Rwanda Food and Drugs Authority
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MINUTES OF THE MEETING Nº….. /05/FDA/2021 FOR [DHTAR DIVISION]

Date of Meeting 11 May 2021

Venue of the meeting: Zoom

List of participants on behalf of Rwanda FDA

S/Nº	Names	Position
1.	Clarisse IRASABWA	D&HTAR Division Manager
2.	NIYOMAHORO Nadine	Finished and Active Pharmaceutical Products Registration Officer
3.	AYINKAMIYE HONORE	Finished and Active Pharmaceutical Products Registration Officer

Items on the agenda

1. Increasing Efficiency of Regulatory Harmonisation Activities in Africa

Webinar Objectives

1. To create a platform for dialog and experience sharing among stakeholders
2. To highlight best practices and foster increased awareness on Joint Assessment Procedure for registration of medicines in Africa and beyond
3. To identify the challenges for all participating parties and seek for the opportunities to overcome them
4. To share experiences and learnings among applicants and regulators in view of increasing the number of applications submitted and approved in the region through the procedure
5. To provide an opportunity for participants to network

Expected Outcomes

1. To gain better understanding, increase transparency and awareness of the Joint Assessment process in Africa

2. To identify recommendations, next steps and key indicators for increased robustness of the process across regions towards the establishment of AMA

Opening and/or remarks of the meeting

The meeting started at **15:00PM** with the opening remarks of the different representative from different institutions, including:

1. WHO Representative
2. AMRH representative experience on Joint Assessment (JA) procedures:
    - **Mujtaba Ratansi**, Senior Drug Registration Officer/ Regional Technical Officer for EAC-MRH program, Tanzania Medicines and Medical Devices Authority (TMDA),
    - **Saren Shifotoka** - Regulatory Affairs Pharmacist – Namibia for SADC-MRH program,
    - **Samuel Asante Boateng**, Chair, EWG for Evaluation and Registration of Medical Product, Food and Drug Authority – Ghana for ECOWAS-MRH program,
    - **Abdella Kasso**, Director of Medicine registration and Licensing Department, Food and Drug Authority – Ethiopia for IGAD-MRH program,
    - **Okouyi Ndakissa**, Direction du Médicament et de la Pharmacie, Gabon for OCEAC-MRH program.

3. Word Bank representative

The Meeting Proceedings

Title of Item No 1 on the Agenda Panel discussion about experience sharing from Regional Joint Assessment Representatives	
Discussion	**Observation**
The first Panel discussion was about the Experience sharing from different Regional Joint Assessment: ▪ **EAC -MRH Program** ▪ **IGAD -MRH Program** ▪ **SADC -MRH Program** ▪ **ECOWAS -MRH Program** ▪ **OCEAC-MRH Program**	**EAC-MRH program** underlined that Approx. 140 products have been jointly assessed under EAC-MRH and almost half of them been recommended for registration. The rest are still under assessment process. Currently there are no administrative fees apart for the NMRAs fees for registration and GMP inspection. However, there are procedures in place to introduce a small fee to the EAC Secretariat to cover for the administrative costs. Furthermore, Applications for EAC region are submitted to the lead NMRA ie Tanzania Medicines and Medical Devices Authority which use online portal. Efforts are in place to establish EAC integrated information management system (IMS) to be linked to seven (7) NMRA and EAC Secretariat to manage and process applications and share information and reports. **All regional Representatives highlighted the importance and the good impact of the Joint Assessments Procedures in order to accelerate the PD applications evaluation.** **Among the benefits of the procedure, they have included:** ▪ **Timeline's reduction** ▪ **Resources management** ▪ **Experience and knowledge sharing** ▪ **Assessors' capacity building**

	▪ **Deal with variations when products were assessed through the joint assessment process** **On the other hand, they have also stated some challenges:** ▪ **Lack of enough experts with sufficient knowledge in Dossiers Assessment** ▪ **Active involvement of some member States** ▪ **Manufacturers Participation in the procedure**
Title of Item No 2 on the Agenda	
During the second Panel discussion, on the panel we had Local and international manufacturers' representatives where they have shared their experience on the Joint Assessment Procedure	**The panellists have highlighted that the procedure is very important, and it has many different positive impacts on the products availability, however they have stressed on some issues that need to be improved including:** ▪ **GMP inspections participation of the manufactures.** ▪ **Some manufacturers still need to participate in the Pharmacovigilance system after the MA approval** ▪ **Regulatory functions in the region still need to be strengthen** ▪ **Application of Mutual recognition in the region** ▪ **They have also emphasized that the pharmaceutical products procurement needs to be linked to quality, where they said that only products with quality and from GMP compliant manufacturers must be procured.**
Title of Item No 3 on the agenda	

During the Third Panel discussion, on the panel we had Word Bank	**The panellists have discussed on different points including:** ▪ **Timelines** ▪ **Harmonized requirements** ▪ **Logistic approach** ▪ **Clear guidance and adherence at national level** ▪ **Resources needed** ▪ **Transparency and open communication (trust building with Industry)** ▪ **Eligibility** ▪ **Digitalization** ▪ **Development of regulatory tools** ▪ **Strengthening the Regional Joint Assessment procedures**

The meeting has ended at: **18:00PM,** WHO representative has closed the meeting by thanking all the participants and ask to implement the meeting resolutions.

End of Minutes