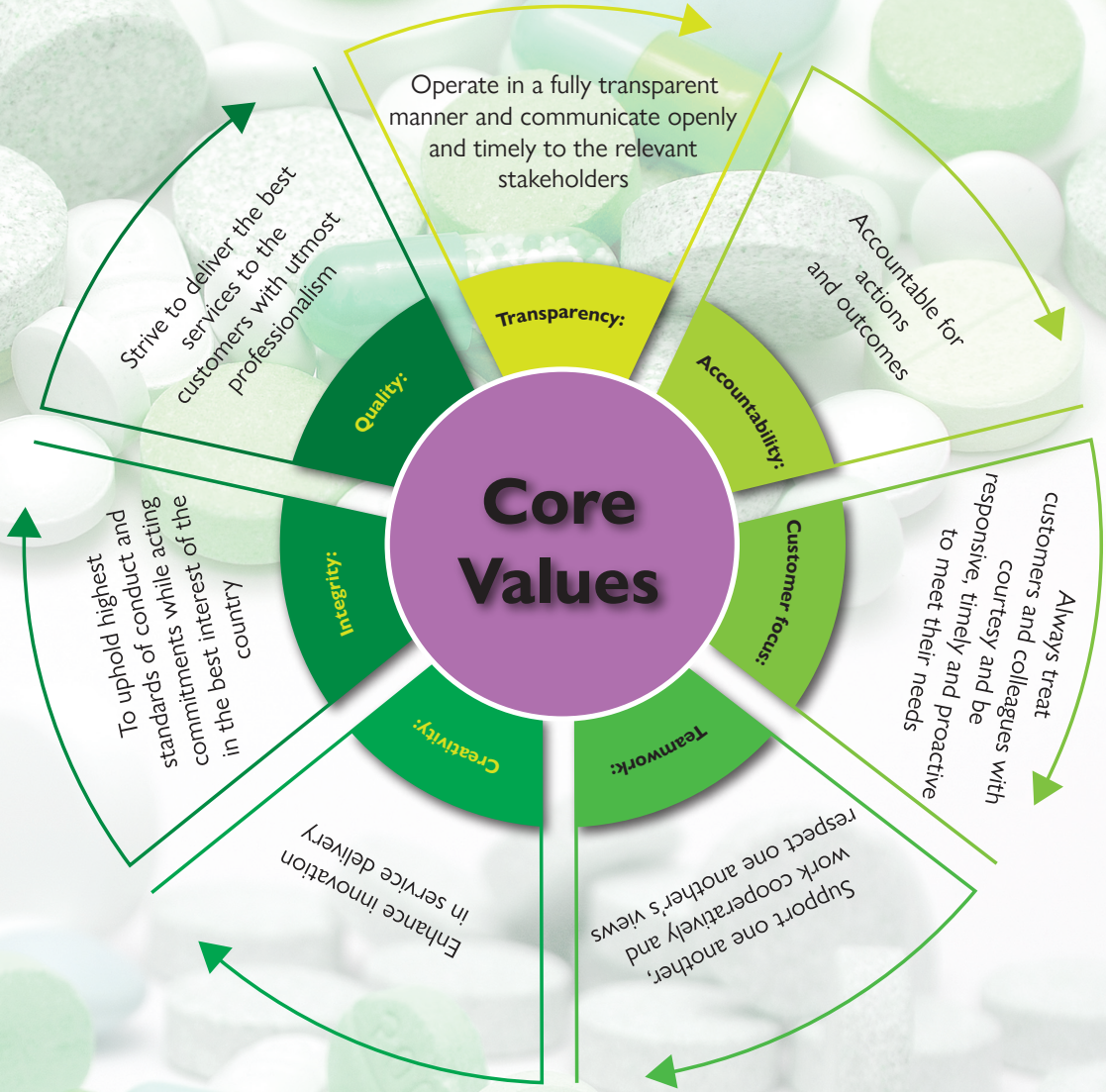
TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA

Tanzania Medicines & Medical Devices Authority

STRATEGIC PLAN

2021/22 – 2025/26


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

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LIST OF ABBREVIATIONS

ADR	Adverse Drug Reactions
AIDS	Acquired Immune Deficiency Syndrome
AMREF	African Medical Research Foundation
BMGF	Bill and Melinda Gates Foundation
CSC	Client Service Charter
CSOs	Civil Society Organizations
DBS	Director of Business Support
DG	Director General
DLS	Director of Laboratory Services
DMC	Director of Medical Products Control
EAC	East African Community
EDCTP	European Developing Countries Clinical Trials Partnership
FIFO	First in First out
GCLP	Good Clinical and Laboratory Practices
GePG	Government Electronic Payment Gateway
GiZ	Gesellschaft fur Internationale Zusammenarbeit
GMP	Good Manufacturing Practices
GN	Government Notice
GPSA	Government Procurement and Supplies Agency
HIV	Human Immunodeficiency Virus
HQ	Headquarters
HR	Human Resource
HRMIS	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
JAICA	Japan International Cooperation Agency
LGAs	Local Government Authorities
LIMS	Laboratory Information Management System
M&E	Monitoring and Evaluation
MAB	Ministerial Advisory Board
MIS	Management Information System

MoH	Ministry of Health
MoHSW	Ministry of Health and Social Welfare
NCDs	Non-Communicable Diseases
NSGPR	National Strategy for Growth and Poverty Reduction
PE	Personnel Emolument
PMS	Post-Marketing Surveillance
PMU	Procurement Management Unit
PoE	Ports of Entry
PO-RALG	President's Office Regional Administration and Local Government
QMS	Quality Management System
RIMS	Regulatory Information Management System
SADC	Southern African Development Community
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
TBS	Tanzania Bureau of Standards
TFDA	Tanzania Food and Drugs Authority
TMDA	Tanzania Medicines and Medical Devices Authority
TMMDA	Tanzania Medicines and Medical Devices Act
TR	Treasurer Registrar
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
WHO	World Health Organization
WLA	WHO Listed Authorities

STATEMENT OF CHAIRPERSON OF THE MINISTERIAL ADVISORY BOARD

During the 21st century, we have witnessed a mounting trend towards the application of new management approaches particularly the use of strategic planning and result-based management. It is from this standpoint that organizations including TMDA have been developing Strategic Plans as important frameworks and governance tools to communicate the organizational goals, actions needed to achieve the goals and other critical elements required to stimulate growth, development and sustainability.

