Rwanda Food and Drugs Authority
Nyarutarama Plaza KG 9 Avenue
Email: info@rwandafda.gov.rw;
website: www.rwandafda.gov.rw

MINUTES OF THE MEETING N°... /03/FDA/2021 FOR [Drugs and Health Technologies Assessment and Registration Division]

Date of Meeting 26/03/2021.

Venue of the meeting: WEBEX.

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

S/N°	Names	Position
1.	Uworoheje Innocent	Veterinary Diagnostics and Medical Devices Registration Officer
2.	Munyaneza Uwitonze Janvier	Medicinal Cosmetics Registration Officer
3.	Nshimiyimana Philbert	Biological Products Registration Officer
4.	Karasanyi Geofrey	Veterinary Medicines Registration and Variations Assessment Officer
5.	Iradukunda Gad Patrick	Medicinal Cosmetics Registration Officer
6.	Ayinkamiye Honoré	FPP and API Assessment and Registration Officer
7.	Niyitegeka Leodomir	Medicinal Cosmetics Registration Officer
8.	Uwamariya Pacifique	Director of Cosmetics and household Chemicals
9.	Irasabwa Clarisse	DM of Drugs and Health Technologies Assessment and Registration
10.	Munyangaju Edouard	Division Manager /Drugs and Food inspection and compliance
11.	Frederic Muhoza	Clinical Trial Specialist
12.	Evariste Byomuhange	Pharmacist in Charge of MIS
13.	Tite Uwambajineza	Human Medicine Lab Officer

Items on the agenda

Peer Review Meeting for Validation of Assessed Products Dossiers

Opening and/or remarks of the meeting

The Meeting has started at **10:30 AM** with the opening remarks given by the DM of Drugs and Health Technologies Assessment and Registration. She started by thanking the whole participants to peer review meeting to validate both assessed hand sanitizers, cosmetic and medicinal product dossiers. The Division manager highlighted that **6** PDs including and **1** human medicinal product, **1** Cosmetic product and **4** hand sanitizers are to be validated with an aim find out whether they qualify to be granted marketing authorization in Rwanda.

The Meeting Proceedings

1. HUMAN MEDICINAL PRODUCT: SANTOCYN® Injection [Oxytocin Solution for Injection]				
Discussion	**Observation**	**Resolutions/ recommendation**	**Responsible person for implementation**	**Timelines**
It was presented that **SANTOCYN® Injection** with reference number **1088/2020** and manufactured by **PT Sanbe Farma** had queries related to API Specifications from FPP manufacturer not dated and signed, API analytical procedures without reference, version number and date, labelling information, expired GMP Certificate, unsigned and non-dated FPP Specifications, FPP Analytical procedures with no reference, version number and date. All of the raised queries have been resolved by the applicant	It was observed that all queries have been resolved by the applicant though on the issue of GMP certificate, the applicant indicated that (NADFC Indonesia) is currently undergoing changes of representative people, so the original GMP certificate in appropriate format was not issued yet, but a valid GMP certificate for administration purposes in Indonesia was provided and a proof of application for GMP inspection by Rwanda FDA was provided.	It was also concluded that: ✓ **The product is recommended for approval.** ✓ If an applicant has applied and paid for GMP inspection by Rwanda FDA, once his/her products fulfils all other requirements and remains with query on GMP inspection, the product will be approved for registration with the condition that the inspection will be carried out later. ✓ For Products applied for through CRP, the product will be registered and the inspection will be carried out later. Moreover, after Rwanda FDA carried first GMP inspection, it will be now possible that for the next time, a desk review can be enough.	Honoré	Done
2. HAND SANITIZERS				
2.1. Experience hand sanitizer gel (Ethanol and hydrogen peroxide)				

It was presented that **Experience hand sanitizer gel** with reference number **6526/2020** and which is manufactured by LABORATOIRE L'EXPERIENCE had queries related to in-process control and critical parameters as well as the stability studies. To these later, satisfactory responses have been provided by the applicant. The product dossier was assessed and given conditional registration. Then after it was found that the manufacturing License was no longer valid but as for now, the valid manufacturing License was issued by Rwanda FDA. Hence the product has been recommended for registration.	It was observed that all raised queries have been resolved by the applicant. However, in the submitted stability study data, it was observed that alcohol concentration reduces with time and the local manufacturers are not used to mention stability indicating parameters like appearance, PH, Alcohol content and bacteridal efficacy yet this is a requirement in standards for hand sanitizer.	It was concluded that: ✓ **The product is recommended for approval.** ✓ Director Pacifique will check whether Rwanda FDA guidelines on registration of hand sanitizers clearly clarify stability studies and stability indicating parameters to be tested. ✓ The manufacturers should be recommended to add the in use shelf-life in product labeling information ✓ Further guidance for local manufacturers on how to prepare their PD for application should continuously be provided ✓ Since the manufacturing licence has one year of validity yet registration certificate has 5	Leodomir	Done

