Rwanda Food and Drugs Authority

Nyarutarama Plaza KG 9 Avenue
Email: info@rwandafda.gov.rw;
website: www.rwandafda.gov.rw

MINUTES OF THE MEETING Nº:….. /01/FDA/2021 FOR FDAR DEPARTMENT

Date of Meeting 29 January 2021

Venue of the meeting:
https://risa-rw.webex.com/risa-rw/j.php?MTID=m4a4738fbeeaf260ad4e9b46ffa0ec9e7

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

	Names	Position
1.	Mr. Joseph KABATENDE	Head of FDAR Department
2.	Mr. Alex GISAGARA	Head of Inspection and Compliance Department
3.	Mrs. Haile-Brugger Sandra Akeza	Advisor, DG
4.	Mrs Clarisse IRASABWA	D&HTAR Division Manager
5.	Mr Desire MUSANGWA	Food Assessment and Registration Division Manager
6.	Mr. Antoine MUKUNZI	QCL Division Manager
7.	Mr. Shadrack NDAYISHIMIYE	Legal Officer
8.	Mr. Theogene NDAYAMBAJE	QMS Specialist
9.	Mr. Honore AYINKAMIYE	API & FPP assessment and registration Officer
10.	Nadine NIYOMAHORO	API & FPP assessment and registration Officer
11.	Marie Ange ISINGIZWE	API & FPP assessment and registration Officer
12.	Diane ITETERE	API & FPP assessment and registration Officer
13.	Jackson KARARA	Registry Maintenance
14.	Mrs. Anitha TUYISHIME	API & FPP assessment and registration Officer
15.	Mrs. Marie Ange UWASE	Regulatory Affairs and Harmonization Advisor
16.	ETs CONTINENTAL	

17.	KIPHARMA	
18.	MULTIPHAR	
19.	AIVEEN RWANDA LTD	
20.	AFRIPHARM LTD	
21.	SURGIPHARM RWANDA	
22.	PYRAMID PHARMA LTD	
23.	DEPOT PHARMACEUTIQUE LE MEDICAL	
24.	VIDAPHARM	
25.	PHILIPS PHARMACEUTICALS RWANDA LIMITED	
26.	SUN ENTERPRISES LTD	
27.	GIOVANNI DAVITE	
28.	JEAN MICHEL MINANI	
29.	LAMBERT KADENDE	
30.	RUTH MUHONGERWA	
31.	JEAN PAUL NDINDIBIJE	
32.	ANGE AMATE	
33.	MUBANO FLORANCE	
34.	GISELE UWERA	

***Note. Participants are more than the listed. Please refer to the recordings of the meeting.**

Items on the agenda

- **Validation of Human Medicinal Authorized Products List, February 2021**

Opening and/or remarks of the meeting

The virtual meeting started at 2:30 PM with the opening remarks of the Head of Department of Food and Drugs Assessment &Registration (FDAR) Mr Joseph KABATENDE on behalf of Rwanda FDA Ag. Director General. He started his remarks by welcoming all participants and thanking stakeholders for their attendance and participation. He also highlighted that the meeting was very important to validate the authorized Medicines list of February, 2021 so that it can be approved and published. He mentioned that the purpose of this list was to make sure all products

on the Rwandan market are under control and to ensure their quality, safety and efficacy for public health protection, which is in Rwanda FDA mandate. He closed his opening remarks by wishing all participants a fruitful meeting.

Meeting development

The meeting continued by the presentation about the summary of Proposed Human Medicinal Products Authorized list February 2021. By Ms Clarisse IRASABWA, the Division Manager of Drugs and Health Technologies Assessment & Registration Division.

In her presentation, she highlighted the background, objectives of the authorized human medicinal product list, the used format, considerations done, source of information, a summary of Stakeholder's feedback challenges and the way forward and then the Final draft authorized human medicinal product list February 2021, where she said that the list had 4416 human medicinal products. She has also informed the participant that the list will be reviewed quarterly and the number of Authorized products will be reduced as the number of Registered Products will be increasing. She concluded her presentation by emphasising that this authorized list is temporary list and all human medicinal products need to comply with the Authority registration requirements.

