EAST AFRICAN COMMUNITY MEDICINES REGULATORY HARMONIZATION (EAC-MRH) PROJECT

15TH EAC JOINT DOSSIER ASSESSMENT MEETING 24TH - 28TH FEBRUARY, 2020

HOTEL DES MILLE COLLINES, KIGALI, REPUBLIC OF RWANDA.

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1.0 Introduction

The EAC-MRH joint assessment & Inspection scheme under the MRH Programme aims to promote streamlined approach in the assessment of quality, safety and efficacy of medicinal products introduced into EAC market since 2015. The programme has so far conducted its 15th joint sessions and a total of one hundred and twelve (112) products received for assessment with fifty-seven (57) recommended for registration.

The products applied through the EAC Joint Procedure are in accordance with the third Expression of Interest issued by EAC in 2019. The programme has led to the reduction in costs and time to the pharmaceutical industry and avoid duplication of efforts/work in NMRAs. The EAC NMRAs have also benefited from the EAC-MRH initiative in capacity building in knowledge and skills in assessment of dossiers and also improved mutual trust among the member states subsequently promoting of reliance and recognition of regulatory decisions.

2.0 Convening of the meeting

The 15th Joint Dossier Assessment Meeting was convened from 24th to 28th February 2020 at **Hotel Des Mille Collines, Kigali, Republic of Rwanda.**

The main objectives of the joint assessment were to:

1. Defining competency requirements and qualification of assessors participating in the EAC joint assessment sessions.
2. Review of communication materials to stakeholders and implementation of EAC Procedure of Active Pharmaceutical Ingredient Drug Master File (API-DMFs).

    a. Development and Finalization of EAC Procedure of Active Pharmaceutical Ingredient Drug Master File (API-DMF).

    b. Development of invitation for Expression of Interest (EOI) – Submission of application of APIMF in the EAC.

    c. Development of the screening checklist for APIMF submission in the EAC.

    d. Development of application form and the cover letter for submission of APIMF in the EAC.

3. Preparation of invitation for fourth Expression of Interest (EOI) – Submission of Applications for Marketing Authorization of Medicinal Products in the EAC.

4. Review and update of the EAC Metric tools for evaluation of timelines for joint assessment and GMP inspection procedures.

5. Joint Review of the Reports from EAC Partner States NMRAs for new application (Tecentriq injection) and query response of Nelstat suspension.

6. Update of register of common applications (mapping of common medical product dossiers) from EAC NMRAs.

7. Plan for the 16th and 17th EAC Joint Assessment Sessions.
8. Writing and signing report of the meeting.

3.0 Constitution of the bureau

The bureau was constituted in the presence of the experts from Republics of; Rwanda, Kenya, South Sudan, Uganda and the United Republic of Tanzania. The Republic of Burundi was not in attendance.
In accordance with the EAC Rules of Procedure for conducting meetings of the Community, Republic of Rwanda chaired the meeting and the Republic of Kenya served as the rapporteur.

4.0 Participants

The meeting was attended by officials and experts from EAC Partner States NMRAs, WHO PQ representative and Officials from the EAC Secretariat.

The full attendance list is hereto attached as **Annex I.**

5.0 Adoption of the agenda

The chairman called the meeting to order at 9:00 am.

The proposed agenda was adopted and is hereto attached as **Annex II.**

6.0 Introductions

The EAC Partner States delegates introduced themselves by name, their current position/Designation, and years of experience at NMRAs, followed by introductions from members of EAC secretariat, and Development partners (WHO PQ representative).

7.0 Opening remarks

7.1 Remarks from the Chairperson

Mr. Joseph Kabatende, Head of Food and Drugs Assessment and Registration Department, Rwanda FDA, in his opening remarks indicated that the Rwanda FDA was delighted to host the delegates, and that the Republic of Rwanda was happy to be part of EAC integration. He informed the meeting that the agency has registered tremendous achievement considering the fact that it is still under development. The Rwanda FDA is currently in a position to send representatives to EAC meetings. He concluded by encouraging collaborations and fruitful deliberations throughout the meeting. He

thanked EAC secretariat for organizing the meeting and welcomed all the participants to enjoy the good environment in Rwanda.

Remarks from the Republic of Rwanda

Mr. Byomuhangi Evariste, Pharmacist-in-charge of Management Information System (MIS), Rwanda FDA, welcome all the participants to the 15th Joint Assessment, noting that sustainability efforts in ensuring hosting by NMRAs is bearing fruits and Rwanda FDA is happy to host the 15th Joint Assessment. He reminded delegates that the objectives of the sessions were to develop documents to guide on competency requirements and ensure quality of evaluation hence quality products in the region. He concluded by thanking EAC Secretariat for organizing the meetings and for developing guidelines that NMRAs refer to and WHO for sending representatives for knowledge sharing. He wished all participants safe stay in Rwanda and fruitful deliberations.

