TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

STRATEGIC PLAN

2017/18 – 2021/22

REVISED EDITION

May, 2020

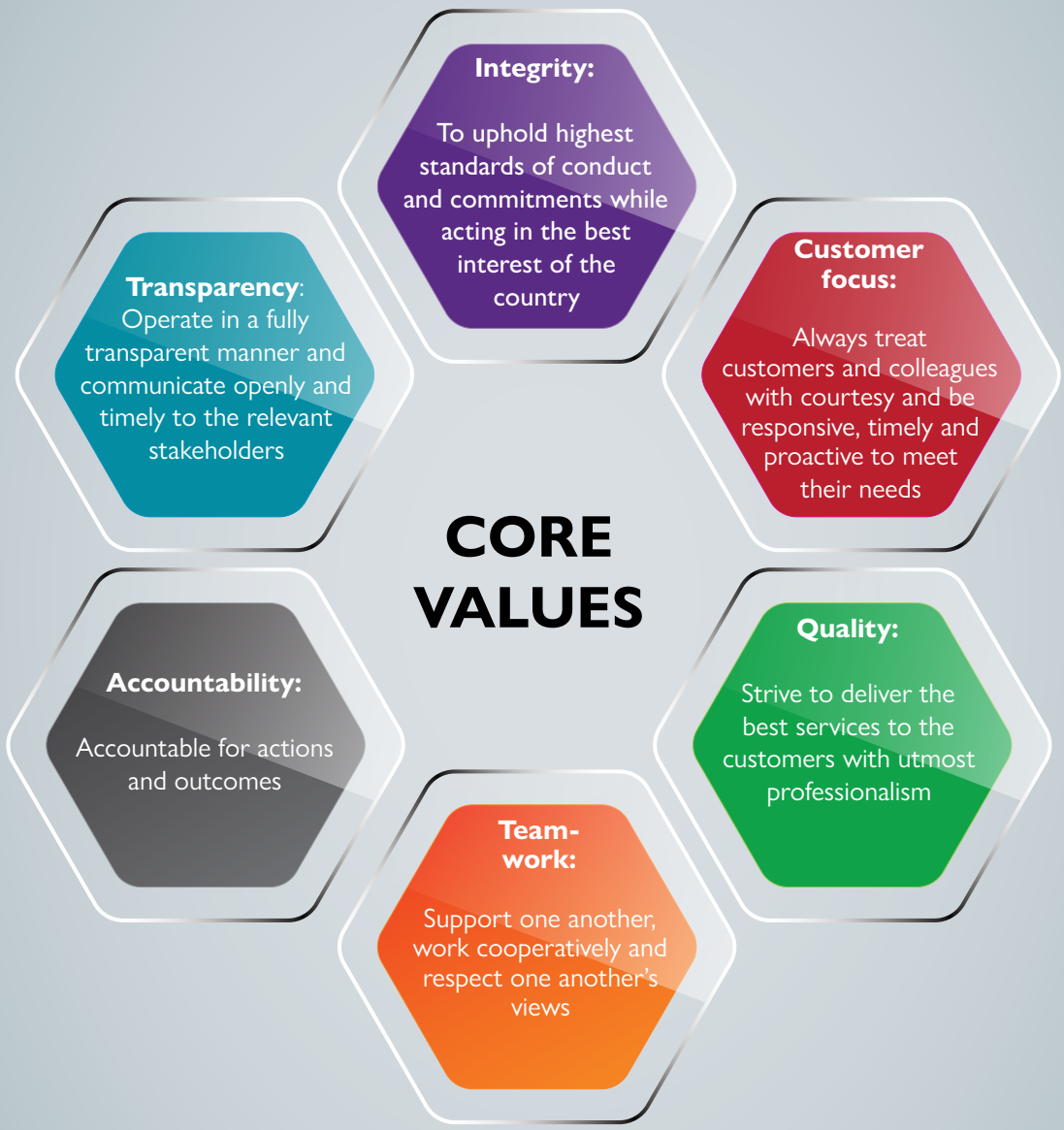
Integrity:
To uphold highest standards of conduct and commitments while acting in the best interest of the country
Customer focus:
Always treat customers and colleagues with courtesy and be responsive, timely and proactive to meet their needs
Transparency: Operate in a fully transparent manner and communicate openly and timely to the relevant stakeholders
CORE VALUES
Quality:
Strive to deliver the best services to the customers with utmost professionalism
Accountability:
Accountable for actions and outcomes
Team-work:
Support one another, work cooperatively and respect one another's views

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ANNEXES

LIST OF ABBREVIATIONS

ADR	Adverse Drug Reactions
AIDS	Acquired Immune Deficiency Syndrome
CSC	Client Service Charter
CSOs	Civil Society Organisations
DBS	Director of Business Support
DG	Director General
DLS	Director of Laboratory Services
DMC	Director of Medical Products Control
EAC	East African Community
FIFO	First in First out
GCLP	Good Clinical and Laboratory Practices
GPSA	Government Procurement and Supplies Agency
GePG	Government Electronic Payment Gateway
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
HQ	Headquarters
HR	Human Resource
HR-MIS	Human Resource Management Information System
HRP	Human Resource Plan
ICT	Information and Communication Technology
IEC	Information, Education and Communication
IMIS	Integrated Management Information System
ISO	International Organization for Standardization
LGAs	Local Government Authorities
LIMS	Laboratory Information Management System
MAB	Ministerial Advisory Board
M&E	Monitoring and Evaluation
MIS	Management Information System
MKUKUTA	Mkakati wa Kukuza Uchumi na Kupunguza Umaskini
MoFP	Ministry of Finance and Planning
MoHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
MoHSW	Ministry of Health and Social Welfare
NCDs	Non-Communicable Diseases
NSGPR	National Strategy for Growth and Poverty Reduction
PMS	Post-Marketing Surveillance
PMU	Procurement Management Unit
PoE	Ports of Entry
PO-PSMGG	President's Office, Public Service Management and Good Governance
PO-RALG	President's Office Regional Administration And Local Government
QMS	Quality Management System
SAEs	Serious Adverse Events
SDS	Service Delivery Survey
SF	Substandard and Falsified
SMART	Specific, Measurable, Achievable, Realistic and Time-bound
SMEs	Small and Medium Enterprises
SOPs	Standard Operating Procedures
SP	Strategic Plan
SWOC	Strengths, Weaknesses, Opportunities and Challenges
TFDA	Tanzania Food and Drugs Authority
TMDA	Tanzania Medicines and Medical Devices Authority (TMDA)
TMMDA	Tanzania Medicines and Medical Devices Act
TR	Treasurer Registrar
WHO	World Health Organisation

STATEMENT BY THE CHAIRMAN OF THE MINISTERIAL ADVISORY BOARD

On behalf of the Ministerial Advisory Board (MAB) to Tanzania Medicines and Medical Devices Authority (TMDA), I am delighted to introduce the revised version of TMDA Strategic Plan (2017/18 – 2021/22) after successful implementation in the first two (2) years 2017/18 – 2018/19 in which the Authority continued to demonstrate excellent performance in regulation of medicines, medical devices and in vitro diagnostics.

Regulatory functions executed within the framework of this strategic plan are laid down as TMDA's mandate in the National Health Policy, the Tanzania Medicines and Medical Devices Act, Cap 2019, the National Five years Development Plan (2016/17 – 2020/21), CCM 2015 Election Manifesto, and the Health Sector Strategic Plan IV (2015 – 2020). These functions are further realized through TMDAs own vision of' "Being the leading African Regulatory Authority in ensuring safety, quality and effectiveness of medicines and medical devices for all".

To further enhance the performance and capacity of TMDA in delivering regulatory services and hence protecting the public health, the Authority revised its Strategic Plan in order to encompass the new mandate of the Authority according to the amendment made through the Finance Act, No.8 of 2019. Apart from addressing issues specifically focusing on the safety and quality of regulated products, fundamental issues have also been emphasized in relation to improving the social services for employees including gender, environmental protection, HIV/AIDS services and management of Non-communicable diseases (NCDs). Furthermore, implementation of National Anti-Corruption Strategy has been taken into consideration.

This revised version of the strategic plan outlines regulatory functions and activities to be undertaken, resources needed for their implementation as well as framework for monitoring of implementation of the activities. Sources of funds needed to support this strategic plan are derived from fees and charges on services rendered by the Authority, Government Subvention and contributions from Development Partners. In this regard, I urge the TMDA Management and all staff to embrace the core values stipulated in the plan as the Authority's hallmark and make close monitoring and management of resources so as to achieve the objectives and consequently the targets set out herein.

MAB is committed to providing the necessary support including liaising with the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) to facilitate thorough execution of this Plan. I wish the Management and all staff a fruitful implementation of this revised Strategic Plan (2017/18 – 2021/22) for the remaining period.

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Amb. Dr. Ben Moses
CHAIRMAN
MINISTERIAL ADVISORY BOARD

STATEMENT BY THE DIRECTOR GENERAL

I would like to present a revised Strategic Plan - SP (2017/18 – 2021/22) which illustrates a revised outlook of TMDA for implementation during the upcoming period (2020/21 – 2021/22). The SP defines the seven (7) strategic objectives, numerous strategies and targets that are necessary to achieve the Authority's mission of protecting and promoting public health by ensuring safety, quality and effectiveness of medicines, medical devices and diagnostics. In addition, this SP sets out the key performance indicators which will be utilized to assess the level at which the objectives and targets are to be met.

The Authority had conducted a thorough Midterm Self-Assessment of the SP implementation for the purpose of evaluating the performance during the previous two (2) years (2017/18 – 2018/19). Based on the assessment conducted, issues for consideration during the review of the SP were identified and accommodated, including the changes brought through the Finance Act No. 8 of 2019 in relation to the mandate of TMDA.

The Vision of TMDA is to become the leading Regulatory Authority in ensuring safety, quality and effectiveness of medicines, medical devices, diagnostics and other health related products for all. The Vision and Mission statements of TMDA have been amended to reflect the current mandate in relation to regulatory functions of the Authority. In order to accomplish the TMDA Vision and Mission, a great emphasis will be given on the following seven (7) strategic objectives:

A. HIV/AIDS and Non Communicable Diseases (NCDs) reduced and Services improved;
B. National Anti-Corruption Strategy implemented, enhanced and sustained;
C. Gender and Environmental issues improved;
D. Quality, effectiveness and safety of medicines, medical devices and diagnostics assured;
E. Laboratory services improved;
F. Public education strengthened and customer services improved; and
G. Institutional capacity to deliver regulatory services strengthened.

The attainment of the above objectives will be TMDA's top most priority for the continuing period of SP execution so as to meet and where possible to exceed the customer needs and expectations; and to protect and promote public health in general. Therefore, the TMDA Management is entirely dedicated to deliver the required resources and support for effective implementation of the SP. Periodically, the SP will be monitored and evaluated to ensure that the anticipated performance outcomes are achieved.

I am very grateful to all members of TMDA Management and employees who contributed through provision of their ideas, suggestions, experience, expertise and time for the review of this SP. I would like to express special thanks to members of the MAB for their guidance, devotion and continued support throughout the review of the SP.

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Adam Mitangu Fimbo
ACTING DIRECTOR GENERAL

ACKNOWLEDGEMENT

I would like to express my sincere appreciations to all TMDA staff who facilitated and contributed successfully in the revision of the Strategic Plan following its implementation in the first two (2) years.

A debt of gratitude is specially owed to Planning, Monitoring and Evaluation team particularly Mr. Damas Matiko, Mr. William Nkondokaya, Mr. John Mwingira and Ms. Deborah Wami who tirelessly devoted their time and efforts in ensuring completion of this Strategic Plan.

The work could not have been completed without guidance, comments, inputs and support from TMDA Management members who are also profoundly obliged.

Lastly, I wish to profusely thank the Ministerial Advisory Board (MAB) for useful inputs, observations and opinions which were undeniably the bedrock upon finalization and approval of the revised Strategic Plan.

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Chrispin Mesiaki Severe
DIRECTOR OF BUSINESS SUPPORT

EXECUTIVE SUMMARY

The revised Strategic Plan (SP) (2017/18 to 2021/22) is based on TMDA's mandate provided under the Tanzania Medicines and Medical Devices Act, Cap. 219 and the Finance Act No. 8 of 2019. TMDA is mandated to protect and promote public health by ensuring the quality, safety and effectiveness of medicines, medical devices and diagnostics.

Revision of this fourth SP has considered gaps and challenges encountered during the first two years of its implementation as evidenced from findings obtained through the self-assessment, Monitoring and Evaluation (M&E) on performance, risks identified through the Quality Management System, internal and external quality audits based on ISO 9001:2015 and Performance audit reports.

The revised version is organized into four (4) chapters. The First chapter covers the TMDA organizational structure and how it was established. The second chapter presents situation analysis describing performance review of the SP implementation in the first two years, (2017/18 – 2018/19). Chapter three describes the actual plan covering the following key aspects Mission, Vision, Core Values, Revised strategic objectives, Strategies, Targets and Key Performance Indicators. Chapter four explains more about results framework and M&E plan.

Generally, review of the plan revealed good performance in which the former TFDA managed to process and register 21,254 (95%) out of 22,407 new premises applications after complying with the set out requirements. Further, a total of 11,942 products were evaluated for registration and 9,140 (77%) were registered. Inspections were conducted in 38,303 premises out of which 30,022 (78%) complied with the requirements. This is equivalent to average of 19,151 registered premises dealing with regulated products inspected per annum and average of 15,011 (78%) which complied with the requirements.

During the period under review, pass rate of the analysed medicine samples raised from 97% to 99% while the rate of medical devices and diagnostics increased from 82% to 98% and from 87% to 100%, respectively. Meanwhile, the pass rate for food raised from 79% to 82% whereas the pass rate for cosmetics decreased from 98% to 93%.

Other notable achievements obtained during the period under review include; establishment of the Western and Eastern Lake Zone offices, growth in internal revenue collections from TZS 42.922 billion in 2017/18 to TZS 47.998 billion in 2018/19, which is 12% increase, clean audit reports throughout the same period, maintenance of ISO 9001:2015 accreditation and WHO pre-qualification, WHO Maturity Level 3 attainment and remittance of TZS 21.6 billion as contribution to the Government Consolidated Fund.

The Vision, Mission and quality policy statements have been improved in this revised SP in the context of the new TMDA mandate. Additionally, this revised plan has seven (7) Strategic Objectives after excluding the Strategic objective (E) which was related to regulation of food products in response to the new changes as set in Finance Act, 2019. The objectives have been arranged starting with crosscutting ones as follows:-

A. HIV/AIDS and Non Communicable Diseases (NCDs) reduced and Services improved;
B. National Anti-Corruption Strategy effectively implemented and sustained;
C. Gender and environmental issues improved;
D. Quality, safety and effectiveness of medicines, medical devices and diagnostics assured;
E. Laboratory services improved;
F. Public education strengthened and customer services improved; and
G. Institutional capacity to deliver regulatory services strengthened.

Rationale, strategies, targets, milestones and key performance indicators (both output and outcome indicators) have been revised for each strategic objective so as to facilitate M&E and easy measurement of performancee. The M&E plan, a results framework matrix and reporting plan have been revised to bring about responsibility and accountability in the implementation of this SP.

CHAPTER 1 INTRODUCTION

1.1 Background Information

Tanzania Medicines and Medical Devices Authority (TMDA) was established as a semi-autonomous regulatory body under the Ministry of Health, Community Development, Gender, Elderly and Children which is responsible for protecting and promoting public health by ensuring safety, quality and effectiveness of medicines, medical devices and diagnostics.

TMDA formerly TFDA became operational on the 1st July, 2003 as the Tanzania Food and Drugs Authority or its acronym TFDA. This name was changed into a new acronym of TMDA following the amendment of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 through the Finance Act, No. 8 of 2019 which apart from changing the name of the Act into Tanzania Medicines and Medical Devices Act, Cap 219, it also transferred the functions of regulating the quality and safety of food and cosmetics to the Tanzania Standard Act, Cap 130 which is under the Tanzania Bureau of Standards (TBS).

TMDA operates as an Executive Agency within the framework of the Executive Act No. 30 of 1997. Under the Tanzania Medicines and Medical Devices Act, Cap 219, TMDA discharges the following functions:-

A. Regulating manufacturing, importation, distribution and selling of medicines, medical devices and diagnostics
B. Inspecting manufacturing facilities and business premises of regulated products and make sure the standards required are reached;
C. Evaluating and registering medicines, medical devices and diagnostics before granting market authorization;
D. Issuing of registration certificates and business permits for premises dealing in regulated products;
E. Assess the quality and safety of regulated products;
F. Performing laboratory analysis and investigations of regulated products;
G. Monitoring adverse effects and use of products in the market;
H. Promoting rational use of medicines, medical devices and diagnostics; and
I. Educating and providing appropriate information to stakeholders and public at large regarding the regulated products.

1.2 Rationale of the Strategic Plan (SP)

This revised SP builds on first two year performance from its implementation by the then TFDA in 2017/18 and 2018/19. It has also incorporated implementation gaps that were identified during the midterm self assessment.

