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: …. /02/FDA/2021 FOR PEER REVIEW

Date of Meeting: 12/05/2021&14/05/2021

Venue of the meeting: Virtual

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

S/N°	Names	Position
1	NIYOMAHORO Nadine	FPP and API Assessment and Registration Officer
2	NSHIMIYIMANA Philbert	Biological Products Registration Officer
3	IRADUKUNDA Gad Patrick	Medicinal Cosmetics Registration Officer
4	UWERA Nadia	Veterinary Medicines Registration and Variations Assessment Officer
5	NSABIMANA Isaie	Vaccines and other Biosimilars Registration Officer
6	AYINKAMIYE Honore	FPP and API Assessment and Registration Officer
7	NIYITEGEKA Leodomir	Medicinal Cosmetics Registration Officer
8	ITETERE Diane	FPP and API Assessment and Registration Officer
9	ISINGIZWE M.Ange	FPP and API Assessment and Registration Officer
10	TUYISHIME Anitha	FPP and API Assessment and Registration Officer
12	SHYIRAMBERE Serge	Radiopharmaceutical and Radiotherapy product assessment and registration officer
13	KYANKONI Godfrey	Diagnostics and medical devices registration officer
14	MUHAYIMANA Placide	Diagnostics and medical devices registration officer
15	NSANZIMFURA J.Pierre	Herbal medicine assessment and registration officer
16	MUHONGERWA Ruth	Herbal medicine assessment and registration officer
17	MUSAFIRI Eustache	Veterinary Medicines Registration and Variations Assessment Officer
18	KARASANYI Geofrey	Veterinary Medicines Registration and Variations Assessment Officer
19	TUYISENGE Felix	Vaccines and other Biosimilars Registration

		Officer
20	UWOROHEJE Innocent	Veterinary in vitro diagnostics and medical devices registration officer
21	MURERAMANZI Olivier	Biological Products Registration Officer
22	MASENGESHO Gentille	Public health Laboratory Chemicals Registration Officer
23	MUHOZA Frederic	Clinical trial specialist
24	UWAMBAJINEZA Tite	Human medicines testing officer
25	BYOMUHANGI Evariste	Pharmacist
26	NTIRENGANYA Lazare	DM Pharmacovigilance and Food Safety Monitoring
27	IRASABWA Clarisse	DM of Drugs and Health Technologies Assessment and Registration Officer

Item on the agenda

Presenting final dossier assessment reports of Human medicinal products, Antiseptic and disinfectant products and veterinary medicinal product to Peer review committee for approval (32 Products).

Opening and/or remarks of the meeting

The meeting started at 08:30 am with the opening remarks of the Division Manager of Drugs and Health Technologies Assessment and Registration Clarisse IRASABWA who introduced the participants and presented the agenda of the meeting.

Item on Agenda	Comments and recommendation	Responsible person for implementation	Timelines
Presentation of the final assessment report of **SALAMA Hand Sanitizer**	**SALAMA Hand Sanitizer** manufactured by Speranza group LTD Sanitizer was well presented and with all requirements except the product CoA but the applicant committed to submit it once received from RSB. The fact that the product complies with the safety and efficacy requirements considering the CoA performed by Rwanda FDA quality laboratory when its pH, alcohol content met the acceptable ranges **it was recommended for approval.** **It was recommended to CHC-AR unit to follow up and monitor the applicant commitment.**	The assessment report was presented by Mr. NIYITEGEKA Leodomir	**N/A**
Presentation of the final assessment report of **TRESOR NATURE HAND SANITIZER (AEROSOL)**	**TRESOR NATURE HAND SANITIZER(AEROSOL)** manufactured by Fragrance World Ltd was well presented with all requirements except the product stability data and the bactericidal efficacy data, but the applicant committed to submit those missing data once received from Bureau Veritas. The fact that the product complies with the safety and efficacy requirements considering the CoA performed by Rwanda FDA quality laboratory when its pH, alcohol content met the acceptable ranges **it was recommended for approval.** **It was recommended to CHC-AR unit to follow up and tightly monitor the applicant commitment.**	The assessment report was presented by Mr.NIYITEGEKA Leodomir	**N/A**
Presentation of the final assessment report of **TRESOR NATURE HAND SANITIZER**	**TRESOR NATURE HAND SANITIZER (GEL)** manufactured by Fragrance World Ltd was well presented with all requirements except the product stability data and the bactericidal efficacy data, but the	The assessment report was presented by Mr. NIYITEGEKA Leodomir	**N/A**

