
EAST AFRICAN COMMUNITY

# EAST AFRICAN COMMUNITY MEDICINES REGULATORY HARMONIZATION (EAC-MRH) PROGRAMME

## REGIONAL STAKEHOLDERS CONSULTATION MEETING TO REVIEW AND VALIDATE THE HARMONIZED GUIDELINES, STANDARDS AND REQUIREMENTS DEVELOPED UNDER THE EAC-MRH PROGRAMME

SNOWCREST HOTEL, ARUSHA - TANZANIA
17th – 18th MARCH, 2014

MEETING REPORT

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**Regional Stakeholders Consultation Meeting to review and validate medicines harmonized Guidelines, Standards and Requirements developed under the East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme**

**Snowcrest Hotel, Arusha - Tanzania**

**17th to 18th March 2014**

## 1.0 INTRODUCTION

The first Regional stakeholder's meeting on East African Community Medicines Regulatory Harmonization (EAC-MRH) programme was convened at Snowcrest hotel, Arusha, Tanzania from 17th to 18th March, 2014. The meeting was conducted following approval by the third EAC-MRH Programme Steering Committee meeting of the 2nd to 3rd September, 2013 and after similar meetings at national level conducted in all Partner States from September to October 2013.

### 1.1 Convening of the meeting

The meeting was convened in order to review and validate the regional medicines regulatory harmonized guidelines, standards and requirements developed by the four (4) Technical Working Groups (TWGs) of the EAC MRH project namely:

i) Medicines Evaluation and Registration (MER)

ii) Good Manufacturing Practices (GMP)

iii) Quality Management System (QMS)

iv) Information Management System (IMS)

### 1.2 Constitution of the Bureau

In accordance with the existing EAC Rules of Procedure, the EAC Policy Organs and Technical Meetings, this meeting was chaired by **Dr. Kipkerich Koskei**, the Chief Pharmacist and Registrar, Pharmacy and Poisons Board from the Republic of Kenya while **Mr. Habib A. Shariff**, Chief Pharmacist, Ministry of Health Zanzibar, United Republic of Tanzania served as the rapporteur. The bureau was constituted in the presence of all Partner States namely Republic of Kenya, United Republic of Tanzania, Republic of Burundi, Republic of Rwanda and Republic of Uganda.

## 1.3 Participants

The meeting was attended by the representatives from the EAC Partner States' Ministries of Health, Ministries of East African Affairs, Ministries of Trade and Commerce, National Medicines Regulatory Authorities (NMRAs), National Medicines Regulation Officers (NMROs), Pharmacy Councils, Pharmacy Universities/Schools/Colleges, National Medical Stores, National Bureau of Standards, National Revenue Authorities, National Pharmaceutical Manufacturers' Associations, National Associations of Pharmaceutical Industries, representatives from consumers, members of the four TWGs, World Bank, World Health Organization (WHO), New Partnership for African Development (NEPAD) Agency, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the EAC Secretariat.

The full list of participants is hereto attached as **Annex I.**

## 1.4 Adoption of Agenda

Agenda was adopted with no amendments and is hereto attached as **Annex II.**

## 1.5 Official Opening of the meeting

### 1.5.1 Welcome Statement by the Chairperson

**Dr. Kipkerich Koskei,** the Chief Pharmacist and Registrar, Pharmacy and Poisons Board from the Republic of Kenya welcomed participants to the meeting and thanked everyone for finding time to attend the meeting. He reminded participants that the people in the EAC depend very much on the outcome of the work the NMRAs are doing in promoting and protecting health in the region. He also reminded participants on the purpose of EAC MRH project in improving access to medicines through harmonization of registration requirements as presented by the EAC Secretariat. He concluded his remarks by welcoming the heads of delegation to give their remarks.

