Doc. No. TFDA/DMC/CTPV/PMS/R/008

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

2018/2019

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Issue:2

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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

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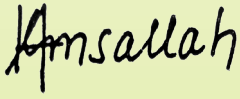
Similarly, I would like to thank all TMDA Zone Managers, TMDA section which coordinates PMS activities, drug inspectors who participated in sample collection; evaluator's who reviewed the product information and analysts who carried out laboratory testing for their valuable inputs in developing this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

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



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

FOREWORD

The Tanzania Medicines and Medical Devices Authority is a regulatory body which is responsible for monitoring safety of medicines and medical devices circulating in Tanzania through various regulatory mechanisms including the Post Marketing Surveillance (PMS).

Medicines circulating in the market are monitored by using a structured three years programme prepared by TMDA whose annual implementation is done through PMS planning, budgeting and training of inspectors before collection of medicine samples.

Through PMS, samples of medicines are collected from the market using a prepared sampling plan for the purpose of ascertaining their quality. The PMS process involves physical collection of samples, product information review and testing in the TMDA WHO prequalified laboratory.

A total of 208 samples were collected, out of which 158 and 50 were human and veterinary medicines respectively. Product Information Review (PIR) results show that 5.3% (11/208) of the collected medicines samples had deficiencies. All samples of human medicines passed confirmatory tests while for veterinary medicines one sample of Albendazole 10% suspension failed the assay test.

Among noted deficiencies observed during product information review include labels of some products were missing the name and address of manufacturer, inappropriate storage condition on package insert, inappropriate storage condition on the label, lack of manufacturing date as well as registration number on the label.

In this report are the results of the quality of human and veterinary medicines namely; Cloxacillin sodium for injection, Benzylpenicillin sodium, Fortified procaine penicillin, Atovarstatin, Dihdroartemisinin+Piperaquine and Albendazole suspension 10% surveyed in the year 2018/19.

Moreover, the efficiency of PMS planned activities have been excellently achieved through a coordinated team work which involved various stakeholders within and outside TMDA. I thank all who were involved, including our collaborators and partners for the job well-done.

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

EXECUTIVE SUMMARY

In the financial year 2018/19, 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 anti-malaria, antibiotics and anti-hypertensive medicines namely Dihydroartemisinin piperaquine phosphate tablets, Cloxacillin sodium for injection, Benzylpenicillin sodium fortified procaine penicillin and Atovarstatin tablets. The veterinary medicine assessed was Anthelminthic medicine namely Albendazole suspension 10%.

Systematic method for sample collection was used which involved supply 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, Kilimanjaro, Njombe, Iringa, Ruvuma, Morogoro, Geita, Dodoma, Arusha, Mbeya, Rukwa, Manyara and Shinyanga.

All sampled medicines were subjected to Tier I screening tests which involved Product Information Review (PIR) and laboratory screening test. Ten percentage (10%) of samples which passed screening test were taken to Tier II confirmatory testing at TMDA WHO prequalified laboratory.

A total of 158 (52.67%) samples of human and 50 (62.5%) veterinary medicines were collected out of 300 and 80 planned samples respectively. PIR was conducted to all collected samples and results revealed that only 11 samples out of 208 (5.3%) were found with deficiencies. The Marketing Authorization Holders (MAH) of the samples failed PIR were directed to comply with labelling

requirements.

All samples of human and veterinary medicines passed screening test on physical appearance, identification and disintegration for solid dosage forms.

Ten percent (10%) of samples which passed screening tests were subjected to confirmatory testing and all twenty five (25) samples of human medicines passed the tests. Among the five (5) samples of veterinary medicines tested only one (1) sample failed the tests. The regulatory action of withdrawing the failed veterinary product from the market was taken and MAH was directed to submit investigation report.

Generally, results of the survey indicate improvement in compliance to labelling requirements and similarly confirmatory test has improved compared to previous surveys.

1. INTRODUCTION

TMDA is conducting structured Post Marketing Surveillance (PMS) studies on the selected registered medicines in order to establish status of quality of medicines circulating on Tanzania market, and protect the public against substandard and falsified medicinal products. PMS is considered as a systematic quality assurance measure to monitor quality of registered medicines. Findings from these studies are used to streamline and strengthen regulatory framework of medicines in the country.

PMS is implemented through proper planning and systematic sampling of medicines from the market using a pre-defined sampling plan. Proper planning and systemic sampling ensures good representation of medicines used for treatment of priority diseases. Trained and qualified sample collectors from respective TMDA zone office are involved in sampling of selected medicines as per sampling plan.

Medicine quality assessment entail product information review against TMDA labelling requirements and approved product labelling and package insert, physical examination of product samples, screening and confirmatory testing of the collected medicines samples.

The survey was implemented in 14 regions and included medicines for human and veterinary use. The studied medicines included Cloxacillin sodium for injection, Benzylpenicillin sodium, Fortified procaine penicillin, Atorvastatin, Dihydroartemisinin/piperaquine phosphate and Albendazole suspension 10%.

Sampling of medicines was done from different sites in the country

including public and private medicines distribution channels. These included Medical Stores Department (MSD), hospitals, dispensaries, health centres, wholesale and retail pharmacies as well as Accredited Drug Dispensing Outlets (ADDO) and veterinary outlets in Mwanza, Dar es Salaam, Kilimanjaro, Njombe, Iringa, Ruvuma, Morogoro, Geita, Dodoma, Arusha, Mbeya, Rukwa, Manyara and Shinyanga regions.

TMDA developed and is implementing the fourth structured PMS programme for a period of three years between 2017/18 and 2019/20. In this survey, it was revealed that one sample of veterinary medicine did not meet the quality standards during implementation of the PMS phase III and IV for 2018- 2019 and gives alert for continuous monitoring of products circulating on Tanzania market.

