Doc. No. TMDA/DMC/CTPV/PMS/R/005

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA

Tanzania Medicines & Medical Devices Authority

ANNUAL POST MARKETING SURVEILLANCE (PMS) REPORT FOR SELECTED HUMAN AND VETERINARY MEDICINES CIRCULATING IN TANZANIA

2019/2020

ISSUE 10

Contents

Abbreviations

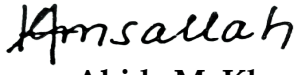
ADDO	-Accredited Drug Dispensing Outlet
DG	- Director General
DLS	- Directorate of Laboratory Services
DMC	- Directorate of Medical Products Control
GMP	- Good Manufacturing Practices
HC	- Health Centre
LGAs	- Local Government Authorities
MAH	- Marketing Authorization Holders
MOHCDGEC	- Ministry of Health, Community Development, Gender, Elderly and Children
MSD	- Medical Stores Department
PIR	- Product Information Review
PMS	- Post Marketing Surveillance
QA	- Quality Assurance
QC	- Quality Control
SOPs	- Standard Operating Procedures
SPC	- Summary of Product Characteristics
TMDA	- Tanzania Medicines and Medical Devices Authority
TLC	- Thin Layer Chromatography
WHO	- World Health Organization

Acknowledgement

I would like to take this opportunity on behalf of TMDA Management to thank those who in one way or another assisted in preparing this document. Special thanks are extended to the following: Mr Sunday Kisoma, Ms. Kissa Mwamwitwa, Dr. Henry Irunde, Dr. Betty Maganda, Mr. Seth Kisenge, Mr. Moses Nandonde, Dr. Goodluck Gotora, Dr. Elirehema Mfinanga, Dr. Emmanuel Mutakyahwa, Ms Nellin Shiletiwa, Mr. Japhari Mtoro, Ms. Doreen Nyaki, Mr. Maganga Bundala and Mr. Wigilya Mikomangwa who worked tirelessly in the development of this report.

I also appreciate the secretarial services which were offered by Ms. Joyce Komba. Similarly, I would like to thank all TMDA Zone Managers, TMDA section which coordinates PMS activities, drug inspectors who participated in sample collection; evaluator's who reviewed the product information and analysts who carried out laboratory testing for their valuable inputs in developing this document.

Finally, I appreciate the contribution of TMDA management for their support and leadership which facilitated the successful implementation of the PMS activities.



Akida M. Khea
ACTING DIRECTOR MEDICAL PRODUCTS CONTROL
TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

FOREWORD

Monitoring of the quality, safety and efficacy of medicines circulating in the market is fundamental in protecting public health. Routine surveillance of medicines after registration (Post Marketing Surveillance - PMS) is one of the key responsibilities of a functional national medicine's regulatory authority. PMS helps medicines users, especially patients, who are key stakeholders in the pharmaceutical industry, to build confidence in the medicines they use that they will meet the expected standards for quality, safety and ultimately treat the intended diseases.

PMS also helps to timely detect and remove falsified and substandard medicines from the market thus protecting the public against the possible hazards associated with their use.

In view of this importance, Tanzania Medicines and Medical Devices Authority has developed and maintained a PMS system since 2009. The Authority has been developing a three-year PMS program where selected registered medicines are monitored based on a variety of risk criteria including reports of complaints from various stakeholders. The implementation of the plan was divided into four phases (I - IV), and in each phase, a sampling plan was set based on various risk criteria.

A total of 485 samples were collected from the market in representative regions countrywide using a carefully designed sampling plan. After collection, product information review (PIR) was performed and later on laboratory testing on selected critical parameters was carried out. Out of these, 273 (56%) were human and, 212 (44%) were veterinary medicines. Results for PIR indicated that 226 samples (46.60%) had various deficiencies at the PIR stage whereby 63.27% were human and 36.73% were veterinary medicines.

The remarkable deficiencies observed during PIR included lack of the name and physical address of the product's manufacturer, improper storage condition, different shelf lives from the approved ones or lack of manufacturing and expiry dates altogether.

Of all samples which were subjected to confirmatory laboratory testing, only one sample (Albendazole 10% suspension – for veterinary use) failed the assay test.

The report presents methodology and detailed results for PMS of selected medicines for 2019 and 2020.

Overall, the PMS exercise was excellently planned and the execution was well coordinated. Implementation was carried out by various dedicated stakeholders within and outside TMDA. Key lessons learned from the PMS exercise will be used to improve the quality, safety and ultimately efficacy of medicines circulating in Tanzanian market.

Moreover, it will assist TMDA to improve the subsequent PMS programes and ultimately protect public health.

I would like to commend all esteemed stakeholders involved including our collaborators and partners for making the 2019/20 PMS programme success.

Adam Mitangu Fimbo
ACTING DIRECTOR GENERAL
TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Executive Summary

In the financial year 2019/20, TMDA assessed the quality of selected human and veterinary medicines circulating on the market as part of implementation of the three years (2017 – 2020) PMS program. The selected human medicines were Ciprofloxacin, Amoxicillin DT, Furosemide tablets and oxytocin Injection, while Albendazole suspension 2.5% and 10%, Diminezene diaceturate powder for injection were selected for veterinary medicines.

Systematic method for sample collection was used where by samples were collected from public and private hospitals, pharmacies, dispensaries, accredited drugs dispensing outlets (ADDOs), Medical Stores Department (MSD) and veterinary medicines outlets. The outlets were located in Mwanza, Dar es Salaam, Ruvuma, Morogoro, Geita, Dodoma, Singida, Kagera, Arusha, Mbeya, Songwe, Lindi, Mtwara, Kigoma, Mara, Simiyu, Katavi, Manyara and Shinyanga.

A total of 273 (58.3%) samples of human and 212 (132.5%) veterinary medicines were collected out of 468 and 160 planned samples respectively.

All sampled medicines with exception of oxytocin injection were subjected to Tier I screening tests which involved Product Information Review (PIR) and laboratory screening test. Results of PIR revealed that 143 samples out of 274 (52.2%) of human medicines and 83 out of 211 (39,3%) of veterinary medicines did not comply with requirements. The Marketing Authorization Holders (MAH) of the samples failed PIR were directed to comply with labeling requirements.

All samples of human medicines subjected to screening test passed while one of veterinary medicine failed

A total of 53 samples, (28 human medicines and 25 veterinary medicines) were taken to Tier II confirmatory testing at TMDA-WHO prequalified laboratory. Among 53 samples, 52 passed the tests while one sample of Albendazole suspension failed and it was withdrawn from the market.

Generally, laboratory test results of the selected medicines with exception of Albendazole suspension showed compliance to specifications which indicate functioning of regulatory systems in the country.

