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Report of East African Community Benchmarking visit to the European Medicines Agency, 18-19 May 2017

Part of the East African Community Medicines Regulatory Harmonization (EAC-MRH) Project

1. Introduction

The East African Community (EAC) is a regional intergovernmental organization of six Partner States namely the Republics of Burundi, Kenya, Rwanda, South Sudan, Uganda and the United Republic of Tanzania. The six Partner States have seven National Medicines Regulatory Authorities (NMRAs) namely Tanzania Food and Drugs Authority (TFDA) and Zanzibar Food and Drugs Board (ZFDB) of the United Republic of Tanzania; National Drug Authority (NDA) of the Republic of Uganda; Department of Pharmaceuticals and Medical Laboratories (DPML) of the Republic of Burundi; Pharmacy and Poisons Board (PPB) of the Republic of Kenya; Pharmacy Task Force (PTF) of the Republic of Rwanda and Drugs and Food Control Authority (DFCA) of the Republic of South Sudan.

The EAC Partner States supported by the EAC Secretariat are currently pursuing several initiatives to increase the availability of affordable, safe and quality assured medical of medical products and health technologies to the EAC citizens. The region has put in place policies, strategies, regulatory framework and interventions to strengthen regional capacity and streamlined regulatory procedures in line with the Treaty for establishment of the East African Community, Chapter 21, Article 118.

The seven (7) NMRAs are currently implementing Medicines Regulatory Harmonization which aims to streamline regulatory procedures and ensure quick access to safe, affordable, quality and efficacious medicinal products and health technologies. Since the launch of the East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme on 30th March 2012, the EAC region have been conducting joint product evaluation and registration and good manufacturing practice (GMP) inspections. As part of expansion of EAC-MRH scope, the region is working towards cooperation and collaboration in good clinical practice (GCP) inspections and clinical trial control oversight and information sharing. For more details on EAC-MRH, please visit www.mrh.eac.int

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Taking into account the need to ensure continuity of regulatory systems strengthening and harmonization in EAC, it is evident there a need to establish regional systems and structures to sustain on-going joint regulatory activities to regulate efficiently and effectively medical products and health technologies in EAC market.

The proposed regional structure will not replace National Medicines Regulatory Authorities (NMRAs) and is intended to be an independent self-sustaining institution of the EAC, legally mandated by Partner States with the goal of increasing availability of affordable, quality, safe and efficacious innovative medicines in the region. The agency is expected to provide regulatory oversight of selected medical products as well as promote cooperation, convergence, harmonization, reliance and mutual recognition of regulatory decisions and enhance work and information sharing.

The visit to the European Medicines Agency took place on 18-19 May 2017. The Chief Executive Officers of the EAC Partner States National Medicines Regulatory Authorities, Permanent Secretary Ministry of Health-Republic of Rwanda, representative from Ministry of East African Community, Labor and Social Protection-Republic of Kenya and EAC Secretariat, undertook the benchmarking visit. The 2-day meeting included presentations and discussions among participants on how to build such a networking Agency, based on the experience and lessons learned at EMA.

2. Recommendations and Way Forward for the EAC Heads of national medicines regulatory authorities

The EAC Heads of NMRAs and the EAC Secretariat made the following recommendations coming from the meeting:

a) Establish EAC Centralised Medicines and Food Safety Agency which is self sustaining through fees and technical expertise from Partner States;

b) Strengthen EAC Forum of Heads of NMRAs with a clear framework for decision making;

c) Review EAC Joint Assessment Procedure/Criteria to include New Innovative Medicinal Products;

d) Develop Fees Structures in EAC that support Joint Medicines Regulatory Services; and

e) Strengthen collaboration and cooperation between EAC and EMA specifically on capacity building on the use of EMA Scientific Opinions from Article 58, and evaluation of biosimilars and orphan medicines.