The plan took into consideration the directives provided in the Finance Act, 2019 and National developmental objectives outlined in the National Five Year Development Plan II (2016/17-2020/21). This revised SP provides strategic direction for deployment of institutional resources in order to achieve TMDA mission and vision as well as other national objectives as delineated in the national planning frameworks such as National Strategy for Growth and Poverty Reduction (NSGPR), National Health Policy 2007, Health Sector Strategic Plan IV and Vision 2025.

1.3 TMDA's Institutional Framework

TMDA is managed by the Director General who is answerable to the Permanent Secretary of the Ministry responsible for Health. TMDA has a Ministerial Advisory Board (MAB) that advises the Minister responsible for health on the Authority's Strategic issues.

The Director General is responsible for proper management of the Authority's resources. The office of the Director General has six (6) units namely; Internal Audit, Finance and Accounts, Quality and Risk Management, Communication, Public Relations and Education, Procurement Management and Legal Services.

In addition, there are zone offices, which are directly responsible to the Director General through the Zone Managers who oversee service delivery at zone offices. Currently there are eight (8) zone offices namely; Eastern, Central, Southern Highlands, Western Lake, Eastern Lake, Northern, Southern and Western zones.

TMDA functions are executed through three (3) Directorates and Zones namely Medical Products Control, Laboratory Services and Business Support. There are 9 sections under these three (3) Directorates. (**Annex I**).

Due to limited capacity, TMDA has delegated some of its functions and powers to the Local Government Authorities vide the Delegation of Powers and Functions Order, 2015 in order to improve service delivery.

1.4 Methodology

This revised SP has been prepared based on the format prescribed in the Medium Term Strategic Plan and Budgeting Manual (2008) issued by President's Office, Public Service Management and Good Governance (PO-PSMGG). The review of this SP was based on the results and findings obtained from the self-assessment, Monitoring and Evaluation on performance, risks identified through the Quality Management System, internal and external quality audits based on ISO 9001:2015 and Performance audit report after first two years of SP implementation

Additionally, the review of the Plan took into account national planning framework documents such as: National Five Year Development Plan (2016/17 -2020/21), Health Policy (2007), CCM 2015 Election Manifesto, Health Sector Strategic Plan IV and National Development Vision 2025.

Analysis of information collected from documentary review and self assessment report was used as valuable inputs in the review. The situational analysis provided a basis for determining TMDA's future direction and review of strategies, targets and Key performance indicators in the current institutional context.

1.5 Strategic Plan layout

The revised version of the Plan comprises of four chapters. Chapter one describes historical background, legal and institutional framework, mandate, roles and specific functions, methodology and layout of the plan. Chapter two presents situation analysis which includes introduction, performance review, stakeholders' analysis, Strengths, Weaknesses, Opportunities and Challenges (SWOC) analysis, recent initiatives and critical issues. Chapter three consists of objectives, strategies, targets and key performance indicators. Chapter four presents results framework comprising of results framework matrix, monitoring plan, reviews and milestones, evaluation and reporting plan.

1.6 Assumptions

The following assumptions were taken into account during the preparation and development of this plan:

(a) TMDA will continue to operate as a regulatory agency in regulation of medicines, medical devices and diagnostics in unforeseeable future;

(b) National economy and political environment will remain stable during implementation of this Plan; and

(c) Local Government Authorities will continue to implement TMDA's functions delegated to them in accordance with the Regulations for Delegation of Powers and Order, 2015.

CHAPTER 2 SITUATION ANALYSIS

2.1 Introduction

The situation analysis is a significant exercise carried out to identify the current situation in terms of internal and external factors that may facilitate or hinder envisaged Vision of TMDA. The aspects that are discussed in this chapter include SWOC analysis. Others are stakeholder analysis and past performance review.

2.2 Past performance review

Review of the past performance dwell on the targets and activities that were implemented by the then TFDA during the first two years (2017/18 and 2018/19) of SP execution. Results from the self-assessment on implementation of the Plan for the first two years show that the overall achievement of the planned targets for the past two years (2017/18 and 2018/19) was 73%. The detailed description of the performance for each strategic objective is provided in the sections 2.2.1 – 2.2.8.

2.2.1 Objective A: Services to HIV/AIDS and Non Communicable Diseases (NCDs) reduced and Services improved

TFDA continued to sensitize its employees on HIV/AIDS and NCDs within the first two years of implementation of the fourth SP. The target on annual basis was to sensitize 95% of staff. However, evaluation showed that on average, 57% of the employees were sensitized annually from 2017 to 2018. Sensitization of all employees could not be achieved because in the first year the exercise focused on sensitization to zone office employees and some of them were not available during the sensitization because of other work related commitments. Furthermore, 60% of sensitized staff were willing to test for HIV/AIDS and or to do health check for NCDs.

In addition, employees living with HIV/AIDS who have declared their status were supported as per Circular No. 2 of 2014 [To Support Public Servants Living with HIV/AIDS and Non-Communicable Diseases (NCD) and Guidelines for Management of HIV/AIDS and Non-Communicable Diseases in Public Service. The overall performance of this objective for the period under review was 63%. The Authority has to put efforts to sensitize staff on awareness and wellness programmes so as to reduce incidence of HIV/AIDS and NCDs within the organization.

2.2.2 Objective B: National Anti-Corruption Strategy enhanced, sustained and effectively implemented

Sensitization seminars on anti-corruption and public service ethics to all employees were provided and ensured that they declared their conflict of interest. During the period under review, over 85% of staff signed the forms for declaration of conflict of interest annually. Moreover, the Authority improved transparency through automation of its services and procedures to customers. Currently, applications for import and export permits are done online. Laboratory Information Management System (LIMS) was installed for handling samples and laboratory test results. Further, the Authority has also been implementing various operational guidelines to ensure consistency in decision making during enforcement of the Law. Despite these achievements, the Authority need to devise new mechanisms and different interventions for combating corruption in work places such as to identify and mitigate areas that are prone to corruption.

2.2.3 Objective C: Gender and Environmental issues improved

TFDA planned to train five (5) women on managerial skills on annual basis to improve their competitiveness in leadership positions. TFDA managed to train an average of five women on leadership and managerial skills. By June 2019, the ratio of women to men employees was 1:2 (97 women and 214 men), while the ratio of women to men at managerial posts was 1:4 for Directors and 1:6 for Managers. This inequality calls for management intervention to increase the proportion of women at the managerial posts. Based on the assessment the overall performance of this strategic objective for the period under review was 66%. Furthermore, management need to take into consideration other aspects related to gender mainstreaming such as improvement of infrastructures, appointment to vacant positions and teams for special tasks.

On environmental conservation, the Authority managed to automate its services which besides improving work efficiency also reduced paper usage. In addition, planted trees, garden and surroundings were maintained at the Authority's offices.

2.2.4 Objective D: Quality, effectiveness and safety of medicines, cosmetics, medical devices and diagnostics assured

The Authority had 6,238 applications for registration of medicines, cosmetics, medical devices and diagnostic products and 21,254 for registration of premises dealing in these products. In addition, TFDA planned to conduct inspection of premises, consignments at ports of entry and clinical trials.

Based on the self assessment report, the performance indicates that the average percentage of evaluated applications for registration of medical products for two years were 62% and 97% during the year 2017/18 and 2018/19 respectively against the planned average of evaluated of 78% and 80% for the two years.

The average percentage of evaluated applications for registration of premises dealing with regulated products was 80% for both two years.

… in the 2017/18 and 2018/219 there was an increase of compliance rate for registered outlets dealing with regulated products from 94% to 201% for cosmetics, 77% to 158% for medical devices and diagnostics and 117% to 179% for medicines.

There is an increase in percentage of approved consignments inspected at ports of entry from 44% to 66% whereas percentage compliance of inspected premises decreased from 182% to 179% in 2017/18 and 2018/19 respectively. The average compliance rate planned to be achieved in domestic medicine manufacturing facilities with GMP requirements was 48%, the assessment report revealed that within the two years the average compliance rate was 80%.

Furthermore, in the 2017/18 and 2018/19 there was an increase of compliance rate for registered outlets dealing with regulated products from 94% to 201% for cosmetics, 77% to 158% for medical devices and diagnostics and 117% to 179% for medicines. The increase of compliance rate has been the results of regular trainings to domestic medicines manufacturers, inspections and increased awareness on GMP requirements to customers. These findings imply that there is significant assurance on the quality, effectiveness and safety of medicines, cosmetics, medical devices and diagnostics circulating in the market. Under the period of review this strategic objective had a good performance of 79% based on the analysis of its indicators. The Authority has to continue strengthening its interventions on the controlling of the quality and safety of regulated products. Figure 1 below shows the average performance in percentage for indicators related with objective D for two years under review

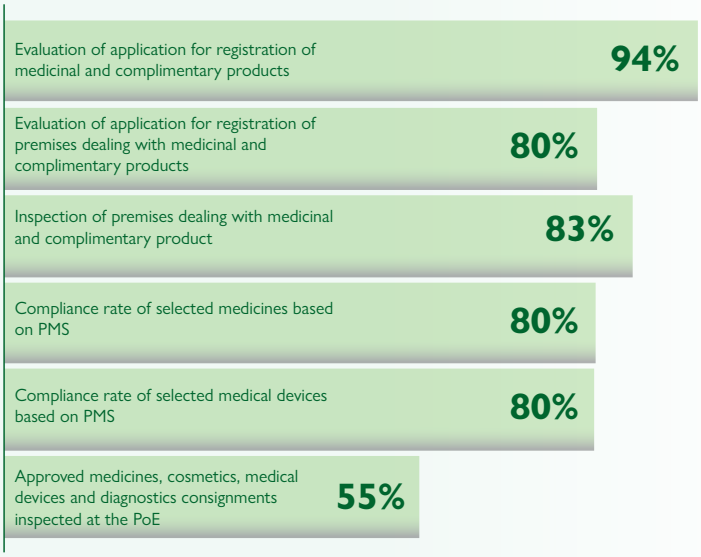


Figure 1: Overall performance of Objective D for aggregated indicators

2.2.5 Objective E: Safety and quality of food and dietary supplements improved

TFDA planned to evaluate 5,924 applications for registration of food and dietary supplements and 13,123 premises dealing with these products for the past two years. The Authority also planned to conduct post market surveillance for food and dietary supplements, inspection of premises and consignments at ports of entry; and mapping of Small and Medium Scale food processors (SMEs).

According to the self assessment report, performance reveals that average number of evaluated applications for registration of food and dietary supplements was 5,682 (96%) for food and dietary supplements within the period under review, out of which 4,980 food products were registered. Similarly, the same report indicates that the average number of application for registration of food premises evaluated was 13,048 and out of which 12,249 (93%) were registered.

In addition, Post Marketing Surveillance (PMS) Programme for year 2017/18 and 2018/19 revealed an increase in percentage of compliance from selected PMS pre-packed food from 80% to 100%, respectively. With regard to compliance of premises dealing with food and dietary supplements, assessment report shows that there was an increase in compliance rate with GMP requirements for food manufacturing facilities from 80% in year 2017/18 to 100% in 2018/19. On other hand, compliance rate for food selling outlets was 80% for both years under review. In addition, percentage of approved food and dietary consignment inspected at ports of entry was maintained at 80% in both years, therefore the overall performance of this objective was 82%. These findings imply that there was significant assurance on safety and quality of food and dietary supplements circulating in the market. **Figure 2** shows the average performance of the indicators related to core functions under this objective.

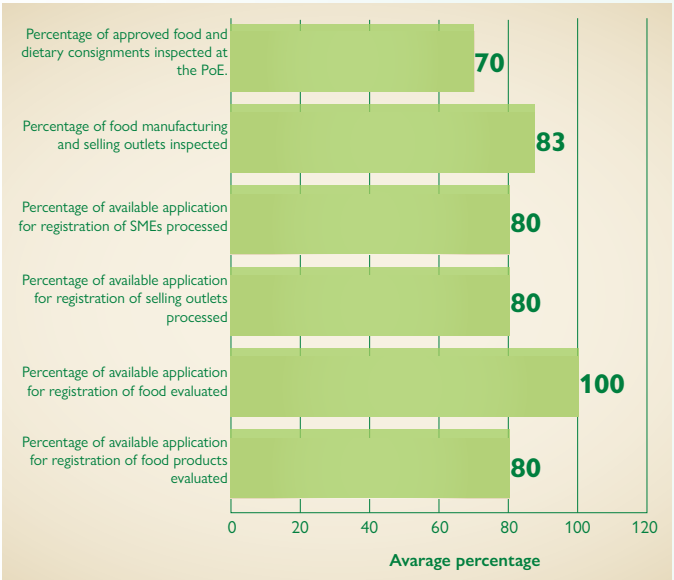


Figure 2: Overall performance of Objective E for aggregated indicators

2.2.6 Objective F: Laboratory services improved

During the period under review, the Authority's Laboratory received a total of 6,114 and 5,067 samples of regulated products in 2017/18 and 2018/19 respectively intended for laboratory analysis so as to ascertain their quality.

According to self assessment report, average percentage of analysed samples for food, medicines, medical devices, diagnostics and cosmetics increased from 87% in 2017/18 to 100% in 2018/19. Likewise, the compliance rate for analysed products rose from 85% to 90%. The summary of analysis for each product category is presented in **Table 1.**

Table 1 : Comparison of Laboratory sample analysis for 2017/18 and 2018/19

Name of the Product	2017/18					2018/19				
	Number of Samples			Compliance		Number of Samples			Compliance	
	Received	Analysed	%	Number	%	Received	Analysed	%	Number	%
Medicines	1,466	1,305	89%	1,272	97%	1,818	1,818	100%	1,808	99%
Medical devices	259	171	66%	141	82%	215	215	100%	210	98%
Cosmetics	290	155	53%	152	98%	496	496	100%	462	93%
Diagnostics	322	234	73%	204	87%	59	59	100%	59	100%
Food	3,777	3,471	92%	2,747	79%	2,479	2,479	100%	2,041	82%
Total	**6,114**	**5,336**	**87%**	**4,516**	**85%**	**5,067**	**5,067**	**100%**	**4,580**	**90%**

Further, the report shows that laboratory capacity of releasing results for tested samples within turnaround time (i.e. per Clients Service Charter) improved from 62% to 91% against the set target of 66% and 68% for 2017/18 and 2018/19, respectively. Furthermore, TFDA laboratory maintained accreditation for ISO/IEC 17025 and WHO pre qualification for the same period.

In view of the above, these records indicate that for the past two years the overall performance of this objective was 78% which implies that the Laboratory had enough capacity of analyzing the products and provides the results within the required turnaround time. Besides this achievement, the compliance rate of 90% provides assurance to consumers and the general public on quality of regulated products circulating in Tanzania market. However, more resources are required to strengthen the capacity of Laboratory operations especially in the testing of medical devices and diagnostics.

2.2.7 Objective G: Public education strengthened and customer services improved

TFDA planned to strengthen public education and improve customer services by developing and disseminating IEC materials, conducting public education and customer care programmes, provide services as per CSC and conducting service delivery survey.

The period under review, TFDA developed and disseminated a total of 126 (132%) out of 95 planned different types of IEC materials which include but not limited to posters, bill boards, brochures, display boards, slides, video tapes, radio and television programs and magazines.

In addition, performance on services offered within CSC standards was maintained at 80% in both years against the planned performance of 50% and 55% in 2017/18 and 2018/19, respectively. With regard to attendance of customer complaints, TFDA managed to attend all customer complaints received under revised period. There is also an increase in staff sensitization on customer care from 35% to 80% in 2017/18 and 2018/19, respectively. The overall performance of this objective was 63%. This achievement on provision of services and attending customer complaints was attributed to sensitization of staff on customer care issues and implementation of quality management systems.

Despite the stated achievements, TFDA could not manage to conduct Service Delivery Survey (SDS) as planned due to lapse of time for conducting survey. The survey is planned to be conducted in the financial year of 2020/21 and the result from the survey will help measure the level of public awareness and customer satisfaction index in relation to the Authority's functions and service delivery.

2.2.8 Objective H: Institutional capacity to deliver services strengthened

TFDA planned to strengthen its capacity to deliver its services by automation of services, implementing its budget and procurement plan, conducting consultative meetings with LGAs, collecting revenues from its planned sources reviewing of SOPs and expansion of TFDA HQ laboratory in Dar es Salaam and construction of central zone office .

TFDA achieved to implement its budgeted activities by 100% in 2017/18 and 90% in 2018/19 as per work plan, respectively. In addition, procurement plan was implemented at 100% and 87%, respectively.

With regard to audits conducted at TFDA, the Authority managed to sustain ISO 9001: 2015 certification and was able to attain Clean Audit Reports from Controller and Auditor General for two consecutive years.

Moreover, the other achievements recorded during the same period include; establishment of the Western and Eastern Lake Zone offices, growth in internal revenue collections from TZS 42.922 billion in 2017/18 to TZS 47.998 billion in 2018/19, which is an increase of 12%.

During the same period, automated services were maintained to both Headquarters and Zone offices. The number of staff increased from 272 in 2017/18 to 311 in 2018/19, which is 14% increase. The overall performance of this objective was 80% for the past two years under review. Furthermore, working tools including laboratory equipment and reagents, computers, motor vehicles, motor cycles and furniture were procured and deployed.

TFDA improved and maintained elaborate systems for registration of products, inspection, PMS, Pharmacovigilance, Food Borne Diseases surveillance, human resource, financial management, procurement and asset management, quality management, Laboratory Information management System (LIMS) and Integrated Management information system (IMIS).

