



**RWANDA FDA**

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## **POST MARKETING SURVEILLANCE PLAN 2020-2021**

### **1.0 INTRODUCTION**

According to the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA, its organization and functioning especially in Article 8 paragraph 9, Rwanda FDA is mandated to conduct pharmacovigilance and post marketing surveillance for safety and quality of products regulated under this Law; It is in this regards Rwanda FDA has established the post marketing surveillance plan for 2020/2021 which states the objectives, methodology, activities to be undertaken during this fiscal year, the list of products and the criteria for selection of the products/molecules that are to undergo quality tests in the laboratory and the estimated budget. Furthermore, the selection of sites where the sampling will be done is detailed as well as the guide on sampling. Tools that should be used during the implementation of the plan are part of the document as annexes.

The Post marketing surveillance plan will cover different components for PMS system in the country including regulatory framework, PMS sampling, statutory documents guiding PMS in the country such as guidelines, system and structures including equipment and materials.

### **1.1 Background**

Rwanda FDA is mandated to protect public health by ensuring safety, quality and efficacy of medicines and other regulated products. This core priority will be achieved by strengthening of systems, processes and procedures for post marketing regulatory activities for medicines and

healthcare products, capacity building, Management and planning of PMS activities, however, the focus of the PMS quality surveillance plan is mostly on quality of the product.

It is important to note that poor quality medicines may result into increased morbidity and mortality, treatment failure, adverse reactions, antimicrobial resistance, wastage of financial resources, wastage of human resources, increase in health expenditure, loss of confidence in conventional medicines and loss of confidence in the healthcare system. Poor quality veterinary products negatively affect animal productivity and the economy among others. This calls for a robust method for conducting Post marketing surveillance.

## **2.0 Objectives**

The main objective of the Post marketing surveillance plan is to build enabling structure and system for quality of medicines

### **2.1 Specific objectives**

- a) To establish regulatory framework for post marketing surveillance
- b) To equip the Quality Control Laboratory for PMS activities
- c) To build the capacity for Rwanda FDA staff to undertake PMS activities
- d) To carry out sampling and testing of selected products
- e) To conduct quality control tests on the samples obtained using validated and/or approved methods
- f) To provide evidence based test results to inform regulatory action against identified substandard products

## **3. Methodology**

### **3.1 Regulatory framework**

- ☐ A technical assistance will be needed for drafting the PMS regulation and different stages of document approval including stakeholder's consultation for inputs and ideas
- ☐ Rwanda FDA will develop the PMS guideline and SOPs to provide guidance on conduct of Post marketing surveillance activities in Rwanda and also different tools will be developed including forms, formats as per Rwanda FDA Quality Management system

**Table 1: PMS REGULATORY FRAMEWORK/STATUSTORY DOCUMENTS 2020-2021**

S/ N	PMS Component	Action item category	Description	Targets for Completion (2012020)				Responsibl e Entity	Document/Deliverabl e
				Q1	Q2	Q3	Q4		
1	Legal Framework	Regulation	Regulation to stipulate that any PMS activity must be done by the FDA.	X				Rwanda FDA	Regulations on PMS
			Regulation to stipulate that any medical product quality survey in the country must be supervised by the FDA						
			Requirements for manufacturers, Importers, distributors and Healthcare institutions to inform FDA of any suspicious or defective medical products						
			Mandate to collect and test samples of medical products from supply chain. Should include authority to collect samples without payments						
			Define Administrative sanctions, including provisions for withdrawal of marketing authorizations						

			recall and disposal of seized or confiscated medical product						
2	Guidelines	Human Resources	PMS Guidelines should indicate clear roles and responsibilities for Inspectors, MAH, and PMS staff		x			Rwanda FDA	PMS Guidelines
		Management and Planning	Include in PMS guidelines - stakeholders involvement in planning of PMS should include health programs and FDA staff					Rwanda FDA	
		Sampling and Testing	Develop guidelines on how to implement PMS.					Rwanda FDA	
		Enforcement Actions	Develop guidelines for recall and disposal of seized or confiscated medical product. Need a guideline to address waste management for medical products.					Rwanda FDA	Guidelines on Recall and Disposal of Medicine or Health commodities
		Communication	Define "other concerned persons" and include communication to relevant stakeholders					Rwanda FDA	PMS Guidelines
3	SOPs	SOPs	Analytical procedures		x				Lab SOP on multiple subjects related to PMS testing and staff training

### **3.2 Capacity building**

Rwanda FDA will identify PMS capacity building needs for respective staff for proper conduct of PMS activities and will partner with stakeholders in the capacity building

### **3.3 Sampling and Quality Testing**

Rwanda FDA will conduct a cross-sectional survey whereby products will be picked from selected facilities, along the supply chain from both Private and Public sector at different levels including Central, regional and district levels. The survey will utilize the principles and tool of PMQS in LMICi to determine the sample sites (location), the sample size and the number of products to be picked from a given sample site.

