



**EAST AFRICAN COMMUNITY**

**NATIONAL STAKEHOLDER'S CONSULTATION  
MEETING TO VALIDATE DRAFT EAC MEDICINES  
AND HEALTH TECHNOLOGIES POLICY, STRATEGIC  
PLAN (2017-2021) AND MUTUAL RECOGNITION  
FRAMEWORK**

**29<sup>TH</sup> TO 30<sup>TH</sup> SEPTEMBER, 2016, ZANZIBAR, UNITED  
REPUBLIC OF TANZANIA**

**REPORT OF THE MEETING**

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## **1.0 Convening of the meeting**

The first stakeholder's consultation meeting to validate draft East Africa community (EAC) medicines and health technologies policy, strategic plan (2017-2021) and cooperation framework was convened from 29<sup>th</sup> to 30<sup>th</sup> September, 2016 at Zanzibar Beach Resort, Zanzibar. The meeting was attended by participants from Ministry of Foreign Affairs and East African Cooperation, Ministry of Health, Zanzibar Food and Drugs Board, Zanzibar Association of Pharmaceutical Industries, Government Chemists Laboratory Agency, Consumers Association, Chamber of Commerce, College of Health Sciences Zanzibar, Bureau of Standards Zanzibar, Zanzibar Planning Commission, Attorney General Office, Ministry of State (Vice President Office) Constitution and Legal Affairs Public Services and Good Governance, Ministry of Industry and Trade, and representatives from the EAC Secretariat. The following Development Partners were represented by AU NEPAD Agency and World Bank.

The list of Participants is attached as **Annex I**:

## **2.0 Adoption of the Agenda and the Programme**

The Agenda and Programme of the meeting were adopted and are hereto attached as **Annex II**

## **3.0 Purpose of the meeting**

The purpose of the meeting was to validate the following;

- (i) Draft EAC Medicines and Health Technologies Policy;
- (ii) Draft EAC Medicines and Health Technologies Strategic Plan 2017-2021;
- (iii) Cooperation Framework for NMRAs; and
- (iv) Assessment Report

## **4.0 Welcome remarks**

### **4.1 EAC Secretariat**

The representative of the EAC Secretariat Mr. Stephen Agaba, the Principal Legal Officer, on behalf of the EAC Secretary General, thanked the participants to the meeting for their commitment to spend their time to come and participate in the national stakeholders consultation meeting for discussion of various regional documents, that included the regional pharmaceutical policy among others.

In addition he thanked the Zanzibar Revolutionary Government for the commitment and continued support it has been given to the regional and Secretariat in particular that has propelled the regional integration agenda. He concluded his remarks by requested the stakeholders to have time to go through the documents and take process is very important to be able to contribute and enrich the draft documents at the Partner states before regional approval and adoption for implementation.

#### **4.2 Chief Pharmacist**

Mr. Abdulhalim Mohd Mzale, the Acting Chief Pharmacist, in his remarks he thanked the EAC Secretariat for organizing, coordinating and supporting National activities on Pharmaceutical area, he also appreciated stakeholders for participating on the meeting despite heavy competitive commitment. He concluded his remarks by wishing all fruitful deliberation.

#### **4.3 Ministry of Foreign Affairs and East African Cooperation**

Mr. Othman Maalim Othman, Officer from Ministry of Foreign Affairs and East African Cooperation Zanzibar Office in his remarks thanked all the stakeholders participating in the national consultation on the EAC Regional Pharmaceutical Policy and relevant documents under review.

#### **5.0 Opening the meeting**

The meeting was officially opened by the Director General Ministry of Health Zanzibar Dr. Jamala Taib, in his opening remarks he started by welcoming all the participants to the meeting, he further thanked all participants for accepting the invitation to the meeting.

He extended his appreciation to the East African Community (EAC) specifically to the Medicines Regulatory Harmonization (MRH) Project team for their continual support and commitment in implementing National programs on strengthening medicines regulatory activities which aimed on improving quality of medicines as well as increasing accessibility to all people within the EAC region to supply of safe and cost-effective medicines and health technologies to all people of the EAC and their rational use by prescribers, dispensers and consumers.

On his remarks, he highlighted the importance of gatherings which enable building of a productive dialogue between experts from member countries it also provide an invaluable opportunity for networking and fruitful contacts between countries.

He informed participant that the EAC Secretariat and the Partner States through regional Expert Working Group (EWG) of Policy and Legal Frame of EAC MRH Project jointly developed the East African Regional EAC medicines and health technologies policy, Strategic Plan (2017 - 2021) and Mutual Recognition Framework Agreement and requested stakeholders to

thoroughly review the draft documents that have been developed and give their technical inputs so as to guide the Secretariat on the on-going work.

In addition to that he also cautioned the use of infective, poor quality, harmful medicines can result in therapeutic failure, exacerbation of disease, resistant to medicines and sometimes death. It also undermines confidence in health systems, health professionals, pharmaceutical manufacturer and distributors.

In conclusion of his remarks on behalf of the Ministry of Health, he wished all participants of the meeting fruitful deliberation and happy stay in Zanzibar.

## **6.0 Presentation of the Draft EAC Medicines and Health Technologies Policy**

During the review and inputs process into the draft EAC Medicines and Health Technologies Policy document to the national stakeholders, Ms. Jane Mashingia, Senior Health Officer from EAC Secretariat presented Medicines and Health Technologies Policy.

Participants observed that some demographic information for United Republic of Tanzania (Zanzibar) was missing and that the data presented was for the United Republic of Tanzania (Mainland) only.

