Rwanda Food and Drugs Authority
Nyarutarama Plaza KG 9 Avenue
Email: info@rwandafda.gov.rw;
website: www.rwandafda.gov.rw

MINUTES OF THE MEETING N°..... /...../FDA/..... FOR Department of Drug and Food Assessment and Registration

Date of Meeting 08th June 2021

Venue of the meeting: Virtual through WebEx

Attendance List (Hard copy To be by hand signed and attached on these minutes)

	Names	**Position**
1.	Joseph KABATENDE	HoD of the Food and Drugs Assessment and Registration Department
2.	Dr Eric NYIRIMIGABO	DM of Human Medicines and Medical devices assessment and registration Division
3.	Dr MUKIZA Janvier	DM of Cosmetics and Households assessment and registration division
4.	Dr Rosine MANISHIMWE	DM of Veterinary Medicines and Medical devices
5.	Deo Gasana	Finished and active pharmaceutical products analyst
6.	LAZARE NTIRENGANYA	DM of Pharmacovigilance and Post marketing surveillance division
7.	Clarisse IRASABWA	Finished and active pharmaceutical products analyst
8.	Dr Emil MWIKARAGO	Medical devices assessment analyst
9.	Dr Richard HABIMANA	Vaccines and Biosimilar assessment analyst
10.	Tite UWAMBAJINEZA	Radiopharmaceutical and Radiotherapy products analyst
11.	Jurdas SEZIRAHIGA	Public Health and Laboratory Chemicals analyst
12.	Pacifique UWAMARIYA	Cosmetics Analyst
13.	Desire MUSANGWA	Food assessment and registration Analyst
14.	Jose-Edouard MUNYANGAJU	Veterinary Medicines analyst

15.	Dr Doreen INGABIRE	Veterinary IVDs and Medical devices Analyst
16.	Honore AYINKAMIYE	Ag Finished and active pharmaceutical products registration Specialist
17.	Nadine NIYOMAHORO	Ag Finished and active pharmaceutical products registration Specialist
18.	Marie Ange ISINGIZWE	Ag Finished and active pharmaceutical products registration Specialist
19.	Diane ITETERE	Ag Biological products registration Specialist
20.	Serge SHYIRAMBERE	Ag Vaccines and Biosimilar products registration specialist
21.	Anitha TUYISHIME	Ag Herbal medicines registration specialist
22.	Ruth MUHONGERWA	Ag Herbal medicines registration specialist
23.	Isaie NSABIMANA	Ag Vaccines and Biosimilar products registration specialist
24.	Jean DAMASCENE DUSABIMANA	Ag Vaccines and Biosimilar products registration specialist
25.	KARARA Jackson	Ag Port of Entry specialist
26.	Dr Eustache MUSAFIRI	Ag Port of Entry specialist
27.	KYANKONI Godfrey	Ag Port of Entry specialist
28.	Dr Nadia UWERA	Ag Veterinary medicines registration specialist
29.	Dr KARASANYI Geofrey	Ag Veterinary medicines registration specialist
30.	Janvier MUNYANEZA	Ag Pesticides Testing Officer
31.	Gentille MASENGESHO	Ag Public Health and lab chemicals Specialist
32.	Leodomir NIYITEGEKA	Ag Medicated cosmetics specialist
33.	Patrick Gad IRADUKUNDA	Ag Medicated cosmetics specialist
34.	Frederic MUHOZA	Clinical trials specialist
35.	Theogene Ndayambaje	QMS specialist
36.	MUBANO Florence	KIPHARMA LTD
37.	Ines BUKI	Country Director PSM
38.	MIRIMO Jean	MTaPs- USAID
39.	Jean Paul MUKUNDIYUKURI	PIH
40.	Ignace NDEKEZI	RWANDA Medical Supply
41.	Rwanda Veterinary Doctors Council	

42.	Dr Spridio NIYODUSENGA	VetLink pharmacy ltd
43.	RWANDA FRATERNITY AGAINST HAEMOPHILIA	
44.	Biofarmacia ltd	
45.	NIYOYITA Zacharie	RENE Pharmacy ltd
46.	Frank BUTERA	PRAFFIN LTD
47.	NGIRIMANA Nelly Diana	WESSEX LTD

