Doc. No. TMDA/DMD/MDV/PMS/R/003

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

POST MARKETING SURVEILLANCE FOR MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS REPORT 2023/24

SEPTEMBER, 2024

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LIST OF ABBREVIATIONS

HBV RDTs	-	Hepatitis B Virus Rapid Diagnostic Tests
HIV RDTs	-	Human Immunodeficiency Virus Rapid Diagnostics Tests
IFU	-	Instruction for Use
ISO	-	International Organisation for Standardization
IVDs	-	In - vitro Diagnostics
MDs	-	Medical Devices
mRDTs	-	Malaria Rapid Diagnostic Tests
MSD	-	Medical Stores Department
MoH	-	Ministry of Health
PIR	-	Product Information Review
POP	-	Plaster of Paris
PMS	-	Post Marketing Surveillance
TMDA	-	Tanzania Medicines and Medical Devices Authority
TMDA Act	-	Tanzania Medicines and Medical Devices Act, Cap 219
TMDA QCL	-	Tanzania Medicines and Medical Devices Authority Quality Control Laboratory
WHO	-	World Health Organization

DEFINITION OF TERMS

For the purpose of this report, the following terms or phrases are defined as follows:

In - vitro Diagnostics:

Means a medical device whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body and animals principally to provide information for diagnostic, monitoring or compatibility purposes and includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.

Medical device:

Means an instrument, apparatus, laboratory equipment and reagents, implement, machine, appliance, implant, medical equipment, contrivance, in-vitro reagent or calibrator, software, material or other similar or related article which-

a) is intended by the manufacturer to be used, alone or in combination for human beings or other animals for one or more of the specific purposes(s) of-
    i. diagnosis, prevention, monitoring, treatment or alleviation of diseases or compensation for an injury;
    ii. investigation, replacement, modification or support of the anatomy or of a physiological process;
    iii. supporting or sustaining life;
    iv. control of conception;
    v. disinfection of medical devices;
    vi. providing information for medical or diagnostic purposes by means of in-vitro examination or specimens derived from the human body or other animals; and
b) does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.

Monitoring:

Means the systematic and continuous process of collecting, analyzing and use of information for the purpose of control and decision-making.

Outcome:

Means results obtained from the PMS Programme such as percentage of PMS medical devices and diagnostics complying with labelling, quality and performance requirements.

Output:

Means an immediate result obtained from the PMS Programme such as percentage of planned PMS samples for medical devices and diagnostics collected (Deliverables).

Programme:

Means post marketing surveillance programme for medical devices and in-vitro diagnostics implemented in three (3) years.

Sample:
Means number of units (i.e., same product name, manufacturer, device type, package size, packaging material and strength) representing the same batch/lot and collected at the same location/outlet.

Sampling Plan:
Means a documented description of the location for sample collection, number of units and/or quantity of material that should be collected and associated acceptance criteria.

ACKNOWLEDGMENTS

On behalf of Tanzania Medicines and Medical Devices Authority (TMDA) Management, I would like to thank those who in one way or another assisted in preparation of this report. Special thanks are extended to the following TMDA staff; Ms. Mary Masanja, Mr. Kazimil Kishosha, Mr. Emmanuel Masunga, Ms. Rose Maingu, Mr. Haninu Nakuchema, Mr. James Tanguye and Mr. Frank Paschal who developed this report.

Similarly, I would like to acknowledge contribution made by TMDA Zone Managers and Inspectors in collaboration with President's Office Regional Administration and Local Government Inspectors who participated in sample collection. I also extend my sincere gratitude to evaluators who reviewed product information, analysts who carried out laboratory testing and all experts involved in this PMS programme.

Preparation of this report would not have been possible without commitment from TMDA staff and contributions made by our stakeholders who gave their valuable time and knowledge during the implementation of this phase one of the PMS programme. Their endeavour devotion is highly appreciated.

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

The proper measures based on the outcome of this report will ensure medical devices and in-vitro diagnostics circulating on the market are performing as intended by manufacturers.

Dr. Kissa W. Mwamwitwa
DIRECTOR OF MEDICAL DEVICES AND DIAGNOSTICS CONTROL

FOREWORD

Regulation of medical devices involves three main elements: pre-marketing, placing on the market and post-marketing controls. Pre-marketing control includes the issuance of marketing authorization; placing on the market involves licensing of premises; and post-marketing control covers inspection, surveillance and regulatory action(s).

Post Marketing Surveillance (PMS) is a systematic way of monitoring medical devices and diagnostics on the market. The first phase of the structured three (3) year PMS programme 2023/24 was implemented by the Directorate of Medical Devices and Diagnostics (DMD) through the Vigilance and Post-Marketing Surveillance Section. The implementation phase involved preparation of sampling plan, training of sample collectors, sample collection, product information review (PIR), laboratory analysis, report writing and execution of regulatory actions.

The first phase (2023-2024) of the current PMS Programme (2023/24-205/26) involved surveillance of ten (10) different types of medical devices and in-vitro diagnostics namely; syringes, male condoms, IV cannulas, malaria rapid diagnostic tests, human immunodeficiency virus rapid diagnostic tests, Plaster of Paris, spinal needles, hepatitis B virus rapid diagnostic tests, absorbent cotton gauges and blood bags were collected from eight (8) selected regions, evaluated and tested.

In this phase, a total of 352 (92.6%) samples (271 medical devices and 81 in-vitro diagnostics) were collected out of 380 planned samples. A total of 295 (83.8%) out of 352 samples passed PIR and 57 (16.2%) failed. The most notable deficiencies on product information observed were name and address of the manufacturer (11.4%) and product label (7.7%).

With respect to laboratory analysis, a total of 348 (99.1%) out of 352 collected samples met criteria for testing and were submitted to TMDA Quality Control Laboratory (TMDA QCL) for quality and performance checks. Out of the submitted samples, 347(99.7%) were tested for compliance with laboratory quality and performance parameters with exception of 1 (0.3%) sample that had expired. Majority (90.5%) of tested samples met quality and performance requirements. Nevertheless, 33 (9.5%) samples of a single category of selected devices, which is absorbent cotton gauze, failed the laboratory tests.

The Authority directed marketing authorization holders (MAH's) to rectify the observed anomalies for devices that failed product information review, conduct investigation to devices that were found to have poor quality and submit corrective actions. Devices that failed laboratory testing were recalled from the market to prevent further use and protect users from harm.

Overall, this surveillance has revealed that most of medical devices and in-vitro diagnostics circulating on the Tanzanian market comply with regulatory requirements.

Dr. Adam M. Fimbo
DIRECTOR GENERAL

1.0 INTRODUCTION

TMDA is an Executive Agency under the Ministry of Health (MoH) responsible for regulating the quality, safety and effectiveness of medicines, medical devices and diagnostics circulating in Tanzanian market. Medical devices and in-vitro diagnostics circulating in the country are therefore ensured to be of good quality, safe and performs as intended by the manufacturer. Regulation of these products is done through various mechanisms including Post Marketing Surveillance (PMS).

PMS is the monitoring of quality of medical devices and in-vitro diagnostics once they reach the market after authorization. It involves collection of samples, Product Information Review (PIR) and testing in the TMDA Quality Control Laboratory (QCL) which is prequalified by the World Health Organization (WHO). This is done to ensure that medical devices and in-vitro diagnostics in the market meet and maintains prescribed standards.

The Authority has two (2) ways for conducting PMS which are structured and routine approaches. Unlike the unstructured approach where medical devices are randomly sampled and tested, the structured approach entails developing of a PMS programme which defines systematically how medical devices and in-vitro diagnostics can be monitored in the market. The focus of the programme is to streamline and standardize the process of PMS which involves preparation of sampling plan, training of sample collectors, collection of samples, product information review and quality testing at TMDA QCL.

The structured PMS programme is the three (3) years survey which is conducted on annual basis. The current programme for the selected medical devices and in-vitro diagnostics runs from 2023/24 to 2025/26. The Directorate of Medical Devices and Diagnostics through Vigilance and Post Marketing Surveillance Section has completed one year implementation of PMS Programme for the selected medical devices and in-vitro diagnostics for the year 2023-2024.

Samples were collected from eight (8) regions including Arusha, Dar es salaam, Iringa, Kagera, Katavi, Mara, Mtwara and Njombe. Samples were collected from various levels of healthcare systems such as Medical Stores Department (MSD), hospitals, health centres, dispensaries, medical device outlets/premises and pharmacies. The collected samples were subjected to PIR and laboratory analysis.

The Surveillance targeted 10 different types of medical devices and in-vitro diagnostics which are Syringes, Male Condoms, IV Cannula, mRDT, HIV RDT, POP, Spinal Needle, HBV RDT, Absorbent Cotton Gauze and Blood Bags.

2.0 OBJECTIVES

2.1 Broad objective

The broad objective was to monitor the quality, safety and performance of selected medical devices and in-vitro diagnostics circulating on Tanzanian market.

2.2 Specific objectives

The specific objectives of the surveillance were:

2.2.1 To evaluate compliance of devices to quality requirements;
2.2.2 To assess the compliance of devices to performance requirements;
2.2.3 To determine the level of existence of poor - quality products in the market; and
2.2.4 To find out the best regulatory measures based on the outcome.

3.0 RATIONALE

During marketing authorization, medical devices and in-vitro diagnostics are approved for use based on assessment of their quality, safety and performance. However, once devices are on the market, they are subjected to different storage conditions and handling practices that may alter these important attributes of quality and performance and may result to inaccurate diagnosis, irrational treatment, financial loss due to repeated treatments and poor health outcomes. Therefore, this surveillance was conducted to establish evidence on the quality and performance of medical devices and in-vitro diagnostics with ultimate goal of protecting public health against the use of substandard and falsified products.

4.0 METHODOLOGY

4.1 Study design

Descriptive cross sectional study design was applied to evaluate the quality and performance of medical devices and in-vitro diagnostics in Tanzania. This design was selected to provide the snapshot of the status of these products once they are in the market.

4.2 Study sites

The study areas were MSD, hospitals, health centres, dispensaries, medical device outlets/premises and pharmacies from eight (8) regions namely Arusha, Dar es salaam, Iringa, Kagera, Katavi, Mara, Mtwara and Njombe.

4.3 Sample size

A total of 380 samples were planned to be collected based on approved PMS sampling plan for the year 2023/2024. The sampling plan contained detailed information on the sampling levels, sampling sites, product names, quantity and pack sizes (**Annex I**). The number of units to be collected was determined based on the requirements to facilitate testing.

4.4 Sampling method

Convenient sampling technique was applied whereby available samples at the visited premise were sampled. A multistage sampling technique was applied whereby regions and districts included in the study were selected based on purpose (purposeful sampling).

4.5 Inclusion criteria

The selection of regions and devices to be included in the programme differed according to pre-established selection criteria as described.

4.5.1 Criteria for selection of regions

The regions with the following characteristics were included in the programme;

(a) Densely populated regions.
(b) Regions bordering neighbouring countries and having official border points.
(c) Regions not covered in previous PMS studies.
(d) Regions with high HIV/AIDS and malaria prevalence rates.

4.5.2 Criteria for selection of medical devices and in-vitro diagnostics

Medical devices and in-vitro diagnostics with the following characteristics were included in the programme, the devices:

(a) Reported to have quality and performance concern through the vigilance system.
(b) That failed quality and/or performance parameters from previous PMS programme;
(c) That are highly used within the country;
(d) From manufacturers and importers with a history of reported substandard products;
(e) For public health importance.
(f) That are manufactured by domestic facilities.

4.6 Exclusion criteria

Devices to be excluded in the programme differed according to pre-established criteria as follows:

(a) Near to expiry devices whose remaining shelf life is less than six months;
(b) Inadequate laboratory testing capacity; and
(c) Devices of doubtful availability in the market.