All sampled human and veterinary medicines were analysed at TMDA World Health Organization (WHO) pre- qualified Laboratory to ascertain quality. The prepared 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 2018/2019 as per 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 strategies to address the problems identified by the survey.

2.3 Exploratory Objective

2.3.1 To determine availability of selected medicines i.e Albendazole suspension 10%, Cloxacillin sodium for injection, Benzylpenicillin sodium injection, fortified procaine penicillin injection, Atovarstatin tablets and Dihydroartemisinin+piperaquine phosphate tablets.

3. METHODOLOGY

3.1 Sampling Sites

In each of selected regions, two councils were randomly selected and studied. A total of 14 regions participated in the survey and were selected based on the following criteria: -

- Regions bordering other countries
- Regions that are not frequently inspected
- Areas reported to have medicine quality problems
- Regions not involved in the previous PMS programmes
- Disease endemicity

3.2 Sampling

3.2.1 Collection of Samples

Sampling of selected medicines was done based on sampling plan attached as **Annex I.** Sampling plan highlighted detailed information on sampling sites, name of product, number of brands to be collected for each product, number of batches for each product, dosage forms, strength, pack size and number of units to be collected for each product. It also detailed specific sites of sampling at regional and district levels.

Samples were collected by using attached sampling form **(Annex II)** in their original containers by trained inspectors from each of TMDA zone offices and local government authorities in accordance with the Standard Operating Procedure.

3.2.2 Handling of collected samples

Each collected sample was coded according to the prescribed coding format. Coding was done to identify samples collected from different regions and thus helped to differentiate and avoid mix up. Coded samples with respective sampling form were kept in the labelled sampling bag and sealed. Before and after transportation of the samples to TMDA office in Dar es Salaam, measures were taken to ensure that samples were stored according to manufacturers' recommended storage conditions as prescribed in the product labels.

3.3 Screening Testing (Tier I)

Samples were screened for the information provided on labels and package inserts through Product Information Review (PIR), physical examination and those with minilab screening methods were tested for disintegration test as well as identification test by Thin Layer Chromatography (TLC).

3.3.1 Product Information Review (PIR)

Information provided on the labels of primary and secondary packaging and that in the package inserts was reviewed with the aim of verifying if they still comply with labelling requirements and approved product information.

Information details checked during PIR included: -

- Generic and trade name (if any), dosage form and strength.
- Appearance or description of the dosage form.
- Name and address of manufacturer.
- Batch or lot number.

- Manufacturing and expiry dates.
- Packaging and pack size.
- Package inserts.
- Registration number.
- Language.
- Storage instructions.

PIR results were recorded in the designed screening form provided as **Annex III.**

3.3.2 Laboratory Screening

All collected medicines samples were subjected to laboratory screening tests for physical examination, identification and disintegration.

3.3.2.1 Disintegration Test

Disintegration test was used to test the possibility of solid dosage form to break into small particles which can thus dissolve and undergo dissolution to release active pharmaceutical ingredient. This was done by using disintegration test machine. The tablets which did not disintegrate within 30 minutes indicated potential dissolution problems necessitating confirmatory testing.

3.3.2.2 Identification Test by Thin layer Chromatography

TLC method was used for quantitative determination of active ingredients, related substances and impurities present in the dosage form. This method employs the principle of comparing spots obtained between test and reference solutions. The principal spot obtained with the test solution must correspond with the chromatographic

runs of the lower and higher standard solutions in terms of colour, shape, size, intensity and retardation factor (R_f) value.

3.4 Laboratory Confirmatory Testing (Tier II)

Samples of medicines which did not have minilab screening methods were taken for laboratory tests according to their pharmacopoeia monograph or manufacturer's methods. All samples that failed screening test, all samples with doubtful screening results and 10% of all passed samples were selected for confirmatory testing. Confirmatory testing was performed by analysing each product as per pharmacopoeia monograph requirements. Parameters checked for each type of medicine were as shown in the table 1 below.

Table 1: Method of analysis used for the parameters tested in each medicine

Category of medicines	Type of medicine	Parameters tested	Analytical Method used
Human Medicines	Atovarstatin tabs.	Identification, disintegration and Assay	USP 38NF 36,
	Cloxacillin inj.	Identification and assay	BP 2018
	Benzyl penicillin inj.	Identification, Assay + Related substance	BP 2018
	Procaine benzyl penicillin inj,	Identification, Assay + Related substance	BP 2018
	Dihydroartemisinin + Piperaquine Phosphate (Duo-cotecxin) tabs.	Identification, disintegration and Assay	In-house
Veterinary Medicines	Albendazole oral suspension 10%	Identification and Assay	USP 41NF36

4. RESULTS

4.1 Sample collection

Different criteria were used during selection of human and veterinary medicines to be monitored. Type of medicines and criteria were as shown in table 2 below:

Table 2: Medicines selected for quality assessment

Medicine Category	Product	Selection criteria
Human Medicines	Cloxacillin injection	Medicines containing active ingredients known to have stability problems; Lifesaving medicines for women, children and infants
	Atorvastatin tablets	Medicines for treating Non-Communicable Diseases (NCDs)
	Benzyl Penicillin injection	Lifesaving medicines for women, children and infants
	Dihyroartemisin/ piperaquine tablets	Medicines which have indicated poor quality and safety performance on the market
Veterinary Medicines	Albendazole 10% suspension	Veterinary Medicines

4.1.1 Human Medicines sample collection

A total of 158 samples of human medicines were collected during Phase III and IV in the year 2018/19. Samples were collected at regional level and two (2) districts from eleven (11) different regions. Out of 158 samples collected, 29% (46/158) were Dihydroartemisin/ Piperaquine tablets, 38% (60/158) were Atorvastatin tablets, 28% (44/158) were Benzyl penicillin injection, 4.4% (7/158) were Cloxacillin Sodium injection and 0.6% (1/158) was for Benzathine Penicillin injection as summarized in Table 3.

