



## Rwanda Food and Drugs Authority

Nyarutarama Plaza KG 9 Avenue

Email: [info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw);

website: [www.rwandafda.gov.rw](http://www.rwandafda.gov.rw)

### **MINUTES OF THE MEETING N°.... /04/FDA/2021 FOR [Division of Drug & Health Technologies Assessment and Registration]**

**Objective:** To evaluate the assessment progress and priorities planned in the coming months of May and June 2021

**Date of Meeting:** 23/04/2021.

**Venue of the meeting:** Office of the Division Manager

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

S/N°	Names	Position
1.	SHYIRAMBERE Serge	Radiopharmaceuticals Assessment and Registration officer
2.	UWERA Nadia	Veterinary Medicines Registration and Variations Assessment Officer
3.	NIYOMAHORO Nadine	FPP and API Assessment and Registration Officer
4.	NSABIMANA Isaïe	Vaccines and Biosimilar Registration Officer
5.	NIYITEGEKA Léodomir	Medicinal Cosmetics Registration Officer
6.	KARASANYI Geofrey	Veterinary Medicines Registration and Variations Assessment Officer
7.	IRASABWA Clarisse	DM of Drugs and Health Technologies Assessment and Registration

#### **Items on the agenda**

1. Assessment Progress.
2. Priorities and plan for the week of 26-30 April 2021
3. Setting a plenary meeting to discuss on assessment reports.
4. AOB.

#### **Opening and/or remarks of the meeting**

The meeting has begun at 9:30 AM with the opening remarks of the Division Manager of Drug & Health Technologies Assessment and Registration Division, by welcoming the meeting participants.

A handwritten signature in blue ink, consisting of a stylized 'S' followed by a loop and a vertical stroke.

The chair of the meeting has highlighted the key points of the meeting such as the assessment progress, documents to be developed, the training required for capacity building of the assessors, self-assessment that will take place in June 2021 and WHO assessment. Also DM calls upon all assessors to work hard in order to intervene and support the wishes of His Excellence President Paul KAGAME and other country Leaders concerned in collaboration with Rwanda FDA to bring a Vaccine manufacturing plant in Rwanda. This requires that the Authority be ranked to maturity level 3 from level 1 after the assessment of WHO that will take place in August 2021. The meeting took place respecting the existing government measures against the spread of COVID-19.



## The Meeting Proceedings

1. Assessment Progress of the human medicines dossiers and dossiers of other units.			
Discussion	Observation	Resolutions/ recommendation	Responsible person for implementation
<p>DM requested every unit representative staff to give the updates of Unit on progress for planned activities and unit pictures are as follow:</p> <ul style="list-style-type: none"> <li>- 32 dossiers have been assessed in Vaccines and other Biologics Assessment and Registration Unit</li> <li>- 20 dossiers have been assessed in Veterinary Medicines Devices Assessment and Registration unit</li> <li>- 21 dossiers have been assessed in Human Medicine and Devices Assessment and Registration Unit</li> <li>-25 dossiers have been assessed in Cosmetics and Household Chemicals Assessment and Registration Unit.</li> </ul>	<p>It was observed that all Assessor tried their best so as to achieve the target set and their hard working was appreciated.</p>	<p>To continue working hard so as all assessors will achieve the target.</p>	<p>Every Assessor is encouraged to end the task assigned.</p> <p>30<sup>th</sup> April 2021 and evaluation time of the outcome will be done by the beginning of May 2021</p>



<p>-DM informed the participants that they wish every assessor to have access to Online Pharmacopoeia of human medicine and veterinary medicine as well as standards used in cosmetics and household chemicals unit in order to facilitate and quick assessment and consultancy as well.</p>	<p>The online Pharmacopoeia and standards will help assessor to perform their work easily and quickly, hence the work results will be consistent.</p>	<p>Sitting by Unit will be done from Monday 26<sup>th</sup> April 2021</p>	<p>DM of Drugs and Health Technologies Assessment and Registration.</p>	<p>From Monday 26<sup>th</sup> April 2021</p>
<p>-The staffs should sit in the available working stations according to their respective Units.</p> <p>-Internet issue was raised that is very poor and slow in 2<sup>nd</sup> floor and this slow down the assessment performance.</p>	<p>Sitting according to the Units will easy consultancy and discussion between the assessors of the same unit.</p> <p>The poor internet network does not allow the assessors to perform well some assigned task such as reporting, searching more information on the dossier he/she is assessing, ...</p>	<p>There is a device that must be installed in 2<sup>nd</sup> floor in order to enhance the internet network.</p>	<p>Assessors of Drugs and Health Technologies Assessment and Registration division</p> <p>IT staffs</p>	<p>The device to quick and enhance the internet issue must be installed by the end of April 2021.</p>
<p>-There is a WHO assessment of our regulatory Authority</p>	<p>The Authority is forcing to implement all the planned activities in order to be ready for</p>	<p>The retreat, workshop and training planned will increase the capacity building of the assessors</p>	<p>The Leaders of Authority and staffs concerned.</p>	<p>Continuous</p>
<p><b>2. Priorities and plan for the week of 26-30 April 2021</b></p>				

