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UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

EVALUATION REPORT ON POST MARKETING SURVEILLANCE PROGRAMME FOR MEDICAL DEVICES AND IN VITRO DIAGNOSTICS (2020/21 - 2022/23)

MAY, 2024

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TABLE OF CONTENTS

ABBREVIATIONS

ASTMF	-	American Society for Testing and Materials - Floor Surface
BP	-	British Pharmacopeia
DIS	-	Draft International Standard
HIV RDTs	-	Human Immunodeficiency Virus Rapid Diagnostics Tests
ISO	-	International Organisation for Standardization
IUDs	-	Intra Uterine Devices
IV	-	Intravenous
IVD	-	In Vitro Diagnostics
MAH	-	Marketing Authorization Holder
MD	-	Medical Devices
MoH	-	Ministry of Health
mRDTs	-	Malaria Rapid Diagnostic Tests
MSD	-	Medical Stores Department
PIR	-	Product Information Review
PMS	-	Post Marketing Surveillance
POP	-	Plaster of Paris
QCL	-	Quality Control Laboratory
QMS	-	Quality Management System
TMDA Act	-	Tanzania Medicines and Medical Devices Act, Cap 219
TMDA	-	Tanzania Medicines and Medical Devices Authority
UPT	-	Urinary Pregnancy Test
USA	-	United States of America
USP	-	United States Pharmacopeia
WHO	-	World Health Organization

DEFINITION OF TERMS

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

Evaluation: A periodic assessment of the extent to which the objectives stated in the PMS Programme 2020/21 – 2022/23 have been achieved in relation to the efficiency, effectiveness, impact, sustainability and relevance.

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 more of the specific purpose(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: The systematic and continuous collecting, analyzing and use of information for the purpose of management control and decision-making.

Outcome: Percentage of PMS medical devices and diagnostics complying with labeling, quality and performance requirements.

Output: An immediate result obtained from the PMS Programme such as percentage of planned PMS samples for medical devices and diagnostics collected.

Programme: Is defined as post marketing surveillance programme for medical devices and in vitro diagnostics implemented in three years.

Sample: Means the 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 description of the location, number of units and/or quantity of material that should be collected and associated acceptance criteria.

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

Kissa W. Mwamwitwa
DIRECTOR OF MEDICAL DEVICES AND DIAGNOSTICS CONTROL

FOREWORD

Post Marketing Surveillance (PMS) of medical devices is a methodology used to monitor the quality, safety and performance of devices circulating on the market. Monitoring is performed to ensure that medical devices and diagnostics meet and maintains prescribed standards of quality, safety and performance to protect public health.

The monitoring of quality and performance of medical devices and in vitro diagnostics circulating on the market is done through both structured and unstructured approaches. The structured PMS programme is a three-year programme which is implemented annually and involves planning, budgeting and implementation. The implementation phase involves training of sample collectors, collection of samples, product information review (PIR), laboratory testing, evaluation of results, regulatory actions and report writing.

This PMS programme was conducted in 18 regions of Tanzania Mainland from 2021 to 2023. The programme targeted collection of 25 types of selected medical devices and in vitro diagnostics from different levels of healthcare facilities and various medicines and medical devices outlets.

In this programme, a total of 1,038 (92.6%) out of 1121 planned samples were collected. The review of product information of all collected samples revealed that 150 (14.5%) samples did not comply with the labelling requirements. The notable non-compliances observed were lack of names and addresses of manufacturers, instructions on storage conditions and some devices did not have permanent labels on the secondary packaging.

In addition, 890 (90.5%) of 983 tested samples passed the quality control tests and the remaining 93 (9.5%) samples failed the test. Parameters failed were diameter and suture breaking load for surgical sutures, absorbance, sinking time and water holding capacity for cotton wool, sinking time for absorbent gauze, percentage content of calcium sulphate hemihydrate for plaster of paris (POP), lack of fluid filter for intravenous giving set and rewet under load for baby diaper.

The Authority directed marketing authorization holders (MAHs) to rectify the observed anomalies for devices that failed product information review, conduct investigations 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.

This surveillance has revealed that, 76% of medical devices and in vitro diagnostics circulating on the Tanzanian market comply with both product information and laboratory testing requirements. The observed overall failure rate of 0.7% calls for continuous monitoring which will help to identify defective devices to allow the Authority to take the required regulatory actions. Protecting public health requires constant monitoring of the quality and performance of the devices circulating on the market.

Dr. Adam M. Fimbo
DIRECTOR GENERAL

1.0 INTRODUCTION

TMDA is an Executive Agency under the Ministry of Health responsible for regulating the quality, safety and effectiveness of medicines, medical devices and diagnostics circulating in Tanzanian market. Regulation is done through various monitoring mechanisms including Post Marketing Surveillance (PMS). PMS involves collection of samples, review of product information (PIR) and testing in the TMDA WHO-prequalified laboratory.

PMS of medical devices is a methodology used to monitor the quality, safety and performance of devices circulating in the market. Monitoring is performed to ensure that medical devices and diagnostics in the market meet and maintains prescribed standards of quality safety and performance in order to protect public health. This programme involves surveillance of devices already placed in the market.

PMS involves sampling of medical devices from the market using a prepared sampling plan, training of sample collectors, collection of samples, product information review (PIR) and quality testing at TMDA laboratory. The PMS programme is usually conducted in three (3) financial years. The third programme (2020/21 – 2022/23) was conducted in three phases 2020/21, 2021/22 and 2022/23.

The surveillance was conducted in eighteen (18) different regions namely Dar es Salaam, Singida, Tanga, Katavi, Mara, Lindi, Arusha, Morogoro, Njombe, Simiyu, Tabora, Mtwara, Dodoma, Iringa, Kigoma, Manyara, Mwanza and Coastal Region. Samples were collected from Medical Stores Department (MSD), hospitals, health centres, dispensaries, wholesale and retail pharmacies, and medical devices outlets.

The programme targeted 25 different types of selected medical devices and in vitro diagnostics which include HIV rapid diagnostics tests (HIV RDTs), malaria diagnostics tests (mRDTs), surgical sutures, surgical gloves, syphilis rapid diagnostics tests, surgical blades, syringes, I.V cannula, urinary pregnancy test (UPT), male condoms, baby and adult diapers, sanitary pads, intrauterine devices (IUDs), Plaster of Paris (POP), adhesive plaster, blood glucose test strips, cotton wool, gauze, surgical face mask, spinal needle and I.V giving sets. Samples collected were manufactured and/or imported from China, India, Thailand, Pakistan, Spain, Turkey, Malaysia, USA, Ireland, Germany, South Africa, South Korea, Kenya and Tanzania.

During implementation, samples were collected as per selection criteria, defined locations and quantity in accordance with the Programme and prepared sampling plan for each phase. Product information review (PIR) was conducted for each collected sample to verify the correctness of labeling information and physical description was also performed to verify package integrity. Collected samples were

subjected to laboratory testing in accordance with prescribed standards at the TMDA Quality Control Laboratory to verify quality and performance.

This evaluation was carried out in order to assess the implementation status of the PMS programme of 2020/21 - 2022/23 and hence determine its success and challenges with the aim of improving future programmes and the quality of medical devices circulating in the Tanzanian market.

2.0 OBJECTIVES

2.1 Broad objective

The broad objective was to evaluate the quality and performance of selected medical devices and in vitro diagnostics circulating in the Tanzanian market.