		years of validity, this requires the department of registration to work closely with those from inspection department so that once a manufacturing licence is not renewed, the MA is also terminated. ✓ Lastly, much effort should be invested in PMS so that any products which does not conform with quality standards it has been registered with is withdrawn from the market.		
2.2. Experience hand sanitizer solution hydroalcoholic antibacterial (Ethanol and hydrogen peroxide)				
It was presented that **Experience hand sanitizer solution hydroalcoholic antibacterial** with reference number **8264/2020** and which is manufactured by LABORATOIRE L'EXPERIENCE had queries related to in-process control and critical parameters as well as the stability studies. To these later,	It was observed that all raised queries have been resolved by the applicant. However, in the submitted stability study data, it was observed that alcohol concentration reduces with time and the local manufacturers are not used to mention stability indicating parameters like appearance, PH, Alcohol content and bacteridal efficacy yet this is	It was concluded that: ✓ **The product is recommended for approval.** ✓ Director Pacifique will check whether Rwanda FDA guidelines on registration of hand sanitizers clearly clarify stability studies and stability	Leodomir	Done

satisfactory responses have been provided by the applicant. The product dossier was assessed and given approval for registration with recommendation. Then after it was found that the manufacturing License was no longer valid but as for now, the valid manufacturing License was issued by Rwanda FDA. Hence the product has been recommended for registration.	a requirement in standards for hand sanitizer.	indicating parameters to be tested. ✓ The manufacturers should be adding the in use shelf-life in product labeling information ✓ Further guidance for local manufacturers on how to prepare their PD for application should continuously be provided ✓ Since the manufacturing licence has one year of validity yet registration certificate has 5 years of validity, this requires the department of registration to work closely with those from inspection department so that once a manufacturing licence is not renewed, the MA is also terminated. ✓ Lastly, much effort should be invested in PMS so that any products which does not		

		conform with quality standards it has been registered with is withdrawn from the market.		
2.3. TOPLIFE HAND SANITIZER GEL (Ethanol 80% v/v Hydrogen peroxide)				
It was presented that Toplife hand sanitizer gel with reference number **6556/2020** and which is manufactured by **TOP LIVO LIMITED** had queries related to GMP, material safety datasheet, manufacturing flow chat and its description, COA, Appearance, PH and Alcohol content, analysis report with missing parameters which assessor traced at Kenya bureau of Standard web and stability study. Some queries have been well resolved whereas others were judged as minor.	It was observed that the raised queries have been resolved by the applicant or judged as minor queries by assessor. It was also observed that foreign companies have advanced knowledge in preparing PD to submit for registration when compared to local manufacturing companies. Therefore, teaching local manufacturing companies should be enforced.	**The product is recommended for approval.**	Patrick	
2.4. TOPLIFE HAND SANITIZER Liquid (Ethanol 80% v/v Hydrogen peroxide)				
It was presented that Toplife hand sanitizer gel with reference	It was observed that the raised queries have been resolved by	**The product is recommended for approval.**	Patrick	Done

number **6556/2020** and which is manufactured by **TOP LIVO LIMITED** had queries related to GMP, material safety datasheet, manufacturing flow chat and its description, COA, Appearance, PH and Alcohol content, analysis report with missing parameters which assessor traced at Kenya bureau of Standard web and stability study. Some queries have been well resolved whereas others were judged as minor.	the applicant or judged as minor queries by assessor. It was also observed that foreign companies have advanced knowledge in preparing PD to submit for registration when compared to local manufacturing companies. Therefore, teaching local manufacturing companies should be enforced.			
3. DERMOL EMOLLIENT CREAM (White soft paraffin 14.5%W/W, Liquid paraffin 12.6% W/W)				
It was presented that EMOLLIENT with reference number 5773/2020 and which is manufactured by BIODEAL LABORATORIES LIMITED had queries related to containing prohibited ingredient(Petrolatum), stability studies, dermatological	It was observed that the applicant has firstly applied showing that his product is a pharmaceutical product. Rwanda FDA has recommended him to apply as cosmetic product. The applicant has already paid **1250USD**	**The product is recommended for approval.**	Janvier	Done

effect, COA. All queries have been satisfactorily resolved.	application fees for a medicinal product instead of **1000USD** (at the time of first application) for cosmetic product that has changed to **500USD** after current revision of regulations related to regulatory services tariff/fees and fines by Rwanda FDA. This means the Authority owes the applicant a sum of **250USD**.			

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

The meeting has ended at: **1h15 PM**

End of Minutes

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