4.7 Sample collection

4.7.1 Sample Collectors

A list of 15 designated PMS focal personnel (**Annex II)** was obtained from TMDA HQ and Zonal offices and were recruited and trained as sample collectors. The training focused on sampling plan and procedures including orientation on use of sample collection tools.

4.7.2 Sample collection tools

Sampling tools included specialized TMDA sampling form number TMDA/DMD/MDV/F/006 (Annex III), specialized envelopes/bags, marker pens, mask tapes and carton boxes which were provided to ensure that samples are collected as required.

4.7.3 Sampling

Samples were collected in their commercial package and details were recorded on the sample collection form. In addition, sample collectors were provided with Terms of Reference to provide guidance on collection of the samples (Annex IV)

4.8 Sample handling, transportation and storage

Each collected sample was coded according to the format prescribed in the Procedure for Post Marketing Surveillance of Medical Devices and in-vitro Diagnostics (TMDA/DMD/MDV/SOP/004). The code format is designed in such a way to provide information on site where the sample was collected, name of the product, sequential number of the sample and date of collection. The arrangement of the code was as follows; (Region/District/Facility (Area)/Product/Sequence number/Sampling date (dd.mm.yy). Coding was done for identification of the source and for avoiding possibility for mix-ups.

Coded samples with respective sampling forms were kept in a labelled sampling envelopes/bag. Samples were kept and stored according to the manufacturer's recommended storage conditions as prescribed on the product label. The transportation and storage of samples were done in accordance with section 3.11 of the "TMDA Guidelines for Premises Licensing and Good Distribution Practices, First Edition June, 2023." Samples were transported to TMDA Eastern Zone office for PIR and laboratory testing. Adequate measures were taken to ensure that collected samples were transported in good conditions from sites of collection to the laboratory to maintain their integrity.

Collected samples were kept in a well secured environment protected from light, air, moisture, heat or any other risk that could affect their integrity and were kept in special room under access control. After completion of laboratory testing, the remaining units of samples were kept in a designated store in accordance with manufacturer's recommendations. The remaining units may be stored for the period up to one (1) year post expiry before being disposed of as per TMDA procedures for disposal.

4.9 Sample analysis

The analysis of samples was done to assess the compliance of the collected samples to established standards which includes pharmacopoeia standards, ISO standards (International Organisation for Standardization) and TZS standards. The analysis of samples was done in two stages which are PIR and laboratory quality control testing. These stages are as described below;

4.9.1 Product Information Review (PIR)

PIR was conducted by review of devices information on their primary and secondary packaging labels and accompanying manuals/catalogue/inserts/instructions for use for conformity to TMDA approved product information and labelling requirements using the Medical Devices and in-vitro Diagnostics PMS PIR Checklist number TMDA/DMD/MDV/C/001 (**Annex V**).

In addition, samples were subjected to visual and physical verification of information about the manufacturer details and their integrity. Parameters checked were appearance or description, physical damage and foreign contaminant, dirty marks and proper seal, colour change and

number of items per pack. These parameters were checked against approved products information.

4.9.2 Quality control testing

Each device has different inherent physical and chemical attributes. Because of this, quality control testing was done depending on the recommended quality and performance parameters based on the TMDA QCL capacity. The recommended tested parameters per each device were stated in the programme (**Table 1)**.

Table 1: Type of device and Test parameters

SN	Type of device	Recommended Test Parameters
1.	Syringes	(a) Sterility (b) Water air leakage
2.	Male Condoms	(a) Dimensions; Length and width (b) Burst volume and pressure (c) Freedom from holes, (d) Package integrity as per ISO 4074: 2015
3.	POP	As per BP Percentage of $CaSO_4.½H_2O$
4.	mRDT kits	(a) Analytical sensitivity and (b) Specificity as per WHO standard
5.	HIV RDT kits	(a) Analytical sensitivity and (b) Specificity as per WHO standard
6.	IV Cannula	(a) Sterility, (b) Water air leakage
7.	Absorbent Gauze	As per BP (a) Sinking time (b) Water holding capacity (c) Thread count (d) Loss on drying
8.	HBV RDTs kits	(a) Analytical sensitivity and (b) Specificity as per WHO standard
9.	Spinal needle	(a) Container closure integrity (b) Sterility (c) Strength
10.	Blood bag	(a) Physical examination (b) Sterility

5.0 RESULTS

5.1 Samples collected

A total of 352 (92.6%) samples (271 medical devices (MDs) and 81 in-vitro Diagnostics (IVDs)) were collected out of 380 planned samples. Samples of medical devices collected were 271 (102.7%) out of 264 planned samples while in-vitro diagnostics was 81 **(**69.8%) out of 116 planned samples. Samples of male condoms (123.3%), POP (112.0%), syringes (108%), and absorbent cotton gauze (105.9%) and IV cannula (102.0%) were over collected whereas the least collected samples were MRDT kits (75.0%), HIV RDT kits (65.2%) and HBV RDT kits (60%) (**Table 2).**

Table 2: Planned versus collected samples

S/N	Description		Dar es Salaam	Arusha	Njombe	Iringa	Mtwara	Kagera	Katavi	Mara	Total	% collected
Medical Devices												
1.	Syringes	Planned	15	6	5	6	3	5	5	5	**50**	**108**
		Collected	18	6	5	6	6	5	5	3	**54**	
2.	Male Condoms	Planned	10	4	3	3	2	3	2	3	**30**	**123.3**
		Collected	12	8	3	3	2	3	3	3	**37**	
3.	POP	Planned	8	4	2	3	2	2	2	2	**25**	**112.0**
		Collected	10	4	2	4	2	2	2	2	**28**	
4.	IV Cannula	Planned	12	7	5	5	5	5	5	5	**49**	**102.0**
		Collected	13	8	5	5	5	5	5	4	**50**	
5.	Absorbent Gauze	Planned	16	7	4	6	4	5	5	4	**51**	**105.9**
		Collected	10	4	2	4	2	2	2	2	**28**	
6.	Spinal Needle	Planned	9	5	2	2	2	2	2	2	**26**	**92.3**
		Collected	9	5	2	2	1	2	2	1	**24**	
7.	Blood Bags	Planned	10	3	3	5	3	3	3	3	**33**	**72.7**
		Collected	5	3	2	2	2	3	3	4	**24**	
Medical device total collection											**271**	**102.7**
In-vitro Diagnostics												
1.	HBV RDTs	Planned	4	2	1	1	0	1	0	1	**10**	**60.0**
		Collected	1	2	1	1	0	0	0	1	**6**	
2.	mRDTs	Planned	19	9	5	6	5	6	5	5	**60**	**75.0**
		Collected	8	5	5	6	5	6	5	5	**45**	
3.	HIV RDTs	Planned	14	5	4	6	4	5	4	4	**46**	**65.2**
		Collected	0	5	5	6	2	4	4	4	**30**	
In-vitro diagnostics total collection											**81**	**69.8**
Planned samples-MDs & IVDs			**117**	**52**	**34**	**43**	**30**	**37**	**33**	**34**	**380**	**92.6**
Collected samples			**95**	**53**	**34**	**41**	**29**	**35**	**34**	**31**	**352**	
% collection per region			**81.2**	**101.9**	**100.0**	**95.3**	**96.7**	**94.6**	**103.0**	**91.2**	**92.6**	

a) Samples by collection sites

Most of samples were collected from hospitals (41.8%) and pharmacies (39.2%) followed by health centres (9.7%) whereas MSD, dispensaries and medical device outlets contributed less

than 5% (**Table 3**). Representation of the sample collected per region mostly were collected from Dar es salaam 95% **(Table 4).**

Table 3: Distribution of number of samples collected per sites

S/N	Type of device	Description of collection sites						
		MSD	Hospital	Health Centre	Dispensary	Pharmacy	Medical Device Outlet	Total
1.	Syringes	0	16	4	2	32	0	**54**
2.	Male Condoms	0	11	3	1	22	0	**37**
3.	mRDT	8	18	5	2	10	2	**45**
4.	HIV RDT	1	22	6	1	0	0	**30**
5.	POP	0	11	0	0	16	1	**28**
6.	IV Cannula	0	20	8	2	16	4	**50**
7.	Absorbent Gauze	0	17	5	1	30	1	**54**
8.	HBV RDT	0	3	1	0	2	0	**6**
9.	Spinal Needle	0	11	1	0	9	3	**24**
10.	Blood Bags	3	18	1	0	1	1	**24**
Total Devices Collected per collection site		**12**	**147**	**34**	**9**	**138**	**12**	**352**
Percentage of site collection		**3.4**	**41.8**	**9.7**	**2.5**	**39.2**	**3.4**	**100**

Table 4: Summary of collection site according to region

S/N	Region	Description of collection sites						
		MSD	Hospital	Health Centre	Dispensary	Pharmacy	Medical Device Outlet	Total
1.	Dar es Salaam	8	16	9	1	53	8	**95**
2.	Arusha	0	21	8	0	24	0	**53**
3.	Njombe	0	23	4	0	7	0	**34**
4.	Iringa	2	20	3	5	11	0	**41**
5.	Mtwara	1	15	0	2	11	0	**29**
6.	Kagera	1	16	6	1	11	0	**35**
7.	Katavi	0	21	1	0	10	2	**34**
8.	Mara	0	15	3	0	11	2	**31**
Total		**12**	**147**	**34**	**9**	**138**	**12**	**352**

b) Samples by lots/batches

A total of 242 different lots/batches of samples were collected from 73 brands of different manufacturers. The number of lots/batches collected by product type is; I.V Cannula (38), syringes (37), absorbent cotton gauze (34), mRTD (33) and male condoms (33) while few were collected for blood bags (7) and HBV RDT kits (6). The list of lot/batches per brand is detailed in **Annex VI.**

c) Samples by country of origin

The samples collected originated from 11 countries, mostly China (32%) and India (32%) while the least were from Malaysia (1%), Tanzania (0.6%) and South Africa (0.3%). The description of type of device by source country is provided in the following table **(Table 5).**

Table 5: Countries of original for the sampled devices

SN	Type of device	Country of origin for the collected brands of devices											Total
		China	India	Kenya	Tanzania	Pakistan	Thailand	Malysia	Republic of Korea	South Africa	Turkey	Egypt	
1.	Syringes	33	0	10	0	0	0	0	0	0	4	7	**54**
2.	Male Condoms	0	16	0	0	0	17	4	0	0	0	0	**37**
3.	mRDT	5	21	0	0	0	0	0	18	1	0	0	**45**
4.	HIV RDT	0	2	0	0	0	0	0	28	0	0	0	**30**
5.	POP	24	0	0	0	0	0	0	0	0	4	0	**28**
6.	IV Cannula	0	41	1	0	0	0	0	0	0	8	0	**50**
7.	Absorbent Gauze	29	0	0	2	23	0	0	0	0	0	0	**54**
8.	HBV RDT	3	3	0	0	0	0	0	0	0	0	0	**6**
9.	Spinal Needle	3	21	0	0	0	0	0	0	0	0	0	**24**
10.	Blood Bags	19	3	1	0	0	0	0	0	0	0	1	**24**
Total		**114**	**112**	**12**	**2**	**15**	**17**	**4**	**46**	**1**	**26**	**8**	**352**
Percentage (%)		**32**	**32**	**3**	**0.6**	**4**	**5**	**1**	**13**	**0.3**	**7**	**2**	

d) Compliance by registration status

Most of the samples collected were registered/notified 315 (89.5%) while 37 (10.5%) samples were not registered/notified as illustrated in the Table 6 below;

Table 6: registration status of collected samples

Na.	Medical Device	Registered	Unregistered	Total
1.	Syringes	43	11	**54**
2.	Male Condoms	37	0	**37**
3.	mRDT	45	0	**45**
4.	HIV RDT	30	0	**30**
5.	POP	23	5	**28**
6.	IV Cannula	46	4	**50**
7.	Absorbent Gauze	41	13	**54**
8.	HBV RDT	5	1	**6**

Na.	Medical Device	Registered	Unregistered	Total
9.	Spinal Needle	22	2	**24**
10.	Blood Bags	23	1	**24**
Total		**315**	**37**	**352**

5.2 Quality and performance of collected samples

5.2.1 Product Information Review

PIR was conducted on 16th – 20th October,2023 using Medical Devices and in-vitro Diagnostics PMS PIR Checklist number TMDA/DMD/MDV/C/001 and registered products details available in the Regulatory Information Management System (RIMS). A total of 357 collected samples were subjected to PIR (**Table 7)**.