Among other things, this fifth TMDA SP is set to describe the current state of affairs of the Authority, desired future outcomes, priorities and resources required to realize the vision. We at TMDA strongly believe that there is no other concrete strategy to accomplish and fulfill the mandates, functions and activities that meet national and international standards without having a clear and comprehensive conduit in this case strategic planning.

As the Chairman of the Ministerial Advisory Board (MAB), I would like to uphold the desire, enthusiasm and commitment of the TMDA Management in discharging its functions. The right Vision that is projected towards improving and transforming the organization through a more results-oriented management approach is furthermore acknowledged. I have no doubt that the same spirit and vigor will be translated into implementation of this new five year Strategic Plan (2021/22-2025/26).

Throughout the implementation phase, the Board will provide full support to the TMDA Management in realizing the Vision and bjectives set. The strategies, deliverables and milestones set in this Plan are not only relevant but also vital to attaining the Mission of TMDA.

Henceforth, on behalf of the MAB, I would like to assure the general public, stakeholders and customers that TMDA is fully committed to use this Strategic Plan as a means or vehicle that will take us to the next performance level.

Eric F. Shitindi
MAB Chairman

STATEMENT OF THE DIRECTOR GENERAL

TMDA is mandated to regulate the quality, safety and effectiveness of medicines, medical devices and diagnostics. Beginning 30th April 2021, the Authority was designated by the Minister responsible for health to control the usage of tobacco products vide GN No. 360. To effectively discharge these mandates and attain its objectives, it is apparent that TMDA needs a well-articulated and comprehensive strategy to chart out a strategic direction or road map for continuous organizational growth and development.

It is from this background that the formulation, implementation and evaluation of strategic plans are integral parts of the governance, management and good practices at TMDA. Staff, Management and MAB believe strongly that the observed performance, stability, growth, development and sustainability are the result of effective implementation of previous Strategic Plans (SP). With the same spirit, I believe that the implementation of this new SP will be an impetus to steer further stability, development and growth of TMDA for the wider interests of the population.

This five-year TMDA Strategic Plan (2021/22 – 2025/26) highlights a number of strategic objectives, strategies and targets that are pivotal in attaining TMDA's Mission of protecting and promoting public health by ensuring safety, quality and effectiveness of medicines, medical devices diagnostics and other health related products**.** This SP has outlined key performance indicators which will be measured according to the set targets.

In realizing this Mission, the Authority has modified its Vision statement from being *"the leading Regulatory Authority in ensuring safety, quality and effectiveness of medicines, medical devices, diagnostics and other health related products for all"* to a new version which reads *"to achieve regulatory excellence in ensuring quality, safety and effectiveness of medicines, medical devices, diagnostics and other health related products".*

In view of the revised Vision, the Authority has added two more strategic objectives from the previous seven (7). The objectives on assuring quality, safety and effectiveness of medicines, medical devices and diagnostics have been divided into two and one on strengthening tobacco products control added taking into account the new mandate on this area. The rest have been maintained considering the findings of the end term evaluation which recorded 95% achievement of all indicators set after implementation of the fourth SP.

Achievement of the new strategic objectives will depend on the capacity to deliver services effectively and efficiently. In this regard, the Management is committed to providing leadership and resources throughout the implementation of the Plan.

I feel indebted to all staff of TMDA for their contribution and readiness to implement this plan. Many thanks are extended to the MAB for their guidance, support and endorsement of this new Strategic Plan (2020/21-2025/26).

Adam Mitangu Fimbo
Director General

ACKNOWLEDGEMENTS

A number of individuals have contributed towards successive development of the TMDA five-year Strategic Plan which is to be implemented from 2021/22 to 2025/26 financial years. First and foremost, I wish to sincerely express my gratitude to a team of staff from the Planning, Monitoring and Evaluation Section (PME) namely Mr. Damas Matiko Nyang'anyi, Mr. John Mwingira, Ms. Esther Mwera, Mr. William Nkondokaya and Ms. Deborah Wami for the hard work, efforts and time devotion during the initial drafting, compilation and ensuring thorough completion of this Strategic Plan.

Special thanks are also bestowed to the Lead Facilitator, Dr. Zabron Kengera from the University of Dar es Salaam and Ms. Rehema Msamy for their technical inputs and support, commitment and dedication throughout the whole process of developing this plan.

Contributions and active participation of TMDA Directors and Managers as well as fruitful comments, critics and opinions from members of TMDA Workers Council in enriching this plan particularly its objectives and strategies are irrefutably acknowledged.

Lastly, I would like to express my heartfelt appreciation to the members of the Ministerial Advisory Board (MAB) for their valuable guidance, constructive inputs and eventual approval of this 5th edition TMDA Strategic Plan.

Chrispin Mesiaki Severe
Director of Business Support

EXECUTIVE SUMMARY

Tanzania Medicines and Medical Devices Authority (TMDA) is a semi-autonomous regulatory body under the Ministry of Health (MoH) with a Mission of protecting and promoting public health by ensuring safety, quality and effectiveness of medicines, medical devices diagnostics and other health related products.