2.2 Specific objectives

The specific objectives of the surveillance were:

2.2.1 To assess compliance of devices to labelling requirements;

2.2.2 To evaluate compliance of devices to quality requirements;

2.2.3 To determine the compliance of devices to performance requirements; and

2.2.4 To determine the best regulatory measures based on the outcome.

3.0 RATIONALE

Marketing authorization of medical devices and in vitro diagnostics involves rigorous review of their quality and performance through laboratory testing to ensure that they meet minimum established requirements. Once devices are on the market, they are subjected to different storage conditions and handling practices that may alter their quality and performance characteristics and may result to inaccurate diagnosis, irrational treatment and poor health outcomes. Therefore, this PMS programme was conducted so as to provide evidence on the quality and performance of medical devices and in vitro diagnostics with ultimate goal of protecting public health.

4.0 METHODOLOGY

4.1 Study design

This was a descriptive cross sectional post marketing survey for evaluating the quality and performance of medical devices and in vitro diagnostics in Tanzania.

4.2 Study sites

Selection of the study sites was based on the following criteria; densely populated regions, regions bordering neighbouring countries and having official border points, regions not covered in previous PMS studies, regions with high HIV/AIDS and malaria prevalence rates. Hence, the surveillance was conducted in eighteen (18) regions namely Dar es Salaam, Singida, Tanga, Katavi, Mara, Lindi, Arusha, Morogoro, Njombe, Simiyu, Tabora, Mtwara, Dodoma, Iringa, Kigoma, Manyara, Mwanza and Coastal Region. Samples were collected from Medical Stores Department (MSD), hospitals, healthcare centres, dispensaries, wholesale and retail pharmacies, and medical devices outlets.

4.3 Sample size

A total of 1,121 samples were planned to be collected based on approved PMS sampling plan for all three phases. The sampling plans 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 during selection of sites for sample collection and purposive sampling was used for selection of devices from the sites as per approved PMS sampling plans.

4.5 Inclusion criteria

The following inclusion criteria were applied to select types of devices:

(a) Defective devices that were reported to the Authority;

(b) Devices that failed quality and/or performance parameters from previous PMS programmes;

(c) Devices that are highly used within the country;

(d) Devices from manufacturers and importers with a history of reported substandard products;

(e) Devices for contraception and prevention of sexually transmitted diseases; and

(f) Devices that are manufactured by domestic facilities.

4.6 Exclusion criteria

(a) Near to expiry devices whose remaining shelf life is less than six months;

(b) Inadequate laboratory testing capacity;

(c) Devices of doubtful availability in the market; and

(d) Devices under clinical trials Phase I, II and III.

4.7 Sample collection

Sample collection exercise was preceded by training of sample collectors on sampling plan, procedures and were oriented on sample collection tools. Sample collection was done by using a specialized TMDA sampling form number TMDA/DMD/MDV/F/006 (**Annex II**). Sample collection tools provided were specialized envelopes/bags, marker pens, mask tapes and carton boxes. Samples were collected in their original packaging and details were recorded on the sample collection form. In addition, sample collectors were provided with terms of reference.

4.8 Sample handling, transportation, and storage

Each collected sample was coded according to the prescribed coding format (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/bags. Samples were kept and stored according to the manufacturer's recommended storage conditions as prescribed on the product label. The 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 so as to maintain sample 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. They were kept in special room under access control. All records pertaining to collected samples were kept confidential. After completion of laboratory testing, the

remaining units of samples were kept in a designated archives in accordance with manufacturer's recommendations.

4.9 Sample analysis

Analysis of samples was done to assess the compliance of the collected samples to standards. The samples were assessed in two stages which were PIR and laboratory quality control testing.

4.9.1 Product Information Review (PIR)

All collected samples were subjected to PIR which involved 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.

In addition, samples were subjected to visual and physical verification of information about the manufacturing details and sample 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. Details of PIR were recorded in the Medical Devices and In Vitro Diagnostics PMS PIR Checklist number TMDA/DMD/MDV/C/001 (**Annex III)**.

4.9.2 Quality Control Testing

All collected samples were submitted to TMDA Quality Control Laboratory (QCL) for testing after PIR was completed. At this stage, assessment was done by testing of quality control parameters. Testing was performed by analyzing each product as per their respective pharmacopoeial monograph requirements, ISO standards and WHO recommended methods as shown in **Table 1.**

Table 1: Recommended tests as per PMS Programme and method sources

SN	Type of device	Recommended tests as per PMS Programme	Method source
1.	Surgical blade	− Sterility	a) USP
2.	Surgical Sutures	− Sterility, − Mechanical test (failure load, elongation, knot slippage or knot breakage) and physical test − Minimum breaking load as per BP − Needle attachment as per BP	a) USP b) BP
3.	I.V Giving Set	– Sterility; – Needle point; – Vent fitting; and – Strength of union between needle hub and needle tube.	a) ISO 8536

SN	Type of device	Recommended tests as per PMS Programme	Method source
4.	Urine Pregnancy Tests (UPT)	− Analytical sensitivity and − Specificity.	a) Manufacturer
5.	Syringes	– Mechanical testing; – Package and sterile seal Integrity test; and – Sterilization testing.	a) ISO 7886
6.	Sanitary Pads	– Total Aerobic Viable Count and Total Combined Yeasts & Moulds; – Performance tests such as absorbency capacity, absorbency rate; and – PH of aqueous extract, as per EAST African standard.	a) TZS 1659 b) TZS 279
7.	Baby and Adult diapers	– Total Aerobic Viable Count and Total Combined Yeasts & Moulds, – Performance tests such as Total absorptive capacity, minimum absorption rate; – PH, – rewet and – Acquisition time for baby diapers;	a) USP b) EAS969
8.	Gloves (Sterile)	− Testing for freedom from holes, − Testing for physical properties (Dimensions, force at break) − Testing for biological evaluation (Total extractable protein − Endotoxin) and − Sterility as per ISO: 11193, ISO 10282:2014	a) ISO 10282 b) ISO 1193
9.	Intrauterine device (IUD)	- Sterility - Dimension - Shape - Tensile strength - Seal integrity	a) ISO/DIS 7439
10.	Male Condoms	− Lubrication, − Burst volume and pressure − Freedom from holes, − Visible defects − Package integrity as per ISO 4074: 2015	a) ISO 4074
11.	Malaria Rapid Diagnostic Tests	− Analytical sensitivity and − Specificity as per WHO standard.	a) WHO
12.	HIV/AIDS test kits	As per WHO standard. − Analytical sensitivity and − Specificity	a) WHO
13.	Syphilis Rapid Diagnostic test kits	− Analytical Sensitivity and − Specificity	a) Manufacturer
14.	IV Cannula	– Sterility; – Mechanical testing, package; and – Sterile seal integrity testing (ISO 10555-1:2013)	a) ISO 7886
15.	Plaster of Paris (POP)	As per BP − Adhesiveness - Setting time - Weight per unit area	a) BP

SN	Type of device	Recommended tests as per PMS Programme	Method source
16.	Cotton wool	As per BP − Absorbency − Alkalinity and acidity	a) BP
17.	Gauze	As per BP − Absorbency and − Acidity or alkalinity	a) TZS 278
18.	Blood Glucose Test Strips	− Analytical sensitivity and specificity.	-
19.	Spinal needle	- Mechanical testing - Seal integrity - Sterility	a) ASTMF 1929 b) USP

5.0 RESULTS

5.1 Samples collected

A total of 1,038 (92.7%) samples of medical devices and in vitro diagnostics were collected out of 1,121 planned samples. Performance status in each year revealed high rate of success in the first year 2020/2021 where the number of samples collected was 285 (106.3%) out of the planned 268 samples. There was a decrease in the number of collected samples in the subsequent two years 92.8% (2021/2022) and 85.6% (2022/2023) (**Table 2**).