Remarks from the Republic of Kenya

Dr. Peter Mbwiiri, the Deputy Director, Product Evaluation and Registration Directorate, Pharmacy and Poisons Board, Kenya thanked Rwanda for hosting the delegates in a beautiful city and EAC for organising.

He noted the progress of harmonization and urged the delegates to up the vision by strengthening the EAC MRH to enable other regional economic communities (RECs) to trust the outputs by EAC and to be emulated by the global community. He highlighted the need for building new models including the implementing of EAC APIMF procedure as a game changer in the region and that EAC will be the first in the region to implement.

He concluded by impressing on delegates to change the way of conducting business in the Joint assessment sessions and embrace good attitude to enable betterment of service delivery.

Remarks from the Republic of Uganda

Mr. Noel Aineplan, the EAC-MRH Focal Person, NDA- Uganda, thanked the Republic of Rwanda for hospitality extended to the delegates. He reiterated NDA commitment to the harmonization agenda and on behalf of the Secretary to the Authority pledged support and in an effort of cost sharing, the NDA will host the next 16th JA session scheduled for July, 2020.

Remarks from Republic of South Sudan

Mr. Maper Dut Ador, Senior inspector from DFCA, Republic of South Sudan, thanked the EAC for organizing the meeting and Rwanda FDA for hosting the 15th Joint Assessment Session.

He informed the meeting that DFCA is delighted to be part of the EAC Joint Assessment and that DFCA has benefited from the MRH program and that medicines registration commenced in January, 2020. He concluded by wishing all delegates fruitful deliberations.

Remarks from TMDA, United Republic of Tanzania

Ms. Mary M. Masanja, the Principal Drug Registration Officer, on behalf of TMDA thanked the Republic of Rwanda for hosting the 15th EAC joint assessment session at one of the best venues. She informed the meeting that TMDA being the lead NMRA for medicine registration, has benefited from the EAC-MRH program through capacity building in assessment of product dossiers and contributed to strengthening the national system and procedures. She noted that TMDA is highly delighted by the trust accorded to them by others Partner States NMRA. In view of this, she urged all delegates to put their best efforts in ensuring that this session is fruitful, and that the required documents are developed/reviewed and completed. This will ensure that planned activities are implemented for the benefit of all NMRAs and the region.

Remarks from ZFDA, United Republic of Tanzania

Ms. Hidaya Juma Hamadi, the Focal Person EAC-MRH Programme, Zanzibar Food and Drugs Authority, thanked all the delegates for attending the meeting, the Republic of Rwanda for hosting the session in an effort to ensuring sustainability of the harmonization initiatives.

She informed the meeting that ZFDA is happy to be part of the Joint Assessment and made pledges of hosting the 17th Joint Assessment. She concluded by wishing all delegates fruitful deliberations.

Remarks by World Health Organization Representative

Mr. Akida Msallah Khea, WHO representative, thanked the organisers of the 15th Joint Assessment including the Republic of Rwanda and the EAC Secretariat for their efforts in ensuring success of Joint Assessment sessions. He noted the very impressing achievements of the MRH programme and that the support from the EAC Partner States NMRAs in hosting Joint Assessment sessions by facilitating their staff participation.

On behalf of WHO, he reiterated WHO commitment to providing continuing technical support. He highlighted objective of the 15th Joint Assessment was to develop documents including the competence requirement for assessors in EAC and communication materials, such as EAC APIMF procedure to stakeholders. He concluded by thanking the host country and wished all the delegates nice stay in the beautiful environment of Kigali.

Remarks from the EAC Secretariat

Ms. Jane Mashingia, Senior Health Officer, EAC Secretariat, thanked Rwanda FDA for hosting the meeting, an indication of commitment, and thanked other NMRAs for their continued support.

She urged the members to maintain the momentum to ensure EAC remains the main reference point for other RECs on matters related to regulation and Harmonization.

She emphasized EAC role in coordinating the joint activities, monitoring document development progress, evaluating the outcomes of the initiative for the last 7 years and finally improve stakeholder engagements. She impressed upon the delegates to achieve objectives of the 15th Joint Assessment session.

She concluded her remarks by thanking the AMRH Partners for technical and financial support and wished all the delegates fruitful deliberations.

8.0 Defining competency requirements and qualification of assessors participating in the EAC joint assessment sessions.

The Competence requirements, training needs and nomination of medicine assessors for participating in EAC joint assessment was discussed and is hereby attached as **Annex: III**

9.0 Development of Guidance documents for implementation of EAC Procedure of Active Pharmaceutical Ingredient Master File (APIMF).

