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: …. /……/FDA/2021 FOR PEER REVIEW

Date of Meeting: 17/06/2021

Venue of the meeting: Virtual

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

S/N°	Names	Position
1.	Dr.Eric NYIRIMIGABO	Division Manager of Human Medicine and Devices Assessment and Registration
2.	Dr.Rosine MANISHIMWE	Division Manager of Veterinary Medicine Devices and Assessment and Registration
3.	Dr.Janvier MUKIZA	Division Manager of Cosmetics and Household Chemicals Assessment and Registration
4.	Dr.Doreen INGABIRE	Veterinary Medicines in Vitro Diagnostics and Medical Devices Registration Analyst
5.	Dr.Richard HABIMANA	Vaccines and Biosimilar Registration Analyst
6.	Clarisse IRASABWA	Finished and Active Pharmaceutical Products Registration Analyst
7.	Deo GASANA	Finished and Active Pharmaceutical Products Registration Analyst
8.	Tite UWAMBAJINEZA	Radiopharmaceuticals and Radiotherapy Products Assessment and Registration Analyst
9.	Dr.Emil Ivan MWIKARAGO	Diagnostics and Medical Devices Registration Analyst
10.	Jurdas SEZIRAHIGA	Public Health and Laboratory Chemicals Registration Analyst
11.	Honore AYINKAMIYE	Ag Finished and Active Pharmaceutical Products Registration Specialist
12.	Marie Ange ISINGIZWE	Ag Finished and Active Pharmaceutical Products Registration Specialist
13.	Nadine NIYOMAHORO	Ag Finished and Active Pharmaceutical Products Registration Specialist
14.	Anitha TUYISHIME	Ag Herbal Medicines Assessment and Registration Specialist

15.	Ruth MUHONGERWA	Ag Herbal Medicines Assessment and Registration Specialist
16.	Dr. Placide MUHAYIMANA	Ag Diagnostics and Medical Devices Registration Specialist
17.	Serge SHYIRAMBERE	Ag Vaccines and Biosimilar Registration Specialist
18.	Damascene DUSABIMANA	Ag Vaccines and Biosimilar Registration Specialist
19.	Olivier MURERAMANZI	Ag Biological Products Registration Specialist
20.	Diane ITETERE	Ag Biological Product Registration Specialist
21.	Geoffrey KARASANYI	Ag Veterinary Medicines Registration and Variation Assessment Specialist
22.	Nadia UWERA	Ag Veterinary Medicines Registration and Variation Assessment Specialist
23.	Felix TUYISENGE	AgVeterinary in vitro Diagnostics and Medical Devices Registration Specialist
24.	Patrick GAD IRADUKUNDA	Ag Cosmetics Registration Specialist
25.	Leodomir NIYITEGEKA	Ag Cosmetics Registration Specialist
26.	Gentille MASENGESHO	Ag Public Health and Laboratory Chemicals Registration Specialist
27.	Innocent UWOROHEJE	Ag Veterinary Medicines Testing Officer
28.	Jean Pierre NSANZIMFURA	Ag Cosmetic Testing Officer
29.	Janvier MUNYANEZA	Ag Pesticides Testing Officer
30.	Jackson KARARA	Ag Food and Drugs Port of Entry Inspection Specialist
31.	Jeremie NTEZIYAREMYE	Industrial and Market Specialist

Item on the agenda

Presenting final dossier assessment reports of Human medicines products, Antiseptics and disinfectants products to the Peer review committee for approval (27 Products).

Opening and/or remarks of the meeting

The meeting started at 03:05 pm with the opening remarks of the Division Manager of Human Medicine and Devices Assessment and Registration, Dr. Eric Nyirimigabo who introduced the participants and presented the agenda of the meeting.