(GEL)	applicant committed to submit those missing data once received from Bureau Veritas. The fact that the product complies with the safety and efficacy requirements considering the CoA performed by Rwanda FDA quality laboratory when its pH, alcohol content met the acceptable ranges **it was recommended for approval.** **It was recommended to CHC-AR unit to follow up and tightly monitor the applicant commitment.**		
Presentation of the final assessment report of **TRESOR NATURE HAND SANITIZER (LIQUID)**	**TRESOR NATURE HAND SANITIZER (LIQUID)** manufactured by Fragrance World Ltd was well presented with all requirements except the product stability data and the bactericidal efficacy data, but the applicant committed to submit those missing data once received from Bureau Veritas. The fact that the product complies with the safety and efficacy requirements considering the CoA performed by Rwanda FDA quality laboratory when its pH, alcohol content met the acceptable ranges **it was recommended for approval.** **It was recommended to CHC-AR unit to follow up and tightly monitor the applicant commitment.**	The assessment report was presented by Mr. NIYITEGEKA Leodomir	**N/A**
Presentation of the final assessment report of **K-HAND SANITIZER**	**K-HAND SANITIZER** manufactured by KIPHARMA Ltd has been well presented with all requirements except the stability data that was not present, but the applicant committed to submit the stability data by April 2021 and noted that the commitment has reached the deadline. It was recommended to CHC-AR unit to write an email reminding the commitment done and **after the submission of the stability data the product will be certified.**	The assessment report was presented by Mr. NIYITEGEKA Leodomir	**Immediate**
Presentation of the final	**IMPACT SANITIZER** manufactured by SCIMPACT Ltd was well	The assessment report was presented	**N/A**

assessment report of **IMPACT SANITIZER**	presented with all requirements except the product stability data, but the applicant committed himself to submit those missing data once finished. The fact that the product complies with the safety and efficacy requirements considering the CoA performed by Rwanda FDA quality laboratory when its pH, alcohol content met the acceptable ranges **it was recommended for approval.** **It was recommended to CHC-AR unit to follow up and tightly monitor the applicant commitment.**	by Mr. NIYITEGEKA Leodomir	
Presentation of the final assessment report of **PIPERAZINE CITRATE WSP**	**PIPERAZINE CITRATE WSP 100%w/w is a veterinary medicinal product** manufactured by VET CARE AFRICA. The applicant is VETCARE AFRICA and Local technical representative is PLANET VET. It has applied through Mutual recognition procedure (MRP/EAC), where Kenya is chosen as Reference country , Rwanda and Uganda as concerned countries. Assessment report has been shared and GMP Certificates were issued by each partner states. All raised queries have been satisfactory resolved and **the product is recommended for approval**	The assessment report was presented by Mr. MUSAFIRI Eustache	**N/A**
Presentation of the final assessment report of **ABACAVIR SULFATE USP.LAMIVUDINE**	**ABACAVIR SULFATE USP.LAMIVUDINE120/60 mg is a human medicinal product** manufactured by LUPIN Ltd, it was assessed through CRP and the fact that all queries were addressed and resolved and **the product is recommended for approval.**	The assessment report was presented by Mr. AYINKAMIYE Honore	**N/A**
Presentation of the final assessment report of **EMICITABINE and TENOFOVIR**	**EMICITABINE and TENOFOVIR DISOPROXIL FUMARATE Tablets 200 mg/300mg is a human medicinal product** manufactured by LUPIN Ltd was assessed through CRP and the fact that all queries were addressed and resolved and **the product is recommended for**	The assessment report was presented by Mr. AYINKAMIYE Honore	**N/A**