#### **3.3.1 Survey period**

The post marketing surveillance activities will be conducted from **July 2020 to June 2021**.

#### **3.3.2 Samples to be picked per quarter**

Samples shall be collected on campaign basis where specific products shall be sampled per quarter per different levels

#### **3.3.3 Criteria for selection of products**

The specific criterion for selection of the molecules and the products is as below.

- a) Previous or current reports and complaints of inferior quality within the last 12 months
- c) Products with previous reported serious unexpected adverse drug reactions.
- d) Products which have previously failed quality tests from Quality Control Laboratory reports
- e) Products which have been flagged by other regulatory authorities
- f) Products on donor-funded PMS programs (WHO, GF etc.)
- g) Products for the management of different diseases
- f) Products widely used
- g) Orphan medicines

### 3.3.4 The number of samples per category of product

Using the Medicine Risk-Based Surveillance Tool developed by USP, the sample size of medicines and facilities to sample from were determined as elaborated in section 3.1 above. Fischer's formula was used. below to determine the appropriate sample size.

$$n_0 = Z^2 p(1-p) / e^2$$

Where

- a)  $n_0$  is the sample size (in this case number of facilities from which samples are to be picked)
- b)  $Z$  is the *Z value* (e.g. 1.96 for 95% confidence level) and  $Z^2$  is the normal curve that cuts off an area ( $\alpha$  at the tails).
- c)  $e$  is the desired level of precision
- d)  $p$  is the estimated proportion of an attribute that is present in the population or otherwise the prevalence

### 3.3.5 Choice of sample collection sites

#### Collection sites and sampling methods

Samples will be collected from all 4 provinces and the City of Kigali across the country. The specific sampling sites will be determined by the use of the RB-Sampling tool and samples will be collected by campaign method.

### 3.3.6 Distribution of sample collection site

Province	Distribution level	Facility type
1. City of Kigali 2. Western Province 3. Eastern Province	Level 1	<ul style="list-style-type: none"><li>- Central medical store</li><li>- Ports of entry</li><li>- Wholesale pharmacies</li></ul>
1 City of Kigali 2. Western Province 3. Eastern Province 4. Southern Province 5. Northern Province	Level 2	<ul style="list-style-type: none"><li>- Retail Pharmacies</li><li>- Public Hospitals</li><li>- Private Hospitals</li></ul>

1. City of Kigali Level	Level 3	<ul style="list-style-type: none"> <li>- Health centers</li> <li>- Private clinics/NGO clinics</li> </ul>
2. Western Province		
3. Eastern Province		
4. Southern Province		
5. Northern Province		

### **3.4 Sample collection**

For purposes of the PMS, a sample means an item collected from each medicine's presentation (identified by the name, packaging label, content of APIs, dosage form, strength, batch number and manufacturer) at the same collection site. Hence a product of the same: name, packaging, content of APIs, dosage form, strength, batch number and from the same manufacturer collected in two different sites represents two samples.

There will be periodic data review on the brands picked to avoid leaning on one brand but encourage picking diverse brands from the categories of drugs to be sampled.

Wherever practical, the samples shall be collected from the private and public sectors and the private not for profit / NGOs sector.

Where necessary especially private sector payment for samples will be made by the sampling team from Rwanda FDA of at the time of collection of samples from the drug outlets. Original headed receipts or stamped receipts from the pharmaceutical facility indicating the name and location of the medicines facility shall be obtained for accountability purposes.

### **3.5 Sampling guide**

a) Number of dosage units collected per sample should be specified for each sample in *Annex 13* and the SOP for sampling shall be followed.

b) Only un-opened original packages shall be collected, the number of units per sample shall be dependent on the pack size.

c) If there are less tablets or suspension available for a particular batch than required, the sample shall not be collected and another batch shall consequently be selected.