Table 3: Number of Human Medicines samples collected in Phase III & IV

Region	PHASE 1II and IV (July 2018 – June 2019)				Total
	Anti-Malaria	Antibiotics		Anti-hypertensive	
	Dihydroartemisin + Piperaquine tablets	Benzyl penicillin injection	Cloxacillin Sodium injection	Atorvastatin tablets	
Dar es Salaam	24			24	**48**
Mwanza	9			8	**17**
Arusha	2	6		10	**18**
Dodoma	5			10	**15**
Mbeya	4			6	**10**
Rukwa	2	5	1	2	**10**
Ruvuma		12	2		**14**
Njombe		3			**3**
Kilimanjaro		18*	3		**21**
Iringa		1	1		**2**
Total	**46**	**45**	**7**	**60**	**158**
Percentage (%)	**29.1**	**28.5**	**4.4**	**38**	**100**

*****Include 1 sample of Benzathine penicillin*

4.1.2 Veterinary Medicines

Samples of Veterinary Medicines were collected in both phase III and phase IV, from six (6) regions namely Manyara, Arusha, Geita, Morogoro, Kilimanjaro and Shinyanga. Of these regions, Shinyanga was a leading region where 32% (16/50) of samples were collected followed by Manyara 28% (14/50) and Morogoro was the least region where only 18% (9/50) of samples were collected. This is shown on table 4 below:

Region	Phase III - IV (July 2018 to June 2019)	Total (%)
	Albendazole 10% suspension	
Manyara	14	**28**
Arusha	5	**10**
Kilimanjaro	1	**2**
Geita	5	**10**
Morogoro	9	**18**
Shinyanga	16	**32**
Total	**50**	**100**

4.2 Samples Collection Sites

Figure 1 below shows, a total of 158 samples of Human Medicines which were sampled from different medicines distribution channels namely; MSD, Hospitals, Pharmacies, Health Centres, Dispensaries and ADDOs. The results show that, the high 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). Atorvastatin, Dihydroartemisinin + piperaquine and Benzyl penicillin accounted for the large number of human medicines collected from the pharmacies.

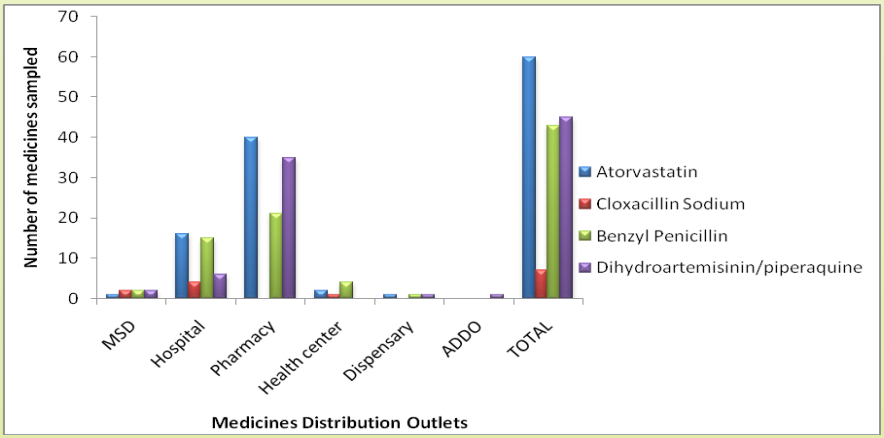


Figure 1: Number of human medicines sampled at different levels of distribution channel

Also, 50 samples of Veterinary Medicines were sampled from Veterinary Pharmacies 16% (8/50) and ADDOs Veterinary 84% (42/50). The majority of sampled medicines were collected from ADDO Veterinary outlets as indicated in figure 2 below.

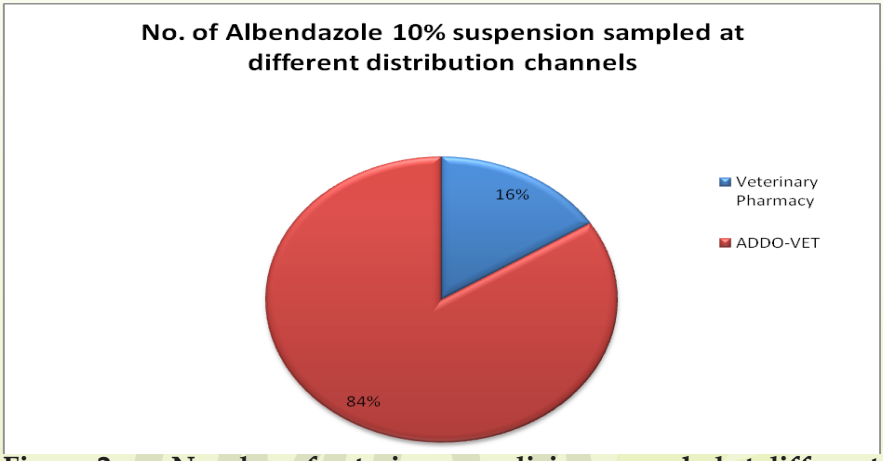


Figure 2: Number of veterinary medicines sampled at different levels of distribution channel

Majority of collected Samples of Human Medicines (Dihydroartemisin/Piperaquine tablets, Benzyl penicillin injection, Cloxacillin sodium injection and Atorvastatin tablets and Veterinary Medicines (Albendazole 10% suspension) were imported from different manufacturers as shown in Table 4 below. Few samples of veterinary medicines were collected from domestic manufacturers.