In addressing the missing data, the participants provided the meeting with data on Maternal Mortality Ratio, and the current figure provided are: 307/100,000 live Birth; and under five mortality rate 67.4/1000 live birth based on the Census 2012.

Additional raised comments during the presentation of the documents, was on the information provided in the situation analysis about the existing capacities of Partner States NMRAs which indicated that in general it was still low in many aspects (especially Research and Human Resources). In this regard, stakeholders recommended that information in the situation analysis be updated to reflect the current region's existing medicines regulatory capacities.

The revised draft EAC Medicines and Health Technologies Policy with incorporated inputs by United Republic of Tanzania (Zanzibar) stakeholders is hereto attached as **Annex III:**

### **Recommendations:**

- a. On table 1, status of implementation of components of National Medicines Policy should be elaborated to capture the real situation in Zanzibar.
- b. Information management system development should consider quality data, security and integrity.
- c. Health Data and information specific for the United Republic of Tanzania (Zanzibar) should be incorporated in the documents
- d. Strategy to monitor Regional Rational use of Medicines should be developed
- e. After being reviewed by stakeholders of the United Republic of Tanzania (Zanzibar), the draft EAC Medicines and Health Technologies policy was endorsed for consideration by regional stakeholders and EAC Policy Organs.

## **7.0 Presentation of the Draft EAC Medicines and Health Technologies Strategic Plan (2017-2021)**

Ms. Jane Mashingia from EAC Secretariat presented the draft document to the stakeholders for consideration and inputs.

The revised draft EAC - Medicines and Health Technologies Strategic Plan 2017 - 2021 with incorporated inputs by national stakeholders is hereto attached as **Annex: IV**

### **Recommendations:**

- a. EAC Secretariat to add data and relevant information from the “National Health Account Reports” as Baseline and target on strategic objective of medicine financing and pricing.
- b. EAC Secretariat to review the document and add strategic statement which abolishes percentage of Out Pocket as one method of payment of medicine which become very high.
- c. After being reviewed by stakeholders of the United Republic of Tanzania (Zanzibar) the draft EAC Medicines and Health Technologies Strategic Plan (2017-2021), was endorsed for consideration by regional stakeholders and EAC policy organs.

## **8.0 Presentation on Mutual Recognition Agreement and Negotiations Process for NMRA.**

Ms. Staicy Wagala, Trade Expert from EAC Secretariat presented an overview on Mutual Recognition Agreements (MRAs) which is more closely related to the Cooperation Framework for EAC -NMRAs in relation to the regulation of Medicines and Health Technologies in the EAC - Partner States.

In her presentation she gave key highlights on critical areas that need to be well detailed and clarified to ensure smooth implementation of such Cooperation Framework. Some of the areas mentioned included the following among others:

- i. Roles, responsibilities and obligations of different parties to the framework.
- ii. Financing for the operationalization of the Cooperation framework.
- iii. The need to have a clear scope that Cooperation Framework covers.

**The presentation is hereto attached as Annex: V**

## **9.0 Presentation of the EAC-NMRAs Cooperation Framework.**

Mr. John Patrick Mwesigye, from EAC Secretariat presented a draft EAC - NMRAs Cooperation Framework in relation to the regulation of Medicines and Health Technologies in the EAC - Partner States.

Presenter highlighted principles of the cooperation framework, scope and areas of cooperation among others.

During the presentation stakeholders were informed of a few inputs that were incorporated by (Tanzania - Mainland) team during their stakeholders meeting and finally requested participants for inputs, comments consideration and approval of the documents and also urge policy makers to mobilize resources for implementation.

The stakeholders meeting provided inputs into the EAC -Partner States NMRAs draft Cooperation Framework (CFW); and these include the following among others:

- i. To use the word “voluntary” in collaborative procedure under the cooperation framework.
- ii. Under the scope to include Regulation of health Technologies and Regulation of Clinical trials.
- iii. Definitions of the word Requirement and Standard should be provided.
- iv. On the responsibilities of NMRAs to add any other related regulatory area that NMRAs shall agree upon from time to time.
- v. On Article 7.0, paragraph 7.2.3 it was recommended to review the paragraph to cover areas and activities prescribed under EAC - NMRAs joint activities.

- vi. On Article 7.0, paragraph 7.2.6, the meeting recommended for the region to convene a meeting of Regulators, Industry and Legal to discuss and determine on the next steps.
- vii. On Article 10.0, paragraph 10.2 has been added to address the issue regarding to the payment of fees to the recipient NMRA which will be paid to the NMRA that will be providing the service or information. The structure and modalities shall be prescribed in the ongoing EAC – NMRAs financial sustainability study Model.

The reviewed draft document with inputs is hereto attached as **Annex: VI**

**Recommendation:**

**After the review by stakeholders of the United Republic of Tanzania (Zanzibar) the draft Cooperation Framework, was endorsed for consideration by regional stakeholders and EAC policy organs.**

**10.0 Closure of the meeting**

The meeting was closed at 17:00 hours.

**Signed on this 30<sup>th</sup> day of September, 2016 by:**

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<b>Zahran Ali Hamad,</b>	<b>Nizar Abou Machano</b>	<b>Othman Maalim Othman,</b>
	Representative of	
<b>Director of Central Medical Store, Ministry of Health Zanzibar</b>	<b>Zanzibar Association of Pharmaceutical Industries.</b>	<b>Ministry of Foreign Affairs and East Africa Cooperation United Republic of Tanzania (Zanzibar)</b>