Items on the agenda

a) Opening Remarks by Head of Department of Drug & Food Assessment and Registration and introduction of new managers as per new Rwanda FDA structure

b) Presentation of the Objectives of the Workshop, the list regulatory documents to be validated and updated regulations to the stakeholders

c) Q&A

d) Presentation on Guidelines on Reliance for Regulatory Decision-Making

e) Q&A

f) Guidelines On Submission of Documentation for Renewal of Registered Human and Veterinary Medicinal Products

g) Q&A

h) Guidelines for Authorization for Emergency Use of Medicinal Products, Medical Devices and IVDS

i) Q&A

j) Guidelines for Donation of Medical Products

k) Q&A

l) Guidelines on Good Review Practices

m) Q&A

n) Authorized List for Veterinary Vaccines

o) Q&A and open discussion

p) Closing remarks and vote of thanks

Opening of the meeting

The meeting started at 2:15PM with the opening remarks of the Head of the department, Drugs and Food Assessment and Registration welcoming the stakeholders and introducing new managers of department who had recently been appointed by the Cabinet as per new Rwanda FDA structure.

Resolutions of the meeting

Item on Agenda	Comments and recommendation	Responsible person for implementation	Timelines
Opening Remarks by Head of Department of Drug & Food Assessment and Registration and introduction of new managers as per new Rwanda FDA structure	Head of the department, made a welcome remark by thanking the invited stakeholders for attendance. He also introduced new managers of the department as per new Rwanda FDA structure who had recently been appointed.		
Presentation of the Objectives of the Workshop/validation meeting, the list of regulatory documents to be validated	**Objectives:** Introduction of new regulatory documents that are going to be validated/discussed and receiving inputs and comments in order to improve them before there are submitted for further approval processes. The presenter highlighted the need for presenting these documents for stakeholders to read through them and give their inputs/comments and also urged them get familiar to these new regulatory tools in place for better compliance		
	List of regulatory documents that was validated and updated: • Regulation N°CBD/TRG/010 Governing registration of medicinal products and • Regulation N° CBD/TRG/012 Governing registration of medical devices • Guidelines On Reliance for Regulatory Decision-Making,	Stakeholders gave their comments during the validation meeting but also were requested to send in their comments for integration so that these documents are submitted for approval. These documents had been uploaded on the	Not later than Wednesday (09 June 2021)

	• Guidelines On Submission of Documentation for Renewal of Registered Human and Veterinary Medicinal Products • Guidelines for Authorization for Emergency Use of Medicinal Products, Medical Devices and IVDS, • Guidelines for Donation of Medical Products and • Guidelines on Good Review Practices.	stakeholders portal for review and comments on the Rwanda FDA website in stakeholders section	
Updates on the new additions/changes to the reviewed regulations to the stakeholders by Clarisse IRASABWA	On Regulation N°CBD/TRG/010 Governing registration of medicinal products and Regulation N° CBD/TRG/012 Governing registration of medical devices approved in April 2020, some articles related to reliance for regulatory decision making, Authorization for Emergency Use and Donation of medical products were added and the rationale was highlighted to stakeholders	Stakeholders were requested to provide their comments on guidelines and regulations uploaded on the website in stakeholders section	Comments were to be provided Not later than Wednesday (09 June 2021) as these documents needed urgent attention
Presentation on Guidelines on Reliance for Regulatory Decision-Making by Isaie NSABIMANA	He highlighted the Mission and the Scope of Rwanda FDA and linked the need to have in place the Guidelines on Reliance for Regulatory Decision-Making. He presented what is guidelines covered by the guidelines and intended reliance activities regarding to all types of medical products and regulatory activities using reliance approaches (verification of sameness, confirmation of applicability of the assessment outcomes, Abridged assessment and Joint assessment or working-sharing). He also indicated that these guidelines will be a crosscutting one as it covers all regulatory functions (Registration, GMP Inspections, Clinical Trials and Quality control).	Stakeholders were requested to provide their comments on guidelines and regulations uploaded on the website in stakeholders section	Comments were to be provided Not later than Wednesday (09 June 2021) as these documents needed urgent attention