Table 4: Human Medicines and Veterinary Medicines sampled with respective Manufacturer(s)

Product	No. of samples	Manufacturer	Country of origin
Dihydroartemisin/ Piperaquine tablets	27	KBN Zhejiang Pharmaceuticals	China
	11	Ajanta Pharma Limited	India
	8	Guilin Pharmaceuticals Co. Ltd	China

Benzyl penicillin injection	32	North China Pharmaceutical Co., Ltd., Hebei	China
	9	CSPC Zhongnuo Parmaceutical (Shijiazhuang) Co., Ltd.	China
	4	Reyoung Pharmaceutical Co., Ltd., Shandong Province	China
Cloxacillin sodium injection	7	CSPC Zhongnuo Parmaceutical (Shijiazhuang) Co., Ltd. Shijiazhuang City	China
Atorvastatin tablets	23	MSN Laboratory Limited, Anrich Industrial Estate,	India
	6	Medley Pharmaceuticals Ltd., Andheri East, Mumbai	India
	14	Ind-Swift Ltd., Global Business Unit, Jawaharpur,	India
	6	Cadila Pharmaceutical Ltd, 1389 Transad Road, Ahmedabad	India
	3	Sun Pharmaceuticals Ltd, Silvassa 396230	India
	2	Ajanta pharma limited, Charkop Kandvil (W), Mumbai	India
	4	Lincoln Pharmaceuticals	India
	2	Unichem Laboratories	India

Human medicines samples -Total	**158**		
Albendazole 10% suspension	23	Hebei Yuanzheng Pharmaceutical Co. Ltd., Hebei Province	China
	12	Nerix Pharma Ltd., Nairobi	Kenya
	7	Ashish Life Science Pvt Ltd	India
	2	Norbrook Kenya Ltd., Nairobi	Kenya
	5	Farmers Centre Ltd., Dar Es Salaam	Tanzania
	1	Univet	Ireland
Veterinary medicines samples - Total	**50**		
Human & Veterinary medicines samples	**208**		

None of sampled human medicines samples were domestically manufactured while 10% (5/50) of Veterinary medicines (Albendazole 10% suspension) were manufactured locally. Human Medicines sampled were imported from China 55% (87/208) and India 45% (71/208). Of the sampled Veterinary Medicines majority were imported from China 46% (23/50), followed by Kenya 28% (14/50) and the least was from India 2% (1/50). These results are summarized in Figure 3.

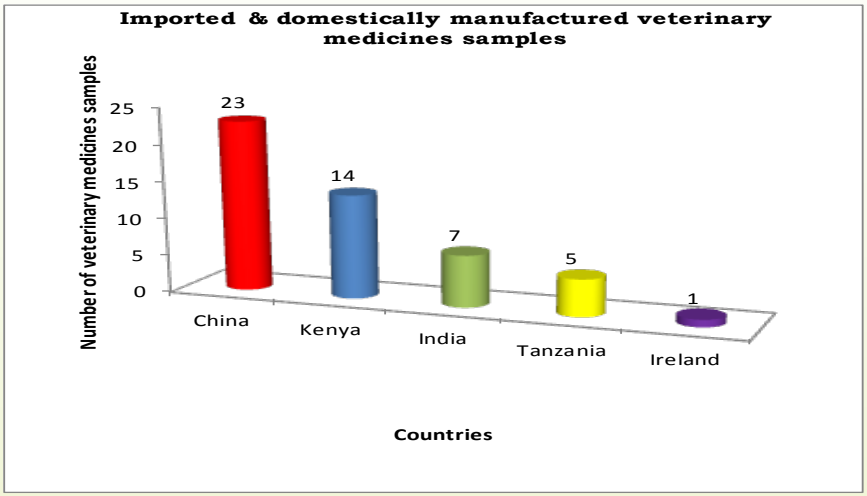


Figure 3: Number of Veterinary Medicines sampled with respective Manufacturer

4.3 Tier I Screening

4.3.1 Product Information Review

Of the collected human and veterinary medicine samples, product information was reviewed against the TMDA labelling and packaging requirements and approved product information. A total of 158 and 50 samples of human and veterinary medicines respectively were reviewed. Labels of only 5.3% (11/208) of the collected human and veterinary medicines samples had deficiencies. For the samples of human medicine reviewed, name and address of manufacturer was not indicated on the package insert of 7 samples of cloxacillin sodium injection, manufacturing date was not indicated on the label of one (1) sample of Atorvastatin tablets.

In addition, storage condition indicated on the labels of 2 samples of Benzyl penicillin powder for injection was not in accordance with

Zone IVb labeling requirements. For the veterinary medicines TMDA registration number was not indicated on the primary packaging of 1 sample of albendazole suspension. The results are shown in the figure 4 below.

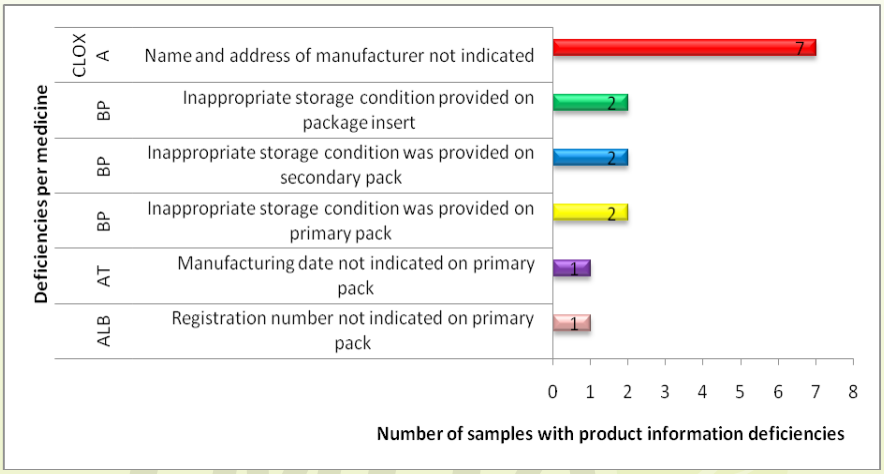


Figure 4: Number of human and veterinary medicines with deficiencies on the labels and package inserts

