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 15/03/2021.

Venue of the meeting: Office of the **Head Department.**

Attendance List (Hard copy to be attached on these minutes)

S/N°	Names	Position
1.	Nsanzimfura Jean Pierre	Herbal Medicines Assessment and Registration Officer
2.	Uworoheje Innocent	Veterinary Diagnostics and Medical Devices Registration Officer
3.	Munyaneza Uwitonze Janvier	Medicinal Cosmetics Registration Officer
4.	Niyomahoro Nadine	FPP and API Assessment and Registration Officer
5.	Nshimiyimana Philbert	Biological Products Registration Officer
6.	Dusabimana Jean Damascene	Biological Products Registration Officer
7.	Muhongerwa Ruth	Herbal Medicines Assessment and Registration Officer
8.	Tuyisenge Felix	Vaccines and other Biosimilars Registration Officer
9.	Karasanyi Geofrey	Veterinary Medicines Registration and Variations Assessment Officer
10.	Tuyishime Anitha	FPP and API Assessment and Registration Officer
11.	Masengesho Gentille	Public Health Laboratory Chemicals Registration Officer
12.	Iradukunda Gad Patrick	Medicinal Cosmetics Registration Officer
13.	Iterere Diane	FPP and API Assessment and Registration Officer
14.	Shyirambere Serge	Radiopharmaceuticals Assessment and Registration officer
15.	Uwera Nadia	Veterinary Medicines Registration and Variations Assessment Officer
16.	Musafiri Eustache	Veterinary Medicines Registration and Variations Assessment Officer
17.	Muhayimana Placide	Diagnostics and Medical Devices and Registration officer
18.	Isingizwe Marie Ange	FPP and API Assessment and Registration Officer
19.	Gahongayire Eustachie	Administrative Assistant to HoD

20.	Nteziyaremye Jeremie	Industrial and Market Specialist
21.	Nsabimana Isaïe	Vaccines and other Biosimilars Registration Officer
22.	Karara Sylvestre Jackson	Registry Maintenance Officer
23.	Ayinkamiye Honoré	FPP and API Assessment and Registration Officer
24.	Niyitegeka Leodomir	Medicinal Cosmetics Registration Officer
25.	Uwamariya Pacifique	Director of Cosmetics and household Chemicals
26.	Irasabwa Clarisse	DM of Drugs and Health Technologies Assessment and Registration
27.	Kabatende Joseph	HoD of Food and Drugs Assessment and Registration

Absent with a reason

S/N	Names	Positions
1	Olivier Mureramanzi	Biological Products Registration Officer
2	Kyankoni Godfrey	Diagnostics and Medical Devices assessment and Registration officer

Items on the agenda

1. Authorized list (how do we handle complaints emerging from the recently published list)
2. Products Dossier handling and assessment
3. Progress & prioritizations
4. Handling and Storage of submitted dossiers & samples
5. Available Facilities & equipment (Internet, computers, ….)
6. Feedbacks & communications
7. Rwanda FDA current ongoing Restructuring
8. Way forward
9. AoB

<u>Opening and/or remarks of the meeting</u>

The meeting started at 8h15AM with the opening remarks from the HoD of Food and Drugs Assessment and Registration. He started by welcoming the meeting participants and thanking them for their attendance. All participants had time for self-introduction and thereafter, the chair of the meeting (HoD) highlighted key items on the agenda. Before the starting of the meeting, he requested participants to respect the covid-19 measures whether at work or where we live to both protect themselves and others.

The chair of the meeting further highlighted why this meeting was very important for the division staff to meet as we wanted to align ourselves the urgent priorities to better serve our clients and also perform towards achieving the institution's mandate.

The Meeting Proceedings

1. Authorized List (how do we handle complaints emerging from the recently published list)				
Discussion	**Observation**	**Resolutions/ recommendation**	**Responsible person for implementation**	**Timelines**
A list of medicinal products on Rwandan market has been made based on the submitted products dossiers applications together with consultation of stakeholders. It was presented that the first published list of authorized medicinal products was about **6000** products but the currently published list showed about **4500** products. The difference between the two list was due to the fact that a product applied for were not on the previous authorized list.	To address complaints and ensure that, the authorized list is maintained. In doing this, a weekly strategy for updating the list of human medicinal products was instituted and so many complaints have been addressed through this. To properly implement this strategy, a general email for complaints collection was availed to all clients/applicants [areports@rwandafda.gov.rw] and a circular was issued in this regards. This will facilitate the quarterly updates of the recently published authorized list which is available on the Rwanda website. Applicants/clients and or partners may submit their requests for addition on the list after a thorough assessment of the request, the products may be added or shall be	(1) Every Thursday, the team in charge of authorized list will be meeting to add new dossiers on the list, correct errors encountered and/or handle stakeholders' complaints related to the published list (2) Every 3months, updated list has to be published on Rwanda FDA website (3) A team in charge of updating the authorized list has been established (4) There should be effective communication to make sure that all intended stakeholders are reached out. In this regard, it was agreed that a group email for all stakeholders will be created so that, once communicated, all stakeholders get transmitted information in real time (5) It was concluded that HoD will make a follow up so that a meeting with partners (importers, applicants) and these (RMS, CHUK, KMH, PIH….)) for better compliance.	(1) Honore, Nadine, Diane, Isaie in coordination of DM (2) Honore, Nadine, Diane and Isaie (3) Honore will coordinate the activity (4) DM will make a follow up (5) HoD will make a follow up	Once per week Every 3months NA NA 19/3/2021