Regardless of notable achievements, the Authority still faces the following challenges and bottlenecks: -

(a) Shortage of staff and office space in Zone Offices; and

(b) Inability to start the expansion works of the Laboratory building in Dar es Salaam Office and construction works of Central zone office in Dodoma.

Based on the scope of TFDA functions, there is a need to redefine and standardize the size of Zone offices in terms of geographical coverage or establishment of regional offices in order to improve efficiency in service delivery. Furthermore, the Authority needs to employ more staff, acquire more working facilities and plan for construction of zone laboratories. **Figure 3** shows summary of overall performances of for each strategic objective for the past two years based on the self-assessment conducted.

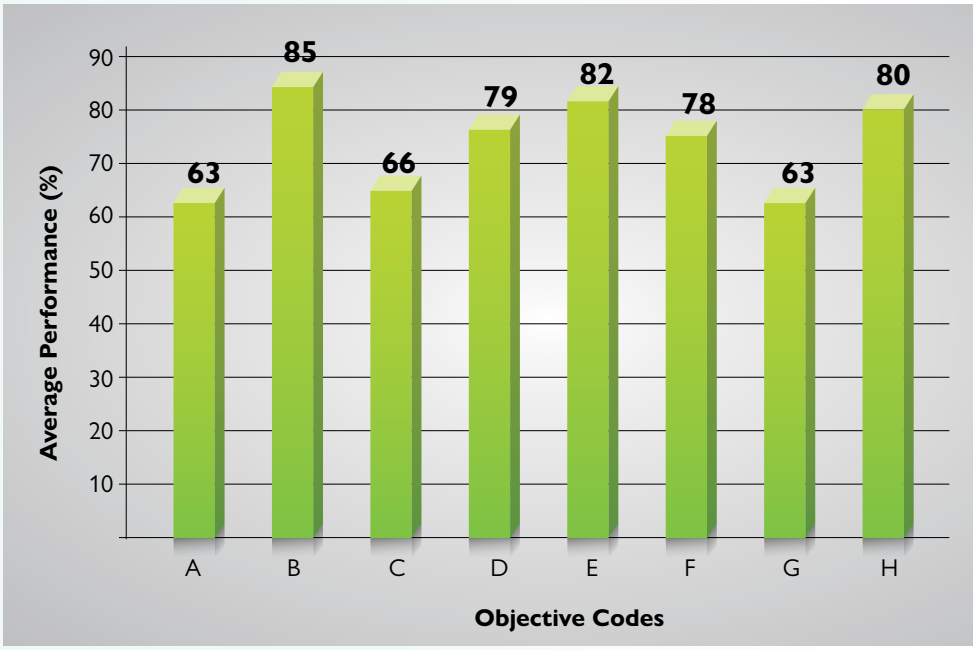


Figure 3: Summary of overall performance of each objective based on key performance indicators

According to the findings presented in **Figure 1**, it is revealed that the overall average performance for the past two years was 73% with Objective B having the highest performance of all followed by Objective H, F, D and E, C, A and G in that order. Comparatively, average performance rose by 13% from 67% to 80% for the years 2017/18 and 2018/19, respectively.

2.3 Stakeholders' Analysis

A detailed stakeholder analysis was conducted to determine their expectations, impact and position with regards to TMDA services as summarized in the **Table 2** below:

Table 2: Stakeholders' analysis

S/N	Stakeholders	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority (H,M,L)
1	Consumers	(i) Safety Quality, effectiveness and performance of regulated products (ii) Information regarding regulated products TMDA services provided according to CSC	(i) Increased hazards associated with consumption of regulated products (ii) Increased customer complaints (iii) Intervention from higher authorities that may negatively affect TMDA	H
2	Ministry responsible for Health	(i) Effective and efficient implementation of Health Policy (ii) Fully implementation of TMDA mandate (iii) Technical advice on safety, quality, effectiveness and performance of regulated products (iv) Performance reports	(i) Poor regulation of regulated products (ii) Shortage of reliable information for decision making by the Minister (iii) Lack of confidence and trust with TMDA (iv) Ministry intervention to rectify the situation	H
3	Ministry responsible for Livestock Development and Fisheries.	(i) Safety Quality and effectiveness of veterinary medicines, vaccines and devices. (ii) Technical advice and feedback on veterinary medicines, vaccines and antimicrobial drug resistance. (iii) Information and education on rational use of veterinary medicines	(i) Uncertainty on the Safety, quality and effectiveness of veterinary medicines and vaccines. (ii) Uninformed decisions on the fate/use of veterinary medicines (iii) Ministry intervention to rectify the situation (iv) Inadequate collaboration	M
4	Ministry responsible for Industry and Trade	(i) Trade facilitation for regulated products (ii) Information and education (iii) To facilitate formalization of domestic manufacturers and their products.	(i) Inadequate collaboration (ii) Poor quality, safety and effectiveness, of manufactured products (iii) Increased Technical Barriers to Trade (iv) Ministry intervention to rectify the situation	M

S/N	Stakeholders	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority (H,M,L)
5	Ministry responsible for Finance and Planning	(i) Effective and efficient implementation of National Development Plans (ii) Performance reports (iii) Fully implementation of TMDA mandate (iv) Financial prudence	(i) Shortage of reliable information for decision making by the Minister (ii) Lack of confidence and trust with TMDA (iii) Ministry intervention to rectify the situation	H
6	Office of the Treasury Registrar	(i) Effective and efficient implementation of Registrar's directives (ii) Performance reports (iii) Fully implementation of TMDA mandate (iv) Collection of fees and charges (v) Financial prudence	(i) Shortage of reliable information for decision making by the Minister (ii) Lack of confidence and trust with TMDA (iii) Registrar's intervention to rectify the situation	H
7	President's Office Public Service Management and Good Governance	(i) Effective and efficient Public service delivery (ii) Performance reports (iii) Fully implementation of TMDA mandate (iv) Provision of conducive working environment to employees	(i) Shortage of reliable information for decision making by the Minister (ii) Lack of confidence and trust with TMDA (iii) Ministry intervention to rectify the situation	H
8	Manufacturers and other dealers of the regulated products	(i) Fairness and transparency (ii) Timely approval and Certification (iii) Clear and streamlined procedures for services (iv) Clear and prompt feedback as per CSC (v) Proper complaints handling (vi) Regular forums to discuss regulatory issues (vii) Information and education	(i) Limited compliance on regulated products (ii) Decreased revenue collection (iii) Increased complaints (iv) Inadequate collaboration (v) Intervention from higher authorities that may negatively affect TMDA (vi) Increased cost of enforcement (vii) Poor feedback on malpractice and product performance in the market	H
9	Media	Information, transparency and cooperation	i) Bad mouthing and poor collaboration ii) Poor image of TMDA to the public	H

S/N	Stakeholders	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority (H,M,L)
10	Practitioners, Researchers and Training Institutions	(i) Timely approval and certification (ii) Fairness and transparency (iii) Information and education (iv) Safe, quality and effective products circulating in the market	i) Bad mouthing and inadequate collaboration ii) Poor image of TMDA to the public iii) Poor feedback on malpractice and product performance in the market	H
11	Suppliers	(i) Information (ii) Contract (iii) Timely payments (iv) Fairness and transparency	(i) Failure of TMDA to attain its targets (ii) Delay/shortage of supplies (iii) Disputes and litigations (iv) Increased substandard goods and services	H
12	Civil Society Organizations (CSOs)	(i) Information on TMDA services (ii) Collaboration/ cooperation (iii) Transparency	i) Bad mouthing and inadequate collaboration ii) Poor image of TMDA to the public iii) Poor feedback on malpractice and product performance in the market	M
13	International Organizations and Development partners	(i) Progress reports for supported projects (ii) Information and education (iii) Transparency and Cooperation (iv) Technical advice on respective development projects	(i) Bad mouthing and poor collaboration (ii) Failure to attain targets (iii) Withdrawn supports from development partners (iv) Intervention from higher authorities that may negatively affect TMDA	M
14	Law Enforcers	(i) Policy, laws, regulations and guidelines (ii) Recognition (iii) Information and education (iv) Transparency and cooperation (v) Commitment (vi) Resources	(i) Inadequate collaboration and bad mouthing (ii) Poor image of TMDA (iii) Intervention from higher authorities that may negatively affect TMDA (iv) Complaints from customers and general public	H

S/N	Stakeholders	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority (H,M,L)
15	Local Government Authority	(i) Policy, laws, regulations and guidelines (ii) Recognition (iii) Information and education (iv) Transparency and cooperation (v) Commitment (vi) Resources	(i) Inadequate collaboration and bad mouthing (ii) Poor image of TMDA (iii) Poor implementation of delegated powers and functions (iv) Complaints from customers and general public	H
16	Other Government Institutions	(i) Transparency, information sharing and cooperation (ii) Technical advice	(i) Bad mouthing and poor image of TMDA to the public (ii) Inadequate collaboration	L
17	Politicians	(i) Effective implementation of the policy and law (ii) Proper management and utilization of resources (iii) Transparency, information and education (iv) Provision of technical advice	(i) Bad mouthing and poor image of TMDA to the public (ii) Political interventions that may negatively affect TMDA (iii) Inadequate collaboration	H
18	Employees	(i) Clear working guidelines and staff regulations (ii) Equitable remuneration (iii) Career development (iv) Conducive working environment (v) Harmonious working relationship (vi) Care and support (vii) Adequate working tools	(iv) Low morale (v) Low productivity (vi) Unethical practices (vii) Increased attrition rate (viii) Unsatisfied external customers (ix) Increased complaints from staff (x) Intervention from higher authorities that may negatively affect TMDA (xi) Increased labor disputes and litigations	H

Key: H=High, M=Medium, L=Low

2.4 Strengths, Weaknesses, Opportunities and Challenges (SWOC) Analysis

Strengths, Weaknesses, Opportunities and Challenges (SWOC) analysis was carried out in respect to the prevailing internal and external environment that can impact realization of TMDA mission and vision. The SWOC analysis results provide for aspects that are addressed in this SP.

The strengths of TMDA reflect its internal capacity to offer services on regulatory functions while its weaknesses highlight areas that would require intervention to remedy the current environment. The opportunities are external factors that need to be leveraged for the benefits of the organization while challenges are to be managed or turned into opportunities. Results of the analysis for strengths, weaknesses, opportunities and challenges are detailed in **Table 3**.

…opportunities are external factors that need to be leveraged for the benefits of the organization

Table 3: SWOC Analysis

Area	Strengths	Weaknesses
Human Resource Management	(a) Existence of Human Resource plan (b) Existence of reputable and committed Management (c) Existence of MAB and Technical Committees (d) Competent, motivated and committed staff (e) Team work spirit (f) Presence of Training programme (g) Presence of Scheme of Services and OPRAS (h) Existence of HRMIS (i) Presence of a library with resources on regulatory affairs	(a) Inadequate number of staff (b) Inadequate staff mentoring and counseling (c) Lack of succession plan (d) Inadequate remuneration (e) Inadequate gender mainstreaming (f) Lack of special incentive schemes for PoE inspectors (g) Inadequate training to inspectors at PoE and LGAs
	Opportunities	**Challenges**
	(a) Qualified/skilled labor from the market (b) Qualified personnel at local government authorities	(a) Delays in recruitment of staff from PO-PSM
	Strengths	**Weaknesses**
Business Processes	(a) Presence of internal financial and staff regulations (b) Presence of Organization structure (c) Existence of eight (8) TMDA Zone offices	(a) Zone offices are under staffed (b) Inadequate M&E of TMDA functions

	(d) Existence of legislation, guidelines and SOPs guiding the provision of TMDA services (e) Presence of Quality assurance centers (f) Being EAC Center of excellence for medicines evaluation and registration (g) Presence of Integrated Management Information System (h) Existence of Quality Management System (QMS) (i) Powers to collect and utilize funds (j) Presence of infrastructure and facilities (k) Presence of well equipped and WHO pre-qualified laboratory (l) Attainment of WHO Maturity Level 3 status on regulation of medicines (m) Existence of delegation powers and function to LGAs regulations (n) Existence of Fees and Charges regulations	(c) Inadequate PMS programme for medical devices and diagnostics (d) Inadequate capacity to conduct scheduled inspections (e) Inadequate capacity to meet CSC standards (f) Inadequate competence in regulation of medical devices and diagnostics (g) Lack of unit to take care of estate related matters (h) Reliance on foreign technical support for MIS services (i) Unreliable network services (j) Centralized laboratory services (k) Majority of TMDA documents are in English (l) Lenient penalties prescribed in the TMDCA, Cap 219 (m) Inadequate control of product promotion and advertisement (n) Delays in procurement processes and procedures hence affecting delivery of laboratory chemicals and consumables
	Opportunities	**Challenges**
	(a) Presence of supportive government policies, legislation and national framework guidelines and strategies (b) Availability of new technologies such as the use of smart phones in product verifications and GePG in payment of fees and charges (c) Existence of the Parliament which can enact and review legislations (d) Political will and support. (e) National Five Year Development Plan II which promotes industrialization; (f) Presence of regional and international cooperation; (g) Presence of LGAs and other law enforcers	(a) Inefficient investigation and prosecution by law enforcers (b) Keeping pace with advanced technologies; (c) Porous borders (d) Lack of approved sites to dispose hazardous waste products (e) Lack of national portal for import and export control. (f) Overlapping of functions with other regulatory authorities (h) Bureaucratic approval of laws and reviews (i) Over-reliance on imported products hence high chance of falsified and substandard products (j) Low number of local suppliers for laboratory consumables (k) Delays in clearance of imported laboratory chemicals and consumables by GPSA

	Strengths	Weaknesses
Customer care	(a) Existence of Clients' Service Charter (CSC) ; (b) Existence of Communication and Public Education Strategy (c) Existence of complaints handling mechanisms (d) Presence of customer care desks (e) Existence of TMDA Website and online portal (f) Presence of dedicated staff with mobile phone to assist customers on use of the online portal (g) Public education programmes (h) Periodical Services Delivery Survey	(a) Inadequate implementation of Communication and Public Education Strategy (b) Inadequate responsiveness to customer requirements and services (c) Medium transparency and accountability to customers (d) Limited access to TMDA services at regional and district levels as per CSC
	Opportunities	**Challenges**
	(a) Increased demand for TMDA services (c) Technological advancement	(a) Low voluntary compliance among dealers (b) Low knowledge on regulatory products and illiteracy (c) Limited access to financial capital, appropriate premises and technology by product dealers (d) Inability to cope with new sophisticated technology
	Strengths	**Weaknesses**
Stakeholders	(a) Good collaboration with stakeholders (b) Existence of private goods and service providers (c) Good reputation within and outside the country; and (d) Regional and international regulatory collaboration	(a) Lack of formal stakeholders' forum to discuss regulatory issues (b) Inadequate linkage between TMDA and PO-RALG (c) Inadequate awareness and collaboration from some law enforcers
	Opportunities	**Challenges**
	(a) Increased consumers' demand for safe, quality, effective and performing products (b) Existence of Development Partners to support TMDA functions (c) Existence of CSOs interested in TMDA functions (d) International and regional integration initiatives	(a) Overlapping functions between the TMDA and other regulatory agencies (b) Inadequate domestic suppliers for reagents, chemicals, equipment and technical services

2.5 Recent Initiatives

Number of initiatives have been recently undertaken to address system weaknesses and staff welfare issues as described below.

2.5.1 Main activities implemented for the years 2017/18 and 2018/19

(a) Automation of some of TFDA services;
(b) Upgrading of Electronic Management Information System to improve service delivery and in record keeping;
(c) Regional harmonization of product regulation systems to improve access to safe and quality products in the region;
(d) Initiation of process for enactment of the Tanzania Medicines and Medical Devices Act Cap. 219;
(e) Acquisition of ISO 9001:2015 for Quality Management System;
(f) Attainment of WHO Maturity Level 3 status and maintaining of WHO pre-qualification for medicines;
(g) Recruitment of additional 39 staff;
(h) Staff training and development in long term programmes (25 Masters and 4 PhDs);
(i) Procurement of 11 motor vehicles; and
(j) Establishment of toll free system at HQ and zone offices.

2.5.2 Accomplished Milestones

(a) Establishment of areas prone to corruption regarding TMDA services;
(b) Establishment of window/desk to support food SMEs;
(c) Training of food evaluators on genetically modified food;
(e) Development of guidelines for identification and registration of Food SMEs;
(f) Procurement and installation of equipment for Lake zone laboratory;
(g) Development and implementation of guidelines for research and project proposal writing;
(h) Development of comprehensive public education and customer care strategy;
(i) Sustaining of ISO 9001:2015 accreditation;
(j) Attaining Clean Audit Reports;
(k) Equipping of laboratory for medical devices testing;
(l) Revising and implementing Scheme of Service and salary structure;
(m) Completion of First Institutional self-assessment;
(n) Automation of services;
(o) Identification and mitigation of risks;

(p) Remittance of TZS 21.6 billion as contribution to Consolidated Fund;
(q) Integration and licensing, Epicor and HR-MIS systems; and
(r) Increase in revenue collections from TZS 42.922 billion to TZS 47.988 billion.

