Rwanda Food and Drugs Authority

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Minutes of the Meeting of Drugs & Health Technologies Assessment and Registration Division

Date of Meeting, 25th June, 2020

Venue of the Meeting: Kigali at MoH, 5th Floor-Conference Room

Attendance List (To be signed and attached on these minutes)

Items on the agenda

1. **Peer review for validation of assessed dossiers**

Opening of the Meeting

The Meeting has started at **14:30PM** with the opening remarks given by the Division Manager of Drug & Health Technologies Assessment and Registration. She started by thanking the whole participants to peer review meeting to validate 21 assessed product dossiers.

Adoption of the agenda

Resolutions of the peer review meeting

S/N	PRODUCT NAME	ASSESSMENT PROCEDURE	MAIN QUERIES	COMMENTS	DECISIONS
1	FLUDORA ® FUSION	Full assessment	• Local Technical Representative (LTR) • GMP inspection report	• Queries were resolved • FDA to schedule GMP Inspection	Approved
2	DOLUTEGRAVIR	Abridged procedure	• Submitted FFP specification was not similar to those found in WHOPQT • Query for GMP inspection	• Need to harmonize submitted data to the one submitted to WHO • Relevant queries should be raised • Rwanda FDA will send a letter requesting the applicant to apply for GMP inspection to comply with Rwanda FDA guidelines • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval

3	EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE	Abridged procedure	• Submitted API & FPP specification data was not similar to those found in WHOPQT • Query for GMP inspection	• Need to harmonize submitted data to that one submitted to WHO • Relevant queries should be raised • Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
4	ARTESUNATE SUPPOSITORIES 100 MG	Abridged procedure	• Appointment letter for LTR was not traced • Submitted API & FPP specification data was not similar to those found in WHOPQT • Query for GMP inspection	• Need to harmonize submitted data with one submitted to WHO • Relevant queries should be raised • Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately. • Rwanda FDA will consult other NMRA to benchmark registration process and National programs	Pending for approval
5	RIFAMPIN/ISONIAZID	Abridged procedure	• General queries were presented • Query for GMP inspection	• There is a need to provide the updated data similar to those that have been submitted to WHOPQT. • Relevant queries should be raised; • Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines • Peer review committee recommended that once the applicant provides satisfactory query responses,	Pending for approval

				Marketing Authorization will be granted to him/her immediately.	
6	RIFAMPIN 150MG, ISONIAZID 75MG, PYRAZINAMIDE 400 MG AND ETHAMBUTOL HYDROCHLORIDE 275 MG TABLETS USP	Abridged procedure	• General queries were presented • Query for GMP inspection	• There is a need to provide the updated data similar to those that have been submitted to WHOPQT. • Relevant queries should be raised; • Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
7	RIFAMPIN/ ISONIAZID/ /ETHAMBUTOL HCL 150 / 75 /275 MG TABLETS	Abridged procedure	• General queries were presented • Query for GMP inspection	• There is a need to provide the updated data similar to those that have been submitted to WHOPQT. • Relevant queries should be raised; • Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
8	LUMARTEM 80/480MG	Abridged procedure	• General queries were presented • Query for GMP inspection	• There is a need to provide the updated data similar to those that have been submitted to WHOPQT. • Relevant queries should be raised; • Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval

9	LUMARTEM 40/240MG	Abridged procedure	• General queries were presented • Query for GMP inspection	• There is a need to provide the updated data similar to those that have been submitted to WHOPQT. • Relevant queries should be raised; • Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
10	LUMARTEM 60/360MG	Abridged procedure	• General queries were presented • Query for GMP inspection	• There is a need to provide the updated data similar to those that have been submitted to WHOPQT. • Relevant queries should be raised; • Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
11	NEVIMUNE BABY	Abridged procedure	• General queries were presented • Query for GMP inspection	• There is a need to provide the updated data similar to those that have been submitted to WHOPQT. • Relevant queries should be raised; • Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval

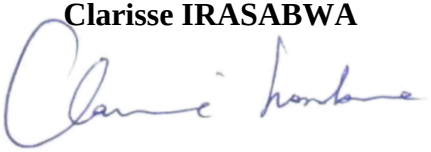
12	TRICLOFEN	Full assessment	• Applicants responded to the query related to GMP by requesting Rwanda FDA to waive this query as their facility was pre-qualified by WHO. • Valid GMP certificate from WHO was provided	• Query response was not accepted • As long as applicant did not apply for CRP, being inspected by WHO does not resolve the query of GMP however, applicant is required to apply for GMP as required by Rwanda FDA guidelines • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
13	GRAMOCEF-CV	Full assessment	Query for GMP inspection	•Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; •Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
14	ESOMEPRAZOLE 40MG	Full assessment	Query for GMP inspection	•Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; •Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval

15	SEVELAMER CARBONATE 400MG TABLETS	Full assessment	Query for GMP inspection	• Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
16	LIDOCAINE HYDROCHLORIDE	Full assessment	Query for GMP inspection	• Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
17	METOCLOPRAMIDE INJECTION	Full assessment	Query for GMP inspection	• Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
18	TACROVATE OINTMENT	Full assessment	Query for GMP inspection	• Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
19	OFLOXACIN 200MG AND ORNIDAZOLE 500MG TABLETS.	Full assessment	Query for GMP inspection	• Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines;	Pending for approval

				• Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	
20	DYNACORT-6	Full assessment	Query for GMP inspection	• Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval
21	FLORANORM	Full assessment	Query for GMP inspection	• Rwanda FDA have to send a letter requesting applicant to apply for GMP inspection to comply with Rwanda FDA guidelines; • Peer review committee recommended that once the applicant provides satisfactory query responses, Marketing Authorization will be granted to him/her immediately.	Pending for approval

CLOSING OF THE MEETING

The Chairperson of the meeting, Mrs. Clarisse IRASABWA, Drugs and Health Technologies Division Manager, thanked again the participants of peer review committee for their presence and achievement of 21 validated assessed dossiers.

	Names, signature and institution stamp		Names and signature
Chair of the Meeting	**Clarisse IRASABWA** 	Rapporteur	**MUSAFIRI Eustache**