Table 7: Collected samples subjected to PIR

S/N	Type of product	Number of samples collected	Number of samples subjected for PIR
1.	Syringes	54	54
2.	Male Condoms	37	37
3.	IV cannula	50	50
4.	mRDT	45	45
5.	HIV RDT	30	30
6.	HBV RDT	6	6
7.	POP	28	28
8.	Spinal Needle	24	24
9.	Absorbent Gauze	54	54
10.	Blood Bags	24	24
Total		**352**	**352**

a) Compliance level

The compliance by type, brand and lots/batch of devices. A total of 295 (83.8%) out of 352 samples passed PIR and 57 (16.2%) failed. The highest samples failure rate were blood bags 83.3% followed by syringes 40.7%, HBV RDT kits 16.7%, MRDT 15.6% and absorbent cotton gauze 13% (**Table 8** and **Figure 1**).

Table 8: Compliance by type of devices and number of samples

SN	Type of device	Reviewed (PIR)	Passed/ complied	Failed/ did not comply	% failed sample
1.	Syringes	54	32	22	40.7
2.	Male Condoms	37	37	0	0.0
3.	IV cannula	50	50	0	0.0
4.	mRDT	45	38	7	15.6
5.	HIV RDT	30	30	0	0.0
6.	HBV RDT	6	5	1	16.7
7.	POP	28	28	0	0.0
8.	Spinal Needle	24	24	0	0.0

SN	Type of device	Reviewed (PIR)	Passed/ complied	Failed/ did not comply	% failed sample
9.	Absorbent Gauze	54	47	7	13.0
10.	Blood Bags	24	4	20	83.3
Total samples		**352**	**295**	**57**	**16.2**

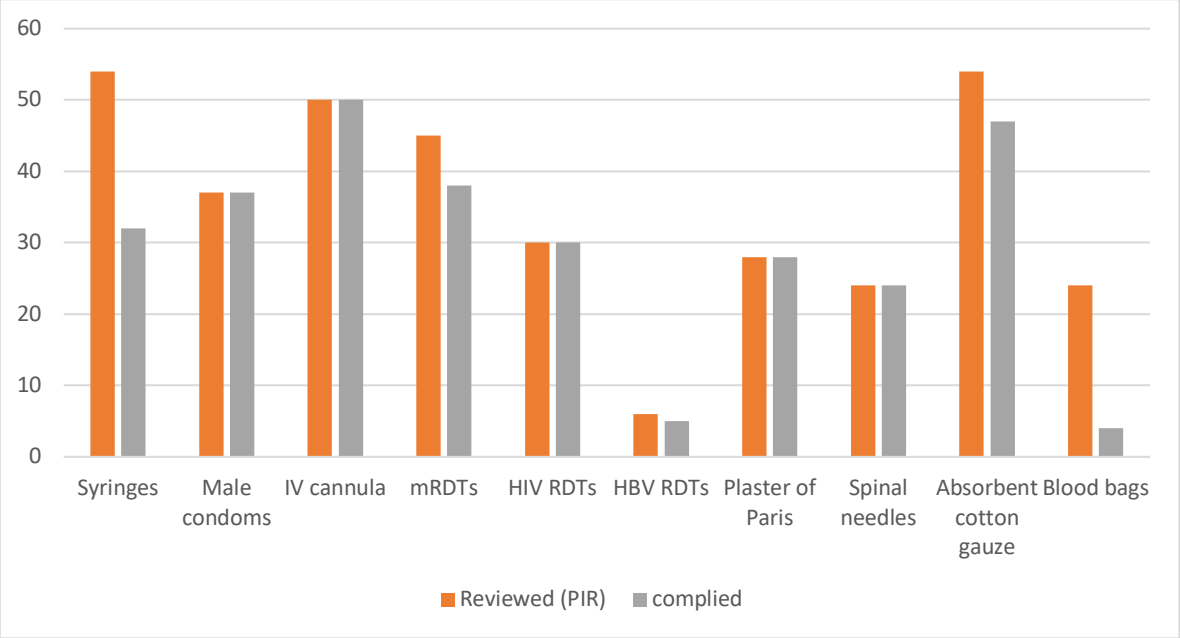

Figure 1: Compliance by type of devices and number of samples

Table 9: Distribution of samples failed PIR versus their registration status

SN	Type of device	Failed PIR		Total
		Registered/Notified	Not Registered/ notified	
1.	Syringes	22	0	22
4.	mRDT	7	0	7
6.	HBV RDT	0	1	1
9.	Absorbent Gauze	2	5	7
10.	Blood Bags	20	0	20
Total samples		**50**	**7**	**57**

b) Compliance by brand

A total of 10 (10.0%) out of 73 sampled brands failed PIR. Brands from absorbent cotton gauze (4), Syringes (1), mRDT (2), Blood bag (2) and HBV RDT kits (1) **Annex VI.**

c) Compliance by lots/batches

Of all 242 collected batches, 27 (11.2%) batches failed PIR. Batches from Syringes (6.2%) failed the most compared to mRDT (1.7%), Absorbent Cotton Gauze (1.7%), Blood bag (1.2%) and HBV RDT kits (0.4%) **Annex VI.**

Observed deficiencies

During PIR review 8 notable deficiencies were observed. The deficiencies in the manufacturer name and address were observed in 40 (11.4%) of the collected samples followed by deficiencies in product label 19 (7.7%) and deficiencies in the brand name of the device 18 (5.1%) compared to the other five (5) deficiencies noted **(Table 10} (Figure 2).**

A total of 20 (83.3%) out of 24 samples of blood bags had mismatch of information regarding the name and address of manufacturer between the physical sample and the information present in RIMS.

A total of 22 out of 54 samples of Neoject Auto Disable Syringes 10mls had mismatch of information in three areas:

(i). The physical address of the manufacturing site on the sample differed from the one in the RIMS;
(ii). Absence of “plus symbol” on the label of the physical sample in reference with the approved mock up label uploaded in RIMS; and
(iii). mock up label in RIMS contains the word "non pyrogenic" while the physical sample label does not.

The name of physical sample “Neoject re use prevention syringe 5mls” did not match with the corresponding name of the approved device “Neoject auto disable syringe 5mls” found in the RIMS.

Failed samples of mRDT kit had two (2) labelling issues; (a) buffer bottle had no brand name and physical address of the manufacture and (b) the IFU (Instruction for Use) does not contain manufacturer name and physical address.

Failed samples of absorbent cotton gauze lacked one or more of the following; batch number, manufacturing and expiry date and storage conditions. In addition, some had manufacture different from the one on the registered device.

One (1) failed sample of HBV RDT kits (Diagnostar) had no name and physical address of manufacture on the primary package.

Table 10: Number of samples and observed deficiencies

SN	Description of deficiencies	Number of device samples with deficiencies		Total number of deficiencies	Percentage (%)
		MD	IVD		
1.	Deficiencies in the brand name of the device	18	0	18	5.1
2.	Deficiencies in common name	4	0	4	1.1
3.	Deficiencies in the manufacturer name and address	40	0	40	11.4
4.	Deficiencies in package insert	0	8	8	2.3
5.	No batch or lot number	1	0	1	0.3
6.	Deficiencies in product label	19	8	27	7.7
7.	No storage conditions	4	0	4	1.1

SN	Description of deficiencies	Number of device samples with deficiencies		Total number of deficiencies	Percentage (%)
8.	No manufacturing and expiry date	1	0	1	0.3
Total number of samples		**87**	**16**	**103**	**29.3**

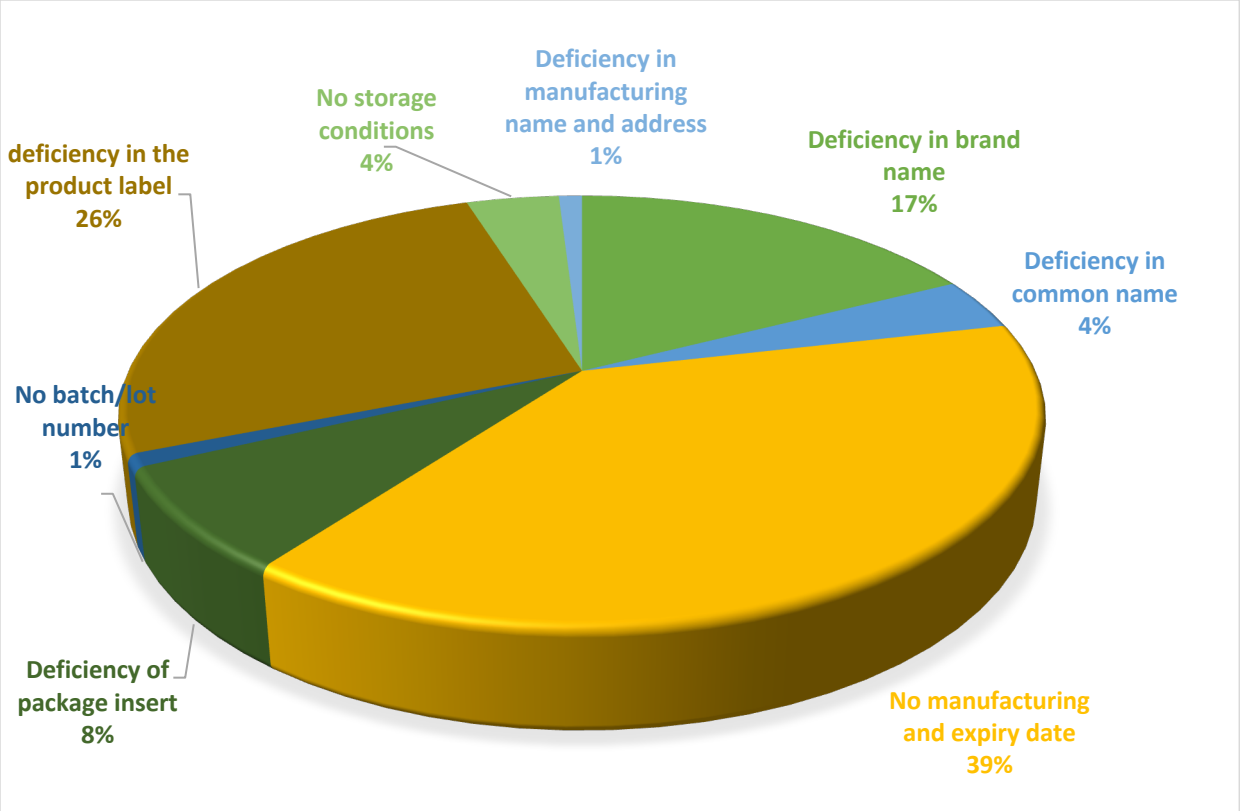

Figure 2: Type and number PIR deficiences on samples reviewed

d) Compliance by source country

Out of 11 countries of origin for the sampled devices, PIR deficiencies were observed in devices originated from 6 (54.5%) countries. Majority of devices samples that failed PIR originated from China (34) followed by Kenya (5), India (2), Pakistan (2), South Africa (1) and Turkey (1) (**Table 11)**.

Table 11: Country of origin for device samples that failed PIR

SN	Country of Origin	Number of device samples with deficiencies
1.	China	34
2.	India	2
3.	Kenya	5
4.	Tanzania	0
5.	Thailand	0
6.	Pakistan	2
7.	South Africa	1
8.	South Korea	0
9.	Malaysia	0

SN	Country of Origin	Number of device samples with deficiencies
10.	Turkey	1
11.	Egypt	0
Total		**45**

e) Compliance by collection sites

Majority of sampled devices which failed PIR were obtained from medical device outlets 25%, pharmacies 21.7% and hospitals 15.6% (**Table 12**).