Discussion	Observation	Resolutions/ recommendation	Presenter	Timelines
FASTUM GEL with reference number **0863/2019** and manufactured by **MENARINI Industry Farmaceutiche riunite S.R.I** was presented and had queries, where the applicant has well responded to all queries raised in addition, have applied for GMP inspection and paid the prescribed fees.	**FASTUM GEL** is a gel of mucilaginous consistent, colorless or almost transparent, with an aromatic odour. The initial application was assessed through full assessment with the outcome of "additional data requested" for the first round. It was observed that all queries have been resolved by the applicant.	Based on the information from the assessment report, it has been agreed upon that the safety and efficacy were supported and **the product was recommended for registration.**	Jean Pierre Nsanzimfura.	Done
EASCOF EXPECTORANT manufactured by **Cachet Pharmaceuticals PVT LTD** was presented and responded well to the queries, in addition, have applied for GMP inspection and paid the prescribed fees.	**EASCOF EXPECTORANT** is an Orange-yellow colour clear liquid having sweet taste and pleasant flavour manufactured. The initial application was assessed through full assessment with the outcome of "additional data requested" for the first round. It was observed that all queries have been resolved by the applicant.	Based on the information from the assessment report, it has been agreed upon that the safety and efficacy were supported and **the product was recommended for registration**.	Jean Pierre Nsanzimfura.	Done
SOMAZINA 1000MG ORAL SOLUTION with reference number 1833/2018 &2235/2019 manufactured by **FERRER INTERNATIONAL S.A/SPAIN** was presented and responded well to	**SOMAZINA 1000MG ORAL SOLUTION** is an oral solution manufactured by Ferrer Internacional.S. A. The initial application has been assessed	Somazina 1000mg oral solution has fulfilled the registration requirement and was **recommended for registration**	Jean Pierre Nsanzimfura	Done

the queries. Furthermore, an application for GMP inspection was done and the prescribed fees were paid.	through full assessment procedure with the outcome of additional data at the first round which was fully responded to support the quality, safety and efficacy of the product.			
GAMALATE (TABLETS) with reference number **1830/2018 & 2231/2019** and manufactured by **FERRER INTERNATIONAL S.A/SPAIN** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**GAMALATE (TABLETS) is** blue sugar-coated tablet. The initial application has been assessed through full assessment procedure with the outcome of additional data at the first round which were fully responded to support the quality, safety and efficacy of the product.	Gamalate Tablets has fulfilled the registration requirement and was **recommended for registration**	Jean Pierre Nsanzimfura	Done
GAMALATE B6 ORAL SOLUTION with reference number **1835/2018 &2232** and manufactured by **FERRER INTERNATIONAL S.A/SPAIN** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**GAMALATE B6 ORAL SOLUTION** is a viscous orange liquid with characteristics of odour and taste manufactured by Ferrer Internacional S.A. The initial application has been assessed through full assessment procedure with the outcome of additional data at the first round which were fully responded to support the quality, safety and efficacy of the product.	Gamalate Syrup has fulfilled the registration requirement and was **recommended for registration**.	Jean Pierre Nsanzimfura	Done

BEVAAS-100 with reference number **677/2018** and manufactured by **HETERO BIOPHARMA/INDIA.** The applicant sufficiently responded to the queries regarding the submission of openable and readable documents of process validation protocol and report. The applicant was also requested to apply for GMP inspection and pay the prescribed fees, however, it was noted that a payment fee made was 4985USD implying 15USD less to the presumed payment.	**BEVAAS-100** is a clear and pale yellow to colorless liquid free from particles that can be observed by visual inspection manufactured by Hetero Biopharma Limited. The product fulfilled other requirements and it was recommended that liaise with the office of finance to communicate to the applicant about the remaining amount of 15USD on GMP inspection fees.	**The product is recommended for registration with condition** i.e. the certificate will be issued after payment of 15USD.	Serge Shyirambere	Done
BEVAAS-400 with reference number **676/2018** and manufactured by **HETERO BIOPHARMA/INDIA** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid. The product also shares the query on GMP fees with other products from **HETERO BIOPHARMA/INDIA**	**BEVAAS-400** is a clear and pale yellow to colorless liquid free from particles that can be observed by visual inspection manufactured by Hetero Biopharma Limited. The query related to the application for registering BEVAAS-100 were sufficiently responded to and liaise with the office of finance to communicate to the applicant about the remaining amount of	**The product is recommended for registration with condition** i.e. the certificate will be issued after payment of 15USD.	Serge Shyirambere	Done

	15USD on GMP inspection fees was made to this product as well.			
SEVLAREN 400 with reference number **13973/2018** and manufactured by **Stanford Laboratories Private Limited.** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**SEVLAREN 400** is a white to off white circular shaped biconvex coated tablets plain on both sides manufactured by Stanford Laboratories Private Limited that has sufficiently satisfied the requirements to justify SEQ.	**The product was recommended for registration on condition.**	Serge Shyirambere	Done
LUPRODEX 3.5MG (DEPOT) with reference number **1124/2019** and manufactured by **Bharat Serum & Vaccines Limited** was presented and responded well to the queries. Among the raised queries included a query on the GMP inspection application whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.	**LUPRODEX 3.5MG (DEPOT)** is White to off White Lyophilized Powder for Injection manufactured by Bharat Serum&Vaccines Limited. Application for LUPRODEX 3.5MG (DEPOT) sufficiently responded to the queries related to quality and safety. Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees was recommended.	**The product was recommended for registration with the condition** i.e. the certificate will be issued after payment of 15USD.	Serge Shyirambere	Done