DISOPROXIL FUMARATE Tablets	**approval.** **Note to the applicant:** **The product sample were not submitted, and the applicant is recommended to submit the product sample before or at the first shipment of the product**		
Presentation of the final assessment report of **AKURIT 3**	**AKURIT 3 (Rifampicin, Isoniazid and Ethambutol Hydrochloride Tablets150mg/75mg/275mg) is a human medicinal product** manufactured by LUPIN Ltd was assessed through CRP and the fact that all queries were addressed and resolved and the GMP inspection application has been already done and the GMP inspection fees has been paid accordingly, Thus, **the product is recommended for approval.**	The assessment report was presented by Mr.AYINKAMIYE Honore	**N/A**
Presentation of the final assessment report of **AKURIT 4**	**AKURIT 4 (Rifampicin, Isoniazid, Pyrazinamide and Ethambutol Hydrochloride Tablets,150mg/75mg/400mg/275mg) is a human medicinal product** manufactured by LUPIN Ltd was assessed through CRP and the fact that all queries were addressed and resolved and the GMP inspection application has been already done and the GMP inspection fees has been paid accordingly, Thus, **the product is recommended for approval.** **Note: Considering that the packaging material (Alu/PVC/PVDC) that was previously submitted was not acceptable for it doesn't tolerate on Zone IVB, it was recommended that all AKURIT 4 products should be packaged in Alu-Alu-blisters as accepted packaging material and this should be taken into consideration by Import and export division and GMP division to insure the compliance of this packaging requirement and it was also recommended that Post market surveillance should be done**	The assessment report was presented by Mr.AYINKAMIYE Honore	**N/A**

	regularly to registered products with exceptional issues.		
Presentation of the final assessment report of **Rifampicine Isoniazid 150mg/75mg**	**Rifampicine Isoniazid 150mg/75mg is a human medicinal product** manufactured by LUPIN Ltd was assessed through CRP and the fact that all queries were addressed and resolved Thus, **the product is recommended for approval.**	The assessment report was presented by Mr. AYINKAMIYE Honore	**N/A**
Presentation of the final Assessment report of **EFAVIRENZ, LAMIVUDINE&TENOFOVIR DISOPROXIL FUMARATE**	**EFAVIRENZ, LAMIVUDINE&TENOFOVIR DISOPROXIL FUMARATE 600/300/300 is a human medicinal product** manufactured by CIPLA Uganda was assessed through CRP and the fact that all queries were addressed and resolved Thus, **the product is recommended for approval.**	The assessment report was presented by NIYOMAHORO Nadine	**N/A**
Presentation of the final Assessment report of **PDXane 4000**	**PDXane 4000 is a human medicinal product** manufactured by **Pooversh Darou Bio Pharmaceuticals,** the product was assessed and found that its BMR was submitted but in unofficial language which made it inaccessible for assessment but considering that PDXane 8000 from the same manufacturer has been registered and the manufacturer has paid for GMP inspection, **the product has been recommended for registration.**	The assessment report was presented by NIYOMAHORO Nadine	**N/A**
Presentation of the final Assessment report of **DAFLON 500 mg tablets**	**DAFLON 500 mg tablets is a human medicinal product** manufactured by Servier Egypt industries was assessed and the fact that all queries were addressed and resolved Thus, **the product is recommended for approval.**	The assessment report was presented by TUYISHIME Anitha	**N/A**
Presentation of the final Assessment report of **COVERSYL 10mg**	**COVERSYL 10mg is a human medicinal product** manufactured by Servier Egypt industries was assessed and the fact that all queries were addressed and resolved Thus, **the product is recommended for approval.**	The assessment report was presented by ISINGIZWE Marie Ange	**N/A**
Presentation of the final Assessment report of **COVERSYL 5mg**	**COVERSYL 5mg is a human medicinal product** manufactured by Servier Egypt industries was assessed and the fact that all queries were addressed and resolved Thus, **the product is recommended for**	The assessment report was presented by ISINGIZWE Marie Ange	**N/A**