### 1.5.2 Remarks by the Heads of Delegation

#### 1.5.2.1 United Republic of Tanzania

**Mr. Hiiti B. Sillo,** Director General, Tanzania Food and Drugs Authority (TFDA) welcomed all stakeholders to Tanzania and particularly to Arusha. He reminded stakeholders that one of the mechanisms to overcome barriers to access of essential medicines is through harmonization of medicines regulation which is

now a worldwide agenda. This initiative will provide unlimited business opportunities in fostering greater competitiveness, new economic growth, job creation with the ultimate goal of better access to good quality, effective and safe medicines. He therefore urged stakeholders to seize this opportunity and work closely with the East African Community and the Partner States' National Medicines Regulatory Authorities towards implementation of activities planned under the project. He pledged Tanzania's full support and commitment towards implementation of the project. He acknowledged the work that has been done by the EAC MRH TWGs in compiling scientific information in the developed documents. He concluded his remarks by requesting stakeholder's to provide their inputs and wished participants fruitful deliberations.

**1.5.2.2 Republic of Burundi**

On behalf of the delegation from Burundi and on his own behalf, **Mr. Emmanuel Bamenyekanye**, Director, Department of Pharmacy, Medicines and Laboratories (DPML) thanked the Government of the United Republic of Tanzania for hosting and the EAC Secretariat for organising and facilitating the meeting. He also thanked the AMRH development Partners for the support of the AMRH initiative. He pledged Burundi's full commitment in promoting access to affordable medicines for communicable and non-communicable diseases. He informed the meeting that Burundi is in the process of reviewing and developing a framework that will enhance availability of medicines. He concluded his remarks by once again thanking all stakeholders and development partners for the cooperation shown in this initiative.

**1.5.2.3 Republic of Rwanda**

**Mr. Nyawakira Anicet**, Medicines Information Officer from the Ministry of Health, saluted the chair and rapporteur of the consultative meeting as well as the EAC Secretariat, development partners, WHO, GF, NEPAD and GIZ and the invited stakeholders from all Partner States. He thanked all the EAC MRH TWGs for the work they have done in developing tools which will be used in harmonization of medicines regulation in the EAC Partner States' NMRAs. He reminded that regulation of health products is the backbone for ensuring access to quality, safe and effective health products to citizens of EAC, as stated in the Chapter 18 of the EAC treaty.

He assured the meeting that Rwanda is in full support of the project and it has enacted the law for establishing Rwanda Food and Medicines Regulatory Authority (RFMA). He also informed the meeting that Rwanda is currently developing orders, policies and process to implement this law. Rwanda is also participating in the twining program which aims at strengthening the capacity of current regulatory functions. He further said that, Rwanda has started to

domesticate some of regulatory documents and tools developed under the EAC MRH project. He concluded his remarks by inviting all stakeholders to provide inputs and/or comments for improving the documents which have been developed by the TWGs. He finally wished participants fruitful deliberations.

### 1.5.2.4 Republic of Uganda

**Mr. Martin Oteba,** the Assistant Commissioner Health Services, Pharmacy from the Ministry of Health thanked the United Republic of Tanzania for accepting to host the regional stakeholders' meeting. He informed the meeting that Uganda has been associated with the processes in the development of harmonized guidelines, manuals and standards. He also informed the meeting that Uganda was given the task to lead the TWG on cGMP and looked forward to stakeholders' endorsement of the developed cGMP guidelines. On behalf of the delegation, he assured the meeting that Uganda is committed and will implement the outcomes of this harmonization process.

### 1.5.2.5 Republic of Kenya

**Dr. Ronald Inyangala,** Director of Finance and Administration, Pharmacy and Poisons Board, the Republic of Kenya thanked the United Republic of Tanzania for hosting and the EAC Secretariat for organising and facilitating the regional stakeholder's meeting. He also thanked stakeholders for finding time to come and contribute towards the harmonization process. He informed the meeting that medicines harmonization has a role in delivery of quality health services to the people and in the mind of stakeholders to facilitate trade. He informed the meeting that the regional stakeholder's meeting will not go into the details of the developed documents but rather dwell on the comments that were provided during the national stakeholder's meetings. He concluded his remarks by wishing participants fruitful deliberations.