Keywords: *ALB=Albendazole Suspension*
AT=Atorvastatin tablets
BP=Benzyl Penicillin injection
CLOXA=Cloxacillin sodium injection

4.3.2 Visual Inspection Test

Results of visual inspection test revealed that 98.1% (155/158) of human medicines and 100% (50/50) of veterinary medicines samples 100% (50/50) passed the test.

Three human medicines samples that failed were not submitted for further testing. Of the failed samples, two samples had expired

(Dihydroartemisine+ Piperaquine tablets and Procaine Benzyl peniciline injection) and one sample was out of the sampling scope (Benzathine Penicilline Injection).

4.3.3 Disintegration and Identification Test

All collected samples of Dihydroartemisin/Piperaquine tablets (46), Benzyl penicillin injection (45), Cloxacillin Sodium injection (7), Atorvastatin tablets (60) for human medicines and veterinary medicines - Albendazole 10% suspension (50) were subjected to identification test by using Thin Layer Chromatograph (TLC) method and all passed identification test.

For oral solid dosage forms of Dihydroartemisin/Piperaquine and Atorvastatin tablets were tested for disintegration. All the samples disintegrated within 30 minutes at 37°C (between 1-6 minutes). These results indicated that, there were no signs of disintegration problems that would have necessitated dissolution testing of the samples.

4.4 Confirmatory Testing

Based on selection criteria, a total of 30 samples (25 Human Medicines and 5 from Veterinary Medicines) were taken for confirmatory testing as shown in the **table 5**.

Table 5: Number of Samples Selected for Confirmatory Testing					
Category of medicine	**Product name**	**Samples Collected**	**Samples Screened**		**No. of Samples selected**
			Passed	**10% of the passed**	
Human medicines	Dihydroartemisin+ Piperaquine tablets	46*	45	4.5	5
	Benzyl penicillin injection	45**	43	4.3	9
	Cloxacillin Sodium injection	7	7	0.7	4
	Atorvastatin tablets	60	60	6	7
	Total	**158**	**155**	**15.5**	**25**
Veterinary medicines	Albendazole 10% suspension	50	50	5	5
Total		**208**	**205**	**20.5**	**30**

** One sample expired before screening test*

*** One sample expired before and one was sampled out scope (Benzathine Inj.)*

The results show that, all human medicine samples 100% (25/25) subjected to confirmatory test complied with the tested parameters.

However, 17% (1/5) of veterinary medicine sample (Albendazole 10% suspension) did not comply with specifications for assay test by having amount below the acceptable range of 90 - 110%. Parameters tested for each type of medicine were provided in the table 6. Laboratory results are attached as **annex IV**.

Table 6: Parameters and method of analysis for testing of medicine samples			
Category	**Type of medicine**	**Parameters tested**	**Analytical Method used**
Human Medicines	Atovarstatin tablets.	Identification, disintegration and Assay	USP 38NF 36,
	Cloxacillin injection.	Identification and assay	BP 2018
	Benzyl penicillin injection.	Identification, Assay + Related substance	BP 2018
	Procaine benzyl penicillin injection	Identification, Assay + Related substance	BP 2018
	Dihydroartemisinin + Piperaquine tablets.	Identification, disintegration and Assay	In-house
Veterinary Medicines	Albendazole oral suspension 10%	Identification and Assay	USP 41NF36

5. DISCUSSION

Poor-quality medicines present a serious public health problem. Falsified and substandard medicines have been of great concern particularly in developing countries like Tanzania. Thus, to ensure medicines of good quality are circulating on Tanzania market phase III and IV of Post Marketing Surveillance (PMS) of human and veterinary medicines was conducted in 14 regions in the Tanzania mainland in line with the approved PMS programme for 2017-2020. Samples of medicines were collected from different levels of the pharmaceutical distribution channels starting from national, regional and district levels.

The samples and regions were selected using criteria set in the PMS programme [1,2] which included but not limited to experience gained in previous PMS programmes, medicines containing active ingredients known to have stability problems and medicines from manufacturers whose products were previously reported to have high incidences of failing laboratory tests. Other reasons include

reports on quality of medicines received by TMDA from various sources and changes in disease pattern.

The number of samples collected for both human and veterinary medicines were 208 which comprise only about 55% (208/380) of the planned sample size. Of the sampled medicines 158 and 50 were for human and veterinary medicines respectively. Low percentage of the collected samples could be explained by unavailability of some medicines at district levels and healthcare facilities during sample collection. This is a common problem during sample collection especially in peripheral areas where the medicine supply is still low. Similar problems have been reported in previous PMS programmes (1,2)

Samples were collected from Dar es Salaam, Arusha, Kilimanjaro, Mwanza, Shinyanga, Dodoma, Manyara, Ruvuma, Mbeya, Morogoro, Rukwa, Geita, Njombe and Iringa in descending order of quantity collected. Dar es Salaam, Arusha and Kilimanjaro were observed to contribute a relatively higher number of samples of human medicines as the cities are highly populated with high business volume [1,2]. Majority of samples of veterinary medicines were collected from Shinyanga and Manyara regions known to have larger numbers of livestock [2].