	approval. **The product sample were not submitted, and the applicant is recommended to submit the product sample before or at the first shipment of the product**		
Presentation of the final Assessment report of **ENDOPROST**	**ENDOPROST 125 Mcg is a human medicinal product** manufactured by BHARAT SERUM&VACCINE Ltd was assessed and the fact that all queries were addressed and resolved Thus, **the product is recommended for approval.**	The assessment report was presented by SHYIRAMBERE Serge	**N/A**
Presentation of the final Assessment report of **LORENZE**	**LORENZE 10mg is a human medicinal product** manufactured by MEGA LIFE SCIENCE Public Company Ltd was assessed and the fact that all queries were addressed and resolved Thus, **the product is recommended for approval.**	The assessment report was presented by SHYIRAMBERE Serge	**N/A**
Presentation of the final Assessment report of **DERISE 25mg**	**DERISE 25mg is a human medicinal product** manufactured by HETERO BIOPHARMA Ltd was assessed and the fact that all queries were addressed and resolved Thus, **the product is recommended for approval.**	The assessment report was presented by Mr.TUYISENGE Felix	
Presentation of the final Assessment report of **DERISE 40mg**	**DERISE 40mg is a human medicinal product** manufactured by HETERO BIOPHARMA Ltd was assessed and presented. The fact that all queries were addressed and resolved, **the product is recommended for approval.**	The assessment report was presented by Mr.TUYISENGE Felix	**N/A**
Presentation of the final Assessment report of **EMITINO Tablets 4mg**	**EMITINO Tablets 4mg is a human medicinal product** manufactured by CACHET PHARMA was assessed and presented that the Specifications of the primary packaging were previously provide but not signed and the applicant were asked to provide the signed specifications however when responding to this query the applicant submitted the signed specifications for EMITINO 30 ml instead of EMITINO 4mg tablets. This issue was judged minor as the suitability of the container closure system has been submitted and accepted. **Therefore, the product is recommended for approval.**	The assessment report was presented by ITETERE Diane	**Immediate**

	Note: **The product sample were not submitted, and it is recommended that the LTR of the product should be communicated to submit the sample before the issuance of registration certificate.**		
Presentation of the final Assessment report of **EMITINO suspension**	**EMITINO 2mg/5ml suspension is a human medicinal product** manufactured by CACHET PHARMA was assessed and presented, all queries were addressed and resolved Thus, **the product is recommended for approval.** **Note:** **the product sample were not submitted, and it is recommended that the LTR of the product should be communicated to submit the sample before the issuance of registration certificate.**	The assessment report was presented by ITETERE Diane	**N/A**
Presentation of the final Assessment report of **LOSACAR H 100/25**	**LOSACAR H 100/25 is a human medicinal product** manufactured by Cadila Health Care Ltd was assessed and presented, all queries were addressed and resolved Thus, **the product is recommended for approval.**	The assessment report was presented by KARASANYI Geoffrey	**N/A**
Presentation of the final Assessment report of **LOSACAR H 50/25**	**LOSACAR H 50/25 is a human medicinal product** manufactured by Cadila Health Care Ltd was assessed and presented, all queries were addressed and resolved Thus, **the product is recommended for approval.**	The assessment report was presented by KARASANYI Geoffrey	**N/A**
Presentation of the final Assessment report of **CIPROQUIN 500**	**CIPROQUIN 500 is a human medicinal product** manufactured by KOPRAN Ltd was assessed and presented, all queries were addressed and resolved except the GMP of API manufacturer that has expired but this query was judged minor because the applicant has paid and applied for GMP inspection for FPP manufacturer, Thus, **the product is recommended for approval.**	The assessment report was presented by UWERA Nadia	**N/A**
Presentation of the final Assessment report of	**DERMOFIX 2mg/g is a human medicinal product** manufactured by **FERRER INTERANACIONAL** was assessed and presented, all	The assessment report was presented	**N/A**