### 1.5.3 Remarks by Development Partners

### 1.5.3.1 The World Bank

On behalf of the World Bank, **Mr. Apollo Muhairwe,** conveyed greetings from Bank Headquarters in Washington D.C. and the regional hub in Nairobi, Kenya. He thanked AMRH Partners especially WHO, NEPAD and the EAC Secretariat with whom the Bank has been working in the implementation of the programme. He informed the meeting that the goal of African Medicines Regulatory Harmonization programme is to improve public health through access to safe, quality, efficacious and affordable medicines.

He also informed the meeting that, the EAC-MRH programme will be implemented in a phased manner depending on the outcome of preceding phase. He informed the meeting that the Bank will soon conduct a mid-term review to assess the progress of the programme and make recommendations on the way forward.

He also informed the meeting that other important work streams have emerged in the process of implementation of EAC MRH namely pharmacovigilance and financial sustainability of NMRAs in the advent of EAC MRH programme. He informed the meeting that the Bank is examining ways of supporting this work including resource mobilization from other development partners.

He informed the meeting that the Bank is now working with other Regional Economic Communities (RECs) namely SADC and ECOWAS to implement similar programmes taking lessons learned from the EAC MRH programme. He urged EAC not to become complacent with the implementation status but see the programme achieve its ultimate impact of reducing mortality rates through access to medicines registered using harmonization approach. He finally looked forward to the completion of the EAC internal processes in approving the documents to enable domestication and use of the guidelines, standards and manuals by the NMRAs.

### 1.5.3.2 World Health Organization (WHO)

On behalf of WHO, **Dr. Alan Prat,** Technical Officer conveyed apologies from Dr. Samvel Azatyan who could not attend this meeting due to other conflicting commitment. He informed the meeting that WHO is satisfied with the progress made in development of harmonized documents under the EAC MRH programme. He urged the Partner States' NMRAs in collaboration with the industry to develop an implementation plan that will be feasible and implementable by the manufacturers.

### 1.5.3.3 New Partnership for African Development (NEPAD) Agency

On behalf of NEPAD Agency, **Prof. Aggrey Ambali** thanked the EAC Secretariat for inviting the Agency in the Regional Stakeholders meeting. He informed the meeting that the Agency is pleased with the progress made in the EAC MRH project. He thanked the EAC Partner States for their hard work in developing the harmonized guidelines. He urged the EAC Secretariat to oversee that the documents are further forwarded to higher organs for approval and consequently domestication by the EAC Partner States NMRAs. He concluded by affirming NEPAD support towards implementation of the activities under the project.

### 1.5.3.4 International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

**Ms. Caroline Mendy,** Manager Regulatory Policy, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) thanked the Secretariat

for the opportunity given to global R&D industry to participate to this meeting. She applauded the EAC Secretariat and the Partner States for the extensive work that had been carried out since the launch of the EAC project, with as a concrete outcome the finalization of a series of harmonization texts. She pleaded for an industry involvement all throughout the harmonization process, so as industry expertise can support ongoing efforts, in particular as we are now starting the implementation phase of the harmonized text.

### 1.5.4 Remarks by the Guest of Honour

On behalf of the Secretary General, EAC Secretariat, **Honourable Jesca Eriyo,** Deputy Secretary General, Productive and Social Sector welcomed participants to Arusha, the city of EAC and particularly to the regional stakeholders' meeting. She informed the meeting the EAC Secretariat is happy with the progress made by the EAC MRH project and thanked all development partners for their technical and financial support. She also thanked TWG experts and Steering Committee for providing oversight of the project. She also informed the meeting that, in order for integration process to proceed well, harmonization is key in every sector. She further informed stakeholders that through harmonization of medicines regulation, industry will trade better and at the same time the NMRAs will benefit through capacity building programmes planned under the project. She thanked experts and stakeholders for their technical expertise, time, input, dedication and support from the Governments and organization.

