



REPORT ON POSTMARKETING SURVEILLANCE SAMPLING PLAN 2019-2020

INTRODUCTION

An important function of regulatory authority involves ensuring that medicines in circulation in the country are safe, efficacious and of good quality. The quality of medicines determines their effectiveness and safety and, hence, the health outcome of the patient. If the quality of medicines is compromised, investments in pharmaceutical commodities, health systems, and pharmaceutical management systems are negated.

Reference to the law establishing Rwanda FDA in its article 3 paragraph 11 the Authority is mandated to conduct Post marketing surveillance and safety monitoring activities, it is with this regard Rwanda FDA through the Division of Pharmacovigilance and safety monitoring collected samples from 4 district pharmacies in order to test its safety and quality of sampled medicines.

Location of where samples were collected

Samples were collected at four districts which are Nyagatare, Gicumbi, Kamonyi and Huye where all samples come from their respective district pharmacies.

Collected samples Identification

N o	Name of medicines	BN	MFD	EXP	Manufacturer	Sampled from
1	Methyldopa 250mg	76221	02/2020	01/2022	Lab&Allied Ltd Kenya	NYAGATA RE DP
2	Doxycycline 100mg	76812	05/2020	04/2023	Lab&Allied Ltd Kenya	NYAGATA RE DP

3	Carbamazepine 200mg	T200044	03/2020	02/2023	ANGEL BIOGENIC PVT LTD/India	NYAGATA RE DP
4	Metformine Hydrochloride 850mg	MHD02	04/2019	03/2022	BAL PHARMA/INDIA	NYAGATA RE DP
5	Amoxicillin 500mg	76735	04/2020	03/2023	Lab&Allied Ltd Kenya	NYAGATA RE DP
6	Amoxicillin+potassium Clavulanate	BABBV0045	12/2019	11/2021	MICROLABS LTD/INDIA	NYAGATA RE DP
7	Albendazole 400mg	F035L901	11/2019	10/2022	Zim Laboratories/India	NYAGATA RE DP
8	Nifedipine 10mg	759039	03/2018	02/2021	Ambalal Sarabhal/India	Gicumbi DP
9	Ciprofloxacin 500mg	FP66L901	11/2019	10/2022	Zim Laboratories/India	GICUMBI DP
10	Quinine Sulphate 300mg	77367	07/2018	07/2023	REMEDICA Ltd	Gicumbi Dp
11	Omeprazole 20mg	OMYH0045	04/2020	03/2022	MICROLABS LTD/INDIA	GICUMBI DP
12	Nifedipine 20mg	76244	02/2020	01/2023	Lab&Allied Ltd Kenya	Gicumbi DP
13	Amoxicillin 250mg	74757	06/2019	-	Lab&Allied Ltd Kenya	Gicumbi DP
14	Amoxicillin 500mg	MX280	07/2019	06/2022	Sparsh Biotech PVT LTD	GICUMBI DP
15	Chlorpheniramine 4mg	75575	10/2019	09/2022	Lab&Allied Ltd Kenya	GICUMBI DP
16	Tramadol 50mg	FP64M902	12/2019	11/2022	Zim Laboratories/India	GICUMBI DP
17	Isoniazid 100mg	NIA706B	07/2017	06/2021	OXALIS LTD	GICUMBI DP
1	Metformin 500mg	T190172	07/201	06/20	ANGEL	GICUMBI

8			9	22	BIOGENIC PVT LTD/India	DP
19	Paracetamol 500mg	1907337	07/2019	06/2024	DAWA LTD/Kenya	GicumbiDP
20	Amoxicillin 250mg	76742	04/2020	03/2023	Laboratory&Allied Ltd	KAMONY IDP
21	Amoxicillin500mg+Clavulanique acid 125mg	193132269	08/2019	08/2022	REYOUNG PHARMACEUTICALS LTD	KAMONY IDP
22	Carbamazepine 200mg	5807235	02/2020	01/2023	Universal Corporation	KAMONY IDP
23	Chlorpheniramine 4mg	1219063	12/2019	11/2022	Biodeal Laboratories Ltd	KAMONY IDP
24	Ciprofloxacin 500mg	76413	03/2020	02/2023	LAB&ALLIED LTD	KAMONY IDP
25	Cloxacillin 250mg	MP19309	Not mentioned	06/2021	MILAN LABORATORIES/INDIA	KAMONY IDP
26	Doxycycline 100	C01026	02/2020	01/2023	AGOG PHARMA LTD	KAMONY IDP
27	Metformine 500	7473	06/2019	05/2021	LAB&ALLIED LTD	KAMONY IDP
28	Metronidazole 250mg	T96019	11/2019	10/2022	AGOG PHARMA LTD	KAMONY IDP
29	Nifedipine 10mg	KR9001	05/2019	04/2022	Lincoln Pharmaceutical Ltd	KAMONY IDP
30	Nifedipine 20mg	75632	10/2019	02/2022	LAB&ALLIED LTD	KAMONY IDP
31	Omeprazole 20mg	BA9014	8/2019	07/2022	Lincoln Pharmaceutical Ltd	KAMONY IDP
32	Paracetamol 500mg	20033	02/2020	01/2024	REGAL PHARMACEUTIC	KAMONY IDP

					AL LTD	
3	Amoxicillin 250mg	YXC9200	12/201	11/20	Yeluri formulation	HUYE DP
3		2	9	22	PVT Ltd	
3	Amoxicillin 500mg+Clav	18313215	09/201	09/20	REYOUNG	HUYE DP
4	ulanique acid 125mg	0	8	21	PHARMACEUTIC ALS LTD	
3	Amoxicillin 500mg+Clav	BABBV0	03/201	02/20	MICRO LABS Ltd	HUYE DP
5	ulanique acid 125mg	036	9	21		
3	Ciprofloxacin	T96032	11/201	10/20	AGOG PHARMA	HUYE DP
6	Chlorhydrate		9	22	LTD	
3	Diclofenac 50mg	76686	04/202	03/20	LAB&ALLIED	HUYE DP
7			0	23	LTD	
3	Metformine 850mg	FW93D9	04/201	03/20	03/2022	HUYE DP
8		01	9	22		
3	Methyldopa 250mg	HMX802	02/201	02/20	Macleods	HUYE DP
9		A	8	21	Pharmaceutical Ltd	
4	Quinine 300mg	76921	05/201	05/20	REMEDICA LTD	HUYE DP
0			8	23		
4	Albendazole 400mg	385563	06/201	05/20	GlaxoSmith	HUYE DP
1			9	24		
4	Omeprazole 20mg	200Z01	04/202	03/20	ANGEL	HUYE DP
2			0	23	BIOGENIC.PVT LTD	
4	Nevirapine 200mg	EI80682	04/201	03/20	Hetero labs Ltd	HUYE DP
3			8	23		

All the above 43 batches of pharmaceutical products were conducted to the lab for quality control Test

Laboratory findings

All 43 batches were tested in our quality control lab and find that they were complied with the specification for the performed test and based on the laboratory findings all of tested batches were fit for use.

Recommendation

- ☐ As the tested batches were coming from 4 districts of our country it should be better to sample at all remaining 26 districts of our country so as to get the picture of all medicines circulating at our market
- ☐ Our quality control laboratory has to be equipped so as to test even medical device as for this first round no medical device was tested
- ☐ The tested batches were tablet our lab should be equipped so as it should be able to test other dosage form such as injectable, suspension, solution, Etc

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