- d) If there are two or more strengths of the same brand available for sampling, samples with the lower strength(s) should be collected.
- e) If there are two or more pack sizes of the same brand available for sampling, samples with the biggest pack size(s) should be collected.
- f) Samples of different brands should be collected rather than several batches of the same brand. If more than required numbers of brands are available for sampling, priority should be given to the most used brands and brands with previous complaints. Whenever the required information is not available, it should be indicated by “NA” in the appropriate space on the sample collection form, where also any abnormalities should be recorded.
- g) Samples should be identified by a unique sample code following the SOP on Sampling.
- h) During sample collection the visual inspection should be performed at the site should be evaluated and described in the sample collection form (**Tool for Visual Inspection of Medicines**)



### Budget for PMS activities 2020/2021

PLANNED PMS ACTIVITIES AND BUDGET BY RWANDA FDA IN FISCAL YEAR 2020/2021									
S/N	PMS Component	Action item category	Activities	Timeline 2020 /2020				Budget(USD)	Document/Deliverable
				Q1	Q2	Q3	Q4		
1	Legal Framework	Regulation	Develop the PMS regulation in Rwanda	x				30,000	Approved PMS Regulations
2	Sampling and Testing	Guidelines	Develop guidelines on how to implement PMS.	x				20,000	Approved PMS Guidelines
3		SOPs	Develop PMS SOPs	x					Approved SOP
4	Capacity building		Training of FDA staff in PMS		x			60,000	Staff trained
5	Laboratory	Purchase Laboratory equipments	Procure lab equipments to support PMS activities		x			2, 271,300.00	Functional QC Laboratory
6		Laboratory testing	Purchase Laboratory reagents		x			500,000.00	Good quality lab reagent available
7			Purchase samples from the market					30,000	sample bought
8			Sampling from the market					40,000	Sampling performed

			Quality control analysis (Internal )	x	x	x	x		Quality control report available
9			Quality control analysis (External QC Prequalified Laboratory )	x	x	x	x	150,000	Quality control report available
			<b>Total</b>					3,101,300	-

**Annex 1: Sampling plan for medicines**

S/N	PRODUCTS NAMES	QUANTITY TO SAMPLE	SOURCE OF SAMPLES
1	Abacavir Tablets	4 boxes	RMS Branches
2	Abacavir and Lamivudine Tablets	4 boxes	RMS Branches
3	Acetaminophen or <b>Paracetamol</b> Tablets	200	Wholesale&retail levels
4	Acetaminophen Extended /sustained/prolonged-Release Tablets	200	Wholesale&retail levels
5	Aciclovir Tablets	200	RMS Branches
6	Acyclovir capsules	200	RMS Branches
7	Acyclovir tablets	200	RMS Branches
8	Albendazole tablets	200	Retail, Wholesale and RMS Branches
9	Albendazole chewable tablets	200	Retail, Wholesale and RMS Branches
10	Allopurinol tablets	200	Retail, Wholesale and RMS Branches
11	Aminophylline tablets	200	Retail, Wholesale and RMS Branches
12	Aminophylline Delayed-Release/ Enteric-coated/ Gastro-resistant Tablets	200	Retail, Wholesale and RMS Branches
13	Amitriptyline Hydrochloride tablets	200	Retail, Wholesale and RMS Branches
14	Amlodipine besylate tablets	200	Retail, Wholesale and RMS Branches
15	Amoxicillin capsules	200	Retail, Wholesale and RMS Branches
16	Amoxicillin tablets	200	Retail, Wholesale and RMS Branches
17	Amoxicillin and Clavulanate Potassium tablets	200	Retail, Wholesale and RMS Branches
18	Amoxicillin and Clavulanic Acid Extended /sustained/prolonged-Release Tablets	200	Retail, Wholesale and RMS Branches