To meet the stated mission, TMDA has developed this five-year Strategic Plan (SP), 2021/22 – 2025/26 to serve as a guide for the Authority to deliver its core mandate pursuant to the Tanzania Medicines and Medical Devices Act, Cap 219 and the Tobacco Products (Regulations) Act, Cap 121.

This fifth TMDA SP is intended to serve three major purposes namely; to replace the fourth SP of 2017/18 – 2021/22, to encourage continuous improvement of the existing practices, systems and operations and to accommodate new changes brought by a combination of factors at national and global levels. The SP is also designed to allow the Authority to meet both today's public and animal health needs and to be fully prepared for the challenges and opportunities ahead to help harness revolutions in science that can be translated into regulated products that promote public health.

This SP has taken into account critical issues highlighted in various Authority's reports such as End Term Evaluation Report of the preceding SP, Service Delivery Survey, 2020 and Performance Audit and Risks Mitigation amongst others. Development of this plan has also considered and is aligned to the national priorities highlighted in the Tanzania Development Vision 2025, National Five-Year Development Plan III (2021/22 - 2025/26), CCM Election Manifesto (2020-2025), Health Policy (2007) and Health Sector Strategic Plan V (2021-2026).

Following approval of TMDA Organizational Structure and Tobacco Products (Regulations) Act, Cap 121, three (3) new Strategic Objectives have been introduced by unpacking Objective D of the previous SP into two (2) and adding one which is related to control of usage of tobacco products. The Plan has now nine (9) objectives of which, six (6) from the previous SP are still valid. For each objective, this SP has identified a number of strategies, targets and performance indicators that will be reviewed from time to time for the purpose of tracking progress and utilize the findings to adjust implementation strategies whenever necessary in the subsequent years.

The implementation of the preceding SP was guided by six (6) core values namely; Integrity, Customer focus, Quality, Teamwork, Accountability and Transparency. In order to promote innovation among staff, a core value of "Creativity" has been added to embrace and nurture this potential aspect for improvement of regulatory service delivery.

TMDA has recorded notable achievements during implementation of the preceding SP as revealed in the End Term Evaluation Report. These achievements include amongst others, sustaining ISO 9001:2015 certification, attaining WHO Maturity Level - 3 and maintaining WHO pre-qualification for the Dar es Salaam laboratory. These achievements consequently translate into assuring the general public of the quality, safety and effectiveness of regulated products circulating on the market including regulatory decisions made by the Authority.

Based on the evaluation of the preceding SP, the Plan has identified eight (8) priority areas that are essential to the continued success of TMDA's public health and regulatory mission. The priority areas embrace; facilitation of domestic medicines, medical devices and diagnostics manufacturing facilities, strengthening capacity for regulation of regulated products, promoting institutional branding, visibility and advocacy, stakeholders' engagement, strengthening of monitoring and evaluation system, rigorous risk and quality management and ICT usage in service provision.

Effective execution of this plan is anticipated to enable the Authority to attain planned milestones, targets and desired WHO accreditation to Maturity Level 4 and ultimately achieving its Vision and Mission. TMDA will avail and commit resources to implement this SP while at the same time engaging all stakeholders in industry, academia and government. The implementation of this Plan will be continually monitored through the execution of monitoring and evaluation plans.

CHAPTER 1

INTRODUCTION

1.1 Background Information

Tanzania Medicines and Medical Devices Authority (TMDA) is a semi-autonomous regulatory body under the Ministry of Health (MoH) responsible for protecting and promoting public health by ensuring safety, quality and effectiveness of medicines, medical devices and diagnostics.

TMDA became operational on the 1st July, 2003 as the Tanzania Food and Drugs Authority or its acronym TFDA. This name was changed into Tanzania Medicines and Medical Devices (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).

Further, the Authority has been mandated with powers and functions to control tobacco products under the Tobacco Products (Regulation) Act, Cap 121 vide Government Notice No. 360 published on 30th April 2021.

The Authority has been discharging its mandate by developing and implementing five-year strategic plans which are actioned through annual work plans and budgets. The Fifth Strategic Plan (2021/22 – 2025/26) was preceded by four (4) consecutive plans.

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) Regulate all matters relating to quality and safety of medicines, medical devices and poisons;

(b) Regulate importation, manufacture, labelling, marking or identification, storages promotion, sell of medicines, and medical devices or any materials or substances used in the manufacture of regulated products;

(c) Ensure that evidence of existing and new adverse events, interactions and information about pharmacovigilance of products being monitored, are analyzed and acted upon;

(d) Ensure that, clinical trials on medicines and medical devices are being conducted in accordance with prescribed standards;

(e) Foster co-operation between the authority and other institutions or stakeholders;

(f) Approve and register regulated products manufactured within or imported into, and intended for use in the Tanzania mainland;

(g) Examine, grant, issue, suspend, cancel and revoke certificates and licences or permits issued by the authority;

(h) Appoint inspectors and order inspection of any premises;

(i) Promote rational use of medicines and medical devices;

(j) Establish and maintain the Tanzania National Formulary and Tanzania Pharmacopoeia;

(k) Provide the public with unbiased information on regulated products

(l) Maintain registers of premises and regulated products;

(m) Be responsible for its human resource management and development;

(n) Attend to and, where possible, take legal measures on complaints made by consumers against manufacturers of regulated products;

(o) Carry out such other functions as may be conferred upon the authority by any written law or as are incidental to the performance of its functions; and

(p) Do such acts or take such measures as are, in the opinion of the authority, necessary or expedient for the prevention of health hazards to consumers which may result from the consumption or use of low or bad quality regulated products.