After the presentation, the Chair of the meeting, welcomed comments and discussions from the participants and he highlighted that the Authority shall publish the list so that it will be used in importation licensing effective February 2021. He also reminded the participants that this list is not a guarantee that they will continue to be imported forever, all products including those pre-registered have to comply with the Authority regulations for human medicinal products registration.

The discussions started by Mr. Giovanni Davite, who was also in the meeting representing the Chair of AIGPHAR (Association d'Importateur Grossiste des Produits Pharmaceutiques au Rwanda), thanked the Authority for the work done and the opportunity given to them so that they can provide their input before the list is published. He encouraged other present stakeholders to benefit this opportunity and share their inputs.

In general, the discussions were focused on the following points:

1. The products not available on the list,
2. Errors for some products on the list
3. If pre-registered products need also to comply to the Rwanda FDA registration requirements
4. Provision of Products Unique Code
5. If the National Standards Treatment Guidelines were considered in preparation of the Authorized medicines list
6. What will happen if new molecules will be needed on the market as per the new STGs

7. If pending VISAs `products will be affected as some products may not reappear on the new list.
8. Timeline for review of the shared Authorized Medicines List before it is approved.

The Head of Inspection and Compliance Department, Mr Alex GISAGARA has intervened and he has emphasized that all products must comply with registration requirements including those pre-registered by submitting the Products Dossiers in CTD format and paying the prescribed registration fees. He has also responded that during the list preparation, the products considered used to be on the Rwandan Market so that there cannot be any worries about the gap when considering the national STGs. He had also clarified that the products that requested VISAs before the list publication will not be affected by the new changes. He ended his intervention by urging stakeholders to review the shared list and communicate to the Authority their feedback on time.

About the issues of Provision and use of Products Unique Code for pharmaceutical product, what will happen if new molecules will be needed on the market as per the new STGs and What will happen if the product is not on the list and it is needed on the market, The HoD Joseph informed the participants that the Authority has started thinking about that and with the collaboration with other involved institutions to develop and implement the Unique code for pharmaceutical products.

For the question of new products need to be introduced on the Rwandan market he responded to the participants that the mechanisms are already established, and the authority will as usually collaborate with involved parties so that everything will be handled in line with the regulations and for the public protection.

The meeting was officially closed by Mr Joseph KABATENDE. In his closing remarks he urged the stakeholders to approach the Authority any time they have any issues or any suggestion that may contribute to the progress of the Authorities' mandate. He confirmed that the communication recently sent to Rwanda FDA from AIGPHAR about the draft of Authorized Human Medicinal Product List shared in December 2020 was received and the Authority will go through it and the feedback will be provided. He has also requested them to go and review the shared new draft list and provide their feedback on time and he concluded by thanking once again the stakeholders for their participations and their commitment to collaborate with Rwanda FDA

Resolutions of the meeting

Item on Agenda	Comments and recommendation	Responsible person for implementation	Timelines
Validation of Human Medicinal Authorized Products List, February 2021	**Stakeholders to review the shared list and communicate the feedback to the authority.**	Stakeholders	By Sunday 31st January 2021
	The Authority shall review all submitted feedbacks and update the Authorized Human Medicinal Product List	D&HTAR Division Manager	By Monday, 1st February 2021
	Approval and Publication of the Authorized Human Medicinal Product List, February,2021	The Authority Management	By Tuesday,2nd February, 2021
	Updating of the Authorized Human Medicinal Products List	D&HTAR Division Manager	On a Quarterly basis
	Use of the Authorized Human Medicinal Product List in the Importation licensing on daily basis	Department of Inspection and Compliance	
	Stakeholders and the Authority have to collaborate to ensure that all human medicinal products available on the Rwandan market have applied for registration	Stakeholders and The Authority Management	

Chair of The meeting	Names, and signature and institution stamp	Rapporteur	Names and signature
	For **Mr. Joseph KABATENDE** **HoD of FDAR**		Digitly signed by AYINKAMIYE HONORE **AYINKAMIYE HONORE**

The meeting has ended at: 4:20 PM

End of Minutes