



## Rwanda Food and Drugs Authority

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### **MINUTES OF THE MEETING N°... /03/FDA/2021 FOR [Drugs and Health Technologies Assessment and Registration Division]**

**Date of Meeting:** 06/04/2021

**Venue of the meeting:** Rwanda FDA Head Office

#### **Attendance List (Hard copy to be by hand signed and attached on these minutes)**

S/N°	Names	Position
1.	Niyomahoro Nadine	FPP and API Assessment and Registration Officer
2.	Nshimiyimana Philbert	Biological Products Registration Officer
3.	Karasanyi Geoffrey	Veterinary Medicines Registration and Variations Assessment Officer
4.	Iradukunda Gad Patrick	Medicinal Cosmetics Registration Officer
5.	Uwera Nadia	Veterinary Medicines Registration and Variations Assessment Officer
6.	Nsabimana Isaie	Vaccines and other Biosimilars Registration Officer
7.	Ayinkamiye Honore	FPP and API Assessment and Registration Officer
8.	Niyitegeka Leodomir	Medicinal Cosmetics Registration Officer
9.	Jackson Sylvestre Karara	Registry Maintenance Officer
10.	Irasabwa Clarisse	DM of Drugs and Health Technologies Assessment and Registration Officer
11.	Kabatende Joseph	HoD of Food and Drugs Assessment and Registrations

**Item on the agenda**

Discussion about the progress of the Monthly Plan related to assessment of human medicines

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

The meeting started at 8H00AM with the opening remarks given by the HoD of Food and Drugs Assessment and Registration. He started by welcoming the meeting participants and thanking them for their attendance. HoD updated the meeting attendees about the purpose of the meeting which is to discuss the progress of the elaborated monthly plan to speed up the PD assessment activity with a purpose of reducing the enormous workload in the unit of human medicines assessment and registration. He reminded that the meeting of this kind will be taking place once per week preferably every Monday. The meeting has taken place respecting the existing government measures against the spread of COVID-19.

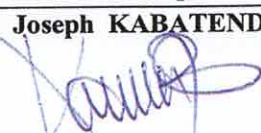

## The Meeting Proceedings

1. Updates on the progress of monthly plan by DM Clarisse				
Discussion	Observation	Resolutions/ recommendation	Responsible person for implementation	Timelines
DM presented about the work distribution in the current month of April. She said that primarily, the list of PDs registered in EAC [Kenya, Uganda and/or Tanzania and whose applications for registration in Rwanda have been submitted, was completed as recommended in the previous meeting. Every assessor was assigned at least 8 PDs [some for 1 <sup>st</sup> , 2 <sup>nd</sup> and others for additional data assessment] to be completed by the end of April. DM also said that the division has planned for a plenary meeting once per week in which the assessment reports and queries for assessed PDs will be presented to all assessors. This will not only help in speeding up the work of assessment and hence, increase of registered PDs but also a learning opportunity for assessors.	It was observed that there are some challenges likely to hinder the achievement of the set target. It was presented that some assessors may fail to complete 8 PDs during this month of April given that: (1) this month contains many public holidays (2) Some assessors have been assigned other duties to give support in COVID-19 vaccination campaign (3) Some PDs on the list do not have QOS in word format yet this is the part of the submitted dossier in which the PD assessment is done. For this later, the PDs with no QOS in word have been replaced by others. (4) there is no safe stores for the PDs and some are still at RSB HQ. Thus, it becomes a challenge once an assessor	<p>(1&amp;2) It has been concluded that despite the presented challenges, assessor will try their best to achieve the assigned task. At the end of the month, there will be a meeting to know the level at which the set target has been achieved and the common challenges encountered which will give us insight on next month plan.</p> <p>(3) It was concluded that the division will make a list of the PDs whose applicants failed to respond to the raised queries after screening. Karara Jackson and Eustachie will carry out an inventory of all letters sent to the applicants and find out whether among those on the above list, there are some for which query letters were not sent to the applicants. Moreover, as a sustainable solution and with reference from the resolutions of the previous division meeting on <b>15/03/2021</b>, it was emphasized that query letters will be sent via department email and regular follow up about outgoing and incoming letters must be enforced. Moreover, an acknowledgement email will also be issued to applicant informing him/her that his/her product was received by the authority and if</p>	(1&2) all assessors  (3) Karara and Eustachie	April, 2021  NA