3. Final comments

Speaking at the conclusion of the meeting, EMA's Executive Director noted that this visit demonstrated the commitment and hard work of regulators in the East African Community to improve public health by ensuring access to affordable, safe, efficacious and quality medicines to citizens. Referring to the workshop between the Agency's Committee for Medicinal Products for Human Use (CHMP) and African regulators on 2-3 March 2017 in Malta, he repeated the commitment of the European Medicines Agency to engage with African regulators and promote mutual trust, confidence and reliance on regulatory decisions.

In addition to the EMA's efforts in strengthening regulatory capacity within the African continent, the East African Community Medicines Regulatory Harmonization initiative has played a major part in

strengthening the individual EAC NMARs, which are at different levels of development and continental aspirations of establishing an African Medicines Agency under the African Union Commission.

The benchmarking study visit concluded that the establishment of an EAC regional structure is important to sustain the ongoing joint regulatory harmonisation activities. Sustainability of the regional structure/coordination unit is feasible through revenues collected from industry fees. The EAC Heads of NMRAs agreed to harmonise fee structures for EAC activities and streamline payment procedures. In order to avoid duplication, the focus of EAC initiatives will be reviewed and the target will be for innovative medicinal products. The EAC Secretariat will prepare a concept note on the business case which will be considered by EAC Heads NMRAs in their forthcoming meeting to be held from 27th to 28th July 2017 in Kampala, Republic of Uganda.

Annex: Agenda of the meeting

Chair: Head of International Affairs Division

Day 1 - Thursday 18 May 2017

Time	Topics for discussion	Participants
09:00–10:30	**1. Welcome and introduction** ▪ Introduction of participants - Expectations from EAC ▪ EMA activities and history ▪ Administration ▪ Planning and Reporting ▪ *Q&A*	▪ EAC representatives ▪ Head of International Affairs Division *(ad interim)*, and Head of Portfolio Board Division ▪ Head of Administration and Corporate Management Division *(ad interim)*, Head of Finance Department *(ad interim)* Head of Staff Relations and Support Department
10:30–11:00	***Coffee break***	*All*
11:00–12:30	**2. EMA internal controls and collaboration with NCAs** ▪ Funding – sustainability ▪ Conflicts of interest and Fraud policy ▪ NCA collaboration- subsidiarity ▪ *Q&A*	▪ EAC representatives ▪ Head of Strategic Planning and Governance Department ▪ Head of Staff Relations and Support Department ▪ Legal Administrator, Legal Department ▪ Head of Experts & Declaration of Interests Management ▪ Head of International Affairs Division *(ad interim)*, and Head of Portfolio Board Division
12:30–13:30	***Lunch – EMA Function Room (4th Floor)***	*All*
13:30–15:00	**3. Life-cycle of medicines** ▪ Medicines and devices, biosimilars, etc ▪ Pre-approval phase (Scientific Advice, orphan, paediatrics) ▪ *Q&A*	▪ EAC representatives Head of Human Medicines Research & Development Support Division

Time	Topics for discussion	Participants
15:00–15:30	***Coffee break***	*All*
15:30–17:00	**4. Medicines approval** ▪ Approval, CHMP opinions and Article 58 ▪ Committee oversight, Working Parties and Regulatory science ▪ *Q&A*	▪ EAC representatives ▪ Head of Human Medicines Evaluation Division / Head of Scientific & Regulatory Management Department ▪ Head of Scientific Committees Regulatory Science Strategy Division and Head of Scientific Committees Secretariat
	10' break	
17:10–17:45	**5. Veterinary medicines** ▪ Specifics ▪ Maximum residue limits (MRLs) ▪ Q&A	▪ EAC representatives ▪ Head of Veterinary Regulatory & Organisational Support
18:10–19:30	**Tour of building facilities and Reception**	*All and speakers of both days*

