RWANDA FDA
Rwanda Food and Drugs Authority
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MEETING NAME: METTING WITH STAKEHOLDERS TO RESPONDE ON VARIES QUESTIONS ON 27TH MARCH 2019

VENUE: Classic Hotel (Big Hall)

DATE OF THE MEETING: 27/03/2018

STARTING TIME: 02:00 PM

CLOSING TIME: 05:00 PM

1.0 IN ATTENDANCE

The signed attendance list is hereto attached

2.0 ITEMS ON THE AGENDA OF THE MEETING

2.1 Challenges on the deadlines to submit CTD format dossiers of products on the market in order to comply with the Circular on assessment & registration of regulated products n°093/RwandaFDA/2018 of 24th December 2018

2.2 Orphelin products which may not be able to pay registration fees

2.3 Products supplied by the distributors not by the manufacturers (eg. European products)

2.4 Rejection of products in special case import visa

2.5 Delay of Import Visa and import License

2.6 Exemption list

3. 0 OPENING OF THE MEETING:

The meeting was convened and chaired by the acting Director General of Rwanda FDA who welcomed all the participants and made remarks on the mission and mandate of Rwanda FDA. He recognised the importance of stakeholders in implementing the regulation of medicines on Rwandan Market and reminded them their responsibilities in regulation and he thanked them for their good collaboration.

The chair of AIGPHAR (Association des importateurs grossistes en produits pharmaceutiques) also thanked Rwanda FDA to organise a meeting in a very short time after receiving their letter in order to respond to the stakeholders issues in regulation of pharmaceutical products on Rwandan market.

#	Problem/Raised Matters	Consensus/Recommendations	Responsible	Timelines
POINTS ON AGENDA: **1. Challenges on the deadlines to submit CTD format dossiers of products on the market in order to comply with the Circular on assessment & registration of regulated products n°093/RwandaFDA/2018 of 24th December 2018**				
	Some manufacturers have expressed their worries of not being able to meet the deadline, as they have only one centralized unity to prepare the CTD format dossier, and they have pre-determined schedule that may arrive to 2 years or more. The importers proposed the extension of the deadline up to 36 months in order to submit the complete required information in CTD format products dossier and fees. The manufacturers would provide commitments to comply with the new timeline and provide where applicable CTD format from EAC country and/or a CPP (Certificate of pharmaceutical Product) from an SRA (Stringent Regulatory authority) Country.	Rwanda FDA extended the period from 6 months to 12 months, meaning by 31st December 2019 all products medicines on the market have to comply with the circular on assessment and registration n°093/RwandaFDA/2018 of 24th December 2018. Special cases will be considered for manufacturers or applicants which have many products on the market and they will give plan on how they will comply to the above said circular.		31st December 2019

2. Orphelin medicines products which may not be able to pay registration fees				
	There are products so called Orphelin medicines with less volume/rotations sales that the registration fees may be higher than their sales so manufacturers may not be interested to register the products. The importers proposed for the benefit of the patients for the products that are already on the market, where there is no any other equivalent product registered, to be authorized on special importation cases while importers would continue to convince manufacturers to register the products.	These products will be considered like others, they will have to submit CTD format product dossier and they will pay fees for registration by 31st December 2019 no exception will be made. The importers will provide the list of concerned products for consideration by Rwanda FDA.	All	31st December 2019
3. Products supplied by the distributors not by the manufacturers (es. European products)				
	Products coming from distributors especially European market (eg. Distriphar, EPDIS, Tridem...) and the manufacturers are not aware of their products being on Rwandan market and maybe they are not even interested with this market because it is too small. The Rwandan importers/wholesalers proposed to be given more time to convince their distributors in order to encourage manufacturers to give importance to Rwandan market and register their products but this will take time and the products will be still needed on the market.	These products will be considered like others, they will have to submit CTD format product dossier and they will pay fees for registration by 31st December 2019, no exception will be made due to the reason that manufacturers are not interested with the Rwandan Market. Rwanda FDA has given 6 more months to importers and manufacturers to comply with the registration requirements.	All	31st December 2019