Table 2: Samples collection for three years (2020/21 – 2022/23)

Year	Planned Samples	Collected Samples	% Samples collected
2020/2021	268	284	106
2021/2022	333	309	92.8
2022/2023	520	445	85.6
Total (2020/21-2022/23)	**1,121**	**1,038**	**92.6**

Out of the collected samples from 2020/21 to 2022/23, 709 (68.3%) were medical devices and 329 (31.7%) were in vitro diagnostics. There was an increase in trend on collection of medical devices from 188 in the year 2020/21 to 305 in 2022/23. Similarly, the collection of in vitro diagnostics increased from 96 in 2020/21 to 140 in 2022/23 (**Figure 1**).

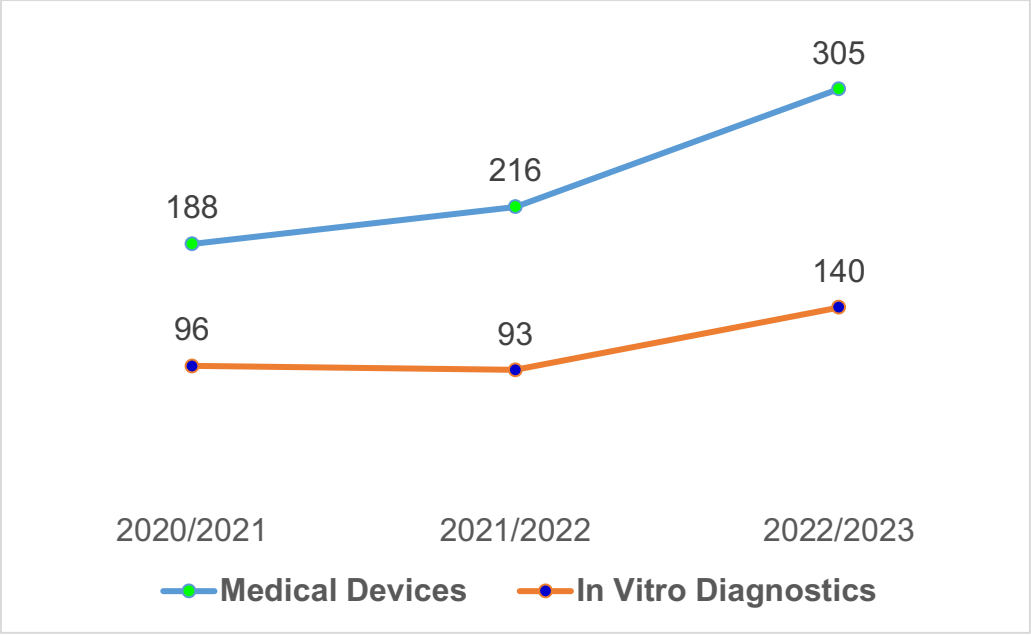

Figure 1: Distribution of medical devices and in vitro diagnostics collected for three years 2020/21 – 2022/23

The distribution of number of samples collected from year 2020/21 - 2022/23 by level of sampling sites is as described in **Table 3**. Most (51.3%) of the samples were collected from pharmacy followed by health facilities (36%). Few samples were collected from supermarkets (1.1%) and ADDO (0.3%). On the other hand, most of the samples collected were mRDTs (15.6%) and HIV RDTs (13.3%). The least collected samples were surgical gloves, surgical blades and intra uterine device 2.4% apiece. The sampled devices originated in 14 countries (**Table 4**)

Table 3: Distribution of samples and number collected per sites for three years 2020/21 - 2022/23

SN	Type of device	MSD	Hospital/ Health Centre	Pharmacy	Medical Device Outlet	ADDO	Super market/ Shop	Total	%
1.	Malaria RDT	18	103	35	6	0	0	**162**	**15.6**
2.	HIV RDT	25	110	3	0	0	0	**138**	**13.3**
3.	Plaster of Paris	0	23	39	5	0	0	**67**	**6.5**
4.	Absorbent Cotton Gauze	0	22	36	9	0	0	**67**	**6.5**
5.	Blood Glucose Test Strips	0	21	25	9	0	0	**55**	**5.3**
6.	Sanitary pads	0	0	52	0	1	0	**53**	**5.1**
7.	UPT	0	8	32	11	0	0	**51**	**4.9**
8.	Male condoms	0	8	41	0	1	0	**50**	**4.8**
9.	Surgical gloves	0	1	24	0	0	0	**25**	**2.4**
10.	Surgical blades	0	3	22	0	0	0	**25**	**2.4**
11.	Cotton wool	0	0	49	0	1	0	**50**	**4.8**
12.	Baby diapers	0	0	36	0	0	11	**47**	**4.5**
13.	Syringe	2	12	29	1	0	0	**44**	**4.2**
14.	IV cannula	1	9	33	1	0	0	**44**	**4.2**
15.	Spinal needle	1	23	10	5	0	0	**39**	**3.8**
16.	Surgical sutures	3	2	31	2	0	0	**38**	**3.7**
17.	Syphilis RDT	0	10	10	10	0	0	**30**	**2.9**
18.	IV infusion set	0	2	26	0	0	0	**28**	**2.7**
19.	Intra Uterine Device	8	17	0	0	0	0	**25**	**2.4**
Total		**58**	**374**	**533**	**59**	**3**	**11**	**1,038**	**100**
%		**5.6**	**36.0**	**51.3**	**5.7**	**0.3**	**1.1**	**100**	

The samples collected for three years 2020/21 - 2022/23 originated in 14 countries (**Table 4**).

Table 4: Countries of original for the sampled devices

SN	Country of Origin of the samples
1.	China
2.	Germany
3.	India
4.	Ireland
5.	Kenya
6.	Malaysia

7.	Pakistan
8.	Spain
9.	Tanzania
10.	Thailand
11.	Turkey
12.	South Africa
13.	South Korea
14.	USA
Total	**14**

5.2 Quality and performance of collected samples

5.2.1 Product Information Review

A total of 888 (85.5%) out of 1,038 samples passed PIR and 150 (14.5%) failed. Most (96.8%) of the passed samples were observed in the year 2021/22. Most (24.7%) of the failed samples were observed in the year 2022/23 (**Table 4**).