2.6 Critical issues

Based on the situation analysis, various areas were identified as critical for improvement and must be addressed in the plan. They include but not limited to:-

(a) Strengthening regulation of medicines, medical devices, diagnostics and other regulated products;
(b) Enactment of Tanzania Medicines and Medical Devices Act.
(c) ICT usage in service provisions;
(d) Facilitation of domestic manufacturing facilities ;
(e) Public education, customer care and complaints handling;
(f) Recruitment, Staff wellness, motivation and career development;
(g) Succession planning and implementation;
(h) Gender mainstreaming;
(i) Estates and property management;
(j) Centralized laboratory services;
(k) Establishment of TMDA stakeholders forum;
(l) Construction of TMDA Office in Dodoma;
(m) Strengthening import controls ;
(n) Strengthening of Zone offices by hiring staff and improvement of infrastructures;
(o) Strengthening Monitoring and Evaluation of TMDA functions;
(p) Financial sustainability;
(q) Provision of adequate resources (Motor Vehicles, ICT equipment);
(r) Provision of Laboratory equipment and consumables;
(s) National, Regional and International collaboration;
(t) Areas prone to corruption regarding TMDA services;
(u) Operational research and project on TMDA functions;
(v) Conducting SDS;
(w) Review and monitoring of CSC; and
(x) Review of internal financial and staff regulations.

The identified weaknesses, opportunities and critical issues are well taken care of in chapter three under the appropriate strategic objectives, strategies, targets and key performance indicators are set to track their performance. Strategies have also been identified to manage the foreseen challenges so as not to affect implementation of the plan.

CHAPTER 3 THE PLAN

3.0 Introduction

This chapter presents two year plan for executing TMDA functions in line with other national initiatives. The plan will be implemented from 2020/21 - 2021/22. This chapter provides for the vision, mission, quality policy statement, core values, objectives, strategies, targets and key performance indicators.

3.1 Mission, Vision, Core Values, Quality Policy and Philosophy Statements

3.1.1 Vision Statement

To be the leading Regulatory Authority in ensuring safety, quality and effectiveness of medicines, medical devices, diagnostics and other health related products for all.

3.1.2 Mission Statement

To protect and promote public health by ensuring safety, quality and effectiveness of medicines, medical devices, diagnostics and other health related products.

3.1.3 Core Values

TMDA embraces and institutionalize values that ensure satisfaction and expectations of stakeholders. All TMDA employees are committed to upholding the following values as character of identity: -

1. **Integrity**: To uphold highest standards of conduct and commitments while acting in the best interest of the country.
2. **Customer focus**: Always treat customers and colleagues with courtesy and be responsive, timely and proactive to meet their needs.
3. **Quality:** Strive to deliver the best services to the customers with utmost professionalism.
4. **Teamwork:** Support one another, work cooperatively and respect one another's views.
5. **Accountability**: Accountable for actions and outcomes.
6. **Transparency**: Operate in a fully transparent manner and communicate openly and timely to the relevant stakeholders

3.1.4 Quality Policy Statement

"TMDA is committed to provide quality services in response to customer needs and expectations. We shall strive to balance the interests of our stakeholders without compromising quality, safety and effectiveness of medicines, medical devices and diagnostics by managing the Authority with utmost professionalism.

TMDA is committed to comply with the requirements of ISO 9001:2015 Standard and continually improve effectiveness of Quality Management System. We shall manage and provide resources for continuous improvement of our services to ensure customers' satisfaction."

3.1.5 Philosophy

TMDA strives to offer quality regulatory services in the pursuit of protecting public health and environment by using competent and dedicated staff.

3.2 Strategic Objectives

To achieve TMDA's vision and mission, seven (7) Strategic Objectives and respective rationale have been developed. For each objective, several strategies, targets and performance indicators have been identified. The Strategic Objectives are;

A. HIV/AIDS and NCDs reduced and Services improved;
B. National Anti-Corruption Strategy effectively implemented and sustained;
C. Gender and environmental issues improved;
D. Quality, safety and effectiveness of medicines, medical devices and diagnostics assured;
E. Laboratory services improved;
F. Public education strengthened and customer services improved; and
G. Institutional capacity to deliver regulatory services strengthened.

3.2.1 Objective A: HIV/AIDS and Non-Communicable Diseases (NCDs) reduced and Services improved

3.2.1.1 Rationale

HIV/AIDS continues to pose a great threat to health and lives in the community. AIDS does not have any cure, and the costs of managing the disease are high and aggravated by secondary infections associated with it. TMDA employees just like any other community are also at risk of acquiring HIV/AIDS.

Stigma for people living with HIV/AIDS contributes to reluctance for infected individuals to declare their status and thus making it difficult for them to receive assistance to manage their condition. This state of affairs calls for an intervention to minimize or eradicate new HIV infections, promote disclosure of HIV/AIDS status, reduction of stigma and provision of assistance to HIV/AIDS infected individuals.

NCDs are diseases that are not infectious and cannot be transferred to others. The main types of NCDs include cardiovascular diseases, cancer, chronic respiratory diseases and diabetes. Social-demographic and economic transition as well as changes in lifestyle specifically concerning unhealthy diet, low level of physical activity, alcohol intake and tobacco usage are common risk factors implicated in the etiology of NCDs. The NCDs cause morbidity and mortality, leading to social and economic burden on the individual, community, employers, health system and national economy as a whole. For the employer, the burden is related to reduced productivity as NCDs cause repeated absenteeism at work places and loss of income through providing care and treatment for those affected. Interventions focusing to increase awareness of NCDs, associated risk factors and prevention activities are critical and therefore need to be addressed in order to manage the problem at workplace.

3.2.1.2 Strategies

Effective implementation of the National Guidelines for Management of HIV/AIDS and NCDs in Public service of 2014.

3.2.1.3 Targets

(a) Awareness, care and support on HIV/AIDS and NCDs to TMDA staff provided by June 2022;

3.2.1.4 Key Performance Indicators

Output Indicators

(a) Awareness programme in place;

(b) Staff wellness programme in place;

(c) Percentage of staff sensitized on HIV/AIDS and NCDs; and

(d) Percentage of staff sensitized on wellness programme.

Outcome Indicators

(a) Percentage of sensitized staff attending voluntary health check-ups for NCDs, HIV/AIDS; and

(b) Percentage of staff attending wellness programme.

3.2.2 Objective B: National Anti-Corruption Strategy effectively implemented and sustained

3.2.2.1 Rationale

Corruption is a socio-economic problem prevailing in both public and private sectors. Its effects are far reaching, since it deprives people's rights, create unnecessary bureaucracy and limit access to social services. TMDA being a regulatory Authority is prone to corruption; corrupt practices if not avoided may lead to unprofessional decisions, loss of Government revenues, loss of confidence in TMDA regulatory decisions, loss of reputation, denial of customers and staff rights and exposure of the public to unfit products.

TMDA has put in place some initiatives to prevent and control corruption at place of work by improving transparency on TMDA procedures, automation of services, handling of customer complaints, enforcement of compliance guidelines, presence of integrity committee, display of bill boards carrying messages of corruption free zone and conducting internal audits. Besides such interventions, more efforts are required to ensure that TMDA is corruption free

3.2.2.2 Strategy

Promote good governance, integrity and ethical values.

3.2.2.3 Targets

(a) Anti-corruption Strategy and Good Governance enforced to TMDA staff by June 2022; and

(b) Public Service Code of Ethics and Conduct instilled to staff by June 2022.

3.2.2.4 Key Performance Indicators

Output Indicators

(a) Percentage of staff sensitized on Ant-Corruption Strategy and Public Service Code of Ethics and Conduct;

(b) Number of areas of TMDA services prone to corruption identified and mitigated;

(c) Percentage of staff signing declaration of conflict of interest forms; and

(d) Number of staff taken to court on corruption charges.

Outcome Indicators

(a) Percentage of conformity to FIFO in registration and issuance of permits; and

(b) Percentage of complaints related to corruption investigated and concluded.

3.2.3 Objective C: Gender and environmental issues improved

3.2.3.1 Rationale

Currently, among TMDA staff, 80 (32%) are women and 171 (68%) are men. The composition of top management of TMDA is not gender sensitive as all the directors are men. At managers level, out of 22 managers, six (6) are women which is equivalent to 38%. To date TMDA has not employed any person with disability and has no user friendly infrastructure to cater for physically challenged persons. This situation indicates inadequate gender mainstreaming in planning which calls for deliberate intervention to bring in appropriate ratio of women to men in various aspects and improvise infrastructure for persons with disabilities.

Various activities undertaken by TMDA may have impact on the environment. Such activities which include use of papers, disposal of unfit products and laboratory wastes might lead into environmental pollution. The authority has taken initiatives of provision of temporary storage facilities for laboratory chemical wastes, make use of existence public and private facilities for disposal of unfit products, planting trees in the nearby surroundings, maintenance of gardens and office cleanliness. More interventions such as constructions of incinerator for self disposal of unfit products are required to conserve the environment.

3.2.3.2 Strategies

(a) Mainstream gender issues in Authority plans; and

(b) Integrate environment management practice in TMDA activities.

3.2.3.3 Targets

(a) Infrastructures to support physically challenged persons provided by June, 2022;

(b) Women empowered at all levels by June, 2022; and

(c) Mechanism for storage of wastes in place by June, 2022.

3.2.3.4 Key Performance Indicators

Output Indicators

(a) User friendly infrastructure for physically challenged persons in place;

(b) Facilities for handling of waste in place;

(c) Percentage of women empowered at all levels;

(d) Percentage of physically challenged staff empowered at all levels; and

(e) Percentage completion of construction of incinerator for disposal of unfit products.

Outcome Indicators

(a) Proportion of women among staff;

(b) Proportion of women at managerial positions;

(c) Proportion of physically challenged persons among staff; and

(d) OSHA certification acquired and sustained at all TMDA offices.

3.2.4 Objective D: Quality, effectiveness and safety of medicines, medical devices and diagnostics assured

3.2.4.1 Rationale

The use of medicines, medical devices and diagnostics of acceptable quality and safety is important for the well-being of the society. The desired health benefits such as effective treatment and management of diseases is highly attributed to quality and safety of medicines, medical devices and diagnostics.

The problem of substandard and falsified medicines, substandard medical devices and diagnostics is very common not only in Tanzania but also in other countries. According to WHO about 10% of medicines circulating in low income countries are substandard and falsified (SF). The systems for regulation of medical devices and diagnostics are in early stages of development in Tanzania.

To date, Tanzania imports about 80% of the medicines, medical devices and diagnostics which calls for more domestic production of these products. Currently, there are 11 domestic manufacturing facilities for medicines and five (5) medical devices.

In view of the above facts, TMDA will streamline the regulation of regulated products and shall continue facilitating domestic production in order to reduce dependence on importation.

3.2.4.2 Strategies

(a) Strengthen the systems for regulation of medicines, medical devices and diagnostics;

(b) Promote voluntary compliance among dealers and customers;

(c) Engage and maintain regional collaboration and international harmonization initiatives for regulation of medicines, medical devices and diagnostics; and

(d) Support domestic manufacturers and SMEs dealing in medicines, medical devices, diagnostics and other health related products to comply with legal and regulatory requirements.

3.2.4.3 Targets

(a) Premises dealing in medicines, medical devices, diagnostics inspected by June, 2022;

(b) Marketing Surveillance and vigilance of medicines, medical devices and diagnostics conducted by June, 2022;

(c) Products (medicines, medical devices and diagnostics) registered by June, 2022; and

(d) Clinical trials approved and inspected by June, 2022.

3.2.4.4 Key Performance Indicators

Output Indicators

(a) Percentage of applications for registration of premises for medicines, medical devices and diagnostics processed;
(b) Percentage of registered outlets for medicines, medical devices and diagnostics inspected;
(c) Percentage of product applications for registration of medicines, medical devices and diagnostics assessed;
(d) Percentage of planned PMS samples for medicines, medical devices and diagnostics collected;
(e) Percentage of applications for authorization of clinical trials evaluated;
(f) Percentage of approved clinical trials inspected;
(g) Percentage of received field safety reports of medicines, medical devices and diagnostics assessed;
(h) Percentage of authorized clinical trials entered into clinical trial registry;
(i) Percentage of domestic medicines, medical devices and diagnostics manufacturing facilities inspected for GMP;
(j) Percentage of overseas manufacturing facilities for medicines, medical devices and diagnostics inspected for GMP;
(k) Percentage of received import/ export applications approved;
(l) Percentage of approved consignments inspected at the PoEs;
(m) Percentage of registered health laboratories inspected;
(n) Percentage of evaluated applications for registration of regulated products entered/ uploaded into IMIS;
(o) Number of ADR reports received;
(p) Percentage of received ADR reports assessed; and
(q) Percentage of received ADR reports uploaded to Vigiflow database.

Outcome Indicators

(a) Percentage of applications for registration of medicines, medical devices and diagnostics approved/rejected within specified time period (as per CSC);
(b) Percentage of selected PMS human and veterinary medicines complying with quality requirements;
(c) Percentage of non compliant products/batches of regulated products recalled;
(d) Percentage of domestic medicines, medical devices and diagnostics manufacturing facilities complying with GMP and Quality System requirements;
(e) Percentage of clinical trials compliant with GCLP requirements;
(f) Percentage of compliance of inspected selling outlets for medicines, medical devices and diagnostics;
(g) Percentage of compliance of registered health laboratory inspected; and
(h) Percentage of processed import/ export application approved.

3.2.5 Objective E: Laboratory services improved

3.2.5.1 Rationale

TMDA laboratory is established under Section 14(1) of the Tanzania Medicines and Medical Devices Act, Cap 219. It is mandated among other functions to perform analysis of medicines, medical devices, diagnostics, drug adjuvant, and packaging materials in order to facilitate efficient regulatory functions and decisions. The Laboratory is also mandated to coordinate operational and applied researches and training as might be determined by the Authority.

The annual performance reports for 2017/18 and 2018/19 indicate that the capacity of this laboratory to analyse the received samples was 87% and 100% respectively. The report shows laboratory capacity of releasing results for tested samples within turnaround time as per Clients Service Charter (CSC) improved from 60% to 80%.

The Authority should sustain the Laboratory performance registered in the period under review and escalate the performance of the Laboratories by equipping it with state of art equipment and skilled labour. Furthermore, Authority has to put in place more strategies for marketing the Laboratory in East African Community (EAC), Southern African Development Community (SADC) and other countries

This calls for enhanced capacity building of the TMDA laboratories by increasing number of human resources, laboratory equipment, extending and upgrading infrastructures and services to zone offices and diversifying the scope of quality and safety parameters to be analysed. This objective will also support formalization of manufacturing facilities of regulated products through provision of laboratory services for their products.

3.2.5.2 Strategies

(a) Decentralize laboratory services to zone offices;

(b) Ensure availability of the state of art laboratory equipment;

(c) Deploy competent and skilled laboratory personnel; and

(d) Ensure accreditation of ISO/IEC 17025 certification and expand scope for WHO prequalification.

3.2.5.3 Targets

(a) Samples of medicines, medical devices and diagnostics tested by June, 2022;

(b) TMDA laboratories strengthened by June, 2022; and

(c) Operational and applied researches on regulatory functions conducted by June, 2022.

3.2.5.4 Key Performance Indicators

Output indicators

(a) Percentage of received samples of medicines, medical devices, diagnostics, antiseptics and disinfectants tested;

(b) Percentage of PMS samples of medicines, medical devices and diagnostics tested;
(c) Percentage of planned researches conducted;
(d) Number of new analytical methods accredited for TMDA laboratories in Dar es Salaam and Mwanza;
(e) Percentage of non regulatory samples from external customers tested;
(f) Number of successful Proficiency Testing (PT) Schemes outcomes;
(g) Percentage of planned internal audits conducted;
(h) Percentage of Quality Assurance (QA) centres performing medicine screening schemes;
(i) Number of samples screened at QA centres;
(j) Percentage of planned processes and procedures reviewed; and
(k) Percentage of laboratory equipment calibrated/maintained.

Outcome indicators

(a) Percentage of laboratory results released within the turnaround time as per CSC;
(b) Level of customers satisfaction in relation to laboratory services;
(c) Percentage of identified research problems concluded and results disseminated;
(d) ISO/IEC 17025 and WHO pre-qualification for TMDA laboratory in Dar es salaam sustained; and
(e) ISO/IEC 17025 and WHO pre-qualification for Mwanza laboratory attained and sustained.

3.2.6 Objective F: Public education strengthened and customer services improved

3.2.6.1 Rationale

Public education on regulated products is of paramount importance because it has a relationship with compliance to law and rational use of regulated products. Public education provides information that influence behaviour of customers, consumers and general public in relation to compliance use of products.

Public education and information is equally important for practice and use of products that are linked to life style or fashion such as use of contraceptives and body slimming/ fattening. The use of such products may not be for health purposes, but rather they are used for fashion. The ultimate goal of public education and information on regulated products is reduction of enforcement costs, protection and promotion of public health.

TMDA has been implementing public education and communication through TV and radio programmes, distribution of IEC materials, participation in exhibitions, outreach campaigns, press conferences, social media and press releases.

TMDA established customer care desk, one stop customer service centre, customer complaints handling desk and training of staff on customer care in order to improve customer services.