1. Introduction

Globally, substandard and falsified medicines pose a serious public health problem as they may cause harm to patients and fail to treat the diseases for which they were intended. Equally alarming, falsified and substandard medicines contribute to antimicrobial resistance and drug resistant infections.

In order to protect the public against falsified and substandard medicines, Tanzania Medicines and Medical Devices Authority (TMDA) conducts a regular and structured Post Marketing Surveillance (PMS) of selected registered medicines in Tanzanian market in order to ascertain the quality standard in compliance. PMS is a systematic quality assurance measure to monitor quality of registered medicines and it aims at establishing the status of quality of medicines circulating in Tanzanian market and protects the public against falsified and substandard medicines. It provides valuable information on the quality of medicines once they enter the market, the information which is often unavailable prior and during registration process.

The PMS is implemented through systematic and meticulous planning using a pre-defined sampling plan of medicines circulating in the market. The focus is to ensure a fitting representation of medicines targeting human and veterinary priority diseases in the country. Sample collection for selected medicines was conducted by trained and qualified sample collectors in line with the pre-determined sampling plan.

Sampling was conducted in 20 regions (Dar es Salaam, Pwani, Arusha, Manyara, Dodoma, Morogoro, Singida, Mbeya, Songwe, Katavi, Ruvuma, Lindi, Mtwara, Mwanza, Mara, Kagera, Simiyu, Shinyanga, Tabora na Kigoma) involving human and veterinary medicines which were collected from Medical Stores Department (MSD) the supplier of medicines and medical products to public health facilities in Tanzania. Also, from public and private health facilities, whole sale and retail pharmacy outlets; accredited drug dispensing outlets (ADDO), the lowest access point of medicines in Tanzania and from veterinary outlets in the same regions. Both private and public medicines distribution channels were involved.

The studied medicines included Ergometrine, Oxytocin, Ciprofloxacin tablets, Furosemide IV, Ammoxicillin Dispersible Tablets for human use and Diminazene Diaceturate, Albendazole (2.5% & 10%) suspension and Enrofloxacin solution for veterinary use.

The scope of the PMS included screening which incorporated review of product information (summary of product characteristics, package leaflet and labelling) and preliminary laboratory tests such as appearance, disintegration and identification. Of these, 10% of the medicines which passed this screening procedures and all medicines

which didn't pass were subjected to laboratory confirmatory tests (assay, dissolution, related substances and content of uniformity of dosage unity).

All sampled human and veterinary medicines were analysed at TMDA - a World Health Organization (WHO) pre- qualified Laboratory to ascertain quality. This report highlights results obtained and regulatory actions taken by TMDA.

2. OBJECTIVES

2.1. Broad Objective

To determine quality of selected human and veterinary medicines circulating on Tanzanian market in the year 2019/20 as per the sampling plan.

2.2. Specific Objectives

The specific objectives of the surveillance were: -

2.2.1. To determine compliance of collected medicines samples to labelling requirements by conducting PIR.

2.2.2. To establish quality of selected medicines samples by conducting laboratory quality control tests.

2.2.3. To take relevant regulatory action(s) and propose strategiesto address the problems identified by the survey.

2.3. Exploratory Objective

To determine availability of the selected medicines i.e Ergometrine IV, Oxytocin, Ciprofloxacin tablets, Furosemide IV, Amoxicillin Dispersible Tablets for human use: and Diminazene Diaceturate, Albendazole (2.5% & 10%) suspension and Enrofloxacin solution for veterinary use.

3. METHODOLOGY

3.1. Medicines Selection

Medicines for quality monitoring were selected based on the following criteria:

a) Medicines that are used for treating diseases of public health importance;
b) Medicines which were confirmed to be of poor quality in the previous PMS programmes;
c) Medicines which are used by special groups of people at risk such as children and pregnant women;
d) Medicines that are irrationally prescribed and dispensed;
e) Medicines that are prone to resistance due to non-adherence;
f) First line medicines with complicated dosage regimen; and
g) Medicines which require prolonged administration to a larger population and a number of them are used in combination.

3.2. **Sampling sites**

Samples were collected from randomly selected sites which included Medical Stores Department (MSD), public and private hospitals, health centres, dispensaries, importers, wholesale and retail pharmacies in 20 selected regions of the country.

The regions were selected based on the following criteria: -

a) Regions bordering other countries;
b) Regions that are not frequently inspected;
c) Areas reported to have medicines quality problems;
d) Regions not involved in the previous PMS programmes; and
e) Disease endemicity.

3.3. **Sampling**

3.3.1. Collection of Samples

Collection of samples at various levels of supply chain was based on the developed sampling plans. Sampling plans were prepared and contained detailed information on sampling sites at regional and district levels, product name, number of brands to be collected, dosage forms, strength and pack size. Sampling plans are attached as **Annex I.** Samples were collected according to Standard Operating Procedure No…by trained medicine inspectors from TMDA and Local Government Authorities. Samples were collected in their original containers and/or packages together with their package insert. Details of the collected samples were recorded in the sample collection form attached as **Annex II**.

3.3.2. Sample handling and transportation

Each collected sample was coded according to prescribed coding format. Coding was done to identify samples collected from different sampling sites and thus helped to differentiate and avoid mix up. Coded samples with respective sampling form were kept in the labelled sampling bags and sealed there after taken to TMDA zonal offices for data entry in Regulatory Information Management System (RIMS).

On completion samples were transported to TMDA HQ Sub Office for screening and confirmatory testing. Before and after transportation of samples, measures were taken to ensure that samples were stored according to manufacturers' recommended storage conditions as prescribed in the product labels.

4. Sample Analysis

4.1. Screening

Screening tests involved Product Information Review (PIR), physical/visual inspection, disintegration test and identification test by Thin Layer Chromatography (TLC) or UV – Vis Spectrophotometer.

4.1.1. Product Information Review (PIR)

All samples were subjected to product information review (PIR). This involved the review of information contained on the primary and secondary packaging, package inserts and label of each sample for conformity to the TMDA approved product information and labelling requirements. Apart from appropriateness and legibility of the information on the label and associated insert, appropriateness of the type of container used, stickiness and printing on the label were also checked.

4.1.2. Physical/visual inspections

Visual inspections were conducted so as to give information about product quality prior to further laboratory testing of samples in comparison with registration information. Injectable solutions were examined for leakage, particles, homogeneity, fill volume and colour change. For the case of oral solid dosage forms color change, spots, moulds, abrasions, and odor were checked.

4.1.3. Simple disintegration Test

Disintegration test was conducted to assess the possibility of solid dosage form to break into small particles that can dissolve and undergo dissolution to release active pharmaceutical ingredient. The tablets which did not disintegrate within 30 minutes indicated dissolution problems necessitating confirmatory testing in which dissolution tests were conducted as per their respective compendial monographs.