DERMOFIX	queries were addressed and resolved except the query regarding the stability data which did not cover the shelf life and the submitted answer was for Zalain cream for batches (J001, J002,) and (J001) of Dermofix. The fact that the product has fulfilled all other requirements, **it is recommended for approval,** **However, the clarification between Zalain cream and Dermofix should be firstly provided before the issuance of registration certificate.**	by Dr. MUHAYIMANA Placide	
Presentation of the final Assessment report of **REPOITIN 4000 IU PFS**	**REPOITIN 4000 IU PFS is a human medicinal product** manufactured by SERUM INSTITUTE of India was assessed and presented, all queries were addressed and resolved except the query regarding the GMP inspection, However the applicant has applied for EAC joint GMP inspection and the payment proof is for UGANDA only and after the verification by GMP inspection department it was noted that the product did not pay the fees for GMP inspection as also required by the requirement for EAC joint GMP inspection. **Therefore, the applicant is requested to pay the fees for GMP inspection to Rwanda FDA before the approval.**	The assessment report was presented by NSABIMANA Isaie	**N/A**
Presentation of the final Assessment report of **PAROL ORAL SUSPENSION**	**PAROL ORAL SUSPENSION 250mg/5ml is a human medicinal product** manufactured by ATABAY ILAC FABRIKASI and ATABAY KIMYA was assessed **After a cross-checking of provided information, we realized that the applicant has changed the manufacturing site to which s/he has paid and applied for GMP inspection reason why there is information that s/he must provide for verification before approval.**	The assessment report was presented by NSABIMANA Isaie	**N/A**
Presentation of the final Assessment report of **HELIGO -500 (Kit for H.Pylori)**	**HELIGO -500 (Kit for H.Pylori) is a human medicinal product** manufactured by INTAS PHARMACEUTICAL Ltd was assessed and presented, all queries were addressed and resolved except the query regarding the GMP inspection because the applicant did not applied for	The assessment report was presented by NSANZIMFURA Jean Pierre.	**N/A**

	GMP inspection or paid for it, However, the applicant requested to the authority to evaluate the same to their other products and provide them the feedback and when all products are in the last stage of approval they will apply for GMP. **But the product is still required to pay for GMP inspection and apply for it before the approval**.		
Presentation of the final Assessment report of **FLEXIDOL**	**FLEXIDOL (Ibuprofen BP/methocarbamolUSP,200mg/500mg)** is **a human medicinal product** manufactured by GRACURE PHARMACEUTICAL Ltd was assessed and presented, all queries were addressed and resolved except the query regarding the GMP inspection, the applicant presented the GMP inspection but did not pay for GMP inspection fees, **Thus the product is requested to pay for GMP inspection fees before the approval.**	The assessment report was presented by NSANZIMFURA Jean Pierre.	**N/A**
Presentation of the final Assessment report of **TERBINOL**	**TERBINOL 250mg** is a **human medicinal product** manufactured by NOBEL ILAÇ San ve Tic AŞ was assessed and presented, all queries were addressed and resolved but the CEP No. R1-CEP 2006-148 Rev 02 was mentioned and found valid as checked on EDQM but its copy was not submitted. this query was judged minor as the CEP was checked on EDQM and found valid. **Therefore, the product is recommended for approval**. **It was concluded that for products approved for registration, the applicant should provide the revised SmPC, PIL and product art work to include the Rwanda FDA Registration Number and the date of issue before being imported. This should be applied to all medical products approved for registration by Rwanda FDA.**	The assessment report was presented by NSANZIMFURA Jean Pierre.	**N/A**

	Names, and signature and/or institution stamp		Names and signature
Chair of the meeting	**Clarisse IRASABWA**	Rapporteur	**Gentille MASENGESHO**