1.2 Rationale of the Strategic Plan

The Strategic Plan (SP) is a management tool for defining future direction of the organization, resource mobilization and allocation. Strategic plans are often prepared for different reasons. For the case of TMDA, the Plan is intended to serve three major purposes, firstly is to replace the Fourth SP, secondly as part of the embracing concept of results-based culture to encourage continuous improvement of the existing practices, systems and operations so as to stimulate further organization growth and development. Lastly, it also intends to accommodate new changes brought by a combination of factors at global and national levels.

Further, this Plan responds to government policies and strategies particularly the Tanzania Development Vision 2025, National Five - Year Development Plan III (2021/22 - 2025/26), National Health Policy 2007, Health Sector Strategic Plan V, CCM Election Manifesto 2021-2026) and Tobacco Products (Regulation) Act, Cap 121. This SP will guide the Authority in mobilizing and deploying resources in towards achieving TMDA mission and vision as well as contributing to the national development goals.

1.3 Institutional Framework and Arrangement

TMDA is managed by the Director General who is accountable to the Permanent Secretary of the Ministry responsible for Health. The Authority 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 daily operations and proper management of the Authority's resources and functions. The Director General is assisted by four (4) Directors, seven (7) Heads of Units and eight (8) Zone Managers **(Annex I).**

TMDA functions are executed through four (4) Directorates namely Directorate of Human and Veterinary Medicines (DMC); Directorate of Medical Devices and Diagnostics (DMD), Directorate of Laboratory Services (DLS) and Directorate of Business Support (DBS) whereas the seven (7) Units are Internal Audit, Quality and Risk Management, Legal Services, ICT and Statistics, Procurement, Accounts and finance, Communication and Public education.

Zone offices are directly responsible to the Director General through the Zone Managers who oversee TMDA functions in the respective zones. Distribution of zones and their respective regions is as indicated in **Table 1.**

Table 1: Distribution of Zone Offices and their respective locations

S/N	Zone Office	Office location	Regions covered
1	Eastern	Dar es Salaam	Dar Es Salaam, Coast and Tanga
2	Eastern Lake	Mwanza	Mwanza, Mara and Simiyu
3	Western Lake	Geita	Kagera, Geita, and Shinyanga
4	Northern	Arusha	Arusha, Manyara and Kilimanjaro
5	Southern Highlands	Mbeya	Mbeya, Rukwa, Njombe and Songwe
6	Central	Dodoma	Dodoma, Singida, Iringa and Morogoro
7	Southern	Mtwara	Mtwara, Lindi and Ruvuma
8	Western	Tabora	Tabora, Kigoma and Katavi

Due to limited capacity, the Authority 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 and ensure that its services are accessed and available at all levels.

1.4 Methodology

This SP has been prepared based on the format prescribed in the Medium-Term Strategic Planning and Budgeting Manual (2008) issued by President's Office, Public Service Management and Good Governance (PO-PSMGG). The development of this SP was based on review of findings findings from various reports such as the End Term Evaluation Report of the Fourth SP, Service Delivery Survey 2020, Monitoring and Evaluation Reports, Annual Performance Reports, Risks Identified through the Quality Management System, Internal and External Quality Audits based on ISO 9001:2015 and Performance and Financial Audit Reports.

Similarly, preparation of the Plan involved review of relevant National Policies, Plans and Strategies mainly The Tanzania Development Vision 2025, CCM Election Manifesto 2020-2025, National Five-Year Development Plan III (2021/22 - 2025/26), National Health Policy (2007) and Health Sector Strategic Plan V (2021-2026).

Additional information was obtained through interviews with TMDA Management to garner their opinions regarding the future direction of the institution. Likewise, situational analysis was conducted to identify current TMDA's internal and external factors that may facilitate or hinder achievement of envisaged Vision so as to revise strategies, targets and Key Performance Indicators of the preceding Plan.

1.5 The Layout of Strategic Plan

The Plan comprises of four (4) chapters. Chapter one presents background information, rationale for the new SP, institutional framework and arrangements, methodology and the layout of the Plan. Chapter two describes the situation analysis which consists of performance review, stakeholders' analysis, strengths, weaknesses, opportunities and challenges (SWOC) analysis, recent initiatives and critical issues. Chapter three consists of strategic objectives, strategies, targets, key performance indicators, and financing and sustainability strategy. Chapter four provides for Monitoring and Evaluation 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, diagnostics and control of tobacco products in unforeseeable future;

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

(c) Development partners and other key stakeholders will continue collaborating with the Authority in regulatory functions; and

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

CHAPTER 2

SITUATION ANALYSIS

2.1 Introduction

Situation analysis is a significant exercise to determine the current situation in terms of internal and external factors that may facilitate or hinder attainment of envisaged Vision of TMDA. The aspects that are discussed in this chapter include review of policy context, vision and core values, past performance, SWOC analysis and stakeholders' analysis.

2.2 Policy Context

The National Health Policy (NHP) of 2007 provides the statement to make available to all Tanzanians at all times the essential pharmaceutical products, medical supplies and equipment which are safe and of high quality. TMDA being the technical arm of the Ministry responsible for health on matters related to regulation of quality, safety and effectiveness of medicines, medical devices, diagnostics and other health related products, needs to translate this policy statement into its day-to-day operations.

2.3 Review of Vision Statement

The Vision of fourth TMDA Strategic Plan was "To be the leading Regulatory Authority in ensuring safety, quality and effectiveness of medicines, medical devices, diagnostics and other health related products for all"

In the view of Mission of the Authority which is "To protect and promote public health by ensuring safety, quality and effectiveness of medicines, medical devices, diagnostics and other health related products", it is observed that the Vision statement for the next five years should be revised to reflect the impact that TMDA will bring about to the public. Thus, the Vision statement of TMDA has been changed to be "To achieve regulatory excellence in ensuring safety, quality and effectiveness of medicines, medical devices, diagnostics and other health related products".