In view of the above, TMDA plans to enhance public education and customer care by continuously implementing a comprehensive communication strategy that engage different approaches for successful execution of the developed interventions. Further, the Authority will integrate and implement its whistle blowing policy in order to enhance transparency and hence increase reporting of complaints and concerns pertaining to violation of the TMMD Act or any other serious misconduct. Additionally, TMDA will conduct SDS to measure the level of public awareness and customer satisfaction index in relation to the Authority's functions.

3.2.6.2 Strategies

(a) Review and implement a comprehensive communication and public education strategy;

(b) Engage TMDA stakeholders in all matters related to TMDA functions;

(c) Inculcate TMDA core values to all staff; and

(d) Monitor implementation of Whistle blowing policy and CSC.

3.2.6.3 Targets

(a) Stakeholders collaborative mechanism for dissemination and sharing of information established and implemented by June, 2022; and

(b) Public awareness on quality and safety of TMDA regulated products raised by June, 2022.

3.2.6.4 Key Performance Indicators

Output Indicators

(a) Percentage of planned IEC materials types developed, printed and disseminated;
(b) Percentage of IEC materials on whistle blowing developed, printed and disseminated;
(c) Percentage of employees sensitized on customer care;
(d) Percentage of customer complaints received and attended;
(e) Number of customers attended;
(f) SDS conducted;
(g) Percentage of planned TV and radio programmes developed and aired
(h) Percentage of planned exhibitions participated;
(i) Percentage of planned outreach campaigns conducted;
(j) Number of information updates uploaded in TMDA website and social media platform;
(k) Number of followers on TMDA social media;
(l) Percentage of services offered to external customers within client service charter standards;
(m) Number of press conferences developed and conducted;
(n) Number of press releases developed and issued;
(o) Percentage of services offered to internal customers within the internal CSC;
(p) Percentage of received whistle blower complaints and concerns attended;
(q) Number of stakeholders sensitized on whistle blowing policy; and
(r) Percentage of whistle blowers provided with feedback.

Outcome indicators

(a) Percentage level of general public awareness on TMDA functions;
(b) Percentage level of external and internal customer satisfaction; and
(c) Percentage of customer complaints resolved;
(d) Percentage level of public awareness on whistle blowing policy;
(e) Percentage of whistle blower complaints and concerns investigated and concluded; and
(f) Percentage of serious offenders blacklisted.

3.2.7 Objective G: Institutional capacity to deliver regulatory services strengthened

3.2.7.1 Rationale

Availability of adequate funding, competent human resources, infrastructure, working facilities and systems are important pillars for effective and efficient implementation of regulatory services.

In the past two (2) years, the Authority managed to increase internal revenue collection from 42.922 billion in 2017/18 to 47.998 billion in 2018/19, which is equivalent to 12% increase. In the same period the Authority received Unqualified Audit reports and recruited additional 39 staff from 272 to 311 whereas staff retention rate was 99% for the same period. Furthermore, working facilities such as laboratory equipment, consumables, vehicles, ICT equipment and office furniture's were procured.

TMDA services have been automated by upgrading of Integrated Management Information System (IMIS) and EPICOR, moreover, online portal services have been expanded from import/export services to include other services such as premises registration, medicinal product registration, and electronic reporting system for Adverse Drug Reactions. Additionally, the Authority was able to maintain its Quality Management System (QMS) at ISO 9001:2015.

Despite the notable achievements mentioned earlier on, TMDA still faces shortage of staff and working facilities including office space as the seven (7) zone offices are still in rented buildings.

Thorough and in-depth job evaluation need to be conducted in order to identify duties and responsibilities among directorates, sections, units and staff to ensure equitable distribution of duties and remuneration. Further the size and establishment of zone offices needs to be redefined and standardized because some zones have a size of three (3) regions whereas others have six (6) regions.

In this regard, the Authority needs to continuously improve its services by acquiring equipment and tools, strengthening zone offices, working environment, construction of offices, recruitment of more staff and ensuring financial sufficiency and sustainability. Further, TMDA should enhance the vigorous risk management and ICT usage in service provision.

3.2.7.2 Strategies

(a) Enactment of Tanzania Medicines and Medical Devices Act Cap. 219;
(b) Strengthen capacity for Monitoring and Evaluation;
(c) Strengthen QMS;
(d) Enhance risk management;
(e) Enhance ICT usage;
(f) Provide adequate human and financial resources, working facilities and tools; and
(g) Provide physical infrastructures at both headquarters and zone offices.

3.2.7.3 Targets

(a) TMDA compliance with Public Finance Act 2001 sustained by June 2022;
(b) Legal services timely provided by June 2022;
(c) Administrative services provided by June 2022;
(d) Human resources managed by June, 2022;

(e) Planning, budgeting and their implementation coordinated and monitored by June, 2022;
(f) ICT usage enhanced by June 2022;
(g) Quality and Risk Management Systems improved by June, 2022;
(h) TMDA compliance with Public Procurement Act 2011 sustained by June, 2022;
(i) Zone offices' operations strengthened by June, 2022;
(j) TMDA infrastructures and working facilities provided and maintained by June, 2022; and
(k) Professional development programme implemented by June 2022.

3.2.7.4 Key Performance Indicators

Output indicators:-

(a) New Tanzania Medicines and Medical Devices Act in place;
(b) Percentage of planned activities accomplished;
(c) Percentage of financial resources collected as per planned budget;
(d) Percentage implementation of the HR plan
(e) Percentage of planned Quality audits conducted;
(f) Percentage of planned processes and procedures revised;
(g) Completion level of construction of TMDA Office in Dodoma ;
(h) Percentage of computerized services;
(i) Implementation level of the procurement plan;
(j) Percentage of risks identified as high and very high;
(k) Percentage of staff sensitized on risk management
(l) Number of consultative meetings conducted by Zone Offices;
(m) Percentage implementation of training programme;
(n) Number of project proposals developed; and
(o) Percentage of approved guidelines and manuals printed.

Outcome indicators: -

(a) Percentage budgetary contribution from internal sources;
(b) Clean Financial Audit Report attained;
(c) Percentage of staff retention;
(d) Percentage mitigation of the identified risks;
(e) ISO certification sustained; and
(f) Percentage of proposals funded.

CHAPTER 4 RESULTS FRAMEWORK

4.0 Introduction

The results framework matrix provides for the interventions that lead to achievement of the intended outcomes and finally show how the indicators and progress of the various interventions will be reported to respective stakeholders. It identifies the beneficiaries of services, the overall Development Objective (Goal), linkage between TMDA objectives and other national goals such as Five Year Development Plan II (FYDPII) and National Health Policy. It also shows Results Chain, Results Framework Matrix, Monitoring and Evaluation Plans, Reviews and Reporting Plan.

4.1. The Development Objective

The overall objective of TMDA is to ensure safety, quality and effectiveness of medicines, medical devices and diagnostics.

4.2. Beneficiaries of TMDA Services

There are two levels of beneficiaries of TMDA services. The first level of beneficiaries is manufacturers and distributors of medicines, medical devices and diagnostics. The second level is consumers of the regulated products and institution that receive technical advice and information.

4.3. Results Chain

Result chain is a description of the various stages of an intervention that lead to the changes that are intended. TMDA result chain is composed of a combination of the objectives, targets, activities, inputs, output and outcomes. The basic assumption for developing this result chain is that, there is causal linkage in the various elements of chain, Health Sector Strategic Plan IV and Health Policy. The inputs i.e. utilization of resources will lead to implementation of activities, which will contribute to achievement of targets. Achievement of targets will contribute to achievement of objectives and subsequently to realization of TMDA's development objective.

Achievement of this chain of results will justify use of the budgeted fund in the various interventions and thus contribute to the improvement of Public health in line with medium- and long-term National Plans.

4.4. The Results Framework Matrix

The matrix envisages how TMDA development objective will be realized and the outcome indicators for measuring the achievements. The matrix consists of overall development objective, objective codes and description, outcomes and key performance indicators.

Table 4: Results Framework Matrix

Development Objective	Objective Code	Objective Description	Expected Outcomes
To ensure safety, quality and effectiveness of medicines, medical devices and diagnostics	A	HIV/AIDS and NCDs reduced and Services improved;	a) Improved health status of HIV/AIDS and NCDs patients; b) Reduction of new cases of NCDs and HIV/AIDS; and c) Increased number of staff undergoing voluntary health checkups and participating in wellness programme.
	B	National Anti-Corruption Strategy effectively implemented and sustained;	a) Improved staff knowledge and awareness on prevention and combating corruption; and b) Improved transparency;
	C	Gender and environmental issues improved;	a) Improved proportion of women and physically challenged among staff; b) Increased proportion of women at decision making level; c) Improved Gender mainstreaming in all TMDA functions; and d) Improved working environment.
	D	Quality, safety and effectiveness of medicines, medical devices and diagnostics assured;	a) Improved compliance to quality and safety requirements; b) Presence of quality and safe products in the market; and c) Improved reputation and recognition of TMDA among WHO member states.

The underlying logic is achievements of the outputs will lead to realization of the planned outcomes under each objective, and achievement of the outcomes will lead to achievement of the objectives and will result into achievement of the TMDA's Development objective. The indicators in the matrix will be used to track progress towards achievement of planned outcomes/objectives. The result framework matrix is detailed in **Table 4.**

	Outcome Indicators
	(i) Percentage of sensitized staff attending voluntary health check-ups for NCDs, HIV/AIDS; and (ii) Percentage of staff attending wellness programme.
	(i) Percentage of conformity to FIFO in registration and issuance of permits; and (ii) Percentage of complaints related to corruption investigated and concluded.
	(i) Proportion of women among staff; (ii) Proportion of women at managerial positions; (iii) Proportion of physically challenged persons among staff; and (iv) OSHA certification acquired and sustained at al TMDA offices.
	(i) Percentage of applications for registration of medicines, medical devices and diagnostics approved/rejected with specified time (as per CSC); (ii) Percentage of selected PMS human and veterinary medicines complying with quality requirements; (iii) Percentage of non-compliant products/batches of regulated products recalled; (iv) Percentage of domestic medicines, medical devices and diagnostics manufacturing facilities complying with GMP and Quality System requirements; (v) Percentage of clinical trials compliant with GCLP requirements; (vi) Percentage of compliance of inspected selling outlets for medicines, medical devices and diagnostics; (vii) Percentage of compliance of registered health laboratory inspected; and (viii) Percentage of processed import/ export application approved.

Development Objective	Objective Code	Objective Description	Expected Outcomes
To ensure safety, quality and effectiveness of medicines, medical devices and diagnostics	E	Laboratory services improved	a) Timely release of laboratory results; b) Increased level of customer satisfaction on Laboratory services; c) Increased capacity to test samples; and d) Recognition and reputation of TMDA Laboratories.
	F	Public education strengthened and customer services improved;	a) Increased public awareness on functions and services provided by TMDA; b) Increased customer satisfaction in respect to TMDA service provision; and c) Reduced customer complaints.
	G	Institutional capacity to deliver regulatory services strengthened.	a) Improved efficiency in services delivery; and b) Enhanced financial sustainability.

	Outcome Indicators
	(i) Percentage of laboratory results released within turnaround time as per CSC; (ii) Level of customers satisfaction in relation to laboratory services; (iii) Percentage of identified research problems concluded and results disseminated; (iv) ISO/IEC 17025 and WHO pre-qualification for TMDA laboratory in Dar es salaam sustained; and (v) ISO/IEC 17025 and WHO pre-qualification for Mwanza laboratory attained and sustained.
	(i) Percentage level of general public awareness on TMDA functions; (ii) Percentage level of external and internal customer satisfaction; and (iii) Percentage of customer complaints resolved; (iv) Percentage level of public awareness on whistle blowing policy; (v) Percentage of whistle blower complaints and concerns investigated and concluded; and (vi) Percentage of serious offenders blacklisted.
	(i) Percentage budgetary contribution from internal sources; (ii) Clean financial audit report attained; (iii) Percentage of staff retention; (iv) Percentage mitigation of the identified risks; (v) ISO certification sustained; and (vi) Percentage of proposals funded.

4.5 Monitoring, Review and Evaluation Plans

This sub section details the Monitoring Plan, Review and Evaluation Plans for the SP.

4.5.1 Monitoring Plan

The monitoring plan comprises of indicators and indicator descriptions, baseline, indicator target values, data collection and methods of analysis, indicator reporting frequency and the responsible officers. 158 key performance disaggregated indicators (both output 113 and outcome 45) will be monitored and reported on quarterly, biannual, annual and biennial basis, for the purpose of tracking performance of the planned activities. The monitoring plan is detailed in **Tables 5** and **6** below;

Table 5: Monitoring Plan I (Output based indicators)

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
	OBJECTIVE A: HIV/AIDS infections and Non Communicable Diseases (NCDs) reduced and Services improved													
1	Awareness programme in place.	July, 2017	-	√	√	√	√	√	TMDA	HR MIS	Annually	Programme document	Once	DBS
2	Percentage of staff sensitized on HIV/AIDS.	July, 2017	85	40	81	95	95	95	TMDA	Training Records	Annually	Progress Reports	Annually	DBS
3	Percentage of staff sensitized on NCDs.	July, 2017	85	40	81	95	95	95	TMDA	Training Records	Annually	Progress Reports	Annually	DBS
4	Wellness programme in place.	July, 2017	-	-	-	-	√	√	TMDA	HR MIS	Annually	Programme document	Once	DBS
5	Percentage of staff sensitized on wellness programme.	July, 2017	-	-	-	-	65	75	TMDA	Training Records	Annually	Progress Reports	Annually	DBS

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
	OBJECTIVE B: National Anti-Corruption Strategy effectively implemented and sustained													
1	Percentage of staff signing declaration of conflict of interest forms.	July, 2017	99	104	108	100	100	100	TMDA	Personal and confidential files	Annually	Progress Reports	Annually	DBS
2	Percentage of staff sensitized on Anti-Corruption Strategy and Public Service Code of Ethics and Conduct.	July 2017	-	-	-	-	90	95	TMDA	Training Records	Annually	Progress Reports	Annually	DBS
3	Percentage of new staff signing integrity pledge form.	July 2017	-	-	-	-	100	100	TMDA	Personal and confidential files	Annually	Progress Reports	Annually	DBS
4	Number of areas of TMDA services prone to corruption identified	July 2017	-	-	-	-	2	0	TMDA	Risk Profile database	Annually	Progress Reports	Annually	MQR/MLS
5	Number of staff taken to court on corruption charges.	July 2017	-	-	-	-	0	0	TMDA	Personal and confidential files	Annually	Progress Reports	Annually	DBS
	OBJECTIVE C: Gender and environmental issues improved													
1	Infrastructures for physically challenged persons in place.	July, 2017	√	√	√	√	√	√	TMDA	Review of Maintenance records	Annually	Infrastructure inspection and Construction records	Annually	DBS
2	Facilities for handling of wastes in place.	July, 2017	-	√	√	√	√	√	TMDA	Cleaning records	Annually	Clean environment	Annually	DBS/DLS
3	Percentage completion of construction of incinerator for disposal of unfit products.	July, 2017	-	-	-	-	50	100	TMDA	Construction records/ Site visits	Annually	Progress Reports/ Construction Records/ Site Visits	Annually	DBS/DMC

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
4	Percentage of women and physically challenged staff empowered at all levels.	July, 2017	50	192	185	56	100	100	TMDA	Progress reports	Annually	Progress Reports	Annually	DBS
	OBJECTIVE D: Quality, safety and effectiveness of medicines, medical devices and diagnostics assured													
1	Percentage of available applications for registration of human medicines evaluated.	July, 2017	75	115	113	82	100	100	TMDA	Evaluation database	Quarterly	Progress reports	Quarterly	DMC
2	Percentage of available applications for registration of veterinary medicines evaluated.	July, 2017	80	115	91	86	100	100	TMDA	Evaluation database	Quarterly	Progress reports	Quarterly	DMC
3	Percentage of available applications for registration of herbal medicines evaluated.	July, 2017	90	109	106	96	100	100	TMDA	Evaluation database	Quarterly	Progress reports	Quarterly	DMC
4	Percentage of available applications for registration of biocidals (Antiseptics and Disinfectants) evaluated.	July, 2017	50	133	119	85	100	100	TMDA	Evaluation database	Quarterly	Progress reports	Quarterly	DMC
5	Percentage of available applications for registration of medical devices evaluated.	July, 2017	95	85	91	100	100	100	TMDA	Evaluation database	Quarterly	Progress reports	Quarterly	DMC
6	Percentage of available applications for registration of diagnostics evaluated.	July, 2017	0	200	141	70	100	100	TMDA	Evaluation database	Quarterly	Progress reports	Quarterly	DMC

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
7	Percentage of available applications for notification of class A medical devices and diagnostics.	July, 2017	-	-	-	-	100	100	TMDA	Premises registration database	Quarterly	Progress reports	Quarterly	DMC
8	Percentage of available applications for authorization of clinical trials evaluated.	July, 2017	90	98	88	100	100	100	TMDA	Evaluation database	Quarterly	Progress reports	Quarterly	DMC
9	Percentage of available applications for registration of premises for medicines importers and warehouse processed.	July, 2017	100	100	99	100	100	100	TMDA	Premises registration database	Quarterly	Progress reports	Quarterly	DMC/ZM
10	Percentage of available applications for registration of premises for medical devices and diagnostics importers processed.	July, 2017	95	99	100	100	100	100	TMDA	Premises registration database	Quarterly	Progress reports	Quarterly	DMC/ZM
11	Percentage of available applications for registration of premises for medical devices and diagnostics retailers processed.	July, 2017	95	99	100	100	100	100	TMDA	Premises registration database	Quarterly	Progress reports	Quarterly	DMC/ZM