4. Rejection of products in special case ort visa in PRIMS system				
	Import visa for many products on the market was requested through special case in PRMIS system, now Rwanda FDA obliged all importers to use import visa and choose among products in the system and this causes many issues listed below: a. This communication was given without notice and this will cause troubles because some products which are not in the system are in public tender contracts, RBC MPPD, KFH, CHUK,CHUB... b. Products that are on the Authorized medicines list but not in the system (eg. Nexium Inj, Zoladex 3.6 mg and 10.8 mg) c. Some pre-registered products are not in the system (eg. Symbicort, Galvus Met) d. Products that have been on Rwandan market for more than years and are not in the system (eg. Broncathiol, Tobradex, Aerius Syrup) e. Products like biologics, biosimilars and vaccines (eg. Anti Hepatite Immunoglobulin, vaccines, Engerix) that lack registration guideline, are not in the system f. Products in the system with some errors like country of origin, dosage form, manufacturer etc..(eg. Maxidrol instead of Maxitrol) g. Products that are not pre-registered and they have submitted dossiers for registration from 2015 since then they have not got response but in the meantime they were allowed to be imported on	In PRIMS system all importers were supposed to use import visa for all medicines and special case import for medical devices and equipments or any other products with special consideration. a. The communication was given through consultations and training before the launch of the system (PRIMS), only consumables and medical equipments and products not in the system are allowed in the special case. b. Importers will list these products with the number on Authorized medicine list and submit to Rwanda FDA to be added in the system. c. The importers will provide the pre-registration certificate to Rwanda FDA and they will be added in the system. d. The importers will submit to Rwanda FDA proof that the products have been on the market before this resolution and Rwanda FDA will consider these products for importation. e. Special products like Biologicals, Biosimilars and Vaccines that don't have guidelines for registration will continue to be imported as special case. Vaccines must be WHO prequalified to be accepted on Rwandan market while waiting the registration process to start. f. Importers will notify all errors to Rwanda	All	15th May 2019

	special case import in the syste ecause they are not in the system. h. Products that are in the system and are not supposed to be in our climatic zone and those that was supposed to be in our climatic zone are not there.	FDA in order to correct th . g. These products will have to wait for registration because the submission of product dossier does not mean registration of the product. h. This error will be corrected in the system in collaboration with all importers.		
5. Delay of Import Visa and import License				
	Visa application and License application that are pending for more than one week or waiting for approval this delays the shipment and business.	The delay is due to technical issues of the system and sometimes applications are many and Rwanda FDA staff take time to analyze application and make decision. Technical issues of the system are being solve by our developer and Rwanda FDA will try to give feedback as soon as possible.	Rwanda FDA	Immediate
6. Exemption list				
	Products that are not on exemption list are not accepted in customs	Rwanda FDA will work with Minicofin to include all medicines, medical consumables and equipments in the exemption list.	Rwanda FDA	

6.0 CLOSING OF THE MEETING

The chair of the meeting, Dr. Charles KARANGWA, Ag. DG, Rwanda FDA, thanked again all participants for their contribution and collaboration and reminded them their responsibilities in regulation and compliance to them.

The meeting was adjourned at **05:00 PM**

Done at Kigali on 30 AVR 2019 **.....**

Minutes Taker

Ms. Clarisse Irasabwa
DM/D&HTAR

Chairperson of AIGPHAR

Dr Abel Dushimimana
Chairman of AIGPHAR

Chairperson of Meeting

Dr. Charles KARANGWA
Ag. DG Rwanda FDA

ATTENDANCE LIST

Topic: MEETING OF RWANDA FDA and STAKEHOLDERS

Venue: CLASSIC HOTEL BIG HALL

Date: 27/03/2015

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Topic: MEETING OF RWANDA FDA and STAKEHOLDERS

Venue: CLASSIC HOTEL (BIG HALL)

Date: 27/03/2019

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