



RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 84 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

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

1.0 INTRODUCTION

Rwanda FDA is established by the law N° 003/2018 of 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 so as to ensure the quality and safety of medicines

Based on the reports of suspected poor quality of pharmaceutical products received by the Authority from patients, Health facilities, Wholesale pharmacies and retail Pharmacies Rwanda FDA through its Division of Pharmacovigilance and Food Safety Monitoring organized a two days of conducting investigation for the complaints reported which was conducted in different pharmaceutical establishment in relationship with reported pharmaceutical products under suspect located at Kigali.

The activity started from 16th to 17th February 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 and findings after investigation

SN	Product description	Reported complaint	Findings after investigation
1	Telmisartan 40mg BN:FF9016,Mfd:06/2019,Exp:05/2022	The tablet broken down easily Products got From Mediasol Pharmacy	After our Investigation we fixed the complaint of tablet in blisters which were easily broken down and we took samples to the lab for quality control test and decision shall be taken based on the lab results
2	Methylated spirit	The products was used as disinfectant while there is a suspect of containing Methanol content Product found at Dolupham	After our investigation we realized that this product is in ongoing status as Laboratory up to now did not give us Certificate of analysis we will continue to follow up
3	Extra neutral Alcohol 96%,BN:258,Mfd:Jan/2020,Exp:Jan/2022	Nauseable odour Reported by Gitwe Hospital but supplied by BUFMAR	The reported batch was not available at BUFMAR
4	Phytomenadione Inj. BP 10mg/ml BN:SA20C008E,Mfd:03/2020,Exp:02/2022	Presence of Particulate matters in Vials Reported by MPPD	Samples were taken to the lab for deep investigation and the regulatory action have to be taken based on Certificate of analysis

5	Hyoscine Butylbromide Injection BP 20mg/ml,BN:3H20001,Mfd:07/2020,Exp:06/2022	Presence of Particulate matters in Vials Reported by MPPD	Samples were taken to the lab for deep investigation and the regulatory action have to be taken based on Certificate of analysis
6	Unigentlyl tablet,BN:5807252,Mfd:02/2020,Exp date:01/2023	Missing of tablet within some blister Reported by ELSHADAI PHARMACY but supplied by SUN	After our Visit at SUN we found that products were out of stock and we requested distribution list for further investigation
7	Catheter G18 BN:641806,Mfd:06/2018,Exp:05/2023	During removal of the catheter into vein for some patients it remain into vein and require surgical procedure for the removal Reported by KIREHE DH but Bought From RMS	At RMS we requested them to avail distribution list for further investigation
8	Hepatitis B test Kit,HBs Ag rapid test strip,BN:I2002027,Exp:07/2022	The test gives many false positive Reported by KIREHE DH but Bought From RMS and BUFMAR	At BUFMAR we found that no stock remain in their stock but by following up distribution list we found that other Hospital who received the same batch they did not find any issue related to the quality for that batch

9	Multivitamin tablet BN:T190229,Mfd:09/2019,Exp:August 2021	Some parameters with out of specification like Content of Vitamin D3 and content of Ascorbic acid Reported by MPPD	At RMS we found that no stock of reported batch available, the distribution list was taken for deep investigation so that action should be taken based on the stock available in our country
10	Polygalactin 2/0,910 BN:20190612,Mfd:06/2019,Exp:06/2022	Sutures with big size needle Reported By Kabgayi DH but distributed by SUN	Sample of reported batch was taken for deep investigation
11	Paracetamol 500mg BN:190802,Mfd:08/2019,Exp date:08/2022	Tablet which are not fully filled in the blisters instead of 10tablets per blisters it was 5tablets per blisters Reported by Keystone Pharmacy	At Keystone Pharmacy we found that the reported batch was out of stock and at Ubumwe who supplied the reported batch the product was out of stock
12	Amoxicillin 125mg/5ml(Spamox)BN:X0870,Mfd:04/2019,Exp d:03/2022	Presence of crystals in powder for suspension Reported by High Magnificat Pharmacy/Musanze but distributed by ABACUS	At ABACUS the complaint was fixed as they imported the reported batch and transfer to their branch located at Musanze District where at ABACUS Musanze Branch they quarantined themselves 115bottles

13	Polygalactin BN:190806,Mfd:08/2019,Exp:08/2022	2/0,910 Difficult to penetrate tissue during surgery(Sharpness problem) Reported by CHUK but distributed by Le Medical	At CHUK the complaint was analysed and we took sample of reported batch for further investigation
14	Rosuvastatin BN:PY489,EXP:02/2021	Suspicion on its use after its shelf life Products distributed by KVCG	Based on the list of distribution list from KVCG and Surgipham we visited 5 retails pharmacies who received the reported batch were visited but we noticed that the products were out of stock within months ago
15	Hip-up Cream	Advertising and promoting without approval from Rwanda FDA and in exaggerating manner	We try to find out where this products is available but we missed the premises where they purchase the reported products
16	Contraceptive Pill claiming that no adverse drug reaction by DYNAPHARMA	Social media	DYNAPHARM was visited and find that they do not have such contraceptive pill but they were having food supplement called Herba Wrisana which Maharani that relieve menstrual pain

17	Magnesium sulphate 500 mg/ml, B.N: 8EB12424 Mfg date: 11/2019, exp date:10/2021	The product has issue of labelling Reported by CHUK	At CHUK we found that this product was out of stock
18	Disposable infusion set, B.N: A170312, Mfg: 03/2018, exp date:03/2022	The air was accumulated in infusion set Reported by Kirehe DH but supplied by ABACUS	After our Visit at ABACUS we realized that all products were used and no stock available at ABACUS during the the time of our visit
19	Telmisartan 80mg+Hydrochlorothiazide 12.5mg BN:FF9019,Mfd:06/2019,Exp date: May 2022	After breaking tab into two tablet the color change for the remaining broken tablet Reported by client who got medicine from one Pharmacy in Kigali	Since the reporter did not mention where the product was purchased we did not find this product in all visited pharmacies

4.0 Recommendation to Rwanda FDA

- Rwanda FDA should equipped the quality control laboratory so that we should be able to test the quality of reported suspected poor quality of medical consumables
- ☑ 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

Prepared by:

1. BYIRINGIRO Hesron
PV&PMS Officer

Verified by

NTIRENGANYA Lazare
DM of PV-SM Division

Approved by

GISAGARA Alex
Head of Food and Drugs Inspection and Safety Monitoring Department