4.1.4. Qualitative and semi – quantitative determination of API by using Thin layer Chromatography

TLC method was used for qualitative and semi - quantitative determination of Active Pharmaceutical Ingredient (API) and related degradants present in the dosage form. This method employs the principle of comparing spots obtained between test and reference standard solutions. The principal spot obtained with the test solution must correspond with the spot of the higher reference standard solutions in terms of colour, shape, size, intensity and retardation factor (Rf) value.

4.1.5. Qualitative determination by using UV - Vis Spectrophotometer

UV – Vis Spectrophotometry is an analytical method used for qualitative and quantitative determination of API in pharmaceutical dosage form. In qualitative determination, method employs spectrophotometry principle whereby maxima absorption wave length of the sample (test solution) is compared with maxima absorption of the standard solution.

4.2. Laboratory Confirmatory Testing by using compendial or manufacturer methods

All samples that failed screening tests, all those with doubtful screening results and 10% of all passed samples were selected for confirmatory testing. The confirmatory testing was performed by analysing each product as per their respective pharmacopoeial monograph requirements. The parameters investigated were physical appearance, identification, disintegration, assay, dissolution, pH, weight variation and sterility as summarized in **Table 1** below.

Table 1: Parameters investigated during confirmatory testing of selected samples

Medicine Category	Product	Parameter	Analytical Method
Human Medicines	Amoxicillin	Identification	USP 43 NF 38
		Assay	USP 43 NF 38
		Dissolution	USP 43 NF 38
		Related substance	USP 43 NF 38
	Ciprofloxacin	Identification	BP 2020
		Assay	BP 2020
		Dissolution	BP 2020
		Related substance	USP 43 NF 38
	Furosemide	Identification	BP 2020
		Assay	BP 2020
		Dissolution	BP 2020
		Uniformity	USP 43 NF 38
	Oxytocin Inj	Identification	USP 43 NF 38
		Assay	USP 43 NF 38
		Sterility	USP 43 NF 38
Veterinary Medicines	Diminezinediaceturate tetrahydrate	Identification	OIE monograph for Trypanosidal drugs Quality Control_ version
		Assay	OIE _monograph for Trypanosidal drugs Quality Control
	Albendazole 2.5 & 10%	Identification	B.P 2020
		Assay	B.P 2020

5. Results

5.1. Sample collection

A total of 485 samples of human and veterinary medicines were collected from various regions of the country in which 56.3% (273/485) and 43.7% (212/485) were human and veterinary medicines, respectively.

5.1.1. Human Medicine Samples

Samples were collected at regional level and two (2) districts from eleven (11) different regions. A total of 119 (43.6%) samples of Ciprofloxacin; 72 (26.37%) Furosemide

tablets;66 (24.2%) Amoxycillin tablets;14 (5.1%) Oxytocin injection; and 2 (0.73%) samples of Ergometrine injection were collected.
The highest number of human medicine samples were collected from Dar es Salaam region (26.01%) while the lowest number of samples were collected from Lindi (0.37%) as highlighted in **Table 2**.

Table 2: The number and type of Human Medicines samples collected per region

Region	**Antibiotics**		**Anti-hypertensive**	**Anti-postpartum hemorrhage**			**Total**
	Ciprofloxacin tablets	**Amoxycillin dispersible tablets**	**Furosemide tablets**	**Ergometrine inj**	**Oxytocin inj**		
Dar es Salaam	36	22	11	2	0		**71**
Pwani	0	1	14	0	0		**15**
Dodoma	0	0	19	0	7		**26**
Singida	0	0	15	0	0		**15**
Mwanza	0	0	13	0	3		**16**
Mara	10	6	0	0	0		**16**
Kagera	24	9	0	0	0		**33**
Kigoma	22	11	0	0	0		**33**
Simiyu	15	11	0	0	3		**29**
Lindi	0	0	0	0	1		**1**
Tabora	12	6	0	0	0		**18**
Total	**119**	**66**	**72**	**2**	**14**		**273**
Percentage (%)	**43.6**	**24.2**	**26.4**	**0.7**	**5.1**		

5.1.2. Veterinary Medicine Samples

Samples of Veterinary Medicine were collected from Dar es salaam, Dodoma, Morogoro, Mwanza, Arusha, Manyara, Mbeya, Songwe, Ruvuma, Lindi, Mtwara, Shinyanga, Simiyu and Katavi regions. These samples comprised of 37.74% (80/212) Albendazole solution, 34.43 (73/212) Diminazene Diaceturate solution and 27.83% (59/212) Enrofloxacin solution. The highest number of samples were collected from Arusha (15.09%) while Mtwara contributed the lowest number of samples (0.94%) as presented in **Table 3**.

Table 3: The number and type of Veterinary Medicines samples collected per region

Region	Albendazole solution	Diminazene Diaceturate inj.	Enrofloxacin solution	Total (%)
Dar es Salaam	6	0	16	**10.3**
Dodoma	14	0	0	**6.6**
Morogoro	0	0	14	**6.6**
Mwanza	12	0	0	**5.7**
Arusha	12	0	20	**15.1**
Manyara	0	17	0	**8.0**
Mbeya	18	0	0	**8.5**
Songwe	0	14	0	**6.6**
Ruvuma	7	0	9	**7.6**
Lindi	5	0	0	**2.4**
Mtwara	2	0	0	**0.9**
Shinyanga	0	25	0	**11.8**
Simiyu	4	0	0	**1.9**
Katavi	0	17	0	**8.0**
Total	**80**	**73**	**59**	**212**
Percentage (%)	**37.7**	**34.4**	**27.8**	

5.1.3. Samples Collection Sites

As highlighted above, samples were collected from different medicines distribution channels namely; MSD, Hospitals, Pharmacies, Health Centers, Dispensaries and Accredited Drug Dispensing Outlets (ADDOs) which are famously known as Duka la Dawa Muhimu (DLDM). The results show that, the highest number of Human Medicines samples were collected from Pharmacies 62% (98/158), followed by 26% (41/158) from hospitals and the least were sampled from ADDOs at 0.6% (1/158).