Table 4: Product Information Review (PIR) results

Year(s)	Collected samples	Reviewed (PIR)	Passed/ complied	Failed/ did not comply
2020/2021	284	284	254	30
2021/2022	309	309	299	10
2022/2023	445	445	335	110
Total	**1,038**	**1,038**	**888**	**150**

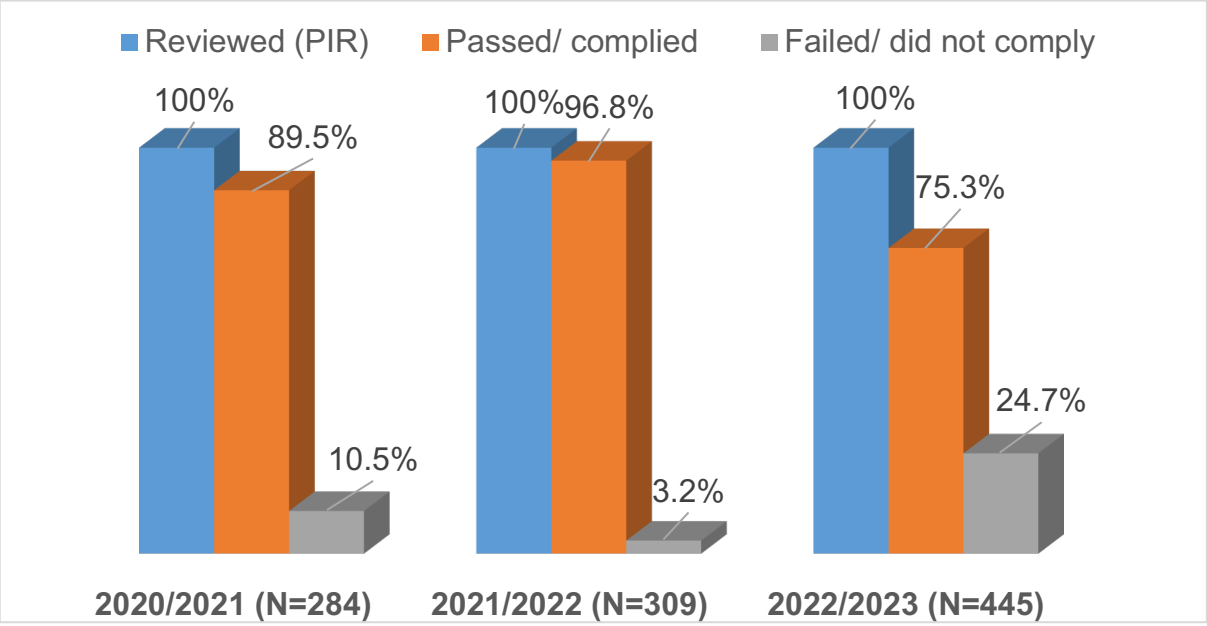

Figure 2: Proportion of samples reviewed and the compliance status

5.2.1.1 Compliance by type of devices and number of samples

A total 12 (63.1%) out of 19 types of device did not comply with PIR. Types of devices with high proportion of failure rate were spinal needle (100%), urine pregnancy test (56.9%), plaster of paris (49.3%) and male condoms (30.8%) (**Table 5**)

Spinal needle had no instructions on storage conditions, easily removable label on secondary packaging and there was no name and address of manufacturer. Urine pregnancy test had no name and address of manufacturer and had no instructions on storage conditions. Plaster of paris (POP) had no instructions on storage conditions and easily removable label on the primary packaging. Male condoms inconsistencies on brand names of device and deficiencies on manufacturer name and address

Table 5: Compliance by type of devices and number of samples

SN	Type of device	Reviewed (PIR)	Passed/ complied	Failed/ did not comply	%
1.	Spinal needle	39	0	**39**	**100**
2.	Urine Pregnancy Tests	51	22	**29**	**56.9**
3.	Plaster of Paris	67	34	**33**	**49.3**
4.	Male condoms	52	36	**16**	**30.8**
5.	IV cannula	44	34	**10**	**22.7**
6.	Surgical blades	23	19	**4**	**17.4**
7.	Surgical sutures	38	31	**7**	**11.8**
8.	Absorbent Cotton Gauze	67	60	**7**	**10.4**
9.	Surgical gloves	25	23	**2**	**8**
10.	Syphilis RDT	30	29	**1**	**3.3**
11.	Cotton wool	50	49	**1**	**2**
12.	Malaria RDT	162	161	**1**	**0.6**
13.	HIV RDT	138	138	**0**	**0**
14.	Syringe	44	44	**0**	**0**
15.	IV infusion set	28	28	**0**	**0**
16.	Baby diapers	47	47	**0**	**0**
17.	Sanitary pads	53	53	**0**	**0**
18.	Blood Glucose Test Strips	55	55	**0**	**0**
19.	Intra Uterine Device	25	25	**0**	**0**
Total		**1,038**	**888**	**150**	**14.5**

5.2.1.2 Observed deficiencies with the corresponding number of samples

During the third PMS survey, 53 PIR deficiencies were observed where by 44 were in medical devices and 9 in vitro diagnostics. The commonest deficiencies (14) observed in medical devices was lack of instructions on storage conditions while for in vitro diagnostics, it was inadequacies in the package insert (**Table 6**).

Table 6: Number of samples and observed deficiencies

SN	Description of deficiencies	Number of device samples with deficiencies		Total number of deficiencies
		MD	IVD	
(a)	Inconsistencies on brand names of device	5	-	5
(b)	Deficiencies on manufacturer name and address	8	1	9
(c)	No batch or lot number	2	-	2
(d)	No word "For Single Use Only"	1	-	1
(e)	No Manufacturing and expiry date	2	-	2
(f)	No storage conditions	14	1	15
(g)	Deficiencies in the Package Insert	-	6	6
(h)	Secondary label not permanent	10	-	10
(i)	No description whether the suture is absorbable or non-absorbable suture	2	-	2
(j)	Missing important information in buffer bottle such as batch/lot number and expiry date	-	1	1
Total		**44**	**9**	**53**

Overall, the parameters that mostly failed PIR were lack of instructions on storage conditions (28.3%), use of sticker label/ removal label on secondary packaging's (18.9%) and lack the name and physical address of the manufacturing facility (17.0%) (**Figure 3**).

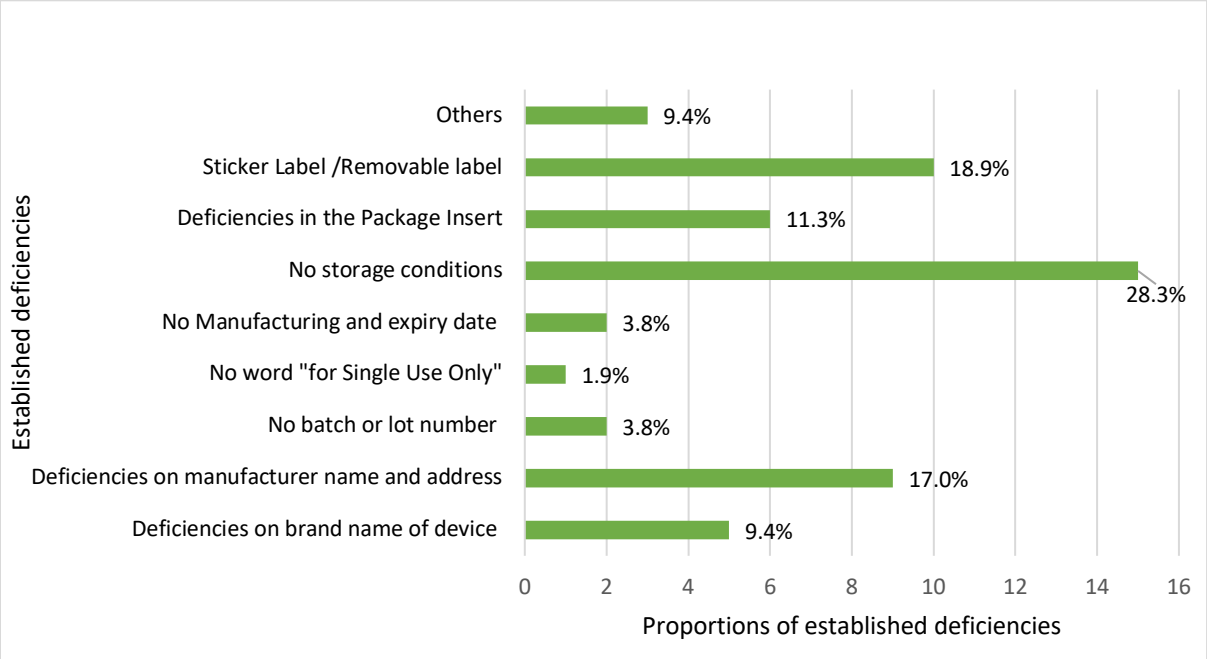

Figure 3: Percentage non-compliance to PIR parameters

5.2.1.3 Non-compliance by source country

Out of 14 countries of origin for the sampled devices, PIR deficiencies were observed in devices from 8 countries. Majority of devices that failed PIR originated from China (21) followed by India (8) and Thailand (8). All samples manufactured and/or

imported from Ireland, Germany, South Africa, South Korea, Kenya and Tanzania complied with PIR (**Table 7**).