Documents in relation to EAC procedure for implementation of Active Pharmaceutical Ingredient Master File (APIMF) were reviewed and are hereto attached as follows:

Annex IV: Procedure on submission of EAC Active Pharmaceutical Ingredient Master File (EAC APIMF).

Annex V: Expression of Interest (EOI) for submission of APIMF in the EAC.

Annex VI: Cover letter and Application form and for submission of APIMF in the EAC.

Annex VII: EAC Screening checklist for the APIMF submission.

10.0 Review of invitation for the fourth Expression of Interest (EOI) – Submission of Applications for Marketing Authorization of Medicinal Products in the EAC.

The Expression of Interest was reviewed and is hereto attached as **Annex VIII.**

11.0 Review and update of the EAC Metric tools for evaluation of timelines for joint assessment and GMP inspection procedures.

The two metric tools were reviewed and are hereto attached follows

Annex IX: Register for tracking of timelines for EAC joint assessment applications.

Annex X: Register for tracking of timelines for EAC joint GMP applications

12.0 Joint Review of the Reports from EAC Partner States NMRAs for query response of Nelstat (Nystatin oral suspension) **and new application of Tecentriq** (Atexolizumab 1200mg/20ml).

In accordance to the dossier distribution to the assessors across the Partner States NMRAs and with guidance from the Chairperson the assessment reports were presented in the plenary by the assessors.

Summary of the outcomes for the 15th Joint assessment reports are highlighted below:

Query Response							
S/No	**Reference number**	**Brand name**	**Generic name**	**Dosage form**	**Applicant**	**Query Responses**	**Outcome of assessment**
1.	EAC17/HM/005	Nelstat	Nystatin 100,000 Units/ml	Oral Suspension	Universal Corporation Ltd, Kenya	First round	Under review, to be completed by 6th/march/2020
New Applications:							
S/No	**Reference number**	**Brand name**	**Generic name**	**Dosage form**	**Applicant**	Types of assessment	Outcome of assessment
1.	EAC19/L01/013	Tecentriq	Atexolizumab 1200mg/20 ml	Solution for injection	F.Hoffman-La Roche Limited	First and second assement of new Dossier	Additional Information

Note

The lead country to conduct second assessment of Nelstat (Nystatin suspension) queries by 6th March 2020 and thereafter selected NMRA's experts to make their inputs for compilation of the final assessment report by 13th March 2020 and thereafter a communication will be sent to the applicant.

13.0 Update of register of common applications (mapping of common medical product dossiers) from EAC NMRAs.

Common applications were mapped and in total nine (9) applications earmarked for Joint assessment. These applications will be subjected to joint assessment after obtaining consent from the applicants.

The mapped applications are hereto attached as **annex XI**

14.0 Plan for the 16th and 17th EAC Joint Assessment Sessions.

The next Joint assessment sessions (16th and 17th) were planned tentatively first week of May 2020, and first week of August 2020 respectively . This will be subject to availability of resources by the NMRAs. EAC will also be exploring possibility of funding from the World Bank

15.0 Recommendations of the meeting:

I. Focal persons to submit updated tools on Medicine Registration and GMP before the Joint Assessment sessions sittings. Also each NMRA should update the registration status for the products recommended for registration under EAC.

II. The Expert Working Group on GMP to initiate the inspection of API manufacturing sites. The lead NMRA on GMP to follow up on this matter.

III. To ensure high standards of assessment of applications, the meeting proposed the implementation of second assessment for Query responses.

IV. To update the EAC compendium with regard to EAC APIMF procedure.

V. A concept Note to be developed on the operationalization of EAC APIMF procedure. The concept note shall include among other things.

a) Application pathway.
b) Fees structure.
c) Legal instruments to be developed.

Closure of the meeting

There being no other business the meeting was closed at 15 00 hours.

Signed on this 28th day of February, 2020 by the heads of delegation

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Mr. Munkwase Grant	**Mr. Evariste Byomuhangi**		**Dr. Peter Mbwiiri**	**Mr. Maper Dut Ador**	**Mr. Mujtaba M. Ratansi**
Regulatory Officer	Pharmacist In Charge MIS		Deputy Director Product Evaluation &Registration	Senior of Inspector	Focal Person EAC MRH /Drug Registration officer
NATIONAL DRUG AUTHORITY,	**RWANDA FOOD & DRUGS AUTHORITY**	**DEPARTMENT OF PHARMACY, MEDICINES AND LABORATORIES**	**PHARMACY AND POISONS BOARD,**	**DRUG AND FOOD CONTROL AUTHORITY**	**TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**
REPUBLIC OF UGANDA	**REPUBLIC OF RWANDA**	**REPUBLIC OF BURUNDI**	**REPUBLIC OF KENYA**	**REPUBLIC OF SOUTH SUDAN**	**UNITED REPUBLIC OF TANZANIA**