Press Conference

The 6th Steering Committee meeting of the East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme

Presented by Hiiti B. Sillo, Director General, Tanzania Food and Drugs Authority and Chairperson

Friday, 6 March 2015

Ladies and gentlemen, on behalf of all members of the EAC-MRH Programme Steering Committee, I am very pleased to welcome you to our Press Conference, here, in Kigali, Rwanda. I would like to thank the EAC Secretariat for the excellent organization of this two days meeting of the 6th Steering Committee of the EAC-MRH Programme which was officially opened by **Honourable Jesca Eriyo**, the Deputy Secretary General for Productive and Social Sectors at the EAC Secretariat.

The EAC-MRH Programme was officially launched on 30th March 2012 with the main purpose of improving access to safe, efficacious and good quality medicines by harmonizing medicines regulation systems and procedures in accordance with national and international best practices.

The Steering Committee was established in order to provide overall oversight and directions towards implementation of activities earmarked under the Programme. The Committee is composed of the Chief Pharmacists from the EAC Partner States' Ministries responsible for Health, the Heads of EAC Partners States' National Medicines Regulatory Authorities' (NMRAs), EAC Secretariat and the African Medicines Regulatory Harmonization (AMRH) Programme Partners namely; the African Union NEPAD Agency, the World Health Organization (WHO), Bill and Melinda Gates Foundation (BMGF), the World Bank (WB), the United Kingdom Department for International Development (DFID) and United States Government.

At this meeting, we are privileged to have representatives from the World Health Organization Regional Office for Africa (WHO/AFRO), Management Sciences for Health/Systems for Improved Access to Pharmaceuticals and Sciences (MSH/SIAPS), West African Health Organization (WAHO), the West African Economic and Monetary Union (UEMOA Commission) and Ethiopian Food, Medicines and Healthcare Administration and Control Authority who were invited as observers.

The EAC-MRH Programme is coordinated by the EAC Secretariat and implemented by the EAC Partner States' NMRAs namely; Department of Pharmacy, Medicines and Laboratories (DPML) of Burundi, National Drug Authority (NDA) of Uganda, Pharmacy and Poisons Board (PPB) of Kenya, Pharmacy Task Force (PTF) of Rwanda, Tanzania Food and Drugs Authority (TFDA) and Zanzibar Food and Drugs Board (ZFDB).

The implementation of Phase I of the EAC-MRH Programme came to an end on 31st December 2014. During that Phase, harmonized guidelines, requirements and standards for Medicines Evaluation and Registration (MER), Good Manufacturing Practices (GMP) and Quality Management Systems (QMS) were developed by the Expert Working Groups (EWGs) and approved by the 29th Ordinary meeting of the EAC Council of Ministers on 20th September 2014 through its Decision **EAC/CM29/Decision 036** and directed the EAC Partner States' NMRAs to domesticate and implement the guidelines, requirements and standards for MER, GMP and QMS in Phase II effectively from 1st January 2015.

To effect the Council's Decision, the EAC Secretariat in collaboration with EAC Partner States NMRAs issued a Press Release on Tuesday 14th January 2015. In order to ensure smooth domestication and implementation of the approved documents in the region, marketing authorization holders and future medicines registration applicants are informed that:-

a) From now onwards, interested applicants may apply for marketing authorization of their medicinal products in the region by referring to the procedure contained in the Press Release issued by the EAC Secretariat on 14th January 2015.

b) The adopted EAC harmonized guidelines on MER, GMP and QMS are accessible online on the following websites:- www.eac.int, www.mrh.eac.int, www.tfda.or.tz, www.pharmacyboardkenya.org, www.nda.or.ug, http//minisante.bi/, www.moh.gov.rw and www.zfdb.go.tz

c) The EAC Secretariat in collaboration with EAC Partner States NMRAs will conduct national stakeholders' sensitization meetings between April and June 2015 on the use and agree on the roadmap for effective implementation of the adopted EAC harmonized guidelines on MER and GMP.

During this two days meeting, the Steering Committee discussed and agreed on implementation of Phase II activities mainly focusing on joint assessments and joint GMP inspections for marketing authorization, improvement of regulatory services by the NMRAs through implementation of harmonized Quality Management System (QMS) and Information Management System (IMS) and advocacy and communication of the EAC-MRH Programme. In this Phase, the region will also expand the scope of the Programme to include Strengthening and Harmonization of Pharmacovigilance and Post Market Surveillance (PMS) systems and regulation of Medical Devices and Diagnostics. Proposals for the two projects are being finalized for approval by the Policy organs of the EAC.

In addition, the meeting discussed the proposal from the Swiss Agency for Therapeutic Products (SWISSMEDIC) to support the EAC-MRH Programme in which areas of support under the Programme were identified and agreed upon.

In conclusion, the meeting agreed to continue pursuing harmonization and integration agenda in the Pharmaceutical Sector in order to improve public health outcomes by ensuring access to medical products of good quality, safety and effectiveness which are affordable. Our commitment as the Steering Committee for this Programme complements provisions of the EAC Treaty and Common Market Protocol.

Thank you for your attention