5.1.4. Distribution of sampled human and veterinary medicines by manufacturers

Almost 89.4% of the collected samples of human medicines and 86.3% of veterinary medicines were imported from different manufacturers. Furthermore, all of the sampled amoxicillin tablets, furosemide tablets, oxytocin and ergometrine injection were imported whereas 24.4% of the sampled ciprofloxacin tablets were manufactured by domestic manufacturers. Approximately 3.0%, 12.0% and 25% of the sampled Diminazene diaceturate injection, enrofloxacin solution and albendazole solution respectively, were

manufactured by domestic industries. Distribution of sampled medicine by manufacturers is presented in **Table 4(a, b, c, d)**

Table 4a: Manufacturers of Ciprofloxacin Tablet samples collected

Nr.	Product	Geographical	Manufacturer	No. of samples
1.	Ciprofloxacin Tablets	Africa (26.1%) (31/119)	Shelys Pharmaceuticals Ltd	13
			Keko Pharmaceutical Industries Ltd	7
			Zenufa Laboratories Ltd	9
			Egyptian International Pharmaceutical Industries Co. Ltd	2
		Asia (67.2%) (80/119)	Cadila Healthcare Ltd	11
			S Kant Healthcare Ltd	7
			Medley Pharmaceuticals Ltd	29
			Lincoln Pharmaceuticals Ltd	19
			Astra Lifecare (India) Pvt Ltd	13
			Theon Pharmaceuticals Ltd	1
		Europe (6.7%) (8/119)	Remedica Ltd	6
			Denk Pharma GmbH & Co Kg	2
		Total		**119**

Table 4(b): Manufacturers of Amoxicillin Dispersible Tablet, Frusemide Tablets, Oxytocin injection and Ergometrine injection samples collected

Nr.	Product	Geographical	Manufacturer	No. of samples
1.	Amoxicillin Dispersible Tablets	Asia (100.0%) (66/66)	Medopharm Pvt Ltd (India)	1
			Sparsh Bio – Tech Pvt Ltd (India)	36
			Milan Laboratories (India) Ltd	27
			Mylan Laboratories Ltd (India)	1
			Astra Lifecare (India) Pvt Ltd	1
		Total		**66**
2.	Frusemide Tablets	Africa (65.3%) (47/72)	Cosmos Limited (Kenya)	20
			Elys Chemical Industries Ltd	27
		Asia (31.9%) (23/72)	Astra Lifecare (India) Pvt Ltd	23
		Europe (2.8%) (2/72)	Remedica Ltd (Cyprus)	1
			DenkPharma GmbH&Co Kg (Germany)	1

		Total		**72**
3.	Oxytocin injection	Asia (28.6%) (4/14)	Aculife Healthcare Pvt. Ltd (India)	3
			Hebei Yuanzheng Pharmaceutical Company Ltd (China)	1
		Europe (71.4%) (10/14)	Peckforton Pharmaceuticals Limited United (Kingdom)	4
			Rotexmedica Gmbh Arzneimittelwerk (Germany)	1
			Salutus Pharma Gmbh (Germany)	5
		Total		14
4.	Ergometrine injection	Asia (100%)(2/2)	Vital Healthcare Pvt. Limited (India)	2
		Total		**2**

Table 4c: Manufacturers of Diminazene diaceturate injection,

Nr.	**Product**	**Geographical**	**Manufacturer**	**No. of samples**
1.	Diminazene diaceturate	Africa (2.7%) (2/73)	Farmers Centre Ltd (Tanzania)	2
		Asia (58.9%) (43/73)	Hebei Yuanzheng Pharmaceuticals Company Ltd (China)	29
			Chongqing Fangtong Animal Pharmaceutical Co.,Ltd (China)	7
			Ashish Life Science Pvt Limited Mumbai (India)	3
			Alivira Animal Health Limited(India)	1
			Hubei Hongyuan Pharmaceutical Co., Ltd (China)	3
		Europe (38.4%) (28/73)	*CevaSanteAnimale (France)*	14
			Kela N.V Hoogstraten (Belgium)	1
			Alfasan (Holland)	11
			LelypharmaZuiveringweg (Nertherlands)	1
			Interchemie (Nertherlands)	1
		Total		**73**

Table 4d: Manufacturers of Albendazole suspension and Enrofloxacin tablets

Nr.	Product	Geographical	Manufacturer	No. of samples
1.	Albendazole suspension	Asia (33.8%) (27/80)	Eagle Vet Tech Co., Ltd (Korea)	3
			Hebei Hope Harmony Pharmaceutical Co. Ltd (China)	1
			Hebei Yuanzheng Pharmaceutical Company Ltd (China)	23
		Africa (66.3%) (53/80)	Farmers Centre Ltd (Tanzania	20
			Medisel (K) Ltd General Kago Rd (Kenya)	1
			Nerix Pharma Limited (Kenya)	19
			Norbrook Kenya Ltd (Kenya)	13
		Total		**80**
	Enrofloxacin	Africa (11.9%) (7/59)	Farmers Centre Ltd (Tanzania)	7
		Asia (28.8%) (17/59)	AetherCentre(Beijing) Biology Co. Ltd (China)	1
			Chongqing Fangtong Animal Pharmaceutical Co., Ltd (China)	10
			Hebei Yuanzheng Pharmaceutical Company Ltd (China)	6
		Europe (59.3%) (35/59)	Kepro B.V (Nertherlands)	8
			Industrial Veterinaria, S.A (Spain)	1
			Invesa Industrial Veterinaria, S.A A Livisto Company (Spain)	6
			Tav-Vet Animal Health (Spain)	16
			VMD Livestock Pharma (Belgium)	4
		Total		**59**

Distribution of sampled human medicines by country

About two third (63.7%) of the sampled human medicines were imported from India, followed by Kenya (17.2%). Twenty-nine (10.6%) samples were manufactured in Tanzania. Germany (3.3%) and Cyprus (2.6%) contributed the sampled medicines almost in equal proportion, similar trend was observed for samples imported from Egypt (0.7%) and China (0.4%) (Figure 1)