She informed the meeting that the EAC has been able to progress quite well in a number of key milestones namely Customs Union, Common Market and Monetary Union. She emphasized on delivery of quality health services including quality medical products in the integration process. She further requested for the private sector to be brought on board to make sure the people of East African Community benefit from integration process. She urged stakeholders to trade and provide health services not only within the EAC region but also beyond the region and the continent. She also urged the NMRAs to help the local manufacturers and private sector to flourish in pharmaceutical business. She concluded her remarks by once again thanking all experts and stakeholders that have been involved in the harmonization process, all development partners for the support and finally wished participants fruitful deliberations.

### 1.5.4 Group Photo

A group photograph with the Guest of Honour is hereto attached as **Annex III.**

## 2.0 Presentation on the aims and objectives of the meeting by the East African Community Secretariat

**Ms. Jane Mashingia,** Senior Health Officer, Medicines and Food Safety made presentation on the aims and objectives of the regional stakeholder's meeting. She informed the meeting that this meeting was convened in order to review and validate the regional medicines regulatory harmonized guidelines, manuals and standards developed by the four TWGs of the EAC MRH project on MER), GMP, QMS and IMS.

She informed the meeting that the EAC Secretariat in collaboration with Partner States NMRAs has been implementing phase I of the project which aimed at developing harmonized guidelines, manuals and standards for the EAC region. She also informed the meeting that these documents were reviewed by national stakeholders in 2013 and comments incorporated by editorial team in January, 2014. She finally requested stakeholders to provide their inputs so that the finalized documents are taken to approving organs of the EAC.

## 3.0 Presentation of the background paper by the EAC Secretariat

**Mr. John Patrick Mwesigye,** Senior Health Officer (Medicines Regulation), made a presentation on the background and overview of the EAC-MRH Programme. In his presentation he highlighted on the EAC MRH project goal, purpose, milestones, management and coordination, overall progress made, challenges faced and achievements obtained so far. He concluded his presentation by urging stakeholders to validate the harmonized documents so that the final documents are forwarded to the forthcoming EAC Ministerial Council Meeting for approval.

The background paper is hereto attached as **Annex IV.**

## 4.0 Presentation on the progress made by EAC MRH Technical Working Groups (TWGs)

### 4.1 TWG on Medicines Evaluation and Registration (MER)

On behalf of the members of the TWG on MER, **Mr. Akida Khea,** Manager, Medicines and Cosmetics Evaluation and Registration, TFDA made a presentation on the progress made in the development of Common Technical Document (CTD) for medicines evaluation and registration. In his presentation, he informed the meeting that the TWG is responsible for development and implementation of an agreed common technical document, training and evaluation of medicines. He also covered recommendations provided by

National and Regional stakeholder's and further elaborated on EAC position on those recommendations.

The presentation on the progress made by TWG on MER is hereto attached as **Annex V.**

**Recommendations:-**

a) **The meeting took note of the recommendation made on the consideration of technology transfer in the evaluation process and the meeting agreed that the matter will be forwarded to TWG on Regional the Pharmaceutical Manufacturing Plan of Action (RPMPOA) for consideration.**

b) **The meeting took note of the recommendation to prioritize and place local products in fast tracking queue. The meeting agreed that the TWG will develop a clear internal guidance on how to handle local products with regard to expedited evaluation and registration.**

c) **The meeting took note on the recommendation made to include veterinary medicines in the harmonization process. The meeting was informed that the focus of the EAC MRH project is on human medicines and therefore separate harmonized guidelines for registration of veterinary medicines will be developed at a later stage.**

d) **The meeting took note on recommendation to consider abbreviated evaluation for sister products from additional site. It was agreed that definition of 'sister' product will be included in the guidelines and will take into consideration products of the same strength from the same company manufactured in different sites among others.**