VASTEN-75 with reference number **3038/2019** and manufactured by **Lincoln Pharmaceuticals Limited, India** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**VASTEN-75** is a white to off-white coloured, round-shaped, flat, uncoated tablet, break line on one side and plain on other side manufactured by Lincoln Pharmaceuticals Limited, India. The application complied with safety, efficacy and quality requirements. **Notice: The first assessment of VASTEN-75 was done in green color instead of red as per presumed in the SOP. This was an internal arrangement for the new staffs to be familiarized with an assessment before getting training on dossier assessment. There are other documents that have been assessed in the same manner.**	**The product was recommended for registration**	Serge Shyirambere	Done
BCG VACCINES FREEZE DRIED with reference number **2988/2016** and manufactured by **Serum Institute, India**. The application was presented in the previous peer review meeting with	**BCG VACCINES FREEZE DRIED** is manufactured by Serum Institute, India. The application for GMP has been cleared.	**The product was recommended for registration**	Nadine Niyomahoro	Done

the remaining query of the application for GMP inspection.				
MEASLES VACCINE LIVE ATTENUATED with reference number **8089/2016** and manufactured by **Serum Institute, India**. The application was presented in the previous peer review meeting with the remaining query of the application for GMP inspection.	**MEASLES VACCINE LIVE ATTENUATED, FREEZE DRIED** is manufactured by Serum Institute, India The application for GMP has been cleared.	**The product was recommended for registration**	Nadine Niyomahoro	Done
REPOITIN IU PFS with reference number **21494/2015 & 4778/2019** and manufactured by **Serum Institute, India**. The application was presented in the previous peer review meeting with the remaining query of the application for GMP inspection.	**REPOITIN IU PFS** is **manufactured** by Serum Institute, India The application for GMP has been cleared.	**The product was recommended for registration**	Nadine Niyomahoro	Done
PAIDOFEBRIL ORAL SUSPENSION with reference number **14386/2018** and manufactured by **Laboratorio Aldo-Union, S.L** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**PAIDOFEBRIL ORAL SUSPENSION** is a white or almost white and homogeneous suspension with an orange odour after agitation manufactured by Laboratorio Aldo-Union, S. L. This was a second assessment of the second round of additional data. It has complied with registration requirement including paying and	**The product was recommended for registration**	Nadine Niyomahoro	Done

	applying for GMP inspection at Rwanda FDA.			
TAPROS 3.75 with reference number **1172/2019** and manufactured by **TAKEDA IRELAND LTD/IRELAND** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**TAPROS 3.75 is a human medicinal product** manufactured by Takeda Pharmaceutical Company Limited. The application passed the first and second assessment at the first round of additional data and has complied with registration requirement including paying and applying for GMP inspection at Rwanda FDA.	**The product was recommended for registration**	Geoffrey Karasanyi	Done
VIPIDOMET 12.5&1000 with reference number **0773/2019** and manufactured by **TAKEDA IRELAND LTD/IRELAND** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**VIPIDOMET 12.5&1000** is a pale yellow, oblong, biconvex, film-coated tablet with "12.5/1000" debossed on one side and "322M" debossed on the other side manufactured by Takeda Pharmaceutical Company Limited. Application of Vipidomet 12.5&1000 passed first and second assessment at the first round of additional data and has shown to comply with registration requirement including paying and applying for GMP inspection at Rwanda FDA.	**The product was recommended for registration**	Geoffrey Karasanyi	Done

The following strengths of **COVERAM** were presented: - **COVERAM 10&10** - **COVERAM 10&5** - **COVERAM 5&10** - **COVERAM 5&5** with the following respective reference number **(3805/2016.A; 3805/2016.D; 3805/2016.B; and 3805/2016.C** manufactured by **SERVIER (IRELAND) INDUSTRIES LTD** was presented and responded well to the queries. The application and proof of payment for GMP inspection by the Rwanda FDA was acknowledged.	**COVERAM 10&10** is a white round-shaped tablet, engraved with"10/10" on one face and ⌲ on the other face manufactured by Servier (Ireland) Industries LTD **COVERAM 10&5** is White Triangular——shaped tablet, engraved with"10/5" on one face and ⌲ on the other face manufactured by Servier (Ireland) Industries LTD **COVERAM 5&10** is a white square-shaped tablet, engraved with"5/10" on one face and ⌲ on the other face manufactured by Servier (Ireland) Industries LTD **COVERAM 5&5** is a white rod-shaped tablet, engraved with"5/5" on one face and ⌲ on the other face manufactured by Servier (Ireland) Industries LTD	**The product was recommended for registration**	Anitha Tuyishime	Done

