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

17TH EAC JOINT DOSSIER ASSESSMENT MEETING 28th MAY, 2020

Second 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.

2.0 Convening of the meeting

The 17th Joint Dossier Assessment Meeting was convened from 28th May 2020.
This was the second virtual meeting following the COVID-19 Pandemic.

The main objectives of the joint assessment were to:

1. Review of the reports submitted from the Query Responses from the Applicants.
2. Review of pending assessment report (Gefitinib Bioequivalence report)
3. Joint Review of the EAC API CompediumGuidelines on submission and evaluation of EAC-APIMF and Standard operating procedures
4. Plan for the Training sessions
5. Discussion of Any other Business (AOB)

3.0 Constitution of the Bureau

The bureau was constituted in the presence of the experts from Republics of Rwanda, Kenya, Uganda, South Sudan and the United Republic of Tanzania. The Republic of Burundi wasere 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.**

Commented [MOU1]: Include the list in annex 1

Dr. Sarah Chesaro

5.0 Adoption of the agenda

The chairman called the meeting to order at 10:00 am.

The proposed agenda was adopted and was documented as:

1. Review of pending assessment reports
2. Review of the EAC APIDMF Procedure and SOP's
3. Plan for training of assessors
4. Review of pending assessment reports
5. AOB

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).

~~R~~**Opening remarks** ~~:-~~

Ms. Nadine Niyomahoro, The Human Medicine Registration ~~Ofiicer~~Officer ; Rwanda FDA, made opening remarks and adopted the agenda for the meeting. The confirmation of the previous minutes was also conducted and read out by Peter Mbwiri from PPB Kenya.

8.0 Joint Review of the Reports from EAC Partner States NMRAs for query response In accordance to the dossier distribution to the assessors across the Partner States NMRAs and with guidance from the Chairperson the assessment reports with previous query responses were presented in the plenary by the assessors. From Kenya who were the 2nd reviewers.

Summary of the outcomes for the 17th 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.	EAC…/HM/….	Bicalutamide	Bicalutamide 50mg	Tablets	Intas Pharmaceuticals Limited	Burundi	Kenya	Additional information & BE to be evaluated.

~~GEFITINID Dossier is to discuss~~ Bioequivalence assessment reports on Gefitinib and Bicalutamide are to be presented by NDA in June.

9.0 Allocation of new applications to EAC Partner States for assessment.
It was noted by TFDA that a total of 4 new application were distributed to EAC Partner States NMRAs for assessment as per the distribution table below ;-

The dossiers were shared to the 1st assessor in respective Countries as outlined in the table below report the assessment reports are hence meant to be shared to the focal persons to facilitate the distribution for 2nd assessment.

	Reference number	Brand name	Generic name	Dosage form	Applicant	1st assessor	2nd assessor
1	EAC20/L01/006	Ocrevus	Ocrelizumab 300 mg/10 mL	Concentrate Solution for Infusion	F. Hoffman-La Roche Limited	DPML	NDA
2	EAC20/A04/007	Palonosetron Hydrochloride	Palonosetron Hydrochloride 0.25 mg/5 mL	Solution for Injection	Cipla Limited	PPB	TMDA
3	EAC20/J05/008	Dolutegravir and Lamivudine 50/300 mg	Dolutegravir and Lamivudine 50/300 mg	Tablets	Cipla Limited	PPB	NDA
4	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
5		Levonorgestrel IUD	Avibela				

Commented [MOU3]: Liaise with Ratansi to give u details of the product

There were concerns that Department of Pharmaceutical Medical Licensing in Burundi has been missing in the meeting. They also have a pending Adrenaline dossier ref no; EAC19/C01/001 that was reviewed and the BMR submitted in French was to be reviewed by them. Status of this dossier needed to be clarified as there has been no communication. The EAC secretariat is to reach out to the republic of Burundi.

10.0 Plan for training of assessors

10.1.1 There will be scheduled Internal online trainings by the EAC expert group planned to be undertaken in July 2020. There will also be subsequent

two day training sessions to be organised based on the prevailing condition The internal training will be on going as we await the advanced training by WHO.

10.1.2 WHO also indicated that they have received training requests from the different NMRAs. The trainings will mainly focus on Bioequivalence, Sterile Products and APIs. A planned virtual training program will be organised as at the moment it will not be possible to conduct physical training and the program from WHO will be shared.

11.0 Review of Review of the EAC APIDMF Procedure and SOP's

The EAC API Compedium was discussed and the document was found to be comprehensive. The document will be recommended for adoption.

12.0 Recommendations

EAC secretariat brought to the attention of the committee that a centralised fee structure and system of payment should be discussed for purposes of having a sustainable harmonisation and integration processes.

It was noted that there was no need for development of other concept papers and instead a financial analysis ~~and~~ on omplementation of a EAC A~~A~~PIMF procedure will be done and tabled in the next head of NMRAs meeting**. TMDA, PPB and NDA were tasked to carry out the financial analysis on costing to be shared with EAC secretariat; the costing would include assessment fees, inspection fees and coordination fee by the EAC secretariat.**

It was also noted that there ~~were~~ was expression of interest but the administrative information on the fee ~~and to go about it~~ had not been discussed yet**.**

13.0 Plan for the 18th EAC Joint Assessment Sessions.

The 18th 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.

14.0 Closing remarks;

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. Especially to the countries that were not able to join us due to internet challenges. She also thanked all participants for their active support in pushing the integration agenda and urged them to keep safe during this period of the Pandemic.

15.0 Closure of the meeting

There being no other business the meeting was closed at 15 30hours.

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