Guidelines On Submission of Documentation for Renewal of Registered Human and Veterinary Medicinal Products by Isaie NSABIMANA	He emphasized on mode of submission, general requirements, product information and evaluation process for Renewal of Registered Human and Veterinary Medicinal Products.	Stakeholders were requested to provide their comments on guidelines and regulations uploaded on the website in stakeholders section	Comments were to be provided Not later than Wednesday (09 June 2021) as these documents needed urgent attention
Q& A	**Comment from Frederic MUHOZA:** I think the safety update reports should be part of submission for application of MA renewal. If it is not considered in the guidelines, you can see how to include that information if any.		
	Q1 from Robyn Howes: would the reliance model also apply to medical devices and IVDs? Would the manufacturing standard ISO 13485 also be considered in place of GMP for MD and IVDs. **Answer from Kyankoni Godfrey**: the reliance is applied on all medical devices and IVDs. **Q2 from MUBANO Florence**: Hope the guidelines for summary and content of the labels and SmPCs you are refering to will be available. ➢ For the application for renew, the applicant will submit the variations approved by the authority, what if there were some variations not yet submitted- is it time to submit them along the review application? ➢ GMP during renew? **Answer from AYINKAMIYE Honore:** SmPC and PIL will be soon published, for variations any variations have to be submitted and approved by the authority.		

Guidelines for Donation of Medical Products by Honore AYINKAMIYE	These guidelines are made for information, guidance and strict compliance by all concerned parties on the procedure and requirements for the donation of medical products in Rwanda. They are applicable to medicinal products, medical devices, IVDs for both in humans and veterinary use. These guideline serves to protect the public health from unsafe, poor quality and ineffective medical products by ensuring Good Donations Practices, and make sure that donated medical products are in compliance with the needs of Country.	Stakeholders were requested to provide their comments on guidelines and regulations uploaded on the website in stakeholders section	Comments were to be provided Not later than Wednesday (09 June 2021) as these documents needed urgent attention
Guidelines on Good Review Practices by Honore AYINKAMIYE	This document is to provide high level guidance on the principles and processes of good review practices for use within Rwanda FDA. It is also applied for the review of quality, safety, efficacy, performance data and information on medical product applications filed with Rwanda FDA for marketing authorization.	Stakeholders were requested to provide their comments on guidelines and regulations uploaded on the website in stakeholders section	Comments were to be provided Not later than Wednesday (09 June 2021) as these documents needed urgent attention
Guidelines for Authorization for Emergency Use of Medicinal Products, Medical Devices and IVDS by Honore AYINKAMIYE	These guidelines provide the regulatory requirements for the Authorization for Emergency Use of a medicinal product, medical devices and IVDs during a declared Public Health Emergency. The AEU is a special procedure for unlicensed medicinal product, medical devices and in vitro diagnostics in the event of a Public Health Emergency.	Stakeholders were requested to provide their comments on guidelines and regulations uploaded on the website in stakeholders section	Comments were to be provided Not later than Wednesday (09 June 2021) as these documents needed urgent attention
Q& A	**Q1 from Rosine MANISHIMWE:** When does an Emergency Use Authorization expire or for how long is it valid?		

	Answer from NDAYAMABAJE Theogene: The AEU shall be valid for one (1) year from the date of issuance of the Authorization letter or when the declaration of the Public Health Emergency has ceased to exist or whichever is earlier. **Q2 from Jean Paul MUKUNDIYUKURI**: What are the prescribed fees for AEU application? **Answer from Clarisse IRASABWA**: It is free of Charge. **Q2 from Jean Paul MUKUNDIYUKURI**: There is need to precise circumstances in which non-registered donated products will be allowed or waived **Answer from Joseph KABATENDE**: The guideline is there to protect the public from unsafe products. Donated products should be registered products or be on the authorized list. We should have the minimum information on the quality of the donated products.		
Authorized List for Veterinary Vaccines	The objectives of the authorized veterinary vaccines list were to establish a list with detailed information on each product, establish a comprehensive database of products that are authorized to be marketed in Rwanda, facilitate the import/export control procedures and establish a baseline tool for mapping registration applications. The source of information on the list was the circular released on 8th of April, 2021 by the Authority whereby all stakeholders involved in vaccines supply chain were contacted via email and phone call to supply information.	Stakeholders were requested to provide their comments on guidelines and regulations uploaded on the website in stakeholders section	Comments were to be provided Not later than Wednesday (09 June 2021) as these documents needed urgent attention
Q& A	Q1 from Spridio NIYODUSENGA: The list is a mix up of vaccines, some antibiotics and hormones. There is		

	need to go through it again before publishing the final version. Secondly, it might be better if the list is presented in a very well-structured way following animal species. Answer from Joseph KABATENDE": The timeline was given for stakeholders to provided information and the list be compiled and deadlines was set up to 14th June 2021, for the stakeholders submit their comments		

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	Names, and signature and institution stamp		Names and signature
Chair of The meeting	Joseph KABATENDE 23/6/2021	Rapporteur	Diane ITETERE

The meeting has ended at: 5:26 pm

End of Minutes