	All COVERAM branded product mentioned above passed the first and second assessment at the second round of additional data and has shown to comply with the registration requirement.			
TRAMACETAL TABLETS with reference number **16065/2017** and manufactured by **Cachet Pharmaceuticals Private Limited** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**TRAMACETAL TABLETS** is a yellow coloured, oblong, biconvex, film-coated tablets with a breakline on one side manufactured by Cachet Pharmaceuticals Private Limited. The application complied with safety, efficacy and quality requirements including the application for GMP inspection however the product sample was not submitted	**The product was recommended for registration but after the submission of samples. Clarisse will follow up.**	Nadia Uwera	Done
VIPIDIA-25 with reference number **0774/2019** and manufactured by **Takeda Ireland LTD** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**VIPIDIA-25 is a human medicinal product** manufactured by Takeda Ireland LTD was assessed and the fact that all queries addressed were resolved.	**The product was recommended for registration.**	Jean Pierre Nsanzimfura	Done

Lamivudine/Tenofovir disoproxil fumarate with reference number **8540/2020** and manufactured by **CELLTRION PHARMA, INC./SOUTH KOREA** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**Lamivudine/Tenofovir disoproxil fumarate 300 mg/300 mg** is a white, oblong shape, film-coated tablets debossed with "C 0" on one side and plain on the other side manufactured by Celltrion, Inc. The product was presented in previous peer review where the remaining query was to clarify the difference in FPP specification number, this has been well clarified.	**The product was recommended for registration.**	Honore Ayinkamiye	Done
FOLIC ACID TABLETS with reference number **2357/2019** and manufactured by **LABORATORY & ALLIED LTD/KENYA** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**FOLIC ACID 5MG TABLETS** is a yellow, circular, biconvex tablet plain on both sides manufactured by Laboratory & Allied Ltd. The application complied with safety, efficacy and quality requirements including the application for GMP inspection however the product sample was not submitted and the proposed pack size of 1000's in HDPE container is not recommended. It has been agreed to contact LTR for sample submission and	**The product was recommended for registration on condition to specify if the accepted container will be used and samples will be submitted. Clarisse will follow up.**	Dr. Placide Muhayimana	Done

	revision of the pack size to less than 90's in the HDPE container.			
SEKROL SYRUP with reference number **3096/2019** and manufactured by **Bilim Ilaç Sanayi ve Ticaret A.Ş** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**SEKROL SYRUP** is a Clear, colourless, cherry odoured Syrup manufactured by Bilim Ilaç Sanayi ve Ticaret A.Ş. The application complied with safety, efficacy and quality requirements moreover, the applicant has applied for GMP inspection.	**The product was recommended for registration.**	Ruth Muhongerwa	Done
EVOKE TABLETS with reference number **2904/2019** and manufactured by **Laboratory & Allied Ltd** was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	**EVOKE TABLETS** is a Blue diamond shaped biconvex film-coated tablets plain on both sides manufactured by Laboratory & Allied Ltd. The application complied with safety, efficacy and quality requirements including the application for GMP inspection.	**The product was recommended for registration.**	Ruth Muhongerwa	Done
PAUSE-500 TABLETS with reference number **1801/2019** and manufactured by **Emcure Pharmaceuticals LTD** was presented and responded well to the queries. Furthermore, an	**PAUSE-500 TABLETS** is White coloured circular biconvex film-coated tablet manufactured by Emcure Pharmaceuticals LTD.	**The product was recommended for registration.**	Dr.Eustache Musafiri	Done

application for GMP inspection was done and the prescribed fees was paid.	The application complied with safety, efficacy and quality requirements including the application for GMP inspection.			

	Names, and signature and/or institution stamp		Names and signature
Chair of the meeting	**Dr. Eric NYIRIMIGABO**	Rapporteur	**Marie Ange ISINGIZWE**

The meeting has ended on: 17th June 2021 at **08h10 PM**

End of Minutes

ANNEX: Screenshots of the participants on Webex