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
12	Percentage of available applications for registration of domestic medicines manufacturing facilities processed.	July, 2017	100	100	100	100	100	100	TMDA	Premises registration database	Quarterly	Progress reports	Quarterly	DMC/ZM
13	Percentage of available applications for registration of domestic medical devices and diagnostics manufacturing facilities processed.	July, 2017	100	100	100	100	100	100	TMDA	Premises registration database	Quarterly	Progress reports	Quarterly	DMC/ZM
14	Percentage of available applications for registration of domestic antiseptics and disinfectant manufacturing facilities processed.	July, 2017	-	-	-	-	100	100	TMDA	Premises registration database	Quarterly	Progress reports	Quarterly	DMC/ZM
15	Percentage of planned PMS samples for selected human medicines collected.	July, 2017	80	64	103	83	100	100	TMDA	PMS database	Quarterly	Progress reports	Quarterly	DMC
16	Percentage of planned PMS samples for selected veterinary medicines collected.	July, 2017	70	52	84	76	100	100	TMDA	PMS database	Quarterly	Progress reports	Quarterly	DMC
17	Percentage of planned PMS samples for selected medical devices collected.	July, 2017	86	86	76	90	95	100	TMDA	PMS database	Quarterly	Progress reports	Quarterly	DMC

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
18	Percentage of planned PMS samples for selected diagnostics collected.	July, 2017	86	90	80	90	95	100	TMDA	PMS database	Quarterly	Progress reports	Quarterly	DMC
19	Percentage of received field safety reports from clinical trial of medicines assessed.	July, 2017	100	100	100	100	100	100	TMDA	Clinical Trial database	Quarterly	Progress reports	Quarterly	DMC
20	Percentage of received safety reports from clinical trial of medical devices assessed.	July, 2017	-	100	100	100	100	100	TMDA	Clinical Trial database	Quarterly	Progress reports	Quarterly	DMC
21	Number of received Adverse Drug Reactions (ADR) reports.	July, 2017	250	52	1320	700	1000	1400	TMDA	ADR Data Base	Quarterly	Progress reports	Quarterly	DMC/ZM
22	Percentage of received ADR reports assessed.	July, 2017	-	-	-	-	99	100	TMDA	ADR Data Base	Quarterly	Progress reports	Quarterly	DMC
23	Percentage of received ADR reports uploaded in the Vigiflow database.	July, 2017	-	-	-	-	100	100	TMDA	Vigiflow Data Base	Quarterly	Progress reports	Quarterly	DMC
24	Percentage of evaluated applications for registration of medicines entered into IMIS.	July, 2017	-	-	-	-	100	100	TMDA	IMIS Data Base	Quarterly	Progress reports	Quarterly	DMC
25	Percentage of evaluated applications for registration of medical devices entered into IMIS.	July, 2017	-	-	-	-	100	100	TMDA	IMIS Data Base	Quarterly	Progress reports	Quarterly	DMC

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
26	Percentage of evaluated applications for registration of diagnostics entered into IMIS.	July, 2017	-	-	-	-	100	100	TMDA	IMIS Data Base	Quarterly	Progress reports	Quarterly	DMC
27	Percentage of evaluated applications for authorization of clinical trials entered into Clinical Trial Registry.	July, 2017	-	-	-	-	100	100	TMDA	Clinical Trial Registry	Quarterly	Progress reports	Quarterly	DMC
28	Percentage of authorized clinical trials entered into the clinical trial registry	July, 2017	-	-	-	-	90	100	TMDA	Review of Clinical Trial Registry	Quarterly	Progress Reports	Quarterly	DMC
29	Percentage of approved clinical trials inspected.	July, 2017	-	167	75	80	100	100	TMDA	Inspection database	Annually	Progress reports	Annually	DMC
30	Percentage of registered outlets for medicines inspected.	July, 2017	50	182	179	65	100	100	TMDA	Inspection database	Quarterly	Progress reports	Annually	DMC/ZM
31	Percentage of registered outlets for medical devices and diagnostics inspected.	July, 2017	50	117	158	80	100	100	TMDA	Inspection database	Quarterly	Progress reports	Quarterly	DMC/ZM
32	Percentage of registered health laboratories inspected.	July, 2017	-	-	-	-	85	90	TMDA	Inspection database	Quarterly	Progress reports	Quarterly	DMC/ZM
33	Percentage of domestic medicines manufacturing facilities inspected for GMP.	July, 2017	63	100	100	100	100	100	TMDA	Inspection database	Quarterly	Progress reports	Quarterly	DMC

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
34	Percentage of domestic antiseptics and disinfectants manufacturing facilities inspected for GMP.	July, 2017	63	100	100	100	100	100	TMDA	Inspection database	Quarterly	Progress reports	Quarterly	DMC/ZM
35	Percentage of domestic medical devices manufacturing facilities audited for quality system	July, 2017	100	100	100	100	100	100	TMDA	Inspection database	Annually	Progress reports	Annually	DMC
36	Percentage of available applications of overseas medicines manufacturing facilities inspected for GMP	July, 2017	70	119	133	75	100	100	TMDA	Inspection database	Quarterly	Progress reports	Quarterly	DMC
37	Percentage of available applications of overseas medical devices and diagnostics manufacturing facilities audited for quality system.	July, 2017	70	119	100	85	100	100	TMDA	Inspection database	Quarterly	Progress reports	Quarterly	DMC
38	Percentage of available applications of overseas diagnostics manufacturing facilities inspected for GMP.	July, 2017	50	50	55	60	100	100	TMDA	Inspection database	Quarterly	Progress reports	Quarterly	DMC
39	Percentage of received medicines import applications processed.	July, 2017	-	-	-	-	100	100	TMDA	Import database	Quarterly	Progress reports	Quarterly	DMC/ZM
40	Percentage of received medicines export applications processed.	July, 2017	-	-	-	-	100	100	TMDA	Export database	Quarterly	Progress reports	Quarterly	DMC/ZM
41	Percentage of received medical devices import applications processed.	July, 2017	-	-	-	-	100	100	TMDA	Import database	Quarterly	Progress reports	Quarterly	DMC/ZM

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
42	Percentage of received medical devices export applications processed.	July, 2017	-	-	-	-	100	100	TMDA	Export database	Quarterly	Progress reports	Quarterly	DMC/ZM
43	Percentage of received diagnostics import applications processed.	July, 2017	-	-	-	-	100	100	TMDA	Import database	Quarterly	Progress reports	Quarterly	DMC/ZM
44	Percentage of received diagnostics export applications processed.	July, 2017	-	-	-	-	100	100	TMDA	Export database	Quarterly	Progress reports	Quarterly	DMC/ZM
45	Percentage of approved consignments inspected at the PoE.	July, 2017	99	44	66	100	100	100	TMDA	Import/Export database	Quarterly	Progress reports	Quarterly	DMC/ZM
46	Number of un authorised adverts monitored.	July, 2017	-	-	-	-	5	5	TMDA	Mass Media	Quarterly	Progress reports	Quarterly	DMC/ZM
	OBJECTIVE E: Laboratory services improved													
1	Percentage of available samples of medicines analysed.	July, 2017	96	92	103	98	100	100	TMDA	LIMS	Quarterly	Progress reports	Quarterly	DLS
2	Percentage of available samples of medical devices tested.	July, 2017	-	103	103	98	100	100	TMDA	LIMS	Quarterly	Progress reports	Quarterly	DLS
3	Percentage of available samples of diagnostics tested.	July, 2017	-	-	-	-	98	99	TMDA	LIMS	Quarterly	Progress reports	Quarterly	DLS
4	Percentage of available samples of biocidals (antiseptics and disinfectants) tested.	July, 2017	-	-	-	-	100	100	TMDA	LIMS	Quarterly	Progress reports	Quarterly	DLS
5	Percentage of PMS samples of medicines analysed.	July, 2017	96	94	103	98	100	100	TMDA	LIMS	Quarterly	Progress reports	Quarterly	DLS

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
6	Percentage of PMS samples of Medical Devices tested.	July, 2017	-	66	103	98	100	100	TMDA	LIMS	Quarterly	Progress reports	Quarterly	DLS
7	Percentage of received non regulatory samples from external customers tested.	July, 2017	-	-	-	-	100	100	TMDA	Review of Analysis report	Quarterly	Progress reports	Quarterly	DLS
8	Number of new analytical methods accredited for TMDA Dar es Salaam Laboratory.	July, 2017	4	6	9	8	9	10	TMDA	Review of Accreditation reports	Annually	Progress reports	Annually	DLS
9	Establishment of IVD Laboratory in Mwanza established and equipped.	July, 2017	-	-	-	-	√	√	TMDA	Progress Reports	Annually	Progress reports	Annually	DLS
10	Number of new analytical methods accredited for Lake zone Laboratory.	July, 2017	-	-	-	-	2	3	TMDA	Review of Accreditation reports	Annually	Progress reports	Annually	DLS
11	Number of analytical method accredited as per ISO standard for condom and IVD testing for Dar es Salaam Laboratory.	July, 2017	-	-	-	-	2	3	TMDA	Review of Accreditation reports	Annually	Progress reports	Annually	DLS
12	Number of successful Proficiency Testing (PT) Schemes outcomes	July, 2017	-	-	-	-	80	85	TMDA	PT Scheme reports	Annually	Progress reports	Annually	DLS
13	Percentage of planned internal audit conducted.	July, 2017	-	-	-	-	100	100	TMDA	Review of Internal Audit reports	Quarterly	Progress reports	Quarterly	DLS

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
14	Percentage of Quality Assurance (QA) centers performing medicine screening schemes.	July, 2017	-	-	-	-	95	100	TMDA	QA Centers reports	Quarterly	Progress reports	Quarterly	DLS
15	Number of samples screened at QA centers	July, 2017	-	-	-	-	850	900	TMDA	QA Centers reports	Quarterly	Progress reports	Quarterly	DLS
16	Percentage of planned processes and procedures reviewed	July, 2017	-	-	-	-	100	100	TMDA	Review of Internal Audit reports	Annually	Progress reports	Annually	DLS
17	Percentage of laboratory equipment calibrated/maintained	July, 2017	-	-	-	-	100	100	TMDA	Review of equipment maintenance records	Annually	Progress reports	Annually	DLS
18	Percentage of planned researches conducted.	July, 2017	-	50	55	60	75	80	TMDA	Review of Research reports	Annually	Progress reports	Annually	DLS
	OBJECTIVE F: Public education strengthened and customer services improved													
1	Percentage of planned IEC materials types developed, printed and disseminated.	July, 2017	-	-	-	-	90	90	TMDA	Progress Report	Annually	Progress Reports	Annually	MCPE
2	Percentage of IEC materials on whistle blowing developed, printed and disseminated	July, 2017	-	-	-	-	90	90	TMDA	Review of Progress Report	Annually	Progress Reports/IEC Materials	Annually	MCPE
3	Service Delivery Survey conducted.	July, 2017	√	-	√	-	√	-	TMDA	Survey	Biennially	Survey Report	Biennially	MCPE
4	Percentage of customers participating in exit interview.	July, 2017	-	-	-	-	75	80	TMDA	Interview (customer exit)	Quarterly	Progress Reports	Quarterly	MCPE
5	Number of information updates uploaded in TMDA website.	July, 2017	-	-	-	-	400	400	TMDA	Review of TMDA Website	Quarterly	Progress Reports	Quarterly	MCPE

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
6	Number of information updates uploaded in TMDA social media platform.	July, 2017	-	-	-	-	200	200	TMDA	Review of TMDA Social media platform	Quarterly	Progress Reports	Quarterly	MCPE
7	Number of followers on TMDA social media	July, 2017	-	-	-	-	5000	6000	TMDA	Review of TMDA social media accounts	Quarterly	Progress Reports	Quarterly	MCPE
8	Percentage of services offered to external customers within client service charter standards (CSC)	July, 2017	-	110	94	60	100	100	TMDA	Review of Monitoring records	Quarterly	Progress reports	Quarterly	MCPE
9	Percentage of services offered to internal customers within internal client service standards	July, 2017	-	-	-	-	80	90	TMDA	Review of Monitoring records	Quarterly	Progress reports	Quarterly	MCPE
10	Percentage of received customer complaints attended	July, 2017	-	100	100	100	100	100	TMDA	Customer complaints register	Quarterly	Progress reports	Quarterly	MCPE
11	Percentage of received whistle blower complaints and concerns attended	July, 2017	-	-	-	-	100	100	TMDA	Whistle blower complaints register	Quarterly	Progress reports	Quarterly	MCPE
12	Percentage of staff sensitized on customer care	July, 2017	90	35	80	95	100	100	TMDA	Training records	Annually	Progress Reports	Annually	MCPE
13	Percentage of planned TV and radio programmes developed and aired	July, 2017	-	-	-	-	95	95	TMDA	Review of list of TV programmes aired	Annually	Progress Reports	Annually	MCPE
14	Percentage of planned exhibitions participated	July, 2017	-	-	-	-	95	95	TMDA	Review of Exhibition reports	Annually	Progress Reports	Annually	MCPE

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
15	Percentage of planned outreach campaigns conducted	July, 2017	-	-	-	-	95	95	TMDA	Review of progress reports	Annually	Progress Reports	Annually	MCPE
16	Number of press release developed and issued	July, 2017	-	-	-	-	5	8	TMDA	Review of press release issued	Annually	Progress Reports	Annually	MCPE
17	Number of press conference conducted	July, 2017	-	-	-	-	5	8	TMDA	Review of press conference conducted	Annually	Progress Reports	Annually	MCPE
18	Number of stakeholders sensitized on whistle blowing policy	July, 2017	-	-	-	-	300	400	TMDA	Review of stakeholders sensitization reports	Annually	Progress Reports	Annually	MCPE
19	Percentage of whistle blowers provided with feedback	July, 2017	-	-	-	-	90	95	TMDA	Review of whistle blower complaints register	Annually	Progress Reports	Annually	MCPE
	OBJECTIVE G: Institutional capacity to deliver regulatory services strengthened													
1	Percentage implementation of planned activities as per work plans.	July, 2017	88	109	90	94	100	100	TMDA	Review of implementation reports	Quarterly	Progress Reports	Quarterly	DBS
2	Percentage of planned financial sources collected.	July, 2017	100	111	98	100	100	100	TMDA	Review of financial reports	Quarterly	Progress Reports	Quarterly	DBS/CA
3	Percentage of planned Quality audits conducted.	July, 2017	-	-	-	-	100	100	TMDA	Quality audit reports	Quarterly	Progress Reports	Quarterly	MQR
4	Percentage of planned internal financial audits conducted.	July, 2017	-	-	-	-	100	100	TMDA	Internal Financial audit reports	Quarterly	Progress Reports	Quarterly	CIA
5	Percentage of planned processes and procedures revised.	July, 2017	-	-	-	-	100	100	TMDA	Review of process and procedures evaluation reports	Annually	Progress Reports	Annually	MQR

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term Values			Revised Values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
6	Completion level of construction of TMDA Office in Dodoma.	July, 2017	-	-	25	50	100	-	TMDA	Review of construction reports	Quarterly	Progress Reports	Quarterly	DBS
7	Percentage of services computerized	July, 2017	33	60	149	65	100	100	TMDA	Review of list services automated	Quarterly	Progress Reports	Quarterly	DBS
8	Percentage of approved guidelines and manuals printed	July, 2017	-	-	-	-	100	100	TMDA	Review of list of approved manuals and guidelines	Annually	Printed guidelines and manuals	Annually	DBS/DMC/ DLS/Heads of Units
9	Implementation level of the procurement plan	July, 2017	95	100	87	98	100	100	TMDA	Review of Procurement Reports	Quarterly	Progress Reports	Quarterly	MPM
10	Percentage of risks identified as high and very high	July, 2017	-	182	216	30	100	100	TMDA	Review of Risk registers	Biannually	Progress Reports	Biannually	MQR
11	Percentage of staff sensitized on risk management	July, 2017	80	111	46	90	80	90	TMDA	Review of risk training Reports	Annually	Progress Reports	Annually	MQR
12	New TMMD Act in place	July, 2017	-	-	-	-	√	√	TMDA	Review of implementation reports	Quarterly	Progress Reports	Quarterly	MLS
13	Number of project proposals developed	July 2017	-	-	-	-	4	4	TMDA	Review of Proposal register	Annually	Progress Reports	Annually	DLS
14	Percentage implementation of HR Plan	July 2017	68	75	80	80	85	85	TMDA	Review of HR MIS	Annually	Progress Reports	Annually	DBS
15	Percentage implementation of training programme	July 2017	-	-	-	-	90	95	TMDA	Review of Training Records	Annually	Progress Reports	Annually	DBS
16	Number of LGA consultative meeting conducted by Zones	July 2017	28	28	28	28	28	28	TMDA	Review of consultative meetings Records	Quarterly	Progress Reports	Quarterly	DBS