e) **The meeting took note of recommendation to recognize regulatory decisions (Mutual Recognition) made by other Partner States. The meeting was informed that the EWG on Policy, Legal and Regulatory Reforms will come up with a solution. In addition the meeting was informed that countries are working on confidence and trust building as one of the steps towards mutual recognition which is the ultimate goal of this initiative.**

f) **The meeting took note of the recommendation made with regard to sharing of registration fees in mutual recognition procedure. The meeting agreed that the EWG on Financial Sustainability will work on the matter and come up with a solution.**

g) The meeting took note of the recommendation made to involve consumers in the harmonization process especially in development of guidelines by the TWGs in order to reflect the needs of the patients. It was agreed that consumers will be involved in stakeholder's consultation meetings at national and regional levels.

h) The meeting took note of the recommendation made to restrict generic products where there is regional capacity. The meeting was informed that TRIPS flexibilities for Least Developed Countries (LDCs) have been extended up to 2021 and therefore EAC can use these flexibilities to restrict importation of generic products where there is regional capacity however cautious note was given to local manufacturers to keep up the pace with the market dynamics.

i) The meeting took note of recommendation made to consider stepwise approach in implementing harmonized guidelines. The meeting recommended that the TWGs on MER and GMP should come up with feasible mechanisms/plan for implementation of harmonized guidelines that will be agreed between the NMRAs and Industry.

j) The meeting agreed to forward all medicines evaluation and registration guidelines made by MER TWG to the forthcoming meeting of the EAC Sectoral Council of Ministers of Health for approval.

4.2.1 TWG on Good Manufacturing Practices (GMP) Inspection

Mr. Denis Mwesigwa, Senior Drug Inspector, National Drug Authority, Uganda made a presentation on the progress made in the development of guidelines, Standard Operating Procedures (SOPs) and manuals on Good Manufacturing Practice (GMP). In his presentation, he informed the meeting that the TWG is responsible for the development of harmonized legal framework and guidelines for GMP inspection. He highlighted the GMP terms of reference, achievements that have been made so far and recommendations obtained from different EAC Partner States national stakeholder's consultation meetings. He concluded by requesting regional stakeholders to validate the GMP guidelines, SOPs and Manuals so that the documents are forwarded to the forthcoming EAC Sectoral Council of Ministers of Health for approval.

The presentation on the progress made by the TWG on GMP is hereto attached as **Annex VI.**

Recommendations:-

a) The meeting took note of the recommendation made to update the annex on waste management in the EAC GMP guideline to be in-line with the latest changes made by WHO.

b) The meeting took note of the recommendation and agreed to revise the meaning of an authorized person so that it is not confused with terminology used in quality control.

c) The meeting took note of the existence of UNIDO project which aims at strengthening local pharmaceutical manufacturers in Kenya and Tanzania. The meeting agreed that the EAC Secretariat should make follow up on the matter so that other remaining countries in the region are included in the project. This will help all the Partner States to benefit at the same time and avoid duplication of work.

d) The meeting took note on recommendation that the EAC guidelines should reflect Good Manufacturing Practice (GMP) and not current Good Manufacturing Practice (cGMP). It was agreed that the guidelines will still require cGMP and local manufacturers should strive to meet cGMP so that our community can get medicines of good quality that are safe and efficacious.

k) The meeting agreed to forward all documents (Manuals, guidelines and SOPs) made by GMP TWG to the forthcoming EAC Sectoral Council of Ministers of Health for approval.

4.3 TWG on Quality Management System (QMS)

On behalf of lead country, the Republic of Kenya, Mr. Peter Ssali, Quality Manager, National Drug Authority, Uganda, made a presentation on the progress in the development of guidelines, requirements and SOPs for implementation of QMS. In his presentation, he informed the meeting that the TWG is responsible for development of guidelines, manuals and standard operating procedures to facilitate uniformity of procedures and decision-making processes within NMRAs. He also presented on the progress made in incorporation of national stakeholders' inputs and recommendations into the developed documents.