2.4 Review of TMDA Core Values

The implementation of the preceding Strategic Plan was guided by six (6) core values namely; **Integrity, Customer focus, Quality, Teamwork, Accountability** and **Transparency.** These values are considered valid and useful for the next five years, however it has been observed that in order to promote innovation and creativity at work place it compels to include such value as "**Creativity"** to embrace and nurture this potential aspect for improvement of service delivery.

2.5 Performance Review of Past Strategic Plan

Review of past performance relied on end term evaluation report pertaining to performance of the outcome indicators in the four years of the Strategic Plan implementation. Generally, results show that the Authority achieved the set targets for an average of 90%. Results on performance for each Strategic Objective are described under subsections 2.4.1 to 2.4.7.

2.5.1 Objective A: HIV/AIDS and NCDs Reduced and Services Improved

Throughout the implementation of its fourth strategic plan, TMDA continued to sensitize its personnel about NCDs, HIV/AIDS and attendance of wellness programs. It was anticipated that, implementation of these strategies would raise voluntary health check-ups for NCDs and HIV/AIDS from 90% to 95% and 85% to 100% respectively. Further, through sensitization it was expected that staff attendance to wellness programs would increase significantly. Summary of overall performance of objective A is presented in **Table 2.**

Table 2: Performance on targets under Objective A

S/N	Indicator description	Baseline	2017/18		2018/19		2019/20		2020/21		Overall Performance (%)	Remarks
			Target	Actual	Target	Actual	Target	Actual	Target	Actual		
1.	Percentage of sensitized staff attending voluntary health check-ups for NCDs	90	90	86	90	70	90	90	95	71	79	Above Average
2.	Percentage of sensitized staff attending voluntary health check-ups for HIV/AIDS	85	90	54	90	59	90	54	100	52	96	Achieved
3.	Percentage of staff attending wellness programme	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	65	28	43	Average

*This indicator was added during the revision of the Strategic Plan in 2020.

Results in **Table 2** reveal that, under this objective one target was achieved whereas performance for target related to staff attending wellness programme had scored average mark which is attributed to low staff turn out. In view of this, the Authority will devise mechanisms to motivate staff to participate in wellness programme, voluntary HIV/AIDs and NCDs health checkups.

TMDA Staff participating in various Sports and Wellness events as part of intervention for reducing Non Communicable Diseases (NCDs) and improving both mental and physical fitness.

2.5.2 Objective B: National Anti-Corruption Strategy Effectively Implemented and Sustained

TMDA planned to contribute on effective and efficient implementation of the National Anti-Corruption Strategy, mainly by promoting good governance, integrity and adherence to ethical values among its staff. It was estimated that implementation of the strategies would make the Authority maintain compliance with FIFO in product evaluation, issuance of permits and laboratory analysis by an average of 90%. It was also expected that the Authority would register and investigate all complaints related to corruption. Performance on implementation of the strategies under this objective is seen in **Table 3.**

Table 3: Performance on targets under Objective B

S/N	Indicator Description	Baseline	2017/18		2018/19		2019/20		2020/21		Overall Performance (%)	Remarks
			Target	Actual	Target	Actual	Target	Actual	Target	Actual		
1.	Percentage conformity to FIFO in products evaluation, issuance of permit and Lab Analysis	90	90	90	90	90	90	90	90	75	83	Achieved
2.	Percentage of complaints related to corruption investigated and concluded.	100	100	100	100	100	100	100	100	100	100	Achieved

Findings from **Table 3** reveal that by June, 2021 compliance of TMDA to FIFO in product evaluation, issuance of permit and laboratory analysis was 83% and no complaint related to corruption was registered. The Authority will sustain these achievements and expand scope for measuring performance of this objective as provided in the Prevention and Combating of Corruption Bureau (PCCB) Guidelines.

Awareness training on prevention and combating of corruption to TMDA staff as facilitated by PCCB. The event was held in 2021 at TMDA Dar es Salaam office.

2.5.3 Objective C: Gender and Environmental Issues Improved

This objective was addressed mainly through mainstreaming gender issues in the Authority's plans and integrating environmental management practices in TMDA activities. It was anticipated that implementation of these strategies would raise proportion of women staff within TMDA from 35% to 37%, proportion of women at managerial position from 22% to 30% and acquiring and sustaining OSHA certification. Results on performance of this objective are presented in **Table 4.**

Table 4: Performance on targets under Objective C

S/N	Indicator Description	Baseline	2017/18		2018/19		2019/20		2020/21		Overall Performance (%)	Remarks
			Target	Actual	Target	Actual	Target	Actual	Target	Actual		
1.	Proportion of women among staff;	35	37	39	38	39	39	38	37	37	97	Achieved
2.	Proportion of women at managerial positions;	22	*N/A	*N/A	26	28	*N/A	*N/A	30	15	54	Average
3.	OSHA certification acquired and sustained	**N/A	**N/A	**N/A	**N/A	**N/A	**N/A	**N/A	100	50	50	Average

* Reporting frequency of this indicator was biennially

** This indicator was added during the revision of the Strategic Plan

Results from **Table 4** indicate that during the four years, the Authority achieved one target in this objective where as other targets had an average score**.** Proportion of women staff holding managerial positions has not been achieved due to the fact that among all the managers, five (5) women are still acting in their positions awaiting confirmation procedures. The Authority will make follow up to relevant authorities to ensure that they are confirmed and apply for OSHA certification for Dodoma and Dar es Salaam Office buildings.