<p>for being ranked (graded) on maturity level 3 (ML3) in the intention of being candidate to have a vaccines manufacturing facility (plant) in Rwanda.</p> <p>- From 26-30 April 2021 there will be a workshop on regulatory documents (Sops, guidelines) which are missing and will be developed. The participants in the aforesaid workshop are AYINKAMIYE Honore, NSABIMANA Isaie, SHYIRAMBERE Serge, Theogene NDAYAMBAJE, Gervais BAZIGA, MUHOZA Frederic, DM IRASABWA Clarisse and HoD Joseph KABATENDE.</p> <p>- There is a plan for retreat of assessment of one month and half from mid May 2021 once the budget will be available so as to</p>	<p>WHO assessment which is planned in August 2021</p>			
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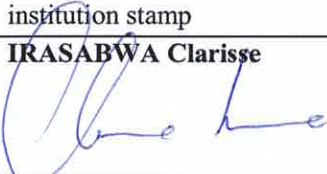

<p>finish a backload of old dossiers not yet assessed.</p> <p>- There is a plan of training on vaccines assessment in the case of capacity building of the assessors.</p> <p>- There is a need to update excel sheets by using a google sheet that will be developed by Innocent UWOROHEJE, Serge SHYIRAMBERE and Nadine UWAMAHORO where every assessor will fulfil the date of first or second assessment for the dossier done by him/her so as to track whether we meet timeline of assessing a dossier from the submission date to the time when the feedback IS sent to the applicant.</p> <p>-Regarding information asked by DA&amp;HR about the training we have attended we will put in the google sheet shared by DA&amp;HR training done and</p>	<p>The update google sheet will bear information if the assessment does not take time which is beyond the timeline mentioned in the guidelines.</p>	<p>The data should be collected in the manner of facilitating the tracking system of the dossiers.</p>	<p>All assessors.</p>	<p>-The collection of data in the google sheet by assessors should be done by 06<sup>th</sup> May 2021</p> <p>-Compilation of data from assessors will be done by 11/05/2021</p> <p>The google sheet should be completed by the staffs of D&amp;HTAR division by mid May 2021.</p>
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what we plan to be built in terms of capacity building.	trained in terms of capacity building.			
<b>3. Setting a plenary meeting to discuss on assessment reports frequency.</b>				
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.	Every Monday morning, we will be having a plenary meeting to discuss on assessment reports of human medicine dossiers as well as the dossiers of cosmetics unit and also to evaluate the progress of assessment.	1 <sup>st</sup> assessors of PD will be presenting it in case first and second assessment are completed.	8 a.m-12p.m every Monday.
<b>4.AoB</b>				
- During providing feedbacks to stakeholders related to Authorized list, the better is to precise its use by Monday of every week.	This WHO prequalification workshop will empower the assessment performance of the assessors	DM recommended that all assessors should attend this WHO prequalification workshop by using the screen and speaker in the meeting room.	All staff of DA&HR	May/2021
- WHO prequalification workshop that will take place in May/2021 will be attended by Serge SHYIRAMBERE and Marie Ange ISINGIZWE and end of registration is 30/04/2021.				

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Rev. N°: 0  
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Chair of The meeting	Names, and signature and/or institution stamp	Rapporteur	Names and signature
	<b>IRASABWA Clarisse</b> 		<b>NIYITEGEKA Léodomir</b> 

The meeting has ended at: 11:30 PM

End of Minutes

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**RWANDA FDA**  
Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

QMS N°: QMS/FOM/022

Rev. N°: 1

Effective date: 11/05/2021

**Rwanda FDA Attendance List**

#	Names	Position	Institution	Contact	E-mail	Signature
1	Isaïe NSABIMANA	Vaccine & Biomedical Reg. officer	Rwanda FDA	0788883011	inabimanan@rwandafda.gov.rw	
2	Uwera Nadia	VMR & VAO	Rwanda FDA	0785537755	nuriwa@rwandafda.gov.rw	
3	Geoffrey KARASIMUYI	VMR & VAO	Rwanda FDA	0785562688	gkarasimuyi@rwandafda.gov.rw	
4	NIDOMAHORO Nadine	FPP & API registration officer	Rwanda FDA	0788576905	nnyomahoro@rwandafda.gov.rw	
5	FERGE SHYIRAMBERE	Radiopharmaceuticals ASR Officer	Rwanda FDA	0788804293	sshyirambere@rwandafda.gov.rw	
6	Leodomir NIYITEGEKA	Medicinal Cosmetics registration officer	Rwanda FDA	0788829087	knigitegeka@rwandafda.gov.rw	