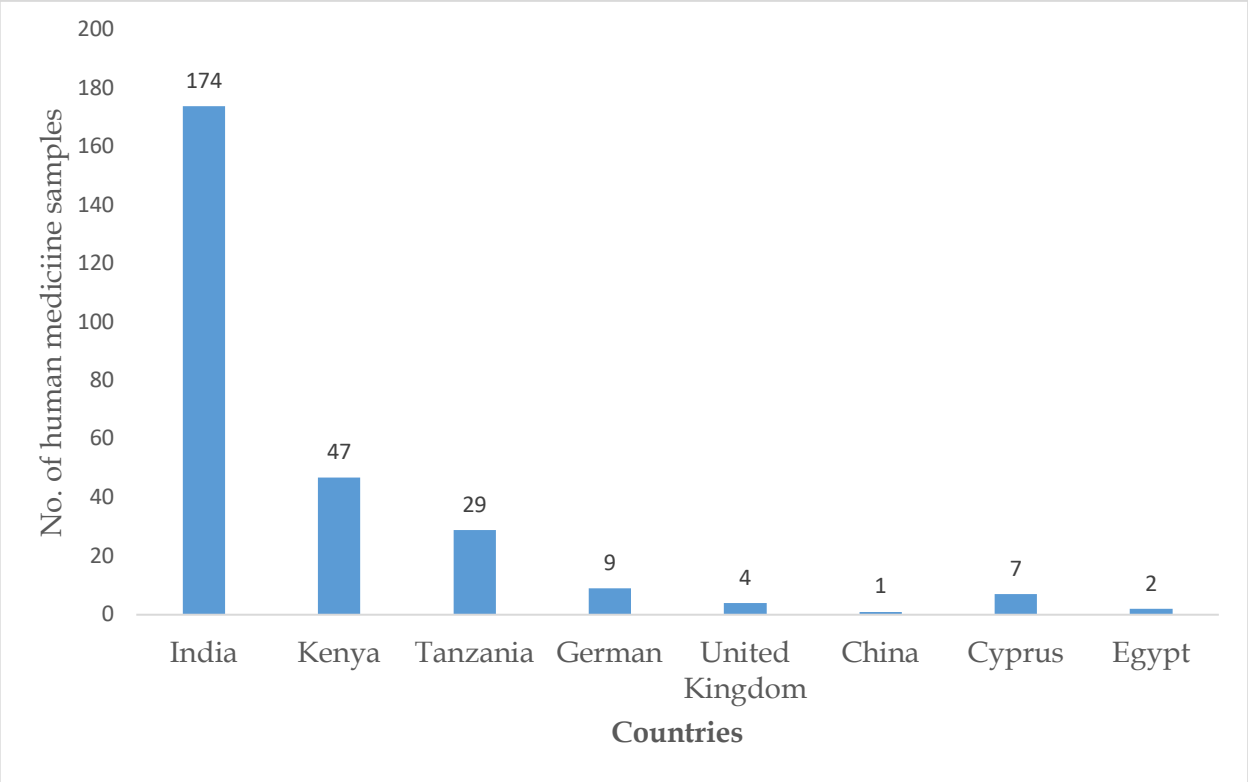


Figure No.1: Number of human medicines sampled with respect manufacturer's countries

Distribution of sampled veterinary medicines by country

Most (37.7%) of the sampled veterinary medicines were imported from China, followed by Kenya (15.6%). Twenty-nine (13.7%) samples were manufactured in Tanzania. Veterinary medicines from Spain contributed 10.9% of the collected veterinary medicines followed by France (6.6%) and Holland (5.2%). (Figure 2)

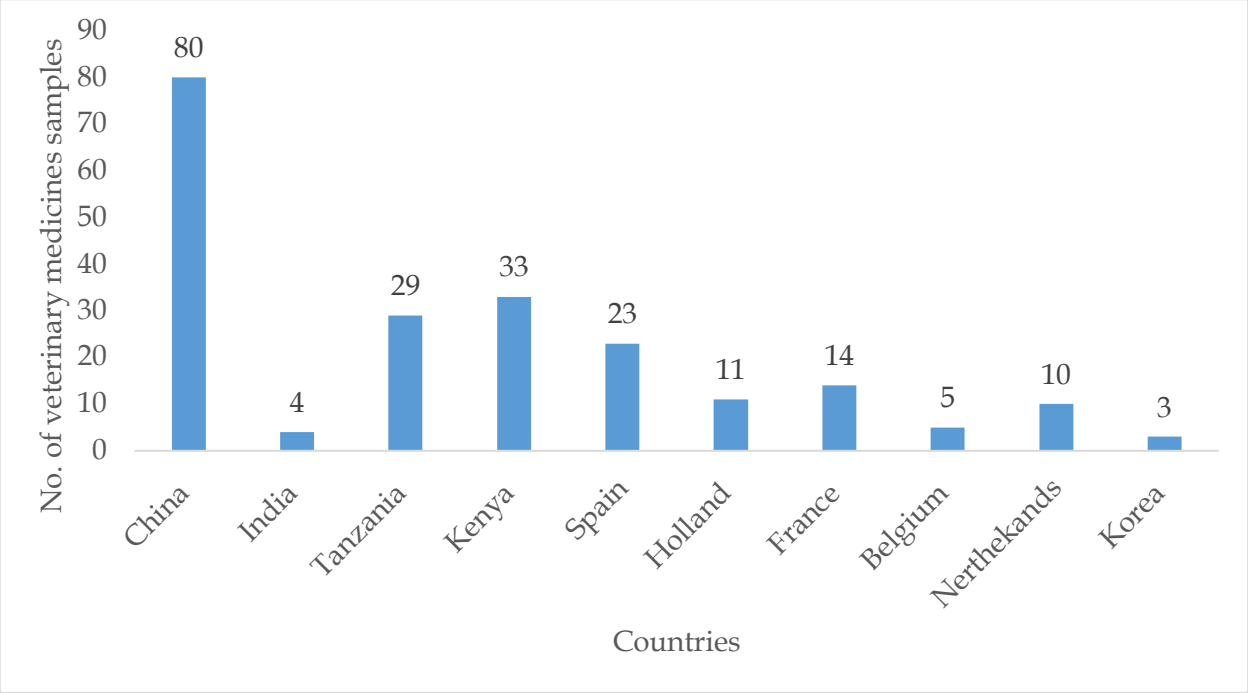


Figure No.2: Number of veterinary medicines sampled with respect to manufacturer's countries

5.1.5. Tier I: Screening

5.1.6. Product Information Review

During the product information review, the total of 219 (45.2%) medicine samples had deficiencies. Of these, 158 (57.9%) were human medicine samples whereas 61 (28.8%) were veterinary medicine samples. Overall, nineteen (19) deficiencies were observed during the review of product information. Of all the sampled human and veterinary medicines, furosemide tablets had high frequency of deficiencies, for instance, it was the only sampled medicine which lacked precautionary statement on the label. Only amoxicillin tablets and ciprofloxacin tablets did not have the important details on the summary of product characteristics (SmPC); majority (36) of which were amoxicillin samples. All the oxytocin injection samples with deficiency were not registered in Tanzania. Of all the sampled human and veterinary medicines; Albendazole solution had the highest number of samples from industries that failed the GMP inspection followed by ergometrine injection. High frequency (16) of enrofloxacin labels and inserts had the storage conditions which did not comply with zone IVb. Table 5.