Table No. 12: Compliance by collection sites

Sampling site	MSD	Hospital	Dispensary	Health Centre	Pharmacy	Medical Device outlet	Total
Total collected	12	147	9	34	138	12	352
Failed	0	23	0	1	30	3	57
% Failed	**0.0%**	**15.6%**	**0.0%**	**2.9%**	**21.7%**	**25.0%**	**16.0%**

5.2.2 Laboratory analysis

A total of 348 (99.1%) out of 352 collected samples of devices were submitted to TMDA-QCL for analysis, except one (1) sample of POP, two (2) samples of HIV RDT and one (1) sample of spinal needle **(Table 13)**

Table 13: Devices subjected to Laboratory testing

SN	Type of device	Collected Samples	Samples for Laboratory testing	
			Submitted	Not submitted
1	Syringe	54	54	0
2	Male Condom	37	37	0
3	POP	28	27	1
4	mRDT	45	45	0
5	Absorbent Gauze	54	54	0
6	HIV RDT	30	28	2
7	Spinal Needle	24	23	1
8	IV Cannula	50	50	0
9	HBV RDT	6	6	0
10	Blood Bag	24	24	0
Total		**352**	**348**	**4**

(a) Compliance by type of devices

Out of the submitted samples for laboratory testing 347 (99.7%) were tested for compliance to laboratory quality and performance parameters except 1 (0.3%) sample of HBV RDT kit was not tested as it expired before being tested. Majority of the samples passed laboratory test parameters, however 33 (9.5%) samples of only one type of device (absorbent cotton gauze) failed laboratory testing **(Table 14) (Figure 3)**.

Table 14: Results for Laboratory Testing

SN	Type of device	Submitted for laboratory testing	Passed	% Passed	Failed sample	% Failed
1	Syringe	54	54	100	0	**0**
2	Male Condom	37	37	100	0	**0**
3	POP	27	27	100	0	**0**
4	mRDT	45	45	100	0	**0**
5	Absorbent Gauze	54	21	38.9	33	**61.1**
6	HIV RDT	28	28	100	0	**0**
7	Spinal Needle	23	23	100	0	**0**
8	IV Cannula	50	50	100	0	**0**
9	HBV RDT	6	5	83.3	0	**0**
10	Blood Bag	24	24	100	0	**0**
Total		**348**	**314**	**90.5**	**33**	**9.5**

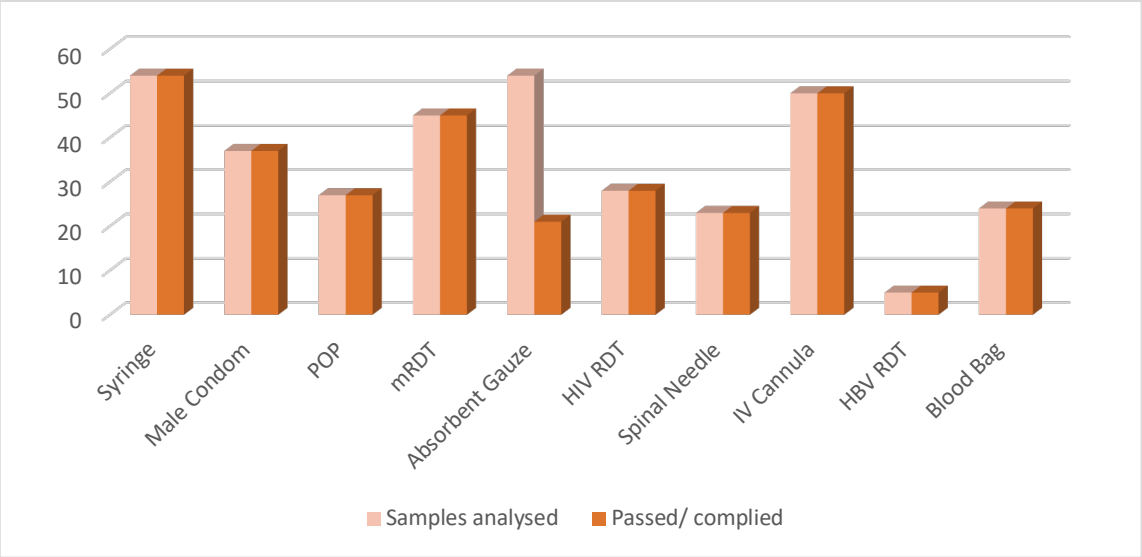

Figure 3: Results for Laboratory testing per type of device

Observed deficiencies in the failed samples: -

All 54 absorbent cotton gauze samples were tested for sinking time, water holding capacity, loss on drying and thread count. All these samples passed specifications of water holding capacity and loss on drying. A total of 31 (57.4%) absorbent cotton gauze samples failed one parameter (thread count) whereas 2 (3.7%) of absorbent cotton gauze samples failed both threads count and sinking time (**Annex VIII**). Similarly, 15 (44.1%) of the 34 batches of absorbent cotton gauze tested failed thread count only compared to 2 (5.9%) which failed both threads count and sinking time (**Annex VIII) (Table 15).**

Table 15: Products and parameters failed during laboratory analysis

Typer of Device	Total number of lots/ batches failed	Number of failed samples	Failed parameters
Absorbent cotton Gauze	2	2	Sinking Time & Thread Count
	15	31	Thread Count

(b) Compliance by source country and market placement

The failed samples of absorbent cotton gauze were manufactured from China, Pakistan and Tanzania. A total of 6 (75%) out of 8 brands from China did not comply with laboratory quality and performance parameters compared to 3 (50%) out of 6 brands from Pakistan and 1 (100%) brand from Tanzania. Five (5) failed brands (4 from China and 1 from Pakistan) were not notified.

Equivocally, a total of 24 (82.7%) out of 29 samples from China did not comply with laboratory quality and performance parameters compared to 7 (30.4%) out of 23 samples from Pakistan and 2 (100%) samples from Tanzania **(Table 16).**

The description of the collected and failed brands of absorbent cotton gauze is as annexed (**Annex IX**)

Table 16: Non - compliance by country of origin, number of samples and brands

S/N	Country of Origin	Number of samples collected	Number of samples failed	% of failed samples	Number of brands collected	Brands Failed			
						Notified brands	Not Notified	Total	%
1.	China	29	24	82.7	8	2	4	6	75
2.	Pakistan	23	7	30.4	6	2	1	3	50
3.	Tanzania	2	2	100	1	1	0	1	100
Total		**54**	**33**	**61.1**	**15**	**5**	**5**	**10**	**66.7**

(c) Compliance by collection sites

Majority of the sampled products which failed quality and performance parameters was obtained from pharmacy 12% (**Table 17**).

Table 17: Compliance by collection sites

Description	Collection site					
	MSD	Hospital/ Health Centre/ Dispensary	Pharmacy	Medical Device Outlets	Supermarket/ Shop	Total
Total tested	8	190	133	10	0	342
Total failed	0	17	16	0	0	33
% Failure	**0%**	**8.9%**	**12.0%**	**0%**	**0%**	**9.6%**

5.2.3 Overall compliance

A total of 295 (83.8%) out of 352 samples which were evaluated for PIR and 314 (90.5%) out of 347 which were tested in laboratory passed, samples from four (4) batches failed both PIR and laboratory quality testing (**Table 18) (Table 19).**

Table 18: Overall compliance status

S/N	Description of assessment	Number of samples	Passed	Failed	% Failure

		reviewed/ tested			
1	PIR	352	295	57	16.2
2	Laboratory quality testing	347	314	33	9.5

Table 19: Batch reference to failed samples for PIR and laboratory testing

S/N	Refence No.	Product Name	Batch Number	Failed PIR parameters	Failed Laboratory parameters
1.	DSM/ILA/PLANET PHARMACEUTICAL LTD/BELSOFT ABSORBENT GAUZE/078/30.09.23	Belsoft Absorbent Cotton Gauze	2016098	Storage condition not indicated	Thread count
2.	ARS/ARS/AGACARE PHARMACY/CROWN ABSORBENT GAUZE/025/27.09.24	Crown Absorbent Cotton Gauze	NIL	Batch number, expiry date, manufacturing date not indicated. The product is not registered.	Thread count
3.	IRI/IRI/ACACIA PAHRM/GAUZE/023/27.09.24	Afyasafe Absorbent Cotton Gauze	26659	Manufacturer name differs from the registered product. The physical sample is Sethi International, Lahore-Pakistan. Name in RIMS is Ali Sons, Karachi-Pakistan	Thread count
4.	KTV/MPD/MCHELE PHARMACY/ASTRACARE ABSORBENT GAUZE ROLL/022/27.09.24	Astracare Absorbent Cotton Gauze	20170417	Manufacturer name differs from the registered product. The name on the physical sample is Huanggang Huangzhou Xianghui Textiles Co; Ltd, China. Name in RIMS is Ali Sons, Office No-4, Al-Furqan Plaza, Block-7, FB. Area, Karachi, Pakistan	Thread count

6.0 DISCUSSION

Medical devices and in vitro diagnostics of poor quality, safety and performance pose serious public health risks. Marketing surveillance enables the Authority to identify potential quality and performance issues that are related with the use of devices. Evaluation of samples for quality and performance provide evidence for regulatory decision thus enabling the Authority to achieve its core mandate of protecting public health.

In this surveillance, it was observed that, the collected samples were less by 7% of the planned sample size. This deficit was contributed by absence of replacement samples of mRDT and HIV test kits from MSD for replacement of the same in the public health facilities and shortages of HBV RDT kits in the market especially in Dar es Salaam during sample collection.

Majority of samples were collected from hospitals and pharmacies because medical devices and diagnostics are essential part of the delivery of high-quality healthcare in hospital settings and in areas where these products are not available, they can easily be obtained from pharmacies. Majority of samples originated from China and India as most importers source medical devices and diagnostics from these countries. Most (90%) of collected samples were registered or notified indicating that their quality, safety and performance have been approved by the Authority prior to their distribution in the country.

The deficiency that was most noted in PIR was the lack/inconsistent name and address of the manufacturers. Devices with no or inconsistent names and addresses of their respective manufacturers are difficult to identify and trace, and may be falsified. Majority of devices samples that failed PIR originated from China as this country is one of the major sources of devices imported to Tanzania. Majority of samples that failed PIR were obtained from medical devices outlets, pharmacies and hospitals as these facilities are the major sources and users of these products respectively.

The observed failure in PIR was largely contributed by variation of the information between the label of the physical sample and approved label uploaded in the RIMS. This variation could be accounted by information being not entered correctly in RIMS during marketing authorization and or the applicant did variation/change of product label without notifying and or these products may have been falsified.

Majority of samples submitted to the laboratory were tested for all parameters as specified in the programme and as per methods specified for each device. However, four samples did not comply with the minimum number of units per sample required for laboratory testing, hence they were not submitted for laboratory testing. Likewise, 1 sample of HBV RDT kit was not tested as it expired before being tested making it unqualified for testing.

The highest laboratory failure rate (61.1%) was observed in absorbent cotton gauze which failed thread count and sinking time parameters. Failure in thread count reduces fluid absorption capacity at the area of tissue injury, thus compromising the healing process and putting patients at risks of infections. The failed samples of absorbent cotton gauze originated from China, Pakistan and Tanzania.

The high failure rate of absorbent cotton gauze sampled from pharmacies (12%) compared to other collection sites can be explained by a wide spectrum of products that are been procured and distributed by these premises.

The observed failure on tested samples of devices was high among non-notified devices (87%) compared to notified ones (41%), this high failure rate may be due to the fact that manufacturers of these products do not indicate the type of gauze on the labels.