Table 6: Monitoring Plan II (Outcome based indicators)

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term values			Revised values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
	OBJECTIVE A: HIV/AIDS infections and Non Communicable Diseases (NCDs) reduced and Services improved													
1	Percentage of sensitized staff attending voluntary health check-ups for NCDs	July, 2017	-	111	59	90	95	98	TMDA	Review of training records	Annually	Progress Reports	Annually	DBS
2	Percentage of staff attending voluntary health check-ups for HIV/AIDS among the sensitized staff	July, 2017	85	111	111	90	100	100	TMDA	Review of training records	Annually	Progress Reports	Annually	DBS
3	Percentage of staff attending wellness programme.	July 2017	-	-	-	-	65	75	TMDA	Review of attendance records	Quarterly	Progress Reports	Quarterly	DBS
	OBJECTIVE B: National Anti-Corruption Strategy effectively implemented and sustained													
1	Percentage conformity to FIFO in product evaluation, issuance of permits and Lab test results	July, 2017	-	90	90	90	90	90	TMDA	Review of IMIS and LIMS	Quarterly	Progress Reports	Quarterly	DBS
2	Number of areas of TMDA services prone to corruption mitigated.	July 2017	-	-	-	-	2	0	TMDA	Review of Risk Profile records	Annually	Progress Reports	Annually	MQR/MLS
3	Percentage of complaints related to corruption investigated and concluded	July, 2017	-	100	100	100	100	100	TMDA	Review of Confidential files.	Annually	Progress Reports	Annually	DBS
	OBJECTIVE C: Gender and environmental issues improved													
1	Proportion of women among TMDA staff	July, 2017	35	33	31	39	35	37	TMDA	Review of recruitment records	Annually	Progress Reports	Annually	DBS

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term values			Revised values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
2	Proportion of disabled among TMDA staff	July, 2017	-	-	-	-	5	5	TMDA	Review of recruitment records	Annually	Progress Reports	Annually	DBS
3	Proportion of women at managerial positions	July, 2017	22	-	28	-	30	-	TMDA	Review of recruitment and appointments	Biennially	Progress Reports	Biennially	DBS
4	OSHA certification acquired and sustained at all TMDA offices	July, 2017	-	-	-	-	√	√	TMDA	Review of OSHA inspection report	Annually	Progress Reports	Annually	DBS
	OBJECTIVE D: Quality, safety and effectiveness of medicines, medical devices and diagnostics assured													
1	Percentage of applications for registration of medicines, medical devices and diagnostics approved/rejected within specified time (as per CSC);	July, 2017	-	50	55	60	65	70	TMDA	Review of assessment Report	Quarterly	Progress Reports	Quarterly	DMC
2	Percentage of selected PMS human medicines complying with quality requirements	July, 2017	95	99	103	98	99	99	TMDA	Review of PMS Reports	Biannually	Progress Reports	Biannually	DMC
3	Percentage of selected PMS veterinary medicines complying with quality requirements	July, 2017	85	78	84	88	95	98	TMDA	Review of PMS Reports	Biannually	Progress Reports	Biannually	DMC
4	Percentage of selected PMS medical devices complying with quality requirements	July, 2017	90	86	76	98	98	99	TMDA	Review of PMS Reports	Biannually	Progress Reports	Biannually	DMC
5	Percentage of selected PMS diagnostics samples complying with quality requirements	July, 2017	-	111	105	95	98	99	TMDA	Review of PMS Reports	Biannually	Progress Reports	Biannually	DMC

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term values			Revised values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
6	Percentage of domestic medicines manufacturing facilities complying with GMP requirements	July, 2017	25	71	100	50	40	60	TMDA	Review of GMP Inspection Reports	Annually	Progress Reports	Annually	DMC
7	Percentage of clinical trials compliant with GCLP requirements	July, 2017	-	111	106	94	98	98	TMDA	Review of Inspection database	Quarterly	Progress Reports	Annually	DMC
8	Percentage of compliance of registered medicines selling outlets	July, 2017	71	117	179	80	85	90	TMDA	Review of Inspection database	Quarterly	Progress Reports	Quarterly	DMC
9	Percentage of inspected consignment approved at POEs	July, 2017	-	-	-	-	85	90	TMDA	Review of Inspection database	Quarterly	Progress Reports	Quarterly	DMC
10	Percentage of compliance of registered medical devices and diagnostics selling outlets	July, 2017	85	77	158	91	85	90	TMDA	Review of Inspection database	Quarterly	Progress Reports	Quarterly	DMC
11	Percentage of non-compliant products/batches of regulated products recalled	July, 2017	100	100	100	100	100	100	TMDA	Review of PMS and recall reports	Quarterly	Progress Reports	Quarterly	DMC
12	Percentage of compliance of registered health laboratories inspected	July, 2017	-	-	-	-	95	95	TMDA	Review of Inspection database	Quarterly	Progress Reports	Quarterly	DMC
13	Percentage of processed applications for importation approved	July, 2017	-	-	-	-	95	100	TMDA	Review of Import database	Quarterly	Progress Reports	Quarterly	DMC
	OBJECTIVE E: Laboratory services improved													
1	Percentage of laboratory results for medicines released within turnaround time (as per CSC)	July, 2017	64	62	91	70	75	90	TMDA	Review of LIMS	Quarterly	Progress Reports	Quarterly	DLS

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term values			Revised values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
2	Percentage of laboratory results for medical devices released within turnaround time (as per CSC)	July, 2017	-	-	-	-	90	95	TMDA	Review of LIMS	Quarterly	Progress Reports	Quarterly	DLS
3	Level of external customers satisfaction in relation to laboratory services	July, 2017	63	47	68	70	80	85	TMDA	Review of Exit interview forms	Quarterly	Progress Reports	Quarterly	DLS
4	Level of internal customers satisfaction in relation to laboratory services	July, 2017	-	-	-	-	73	75	TMDA	Review of Exit interview forms	Quarterly	Progress Reports	Quarterly	DLS
5	Percentage of identified research problems concluded and results disseminated	July, 2017	-	-	50	55	60	65	TMDA	Review of Research proposals	Annually	Research reports	Annually	DLS
6	ISO/IEC 17025 and WHO pre-qualification for TMDA laboratory in Dar es Salaam sustained	July, 2017	Certification	Certification	Certification	Certification	Certification	Certification	TMDA	Review of Accreditation reports	Annually	Progress Reports	Annually	DLS
7	ISO/IEC 19025 and WHO pre-qualification for Mwanza laboratory attained and sustained	July, 2017	-	-	-	Certification	Certification	Certification	TMDA	Review of Accreditation reports	Annually	Progress Reports	Annually	DLS

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term values			Revised values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
8	Percentage contribution in revenue generated from Laboratory services	July 2017	1.6	3	3.5	4	4.5	5	TMDA	Review of Accounts records	Quarterly	Progress Reports	Quarterly	DLS/CA
9	Percentage of staff passed PT Scheme	July 2017	-	-	-	-	90	95	TMDA	Review of PT Scheme records	Quarterly	Progress Reports	Quarterly	DLS
	OBJECTIVE F: Public education strengthened and customer services improved													
1	Percentage of public awareness on TMDA functions	July, 2017	-	50		60		70	TMDA	Survey	Biennially	Progress Reports	Biennially	MCPE
2	Percentage of public awareness on whistle blowing policy	July, 2017	-	-	-	-	-	70	TMDA	Review of Whistle blower Survey	Biennially	Progress Reports	Biennially	MCPE/MLS
3	Percentage of external customers satisfied with TMDA services	July, 2017	67.6	-	75	-	80	-	TMDA	Survey	Biennially	Progress Reports	Biennially	MCPE
4	Percentage of internal customer satisfaction	July, 2017	74	-	80	-	85	-	TMDA	Survey	Biennially	Progress Reports	Biennially	MCPE
5	Percentage of customer complaints resolved	July, 2017	-	83	92	99	100	100	TMDA	Review of Customer complaints register	Quarterly	Progress Reports	Quarterly	MCPE
6	Percentage of whistle blower complaints and concerns investigated and concluded	July, 2017	-	-	-	-	99	99	TMDA	Review of Whistle blower register	Quarterly	Progress Reports	Quarterly	MCPE/MLS
7	Percentage of serious offenders blacklisted	July, 2017	-	-	-	-	20	15	TMDA	Review of Whistle blower records	Biennially	Progress Reports	Biennially	MCPE/MLS

SN	Indicator and indicator description	Baseline		Indicator Target Values					Data collection and methods of analysis				Frequency of reporting	Responsible
				Mid Term values			Revised values							
		Date	Value	Yr1	Yr2	Yr3	Yr4	Yr5	Data source	Data collection instrument and methods	Frequency of data collection	Means of verification		
OBJECTIVE G: Institutional capacity to deliver regulatory services strengthened														
1	Percentage budgetary contribution from internal sources	July, 2017	71	75	80	85	87	88	TMDA	Financial report review	Annually	Progress Reports	Annually	DBS
2	Clean Financial Audit Report attained	July, 2017	√	√	√	√	√	√	TMDA	Review of CAG Audit report	Annually	Progress Reports	Annually	DBS/CA
3	Percentage of staff retention	July, 2017	98	102	102	99	100	100	TMDA	Review of HR report review	Annually	Progress Reports	Annually	DBS
4	ISO Certification sustained	July 2017	√	√	√	√	√	√	TMDA	Review of External quality audit	Annually	Progress Reports	Annually	MQR
5	Percentage mitigation of identified risks	July 2017	50	73	167	75	100	100	TMDA	Review of Risk assessment report review	Annually	Progress Reports	Annually	MQR
6	Percentage of proposals funded	July 2017	-	-	-	-	90	90	TMDA	Review of Proposal register	Annually	Progress Reports	Annually	DLS

4.5.2 Planned Reviews

Two (2) formal performance reviews will be annually conducted during the execution of the revised Strategic Plan. The reviews intend to track progress on achievement of targets and use the findings to adjust implementation strategies whenever necessary in the remaining two years. The respective Directors and Managers will take lead in the review process.

The final review will be conducted in the fifth year (2021/22) in order to determine whether or not the planned outputs and outcomes over the five years period have been achieved against the indicators, and if not, what could have been the reasons for the under achievement. The review will also assess the extent to which achieved targets have contributed towards attainment of five year expected outcomes as well as challenges and lessons learnt over the five years period.

The Director General as the Chief Accounting Officer will be generally responsible for the execution and completion of the Strategic Plan. Details on accomplished milestones are presented in **Table 7** while the specific planned reviews for remaining two years period (2020/21 - 2021/22) that show different milestones and their respective timeframe are summarized in **Table 8**.

Accomplished Milestones (2017/18 and 2018/19)

Data from self assessment report conducted after the implementation of the Strategic Plan for the first two years reveal that 17 out of 29 milestones were completely implemented. Details on the milestones are presented in **Table 7**.

Table 7: Accomplished Milestones

Year	Objective Code	Milestones	Time frame
2017/18	A	Areas prone to corruption regarding TFDA services established	June, 2018
	E	Window/desk to support food SMEs established	June, 2018
		Food evaluators trained on genetically modified food;	June, 2018
		Guidelines for identification and registration of Food SMEs developed	June, 2018
	F	Equipment for Lake zone laboratory procured and installed	June, 2018
		Guidelines for research and project proposal writing developed and implemented	June, 2018
	G	Comprehensive public education and customer care program developed	June, 2018
	H	ISO certification sustained	June, 2018
		Clean financial audit report	June, 2018

Year	Objective Code	Milestones	Time frame
2018/19	F	Microbiology Laboratory Pre qualified	June, 2019
		The laboratory for medical devices testing equipped	June, 2019
	H	Scheme of Service and salary structure revised and implemented	June, 2019
		First Institutional self-assessment completed	June, 2019
		Services automated and provided online	June, 2019
		Licensing, Epicor, HR-MIS systems integrated	June, 2019
		ISO certification sustained	June, 2019
		Clean financial audit report	June, 2019

Table 8: Planned Review Matrix

This plan comprises of unaccomplished milestones for the past two years (2017/18 - 2018/19), that are presented as new milestones which will be implemented for the remaining two years (2020/21 - 2021/22).

	Objective	Milestones	Timeframe	Responsible Person(s)
2020/21	**A**	Awareness programme developed and implemented	June, 2021	DBS
		Staff wellness programme developed and implemented	June, 2021	DBS
	B	Areas prone to corruption regarding TMDA services identified and mitigated	June, 2021	MLS
	C	Construction of incinerator for safe disposal of unfit products completed	June, 2021	DMC/DBS
	E	Facilities for storage of laboratory chemical wastes in place	June, 2021	DLS
		TMDA Laboratory Pre qualification sustained	June, 2021	DLS
		ISO/IEC 17025 Accreditation for TMDA Laboratories sustained	June, 2021	DLS
		The laboratory for testing medical devices and diagnostics equipped	June, 2021	DLS
		The laboratory for testing antiseptics and disinfectants equipped	June, 2021	DLS
	F	SDS conducted	June, 2021	MCPE
	G	New TMMD Act developed	June, 2021	MLS
		Internal Financial and Staff Regulations revised and approved	June, 2021	DBS
		ISO 9001:2015 certification sustained	June, 2021	MQR
		Construction of TMDA Offices in Dodoma completed	June, 2021	DBS
		Organizational structure revised and approved	June, 2021	DBS
		Attaining Clean Financial Audit Report	June, 2021	CA

	Objective	Milestones	Timeframe	Responsible Person(s)
2021/22	D	Attaining WHO Maturity Level 4	June, 2022	DMC
	E	TMDA Laboratory Pre qualification sustained	June, 2022	DLS
		Microbiology Laboratory accredited	June, 2022	
		ISO/IEC 17025 Accreditation for TMDA Laboratories sustained	June, 2022	
	G	In depth job evaluation for equitable distribution of responsibilities completed	Dec, 2022	DBS
		All approved PoEs manned by TMDA inspectors	June, 2022	
		Second Institutional self-assessment completed	Dec, 2022	
		End term evaluation on implementation of the Strategic Plan completed	June 2022	
		ISO 9001:2015 certification sustained	June, 2022	MQR
		Clean financial audit report	June 2022	CA

4.5.3 Evaluation Plan

This consists of evaluation studies to be carried out during the immediate start of the SP implementation, description of each study, evaluation questions, methodology, time frame and the responsible person. A total of eight (8) evaluation studies will be conducted over a period of five years. The studies intend to obtain baseline information and evidence as to whether the interventions and outputs have led to achievement of the envisaged outcomes (described in **Table 8**). Evaluation studies conducted for the first two years is presented in **Table 9** and Evaluation plan matrix for remaining two years is detailed in T**able 10** below;

Table 9: Evaluation Studies Conducted

S/N	Evaluation Study	Description	Evaluation Study Questions	Methodology	Timeframe	Responsible Person
1	Baseline Studies	The studies aim at collecting baseline information which will provide inputs during the evaluation process	What are the baseline values for indicators listed in the Monitoring Plan I & II?	Review of annual reports, Survey, questionnaires and interviews	2016/17 -2017/18	DBS, DMC & DLS
2	First Institutional self-assessment	The assessment intends to determine institutional performance	Has TMDA achieved its objectives after two year of SP implementation?	Desk review, interviews and questionnaires	December, 2019	DBS
3	Midterm evaluation on implementation of the strategic plan conducted	The evaluation aims to measure performance of SP	Have the short term objectives been achieved? What are limitations?	Interviews and questionnaires	2019/20	DBS

Table 10: Evaluation Plan Matrix

S/N	Evaluation Study	Description	Evaluation Study Questions	Methodology	Timeframe	Responsible Person
1	SDS conducted	SDS measures level of public awareness on TMDA functions and level of external customer satisfaction in relation to quality of services delivered by TMDA to its stakeholders	1. To what extent is the general Public aware on TMDA functions? 2. To what extent are TMDA customers satisfied? 3. Are services standards being met as per CSC?	Interviews and questionnaires	December, 2021	DBS
2	Second Institutional self-assessment completed	The assessment intends to determine institutional performance	Has TMDA achieved its objectives after two year of SP implementation?	Desk review, interviews and questionnaires	December, 2021	DBS
3	End term evaluation on implementation of the strategic plan completed	The evaluation aims to measure performance of SP	1. Have the long term objectives been achieved? 2. Can TMDA sustain its operations from its financial internal sources? 3. What was the limitation? 4. What lessons can be learnt from the SP implementation?	Interviews, Questionnaires and review of performance and financial reports	December, 2021	DBS
4	In depth job evaluation completed	The evaluation intends to ensure equitable distribution of responsibilities among directorates, sections/units and staff	Is there equitable distribution of responsibilities among directorates, sections/units and staff?	Consultancy	2021/22	DBS

4.6 Reporting Plan

This subsection details the Reporting Plan, which contains the internal and external reporting plans. The reporting plan is in accordance with existing guidelines, statutory requirements, Medium Term Strategic Planning and Budgeting Manual or as may be required from time to time by any relevant authorities.