Table 5: Frequency distribution table of human and veterinary medicines with observed deficiencies during the product information review in Tanzania

Observed deficiencies	Frequency Medicine samples with deficiencies								
	Alb, n=35	Amo, n=36	Cip, n=62	Dim, n=10	Enr, n=16	Erg, n=2	Fur, n=48	Oxy, n=10	**Total**
Longer shelf life than authorized	10	0	0	0	6	0	20	0	**36**
Manufacturer not indicated on the label	8	0	0	0	6	0	0	0	14
No registration number on the label	16	0	9	9	6	0	21	0	**61**
Expired registration (since 2019)	8	0	9	0	0	0	0	0	17
Registration number not written correctly	8	0	0	0	0	0	0	0	8
Important details missing on the leaflet*	0	36	54	0	0	0	47	0	**137**
Storage conditions on labels do not comply with zone IVb	0	0	6	0	16	0	1	0	23
Product not registered	0	0	0	1	0	0	0	10	11
The label presented does not match with information submitted during registration process	0	0	0	9	0	0	0	0	9
Color on the label different from the approved one	0	0	0	0	10	0	0	0	10
Product name on the label does not indicate the dosage form	0	0	0	0	6	0	0	0	6
Alignment of animals on the label was different from the approved artwork	0	0	0	0	1	0		0	1
No precautionary statement on the label	0	0	0	0	0	0	47	0	**47**
Two products with the same name and manufacturer	0	0	0	0	0	0	20	0	20

Key: Alb-albendazole; Amo-amoxicillin; Cip- ciprofloxacin; Dim- diminazine diaceturate; Enr- enrofloxacin; Erg- ergometrine; Fur- furosemide; SmPC- summary of product characteristics; Oxy- oxytocin

During the review of product information, lack of registration number on the product label was the commonest deficiency followed by lack of details on the SmPC. Some collected samples had extended shelf life than the approved ones while other products

had no pharmaceutical description on the product labels and inserts and the labeled storage conditions did not comply with the zone IVb. Table 5 above.

5.1.7. Visual Inspection Test

All the samples (359) passed the visual inspection test which included examination for leakage, particles, homogeinity, fill volume and colour change of injectable solutions and colour change, spots, moulds, abrations and odour for tablets.

5.1.8. Disintegration and Identification Test

A total of 119 samples of ciprofloxacin tablets and 65 samples of Amoxycillin Trihydrate tablets were identified by TLC and tested for disintegration while 72 samples of Furosemide tablets were identified by UV and subjected to disintegration test. All these samples passed Identification and Disintegration test.

For Albendazole solution and Oxytoxin injection, all the 9 samples of Oxytocin injection passed identification test by TLC while only 79 out of the 80 samples of Albendazole solution passed identification test by UV.

Confirmatory Testing

A total of 53 samples (28 Human Medicines and 25 from Veterinary Medicines) were taken for confirmatory testing. Among the 53 samples, 52 passed the test while one (1) sample of Albendazole solution failed the test (**Table 6)**.

The results show that, all human and veterinary medicine samples 98% (52/53) subjected to confirmatory test complied with the tested parameters.

Table 6: Confirmatory testing

Summary	Dosage	Monograph	Screening Test	Qty Received	Qty Screened			Confirmatory			Remark
					Qty Screened	Pass	Fail	Qty selected	Pass	Fail	
Ciprofloxacin	Tablets	BP	Appearance, Identification TLC and Disintegration	119	119	119	0	7	7	0	
Amoxicillin Trihydrate	Tablets	BP	Appearance, Identification TLC and Disintegration	65	65	65	0	2	2	0	
Furosemide	Tablets	BP	Appearance, Identification UV and Disintegration	72	72	72	0	10	10	0	
Albendazole Solution	Solution	USP	Appearance, Identification UV	80	80	79	1	10	9	1	
Oxytocin	Injection	BP	Appearance, Identification TLC	9	9	9	0	9	9	0	
Diminazen diaceturate	Injection	IOC	Appearance, Identification UV	14	0	0	0	14	14	0	Not subject to screening
Total				**359**	**345**	**344**	**1**	**53**	**51**	**1**	

6. DISCUSION

This survey aimed at determining the availability and quality of selected human medicines (Ergometrine IV, Oxytocin, Ciprofloxacin tablets, Furosemide IV, Amoxicillin Dispersible Tablets) and veterinary medicines (Diminazene Diaceturate, Albendazole (2.5% & 10%) suspensions and Enrofloxacin solution) circulating on Tanzanian market in the year 2019/2020 as per the sampling plan. A total of 485 (77.2%) samples of the planned total (628) medicine samples were collected, this was due to scarcity of some medicines in the market such as ergometrine and unequal distribution of medicine availability in rural versus urban settings; most medicines planned to be collected in rural settings did not attain the planned target. This is in agreement with the study conducted by Mujinja and his colleagues who found that, most of the imported medicines are readily found in urban settings than in rural areas(1).

Ergometrine injection was not readily available in the market; only two (2) medicines samples were collected. This could be due to low rate of importation and not being the preferred medicine for preventing postpartum haemorrhage as it is expensive and less tolerated than oxytocin(2). In order to have representation of medicines in this category, consensus was reached to sample oxytocin (was not in the plan) due to its high rate of use and is regarded as a lifesaving medicine.

Similarly, albendazole suspension for veterinary use was not planned in the current phase (V&VI for year 2019/2020) however, it was included in the sampling process to supplement missing data of laboratory analysis for enrofloxacin due to lack of reference standards for enrofloxacin solution attributed to COVID -19 pandemic in the analysis year. Albendazole suspension was selected since some of its samples failed in the previous PMS phase, 2018/2019, the laboratory reagents were available and it was readily available in the market. Therefore, the laboratory findings of enrofloxacin were not presented in this report.

Most of the sampled medicines were imported, and only few of them were sourced from domestic manufacturers. The imported human medicines were mainly from Asia; India being the leading exporter, followed by manufacturing companies in Africa most of it contributed by Kenya, this is attributed to limited number of manufacturing companies in Tanzania. These findings are in line with the findings of the systematic analysis of data for pharmaceutical imports that reported India as the leading exporter of highest value of pharmaceuticals in Tanzania(3).

Veterinary medicine were also highly imported from Asia; China being the leading exporter. Europe and Africa manufacturing companies contributed almost equally to

the circulating veterinary medicine samples in Tanzania. This is due to the few number of veterinary manufacturing facilities in the country(4).

Product Information Review results for the collected samples indicated that almost half of the collected samples did not comply with regulatory requirements which was higher than the findings of the previous surveys(5). This could be due to the fact that the current survey included a large number of samples and products.

We observed high percentage of products whose leaflets missed important product details similar to the study conducted in India which found inadequate details on the leaflets such as unclear instructions about generic names of other ingredients used, undesirable side effects and use(6).

Lack of registration number on the product label was the second-most observed deficiency by 20.3% which was less than the previous report from Phase I-II of PMS which found higher percentage of product samples with no registration number. This could be due to the efforts to emphasis manufacturers and market authorization holders to indicate the Tanzania registration number on the products.

Additionally, lack of precautionary statement on the product label was observed in 15.7% of all deficiencies, this was high compared to the previous report by Hiiti et al, who found 2.0% of the package inserts collected in the East African countries did not have a statement with regard to the warning and precautions(7). The difference could be attributed to the few numbers of samples (n=93) in their study compared to the current survey (n=485).

Almost all of the collected medicine samples passed the quality parameter tests such as visual inspection, identification test, disintegration test and assay. Only one (1) sample of albendazole suspension failed identification and assay tests. These findings are similar to the study that tested 869 medicine samples from Africa and Asia; about 2.4% of samples were either falsified or substandard(8). In their study, no medicine samples from either India or Kenya were falsified or substandard(8). Considering that, our study had most samples imported from India and Kenya, our confidence is increased that medicines circulating in Tanzania are of good quality.