Majority of the human (100%) and veterinary (90%) medicines collected and herein discussed were imported, which would be attributed by dependence of the country on imported medicines from abroad. This observation is in align with TMDA data from 2017 [3] and a recent study conducted in Tanzania [4].

Collected medicine samples were subjected to screening evaluation involving Product Information Review (PIR),

laboratory disintegration test and identification test by Thin Layer Chromatography (TLC) whereby all samples complied with tested parameters. This rate of compliance shows that there was strong control on importation of medicinal products at the port of entry.

Results of Product Information Review (PIR) depicted that, there were some deficiencices on labelling of the products on primary, secondary packaging and package inserts.

These included absence of the registration number, name and address of manufacturer on package insert, manufacturing date and storage conditions indicated were not in accordance with climatic Zone IVB labelling requirements (5).

The results show a significant decrease of deficiencies observed as compared to the previous PMS reports for other medicines categories (1,2,6,7). Adherence of market authorization holders to the regulatory body requirements on product labelling requirements and package insert information and law enforcement by TMDA, could explain this observed trend in improvement.

All sampled human and veterinary medicines conformed to screening test requirements. This is an interesting result compared to reports from previous PMS program (1, 2, 5, 6). The results further underscore suitability and usability of sample survey techniques for quality assurance of medicines.

In confirmatory testing by full pharmacopeia monograph, all human and veterinary samples tested met the specifications except one (1) sample of veterinary medicines (albendazole 10% suspension) which failed assay test. Sample which failed the assay specifications

had albendazole content of 7.3% which was below the acceptance range between 90-110%. Results for assay test in this study are consistent with reports from various other studies conducted worldwide, which have shown presence of substandard and/or falsified veterinary medicines (8-10). However, these results are far much better compared to results from previous PMS programme (2014-2017) conducted by TMDA (1, 2), specifically for veterinary medicines where in the 2014-2017 programme about 12.1% of the tested samples failed assay test compared to 3.3% of the tested samples in 2018-2019 which failed on the same parameter. This significant improvement in the quality of medicines circulating on the Tanzania market could be accounted for the implementation of PMS programme in the country.

Related substances were analysed according to the British Pharmacopoeia (BP) monograph. A common related substance for tested for both Procaine Benzyl Penicillin and Benzyl penicillin Injections which was verified was ***4-amino benzoic acid*** (***not more than 0.5%)*** and the same was not detected. There was no any other peak for related substance that was detected exceeded 1% as per BP specification.

6. REGULATORY ACTION TAKEN

The following regulatory actions have been taken by TMDA:

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

6.2 Identified poor quality batch of Albendazole suspension 10% has been withdrawn from the market. In addition, manufacturers have been directed to conduct thorough investigation on the batch which failed assay test.

6.3 Importation of future batches of the identified poor-quality products has been suspended until after manufacturers have submitted their investigative reports.

7. CONCLUSION

The survey has revealed a decrease in failure rate of product information review for samples of both human and veterinary medicines 5.3% (11/208) compared to the previous PMS programme 2014 - 2017 in which 80% of sampled medicines (609/759) were not meeting product information requirements. This indicates adequate compliance and enforcement post-registration phase of medicinal product cycle. However, more effort is required for the few failed samples in PIR 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. Strengthening of inspection activities and especially at ports of entry is of paramount importance to identify medicines which are not labelled in the manner that conform to the labelling requirements before being allowed into the country.

Moreover, presence of some substandard veterinary medicines

on the market as evidenced in this survey call 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 veterinary medicines.

8. RECOMMENDATIONS

The following are recommendations from the experience gained in this survey.

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

1.2 Before embarking into sample collection sample collectors should be trained on how to conduct sampling as well as pros and cons for adhering and not adhering to the sampling standard operating procedures.

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

9. LIMITATIONS

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

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

ii. Lack of method for analysis of some medicine samples for example Dihydroartemisin/Piperaquine tablets which required method development and validation, hence time taken for analysis was long.

10. REFERENCES

1. TFDA (2016), *Post Marketing Surveillance Report of the Quality of Selected Medicines under phase III-IX of 2011-2013 PMS Program*. Tanzania Food and Drugs Authority, Dar-es-Salaam, Tanzania.
2. TFDA (2016), *Post Marketing Surveillance Report of the Quality of Antimalarial, Anti-Retroviral and Anti-Tuberculous Medicines Circulating in Tanzania for the year 2012-2015*. Tanzania Food and Drugs Authority, Dar-es-Salaam, Tanzania.
3. Tanzania Food and Drugs Authority Registration Data Base, 2017
4. Wande DP, Sangeda RZ, Tibalinda P, Mutta IK, Mkumbwa S, Bitegeko A, et al. (2019) Pharmaceuticals imports in Tanzania: Overview of private sector market size, share, growth and projected trends to 2021. PLoS ONE 14(8): e0220701. https://doi.org/10.1371/journal.pone.0220701
5. ICH Stability Zones: http://www.pharmaguideline.com/2010/12/different-climatic-zones-for-stability.html accessed on 20th December 2019
6. Mziray S, Mwamwitwa K, Kisoma S, Augustine S, Fimbo A. Post Marketing Surveillance of Anti-malarial Medicines in Tanzania. Pharm Regul Aff. 2017; 6(191):2.
7. Mwamwitwa K, Fimbo A, Mziray S, Nandonde M, Hipolite D, Kijo AS, Maganda B and Kaale E: Post Marketing Surveillance of Antihypertensive Medicines in Tanzania. Pharmaceut Drug Regul Affair J. 2018, 1; 1-10.
8. Kang j, et al. National post marketing surveillance assessment of veterinary medicines in Korea during the past decade (May, 2017). Retrieved from https://www.