	recommended for the addition to the list. This is important because other stakeholders may use that window to import such products basing on the fact that they are on the list without fulfilling requirements.	A letter should be written to invite them for a virtual meeting to discuss the issue		
2. Product Dossier handling and assessment				
It was presented that there is huge workload in the unit of human medicines assessment and registration. So, support from all other units is highly requested so that this workload of PDs to be assessed and be cleared.	(1) All assessors irrespective of their units have conducted a 2 weeks training about PD assessment. Therefore, they can give support to the unit of human medicines assessment and registration. (2) DM has explained that usually assessors from other units give support to human medicines assessment except when they also have also many submitted dossiers. (3) It was also shown that, based on the past experience, assessment retreats are the best way to assess many PDs during a short period of time since once out of the offices, no other duties are signed to assessors and this increases	(1) & (2) All assessors in DHTAR division will be giving support to the unit of human medicines to reduce the workload. (3) HoD has committed to make a follow up about planning and conducting assessment retreats so that once the conditions become favourable (once the spread of COVID-19 pandemic will be haltered and decreased), assessment retreats will be planned and conducted to clear the workload of product dossiers pending for assessment..	Unit representatives and DM will coordinate the activity HoD will make a follow up	NA NA

	their concentration on assessment.			
3. Progress & Prioritizations				
DM briefly updated the audience about the process of PD assessment which starts from PD application reception, screening, first and second assessment, additional data assessment, peer review meeting and then PD approval or rejection. The HoD recommended that, priority should be given to medicines that are already on Rwandan markets which our people are already consuming for which applications have been submitted to Authority as well as products registered in one or more EAC Partner States (Kenya, Uganda and Tanzania) or those registered by SRAs. Relating to weekly report, there should be identification of what the division/department wants to achieve, where does the division/department currently stand and what is the way forward to achieving the set goals. This should be primarily addressing the planned activities.	It was found that once all products on Rwandan markets are registered by Rwanda FDA, it will become easier to the Authority to make a quick follow up if the registered product shows quality related issues than for a product in use yet it is not registered. Conducting post marketing surveillance on products on market will be used to monitor quality and safety profiles of products on market. However, for samples that were submitted for registration, the quality control tests need to be done. If reference standards and equipments are not available in Rwanda FDA QC lab, then the samples may be opted for other regional labs that have regulatory MoUs with Rwanda FDA. Weekly reports are prepared, compiled and reported from	It was concluded that: (1) The screening step of PD assessment will be maintained and thus will consist with checking whether all required information has been provided before starting the actual assessment. The communication to the applicant regarding the outcome of screening will be made through email addressed to the applicant with a copy to the LTR. This will be acknowledging the receipt of the application and after assessment, queries will be sent. (2) Identification of all products on Rwandan markets registered in EAC (Kenya, Uganda and Tanzania) and whose applications for registration have been received by Rwanda FDA (3) Identified products will be subsequently assessed so that those with minor queries are given MA while those with major queries are communicated to their respective applicants. (4) HoD has updated staff that there is a new approach in products registration that will be adopted where effort is to be invested in PMS because at times of submission of applications, applicant is	(1) Olivier, Anitha and M Ange will be implementing this decision using the screening reports email. (2) Honore will coordinate the activity	NA (2) 15-19/3/2021 NA