19	Ascorbic acid tablets	200	Retail, Wholesale and RMS Branches
20	Atenolol tablets	200	Retail, Wholesale and RMS Branches
21	Bisacodyl Delayed-Release/ Enteric-coated/ Gastro-resistant Tablets	200	Retail, Wholesale and RMS Branches
22	Captopril tablets	200	Retail, Wholesale and RMS Branches
23	Carbamazepine tablets	200	Retail, Wholesale and RMS Branches
24	Carbamazepine Extended /sustained/prolonged- Release Tablets	200	Retail, Wholesale and RMS Branches
25	Cephalexin capsules	200	Retail, Wholesale and RMS Branches
26	Cephalexin tablets	200	Retail, Wholesale and RMS Branches
27	Chloramphenicol capsules	200	Retail, Wholesale and RMS Branches
28	Chlorpheniramine maleate tablets	200	Retail, Wholesale and RMS Branches
29	Chlorpromazine hydrochloride tablets	200	Retail, Wholesale and RMS Branches
30	Cimetidine tablets	200	Retail, Wholesale and RMS Branches
31	Ciprofloxacin hydrochloride tablets	200	Retail, Wholesale and RMS Branches
32	Ciprofloxacin hydrochloride Extended /sustained/prolonged- Release Tablets	200	Retail, Wholesale and RMS Branches
33	Clarithromycin tablets	200	Retail, Wholesale and RMS Branches
34	Clarithromycin Extended /sustained/prolonged- Release Tablets	200	Retail, Wholesale and RMS Branches
35	Clomiphene Citrate Tablets	200	Retail, Wholesale and RMS Branches
36	CoartemArtemether/Lumefantrine Tablets	200	Retail, Wholesale and RMS Branches
37	Diclofenac sodium Delayed-Release/	200	

	Enteric-coated/ Gastro-resistant Tablets		Retail, Wholesale and RMS Branches
38	Diclofenac sodium Extended /sustained/prolonged- Release Tablets	200	Retail, Wholesale and RMS Branches
39	Diclofenac sodium and Misoprostol Delayed-Release/ Enteric-coated/ Gastro-resistant Tablets	200	Retail, Wholesale and RMS Branches
40	Doxycycline Capsules	200	Retail, Wholesale and RMS Branches
41	Doxycycline Extended /sustained/prolonged- Release Capsules	200	Retail, Wholesale and RMS Branches
42	Doxycycline hyclate Capsules	200	Retail, Wholesale and RMS Branches
43	Doxycycline hyclate Delayed-Release/ Enteric-coated/ Gastro-resistant Capsules	200	Retail, Wholesale and RMS Branches
44	Doxycycline hyclate Tablets	200	Retail, Wholesale and RMS Branches
45	Doxycycline hyclate Delayed-Release/ Enteric-coated/ Gastro-resistant Tablets	200	Retail, Wholesale and RMS Branches
46	Efavirenz Capsules	200	Retail, Wholesale and RMS Branches
47	Efavirenz Tablets	200	Retail, Wholesale and RMS Branches
48	Ethambutol Hydrochloride Tablets	200	Retail, Wholesale and RMS Branches
49	Fluconazole Tablets	200	Retail, Wholesale and RMS Branches
50	Folic acid Tablets	200	Retail, Wholesale and RMS Branches
51	Furosemide Tablets	200	Retail, Wholesale and RMS Branches
53	Griseofulvin Tablets	200	Retail, Wholesale and RMS Branches
54	Haloperidol Tablets	200	Retail, Wholesale and RMS Branches

55	Hydrochlorothiazide Capsules	200	Retail, Wholesale and RMS Branches
56	Hydrochlorothiazide Tablets	200	Retail, Wholesale and RMS Branches
57	Indomethacin Capsules	200	Retail, Wholesale and RMS Branches
58	Indomethacin Extended /sustained/prolonged-Release Capsules	200	Retail, Wholesale and RMS Branches
59	Isoniazid Tablets	200	Retail, Wholesale and RMS Branches
60	Kanamycin Sulfate Capsules	200	Retail, Wholesale and RMS Branches
61	Kanamycin powder for injection	40	Retail, Wholesale and RMS Branches
62	Ketoconazole Tablets	200	Retail, Wholesale and RMS Branches
63	Lamivudine Tablets	4 boxes	Retail, Wholesale and RMS Branches
64	Lamivudine and Zidovudine Tablets	4 boxes	RMS Branches
65	Lamivudine ,Zidovudine and Nevirapine Tablets	4 boxes	RMS Branches
66	Lamivudine ,Tenofovir and Effavirenz Tablets	4 boxes	RMS Branches
67	Lamivudine and Tenofovir Tablets	4 boxes	RMS Branches
68	Loperamide hydrochloride Capsules	200	Retail, Wholesale and RMS Branches
69	Loperamide hydrochloride Tablets	200	Retail, Wholesale and RMS Branches
70	Losartan potassium Tablets	200	Retail, Wholesale and RMS Branches
71	Mebendazole Tablets	200	Retail, Wholesale and RMS Branches
72	Metformin hydrochloride Tablets	200	Retail, Wholesale and RMS Branches
73	Metformin hydrochloride Extended /sustained/prolonged-Release Tablets	200	Retail, Wholesale and RMS Branches
74	Metoclopramide Tablets	200	Retail, Wholesale and RMS Branches
75	Metronidazole Capsules	200	Retail, Wholesale and RMS Branches