2.5.4 Objective D: Quality, Safety and Effectiveness of Medicines, Medical Devices and Diagnostics Assured

The strategies implemented under this objective were mainly focusing on strengthening regulatory systems, promoting voluntary compliance, maintaining regional and international collaboration and harmonization initiatives and support domestic manufacturers to comply with legal and regulatory requirements.

Implementation of these strategies was expected to improve products and premises compliance to quality and safety requirements**.** Performance of various planned targets and achievements as of June, 2021 have been summarized in **Figure 2.** Details on performance for each target are elaborated in **Table 5.**

Table 5: Performance on targets under Objective D

S/N	Indicator description	Baseline	2017/18		2018/19		2019/20		2020/21		Overall Performance (%)	Remarks
			Target	Actual	Target	Actual	Target	Actual	Target	Actual		
1.	Percentage of applications for registration of medicines, medical devices and diagnostics approved/rejected within specified time period (CSC)	50	50	50	55	55	60	60	65	65	108	Surpassed
2.	Percentage of selected PMS human medicines complying with quality requirements	95	96	99	97	103	98	98	99	100	102	Surpassed
3.	Percentage of selected PMS veterinary medicines complying with quality requirements	85	86	78	87	84	88	88	95	100	114	Surpassed
4.	Percentage of inspected consignment approved at Ports of Entry (POEs)	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	85	118	139	Surpassed
5.	Percentage of clinical trials compliant with GCLP requirements	111	90	111	92	106	94	94	98	98	104	Surpassed
6.	Percentage compliance of registered medicines selling outlets	71	75	117	78	179	80	80	85	88	110	Surpassed
7.	Percentage compliance of registered medical devices and diagnostics selling outlets	85	87	77	89	158	91	91	85	102	112	Surpassed
8.	Percentage of selected PMS diagnostics complying with quality requirements	111	90	111	95	105	95	95	98	102	107	Surpassed
9.	Percentage of non-compliant products/stock/batch of regulated products recalled	100	100	100	100	100	100	100	100	100	100	Achieved
10.	Percentage of processed applications for importation approved	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	95	92	97	Achieved
11.	Percentage of compliance of registered health laboratories inspected	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	95	72	76	Above Average
12.	Percentage of selected PMS medical devices complying with quality requirements	90	95	86	95	76	98	98	98	55	56	Average
13.	Percentage of domestic medicines manufacturing facilities complying with GMP and Quality System requirements	25	40	71	45	100	50	50	40	0	0	Not Achieved

*This indicator was added during the revision of the Strategic Plan in 2020

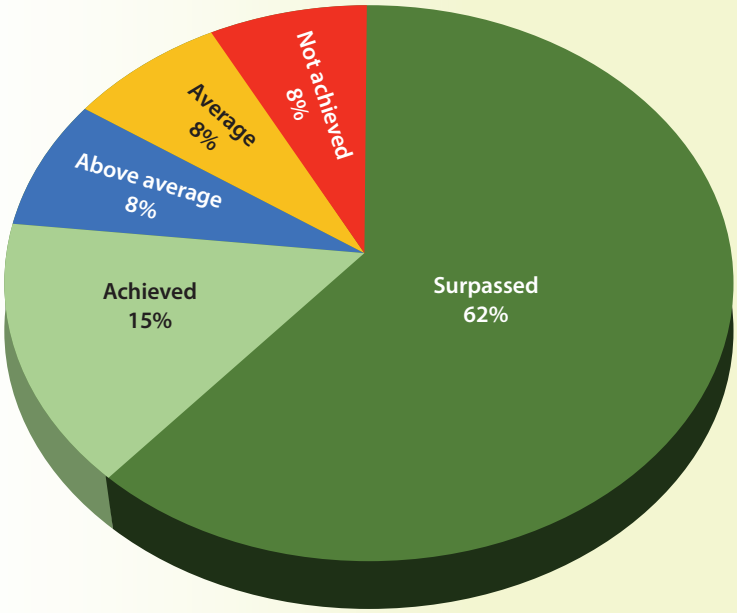

Figure 1: Summary performance on targets under Objective D

Results in **Table 5** and **Figure 1** indicate that most of the targets were achieved whereby 62% of them were surpassed, 15% were achieved and 8% were above average. These findings imply that there is significant assurance on the quality, safety and effectiveness of medicines, medical devices and diagnostics circulating in the market.

Despite the notable achievements, performance on domestic medicines and medical devices manufacturing facilities complying with GMP and Quality System requirements was not achieved. In view of this, the Authority is committed to facilitate domestic manufacturing facilities to comply with the GMP and quality management system requirements. Further, the Authority will foster collaboration with Government departments, agencies and other stakeholders to support domestic manufacturers.

Annual Pharmacovigilance Stakeholders meeting held on 30th June 2021 at TMDA conference hall in Dar es Salaam

Training of Regional Council Inspectors from Southern Highland and Southern Zones on the Principles and Procedures of Inspection as part of TMDA enforcement strategies

2.5.5 Objective E: Laboratory Services Improved

The Authority planned to implement various strategies under this objective which include decentralization of laboratory services to zone offices, ensure availability of the state of art laboratory equipment as well as deployment of competent and skilled laboratory personnel. Other strategies were to sustain laboratory accreditation and expanding the scope for WHO pre-qualification. Implementation of these interventions was expected to improve the capacity of the laboratory to perform sample analysis and releasing of laboratory results within specified turnaround time as presented in **Table 6.**