The meeting has ended at: 14th May 2021 at **11h30 AM**

End of Minutes

RWANDA FDA
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P.O. Box 1948 Kigali
info@rwandafda.gov.rw
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Rwanda FDA_Attendance List

Activity Title: Peer review meeting **Venue:** Virtual **Date :** 12/05/2021 & 14/05/2021

#	Names	Position	Institution	Contact	E-mail	Signature
1	TUYISENGE FELIX	Vaccine & Biosimilar registration officer	RwandaFDA	Phone: 07831 40443	ftuyisenge@rwandafda.gov.rw	FELIX
2.	NSABIMANA Isaïe	Vaccines & Biosimilar Reg. officer	Rwanda FDA	0788883011	insabimana@rwandafda.gov.rw	
3	Geoffrey KAMASANYI	VMRS VAO	Rwanda FDA	0785246691	gkamasanyi@rwandafda.gov.rw	
4	MURERAMANZI Olivier	Biological product Repistretion offic	Rwanda FDA	0788846145	omurneramanzi@rwandafda.gov.rw	
5	Philbert NSHIMIYIMANA	Biological Product registration Officer	Rwanda FDA	0782391159	pnshimiyimana@rwandafda.gov.rw	
6	UWOROHEJE Innocent	VS & Med. Devices Reg. offic	Rwanda FDA	0786938845	iuworoheje@rwandafda.gov.rw	
7	IRADUKUNDA Gad Patrick	Med Cosmetics Registrat° officer	RWANDA FDA	0784 [illegible]	giradukunda@rwandafda.gov.rw	
8	AYINKAMIYE Honoré	SPP & API Reg! Officer	Rwanda FDA	0788801813	hayinkamiye@rwandafda.gov.rw	
9	MUHONGERWA Ruth	Herbal medicines ASS & Reg officer	Rwanda FDA	0788939679	rmuhongerwa@rwandafda.gov.rw	
10	UMUTONI Nadia	VMRS VAO	Rda FDA	0785377795	numutoni@rwandafda.gov.rw	

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Effective date: 11/05/2021

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Activity Title: Peer review meeting **Venue:** Virtual **Date :** 12/05/2021 & 14/05/2021

#	Names	Position	Institution	Contact	E-mail	Signature
	NSANZIMFURA Jean Pierre	Herbal medicines ARS & Reg officer	Rwanda FDA	0788788262	jpnsanzimfura@rwandafda.gov.rw	
	PLACIDE MUHAYIMANA	Diagn & Medical devices reg officer	Rwanda FDA	0783029663	pmuhayimana@rwandafda.gov.rw	
	KVANKONI GODFREY	Diag & Med Dev Reg officer	Rwanda FDA	0735708867	gkyankoni@rwandafda.gov.rw	
	MIYOMAHORO Nadine	FPP & API registration officer	Rwanda FDA	0788576905	nmiyomahoro@rwandafda.gov.rw	
	SERGE SHYIRAMBERE	Radiopharm A & R officer	"	0788804293	Sshyirambere@rwandafda.gov.rw	
	TUYISHIME Anitha	FPP & API Reg. officer	Rwanda FDA	0788800990	atuyishime@rwandafda.gov.rw	
	MASENGESHO Gentille	Public health & lab. chemicals Registration officer	Rwanda FDA	0781604604	gmasengesho@rwandafda.gov.rw	
	IRADUKUNDA CLARISSE	INTERNSHIP	Rwanda FDA	0788639507	ciradukunda@rwandafda.gov.rw	

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Rwanda FDA Attendance List

#	Names	Position	Institution	Contact	E-mail	Signature
1	UWAMBAJINEZA Tite	Human medicine lab officer	Rwanda FDA	0788297415	tuwambajineza@rwandafda.gov.rw	
2	BYOMUHANGO Rwanda	Pharmacist in charge of QMS	Rwanda FDA	0788616150	ebyomuhango@rwandafda.gov.rw	
3						