The overall compliance rate in PIR (83.8%) and laboratory quality testing (90.5%) can be considered satisfactory and could be largely contributed by strengthened regulatory controls in medical devices and in vitro diagnostics which are being imposed by the Authority. However, the Authority should continue strengthening controls on medical device and ensure that dealers of devices in the country comply with requirement of obtaining market authorization for their manufactured or imported products.

The use of assured quality, performance and safety medical devices and in vitro diagnostics helps to improve the accuracy and effectiveness of medical treatment, leading to better patient outcomes. A strong regulatory system is an essential component of the health system that the Authority needs to continue strengthening in order to fulfil its mission of promoting and protecting public health.

7.0 REGULATORY ACTIONS TAKEN

Two (2) batches of absorbent cotton gauze (Acra soft batch number 20210325 and Belsoft batch number 2016098) that failed laboratory analysis for two parameters sinking time and thread count have been recalled from the market.

Manufacturers were directed to recall and investigate on the root cause for those products which failed laboratory analysis and to submit reports on the same to the Authority

8.0 RECOMMENDATIONS

The following recommendations have been proposed:

i. Thorough training to sample collectors to abide with the sampling plan and procedures should always precede sample collection process.
ii. The Market Authorization Holders (MAH) should be enforced to comply with labelling requirements including variations of the labels of products which failed PIR.

9.0 LIMITATIONS

Limitation of the programme include:

i. Insufficient number of units of samples to meet laboratory testing requirements.
ii. Delayed time in obtaining replacement samples from MSD that led to wastage of time for sample collection.
iii. Financial constraints to cater for sample purchasing, training and report writing.

10.0 AREAS FOR IMPROVEMENT

The observed areas for improvement were:

i. Training of sample collectors and reviewers of product information should be conducted.
ii. Devices that failed PIR and laboratory analysis should be included in the next programme.
iii. Parameters that could not be done previously due to limitation of TMDAQCL capacity should be done in the next programme after acquiring the capacity;
iv. Reference material especially device standards should always be available during the laboratory testing;

v. The Authority should consider allocating more funds for the PMS programme, particularly sample collection so that the sample collected could represent the real situation in the market.

11.0 CONCLUSION

The survey revealed that majority of the samples complied with established requirements by TMDA. This signifies well-functioning of the regulatory system. Since few samples did not comply with requirements, this calls for continued monitoring of quality and performance of circulating devices.

12.0 REFERENCES

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3. PIR Report for 2023/2024.
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5. The TMDA (Control of Medical Devices) Regulation, 2015 (GN315).
6. TMDA Guidelines for importation and exportation of medical devices including in-vitro diagnostics and laboratory equipment. Second Edition. April 2020. Available at https://www.tmda.go.tz/pages/import-and-export-control-of-medical-devices. Accessed on 31st January, 2024.

13.0 ANNEXES

Annex 1: Sampling plan

SAMPLING PLAN

POST MARKETING SURVEILLANCE PROGRAMME FOR MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS 2023/24-2025/26
YEAR 1 (2023/2024)

Sampling levels	Sampling sites	Product Name	Number of Samples
NATIONAL LEVEL			
Level 1. National and private procurement and supplies agents	MSD HQ		**380** (Total Samples to be collected)
	Random selected private importers and wholesalers **DSM:** Salama, Oysterbay, Anudha, Kasimwa, Samiro, Pyramid, KAS, Sciex, KS Global, Crown, Tandapharm, Grants Care, Deric 2000, Bariki, Biocare, Jilichem, Bahari, Nebula, Grants Care, Moraf, Umoja Pharmacy, Asante, GAA Holdings na Vital Supplies, DKT International		
Hospital	Muhimbili Orthopaedic Institute (MOI)		
Level 2: REGIONAL LEVEL			
MSD Zonal	MSD Zone Office (DSM, KLM, IRI, MBY, MULEBA, TBR, MTR, MWZ)	**Medical Device/ in-vitro Diagnostics**	**Number of samples distribution region wise**
Public hospitals	**ARUSHA (ARS):** Mount Meru RRH **DAR ES SALAAM (DSM):** Amana and Mwananyamala **IRINGA (IRI):** Iringa RRH **KAGERA (KAG):** Bukoba RRH **KATAVI (KTV):** Katavi RRH **MARA (MAR):** Mwalimu Nyerere Memorial Hospital (MNMH) **MTWARA (MTR):** Ligula RRH **NJOMBE (NJO):** Njombe RRH	**SYRINGES (5cc and 10cc)** • Revital • Neoject • Kojak • MPL • ICO **MALE CONDOMS** • Kiss • Dume • Salama • Bull • Life Guard • Zana	**SYRINGES** ARS - 6 DSM - 15 IRI - 6 KAG - 5 KTV - 5 MAR - 5 MTR – 3 NJO - 5 **Total - 50** **MALE CONDOMS** ARS - 4 DSM - 10 IRI - 3 KAG - 3 KTV - 2 MAR - 3 MTR - 2 NJO - 3 **Total - 30**
Private hospitals	**ARUSHA (ARS):** Arusha Lutheran Medical Centre (ALMC), St. Elizabeth Hospital St. Joseph and Nkuaranga hospital **DAR ES SALAAM (DSM):** Regency, TMJ, Agakhan, Kairuki, Rabininsia, Masana, Hindu Mandal, Kadinali Rugambwa and CCBRT. **IRINGA (IRI):** IMECC **KAGERA (KAG):** Nyakaiga hospital **KATAVI (KTV):** -	**I.V CANNULA (24G, 26G & 28G)** • Heuer • Oneflon • Neovac • I. V. Flon • Polymed	**I.V CANNULA (24G)** ARS - 7 DSM - 12 IRI - 5 KAG - 6 KTV - 5 MAR - 5

Sampling levels	Sampling sites	Product Name	Number of Samples
	MARA (MAR): Omega hospital, CF hospital **MTWARA (MTR):** - **NJOMBE (NJO):** Tanwat hospital		MTR - 5 NJO - 5 **Total - 50**
Wholesalers/ Distributors	**ARUSHA (ARS):** General Pharmacy, Vasco Pharmacuricals Ltd, **DAR ES SALAAM (DSM):** Nakiete, JD, Abacus, Afya Bora, Astra Pharma, Blandina, Core, Global DSM, Heko, Medisurg, Planet, Ian Reddy's, Anudha, Crown Healthcare Ltd, Salama Pharmaceuticals Ltd, and Kas Medics Ltd. **IRINGA (IRI):** Medox, Maranatha and Acacia **KAGERA (KAG):** Bariki Pharmacy, Jeet Pharmacy, Eju Pharmacy, Shikanani **KATAVI (KTV):** Abacus Ltd, Rukwa Pharmacy, Shukrani Pharmacy, Mchele Pharmacy **MARA (MAR):** Mkendo Pharmacy, Apricks Pharmacy, Bigeso Pharmacy, Marambe Pharmacy and Kivuyo Pharmacy **MTWARA (MTR):** Maduma Pharmacy, Dolphin Pharmacy and Resha Pharmacy **NJOMBE (NJO):** Malabata Pharmacy, Mnongelwa Pharmacy, Maranatha Pharmacy, Negi Pharmacy	**mRDT** • First Response • MPL • Paracheck • Meri screen • CareStart **HIV RDT** • Duke • SD Bioline • Abbott **POP** • MPL • Neosafe • Acrasoft • Neocast	**mRDT** ARS - 9 DSM - 19 IRI - 6 KAG - 6 KTV - 5 MAR - 5 MTR - 5 NJO - 5 **Total - 60** **HIV RDT** ARS - 5 DSM - 14 IRI - 6 KAG - 5 KTV - 4 MAR - 4 MTR - 4 NJO - 4 **Total - 46** **PLASTER OF PARIS (POP)** ARS - 4 DSM - 8 IRI - 3 KAG - 2 KTV - 2 MAR - 2 MTR - 2 NJO - 2 **Total - 25**
Level 3. District Level Hospitals and Pharmacies	**ARUSHA (ARS):** **Hospitals:** Arusha City and Meru **Pharmacies:** Bowman, Medicare **DAR ES SALAAM (DSM):** **Hospitals:** Mnazi Mmoja and Magomeni **Pharmacies:** Mdee, RK, Horizon and Oysterbay **IRINGA (IRI):** **Hospitals:** Mafinga TC hospital and Frelimo hospital **Pharmacies:** Mafinga, Manuel, Compassion and Nazareth **KAGERA (KAG):** **Hospitals**: Nyakahanga DDH **Pharmacies:** Zed, ELCT – Karagwe Pharmacy, Tonny **KATAVI (KTV):** **Hospitals**: Mpanda, Mpimbwe and Mlele	**SPINAL NEEDLE (23G & 25G)** • Heuer • Polymed HBV RDTs • Onsite HBsAg Combo • Artron • Nescen • Diagnos	**SPINAL NEEDLE (23G & 25G)** ARS - 5 DSM - 9 IRI - 2 KAG - 2 KTV - 2 MAR - 2 MTR - 2 NJO - 2 **Total - 26** **HEPATITIS B VIRUS RDTs** ARS - 2 DSM - 4 IRI - 1

Sampling levels	Sampling sites	Product Name	Number of Samples
	District hospital **Pharmacies:** MSD Outlet, Chambo, Mizingo, Kingdom and Tadecha **MARA (MAR):** **Hospitals:** Musoma RRH and Tarime TC hospital **Pharmacies:** Kwangwa, SK, Chacha Magasi and Wantuzu **MTWARA (MTR):** **Hospitals:** Mkomaindo **Pharmacies:** Maduma, Mkuti and Samir **NJOMBE (NJO):** **Hospitals:** Njombe TC hospital, Makambako TC hospital **Pharmacies:** Milano, Simime, MAKI, Mwaijala, Kiula, Makambako and Bondi	• Smart • Determine HbsAg • Quick Profile HbsAb **ABSORBENT GAUZE** • Msagara • MSL • Neosafe • Razycot	KAG - 1 KTV - 0 MAR - 1 MTR - 0 NJO - 1 **Total - 10** **ABSORBENT GAUZE** ARS - 7 DSM - 16 IRI - 6 KAG - 5 KTV - 5 MAR - 4 MTR - 4 NJO - 4 **Total - 51**
Level 3. Public and Private Health Centers / Dispensaries	ARUSHA (ARS): **Health centres:** Kaloleni, Nduruma, St. Thomas and Usa-River **Dispensaries:** Sakina, Huruma and Njiro. DAR ES SALAAM (DSM): **Health Centres:** UDSM, Makurumla, Mbezi, Cradre-Msasani, London, Kigogo, Tandale, Buguruni, Vingunguti, Magomeni, Mnazi Mmoja, Pugu Kajiungeni and Ukonga Magereza **Dispensaries:** Tabata Kisiwani, Segerea, Arafa Mamboleo, Nsomeni, Makongo Juu, Kijitonyama, Kunduchi, Mount Ukombozi, Tegeta Mission, Mavurunza and Manzese MARA (MAR): **Health centres:** Nyasho, Bweri, Optic, TGF and Magena **Dispensaries:** Magereza, Gamasara, Kenyamanyori and Bikira Maria IRINGA (IRI): **Health Centres:** Mkwawa, Kimande, Ifunda, Migoli, Ihongelo, JKT Mafinga, Kinyambo, Lothar, Mtandika, Torina, Ihongelo, Aga Khan, Cosmopolitan, Muce, Ngome, DRH, Nipende, Tumaini Jipya and Ukumbi **Dispensaries:** Al-Amal, Hope, Alamano, Chamdindi, Ifunda, Alpha, Ibumu, Idasi, St. Paul, Wambi, Bumilayinga, Kitanzini, Igumbilo, Sokoni, RC Ipogoro, Polisi, Marie-Stopes and Changarawe NJOMBE (NJO): **Health centres:** Njombe, Makambako, Afya Medicare, Anglikan, Nazareti, Mgao, Lyamkena **Dispensaries:** Tumaini, Hekima, Marie-Stopes and RC Makambako	**BLOOD BAGS** • MSL • CPDA1 • Orien-pharm CPDA -1, • Laishi CPDA-1 • Mitra • Polymed Single 450ml CPDA	**BLOOD BAG** ARS - 3 DSM - 10 IRI - 5 KAG - 3 KTV - 3 MAR - 3 MTR - 5 NJO - 3 **Total - 30**