76	Metronidazole Tablets	200	Retail, Wholesale and RMS Branches
77	Metronidazole Extended /sustained/prolonged-Release Tablets	200	Retail, Wholesale and RMS Branches
78	Misoprostol Tablets	200	Retail, Wholesale and RMS Branches
79	Nalidixic acid Tablets	200	Retail, Wholesale and RMS Branches
80	Nevirapine Tablets	200	Retail, Wholesale and RMS Branches
81	Nevirapine Extended /sustained/prolonged-Release Tablets	200	Retail, Wholesale and RMS Branches
82	Nifedipine Capsules	200	Retail, Wholesale and RMS Branches
83	Nifedipine Extended /sustained/prolonged-Release Tablets	200	Retail, Wholesale and RMS Branches
84	Nitrofurantoin Capsules	200	Retail, Wholesale and RMS Branches
85	Norfloxacin Tablets	200	Retail, Wholesale and RMS Branches
86	Nystatin Tablets	200	Retail, Wholesale and RMS Branches
87	Ofloxacin Tablets	200	Retail, Wholesale and RMS Branches
88	Omeprazole Delayed-Release/ Enteric-coated/ Gastro-resistant Capsules	200	Retail, Wholesale and RMS Branches
89	Oxytocin injection	40	Retail, Wholesale and RMS Branches
90	PommadeCamphree	5	Retail, Wholesale and RMS Branches
91	Promethazine hydrochloride Tablets	200	Retail, Wholesale and RMS Branches
92	Propranolol hydrochloride Extended /sustained/prolonged-Release Capsules	200	Retail, Wholesale and RMS Branches
93	Propranolol hydrochloride Tablets	200	Retail, Wholesale and RMS Branches

94	Pyrazinamide Tablets	200	Retail, Wholesale and RMS Branches
95	Pyridoxine Hydrochloride Tablets	200	Retail, Wholesale and RMS Branches
96	Quinine sulfate Capsules	200	Retail, Wholesale and RMS Branches
97	Quinine sulfate Tablets	200	Retail, Wholesale and RMS Branches
98	Ranitidine Tablets	200	Retail, Wholesale and RMS Branches
99	Riboflavin (Vitamin B2) Tablets	200	Retail, Wholesale and RMS Branches
100	Rifabutin Capsules	200	Retail, Wholesale and RMS Branches
101	Rifampicin Capsules	200	Retail, Wholesale and RMS Branches
102	Rifampicin powder for injection	200	Retail, Wholesale and RMS Branches
103	Rifampicin and Isoniazid Tablets	200	Retail, Wholesale and RMS Branches
104	Rifampicin ,Isoniazide and Ethambutol Hydrochloride Tablets	200	Retail, Wholesale and RMS Branches
105	Rifampicin ,Isoniazid ,Pyrazinamide and Ethambutol Hydrochloride Tablets	200	Retail, Wholesale and RMS Branches
106	Rifampicin ,Isoniazid and Pyrazinamide Tablets	200	Retail, Wholesale and RMS Branches
107	Streptomycin sulfate for injection	40	Retail, Wholesale and RMS Branches
108	Sulfamethoxazole and Trimethoprim Tablets or Co-Trimoxazole	200	Retail, Wholesale and RMS Branches
109	Thiamine hydrochloride Tablets	200	Retail, Wholesale and RMS Branches
110	Tinidazole Tablets	200	Retail, Wholesale and RMS Branches
111	Tramadol hydrochloride Tablets	200	Retail, Wholesale and RMS Branches
112	Tramadol hydrochloride Extended /sustained/prolonged-Release Tablets	200	Retail, Wholesale and RMS Branches



113	Tramadol hydrochloride and Acetaminophen/paracetamol Tablets	200	Retail, Wholesale and RMS Branches
114	Warfarin sodium Tablets	200	Retail, Wholesale and RMS Branches
115	Zidovudine Capsules	4 boxes	RMS Branches
116	Zidovudine Tablets	4 boxes	RMS Branches
117	Zinc Sulfate Tablets	200	Retail, Wholesale and RMS Branches
118	Ethanol based hand sanitizers	200	Retail, Wholesale and RMS Branches
119	Isopropyl alcohol based hand sanitizers	2	Retail, Wholesale and RMS Branches
120	SYRUPS, POWDERS AND SUSPENSION Related to the tablet on the above	5	Retail, Wholesale and RMS Branches