researchgate.net/publication/317079155_National_post-market_surveillance_assessment_of_veterinary_medicines_in_Korea_during_the_past_decade

9. Grasswitz TR, Leyland TJ, Musiime JT, Owens SJ, Sones K.R.The Veterinary Pharmaceuticals Industry in Africa: a study of Kenya, Uganda and South Africa (2004). Retrieved from: http://sites.tufts.edu/capeipst/files/2011/03/Grasswitz-et-al.pdf
10. Monteiro A, et al, (2018). Pharmaceutical quality of antihelmintics sold in Kenya. Retrieved from: https://www.researchgate.net/profile/Ana_Monteiro4/publication/13698229

11. ANNEXES

Annex I: Sampling plan

Annex II: Sample collection form

Annex III: Screening Form

Annex IV: Laboratory analysis test results

Annex I: Sampling Plan
SAMPLING PLAN FOR PHASE III-IV

PHASE III: SAMPLING PLAN FOR CONDUCTING PMS OF ATOVARSTATIN AND DIHYDROARTEMISININ/PIPERAQUINE IN DAR ES SALAAM, MWANZA, ARUSHA, MBEYA AND DODOMA REGIONS

Sampling sites	Product Category	Product	Dosage Form	Strength	Number of brand/samples	Number of batches per brand	Unit Pack	Number of unit pack per batch	Total number of packs	Unit cost	Total cost
Level 1: Regional											
MSD	Antimalarial	Dihydroartemisinin /piperaquine phosphate	tablets	20mg	2	1	P/30 tabs	5	10	11,000	-
	Cholestrerol lowering agent	Atovarstatin	tablets	40/320mg	2	1	P/6 tabs	25	50	10,000	-
Importer /Wholesaler	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	11,000	110,000
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	10,000	500,000
Reginal hospital	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	11,000	-
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	0,000	-
Referal hospital	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	11,000	-
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	0,000	-
Retail Pharmacy	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	1,000	110,000
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	0,000	500,000
Private hospital/Faith based organization	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	1,000	110,000
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	0,000	500,000
Sub total					**24**						**1,830,000**

Level 2: Districts											
District 1											
District hospital	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	11,000	-
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	10,000	-
Retail Pharmacy	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	11,000	110,000
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	10,000	500,000
Private hospital/Faith based organisation	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	11,000	110,000
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	10,000	500,000
Sub total					**12**						**1,220,000**
District 2											
District hospital	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	11,000	-
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	10,000	-
Retail Pharmacy	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	11,000	110,000
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	10,000	500,000
Private hospital/Faith based organisation	Cholestrerol lowering agent	Atovarstatin	tablets	20mg	2	1	P/30 tabs	5	10	11,000	110,000
	Antimalarial	Dihydroartemisinin / piperaquine phosphate	tablets	40/320mg	2	1	P/6 tabs	25	50	10,000	500,000
Sub total					**12**						**1,220,000**
Grand Total per region											**4,270,000**
					Grand Total per region 5 regions						**17,080,000**
	Expected number of samples to be collected in a region (districts + region level)				**48**						
	Expected number of samples to be collected from 5 regions (i.e 60 x 5)				**300**						

*** depends on the availability of MSD zone in respective region*

PHASE IV: SAMPLING PLAN FOR CONDUCTING PMS OF PROCAIN BENZYL PENICILLIN AND CLOXACILLIN IN IRINGA, NJOMBE, RUVUMA AND KILIMANJARO REGIONS

Sampling sites	Product Category	Product	Dosage Form	Strength	Number of brand/samples to be collected	Number of batches per brand to be collected	Unit Pack	Number of unit pack per batch to be collected	Total number of packs to be collected	Unit cost	Total cost
Level 1: Regional											
MSD	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	-
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	
Importer /Wholesaler	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	120,000
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	120,000
Reginal hospital	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	-
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	-
Referal hospital	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	-
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	-
Private hospital/Faith based organisation	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	120,000
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	120,000
Retail Pharmacy	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	120,000
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	120,000
Sub total					**24**						**720,000**
Level 2: Districts											

District 1											
District hospital	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	-
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	-
Retail Pharmacy	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	120,000
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	120,000
Private hospital	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	120,000
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	120,000
Sub total					**12**						**480,000**
District 2											
District hospital	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	-
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	-
Retail Pharmacy	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	120,000
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	120,000
Private hospital/Faith based organisation	Antibiotics	Procain Benzyl Penicillin	Injection	2.5/5 MIU	2	1	vials	40	80	1,500	120,000
		Cloxacillin	Injection	250mg/ml	2	1	vials	40	80	1,500	120,000
Subtotal					**12**						**480,000**
Grand Total per region											**1,680,000**
Grand Total per region 4 regions											**6,720,000**
	Expected number of samples to be collected in a Region (regional + districts level)				**48**						
	Expected number of samples to be collected from 4 regions (i.e 60 x 4)				**240**						
*** depends on the availability of MSD zone in respective region*											

TFDA
Tanzania Food & Drugs Authority

PHASE IV: SAMPLING PLAN FOR CONDUCTING PMS OF ALBENDAZOLE ORAL SOLUTION FOR VETERINARY IN MOROGORO, MANYARA, GEITA AND SHINYANGA REGIONS