Table 7: Country of origin for device brands that failed PIR

SN	Country of Origin	Number of Device brands with deficiencies
15.	China	21
16.	India	8
17.	Thailand	8
18.	Pakistan	5
19.	USA	2
20.	Malaysia	1
21.	Turkey	1
22.	Spain	1
Total		**47**

5.2.1.4 Compliance by collection sites

Majority of sampled devices which failed PIR were obtained from pharmacies (18.8%) and medical device outlets (17%) (**Table 8**).

Table 8: Non-compliance by collection sites

Sampling site	MSD	Hospital/ Health Centre	Pharmacy	Medical Device Outlet	ADDO	Super market/ Shop	Total
Total collected	58	374	533	59	3	11	1,038
Failed/did not comply	1	39	100	10	0	0	150
% Failed/did not comply	**1.7**	**10.4**	**18.8**	**17**	**0**	**0**	**14.5**

5.2.1.5 Compliance by market placement

The 150 samples which failed PIR were from 34 types of registered/notified devices and 13 types that were imported through special permits (**Figure 4**).

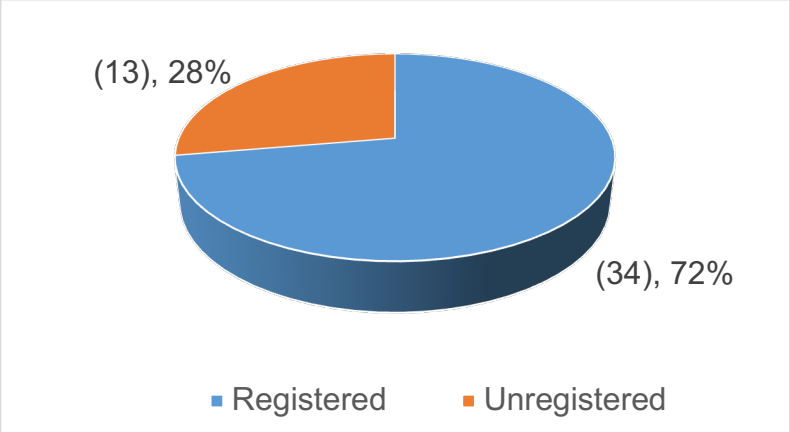

Figure 4: Compliance by market placement

5.2.2 Laboratory testing

A total of 983 (94.7%) out of 1,038 samples were tested for compliance to quality and performance. The remaining 55 (5.3%) of samples were not tested due to low laboratory capacity to test glucose strips which were collected in the year 2022/23. A total of 93 (9.5%) samples out of 983 failed laboratory testing. Highest (24%) failure rate was observed in the year 2020/21 compared to other years as indicated in Table 8 and Figure 5.

Table 9: Results for Laboratory Testing 2020/21 – 2022/23

Year	Submitted samples	Samples Tested	Samples not Tested	Passed samples	Failed samples
2020/2021	284	284 (100%)	0	216 (76.1%)	68 (23.9%)
2021/2022	309	309 (100%)	0	293 (94.8%)	16 (5.2%)
2022/2023	445	390 (87.6%)	55 (12.4%)	381 (97.7%)	9 (2.3%)
Total	**1,038**	**983 (94.7%)**	**55 (5.3%)**	**890 (90.5%)**	**93 (9.5%)**

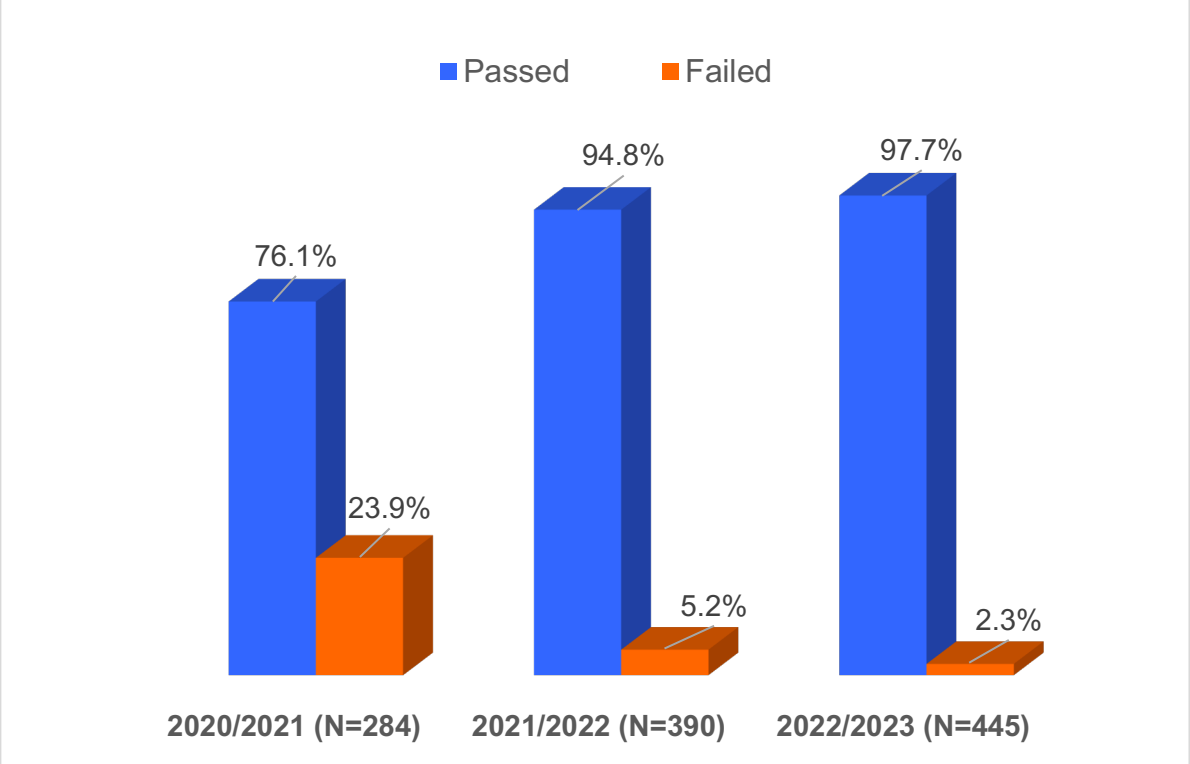

Figure 5: Laboratory compliance rate for three years from 2020/21 – 2022/23

5.2.2.1 Laboratory visual and physical verification

A total of 119 (12.1%) out of 983 samples were eligible and tested for physical inspection of which 102 (85.7%) passed. On the contrary, 16 (5.2%) samples of intravenous giving set that were collected in the year 2021/2022 failed the test. The observed defect was lack of fluid filter in the I.V giving set.