Table 6: Performance on targets under Objective E

S/N	Indicator description	Baseline	2017/18		2018/19		2019/20		2020/21		Overall Performance (%)	Remarks
			Target	Actual	Target	Actual	Target	Actual	Target	Actual		
1.	Percentage of laboratory results for medicines released within the turnaround time as per CSC;	64	66	62	68	91	70	70	75	129	184	Surpassed
2.	Level of internal customers satisfaction in relation to laboratory services	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	73	105	144	Surpassed
3.	Level of external customers satisfaction in relation to laboratory services;	63	65	47	68	68	70	70	80	105	150	Surpassed
4.	ISO/IEC 17025 and WHO pre-qualification for TMDA laboratory in Dar es salaam sustained	100	100	100	100	100	100	100	100	100	100	Achieved
5.	Percentage of staff passed PT Scheme	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	90	78	87	Achieved
6.	Percentage of laboratory results for medical devices released within turnaround time (as per CSC)	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	90	57	63	Above Average
7.	Percentage of identified research problems concluded and results disseminated;	50		-	50	50	55	55	60	100	182	Surpassed
8.	ISO/IEC 17025 and WHO pre-qualification for Mwanza laboratory attained and sustained	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	100	0	0	Not Achieved
9.	Percentage contribution in revenue generated from Laboratory services	1.6	3	_	3.5	_	4	_	4.5	0.4	10	Not Achieved

*This indicator was introduced during the revision of the Strategic Plan

According to the findings in **Table 6**, five (5) targets under this objective were achieved and surpassed whereas three (3) were not achieved. These include target related to operational researches, ISO certification and WHO Pre-qualification for Mwanza laboratory and revenue contribution from laboratory services. The Authority will review operationalization of these targets to elevate their performance.

Sustaining ISO/IEC 17025 Standard and WHO pre-qualification for TMDA Laboratory in Dar Es Salaam and expanding its Scope

The Authority's commitment and innovation in improving and upgrading laboratory service delivery systems in-line with the changing needs and expectations of its esteemed customers has been recorded as one of the factors that enabled the Laboratory to be pre-qualified by the World Health Organization (WHO) and maintain the status since January 2011.

The pre-qualification status has been attained following a number of audits and inspections in all areas of analysis to assess their effectiveness. WHO has been continuously conducting audits whereby in late 2021 WHO inspectors conducted a surveillance audit to assess the compliance to ISO: IEC 17025:2017 standard requirements and Good Practices for Pharmaceutical Quality Control Laboratories. The laboratory was then found to comply with the requirements and maintained its pre-qualification status.

The TMDA Laboratory is amongst the 57 pre-qualified quality control laboratories in the world as per the WHO list of pre-qualified laboratories of June, 2021.

2.5.6 Objective F: Public Education Strengthened and Customer Services Improved

TMDA employed various strategies for strengthening public education and improving customer services through implementation of Communication and Customer Service Strategy, stakeholders' engagement and embracement of core value among staff. Results on assessment of these interventions are summarized in **Table 7.**

Table 7: Performance on targets under Objective F

Indicator description	Baseline	2017/18		2018/19		2019/20		2020/21		Overall Performance (%)	Remarks
		Target	Actual	Target	Actual	Target	Actual	Target	Actual		
Percentage level of general public awareness on TMDA functions	50	*N/A	*N/A	50	50	*N/A	*N/A	60	88	147	Surpassed
Percentage level of external customer satisfaction	68	*N/A	*N/A	75	74	*N/A	*N/A	80	80	101	Surpassed
Percentage level of internal customer satisfaction	74	N/A*	N/A*	80	80	*N/A	*N/A	85	75	101	Surpassed
Percentage of customer complaints resolved	_	99	83	99	92	99	99	100	100	101	Surpassed

* The reporting frequency of this indicator was biennially

Findings from **Table 7** basically demonstrate that, all targets under this objective were surpassed. This outstanding performance is attributed to implementation and monitoring of Clients Service Charter, automation of service processes and increased funding for public education activities and customer care interventions.

Despite the achievement observed under this objective, there were opinions from stakeholders that TMDA is not well known compared to its predecessor TFDA. Thus, the Authority will review its Communication and Customer Service Strategy to improve branding, visibility, lobbying, advocacy and stakeholders' participation and engagement.

TMDA Director General Mr. Adam M. Fimbo receives the Service Delivery Survey Report (2020) from Consultant Dr. Diana Mwiru

Establishment of TMDA School Clubs in different schools in the country is part of TMDA's innovative public education approaches

2.5.7 Objective G: Institutional Capacity to Deliver Regulatory Services Strengthened

TMDA planned to strengthen its capacity to deliver services by enactment of TMDA Act Cap. 219, strengthening M&E and QMS capacity, enhancing risk management and ICT usage and providing adequate resources, working tools and physical infrastructures. It was expected that within the four years of SP implementation, these strategies would increase contribution of revenue from internal sources from 71% to 87%, staff retention from 98% to 100%, attaining clean financial audit reports, sustaining ISO certification and mitigating risks at 100%. Findings of this evaluation are presented in **Table 8.**

Table 8: Performance on targets under Objective G

Indicator description	Baseline	2017/18		2018/19		2019/20		2020/21		Overall Performance (%)	Remarks
		Target	Actual	Target	Actual	Target	Actual	Target	Actual		
Percentage budgetary contribution from internal sources	71	75	75	80	80	85	85	87	87	102	Surpassed
Percentage of staff retention;	98	98.5	99	98.5	100	99	99	100	100	101	Surpassed
Percentage of proposals funded	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	90	100	111	Surpassed
Clean Financial Audit Report attained;	100	100	100	100	100	100	100	100	100	100	Achieved
ISO certification sustained	100	100	100	100	100	100	100	100	100	100	Achieved
Percentage mitigation of the identified risks;	50	55	73	60	167	75	75	100	53	71	Above Average

*This indicator was added during the revision of the Strategic Plan

The findings in **Table 8** show that, with exception to mitigation of the identified risks, other targets were either achieved or surpassed. The achievement is attributable to automation and usage of electronic systems such as EPICOR, RIMS, LIMS and GePG in revenue collection and expenditure. Equally, the Authority has well elaborate incentive schemes that cater for various staff needs. These findings suggest that in four years of Strategic Plan implementation, TMDA has significantly strengthened its capacity to deliver regulatory services. Regardless of notable achievements, there were concern raised by stakeholders on the difficulties encountered on accessing TMDA services particularly in areas where TMDA has no office.