Sampling levels	Sampling sites	Product Name	Number of Samples
	KATAVI (KTV): **Health centres:** St. Aloyce, Ilembo, Town Clinic and Usevya **Dispensaries:** Ndoha, Afya, Upendo, Huruma and TMC KAGERA (KAG): **Health centres:** Nyakayanja, Kayanga and Rwambaizi **Dispensaries:** Chanika, Omurusimbi, Buhamira, Ruhita, Bujuruga, Bukangara, Kishoju and Rugu, Nyaishozi and Nyabiyonza MTWARA (MTR): **Health centres:** **MTR MC:** Likombe, Chuno, Polisi, Mount Royal **Masasi:** Mtandi, Kidibo **Dispensaries:** **Mtarwa MC:** Mikindani and Ufukoni, **Masasi:** Mkuti and Chisegu		

Annex II: List of Trained Sample Collectors

S/N	Directorate/Zone office	Name of sample collector
1.	DMD	David Matle
2.		Amina Kingo
3.		Kazimil Kishosha
4.		Gudula Mpanda
5.		Lineth Apolnary
6.		Fatma Mohamed

7.	Directorate of Laboratory Services	Thomson Mwampamba
8.	TMDA-Northern Zone	Eliya Nyeura
9.	TMDA-Eastern Zone	Yahya Mutungi
10.	TMDA-Southern Zone	Horrace Mbugani
11.	TMDA-Central Zone	Elizabeth Mollel
12.	TMDA-Western Zone	Kiboko Magigi
13.	TMDA-Southern Highland Zone	Selemani Mayala
14.	TMDA-Lake Zone East	Edwin Mtemi
15.	TMDA-Lake Zone West	Anitha Katundu

Annex III: Sample Collection Form

MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS POST MARKETING SURVEILLANCE SAMPLE COLLECTION FORM

TMDA/DMD/MDV/F/006

1. Sample code: ..…….
   (*Region/District/Facility (Area)/Product/Sequence number/Sampling date (dd.mm.yy)*
2. Name of Premises where sample was taken ……..……

3. Physical address ……
   (*Look at other certificates available indicating physical address*).
4. Postal address …… Phone …….. E-Mail ……
5. Date of Sample collection …… Time of sample collection……..……..
6. Name of products ……..……..……
7. Reason for collection ……..……..……
8. Comment on the storage condition at the premise
   i. Clean/Dirty…….Air circulation ……..……..……

   ii. Temperature……Humidity ……..

9. Pack size ……..

10. Name and Address of manufacturer ……

11. Batch/Lot No. on the secondary pack ……

12. Manufacturing Date …….. Expiring Date ……

13. Number of units collected ……

14. Name, signature and contact of the Representative of the premises where sample was collected:

    Name……..Signature……..…… Phone ……..……..

15. Name of Inspector(s)/Sampling officer

S/N	Name	Organization	Signature	Date
1.				
2.				
3.				

Note: Samples should be collected in their original packaging

Annex IV: Terms of Reference

	JAMHURI YA MUUNGANO WA TANZANIA **WIZARA YA AFYA** **MAMLAKA YA DAWA NA VIFAA TIBA**	TMDA Tanzania Medicines & Medical Devices Authority

HADIDU ZA REJEA KATIKA KAZI YA UFUATILIAJI WA UBORA NA UFANISI WA VIFAA TIBA NA VITENDANISHI

1. Tafadhali rejea kichwa cha habari hapo juu.

2. Kurugenzi ya Vifaa Tiba na Vitendanishi kupitia Sehemu ya Ufuatiliaji Usalama imepanga kuanza utekelezaji wa awamu ya kwanza (2023/2024) ya Mpango wa nne (4) wa Ufuatiliaji Vifaa Tiba na Vitendanishi wa miaka mitatu (3) wa ***2023/2024 - 2025/2026*** (***PMS Programme 2023/2024 - 2025/2026***) katika soko kwa lengo la kuhakiki ubora na ufanisi wake.

3. Kazi hii imepangwa kufanyika tarehe 25 Septemba – 4 Oktoba, 2023 katika mikoa ya Dar es Salaam, Katavi, Arusha, Mara, Iringa, Njombe, Kagera na Mtwara ambapo sampuli za vifaa tiba na vitendanishi aina ya syringes, male condoms, mRDTs, HIV RDTs, Hepatitis B RDTs, Plaster of Paris (POP), Absorbent Gauze, I.V cannula, Spinal Needle na Blood Bags zimepangwa kukusanywa kama ilivyoainishwa kwenye jedwali hapa chini.

Na.	Jina la Mkoa	Vifupisho vya Mkoa	Wilaya na vifupisho	Idadi ya Sampuli	Jumla
1.	Dar es Salaam	DSM	1. Ilala CC (**ILA**) 2. Kinondoni MC (**KIN**)	Syringes (5cc & 10cc)	15
				Male condoms	10
				Plaster of Paris (POP)	8
				Malaria RDTs	19
				Absorbent Gauze	16
				HIV RDTs	14
				Spinal Needle (23G & 25G)	9
				I.V Cannula (24G, 26G & 28G)	12
				Hepatitis B RDTs	4
				Blood Bag	10
		Jumla Ndogo kwa Mkoa			**117**
2.	Iringa	IRI	1. Iringa MC (**IRI**) 2. Mafinga TC (**MAF**)	Syringes (5cc & 10cc)	6
				Male condoms	3
				Plaster of Paris (POP)	3
				Malaria RDTs	6
				Absorbent Gauze	6
				HIV RDTs	6
				Spinal Needle (23G & 25G)	2
				I.V Cannula (24G, 26G & 28G)	5
				Hepatitis B RDTs	1
				Blood Bag	5
		Jumla Ndogo kwa Mkoa			**43**
3.	Katavi	KTV	1. Mpanda MC (**MPD**) 2. Mlele DC (**MLE**)	Syringes (5cc & 10cc)	5
				Male condoms	2
				Plaster of Paris (POP)	2
				Malaria RDTs	5
				Absorbent Gauze	5
				HIV RDTs	4
				Spinal Needle (23G & 25G)	2
				I.V Cannula (24G, 26G & 28G)	5
				Hepatitis B RDTs	0
				Blood Bag	3
		Jumla Ndogo kwa Mkoa			**33**
5.	Arusha	ARS		Syringes (5cc & 10cc)	6

Na.	Jina la Mkoa	Vifupisho vya Mkoa	Wilaya na vifupisho	Idadi ya Sampuli	Jumla
			1. Arusha CC (**ARS**) 2. Meru DC (**MER**)	Male condoms	4
				Plaster of Paris (POP)	4
				Malaria RDTs	9
				Absorbent Gauze	7
				HIV RDTs	5
				Spinal Needle (23G & 25G)	5
				I.V Cannula (24G, 26G & 28G)	7
				Hepatitis B RDTs	2
				Blood Bag	3
		Jumla Ndogo kwa Mkoa			**52**
6.	Mara	MAR	1. Musoma MC (**MUS**) 2. Tarime TC (**TAR**)	Syringes (5cc & 10cc)	5
				Male condoms	3
				Plaster of Paris (POP)	2
				Malaria RDTs	5
				Absorbent Gauze	4
				HIV RDTs	4
				Spinal Needle (23G & 25G)	2
				I.V Cannula (24G, 26G & 28G)	5
				Hepatitis B RDTs	1
				Blood Bag	3
		Jumla Ndogo kwa Mkoa			**34**
7.	Kagera	KAG	1. Bukoba MC (**BUK**) 2. Karagwe DC (**KAR**)	Syringes (5cc & 10cc)	5
				Male condoms	3
				Plaster of Paris (POP)	2
				Malaria RDTs	6
				Absorbent Gauze	5
				HIV RDTs	5
				Spinal Needle (23G & 25G)	2
				I.V Cannula (24G, 26G & 28G)	5
				Hepatitis B RDTs	1
				Blood Bag	3
		Jumla Ndogo kwa Mkoa			**37**
8.	Njombe	NJO	1. Njombe TC (**NJO**) 2. Makambako TC (**MAK**)	Syringes (5cc & 10cc)	5
				Male condoms	3
				Plaster of Paris (POP)	2
				Malaria RDTs	5
				Absorbent Gauze	4
				HIV RDTs	4
				Spinal Needle (23G & 25G)	2
				I.V Cannula (24G, 26G & 28G)	5
				Hepatitis B RDTs	1
				Blood Bag	3
		Jumla Ndogo kwa Mkoa			**34**
9.	Mtwara	MTR	1. Mtwara MC (**MTR**) 2. Masasi TC (**MAS**)	Syringes (5cc & 10cc)	3
				Male condoms	2
				Plaster of Paris (POP)	2
				Malaria RDTs	5
				Absorbent Gauze	4
				HIV RDTs	4
				Spinal Needle (23G & 25G)	2

Na.	Jina la Mkoa	Vifupisho vya Mkoa	Wilaya na vifupisho	Idadi ya Sampuli	Jumla
				I.V Cannula (24G, 26G & 28G)	5
				Hepatitis B RDTs	0
				Blood Bag	3
		Jumla Ndogo kwa Mkoa			**30**
		Jumla Kuu			**380**

4. Sampuli hizo zitakusanywa kwa kuzingatia mwongozo wa kukusanya sampuli (*Sampling Guide*) ulioko kwenye **Kiambatisho Na. 1**

Majukumu ya Mchukuaji Sampuli

a) Wachukuaji sampuli kujitambulisha kwenye ofisi za Katibu Tawala wa mkoa na Mkurugenzi wa Jiji/Manispaa/Mji/Wilaya kabla ya kuanza zoezi;

b) Kuhakikisha anakuwa na nyenzo stahiki za kazi kama vile Kitambulisho, PMS Programme 2023/2024 – 2025/2026*,* Hadidu za Rejea, Fomu ya kuchukulia sampuli, *marker pen*, bahasha, *masking tapes* na maboksi ya kufungia sampuli;

c) Kuchukua sampuli za bidhaa kulingana na mwongozo wa Mpango;

d) Kuzipa namba sampuli kwa mfumo wa namba ufuatao: (Region/District/Facility(Area)/Product/Sequence number/Sampling date (dd.mm.yy) **Mfano:** NJO/MAK/Makambako DH/First Response mRDT/001/07.11.22;

e) Kuhakikisha fomu ya kuchukulia sampuli inajazwa ipasavyo na kila sampuli ijazwe kwenye fomu yake;

f) Namba ya sampuli iliyojazwa kwenye fomu lazima iandikwe kwenye kila pakiti ya sampuli husika na sehemu zisizo na maandishi;

g) Baada ya fomu husika kujazwa, Fomu (*original copy*) abaki nayo mchukuaji sampuli na nakala ibaki kwenye eneo sampuli ilipochukuliwa;

h) Wakati wa kuchukua sampuli kwenye maghala ya MSD, mchukuaji wa sampuli atachukua sampuli kiasi kinachotosha kwa ajili ya tathmini pamoja na kiasi kingine cha ziada kwa ajili ya kubadilisha kwenye vituo vya afya vya Serikali na binafsi. Pia sampuli zingine zitanunuliwa kutoka kwa wasambazaji binafsi na idadi ya sampuli za ziada za kuchukua ni kama ilivyoainishwa kwenye barua ya MSD iliyoambatishwa.

i) Kuhifadhi vizuri sampuli pamoja na fomu zilizojazwa katika hali inayoridhisha ndani ya bahasha ambayo nayo itaandikwa namba ya sampuli;

j) Bahasha za sampuli zipakiwe katika makasha (*boxes*) na yafungwe kwa namna ambayo yanazuia sampuli kutikisika wakati wa usafirishaji;

k) Sampuli zitakazokusanywa zisafirishwe kwenda Ofisi ya Kanda ya Mashariki na mawasiliano yafanyike kupitia kwa Bi. Amina Kingo (0715 623362) kwa kutumia njia ya haraka na salama iwezekanavyo;

l) Kuhakikisha manunuzi yeyote yatakayofanyika yafanyike kwa kuzingatia taratibu na kuchukua risiti za EFD na risiti zihifadhiwe vizuri. Inapotokea upatikanaji wa risiti za EFD ni mgumu, mchukuaji wa sampuli achukue risiti ya mkono kwa malipo atakayofanya;

m) Mchukuaji wa sampuli achukue kasha la nje (*secondary package*) kwa sampuli zitakazochukuliwa kwa kufungua kasha husika;
n) Kusambaza fomu na kutoa elimu kwa ufupi juu ya utoaji wa taarifa za madhara na matukio yatokanayo na matumizi ya vifaa tiba na vitendanishi; na

o) Kuandaa taarifa ya kazi katika *format* iliyoambatishwa.