Sampling sites	Product Category	Product	Dosage Form	Strength	Number of brand/sample to be collected	Number of batches per brand to be collected	Unit Pack	Number of unit pack per batch to be collected	Total number of pack to be collected	Unit cost	Cost
Level 1: Regional											
Importer/ Wholesale pharmacy	Antihelmintic	Albendazole	Oral solution	10%	2	1	500ml	6	12	10,000	120,000
Retail pharmacy/Veterinary Shops	Antihelmintic	Albendazole	Oral solution	10%	2	1	500ml	6	12	10,000	120,000
Private Veterinary Clinic	Antihelmintic	Albendazole	Oral solution	10%	2	1	500ml	6	12	10,000	120,000
Open Market/ Auctions	Antihelmintic	Albendazole	Oral solution	10%	2	1	500ml	6	12	10,000	120,000
Sub total					**8**						
level 2: Districts											
District 1											
Retail pharmacy	Antihelmintic	Albendazole	Oral solution	10%	2	1	500ml	6	12	10,000	120,000
ADDO Veterinary Shop	Antihelmintic	Albendazole	Oral solution	10%	2	1	500ml	6	12	10,000	120,000
Open Market/ Auctions	Antihelmintic	Albendazole	Oral solution	10%	2	1	500ml	6	12	10,000	120,000
Sub total					**6**				**36**		
District 2											
Retail pharmacy	Antihelmintic	Albendazole	Oral solution	10%	2	1	500ml	6	12	10,000	120,000
ADDO Veterinary Shop	Antihelmintic	Albendazole	Oral solution	10%	2	1	500ml	6	12	10,000	120,000
Open Market/ Auctions	Antihelmintic	Albendazole	Oral solution	10%	2	1	500ml	6	12	10,000	120,000
Sub total					**6**						**360,000**
Grand Total per region											**360,000**
Grand Total per 4 regions											**1,440,000**
Expected number of samples to be collected in a Regional (region + district level)					**20**						
Expected number of samples to be collected from 4 Regions (i.e 20 x 4)					**80**						

Annex II: Sample Collection Form

MEDICINES POST MARKETING SURVEILLANCE
SAMPLE COLLECTION FORM

1. Sample code: .....

   (Region/product/sequence number/sampling date ddmmyy)***

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.No	Name	Organization	Signature	Date

Note: Samples collected must remain in their original containers.

Annex III: Screening Form

TANZANIA FOOD AND DRUGS AUTHORITY

DIRECTORATE OF LABORATORY SERVICES

MEDICINES QUALITY ASSURANCE CENTERS

Compliance with the basic requirements for information accompanying the product and report on Minilab testing

Product name:_____

INNs: _____

1- External packaging	**Information present on the label**	
Product name	YES	NO
INN	YES	NO
Strength	YES	NO
Batch number	YES	NO
Expiry date	YES	NO
Manufacturer Name & Physical address	....	
Storage conditions	.....	

2- Primary packaging	**Information present on the label**	
Product name	YES	NO
Strength	YES	NO
Unit dose per blister or container stated	YES	NO
Batch number	YES	NO
Expiry date	YES	NO

Manufacturer name (specify only if different from the external packaging under point 1)	YES NO .....

3- Package leaflet	
Presence of the leaflet	YES NO
Language(s) of the leaflet	.....
Composition	YES NO
Manufacturer name & physical address (specify only if different from the external packaging under point 1)	YES NO ....
Storage conditions (specify only if different from the external packaging under point 1)	YES NO ....

4- Observation on any discrepancy between the above points 1, 2 or 3 or non-compliance, if any

5- Report on Minilab testing:

PHYSICAL/VISUAL INSPECTION TEST	
Description of dosage form	
Shape (circular, oval, flat sides, other)	
Uniformity of shape	
Uniformity of colour	
No physical damage (cracks, breaks, erosion, abrasion, sticky)	
Other observations (no foreign contaminant, dirty marks, proper seal - for capsule)	
DISINTEGRATION TEST	
Time of complete Did the drug pass	Time in minute of complete
Disintegration expected disintegration test?	disintegration observed
(30 minutes for uncoated tablet) ----------	
Yes No	
RESULT OF TLC TEST (see Appendix 2 for TLC result interpretation)	

Rf Standard (---): ------- Rf Standard (---): ------- Rf Standard (---): ------- Rf Standard (---): ------- Rf Sample (1): ---------- Rf Sample (2): ---------- Rf Sample (3): ---------- Rf Sample (4): ----------	Did the drug and the standard Spots have the same intensity? ---------- Was there any contaminant spot on TLC? ----------	Did The sample pass quality by using the TLC Test? Yes No

FINAL COMMENTS

The sample conformed with basic testing specifications

The sample not-conformed with basic quality testing

(Reason: .....)

The sample is doubtful for its basic quality testing

(Reason: .....)

REPORT PREPARED BY: Date: ..... Name: ..... Signature:	REPORT REVIEWED BY: Date: ..... Name: ..... Signature.....
ACTION TO BE TAKEN BY THE SUPERVISOR OF MEDICINES QUALITY ASSURANCE CENTER1	
Report the result to TFDA Date of report ..... Signature.....	Send the remaining sample units together with this Form to the TFDA QC lab for further testing Date ..... Signature .....
Reasons given for the chosen action:	

(Footnotes)

1 Action to be taken and communication between should be dependent on country's rules and regulations.

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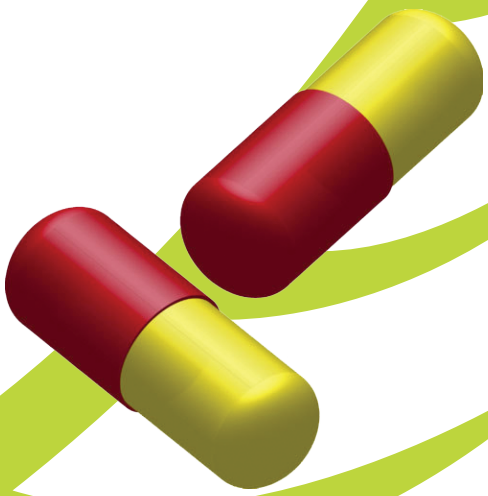

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