Day 2 – Friday 19 May 2017

Time	Topics for discussion	Participants
08:30–10:00	**6. Pharmacovigilance and Inspections** ▪ Expectations from EAC ▪ Pharmacovigilance ▪ Inspections, GMP, GCP, pharmacovigilance ▪ *Q&A*	▪ EAC representatives ▪ Head of Inspections, Human Medicines Pharmacovigilance & Committees Division ▪ Acting Head of Pharmacovigilance and Epidemiology Department, Head of Signal and Incident Management Office ▪ Head of Committees & Inspections Department / Head of Manufacturing & Quality Compliance Office
10:00–10:30	***Coffee break***	*All*
10:30–12:00	**7. Human resources management** ▪ Expectations from EAC ▪ HR policies ▪ Training – EU Network Training Centre ▪ Q&A	▪ EAC representatives ▪ Head of Staff Relations and Support Department ▪ Principal Scientific Administrator, Surveillance & Epidemiology Service
12:00–13:00	***Lunch – EMA Restaurant (4th Floor)***	
13:00–14:30	**8. Information Technology and infrastructure** ▪ Expectations from EAC ▪ EMA architecture ▪ Telematics and relations with national authorities ▪ Q&A	▪ EAC representatives ▪ Head of IT Operations Department ▪ Head of Telematics Office
14:30–14:45	***Coffee break***	*All*
14:45–15:45	**9. Future collaboration** ▪ Expectations from EAC ▪ Remaining questions and answers ▪ Wrap-up	*All*
15:45–16:00	**10. Round-up and close of meeting**	▪ EMA Executive Director

Annex II: list of participants

East African Community (EAC)

- **Dr Pierre Jean Nyemazi**, Permanent Secretary, Ministry of Health, Republic of Rwanda
- **Ms. Jane H. Mashingia**, Senior Health Officer, East African Community
- **Mr Hiiti B.Sillo**, Director General, Tanzania Food and Drugs Authority (TFDA), United Republic of Tanzania
- **Dr Burhani Othman Simai**, Registrar, Zanzibar Food and Drugs Board (ZFDB), United Republic of Tanzania
- **Ms. Donna A. Kusemererwa**, Secretary to the Authority, National Drug Authority (NDA), Republic of Uganda
- **Dr Fred Moin Siyoi**, Deputy Registrar, Pharmacy and Poisons Board (PPB), Republic of Kenya
- **Dr Mawien Atem Arik**, Secretary General, Drug and Food Control Authority (DFCA), Republic of South Sudan
- **Mr Samwel Mwangi Kahenu**, Senior Assistant Director Regional Integration, State Department of East African Community Integration, Ministry of East African Community , Labour and Social Protection, Republic of Kenya

Other organisations

- **Mr Abraham Gebregiorgis**, Technical Officer, Regulatory Networks and Harmonization (RNH), Regulatory Systems Strengthening (RSS), Regulation of Medicines and other Health Technologies (RHT), Essential Medicines and Health Product (EMP), World Health Organization (WHO)
- **Mr Apollo Muhairwe**, Senior Operations Officer, Africa Region, Health, Nutrition & Population, World Bank Group

European Medicines Agency (EMA)

- Executive Director
- Head of International Affairs Division *(ad interim)*, and Head of Portfolio Board Division
- Head of Human Medicines Research & Development Support Division
- Head of Human Medicines Evaluation Division
- Head of Scientific Committees Regulatory Science Strategy Division
- Head of Inspections, Human Medicines Pharmacovigilance & Committees Division
- Head of Administration and Corporate Management Division *(ad interim)*, Head of Finance Department *(ad interim)*
- Head of Staff Relations and Support Department
- Head of Committees & Inspections Department

- Acting Head of Pharmacovigilance and Epidemiology Department, Head of Signal and Incident Management Office
- Head of Scientific & Regulatory Management Department
- Head of Strategic Planning and Governance Department
- Head of IT Operations Department
- Head of Manufacturing & Quality Compliance Office
- Head of Experts & Declaration of Interests Management
- Head of Veterinary Regulatory & Organisational Support
- Head of Scientific Committees Secretariat
- Head of Telematics Office
- Principal Scientific Administrator, Surveillance & Epidemiology Service
- Legal Administrator, Legal Department
- Principal International Affairs Officer
- International Affairs Officer

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