Despite the deficiencies observed in PIR and the one sample that failed the quality control test, this is a clear indication of successful role of TMDA in ensuring the quality of medicines circulating in the market.

7. REGULATORY ACTION TAKEN

The following regulatory actions have been taken by TMDA:

7.1 All manufactures whom their medicines failed product information review (PIR) have been directed to rectify the anomalies which were found during the PIR evaluation.

7.2 Identified poor quality Albendazole 10% suspension batch number 2154511 was investigated and confirmed that this batch was counterfeit and hence withdrawn from the market.

8. CONCLUSION

Based on the survey results for phase V-VI for the year of 2019/2021, one hundred and forty-three (143) out of two hundred and seventy-four (274) samples of human medicines equivalent to 52.19% and eight three (83) out of two hundred and eleven (211) samples veterinary medicines equivalent to 39.34% failed product information review (PIR). This indicate that there is a significant increased non-compliance to product labelling requirement when compared with the survey results of phase III-IV of the year 2018/2019 in which the results of PIR shown that only 5.3% of collected samples of human and veterinary medicines failed.

In this regard, more effort is required to enforce Marketing Authorization Holder (MAH) to ensure that their products meet product information requirements before being imported and allowed to be on the market. In addition, inspection activities need to be strengthened especially at ports of entry to identify medicines which are not labelled in the manner that conform to the labelling requirements before being allowed into the country.

In confirmatory testing, with exceptional of identified counterfeit of Albendazole 10% suspension batch number 2154511 of collected veterinary medicines samples which failed identification test and assay, all remained samples of human and veterinary medicines tested met the specifications. This indicates adequate compliance of post registration enforcement. Nevertheless, it is recommended for continuous monitoring of quality of medicines circulating on the market and reminding distributors and sellers of medicines on the importance of adhering to good distribution practices, storage, labelling and proper handling of human and veterinary medicines.

9. RECOMMENDATIONS

The following are recommended.

9.1 Marketing authorization holders should be reminded to comply with labelling requirements.

9.2 Stake holders who are directly receiving complains with regard to product quality and safety should be involved in sampling plan preparation and implementation of PMS programme.

9.3 Reviewers of product information should be trained regularly so as to improve the recording of deficiencies observed during product information review.

10. LIMITATIONS

Limitations encountered during planning, implementation, analysis and writing up of the report include;

10.1 Difficult in tracing some dossiers and registration samples for comparison during product information review;

10.2 Limited capacity of TMDA Quality Control Laboratory with regards to workload against human resource which lead to delay of analytical results

10.3 Lack of reference standard for of some medicine samples for example Ergometrin solution for injection.

11. REFERENCES

1. Mujinja PGM, Mackintosh M, Justin-Temu M, Wuyts M. Local production of pharmaceuticals in Africa and access to essential medicines: "Urban bias" in access to imported medicines in Tanzania and its policy implications. Global Health. 2014;10(1):1–12.

2. WHO recommendations for the prevention of postpartum haemorrhage. 2006;(10):1–6.

3. Wande DP, Sangeda RZ, Tibalinda P, Mutta IK, Mkumbwa S, Bitegeko A, et al. Pharmaceuticals imports in Tanzania: Overview of private sector market size, share, growth and projected trends to 2021. PLoS One. 2019;14(8):1–17.

4. Tanzania Food and Drugs Authority Registration Data Base. 2017.

5. Tanzania Medicines and Medical Devices Authority. Annual Post Market Surveillance for year 2019/2019. 2019;(9).

6. Ramdas D, Chakraborty A, Swaroop H, Faizan S, Praveen Kumar V, Srinivas BN. A study of package inserts in Southern India. J Clin Diagnostic Res. 2013;7(11):2475–7.

7. Sillo HB, Masota NE, Kisoma S, Rago L, Mgoyela V, Kaale EA. Conformity of package inserts information to regulatory requirements among selected branded and generic medicinal products circulating on the East African market. PLoS One. 2018;13(5):1–13.

8. Petersen A, Held N, Heide L. Surveillance for falsified and substandard medicines in Africa and Asia by local organizations using the low-cost GPHF Minilab. PLoS One. 2017;12(9):1–22.

ANNEX 1: PMS SAMPLING PLAN PHASE III & IV

PHASE V (HUMAN) : SAMPLING PLAN FOR CONDUCTING PMS OF AMOXICILLIN DISPERSIBLE TABLETS AND CIPROFLOXACIN TABLETS IN SIMIYU, MARA, KIGOMA, KAGERA AND DAR ES (HUMAN) SALAAM REGIONS

Sampling level	Sampling sites	Product Category	Product	Dosage Form	Strength	Number of brand to be collected	Number of batch per brand to be collected	Unit Pack	Number of unit pack per batch to be collected	Total number of samples to be collected
	Level 1: Regional									
Regional	MSD warehouse/Retail Pharmacy	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Private Importer	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Wholesaler	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Reginal/Referal hospital	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Retail Pharmacy	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Government hospital	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Private hospital	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Sub total					**28**	**14**			
	Level 2: Districts									
District	**District 1**									
	District hospital	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Retail Pharmacy	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Private hospital/Faith based organisation	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Sub total					**12**	**6**			
	District 2									
	District hospital	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Retail Pharmacy	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Private hospital/Faith based organisation	Antibacterial	Amoxycillin Dispecible Tablets	tablets	250 mg	2	1	P/30 tabs	5	10
		Antibacterial	Ciprofloxacin	tablets	500 mg	2	1	P/100 tabs	2	4
	Sub total					**12**	**6**			
	Grand Total per region									
			Grand Total per region 5 regions							
		Expected number of batches/samples to be collected				**52**				
		Expected number of samples to be collected from 5				**260**				
	*** depends on the availability of MSD zone in respective region*									

PHASE V (VETERINARY) : SAMPLING PLAN FOR CONDUCTING PMS OF DIMINAZENE DIACETURATE TETRAHYDRATE POWDER FOR INJECTION IN SHINYANGA, MANYARA, KATAVI AND SONGWE REGIONS

