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REPORT OF INVESTIGATION CONDUCTED AT KIGALI FOR REPORTED SUSPECTED POOR QUALITY PHARMACEUTICAL PRODUCTS

1.0 INTRODUCTION

Rwanda FDA is established by the law **Nº 003/2018 0f 09/02/2018** determining its mission, organization and functioning with mandate of regulation and control of Food and Drugs through different regulatory functions. The mission of Rwanda FDA is to protect public health by ensuring Safety, Efficacy and Quality of Human and Veterinary medicines, vaccines and other biologics, food, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products and conduct of clinical trials through the regulation and control.

Referring to the article 3 paragraphs 11, Rwanda FDA is mandated to conduct Drug's Post marketing surveillance activities to ensure the quality and safety of medicines

Based on the reports of suspected poor quality of pharmaceutical products received by the Authority from Rwanda Medical supply Ltd and Escort Pharmaceuticals Ltd, the Division of Pharmacovigilance and Food Safety Monitoring conducted investigation for the complaints received which was conducted in different pharmaceutical establishment in relationship with reported pharmaceutical products, the activity was conducted on 28th April 2021

2.0 Objective of investigation

- The objective of this activity was to investigate the suspected poor quality pharmaceutical products reported to the Authority so as to fix the complaint and taking appropriate regulatory action based on the findings of the investigation
- Giving the appropriate feedback to the reporter based on the findings of investigation

3.0 Targeted Pharmaceutical products with the complaints investigated, findings and action taken after investigation

SN	Product description	Reporter	Reported complaint	Importer of suspected products	Findings after investigation and action taken
1	Amoxicillin 250mg capsule BN:MP18485A,Mfd:-,Exp:09/2021	RMS Ltd	Presence of unidentified dark blue/black particles looking like foreign impurities that contaminated the formulation during production	BUFMAR	-After our Investigation the complaint was fixed where by our visual inspection the reported unidentified dark blue/black particles were observed within the powder inside the capsules of the products. -The sample was taken to QC lab for further investigation -The remaining products at BUFMAR were quarantined
2	Nystatin oral suspension 100000I.U/ml,BN:2006004, Mfd:06/2020,Exp:05/2022	RMS Ltd	Sedimentation of the suspension	ABACUS PHARMA Ltd	-After our investigation at RMS we realized the reported complaint where sedimentation of the suspension was realized by visual inspection

					-All quantity at BUFMAR were in quarantine status as mentioned by RMS Ltd -Sample from RMS Ltd was taken to the QC lab for further investigation -At ABACUS Pharma Ltd we found that all quantity were distributed -We collected importation documents and distribution list from Abacus for further investigation
3	Azithromycin dry powder suspension(Zerocin) BN:75363,Mfd:09/2019,Exp: 08/2021	ESCORT PHARMACEUTICALS Ltd	Caking of the powder at the bottom of the bottles	ESCORT PHARMACEUTICALS Ltd	-The reported complaint was identified by our visual inspection -The remaining stock of reported products were quarantined at ESCORT -The sample was taken to QC lab for further investigation

4	Soda lime for Anaesthesia machine BN:45248AR,Mfd:June 2016,Exp:May 2021	CHUK	Compaction of granules of Soda lime	RMS Ltd	-At RMS Ltd we took the distribution list for our deep investigation of the reported case
5	Gynofer BN:GLT1902,Mfd:06/2020,EXP:05/2022	ROYALCARE PHARMACY	Presence of Particulate matters in Vials	PHILLIPPS	At Phillips the distribution list was taken for our deep investigation

4.0 General recommendation

- Pharmacist in different Pharmaceutical establishment should perform regular physical inspection of all pharmaceutical products in their establishments
- Rwanda FDA staff at the port of entry should maximize physical inspection for all pharmaceutical products to early detect and prevent Substandard and falsified medicines
- Regular awareness campaign should be performed by Pharmacovigilance and Food safety monitoring Division to encourage Pharmacist in different pharmaceutical establishment to early report any suspected poor quality medicines to the Authority in order to prevent Substandard and falsified medicines on the market
- This activity of investigating the reported suspected poor quality products should done as soon as possible after receiving the report of suspected poor quality products

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