	wants a physical dossier during the assessment.	<p>possible whether it is scheduled for assessment or there are some missing data to submit before assessment.</p> <p>(4) Related to the storage of the PDs, HoD said that they are aware of the problem and the institution is working on it to find out safe stores for the PDs at Rwanda FDA head office.</p> <p>To speed up the assessment, ensure work harmonization and increase the number of PDs on National registry, there should be agreement among assessors on what essential queries are to be raised to the applicants.</p> <p>Last but not the least, it was reiterated that the monthly work distribution is very important because it has dual functions; one to speed up the work of assessment and reduce the current workload so that later, assessors will start to assess dossiers as they are submitted. The other function is to help in reporting because it will be easy to determine the PDs that have been assessed in any given period of time.</p>	(4) HoD	
<b>2. Authorized List of human Medicines</b>				
DM updated the audience that there is an established group of assessors working on the authorized list every Thursday. If there are some updates or complaints about it, they are	It was observed that, based on the last week meeting of the established a team that works on Rwanda FDA authorized list of human medicines, customer's complaints about	<p>It was recommended that, these stakeholders:</p> <ul style="list-style-type: none"> <li>➤ Should bring samples of their products to Rwanda FDA QCL and pay for testing expenses before product importation.</li> <li>➤ For the next importation, the product will be imported after getting the registration certificate from Rwanda FDA.</li> </ul>	HoD and DM	To be effected

discussed Friday. HoD has requested this group to do all their best to reduce the number of complaints about the authorized list, otherwise, it can be difficult to reach where Rwanda FDA has complete and stable list of human medicines it regulates. It was also presented that there are stakeholders with some tenders to import medical products in Rwanda out of normal regulatory procedure which is a challenge to the Authority.	this list reduced comparing to the previous weeks. For stakeholders like PSM, RMS, RBC, PIH, CHUK and Rwanda Military Hospital (RMH), they often import medical products not registered by Rwanda FDA. Though it what they claim, once these are put on the list without following all the regulatory procedure, this will lead to other applicants to import them without authorization.	<p>➤ The aforesaid stakeholders will be invited by the Authority in the meeting to discuss about the regulatory procedure to be followed and two sessions will be planned. One will be made by PSM, RMS and RBC stakeholders while the other one will be made by CHUK, RMH and PIH stakeholders.</p> <p>➤ Guidelines/regulations for donations will be developed and this will be combining importation and registration procedure of medicinal products.</p>	
<b>3. AoB</b>			
Quality Management system was discussed and it was emphasized that this should be the task of every staff. HoD updated the attendees that Rwanda FDA is waiting for WHO inspection by August, 2021. He reminded the main points considered as target for the inspection which are: the presence of Regulatory documents and the regulatory system but also how the said documents are implemented in the running of the regulatory system.	It was observed that the basics for the coming inspection are in place and HoD recommended that even the few remaining should be put in place emphasizing on the involvement of every staff.	HoD also concluded saying that once the conditions become favourable most specifically after the current COVID-19 pandemic, many training and meetings with experts in drug assessment and regulation will be planned and conducted with the purpose of increasing the capacity of the assessors. Related to assessment retreats to ensure customer's satisfaction while giving feedback to their applications, HoD has shown that the problem is still the current measures against the spread of COVID-19. Once the situation becomes normal. Retreats will be conducted.	HoD and staff in charge of QMS in the division.
			NA

Chair of the meeting	Names, and signature and/or institution stamp	Rapporteur	Names and signature
	<b>Joseph KABATENDE</b> 		<b>Philbert SHIMIYIMANA</b> 

The meeting has ended at: **09h00AM**

End of Minutes

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**RWANDA FDA**  
Rwanda Food and Drugs Authority

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Rev. N°: 0  
Effective date: 20/10/2020

**Rwanda FDA Attendance List**

**Activity Title:** Unity Representatives Division Meeting **Venue:** Rwanda FDA/ HOD of FDAR Office **Date:** 06./04./2021

#	Names	Position	Institution	Contact	E-mail	Signature
1	Joseph KABATENDE	HOD/ FDAR	Rwanda FDA	0788792286	ikabatende@rwandafda.gov.rw	
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4	Jackson Sylvestre KARARA	Registry Maintenance officer	Rwanda FDA	0787451847	ikarara@rwandafda.gov.rw	
5	Honore AYINKAMIYE	FPP&API Ass and Registration Officer	Rwanda FDA	0788802853	hayinkamiye@rwandafda.gov.rw	
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7	Nadine NIYOMAHORO	FPP&API Ass and Registration Officer	Rwanda FDA	0788576905	nnyomahoro@rwandafda.gov.rw	
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9	Gad Patrick IRADUKUNDA	Medicinal Cosmetics Registration Officer	Rwanda FDA	0784300016	piradukunda@rwandafda.gov.rw	
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