QMS N°: ODG/FMT/049

Rev. Nº: 0

Effective date: 02/02/2021 Ref. Doc.: QMS /MAN /002



### **Rwanda Food and Drugs Authority**

Nyarutarama Plaza KG 9 Avenue Email: info@rwandafda.gov.rw; website: www.rwandafda.gov.rw

MINUTES OF THE MEETING Nº:..... /03/FDA/2021 FOR [Division of Drug & Health Technologies Assessment and Registration]

Objective: To make work plan for the month of April 2021

Date of Meeting: 31/03/2021.

Venue of the meeting: Office of the Division Manager

## Attendance list hard copy to be by hand signed and attached on these minutes)

S/Nº	Names	Position  Radiopharmaceuticals Assessment and Registration officer					
1.	Shyirambere Serge						
2.	Uwera Nadia	Veterinary Medicines Registration and Variations Assessment Officer					
3.	Musafiri Eustache	Veterinary Medicines Registration and Variations Assessment Officer					
4.	Muhayimana Placide	Diagnostics and Medical Devices and Registration officer					
5.	Isingizwe Marie Ange	FPP and API Assessment and Registration Officer					
6.	Tuyisenge Felix	Vaccines and Biosimilar Registration Officer					
7.	Nsanzimfura Jean Pierre	Herbal Medicines Assessment and Registration Officer					
8.	Uworoheje Innocent	Veterinary Diagnostics and Medical Devices Registration Officer					
9.	Munyaneza Uwitonze Janvier	Medicinal Cosmetics Registration Officer					
10.	Niyomahoro Nadine	FPP and API Assessment and Registration Officer					
11.	Nshimiyimana Philbert	Biological Products Registration Officer					
12.	Dusabimana Jean Damascene						
13.	Olivier Mureramanzi	Biological Products Registration Officer					
14.	Tuyishime Anitha	FPP and API Assessment and Registration Officer					
15.	Ayinkamiye Honoré	P and API Assessment and Registration Officer					
16.	Iterere Diane	PP and API Assessment and Registration Officer					
17.	Nsabimana Isaïe	Vaccines and Biosimilar Registration Officer					
18.	Niyitegeka Leodomir	Medicinal Cosmetics Registration Officer					
19.	Irasabwa Clarisse	DM of Drugs and Health Technologies Assessment and Registration					



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### Absent with reason

S/N	Names	Positions							
1	Iradukunda Gad Patrick Medicinal Cosmetics Registration Officer								
2	Kyankoni Godfrey	Diagnostics and Medical Devices assessment and Registration officer							
3	Uwamariya Pacifique	Director of Cosmetics and household Chemicals							
4	Muhongerwa Ruth	Herbal Medicines Assessment and Registration Officer							
5	Masengesho Gentille	Public Health Laboratory Chemicals Registration Officer							
6	Iterere Diane	FPP and API Assessment and Registration Officer							

Items on the agenda

- 1. Setting Targets in number of dossiers to be assessed by each assessor in this April in order to solve the issue of the huge workload in the unit of human medicines assessment and registration unit.
- 2. Setting a plenary meeting to discuss on assessment reports frequency.
- 3. Some updates
- 4. AOB.

### Opening and/or remarks of the meeting

The meeting has started around 4:00 PM with the opening remarks of the Division Manager of Drug & Health Technologies Assessment and Registration Division, She started by welcoming the meeting participants and thanked them for their presence, energetic and enthusiasm's characters they possess at work.

The chair of the meeting further highlighted why the meeting was important for the division staff and emphasized on having the culture of setting target and always aim high and it's benefits and never to forget evaluating yourself to check whether you have achieved your targets, she continued by referring to the department meeting which was chaired by HoD on 15/03/2021 where it was recommended that we identify all products on Rwandan markets registered in EAC (Kenya, Uganda and Tanzania) and check whether their applications for registration have been received by Rwanda FDA in order to work on them as quick as possible and solve the issue of the huge workload in the unit of human medicines assessment and registration. The identification of those product applications have already finished, and the remaining work, which is even the aim of the current meeting, is to distribute them among all assessors in order to start working on them.