5.2.2.2 Compliance by type of devices and number of samples

A total of 890 (90.5%) out of 983 samples that were tested passed quality and performance parameters. Out of 18 types of devices tested, majority (72.2%) complied with all tested parameters. The devices with the highest failure were cotton wool (96%), intravenous giving set (57.1%) and surgical suture (50%) (**Table 10**).

Table 10: Non-compliance by type of devices and number of samples

SN	Type of device	Tested	Passed/ complied	Failed/ did not comply	% Failure
1.	Cotton wool	50	2	48	**96**
2.	IV infusion set	28	12	16	**57.1**
3.	Surgical sutures	38	19	19	**50**
4.	Plaster of Paris	67	61	6	**9**
5.	Absorbent Cotton Gauze	67	64	3	**4.4**
6.	Baby diapers	47	46	1	**2.1**
7.	HIV RDT	138	138	0	**0**
8.	Malaria RDT	162	162	0	**0**
9.	Surgical gloves	25	25	0	**0**
10.	Surgical blades	25	25	0	**0**
11.	Male condoms	50	50	0	**0**
12.	Syringes	44	44	0	**0**
13.	IV cannula	44	44	0	**0**
14.	Sanitary pads	53	53	0	**0**
15.	Syphilis RDT	30	30	0	**0**
16.	Spinal needle	39	39	0	**0**
17.	Urine Pregnancy Tests	51	51	0	**0**
18.	Intra Uterine Device	25	25	0	**0**
Total		**983**	**890**	**93**	**9.5**

5.2.2.3 Observed deficiencies in the tested samples

The total number of lots/batches failed were 58 of which 27 were cotton wool that failed absorbance, water holding capacity and sinking time. The failed parameters varied immensely depending on the nature of the device (**Table 11** and **Annex IV**).

Table 11: Products and parameters failed during laboratory testing

SN	Type of device	Total number of lots/ batches failed	Number of failed samples	Failed parameters
2020/2021				
1.	Surgical sutures	12	17	Diameter
		2	2	Diameter and suture breaking load
2.	Absorbent cotton wool	20	37	Water holding capacity and sinking time
		1	1	Absorbance and water holding capacity
		4	8	Water holding capacity

SN	Type of device	Total number of lots/ batches failed	Number of failed samples	Failed parameters
		2	2	Absorbance, sinking time and water holding capacity
3.	Baby diaper	1	1	Rewet under load
Sub total		**42**	**68**	
2021/2022				
4.	I.V giving set	7	16	Lack of fluid filter
Sub total		**7**	**16**	
2022/2023				
5.	Plaster of Paris Bandage	6	6	Percentage of Calcium Sulphate Hemihydrate
6.	Absorbent cotton gauze	3	3	Sinking time
Sub total		**9**	**9**	
Total		**58**	**93**	

5.2.2.4 Compliance by source country and market placement

Majority of devices that failed quality and performance originated from China (52 from 11 brands) followed by Pakistan (27 from 6 brands) and Kenya (7 from 2 brands). Majority (91.4%) of devices that failed samples were registered by the Authority and 4.3% were placed on the market through special import permit (**Table 12**).

Table 12: Non-compliance by country of origin, number of samples and brands

S/N	Country of Origin	Number of samples failed	Number of brands failed	Registered brands	Special imported brands/
1.	China	52	11	11	-
2.	Pakistan	27	6	6	-
3.	Kenya	7	2	2	-
4.	Tanzania	4	1	-	1* (4.3%)
5.	India	3	3	2	1 (4.3%)
Total		**93**	**23**	**21 (91.4%)**	**2 (8.6%)**

Key:

* *The device is eligible for notification. However, it was not notified by the manufacturer at the time of collection.*

5.2.2.5 Compliance by collection sites

Majority of the sampled products which failed quality and performance parameters was obtained from pharmacy (81%) (**Table 13**).

Table 13: Compliance by collection sites

Collection site	MSD	Hospital/ Health Centre/ Dispensary	Pharmacy	Medical Device Outlets	ADDO	Super market/ Shop	Total
Surgical sutures	2	1	13	3	0	0	**19**
Absorbent cotton wool	0	0	47	0	1	0	**48**
Baby diaper	0	0	0	0	0	1	**1**
Intravenous giving set	0	0	16	0	0	0	**16**
Plaster of Paris	0	4	2	0	0	0	**6**
Absorbent cotton gauze	0	0	3	0	0	0	**3**
Total failed	**2**	**5**	**81**	**3**	**1**	**1**	**93**
Total tested	**58**	**353**	**508**	**50**	**3**	**11**	**983**
% Failed per facility	**3.4**	**1.4**	**15.9**	**6**	**33.3**	**9**	**9.5**

5.2.3 Overall compliance

A total 747 (76%) samples out of 983 which were evaluated for PIR and laboratory quality testing passed whereas 983 (90.5%) and 890 (85.5%) passed PIR and laboratory quality testing respectively. However, 7 (0.7%) samples failed both PIR and laboratory quality testing (**Table 14**).

Table 14: Overall compliance status

S/N	Description of assessment	Number of samples reviewed/ tested	Passed	Failed	% Failure
1	PIR	1,038	888	150	14.5
2	Laboratory quality testing	983	890	93	9.5
3	PIR and Laboratory quality testing	983	747	7	0.7

6.0 DISCUSSION

The number of samples collected in this programme is almost double that collected in the last PMS programme [1]. Generally, there was an increase in the number of collected samples from year 2020/21 to 2022/23. This was largely attributed by; increased number of devices in the market, increased budget allocated for PMS programme, improved planning and coordination during sampling activity.

However, in 2021//22 and 2022/23 the planned number of samples to be collected was not attained due to unavailability of some samples such as syphilis RDTs, widal tests and blood grouping tests (2021/22), inadequate number of syphilis RDTs, IUDs, HIV/syphilis dual RDTs (2022/23), lack of electronic fiscal device (EFD) receipts and insufficient number of units required to constitute a sample in some facilities particularly those located at district level.

Most of samples were collected from pharmacies and healthcare facilities as planned due to availability of variety of devices and easy to purchase. The number of samples to be collected per each device was based on the type of devices with high public health importance. Consequently, HIV RDTs and mRDTs were collected in large quantities.

Compared with the previous PMS programme of 2017 – 2020, there has been an increase in the proportion of PIR failure from 11.1% to 14.5% [1]. The observed PIR deficiencies in most devices (lack of instructions on storage conditions, inconsistent/lack of name and address of manufacturers and easily removable label on the secondary packaging) may compromise the quality and appropriate use of respective devices. Failure to comply with PIR, where the lack of storage conditions is amongst the most reported deficiencies, has been previously reported in various medical products available in Tanzania market including antimalarial drugs [2], anti-tuberculosis drugs [3], antiretroviral drugs [4], and veterinary medicine [5]. Lack of clear description on storage conditions may result to deterioration of the device quality and performance characteristics. Devices with inconsistent or without names and addresses of their respective manufacturers are difficult to identify and trace, and may be falsified. These deficiencies were notably observed in spinal needles, urine pregnancy test, POPs and male condoms.

The observed lack of batch or lot number in fewer devices may impair identification and traceability in case of any inconveniences. On the other hand, the lack of expiry date on buffer for syphilis RDTs may affect results and consequently treatment outcome [6]. Lack of description whether the suture is absorbable or non-absorbable may lead to incorrect use. Sutures that initiate a more significant tissue response (mainly absorbable sutures) may lead to sub-optimal outcomes including persistent scar tenderness and suture extrusion. Non-absorbable sutures can cause pain on suture removal and suture marks on the skin [7]. Single use devices that are not indicated as such may encourage re-use and put patients at risks of infections [8].