5. Wakati wa utekelezaji wa zoezi hili, endapo kutatokea changamoto yoyote na kama kuna uhitaji wa mawasiliano, wachukuaji sampuli wawasiliane na Bw. Kazimil Kishosha (0759912211) na Bw. David Matle (0715387521/0754387521).

Nakutakia kazi njema.

Mary M. Masanja
Meneja, Ufuatiliaji Usalama wa Vifaa Tiba na Vitendanishi

15 Septemba, 2023

Annex V: PIR checklist

TMDA Tanzania Medicines & Medical Devices Authority	**MEDICAL DEVICES AND INVITRO DIAGNOSTICS PMS PRODUCT INFORMATION REVIEW CHECKLIST**	***TMDA/DMD/MDV/C/001 Rev #:03***

(This checklist applies to all kits of one sample collected)

1. Sample code _____

2. Common name: _____

3. Brand name: _____

PART I: MEDICAL DEVICES (MDs)

A. LABELLING

1. Primary Package	**Information present on the label**	
Common name	YES ☐	NO ☐
Product code	YES ☐	NO ☐
Batch or lot number	YES ☐	NO ☐
CE mark (where applicable)	YES ☐	NO ☐
Manufacturing date	YES ☐	NO ☐
Expiry date	YES ☐	NO ☐
The word "Sterile" (where applicable)	YES ☐	NO ☐
The word "For single use only" (where applicable)	YES ☐	NO ☐
Manufacturer's Name & Physical address	…… …… ……	
Storage conditions		
Content of the kit	1..... 2..... 3..... 4.....	

2. Package insert/manual/catalogue/IFU		
Language(s) used (English/Kiswahili)	.....	
Is the Manufacturer name and physical address indicated?	YES ☐	NO ☐
Is the storage condition indicated?	YES ☐	NO ☐
Is the indicated storage condition different from the secondary packaging?	YES ☐	NO ☐
Does the IFU contain all the requirements as per guideline?	YES ☐	NO ☐

3. Describe any discrepancy/noncompliance observed under points 1 and 2 above.

_____

_____

B. PRODUCT VISUAL AND PHYSICAL ASSESSMENT

Description of the product (*Describe any discrepancy observed on each component of the product*)	
Physical damage	
Contamination, dirty marks, proper seal	
Registration status	
Other observations depending on the product	

CONCLUSION

☐ The sample conforms with a Product Information Review assessment

☐ The sample does not-conform with Product Information Review assessment

Remarks: ……

……

……

PART II: INVITRO DIAGNOSTOCS DEVICES (IVDs)

A. LABELLING

4. Secondary packaging	**Information present on the label**	
Common name	YES ☐	NO ☐

Product code	YES ☐	NO ☐
Batch or lot number	YES ☐	NO ☐
CE mark (where applicable)	YES ☐	NO ☐
Manufacturing date	YES ☐	NO ☐
Expiry date	YES ☐	NO ☐
The word “Sterile” (where applicable)	YES ☐	NO ☐
The word or symbol “For In-vitro diagnostic use”	YES ☐	NO ☐
The word “For single use only” (where applicable)	YES ☐	NO ☐
Manufacturer’s Name & Physical address	…… …… ……	
Storage conditions		
Content of the kit	1..... 2..... 3..... 4..... 5..... 6.....	

5. Primary packaging *(Information present on the label)*	**Test Cassette**		**Buffer bottle**	
Common name	YES ☐	NO ☐	YES ☐	NO ☐
Brand name	YES ☐	NO ☐	YES ☐	NO ☐
Batch or lot number	YES ☐	NO ☐	YES ☐	NO ☐
Manufacturing date	YES ☐	NO ☐	YES ☐	NO ☐
Expiry date	YES ☐	NO ☐	YES ☐	NO ☐
Words or symbol “Single use only” (Where applicable)	YES ☐	NO ☐	YES ☐	NO ☐
Is the Manufacturer name and physical address indicated?	YES ☐	NO ☐	YES ☐	NO ☐
Is the indicated Manufacturer name and address different from the one on secondary packaging?	YES ☐	NO ☐	YES ☐	NO ☐
Is the indicated Manufacturer name and address different from the one registered?	YES ☐	NO ☐	YES ☐	NO ☐

6. Package insert/manual/catalogue/IFU		
Presence of the insert/manual/catalogue/IFU	YES ☐	NO ☐
Language(s) used (English/Kiswahili)	.....	
Is the package insert readable?	YES ☐	NO ☐
Does the product insert resemble the one approved?	YES ☐	NO ☐
Is the Manufacturer name and physical address indicated?	YES ☐	NO ☐
Is the indicated Manufacturer name and address different from the one on secondary packaging?	YES ☐	NO ☐
Is the storage conditions indicated?	YES ☐	NO ☐
Is the indicated storage condition different from the secondary packaging?	YES ☐	NO ☐
Does the IFU contain all the requirements as per guideline?	YES ☐	NO ☐

7. Describe any discrepancy/noncompliance observed under points 1, 2 or 3 above.

B. PRODUCT VISUAL AND PHYSICAL ASSESSMENT

Description of the product (*Describe any discrepancy observed on each component of the product*)	
Physical damage	
Contamination, dirty marks, proper seal	
Registration status	
Other observations depending on the product	
CONCLUSION ☐ The sample conforms with a Product Information Review assessment ☐ The sample does not-conform with Product Information Review assessment Remarks: ……..…….. ……	
EVALUATED BY: Name: ……..……. Signature: ……..…… Date: ..……..…...	**AUDITED BY:** Name: …..…… Signature: ……..……..……..…… Date: ……..……

Annex VI: List of brands and Lots/batches collected

SN	DEVICE NAME	BRAND COLLECTED	SIZE	LOT/BATCH NUMBER COLLECTED	LOT/BATCH COLLECTED	LOT/BATCH FAILED PIR	LOT/BATCH FAILED LAB. ANALYSIS
1.	Syringes	Surgimed	5ml	22958302	1		
			10ml	22958301	1		
		Neoject	2ml	20221209	1	20221209	

SN	DEVICE NAME	BRAND COLLECTED	SIZE	LOT/BATCH NUMBER COLLECTED	LOT/BATCH COLLECTED	LOT/BATCH FAILED PIR	LOT/BATCH FAILED LAB. ANALYSIS
			5ml	20201104; 20201112 20230218; 20201105 277710; 20239218 217710; 228604 235005;20230423	10	20201104; 20201105 20239218; 217710; 228604; 235005 20230423; 20230218	
			10ml	20221118; 20221226 20221119; 20230108 20221112; 20221208	6	20230108; 20221112 20221119; 20221208 20221226; 20221118	
		Eldawliaico	5ml	2209	1		
			10ml	2209	1		
		MSL	10ml	20221128	1		
		Revital	5ml	234204;066522	2		
			10ml	066522;26523;019323 098022; 235502	5		
		SMinjection	5ml	22958302	1		
		MED D	10ml	2209	1		
		ICO	5ml	2301	1		
			10ml	2301	1		
		Haiou	5ml	22HA3 22HA4	2		
			10ml	20220816	2		
Total		**9**	**-**	**-**	**37**	**15**	**0**
2.	Male Condoms	Dume	NA	L34200302; L28200303 L45200904; L42200902 L43200901; L20200705 L19200706; L41200905 L119200705	9		
		Zana	NA	PG2234; PL22151 PJ2119; PB2118 PJ2288; PH2112 PA2163; PH2222 PC2328; PB2129 PH2202; PG2069 PB23102	13		
		Kiss classic	NA	2210950822:2006952922	2		
		Bull red	NA	L25220103	1		
		Bull orange	NA	L34220101	1		
		Fiesta max dotted	NA	CD489801	1		
		Fiesta ultrathin	NA	RRS489801	1		
		Fiesta	NA	UT459601	1		
		Rough rider	NA	2208891616	1		
		Life guard	NA	DG2112; DJ2201; DJ2203	3		
Total		**10**	**-**	**-**	**33**	**0**	**0**
3	mRDT	Bioline	NA	05EDH013A; 05EDH023A 05EDH027A;05EDH014A 05EDH027A;05EDH01	8		

SN	DEVICE NAME	BRAND COLLECTED	SIZE	LOT/BATCH NUMBER COLLECTED	LOT/BATCH COLLECTED	LOT/BATCH FAILED PIR	LOT/BATCH FAILED LAB. ANALYSIS
				4A 05EDH021A;05EDH013A			
		MPL	NA	011122Y; 0111227 01112Y	3	011122Y; 0111227; 01112Y	
		Abbott	NA	05EDH006B;05EDI001B 05EDH040A;05EDH018A	4		
		Malaria dual	NA	230628066	1	230628066	
		First response rapid test	NA	75H2422S;75G1S22S 01122Y;74J61228 75A05225;75A07225 75G1922S;75G19228 75A02225;75H2222S 75G2122S;74J6122S 74G5622S;74G1922S 75A0522S;75H2522S	16		
		Fastep	NA	I2303205	1		
Total		**6**	**-**	**-**	**33**	**4**	**0**
4.	HIV RDT	Bioline	NA	03ADI002A;03ADI004A 03ADH027A;03ADH033A 03ADH010A.A;03ADH031B 06ADI029A;03ADI004A 03ADH032B;03ADI001A 03ADT001A;03AD1004A 03ADH034A;03ADI003A	14		
		Abbott	NA	03ADH031B-E;03ADI004A 03ADDH041;3AD1004A 03DI004A	5		
Total		**2**	**-**	**-**	**19**	**0**	**0**
5.	POP	Medimax	6x2.7m	CJ21597	1		
		Surgimed	5cm x 2.7m	23969904;22956202	2		
		Medisafe	.5cm x 2.7m	201034	1		
			0cm x 2.7m	190506	1		
		Neocast	5cm x 2.7m	CMPC0201; MPI1101	2		
			.5cm x 2.7m	CMPJ0801; CMPB1101 22956202; 202111	4		
			0cm x 2.7m	CMPA0901	1		
			5cm x 2.7m	CMPA0901	1		
			0cm x 2.7m	CMPA1201; CMPC0401 190506	3		
		Acrasoft	5cm x 2.7m	202111	1		
			0cm x 2.7m	202204	1		
		Plaster Of Paris Bandage BP	5cm x 2.7m	22956202;230302	2		
1.		Naivas Care	15cmx 2.7m	210525	1		
Total		**7**	**-**	**-**	**21**	**0**	**0**
6	IV	Trident	24G	211VCB05C; 2209	3		