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## The Meeting Proceedings

1. Setting Targets in number of worklo	number of dossiers to be a workload in the unit of	nber of dossiers to be assessed by each assessor in this April in order to solve the issue of the huge workload in the unit of human medicines assessment and registration unit.	April in order to solve the and registration unit.	issue of the huge
Discussion	Observation	Resolutions/ recommendation	for	Timelines
DM presented the proposal of assessing eight Dossier [the eight including those of first assessment, second assessment and additional data] per assessor and its' feasibility was discussed on, due to the number of dossiers number were increased compare to the number that was usually assessed.	It was observed that all Assessor accepted the proposal of assessing eight Dossier [the eight including those of first assessment, second assessment and additional data] but there where a request of facilitation if possible because the work will need high concentration.	To be facilitated to get a good lunch near or to the office in order to save time for assessing.	Every Assessor is assigned to assess eight Dossiers [Eight dossiers include those of first assessment, second assessment and additional data] in the month of April 2021.  DM will make an advocacy and a follow up to check whether lunch can be availed.	From 1st April to 30th April 2021 and evaluation time of the outcome will be on 3rd May 2021
	2. Setting a plenary m	Setting a plenary meeting to discuss on assessment reports frequency.	ports frequency.	
Setting plenary meetings to discuss on assessment reports regularly, it would be better every week.	Referring to the previous experience the plenary meetings to discuss on assessment reports were very use full in sharing knowledge among assessors and in increasing the work performance in terms of assessed PDs.	Referring to the previous Every Monday morning, we will 1st assessors of PD will be experience the plenary be having a plenary meeting to discuss on assessment reports were assessment reports were and evaluate the progress of completed.  I sharing assessment and evaluate the progress of completed.  I sharing assessment and evaluate the progress of completed.  I sharing assessment and evaluate the progress of completed.  I sharing assessment are and evaluate the progress of completed.  I sharing assessment are and evaluate the progress of completed.  I sharing assessment are and evaluate the progress of completed.  I sharing assessment are and evaluate the progress of completed.  I sharing assessment are and evaluate the progress of completed.  I sharing assessment are and evaluate the progress of completed.	1st assessors of PD will be presenting it in case first and second assessment are completed.	8 a.m-12p.m every Monday.





-Mr. Karasanyi Geofrey Will brief Mrs. Nadia Uwera for everything in Veterinary Medicine Devices and Assessment &Registration Unit so that she can coordinate the unit once Karasanyi	-Mr. Iradukunda Gad Patrick will be heading Cosmetics & Household Chemicals Assessment and Registration Unit sinceDirector Uwamariya Pacifique is starting her annual leave soon.	-DM informed the meeting that three more new working stations have been received and they will support staff to sit respecting the covid-19 preventive measures. i.e distancing.
Rwanda		3.Som  More sits are available than usual.
ANDA FI		than Every Assessor will be reporting to work every day from 01/04/2021.
nority		Every Assessor
		From 01/04/2021

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April and depending on Tutsi in Rwanda take place the 1994 Genocide against Commemorating week of start the annual leave. level, we should work and how it is prepared at nation We were reminded that the activities. event and communicate to all week, the work organize the of previous commemoration staff on commemoration According to the experience 4.AoB All staff



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Chair of The meeting	Names, and signature and/or institution stamp		Names and signature		
The		Rapporteur	TUYISENGE Felix		

The meeting has ended at: 5:30 PM

### End of Minutes





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# Rwanda FDA Attendance List

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Activity Title: MY SIAM OF DRUGO, HEALTH TECHNOLD GIES ASSESS. Venue: Office of Mr. DIVISION MANAGER Date: 81/03/2021
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