**Rwanda Food and Drugs Authority**
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**MINUTES OF THE MEETING N°: ….. /02/FDA/2021 FOR PEER REVIEW**

**Date of Meeting ……25/02/2021……**

**Venue of the meeting: …Virtual…….**

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

| | Names | Position |
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**Items on the agenda**

a) Presenting final dossier assessment reports of Human medicines and disinfectants to Peer review committee for approval (15 Products).

**Opening and/or remarks of the meeting**

The meeting started at 09pm 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.

**Resolutions of the meeting**

| Item on Agenda | Comments and recommendation | Responsible person for implementation | Timelines |
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| Presentation of the final assessment report of **BARANYWUZWE Hand Sanitizer** | **Baranyuzwe hand sanitizer** was previously approved on condition to submit safety data sheets of each ingredients. The safety data sheets have been submitted and was assessed. **Therefore, Baranyuzwe Hand Sanitizer was recommended for Registration**. | The assessment report was presented by Director Pacifique Uwamariya | N/A |
| Presentation of the final assessment report of **SKY STONE HAND** | Applicant requested to change the name of the product from SOFT CARE hand sanitizer to **SKY STONE HAND SANITIZER** due to conflicting name with other business registered | The assessment report was presented by Mr Leodomir | N/A |

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| **SANITIZER** | with Rwanda Development Board, the request for changing name have been assessed and approved, However, Rwanda FDA recommend the applicant to introduce a batching system and include the Batch Numbers in the submitted stability study protocol that will be adhered to while conducting stability studies.<br><br>Moreover, GMP inspection have been waved for local manufacturers of hand sanitizer to encourage availability of hand sanitizers on market.<br><br>**Therefore, the product was recommended for approval with condition to include batch number to the protocol of stability studies.** | Niyitegeka | |
| Presentation of Assessment report of Human Medicines through WHO Collaborative Registration Procedure:<br>• **Dolutegravil/Lamuvidine/ Tenofovir disoproxil**<br>• **Nevimune baby**<br>• **Lumet tablet**<br>• **Abacavir + Lamivudine** | **Applications of Dolutegravil/Lamuvidine/ Tenofovir disoproxil and Nevimune baby** complied with safety, efficacy and quality requirements. Moreover, the applicant submitted proof of payment of inspection fees acknowledged by Rwanda FDA finance office but he did not submit application for GMP inspection.<br>**Meanwhile, Dolutegravil/Lamuvidine/ Tenofovir disoproxil and Nevimune are recommended for registration with condition that inspection department will do a follow up on the matter to ensure applicant applies for GMP inspection.** | Presented by Mr Honore Ayinkamiye | N/A |
| | **Application of Lumet tablet** passed first and second assessment and has shown to comply with registration requirement including paying and applying for GMP inspection at Rwanda FDA, therefore, **this product was approved for registration.** | Presented by Nadine Niyomahoro | N/A |
| | **Application of Abacavir + Lamivudine** complied with the requirement through first and second assessment. However, it was noted that some specifications were not consistent with those submitted at WHO. Moreover, the applicant explained that they applied for variation, but it is yet to be approved.<br>It was concluded that the applicant will be requested to submit the proof of variation approval by WHO. | | |

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| | It was also noted that the applicant has paid for GMP but not applied for GMP inspection.<br>**Therefore, the product is recommended for registration with condition that inspection department will do a follow up on the matter to ensure applicant applies for GMP inspection.** | | |
| Presentation of final assessment report of EAC joint applications.<br>• **Adrenaline aguettant Solution for Injection,**<br>• **Atropine aguettant Solution for Injection,**<br>• **Ephedrine aguettant Solution.** | Applications of **adrenaline aguettant solution for Injection, atropine aguettant solution for Injection, and ephedrine aguettant solution for Injection** complied with the requirements and passed first and second assessment. However, the applicant will be requested to submit power of attorney to officially appoint Local technical representative (TLR) and pay prescribed fees for GMP inspection at Rwanda FDA.<br>**Therefore, these products are recommended for registration after fulfilling above mentioned condition.** | Presented by Marie Ange Isingizwe | N/A |
| Presentation of final assessment report of product applying for registration directly at Rwanda FDA (NEBTAS 5 Tab, FloraNorm Granules, GRAMOCEF-CV, Pdxane 8000, BCG Vaccine Freeze dried and Measles vaccine live attenuated freeze dried) | **Application of NEBTAS 5 tablets** adequately complied with registration requirements through first and second assessment. However, the applicant insisted that they are GMP compliant and have been inspected by Stringent Regulatory Authorities and EAC regulatory agencies.<br>The applicant was informed that GMP inspection is part of product registration in Rwanda reason why it is mandatory to apply for GMP inspection and pay the prescribed GMP inspection fees before being considered for the registration. The official feedback letter from Rwanda FDA has been sent to the applicant.<br>**Application of FloraNorm Granules** submitted power of attorney appointing marketing authorization holder and changing LTR.<br>Moreover, the applicant was requested to update the PIL to be consistent with information on Mock up and add shelf life and | Presented by Serge Shyirambere | |

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| | pay and apply for GMP inspection at Rwanda FDA.<br>The applicant adequately responded to the queries and have applied and submitted proof of Payment of GMP inspection fees.<br>**Therefore, FloraNorm granules was approved for registration.** | | |
| | **Application for Pdxane 8000 injection** sufficiently responded to the queries requesting to update SmPC to contain consistent storage information with PIL and labels.<br>The applicant was also requested to submit samples to assess consistency of information on the mocks up and labels. After submitting the samples, the information has been assessed and confirmed.<br>**Thus, Pxdane 8000 injection has fulfilled registration requirements and was recommended for registration.** | Presented by Anitha TUYISHIME | |
| | **Application for Gramocef-CV tablets** complied to all registration requirement and has paid for GMP inspection and submit proof of payment issued by Rwanda FDA finance Department. Therefore, Gramocef-CV tablets was recommended for registration. | | |
| | **Application of BCG Vaccine Freeze dried and Measles vaccine live attenuated freeze dried** adequately complied with registration requirements through first and second assessment as he has tried to adequately respond to most of queries. However, the applicant has not applied for GMP inspection in Rwanda and paid the prescribed GMP inspection fees where he insisted that they have applied for GMP inspection through the EAC Joint assessment with presentation the submitted form to NDA Uganda together with payment and copy of communication received from NDA Uganda regarding postponement of GMP audit in view of the current worldwide Covid-19 situation.<br>In conclusion, based on the fact that this BCG | Presented by Isaie NSABIMANA | |

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| | **Vaccine Freeze dried and Measles vaccine live attenuated freeze dried** have not been assessed through EAC joint assessment but assessed as dossier applications for registration to Rwanda FDA, the GMP inspection could also be conducted in the same way.<br>**Therefore, the products are recommended for registration with condition that inspection department will do a follow up on the matter to ensure applicant applies for GMP inspection and pays related prescribed GMP inspection fees.** | | |

| Chair of the meeting | Names, and signature and institution stamp | Rapporteur | Names and signature |
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| |  <br>**Clarisse IRASABWA** | |  <br>**Serge SHYIRAMBERE** |

The meeting has ended at: …01:00 PM

End of Minutes