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°... /06/FDA/2021
of [Stakeholders meeting on awareness of regulatory tool]

Stakeholders meeting N°:.....-/2021)

Date of meeting: **08th July 2021**

Venue of the meeting: **Virtual meeting**

Attendance List

S/N°	Rwanda FDA team	Stakeholders participants among others
1.	Joseph KABATENDE	Lise UWINEZA,
2.	Dr. Eric NYIRIMIGABO	Manzi martin,
3.	Clarisse IRASABWA	Paolo Paganin
4.	Deo GASANA	Emma Bizimana,
5.		Chris,
6.		Nkeziyaremye Jean pierre
7.		Safari EPHREM,
8.		Ngirimana Nelly Diane
9.		Gaston,
10.		Esther MOKAYA,
11.		Glaxo PHARMA
12.		Nelson and Irenee

Items on the agenda

1. Presentation of regulatory documents to stakeholders

Opening and/or remarks of the meeting

The meeting was chaired by Joseph KABATENDE, the head of department Food Assessment/Registration Department. In his opening remarks, welcomed the participants and articulated the important and obligation of the authority to partner with stakeholders and create awareness on regulatory tools that have been developed and published on Rwanda FDA website. He said that since these are documents strict adherence to these guidelines is mandatory, everyone should be aware of the content of these tools.

The Division manager Dr Eric NYARIMIGABO who also moderated the presentation session of the meeting welcomed participants and requested Clarisse IRASABWA to present the relevant guidelines to the stakeholders as outlined on the agenda.

The Meeting Proceedings

Discussion	Resolutions/ recommendation
Presentations	**Moderator**
This session awareness session was presented by Clarisse IRASABWA on the following regulatory document which have been published on Rwanda FDA website ➢ Overview of the mission and the scope of Rwanda FDA in provision of different services to the stakeholders ➢ <u>Regulations;</u> ✓ Regulations N° CBD/TRG/010 governing registration of medicinal products ✓ Regulations N° CBD/TRG/012 governing the registration of medical devices ➢ <u>Guidelines</u> ✓ Guidelines N°DHT/GDL/001 on submission of documentation for registration of human medicial products ✓ Guidelines N°DHT/GDL/021 on abridged procedures for pharmaceutical products assessment ✓ Guidelines N°DHT/GDL/012 for variation of registered human medicinal products ✓ Guidelines N°DHT/GDL/035 on submission of documentation for registration of human biological products ✓ Guidelines N°DHT/GDL/013 for registration of similar biotherapeutic products ✓ Guidelines N°DHT/GDL/024 on submission of documentation for registration of medical devices	Dr Eric NYIRIMIGABO The Division Manager MDAR

Questions and response	Modurated by Joseph KABATENDE (HOD)
Discussion	**Resolutions/ recommendation**
✓ A participant by the names of Jean Pierre requested whether Rwanda FDA would give a query without waiting until when the dossier is assessed through FIFO schedule.	He was told that queries are provided after assessment of the product dossier and samples are assessed following the order of arrival (First in first out) to ensure equity in service delivery
✓ Another participants asked whether products from Europe that have been subjected to reliance could be exempted from abridged assessment	The client was explained the idea behind reliance procedure and its purpose.
✓ Safari expressed concern on dossiers that have exceeded 9M before assessment is done and was concerned local technical representative on explaining it to their partners.	The HOD, Acknowledged the delays in assessing some Dossiers and told the participants that efforts is being done including upgrading Rwanda FDA's systems, staff are working tirelessly even beyond work hours to clear this backlog. New staff are undergoing orientation to provide a boost up to the assessment team and hope that in few months to come, we would be in position to provide the services beyond the scheduled timeline and to best service to our stakeholders.
✓ Chris asked about when RFDA would be planning to conduct GMP inspection on manufacturers who have applied for GMP inspections	He was assured that as soon as travel restrictions have ceased the process will be scheduled and done as earlier planed

✓ Gastave clarified about the tarrif applied on medical devices during different variations.	He was guided that fees applied depend on whether it is a variation (Major/minor) or a variation that may necessitate a new application
✓ One member was asking whether there could be guidelines describing reliance procedure ✓ Jean MICHEL asked on when the Reliance regulatory decision making is used	The HOD explained that the guideline is available and explained that reliance procedure aims at reciprocity and sharing of information during dossier review, in this case the regulatory bodies should be able to rely on each other in order to facilitate decision making
✓ If Rwanda FDA could issue temporary registration on Product Dossier prior to assessment	The HOD explained to participant that as a regulator, we would not have any explanation to register a product before assessment. He said that we should exercise due diligence and rather push this work to be done in reasonable timeframe than to issue temporary registration
✓ Someone wanted to know whether there is a separate guideline for vaccine	The participant was guided that Rwanda FDA has got a guideline for human biological which covers vaccine as well that is also available online for reference
✓ Asked whether registration number should always appear on both primary and secondary packaging	The was guided to refer to the guideline which is available on the website for reference, which requires that registration numbers would appear on both primary and secondary packages
✓ Asked why program products that are not on RBC Program products list are not registered	The participant was guided that if a program medicine is not on the protocol, even if Rwanda FDA would register the product it would not work since it cannot be prescribed when it is not a program medicine.

✓ Diane thanked RFDA for the presentation but requested that some guidelines on the website make references on some forms and was requesting to have access to them.	She was told that stakeholders should have access to those forms on the website where it is possible. But SOPs cannot be shared to stakeholders because are meant for internal use.

	Names, and signature and/or institution stamp		Names and signature
Meeting was Chaired by:	Joseph KABATENDE Head of the Department	Minutes were taken by:	Deo GASANA Finished and Active Pharmaceutical Products registration analyst

The meeting was adjourned at 4.30 pm as scheduled.

End of Minutes