	Sampling sites	Product Category	Product	Dosage Form	Strength	Number of brand/sample to be collected	Number of batch per brand to be collected	Unit Pack	Number of unit pack per batch to be collected	Total number of packs to be collected
	Level 1: Regional									
	Importer/ Wholesale pharmacy	Trypanocidals	Diminazene diaceturate tetrahydrate	Powder for injection	2.36g	2	1	Sachets of 1g	10	20
	Retail pharmacy/Veterinary Shops	Trypanocidals	Diminazene diaceturate tetrahydrate	Powder for injection	2.36g	2	1	Sachets of 1g	10	20
	Private Veterinary Clinic	Trypanocidals	Diminazene diaceturate tetrahydrate	Powder for injection	2.36g	2	1	Sachets of 1g	10	20
	Open Market/ Auctions	Trypanocidals	Diminazene diaceturate tetrahydrate	Powder for injection	2.36g	2	1	Sachets of 1g	10	20
	Sub total					**8**				
	level 2: Districts									
	District 1									
	Retail pharmacy	Trypanocidals	Diminazene diaceturate tetrahydrate	Powder for injection	2.36g	2	1	Sachets of 1g	10	20
	ADDO Veterinary Shop	Trypanocidals	Diminazene diaceturate tetrahydrate	Powder for injection	2.36g	2	1	Sachets of 1g	10	20
	Open Market/ Auctions	Trypanocidals	Diminazene diaceturate tetrahydrate	Powder for injection	2.36g	2	1	Sachets of 1g	10	20
	Sub total					**6**				
	District 2									
	Retail pharmacy	Trypanocidals	Diminazene diaceturate tetrahydrate	Powder for injection	2.36g	2	1	Sachets of 1g	10	20
	ADDO Veterinary Shop	Trypanocidals	Diminazene diaceturate tetrahydrate	Powder for injection	2.36g	2	1	Sachets of 1g	10	20
	Open Market/ Auctions	Trypanocidals	Diminazene diaceturate tetrahydrate	Powder for injection	2.36g	2	1	Sachets of 1g	10	20
	Sub total					**6**				
	Grand Total per region									
			Grand Total per 4 regions							
	Expected number of samples to be collected in a Regional (district + region level)					**20**				
	Expected number of samples to be collected from 4 Regions (i.e 20 x 4)					**80**				

	PHASE VI (HUMAN): SAMPLING PLAN FOR CONDUCTING PMS OF ERGOMETRINE INJECTION AND FUROSEMIDE TABLETS IN MWANZA, DODOMA, SINGIDA AND COAST REGIONS									
Sampling level	**Sampling sites**	**Product Category**	**Product**	**Dosage Form**	**Strength**	**Number of brand to be collected**	**Number of batch per brand to be collected**	**Unit Pack**	**Number of unit pack per batch to be collected**	**Total number of samples to be collected**
Level 1: Regional										
Regional	MSD warehouse/Retail Pharmacy	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Private Importer	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Wholesaler	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Reginal/Referal hospital	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Retail Pharmacy	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Government hospital	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Private hospital	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40gm	2	1	P/100 tabs	2	4
	Sub total					**28**	**14**			
Level 2: Districts										
District	**District 1**									
	District hospital	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Retail Pharmacy	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Private hospital/Faith based organisation	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Sub total					**12**	**6**			
	District 2									
	District hospital	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Retail Pharmacy	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Private hospital/Faith based organisation	Alcaloids	Ergometrin	injection	1ml	2	1	vial	100	200
		diuretic	Furosemide	tablets	40mg	2	1	P/100 tabs	2	4
	Sub total					**12**	**6**			
	Grand Total per region									
						Grand Total per region 4 regions				
	Expected number of samples to be collected from districts & region level					**52**				
	Expected number of samples to be collected from 4 regions (i.e 52 x 4)					**208**				
	*** depends on the availability of MSD zone in respective region*									
	PHASE VI (VETERINARY)I: SAMPLING PLAN FOR CONDUCTING PMS OF ENROFLOXACIN ORAL SOLUTION IN DAR ES SALAAM, ARUSHA, MOROGORO AND RUVUMA									
	Sampling sites	**Product Category**	**Product**	**Dosage Form**	**Strength**	**Number of brand/sample to be collected**	**Number of batch per brand to be collected**	**Unit Pack**	**Number of unit pack per batch to be collected**	**Total number of packs to be collected**
	Level 1: Regional									
	Importer/Wholesale pharmacy	Antibacterial	Enrofloxacin	Oral Solution	2.36g	2	1	100 mls	10	20
	Retail pharmacy/Veterinary Shops	Antibacterial	Enrofloxacin	Oral Solution	2.36g	2	1	100 mls	10	20
	Private Veterinary Clinic	Antibacterial	Enrofloxacin	Oral Solution	2.36g	2	1	100 mls	10	20
	Open Market/Auctions	Antibacterial	Enrofloxacin	Oral Solution	2.36g	2	1	100 mls	10	20
	Sub total					**8**				
	level 2: Districts									
	District 1									
	Retail pharmacy	Antibacterial	Enrofloxacin	Oral Solution	2.36g	2	1	100 mls	10	20
	ADDO Veterinary Shop	Antibacterial	Enrofloxacin	Oral Solution	2.36g	2	1	100 mls	10	20
	Open Market/ Auctions	Antibacterial	Enrofloxacin	Oral Solution	2.36g	2	1	100 mls	10	20
	Sub total					**6**				
	District 2									
	Retail pharmacy	Antibacterial	Enrofloxacin	Oral Solution	2.36g	2	1	100 mls	10	20
	ADDO Veterinary Shop	Antibacterial	Enrofloxacin	Oral Solution	2.36g	2	1	100 mls	10	20
	Open Market/Auctions	Antibacterial	Enrofloxacin	Oral Solution	2.36g	2	1	100 mls	10	20
	Sub total					**6**				
	Grand Total per region									
						Grand Total per 4 regions				
	Expected number of samples to be collected in a Regional (district + region level)					**20**				
	Expected number of samples to be collected from 4 Regions (i.e 20 x 4)					**80**				

ANEEX 2: SAMPLE COLLECTION FORM

TMDA	MEDICINES POST MARKETING SURVEILLANCE SAMPLE COLLECTION FORM	*TMDA/DMC/CTP/F/002* *Rev #:1*

1. Sample code: .....
(Region/product/sequence number/sampling date dd/mm/yy)***

2. Name of Premises where sample was taken: .....

3. Physical Address.....Postal address.....
Telephone No..... Fax No.....
Email address..... (If applicable)

4. Product name of the sample: .....

5. Name of active pharmaceutical ingredient(s) (INN) with strength: .....
.....

6. Dosage form (tablet, oral powder, etc): .....

7. Package size & type: .....

8. Batch/lot number: ..... Date of manufacture: .....
Expiry date: .....

9. Name and physical address of the manufacturer: .....
.....

10. Number of units collected: .....

11. Is the product registered in Tanzania? Yes/ No. If Yes, indicate the registration number:
.....

12. Comment on storage condition of product at the premises:
.....
.....

13. Name and signature of the Representative of the premise where sample was collected:

Name: ..... Signature: ..... Date: .....

14. Name of Drug Inspector (s)/Sampling officer

S/n	Name	Organization	Signature	Date

Note: Samples collected must remain in their original containers.

Approved by MCTP (Signature) _____ Effective Date: 25/03/2020

ORIGINAL COPY