WELCOME STATEMENT BY MR. HIITI B. SILLO, DIRECTOR GENERAL, TANZANIA FOOD AND DRUGS AUTHORITY DURING THE 7TH STEERING COMMITTEE OF EAC MEDICINES REGULATORY HARMONIZATION PROGRAMME

NEW AFRICA HOTEL, DAR ES SALAAM, TANZANIA

30TH JULY 2015

Deputy Secretary General, Productive and Social Sectors, EAC Secretariat

Chief Pharmacists, Ministries of Health of Partner Sates

Heads of National Medicines Regulatory Authorities in EAC Partner States;

AMRH Partners

Members of the Media

Distinguished Guests, Ladies and Gentlemen;

I am very pleased to welcome you to Dar es Salaam and to the 7th Meeting of the EAC MRH Steering Committee. I believe that you are all travelled safe and are in good health for our meeting here in Dar es Salaam.

I would also like to take this opportunity to thank the EAC Secretariat for organizing this meeting we go ahead in implementation of the 2nd phase of East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme.

Hon. Dupty Secretary General,

The main purpose of the East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme is to improve access to safe, efficacious and good quality medicines by harmonizing medicines regulatory systems and procedures in accordance with national and international policies and standards.

The Programme was officially launched on 30th March, 2012, with five specific objectives, and as a first such programme in Africa under the broader African Medicines Regulatory Harmonization Programme. The first phase of the programme came to an end on 31st December 2014. It is expected that during this 2nd phase, all the approved guidelines and requirements will be domesticated in all Partner States and applications for registration of medicines will be received accordingly as per harmonized guidelines. The programme is also expected to achieve specific outputs such joint dossier assessments, joint GMP inspections, Implementation of quality management system and information management systems (IMS) solution and continued capacity building in Medicines Regulatory Sciences.

This meeting is preceded by the 3rd Forum for Heads of NMRAs that took place yesterday in the same venue. As you all know, the Forum was established to facilitate timely decisions across the Partner States and eliminate delays in administrative processes for issuing final marketing authorization for products that have successfully undergone joint reviews. The Forum is also expected to support and sustain the work of EAC-MRH Steering Committee beyond the project period.

Hon. Deputy Secretary General,

The Steering Committee will today receive progress reports on various activities being undertaken by different Expert Working Groups established under under EAC-MRH Programme, and more specifically to discuss: -

- Revised EAC Procedure for Marketing Authorization of Medical Products;

- Project Proposal on Harmonization and Strengthening of Regulation and Quality Assurance of Medical Devices and Diagnostics,

- Project Proposal on Harmonization and Strengthening of Pharmacovigilance and Post Marketing Surveillance Systems for Medicines, health Products and Health Technologies in the EAC Partner States,

- Project Proposal on Harmonization of Regulatory Frameworks for Clinical Trials on Medical Products, Vaccines and Health Technologies;

- Concept Note on Harmonization of Registration of New Vaccines in the EAC Region, Concept note to guide on expansion of scope of EAC-MRH Programme,

- Administrative and Financial Management Issues related to EAC-MRH Programme,

- National & Regional Activities of EAC-MRH Programme (August to December 2015); and

- Improved communication and governance of EAC MRH.

It is my hope that we will have enough time to discuss all these issues and make appropriate decision on each of them.

Hon. Deputy Secretary General,

With this background, it is clear that we have a fully packed agenda for today and we therefore we need to be focused. We should all remember that one key activity which will be used to measure success of EAC-MRH programme is operationalization of joint dossier assessment scheme which is key in achieving the objectives of EAC MRH programme. As a Chair of this for this meeting, I am welcoming suggestions and recommendations which can help EAC Partners States receive many applications for the scheme to take off.

Before I conclude my remarks, I am pleased to inform my colleagues that EAC Compendium guidelines for registration of medicines in Tanzania came into force from 15th July 2015. It is expected that all submission from that date onwards will be based on the harmonized guidelines and requirements. In other words Tanzania has already domesticated the guidelines and is now looking forward to see the joint assessment scheme being operationalized.

Hon. Deputy Secretary General and Heads of NMRAs,

The success of EAC MRH process relies on us. Other RECs and the whole community of medicines regulation harmonization at the continental and global level is watching, our development partners are also watching and Africa is looking at us and waiting for the results to come. This is the time to change gear and move ahead.

With these few remarks I once again welcome you to Dar es Salaam and wish you a very successfull meeting.

Thank you very much and *Karibuni Sana!*