SADC economic community and as regulators, we are also part of the SADC Medicines Regulatory Harmonization initiative. This SADC MRH programme began in the year 2015 and ever since we have been able to harmonize a number of regulatory technical guidelines and procedures.

Together with SADC, we are also members of the East African Harmonization Programme, the AVAREF Harmonization Initiative for Clinical Trials and the GALVMed sponsored Harmonization Programme

for Veterinary Immunological Products. The NEPAD Planning and Coordinating Agency plays a coordinating role under the auspices of the African Medicines Regulatory Harmonization (AMRH) programme which also takes on board other harmonization initiatives all over Africa.

Through these harmonization initiatives, we have been able to meet regularly and discuss matters related to convergence of regulatory requirements with an overall objective of trying to find a way to avoid duplication of work and streamline our processes towards ensuring that medicines are regulated using a common and standardized approach.

Guest of Honor

The benefits of harmonization have begun to be realized and now we have a mutual understanding and confidence of working together in various matters related to regulation of medical products.

Some of the notable achievements embrace organizing and conducting joint dossier assessment sessions and joint GMP inspections. Under SADC MRH programme, these have also been bolstered by the determination, efforts and commitment of five SADC member states namely Zambia, Zimbabwe, Botswana and Namibia famously now abbreviated or known as ZAZIBONA which they have been instrumental in this process. We have just joined this winning team to spearhead the initiative and bring in more vigor and energy in the SADC region.

Guest of Honor

Despite the notable achievements, capacity building is still a constant process that needs to be carried out over and over again and particularly when new staff are added to any organization.

This has been the reason for organizing this training targeting elementary staff who have recently joined or never attended GMP inspection training before.

In connection to this, the training will focus mainly on:

- Imparting knowledge and skills on conducting GMP inspection of pharmaceutical manufacturers through theoretical presentation of different inspection techniques
- Visiting some domestic companies for practical orientation
- Information and experience sharing on inspection approaches amongst regulators

The expectation after this training is that, new Inspectors will be able to apply the skills and knowledge when conducting inspection of manufactures to ensure that medical products are consistently produced and controlled to the required quality standards appropriate to their intended use and specifications.

As GMP inspection is a pre-requisite for marketing authorization, medical products would then be able to be registered and allowed to circulate in our markets.

Guest of Honor

This training workshop will run for around two weeks and I would like to thank the SADC Implementing Team under ZAZIBONA stewardship for making available experienced facilitators who have agreed to facilitate in this workshop.

Guest of Honor, Ladies and Gentlemen

With these few remarks, may I now take the opportunity to humbly welcome you for remarks and official opening of our training programme so that we can proceed.

Thank you for your attention

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