The large number of brands that failed PIR which were manufactured and/or imported from China and India. The failure was attributed by importing more brands/types of devices from these countries. Tanzania imports most of its medical products, including medical devices and in-vitro diagnostics [9,10,11]. It is therefore pertinent to have intact product information to ensure that the products are properly handled and stored in optimal conditions. Most existing medical devices were not built for the challenges often present in many African countries and maybe subjected to suboptimal storage conditions and poor handling that may alter their quality and performance requirements [12].

In this survey, 28% of the 150 PIR failed samples were imported in the country through special permits. A special permit is an importation permit issued under section 57 (1) of the Act to allow the importation of unregistered regulated products

for public interest [13]. TMDA only approves the supply of unregistered devices based on substantiated clinical justification, including the special clinical needs of the unregistered devices by the qualified practitioner in place of registered products. Since these products have not undergone a rigorous registration process, they are more likely to miss some of the country's specific product information required.

Majority of samples submitted to the laboratory were tested for all parameters as specified in the programme. However, the performance test for baby diapers and sanitary pads was not done in line with the PMS programme. The anticipation made during planning to test glucose test strips at TMDA laboratory was not met in time. Consequently, testing of all 55 (5.3%) samples of blood glucose test strips collected in 2022/23 was not carried out. Moreover, sterility test for IV cannula, IV infusion set and syringes was not done.

Highest laboratory failure rate observed in absorbent cotton wool was related to failure in water holding capacity, sinking time and absorbance. Failure in these parameters may compromise the performance of the device and put patients at risks of infections.

The failed intravenous giving set that had not been fitted with fluid filter may allow passage of particulate matter and air bubbles. Consequently, these substances may reach blood stream and cause infections, phlebitis and embolism to patients.

The large diameter observed in 50% of the tested surgical sutures may cause inflammation, reactogenicity and injury to patients once used. Therefore, it is recommended that sutures of appropriate diameter be used for surgical operations.

The observed anomaly in the two (2) samples of sutures with regard to breaking load parameter may impair the suitability of the sutures during surgical procedures and may consequently interfere with the healing process [14]. The ability of the suture to resist breaking under tension (suture breaking load) is important to withstand the tension between connected tissues and to hold them together (durability) without causing tissue damage or inflammation.

Rewet under load is a test used to establish ability of the diaper top sheet to resist transportation back onto the skin of the liquid which has already penetrated the top sheet. If the diaper is unable to resist rewet under load, the user may be exposed to wet diaper. This can cause microbial infections, discomfort and skin reactions such as nappy rashes [15].

The required percentage of Calcium Sulphate Hemihydrate in POP should be greater or equal to 85% to enable its solidification and so as to offer maximum stability and protection around area of injury [16]. This failure was observed in 9% of tested samples thus call for continual monitoring of the failed device in the market.

The observed high failure rate in PIR and in laboratory quality testing from pharmacies and medical device outlets was contributed by more variety of devices collected from these facilities.

The overall high compliance rate in PIR (85.5%), laboratory quality testing (90.5%) and both PIR and laboratory quality testing (76%) could be largely contributed by strengthened regulatory system for medical devices and diagnostics following establishment of a full-fledged directorate for control of these devices. Some regulatory measures that are being implemented include; pre-distribution lot to lot quality testing of some selected devices such as HIV, Malaria and Syphilis RDTs, and condoms and strengthened inspections of premises and ports of entry control. Other measures include product evaluation and registration and quality audit/desk reviews of manufacturing sites.

7.0 MONITORING AND EVALUATION

Each selected key area in implementation of the programme was assessed against PMS implementation outcome obtained throughout the three years 2020/21 to 2022/23 of its execution in order to determine contribution of each factor to the success and failure of the program and also to explore areas of improvement for future programs.

7.1 Evaluation of the Program

7.1.1 Methodology

The methodology of the programme was assessed to determine its contribution to the final PMS outcome and to identify gaps with the aim of improving future surveillance. Summarized results of gaps observed in each component of the methodology (**Table 15**).

Table 15: Gaps observed in PMS components

SN	PMS component	Gaps
1.	OBJECTIVES	Specific objectives were not specific, measurable achievable, relevant, realistic and time-bound (SMART).
2.	METHODOLOGY	**Sampling Plan** Implementation plan were prepared based on market price of product samples to be collected and the allocated budget. The total number of samples to be collected was not stated in the programs. **Sampling location** Samples were collected from health facilities located in main cities and remote areas, however; in some of the remote areas they do not have access to EFD machines and hence samples could not be collected as planned.

SN	PMS component	Gaps
		The sampling design was not stated in the programs.
		Sample code Sample code reflected the first three letters for region and district, DAR/TEM/…. However, there are some of the abbreviations of the region names are popular, therefore the proposed sample code was not followed. e.g., DSM instead of DAR or MZA instead of MWA
		Sample Collection Un-realistic allocation for the number of samples in each region, for instance, results on the sample collection exercise in terms of the number of batches were higher for the small planned sample and lower in the large planned sample such that in the year 2022/23 the percentage of collected samples for Dar es Salaam region was (74%) while the plan was to collect 144% out of the planned sample as compared to Kigoma region that had a percentage of 91% while 46 batches were planned to be collected.
		PIR Uploading of information after PIR in the Laboratory Information Management System (LIMS) there was an interaction with the user's account that interfered with saving the information or moving to the next step.
		Laboratory Testing Delay in laboratory results release and some results were not received e.g. Glucose test strips.
3.	SELECTION CRITERIA OF PRODUCTS TO BE MONITORED	Unavailability of product samples that were planned to be collected e.g., Duo syphilis/HIV RDT in the year 2022/23.
4.	SAMPLING SITE	The unavailability of EFD machines in small outlets led to the failure to collect product samples as planned
5.	COLLABORATION WITH OTHER STAKEHOLDERS	Delays in obtaining replacement samples from MSD
6.	RESOURCES	Insufficient funds for sample purchasing, training for sample collectors and report writing.
7.	TRAINING	The training for sample collectors was not done effectively, some trained staff from the zone were assigned other duties and could not participate in the sample collection exercise as planned.
8.	REGULATORY ACTION TAKEN	Follow-up was not taken to monitor the implementation of the proposed regulatory actions to completion.

7.1.2 Post-Market Surveillance Program Outcomes

Implementation of phase III of the PMS Programme (2020/21-2022/23) came to an end in June 2023. Evaluation of data obtained during the implementation of the programme is instrumental and the results thereof will inform the preparation of the new programme.

7.2 Results as per Strategic Plan Output Indicator

Under TMDA Strategic Plan 2021/22- 2025/26 one of the Key Performance Indicators for Strategic Objective E is aimed at monitoring PMS achievement in terms of the percentage of planned PMS samples collected for medical devices and Diagnostics, as an output indicator whereas the percentage of medical devices and diagnostics complying with performance requirements as an outcome indicator respectively.

Assessment has been made on the achievement of the programme against the stipulated output-based monitoring plan. The output on the percentage of planned PMS samples for selected devices within three years of the Strategic Plan. The sample collection results observed during implementation, results for the year 2020/21 was 106.3% surpassed the target whereas results for the years 2021/22 and 2022/2023 were 92.8% and 85.6% respectively. These results indicate that for the year 2021/22 and 2022/23 the targets were not reached due to missing of some samples identified to be collected in the market (**Table 16**).