SN	DEVICE NAME	BRAND COLLECTED	SIZE	LOT/BATCH NUMBER COLLECTED	LOT/BATCH COLLECTED	LOT/BATCH FAILED PIR	LOT/BATCH FAILED LAB. ANALYSIS
	Cannula			21IVC07C			
		Polyflon	24G	3164422F; 3297822M 8111720M	3		
		Polymed	24G	3120621D; 3215921G 3041823B	3		
		Reflon	24G	R280619			
		Neovac	24G	152212; 352211; 712212 352211; 212208; 812203 252112; 812203; 712212 832203; 212208; 202208 152212	13		
		Karemax	24G	712009	1		
		G-Flon	24G	22E1221	1		
		Oneflon	24G	1L217; 2L237; 8N245 1K132; 2L277; 1K177 OH167; 1L207	8		
		I.V. Flon	24G	2108034; 2103016	2		
		One Flow	24G	2L227; 2L247	2		
		Dispoflon	24G	220638	1		
		Iv Cannula	24G	2112011	1		
Total		**12**	**-**	**-**	**38**	**-**	**-**
7.	Absorbent Gauze	Surgimed	500gm	23969904 22962003 22956203	3		23969904; 22962003
		Neosafe	90cm x 100yds	AS2023033;2022002 S2023023; A52023025 AS2022154; AS2023035 AS2022137; 20221224 AS2023022; 20211125; 2016098;	11		AS2023035; AS2023033; AS2023022; 20211125
			90cm x 100yds	2921477	1		
			90cm x 25yds	20230331	1		20230331
		Razycot	90cm x 100yds	SI- 11123;22161	2		SI- 11123
		Hekosoft	50mg/ 500mg	2022134	1		
		Mwafrisoft	90cm x 100yds	AS2022138	1		
		Msagara	90cm x 100yds	RMG2/2023/04/36 RMGZ/2023/04/40 2023/04/30	3		RMGZ/2023/04/40; 2023/04/30
		Astracare	90cm x 100yds	20170417	1	20170417	20170417
		Acrasoft	90cm x 100yds	20210325	1		20210325
		Naivas Care	500gm	221111	1		221111
		Medisafe	90cm x 100yds	221082; 221081	2	221082	
		MSL	500gm	221002E-1; 200204E-1	2		221002E-1; 200204E-1
		MPL	90cm x100yds	2227703	1		
		Afyasafe	90cm x	26659	1	26659	26659

SN	DEVICE NAME	BRAND COLLECTED	SIZE	LOT/BATCH NUMBER COLLECTED	LOT/BATCH COLLECTED	LOT/BATCH FAILED PIR	LOT/BATCH FAILED LAB. ANALYSIS
			100yds				
		Belsoft	90cm x100yds	2016098	1	2016098	2016098
		Crown	500gm	-	1	-	-
Total		**15**	**-**	**-**	**34**	**4**	**17**
8.	Hepatitis B RDT	Diagnostar	NA	2005118	1	2005118	
		Meriscreen	NA	MI1022086; MI0423042	2		
		Is It	NA	060222	1		
		Laborex	NA	2305088: GCH BSG-301	2		
Total		**4**	**-**	**-**	**6**	**1**	**-**
9.	Spinal Needle	Polymed	23G	3124420D; 8145023D 8054121D; 8130923D 8149122G; 22121986 312452OD;81491229 8128022F;8054221D 8149122	11		
		Heuer	25G	EX.6698	1		
		Surgmed		22965008	1		
		Kindfine	25G	FIN02001	1		
Total		**4**	**-**	**-**	**14**	**-**	**-**
10.	Blood bag	MSL	NA	20230531	1		
		Polymed	NA	23020246; 21090982 22121986	3		
		Lai shi	NA	20220116; 20220117	2	20220117; 20220116	
		Orienpharm	NA	20230330	1	20230330	
Total		**4**	**-**	**-**	**7**	**3**	**-**
GRAND TOTAL		**73**	**-**	**-**	**242**	**27**	**17**

Annex VII: Failed samples and their tested parameters by each brand

SN	Device name	Name of the manufacturer	Lot/Batch number	Man - Exp	Parameter(s) failed	Site collected

SN	Device name	Name of the manufacturer	Lot/Batch number	Man - Exp	Parameter(s) failed	Site collected
1.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	23969904	- Ap. 2028	Thread Count	Usa River HC - Arusha
2.	MSL Absorbent Cotton Gauze	Anji Spenq Industrial Co; Ltd, F16 Building C, Anji Chamber of Commerce Masion, Zhejiang China	221002E-1	Nov. 2022 – Nov.2027	Thread Count	Abacus Pharm - Mtwara
3.	Naivas Care Absorbent Cotton Gauze	Yangzhou Super Union Import & Export Co; Ltd, No. 120 Xishan South Road, Chenj Town, Yizheng City, Jiangsu Province, Jiangsu - China	221111	Jan. 2023 – Dec. 2027	Thread Count	Karagwe DH - Kagera
4.	Naivas Care Absorbent Cotton Gauze	Yangzhou Super Union Import & Export Co; Ltd, No. 120 Xishan South Road, Chenj Town, Yizheng City, Jiangsu Province, Jiangsu - China	221111	Jan. 2023 – Dec. 2027	Thread Count	Vasco Pharmaceutical -Arusha
5.	Neosafe Absorbent Cotton Gauze	Ali Sons, Karachi Pakistan	AS2023035	Feb. 2023 – Jan. 2028	Thread Count	Sunrise Pharmacy - DSM
6.	Neosafe Absorbent Cotton Gauze	Ali Sons, Karachi Pakistan	AS2023035	Feb. 2023 – Jan. 2028	Thread Count	Nakiete Pharmacy - DSM
7.	Neosafe Absorbent Cotton Gauze	Ali Sons, Karachi Pakistan	AS2023033	Feb. 2023 – Jan. 2028	Thread Count	Salama Pharm - DSM
8.	Neosafe Absorbent Cotton Gauze	Ali Sons, Karachi Pakistan	AS2023022	Jan 2023 – Dec 2027	Thread Count	Faru Pharmacy - DSM
9.	Neosafe Absorbent Cotton Gauze	Guangshui Sbetter Medical Products Co; Ltd, Hebei - China	20230331	Marc 2023 – Marc 2028	Thread Count	Salama Pharm - DSM
10.	Neosafe Absorbent Cotton Gauze	Guangshui Sbetter Medical Products Co; Ltd, Hebei - China	20211125	Nov 2021 – Nov 2026	Thread Count	Baraka Pharm - DSM
11.	Razycot Absorbent Cotton Gauze	Sethi International, 29 km Off rawind Road, Lahore - Pakistan	SI - 11123	July 2022 – July 2027	Thread Count	TTCH - Mara
12.	MSL Absorbent Cotton Gauze	Anji Spenq Industrial Co; Ltd, F16 Building C, Anji Chamber of Commerce Masion, Zhejiang China	221002E-1	Nov 2022 – Nov 2027	Thread Count	Marabata Pharm - Njombe
13.	Neosafe Absorbent Cotton Gauze	Guangshui Sbetter Medical Products Co; Ltd, Hebei - China	20230331	Marc 2023 – Marc 2028	Thread Count	Sunrise Pharm - DSM
14.	Acra Soft Absorbent Cotton Gauze	Forlong Medical Co; Ltd, No. 33 Zhihui Road, Huishan District, Wuxi - China	20210325	Marc 2021 - Marc 2026	Sinking Time & Thread Count	Nyakahanga Hosp - Kagera
15.	Belsoft Absorbent Cotton Gauze	Sethi International, 29 km Off rawind Road, Lahore - Pakistan	2016098	Dec 2020 – Dec 2024	Sinking Time & Thread Count	Planet Pharm - DSM
16.	Crown Absorbent Cotton Gauze	Nantongjianan Medical Products Co; Ltd, Jiangsu province, Jiangsu - China	-	-	Thread Count	Agacare Pharm - Arusha
17.	Afya Safe Absorbent	Sethi International, 29 km Off rawind Road,	26659	Aug 2022 – Sep 2027	Thread Count	Acacia Pharm Iringa

SN	Device name	Name of the manufacturer	Lot/Batch number	Man - Exp	Parameter(s) failed	Site collected
	Cotton Gauze	Lahore - Pakistan				
18.	Astracare Absorbent Cotton Gauze	Huanggang huangzhou Xianghui textiles Co; Ltd, China	20170417	Apr 2021 – Apr 2026	Thread Count	Mchele Pharm - Katavi
19.	Msagara Absorbent Cotton Gauze	Msagara Investment Co; ltd, Kwakopa Kinondoni, DMS	2023/04/40	Feb 2023 – Feb 2031	Thread Count	Mafinga Hosp - Iringa
20.	Msagara Absorbent Cotton Gauze	Msagara Investment Co; ltd, Kwakopa Kinondoni, DMS	2023/04/30	Feb 2023 – Feb 2031	Thread Count	Mpanda DH - Katavi
21.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	22962003	Dec 2022 – Nov 2027	Thread Count	NRRH - Njombe
22.	MSL Absorbent Cotton Gauze	Anji Spenq Industrial Co; Ltd, F16 Building C, Anji Chamber of Commerce Masion, Zhejiang China	221002E-1	Nov 2022 – Nov 2027	Thread Count	Bikira Maria Mama wa Huruma HC - Arusha
23.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	23969904	May 2023 – Apr 2028	Thread Count	Mwananyamala RRH- DSM
24.	MSL Absorbent Cotton Gauze	Anji Spenq Industrial Co; Ltd, F16 Building C, Anji Chamber of Commerce Masion, Zhejiang China	221002E-1	Nov 2022 – Nov 2027	Thread Count	Mukendo Pharm - Mara
25.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	22962003	Dec 2022 – Nov 2027	Thread Count	Katavi RRH - Katavi
26.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	23969904	May 2023 – Apr 2028	Thread Count	Likombe DH - Mtwara
27.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	23969904	May 2023 – Apr 2028	Thread Count	Mkomaindo DH - Mtwara
28.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	22962003	Dec 2022 – Nov 2027	Thread Count	Flerimo Hosp – Iringa
29.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	22962003	Dec 2022 – Nov 2027	Thread Count	Kayanga HC – Kagera
30.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	22962003	Dec 2022 – Nov 2027	Thread Count	Mlele Dh – Katavi
31.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	23969904	May 2023 – Apr 2028	Thread Count	Mnazi Mmoja Hospital – DSM
32.	Surgimed Absorbent Cotton Gauze	Surgimed Medical Supplies Co; Ltd, Zhajiang - China	22962003	Dec 2022 – Nov 2027	Thread Count	IRRH - Iringa
33.	MSL Absorbent Cotton Gauze	Anji Spenq Industrial Co; Ltd, F16 Building C, Anji Chamber of Commerce Masion, Zhejiang China	200204E-1	Marc 2020 – Marc 2025	Thread Count	Zep Pharm – Kagera

Annex VIII: Notification status of collected and failed brands of absorbent cotton gauze

S/N	Brand Name	Country of origin	Number of samples collected	Samples failed	Notification status	Failed parameters
1	Acrasoft	China	1	1	Notified	Sinking Time & Thread Count
2	Afyasafe	China	1	1	Notified	Thread Count
3	Astracare	China	1	1	Notified	Thread Count
4	Belsoft	Pakistan	1	1	Notified	Sinking Time & Thread Count
5	Crown	China	1	1	Not notified	Thread Count
6	Hekosoft	Pakistan	1	0	Not notified	Thread Count
7	Medisafe	China	3	0	Not notified	Thread Count
8	MPL	Pakistan	3	0	Notified	Thread Count
9	MSL	China	5	5	Notified	Thread Count
10	Msagara	Tanzania	2	2	Notified	Thread Count
11	Mwafrisoft	Pakistan	1	0	Notified	Thread Count
12	Naives	China	2	2	Not notified	Thread Count
13	Neosafe	Pakistan	18	7	Notified	Thread Count
14	Razycot	Pakistan	1	1	Notified	Thread Count
15	Surgimed	China	13	11	Not notified	Thread Count
Total			**54**	**33**	**-**	**-**