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

16TH EAC JOINT DOSSIER ASSESSMENT MEETING 12TH - 15TH MAY, 2020

First Virtual Meeting

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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 16th joint sessions, but due to COVID-19 Pandemic, the EWG held its first ever virtual meeting.
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 16th Joint Dossier Assessment Meeting was convened from 12th to 15th May 2020. This was the first virtual meeting following the COVID-19 Pandemic.

The main objectives of the joint assessment were to:

1. Review of the Query Responses from the Pharmaceutical Manufacturers and Regulators;
2. Joint Review of the Reports from EAC Partner States NMRAs of New Medicinal Products Dossiers;
3. Discussion of Any other Business (AOB)
4. Plan for the 16th and 17th EAC Joint Assessment Sessions.
5. 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, Uganda and the United Republic of Tanzania. The Republic of Burundi and South Sudan were 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 and their current position/Designation followed by introductions from members of EAC secretariat, and Development partners (WHO PQ representative).

7.0 Opening remarks from the Chairperson

The chairperson, Phn HONORE AYINKAMIYE, Human Medicines Registration Officer at Rwanda FDA, welcomed all the participants to the 16th Joint Assessment Session, and acknowledges everyone's effort for participating to this special joint assessment, as it was organized to be virtually attended due to the COVID-19 pandemic. He reminded the NMRA representatives that the objectives of the sessions were to jointly review the assessment reports that were available, for both new applications and additional data. He concluded by thanking EAC Secretariat for organizing the virtual meeting as the face to face meeting was not possible. He wished all participants to have a fruitful meeting and wished everyone to stay safe in this problematic situation.

8.0 Joint Review of the Reports from EAC Partner States NMRAs for query response and new applications

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:

A. PRESENTATIONS – QUERY RESPONSES –MAY 2020

S/ No	Reference number	Brand name	Generic name	Dosage form	Applicant	1st assessor	2nd assessor	Outcome of assessment

~~1.~~	EAC16/HM/012	Furosemide	Furosemide 40 mg	Tablets	Sandoz GmbH Kundl	PPB	Rwanda FDA	Additional information
~~2.~~	EAC19/G01/030	Fluomizin	Dequalinium Chloride 10mg	Tablets	Dafra Pharma GmbH, Muhlenberg 7, 4052 Basel Switzerland	TMDA	DPML	Recommended for registration
~~3.~~	EAC19/C01/003	Ephedrine Aguettant	Ephedrine Hydrochloride 0.3 mg/mL	Solution for injection	Laboratoire Aguettant	NDA	DFCA	Recommended for registration
~~4.~~	EAC19/A03/002	Atropine Sulphate Aguettant	Atropine sulphate 0.5 mg/5mL	Solution for injection	Laboratoire Aguettant	ZFDA	PPB	Recommended for registration
~~5.~~	EAC19/C01/001	Adrenaline Aguettant	Adrenaline tartrate 0.1 mg/mL	Solution for injection	Laboratoire Aguettant	TMDA	DPML	Recommended for registration
~~6.~~	EAC19/L02/015	Bicalutamide	Bicalutamide 50 mg	Tablets	Intas Pharmaceuticals Limited	DPML	PPB	PPB to share second assessment report by 22nd May, 2020
~~7.~~	EAC19/G04/037	Floezy	Tamsulosin 0.4 mg	Tablets	Mega Lifesciences Public Company Limited	ZFDA	PPB	Conditional approval

S/No	Reference number	Brand name	Generic name	Dosage form	Applicant	1st assessor	2nd assessor	Status
1.	EAC19/C01/038	Phenylephrine	Phenylephrine hydrochlo	Solution for	Laboratoire	ZFDA	NDA	Additional

		Aguettant PFS	ride eq. to Phenylephrine 0.05 mg/mL	Injection	Aguettant			information
2.	EAC20/J01/001	Paradol	Paracetamol 500 mg	Tablets	Dinlas Pharma EPZ Limited	TMDA	Rwanda FDA	Additional information
3.	EAC20/A02/002	Barole	Rabeprazole sodium 20 mg	Solution for Injection	Mega Lifesciences Public Company Limited	Rwanda FDA	PPB	Additional information
4.	EAC20/L01/003	Gefitinib	Gefitinib 250 mg	Tablets	Cipla Limited	NDA	TMDA	The BE part to be submitted by NDA to TMDA by 22nd May, 2020
5.	EAC20/C08/004	Amlovie 5	Amlodipine 5 mg	Tablets	Dafra Pharma GmbH	ZFDA	Rwanda FDA	Additional information
6.	EAC20/C08/005	Amlovie 10	Amlodipine 10 mg	Tablets	Dafra Pharma GmbH	ZFDA	Rwanda FDA	Additional information

9.0 Allocation of new applications to EAC Partner States for assessment.

A total of 4 new application were distributed to EAC Partner States NMRAs for assessment as per the distribution table below;

	Reference number	**Brand name**	**Generic name**	**Dosage form**	**Applicant**	**1st assessor**	**2nd assessor**

	EAC20/L01/006	Ocrevus	Ocrelizumab 300 mg/10 mL	Concentrate Solution for Infusion	F. Hoffman-La Roche Limited	DPML	NDA
	EAC20/A04/007	Palonosetron Hydrochloride	Palonosetron Hydrochloride 0.25 mg/5 mL	Solution for Injection	Cipla Limited	PPB	TMDA
	EAC20/J05/008	Dolutegravir and Lamivudine 50/300 mg	Dolutegravir and Lamivudine 50/300 mg	Tablets	Cipla Limited	PPB	NDA
	EAC20/J05/008	Abacavir, Lamivudine, Lopinavir and Ritonavir Granules 30 mg/15 mg/40 mg/10 mg	Abacavir, Lamivudine, Lopinavir and Ritonavir Granules 30 mg/15 mg/40 mg/10 mg	Granules	Cipla Limited	TMDA	Rwanda FDA

10.0 Plan for the 17th EAC Joint Assessment Sessions.

The 17th Joint assessment session is scheduled tentatively week of 16th to 19th June, 2020. This will be subject to confirmation of virtual meeting by the EAC Secretariat.

11.0 Closing remarks;

Remarks by World Health Organization Representative

Ms. Jacklynne took note of two emerging and recurrent issues that the experts were unable to reach an agreement;

i. Requirement of compendial method whether it was either mandatory or waived
ii. Recommendation on printing of registration numbers on the secondary package

EAC Secretariat

Ms. Jane Mashingia, Senior Health Officer**,** EAC Secretariat, thanked Rwanda FDA for chairing the meeting, an indication of commitment, and thanked other NMRAs for their continued support. She reiterated EAC Secretariat's continued support to the expert's meetings. The thanked all participants for their active support. She concluded by urging experts to review reports and share with the lead country, TMDA on time.

12.0 Recommendations of the meeting:

I. A meeting is scheduled for the 28th and 29th May, 2020 to discuss both the API part of the compendia and BE requirements implementation for local manufacturers
II. The lead country in GMP inspections to follow up on manufacturing site GMP status for EAC jointly assessed products.

13.0 Closure of the meeting

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

Signed on this 15th day of May 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**