4.6.1 Internal Reporting Plan

This internal reporting plan will involve preparation of different types of reports as prescribed in the TMDA guidelines for preparation of progress reports. These reports will be submitted to various levels including MoHCDGEC, MoFP, TR, MAB, DG and Directors. The reports will be prepared on weekly, monthly, quarterly, annually or on demand basis as may be required from time to time. The Reporting Plan is detailed in **Table 11** below;

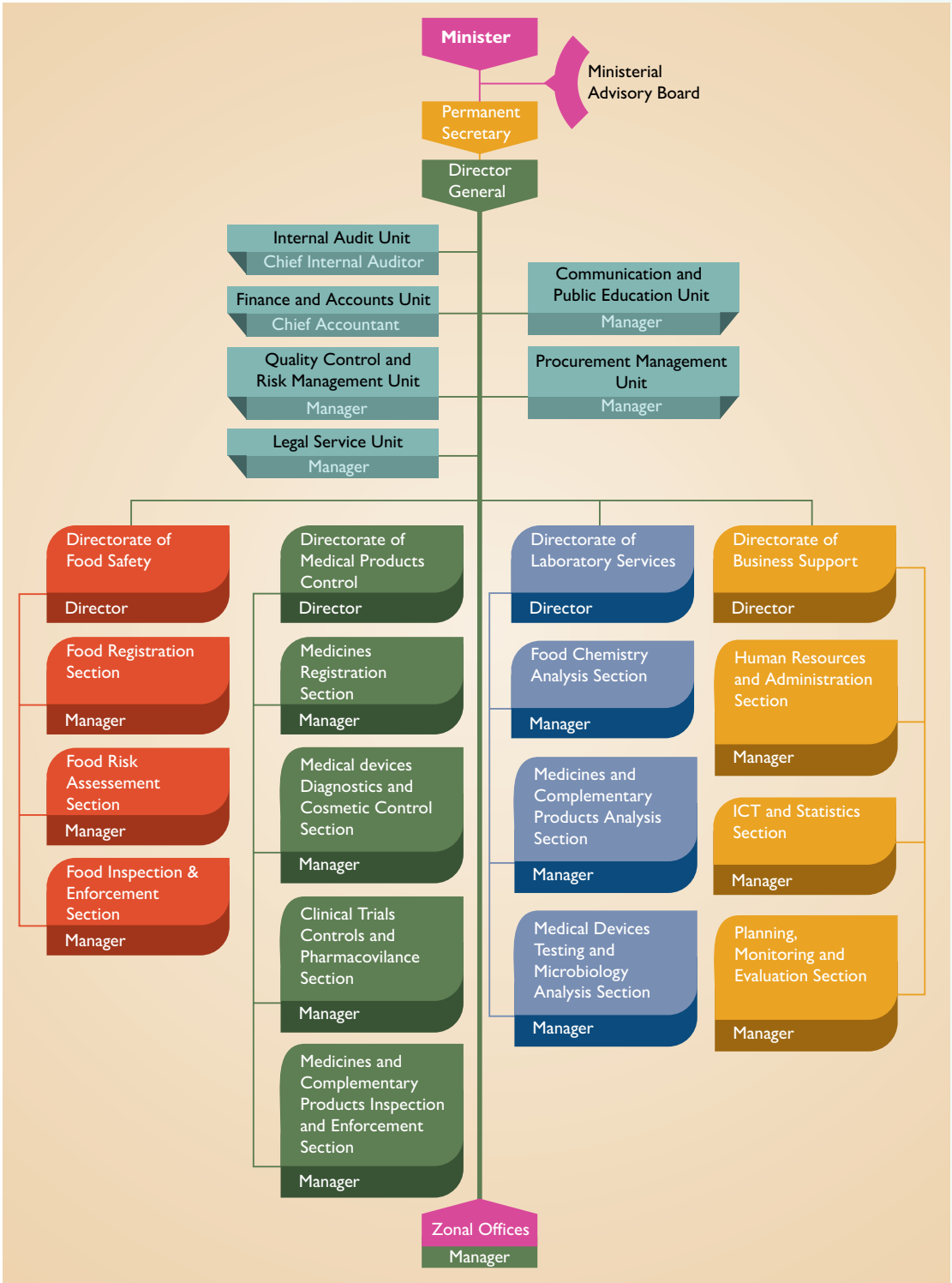
Table 11: Internal Reporting Plan

S/N	Type of Report	Recipient	Frequency	Responsible Person
1.	Weekly report	Director	Weekly	Managers
2.	Monthly report	Management	Monthly	Directors
3.	Quarterly, Mid-year and Annual reports	Directors and Managers meeting	Quarterly & Annually	DBS
4.	Quarterly Report	MAB / MoHCDGEC / TR / MoFP / PO-PSMGG	Quarterly	DG
5.	Mid-year report	MAB / MoHCDGEC / TR / MoFP / PO-PSMGG	Annually	DG
6.	Annual Report	MAB / MoHCDGEC / T R /MoFP / PO-PSMGG	Annually	DG
7.	Five Years Outcome Reports	MAB / MoHCDGEC / PO-PSMGG	Once	DG
8.	Audit Reports	TR/MoFP	Annually	DG

4.6.2 External Reporting Plan

The external reporting plan is for those reports intended for public consumptions which include Annual Financial Statement Report and Performance Report. The reports will be prepared in accordance with the guidelines, standards (IPSAS) and statutory requirements as directed by Government Performance reporting requirements.

Annex I: The Approved Functions and Organizational Structure of TFDA



Annex II: List of Lead Activities

OBJECTIVE	TARGETS	ACTIVITIES	RESPONSIBLE PERSON (S)
A. Services improved and HIV/AIDS and Non Communicable Diseases (NCDs) reduced	(a) Awareness, care and support on HIV/AIDS and NCDs diseases to TMDA staff provided by June 2022	(i) To provide care and support services to staff living with HIV, AIDS, and NCDs (ii) To facilitate participation in sports and games (iii) To develop TMDA awareness programme (iv) To conduct sensitization seminar to TMDA staff on HIV, AIDS and NCDs (v) To conduct counseling to staff on prevention, testing and management of HIV & AIDS and NCDs	DBS
B. National Anti-Corruption Strategy effectively implemented, enhanced and sustained	(a) Anti- corruption strategy and good governance enforced to TMDA staff by June 2022;	(i) To conduct a survey on areas prone to corruption (ii) To develop and institute measures to mitigate the malpractice (iii) To conduct sensitization to staff on ant corruption strategy.	DBS
	(b) Public Staff code of ethics and conduct instilled to staff by June 2022;	(i) To conduct sensitization to staff on ethics, Public Service codes and corrupt practices. (ii) To facilitate integrity committee meeting	DBS
C. Gender and environmental issues improved	(a) Women empowered at all levels by June, 2022;	(i) To review and implement HR plan (ii) To train women on leadership and management principles (iii) To conduct sensitization seminar to staff on gender issues	DBS
	(b) Mechanism for storage of wastes in place by June, 2022..	(i) To construct wastes handling facilities (ii) To construct incinerator for disposal of unfit product	DBS/DMC
	(c) Infrastructures to support physically challenges persons provided by June,2022.	(i) To construct physically challenged persons infrastructures at new TMDA Offices in Dodoma	DBS

OBJECTIVE	TARGETS	ACTIVITIES	RESPONSIBLE PERSON (S)
D. Quality, effectiveness and safety of medicines, medical devices and diagnostics assured	(a) Premises dealing in medicines, medical devices and diagnostics inspected by June, 2022;	(i) To conduct inspection of medicines, medical devices, diagnostics , antiseptics, disinfectants and other health related products (ii) To conduct training of TMDA inspectors (iii) To conduct domestic and overseas GMP inspection of manufacturing facilities for medicines and medical devices; (iv) To supervise disposal of unfit products	DMC/Zone Managers
	(b) Marketing Surveillance and vigilance of medicines, medical devices and diagnostics conducted by June, 2022;	(i) To conduct PMS for regulated products (ii) To conduct stakeholders meeting on pharmacovigilance and PMS	DMC
	(c) Products (medicines, medical devices and diagnostics) registered by June, 2022;	(i) To evaluate applications for promotional adverts; (ii) To conduct evaluation of applications for clinical trials; (iii) To evaluate applications for registration of medicines, medical devices, diagnostics antiseptics and disinfectants and other related products; (iv) To review and implement different guidelines for registration of medicines, medical devices, diagnostics, antiseptics and disinfectants and other related products (v) To review Regulations for registration of medicines, medical devices, diagnostics, antiseptics and disinfectants and other related products (vi) To participate in local conferences and workshops in respect to medicines, medical devices and diagnostics (vii) To participate in regional and international conferences and workshops in respect to medicines, medical devices and diagnostics regulation	DMC
	(d) Clinical trials approved and inspected by June 2022	(i) To evaluate applications for authorization of clinical trials (ii) To conduct inspection of clinical trials sites	DMC

OBJECTIVE	TARGETS	ACTIVITIES	RESPONSIBLE PERSON (S)
E: Laboratory services improved	(a) Samples of medicines, medical devices and diagnostics tested by June 2022	(i) To perform preventive maintenance of Laboratory equipment (ii) To participate in Proficiency Testing scheme	DLS
	(b) TMDA laboratories equipped and operationalized by June 2022	(i) To procure Laboratory equipment, chemicals and consumables	DLS
	(c) Operational and applied researches on regulatory functions conducted by June, 2022	(i) To conduct operational researches on TMDA functions	DLS
F: Public education and customer services strengthened	(a) Stakeholders collaboration mechanism for dissemination and sharing of information established and implemented by June, 2022	(i) To develop and disseminate IEC materials; (ii) To conduct stakeholders consultative meetings.	MCPE/ZM
	(b) Public awareness on quality and safety of TMDA regulated products raised by June, 2022.	(i) To conduct Service Delivery Survey (ii) To develop and air TV and Radio programmes	MCPE
G: Institutional capacity to deliver regulatory services strengthened	(a) TMDA compliance with Public Finance Act 2001 sustained by June 2022	(i) To facilitate preparation and presentation of IPSAS compliant financial statement (ii) To facilitate external financial audit (iii) To conduct oversight of financial operation and revenue collection	CA/CIA
	(b) Legal services timely provided by June 2022	(i) To investigate and prosecute offenders of TMMDA	DBS
	(c) Administrative services provided by June 2022	(i) To provide for recurrent running costs (ii) To facilitate for internal travels for local meetings (iii) To conduct meeting officials from councils	DBS
	(d) Human resources properly managed by June 2022	(i) To provide recruitment expenses (ii) To review TMDA training programme (iii) To conduct HR Audit	DBS

OBJECTIVE	TARGETS	ACTIVITIES	RESPONSIBLE PERSON (S)
	(e) Planning, budgeting and their implementation coordinated and monitored by June 2022	(i) To prepare and consolidate quarterly, Midyear and annual performance report (ii) To prepare TMDA business plan and budget (iii) To conduct Monitoring and Evaluation on implementation of TMDA activities	DBS
	(f) ICT usage enhanced by June 2022	(i) To provide ICT technical support to zone offices (ii) To procure software license and pay for services level agreement and subscription fee	DBS
	(g) Quality and Risk Management Systems improved by June 2022	(i) To facilitate QMS external Auditing (ii) To conduct Management review meetings (iii) To conduct internal quality audit meetings (iv) To identify, assess and monitor institutional risks	MQR
	(h) TMDA compliance with Public Procurement Act 2011 sustained by June 2022	(i) To facilitate tender board meeting (ii) To conduct annual stock taking (iii) To assess compliance to Public Procurement Act and Regulations at Zone Offices (iv) To develop, review annual procurement plan	MPM
	(i) Zone Offices strengthened by June 2022	(i) To supervise implementation of TMDA functions to zone offices	ZOLGAC
	(j) Professional development implemented by June 2022	(i) To train staff in various long courses (ii) To train staff in various short courses (iii) To build capacity of TMDA professionals on career requirement	

GLOSSARY

Activity:
Action taken or work performed in order to produce a given target. Activities are what institutions do and describe processes which are largely internal to the institution. They describe how a target is to be achieved.

Appraisal:
An overall assessment of the relevance, feasibility, and potential sustainability of a series of interventions prior to a decision to undertake or fund them

Assumptions:
Hypotheses about factors or risks which could affect the progress or success of an intervention

Baseline Indicator Value:
Historical value of an indicator. It includes an associated date called the baseline indicator date.

Capacity Building:
A process leading to either (i) skill upgrading, (both general and specific), (ii) procedural improvements, or (iii) institutional strengthening. Capacity building refers to investment in people, institutions, and practices

Competency:
Ability of a company/institution/individual to achieve certain effects or to behave in specific ways. Competencies are one type of resources.

Effect:
Intended or unintended change due directly or indirectly to an intervention.

Effectiveness:
The extent to which an intervention's objectives were achieved, or are expected to be achieved, taking into account their relative importance.

Efficiency:
A measure of how economically resources/ inputs (funds, expertise, time, etc.) are converted to outputs or results.

Evaluation:
A periodic assessment of the efficiency, effectiveness, impact, sustainability and relevance in the context of stated objectives.

Falsified medicines:
Medicines that deliberately or fraudulently misrepresent their identity, composition or source.

Feedback:
Transmission of findings generated through the evaluation process to parties for whom it is relevant and useful so as to facilitate learning. This may involve the collection and dissemination of findings, conclusions, recommendations and lessons from experience.

Goal:
A statement concerning the successful realisation of an impact.

Governance:
The way in which power and authority influence public life, especially economic and social development

Impact:
An effect on well-being. A significant long-term developmental change induced in the user of a service or product. May be direct or indirect, intended or unintended.

Indicator:

A number having a particular measurement purpose. A quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance of a party or institution. Or, a variable that allows the verification of changes in the development intervention or shows results relative to what was planned. Indicators are usually indirect measures of an underlying phenomena or quality (the way "smoke indicates fire" and are usually stated in SMART format. Indicators are often disaggregated to compare results and frequently have time-specified target and baseline values.

Input:

The financial, human, and material resources used during the completion of an activity. Inputs are frequently measured in terms of financial costs

Milestone:

An activity used to identify significant events in a schedule, such as the completion of a major phase. An activity tagged or singled out for special monitoring in terms of progress or completion. The milestone selected should be indicative of a larger or more important process. Milestones can be considered a form of indicator, whether or not something has been produced within a particular deadline

Monitoring:

A continuing function that uses systematic collection of data on specified indicators to provide management and the main stakeholders of an ongoing intervention with indications of the extent of progress and achievement of objectives and progress in the use of allocated funds.

Objective:

A broad statement of what is to be achieved and the improvements to be made. An objective describes an intended outcome or impact and summarizes why a series of actions have been undertaken.

Outcome:

The likely or achieved short-term and medium-term effects of an intervention's outputs. A direct, but intermediary change or improvement in the welfare of the customer or beneficiary as a result of the use of a service (or output). Examples include improved health after visiting a dispensary, or increased knowledge after completing school.

Output:

The products, goods and services which result from an intervention; may also include changes (usually of an immediate nature) resulting from the intervention which are relevant to the achievement of outcomes.

Performance:

The degree to which an intervention or an implementer operates according to specific criteria/ standards/guidelines or achieves results in accordance with stated objectives or plans.

Process:

How something is done

Process Evaluation:

An evaluation of the internal dynamics of implementing institutions, their policy instruments, their service delivery mechanisms, their management practices, and the linkages among these.

Programme:

A time-bound intervention that differs from a project in that it usually cuts across sectors, themes and/or geographic areas, uses a multi-disciplinary approach, involves more institutions than a project, and may be supported by different funding sources

Relevance:

The extent to which the objectives of an intervention are consistent with beneficiaries' requirements, country needs, global priorities and policies. Retrospectively, the question of relevance often becomes a question as to whether the objectives of an intervention or its design are still appropriate given changed circumstances or observed effects.

Results:

The output, outcome or impact (intended or unintended, positive and/or negative) of an intervention.

Results Chain:

The causal sequence for an intervention that stipulates the necessary sequence to achieve desired objectives, beginning with inputs, moving through activities and outputs, and culminating in outcomes, impacts, and feedback.

Risk analysis:

An analysis or an assessment of factors affecting or are likely to affect the successful achievement of an intervention's objectives. It may also mean a detailed examination of the potential unwanted and negative consequences to human life, health, property, or the environment posed by interventions; a systematic process to provide information regarding such undesirable consequences; the process of quantification of the probabilities and expected impacts for identified risks.

SMART:

Attributes of indicators, but sometimes applied to other planning entities, such as Targets or Objectives. SMART stands for: Specific, Measurable, Achievable, Realistic, and Timely; a means for assessing performance indicators.

Stakeholders:

All of those who have an interest (either direct or indirect) in an institution, its activities and its achievements. These may include clients or customers, partners, employees, shareholders/owners, government or regulators.

Strategic Planning:

Is a process that charts an institution's broad direction forward in order to achieve its objectives. A Strategic planning looks at the big picture from a longer-term perspective, decide what it wishes to achieve, main actions it will need to undertake in the future, clarifies institutional priorities, focuses away from day to day operations and provides an opportunity to address important fundamental questions: Where do we want to be?, where are we now?, how will we get there? and how will we know when we are there?

Substandard Product:

A product which does not conform to prescribed specifications

Sustainability:

The continuation of benefits from an intervention after the intervention has been completed. The probability of continued long-term benefits obtained from the intervention. The resilience to risk of the net benefit flows over time.

Target:

The goods or services produced over a given period of time, by an institution, in order to achieve its objectives.

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