The presentation on the progress made by the TWG on QMS is hereto attached as Annex VII.

Recommendations:-

a) The meeting was informed that ISO 9001:2008 standard is currently undergoing revision and hence the need to update the EAC QMS requirements to accommodate changes that will be made in the standard. Furthermore, the meeting recommended to the EAC Secretariat to regularly review QMS standards to accommodate any changes that will be made to the referenced standard.

l) The meeting agreed to forward all documents (Guidelines, SOPs and Manuals) made by the TWG on QMS to the forthcoming meeting of the EAC Sectoral Council of Ministers of Health for approval.

4.4 TWG on Information Management System (IMS)

On behalf of the lead country, the Republic of Rwanda, Mr. Daniel Murenzi, e-Health and Informatics Officer, from the EAC Secretariat made a presentation on the progress made by the TWG on IMS. He informed the meeting that the work of this TWG is to automate medicines registration processes developed by the two TWGs on MER and GMP. He informed the meeting that the TWGs on MER and GMP have developed SIPOC (Supplier-Input-Process-Output-Customer) and have conducted re-engineering of MER and GMP processes. Re-engineered processes will be taken into consideration during the design and development of IMS to be installed into NMRAs and the EAC Secretariat. He also informed the meeting that in the design of IMS, other regulatory functions will be taken into consideration to avoid developing another different system. He concluded his presentation by requesting the stakeholders to take note of the progress made by the TWG and approve development of the IMS to support the work of NMRAs in regulation of medicines.

The presentation on the progress made by the TWG on IMS is hereto attached as Annex VIII.

Recommendations:-

a) The meeting took note of the progress made by the TWG on IMS and recommended to define data interfacing between Partner States and EAC Secretariat.

b) The meeting took note on the recommendation made to the EWG on Policy, Legal and Regulatory Reforms to define stakeholder's data interface to Partner States and EAC Secretariat.

c) **The meeting took note of the financial constraint in the IMS component and recommended to EAC Secretariat to mobilize more resources to support implementation of common IMS in the EAC Partner States' NMRAs and EAC Secretariat.**

d) **The meeting recommended collaboration between the EAC Partner States NMRAs and stakeholders to support implementation of the IMS and business continuity.**

e) **The meeting took note of the commitment made by NEPAD Agency to consider additional funding for TWG on IMS.**

f) **The meeting agreed to forward proposal made by the TWG on the design and development of IMS to the forthcoming meeting of the EAC Sectoral Council of Ministers of Health for approval.**

## 5.0 ANY OTHER BUSINESS

The meeting noted the concern of the EAC local industry with regard to request to defer fulfillment of bioequivalence (BE) requirements for 5 years. This matter was discussed and four Partners States namely United Republic of Tanzania, Republic of Uganda, Republic of Rwanda and Republic of Burundi uphold the requirements for BE and the Republic of Kenya recommended for deferment as requested. The meeting agreed to escalate the matter to the project Steering Committee meeting for further guidance.

## 6.0 CLOSURE OF THE MEETING

The meeting was closed at 4:45 pm.

Signed on this 18th day of March, 2014 by the Heads of Delegation,

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| Dr. Ronald Inyangala, Director, | Mr. Habib A. Shariff Chief Pharmacist, | Mr. Emmanuel Bamenyekanye Director, | Mr. Anicet Nyawakira, Medicines Information Officer | Mr. Martin Oteba, Assistant Commissioner, |
| PHARMACY AND POISONS BOARD, | MINISTRY OF HEALTH, ZANZIBAR | MINISTRY OF PUBLIC HEALTH AND FIGHT AGAINST HIV/AIDS | MINISTRY OF HEALTH | MINISTRY OF HEALTH |
| REPUBLIC OF KENYA | UNITED REPUBLIC OF TANZANIA | REPUBLIC OF BURUNDI | REPUBLIC OF RWANDA | REPUBLIC OF UGANDA |