	unit to DM and department level. This is crucial while determining the division/department performance	likely to present a sample meeting the set specifications but which may be different from the products he/she brings to the market		
4. Handling and Storage of submitted dossiers & samples				
It was emphasized that all PDs should be kept with precautions as they contain confidential information of both APIs and FPP manufacturers.	Considering offices where the division is currently working, no safe place for samples and physical PDs storage and equally, the used computers have low capacity and technical problems which do not guarantee safe storage of soft copies of PDs.	HoD requested that no lost PDs and samples should be reported in the division, we need t make sure that all dossiers and samples are traced and properly kept. It was presented that computers with strong capacity, cupboards and shells have been and we will continue to request them for the purpose of ensuring that secured storage of product dossiers and samples is addressed. However, before this, every staff is requested to safely handle any PD and sample s/he gets into contact.	HoD will make the follow up with CF and a detailed concept on the issue should be prepared to highlight the issue.	NA
5. Available Facilities & equipment (Internet, computers etc.)				
It was presented that all staff in the division have no access to internet in the office. Also, some staff have not received public computers. It was noted that though the assessors have requested CD readers, until now there is only one CD reader in the division.	It was observed that the insufficient internet access, routers, chairs and working stations, well-functioning computers and CD readers hinders the work and delays performance.	Computers with strong capacity, CD readers, routers, chairs and working stations have been requested from the CF and HoD will continue to make follow up.	HoD will make a follow-up	NA

	Trying to cope with this, staff who were not given computers are using their own machines and phone internet.			
6. Feedbacks & Communications				
It was presented that some emails from applicants/stakeholders addressed to the department or division often remain hanging on Rwanda FDA email and do not reach their real destination. During PD application submission, the applications submitted online are not assigned reference numbers making it difficult to trace them once needed.	It was observed that some applications and/or feedbacks from applicants are lost and this delays the timely PD assessment, response to applicants, MA issuance as well as increased customers claims. The PD applications not assigned the reference numbers are difficultly traced once the physical PD is required during or after the PD assessment.	It was proposed that: Department email should be created and communicated to applicants. Proper orientation of customers by central secretariat/reception emphasizing on how PDs applications are submitted and what to submit once a MA for products is required from Rwanda FDA. In relation to PD submitted online due to current preventive measures against COVID-19, receptionists should establish a strategy of how to record these applications and assign to them respective reference numbers.	HoD and DM will make a follow up	
7. Rwanda FDA Current Ongoing Restructuring				
HoD briefed the staff on the aim of the current reforms within government institution. Rwanda FDA was no exceptional and our structure was reviewed to accommodate new and specialized skills and increase the number of staff from **155** to **194**. He also informed the meeting	It was observed that all staff were not informed about the restructuring process and the way forward which they said it was a challenge to their everyday work.	HoD requested staff to continue working hard to accomplish their duties to ensure higher division, department and thus, institutional performance while Rwanda FDA management together with ministry in charge of public service are working hand in hand to finalize the	Rwanda FDA management and MIFOTRA are coordinating the activity	NA

attendees that the restructuring was done to ensure that staff are motivated. It was also explained that Rwanda FDA is proposing to appoint staff who were on the positions of officers as acting specialists so that based on the recommendation by the Ministry in charge of public service, the Rwanda FDA will conduct either internal or external recruitment to appoint staff in the above positions permanently. for Analysts positions, HoD informed the meeting that, these are cabinet appointees position and we will wait for the competent appointing authorities to appoint.		placement process of staff in new positions.		
8. Way Forward				
Staff was urged to work hard so that there are enough registered products in Rwanda FDA registry. The meeting expressed the need to regularly meet on a regular basis.	The department meeting has been found to be required not only to ensure staff know one another but also to discuss different issues related to the work of assessment or any other staff personal issues which may directly or indirectly affect his/her work.	It was agreed upon that the department meeting will be taking place once per Month.	HoD	Once per Month

9. AoB				
Collaboration/cooperation between assessors and the applicants/stakeholders has been discussed. HoD briefed staff on how effectively they can work with applicants/stakeholders highlighting the need to be vigilant while working with clients. Staff should be very attentive and careful while making sure that whatever they discuss is in line work. Staff have requested that a disciplinary committee should be established. It was explained that this will be important because in case of staff misconduct, there will be a defined way of correcting him/her or taking appropriate decisions in accordance with the committed mistake.	It was noted that some staff were not aware of effective communication and collaboration with Rwanda FDA customers and stakeholders. However, after the briefing, staff have shown the understanding of the relevance of Rwanda FDA staff-customer/stakeholders effective collaboration and willingness to abide with the advice from HoD.	HoD concluded the meeting reminding all staff that once an applicant/stakeholder or any other one requests information related to their work at Rwanda FDA, they should provide one preferably once it is in their competence and obligations. Otherwise, staff are advised to orient the customer/stakeholders to someone's else with such competence and obligations at institutional management level.	All staff	NA

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

The meeting has ended at: **11h00 AM**

End of Minutes

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Rwanda FDA Attendance List

Activity Title: DFDAR Meeting **Venue:** Rwanda FDA, 2nd floor **Date:** 15.03.2021