Table 16: Monitoring Plan (Output-Based Indicator)

SN	Indicator name	Indicator Target Values (%)			Results (%)		
		2020/21	2021/22	2022/23	2020/21	2021/22	2022/23
1.	% of planned PMS samples for medical devices and diagnostics collected	100	100	100	106.3	92.8	85.6

It was further observed that, designed specific objectives were not SMART and not in line with Strategic Plan. In view of this, the following are recommended.

a) Sample size for future programs be reviewed to consider specific standard requirements for individual products and to enable laboratory testing of all required parameters for all collected the type of devices.

b) Monitoring Plan to be included in each phase of the program so as to determine the percentage achieved on planned sample collection in future programs.

c) Objectives for future programs should be designed to be SMART and in line with the Strategic Plan.

7.3 Monitoring Plan (Outcome-Based Indicator)

Monitoring outcome based indicator based on percentage of medical devices and In-vitro diagnostics complying with quality and performance requirements for the three years 2020/21, 2021/22 and 2022/23 has been improving over the year (**Table 17**).

Table 17: Monitoring outcome – based indicator

SN	Indicator name	Indicator Target Values			Results		
		2020/21	2021/22	2022/23	2020/21	2021/22	2022/23
1.	Percentage of PMS medical devices and diagnostics complying with performance requirements	55	57	60	77.5	95.1	98.9

8.0 REGULATORY ACTIONS TAKEN

The following regulatory actions have been taken by TMDA:

a) All manufactures whom their medical devices failed product information review (PIR) have been directed to rectify the observed PIR anomalies and submit applications for variation of their registered devices;

b) All device lots/batches that failed laboratory tests were recalled from the market; and

c) Manufacturers of identified poor quality devices were directed to conduct thorough investigation on the batches failed by identifying the root cause, make correction and implement the corrective action(s) and submit report to the Authority.

9.0 CONCLUSION

The overall high compliance rate in PIR (85.5%), laboratory quality testing (90.5%) and both PIR and laboratory quality testing (76%) was largely contributed by strengthened regulatory system for medical devices and diagnostics following establishment of a full-fledged directorate for control of these devices. Through this directorate, TMDA has put in place and is continually strengthening regulatory measures namely; pre-distribution lot to lot quality testing of some selected devices such as HIV, Malaria and Syphilis RDTs, and condoms, inspections of premises and ports of entry control which ensure devices circulating in the country are of acceptable quality and perform as intended. Other measures include strengthened devices evaluation and registration and quality audit/desk reviews of manufacturing sites. All these measures contribute significantly to the Authority's mission of promoting and protecting public health.

The observed failure rates in PIR and laboratory testing call for continuous monitoring of the quality and performance of registered, notified and imported medical devices and diagnostics through post-marketing surveillance.

10.0 LIMITATIONS

During implementation of this programme the following challenges were encountered

10.1 Unavailability of some devices/brands on the market planned to be sampled;

10.2 Insufficient number of units to constitute samples for laboratory testing;

10.3 Inadequate capacity of TMDA Quality Control Laboratory to test some collected samples and all parameters recommended by their respective standards; and

10.4 Inadequate budget allocated for PMS Programme.

11.0 RECOMMENDATIONS

In view of the findings observed in this surveillance, the following are recommended:

11.1 Allocating more funds to the next PMS Programme to enable wide coverage in terms of types of devices, facility levels and regions;

11.2 Improving coordination at all levels during preparation of sampling plans, budgeting and implementation of PMS Programme;

11.3 Training of sample collectors on how to conduct sampling as well as pros and cons for adhering and not adhering to the standard operating procedures for sampling;

11.4 Training of PIR reviewers to improve the recording of deficiencies observed during the exercise;

11.5 Strengthening TMDA Quality Control Laboratory to conduct all test parameters recommended by their respective standards and to test all planned devices included in the PMS Programme; and

11.6 Sending reminder notice to marketing authorization holders (MAHs) on importance to adhere and comply with labelling requirements and applying for variations in cases of changes to product information.

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13.0 ANNEXES

Annex I - Sampling plan

POST MARKETING SURVEILLANCE PROGRAMME FOR MEDICAL DEVICES AND IN VITRO DIAGNOSTICS 2020/21 to 2022/23

SAMPLING PLAN

Sampling levels	Sampling sites	Product Name	Total number of samples to be collected
LEVEL 1: NATIONAL LEVEL			
Public and Private procurement and distributors	MSD HQ		
	Randomly selected private importers/wholesalers		
LEVEL 2: REGIONAL LEVEL			
MSD Zone Office	MSD Zone Office in selected regions		
Public Hospital	Regional Referal Hospital		
Private Hospital	Randomly selected private hospitals		
LEVEL 3: DISTRICT LEVEL (TWO SELECTED DISTRICTS)			
Hospitals and Pharmacies	District Hospital		
	Randomly selected retail pharmacies and medical devices outlets		
Public and Private Health Centers/Dispensaries	Randomly selected Health Centres and Dispensaries		

Annex II – Sample Collection Form

MEDICAL DEVICES AND IN VITRO DIAGNOSTICS POS
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 III:

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 IV: Parameters tested and method source for each device

SN	Type of device	Parameters tested	Method Source
1.	Surgical blade	(a) Sterility test	b) USP 2020
2.	Surgical Sutures	(b) Sterility, (c) Suture length (d) Minimum breaking load as per BP	c) USP 2020 d) BP 2020
3.	I.V Giving Set	(a) Physical inspection (b) Test for leakage	b) ISO 8536-4:2010(E)
4.	Urine Pregnancy Tests (UPT)	(a) Sensitivity (b) Specificity	b) Manufacturer
5.	Syringes	(c) Physical inspection (d) Test for leakage	b) ISO7886/1:(2017)
6.	Sanitary Pads	(a) Microbial cleanliness (b) Absorptive capacity mL (Min) (c) Rate of Absorption per gush, Min, Max (a) Rewet under load	c) TZS 1659:2019 d) TZS 279:2021
7.	Baby and Adult diapers	(d) Microbial cleanliness (e) Absorptive capacity mL (Min) (f) Rate of Absorption per gush, Min, Max (g) Rewet under load	c) USP d) EAS969:2020
8.	Gloves (Sterile)	(a) Test for freedom from holes, (b) Testing for physical properties (Dimensions) (c) Sterility	c) ISO 10282 d) ISO 1193-1
9.	Intrauterine device (IUD)	(a) Tensile force (b) Sterility	b) ISO/DIS 7439:2022
10.	Male Condoms	(a) Burst volume and pressure (b) Freedom from holes, (c) Package Integrity (d) Width and length	b) ISO 4074:2015
11.	Malaria Rapid Diagnostic Tests	(a) Analytical sensitivity and (b) Specificity	b) WHO method
12.	HIV/AIDS Rapid Diagnostic test kits	(a) Analytical sensitivity and (b) Specificity	b) WHO method
13.	Syphilis Rapid Diagnostic test kits	(a) Analytical sensitivity and (b) Specificity	b) Manufacturer
14.	IV Cannula	(a) Physical inspection (b) Test for leakage	b) ISO7886/1:(2017)
15.	Plaster of Paris (POP)	(a) Percentage of CaSO4.1/2H2O	b) BP 1998
16.	Cotton wool	(a) Sinking time (b) Water holding capacity	b) BP 2020
17.	Gauze	(a) Water holding capacity (b) Sinking time	b) TZS 278:2012
18.	Blood Glucose Test Strips	−	-
19.	Spinal needle	(a) Container closure integrity (b) Sterility	c) ASTMF 1929 d) USP 2020