**Annex 2: POST MARKETING SURVEILLANCE PROGRAMME**  
**SAMPLE COLLECTION FORM**

1. Sample code: .....  
 (Region/product/sequence number/sampling date...../...../.....)
2. Name & Address of Premises where sample was taken:
  - a. Physical Address.....
  - b. Postal address.....
  - c. Telephone No.....
  - d. Email address..... (if applicable)
3. Product name of the sample: .....
  - a. Description/identification (colour).....
  - b. Name of active pharmaceutical ingredient(s) (INN)
  - c. Strength .....
  - d. Dosage form (tablet, oral powder, etc): .....
  - e. Package size & type: .....
  - f. Batch/lot number: .....
  - g. Date of manufacture: .....Expiry date.....
4. Name and physical address of the manufacturer: .....
5. Number of units collected (tins, packet).....
6. Is the product registered in the country? Yes/ No.
  - a. If Yes, indicate the registration number: .....
7. Storage condition of product at the premises:.....
8. Details of representative of the premises and Drug Inspector (s)/Sampling officer(s)

<b>S.N o</b>	<b>Name</b>	<b>Organization</b>	<b>Signature</b>	<b>Date</b>

**Note: Samples collected must remain in their original containers**

**Annex 3: Table 2: Samples to be selected and respective parameters**

S/N	Products Names (Medical drugs)	Parameters	Justification	Quarter for sampling
1	Paracetamol Tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Highly consumed	Q1
2	Albendazole tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Reported in the QCL report to be of poor Quality	Q1
3	Amitriptyline Hydrochloride tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Program medicines (Mental Health)	Q1
4	Amlodipine besylate tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Program medicines (NCD)	Q2
5	Amoxicillin tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Highly consumed	Q1
6	Amoxicillin and Clavulanate Potassium tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Highly consumed	Q2
7	Bipivacaine 0.5 % inj sinal	Identification,pH Assay, Extratcable volume, sterility, Related substances	Reported in quality complaints from Health facilities	Q1
8	Captopril tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Highly consumed medicines (NCDs)	Q1
9	Carbamazepine tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Program medicines (Mental Health)	Q3
10	Cimetidine tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Highly consumed medeciens	Q3
11	Ciprofloxacin hydrochloride tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Reported in quality complaints from Health facilities	Q2
12	CoartemArtemether/Lumefantrine Tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Program medicines ( Malaria)	Q1

13	Diclofenac sodium Delayed-Release/ Enteric-coated/ Gastro-resistant Tablets	Identification, Assay, Disintegration and Dissolution	Reported by health facility to be associated with safety issues	Q2
14	Misoprostol 200ug tablets	Identification, Assay, Disintegration and Dissolution	Reported by QCL to be of Poor Quality	Q2
15	RHZE	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Program medicines (Tuberculosis)	Q3
16	Hydrochlorothiazide Tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Highly consumed medicines (NCDs)	Q2
17	Lamivudine ,Tenofovir and Effavirenz Tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Program medicines (HIV)	Q4
18	Lamivudine and Tenofovir Tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Program medicines (HIV)	Q4
19	Ledipasvir/sofosbuvir 90-400mg	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Reported to be inefficacious by health facility	Q2
20	Metformin hydrochloride Tablets	Highly consumed	Highly consumed (NCD program)	Q4
21	Nifedipine Extended /sustained/prolonged- Release Tablets	Identification, Assay and <b>Dissolution</b>	Highly consumed (NCD program)	Q4
22	Omeprazole Delayed-Release/ Enteric-coated/ Gastro-resistant Capsules	Identification, Assay, Disintegration and Dissolution	Highly consumed medicines)	Q3
23	Oxytocin injection	Identification,pH, Assay, sterility and related substances	Reported by Health Facility to be of poor quality	Q2
24	Tramadol hydrochloride Tablets	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Reported by Health Facility to be of poor quality	Q2
25	Phenobarbital tables	Identification, Assay, uniformity of weight, Friability, Disintegration and Dissolution	Suspected to be of poor quality	Q1

26	Gentamycin inj	Identification,pH, Assay, sterility and related substances	Reported by other regulatory authority to be of poor quality	Q1
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