#	Names	Position	Institution	Contact	E-mail	Signature
1	NSANZIMFURA Pierre	Herbal medicines Assessment Reg officer	Rwanda FDA	0788788262	pnsanzimfura@rwandafda.gov.rw	
2	UWOROHEJE Innocent	Vet Diag & Medical Devices Reg officer	Rwanda FDA	0786938845	iuworoheje@rwandafda.gov.rw	
3	MUNYANEZA UWILTONZE JANVIER	Medicated cosm. Reg. officer	Rwanda FDA	0783372820	imunyaneza@rwanda	
4	NIYOMAHORO Nadine	FPP & API Registration officer	Rwanda FDA	0788576905	nniyomahoro@rwandafda.gov.rw	
5	Philbert NSHIMIYIMANA	Biological product Reg. officer	Rwanda FDA	0782189159	pshimiyimana@rwandafda.gov.rw	
6	Jean Damascène UWABIMANA	Bioproduct Reg. officer	Rwanda FDA	0788352770	juwabimana@rwandafda.gov.rw	
7	MUHONGERWA RUTH	Herbal medicines Ass & Reg Officer	Rwanda FDA	0788939679	rmuhongerwa@Rwandafda.gov.rw	
8	TWIZERIMANA FELIX	VACCINE & BIOSIMILAR Reg. officer	Rwanda FDA	0783146443	ftwizerimana@Rwandafda.gov.rw	Felix
9	KARASANYI Geoffrey	Veterinary medicine Registration & Inspection Assistant	Rwanda FDA	0785626681	gkarasanyi@rwandafda.gov.rw	
10	TUYISHIME Aniitha	FPP & API Registration off.	Rwanda FDA	0788800990	atuyishime@rwandafda.gov.rw	

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Rwanda FDA Attendance List

Activity Title: Division meeting with HoD **Venue:** Rwanda FDA **Date:** 15/03/2021

#	Names	Position	Institution	Contact	E-mail	Signature
1.	MASENGESHO Gentille	Public health laboratory chemicals registration officer	Rwanda FDA	0781604604	gmasengesho2@rwandafda.rw.gov.	
2.	RMUKUNDA Gad Patrick	Medicinal Cosmetics Registration officer	Rwanda FDA	0784300016	Pmukunda@rwandafda.gov.rw	
3.	ITETERE Diane	Finished and active pharmaceutical Registration officer	Rwanda FDA	0788502343	ditetere@rwandafda.gov.rw.	
4.	SERGE SHYIRAMBERE	Radiopharmaceuticals ASR officer	Rwanda FDA	0788804293	sshyirambere@rwandafda.gov.rw	
5.	Ukwera Nadia	Veterinary Medicine Registration officer	FDA	0785377795	nukwera@rwandafda.gov.rw	
6.	MUSAFIRI Eustache	VMR & VAO	Rwanda FDA	0784539349	emusafiri@rwandafda.gov.rw	
7.	PLACIDE MUHAYIMANA	Diagnostics & med device reg.	RWANDA FDA	0783029663	Pmuhayimana@rwandafda.gov.rw	
8	ISINGIZWE MARIE ANGE	Human medicine registration	Rwanda FDA	0789612035	misingizwe@rwandafda.gov.rw	
9	Eustachie GAHONGAYIRE	Admin. Assistant	Rwanda FDA	0788890738	egahongayire@rwandafda.gov.rw	

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Rwanda FDA Attendance List

Activity Title: BESAR Meeting **Venue:** Rwanda FDA, Head office, 2nd Floor **Date:** 15/03/2021

#	Names	Position	Institution	Contact	E-mail	Signature
1.	Jerémie Nteziyaremye	Industrials Market Specialist	Rwanda FDA	0783867233	jnteziyaremye@rwandafda.gov.rw	
2.	Isaïe NSABIMANA	Vaccines & Biosimilar Reg. Officer	Rwanda FDA	078888301 1	insabimana@rwandafda.gov.rw	
3	KARARA Sylvestre Jackson	Registry Marketing officer	Rwanda FDA	0787451847	Skarara@rwandafda.gov.rw	
4	AYINKAMIYE Honoré	Ag & ADI Registration Officer	Rwanda FDA	0788802853	hayinkamiye@rwandafda.gov.rw	
5	Léadomir NIYITEGEKA	Medicinal Cosmetics registration officer	Rwanda FDA	078882 9087	lniyitegeka@rwandafda.gov.rw	
6	Pacifique UWAMARIYA	Director of the cosmetic & Household chemical	11	0783491397	puwamariya@rwandafda.gov.rw	
7.	IRASABWA CLARISSE	INTERNSHIP	11	0786395 07	cirasabwa@rwandafda.gov.rw	
8.	KABATENDE Joseph	Intern/FDAR	11	0788792 86	jkabatende@rwandafda.gov.rw	