In this regard, the Authority will consider to extend its services to regional and district levels as well as recruit more staff particularly for zone offices and ports of entry. Further, the Authority will enhance rigorous risk management, M&E, QMS and ICT usage in service provision.

Construction and completion of TMDA building for Central Zone, Dodoma signifies the biggest milestone during the fourth Strategic Plan execution. The building is located on Plot No. 56/1, Block E, Kisasa B along Swaswa Road adjacent to National archives and Opposite Martin Luther Schools.

2.6 Stakeholders' Analysis

A stakeholders' analysis was conducted to identify key TMDA stakeholders, their interests, expectations, and potential impacts in order to devise means of serving them and mobilize their support during the implementation of this Strategic Plan. The results of stakeholders' analysis are presented in the **Table 9.**

Table 9: TMDA Potential Stakeholders

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
1.	Consumers	i. Safety, quality, effectiveness and performance of regulated products; and ii. Information regarding regulated products and services provided.	i. Increased hazards associated with consumption of regulated products; ii. Increased customer complaints; and iii. Intervention from higher authorities that may negatively affect TMDA.	High

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
2.	Ministry responsible for Health	i. Effective and efficient implementation of Health Policy; ii. Fully implementation of TMDA mandate; iii. Technical advice and information on safety, quality, effectiveness and performance of regulated products; and iv. Performance reports.	i. Inadequate support from the Ministry; ii. Lack of confidence and trust with TMDA' and iii. Ministry intervention to rectify the situation.	High
3.	Ministry responsible for Livestock Development and Fisheries.	i. Safety, quality and effectiveness of veterinary medicines, vaccines and devices; and ii. Technical advice and information on safety, quality, effectiveness and performance of veterinary medicines and devices.	i. Inadequate support from the Ministry; ii. Lack of confidence and trust with TMDA; and iii. Ministry intervention to rectify the situation.	High
4.	Ministry responsible for Industry, Trade and Investment	i. Trade facilitation for regulated products ii. Information and education iii. Facilitation and technical guidance for development and formalization of domestic pharmaceutical and medical devices manufacturers.	i. Inadequate support from the Ministry ii. Lack of confidence and trust with TMDA; and iii. Ministry intervention to rectify the situation.	High
5.	Ministry responsible for Finance and Planning	i. Effective and efficient implementation of National Development Plans; ii. Information and performance reports; iii. Fully implementation of TMDA mandate; and iv. Financial prudence.	i. Inadequate support ii. Lack of confidence and trust with TMDA iii. Ministry intervention to rectify the situation	High

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
6.	President's Office Public Service Management and Good Governance	i. Effective and efficient public service delivery ii. Financial self-reliance iii. Information and performance reports iv. Fully implementation of TMDA mandate v. Effective implementation of Public Service Legislations and guidelines	i. Limited support ii. Lack of confidence and trust with TMDA iii. Ministry intervention to rectify the situation	High
7.	Office of the Treasury Registrar	i. Effective and efficient implementation of Registrar's directives; ii. Information and Performance reports; iii. Collection of fees and charges; and iv. Financial prudence	i. Inadequate support ii. Lack of confidence and trust with TMDA iii. Registrar's intervention to rectify the situation	High
8.	Office of the Attorney General	i. Effective and efficient implementation of Attorney General 's directives; and ii. Fully implementation of TMDA mandate;	i. Inadequate support and collaboration; ii. Lack of confidence and trust with TMDA; and iii. Attorney General's intervention to rectify the situation	High
9.	Director of Public Prosecution	i. Effective and efficient implementation of Director of Public Prosecution's directives; and ii. Collaboration and support	i. Inadequate support and collaboration; and ii. Lack of confidence and trust with TMDA	High

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
10.	Manufacturers and dealers of the regulated products	i. Fairness and transparency; ii. Timely approval and Certification; iii. Clear and streamlined procedures for services; iv. Proper complaints handling and timely feedback; v. Regular forums to discuss regulatory issues; and vi. Information and education.	i. Limited compliance on regulated products and bad mouthing; ii. Decreased revenue collection; iii. Increased complaints; iv. Limited support; v. Intervention from higher authorities that may negatively affect TMDA; vi. Increased cost of enforcement; and vii. Poor feedback on malpractice and product performance in the market	High
11.	Media houses and practitioners	i. Information, transparency and cooperation; and ii. Timely payment for assigned duties.	i. Bad mouthing and poor collaboration; and ii. Negative image of TMDA to the public.	High
12.	Practitioners, Researchers and Academia	i. Timely approval and certification; ii. Fairness and transparency; iii. Information and education; and iv. Safe, quality and effective products circulating in the market.	i. Bad mouthing and inadequate collaboration; ii. Negative image of TMDA to the public; iii. Poor feedback on malpractice and product performance in the market.	Medium
13.	Training Institutions & Higher Learning Institutions	i. Information ii. Technical support iii. Field and practical attachment, experience and appraisal reports	i. Low cooperation and support ii. Negative image of TMDA to the public	Low
14.	Service providers	i. Fairness and transparency on issues of contract ii. Information iii. Timely payments	i. Failure of TMDA to attain its targets ii. Delay/shortage of goods and services iii. Disputes and litigations	Medium

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
15.	Civil Society Organizations (CSOs)	i. Information on TMDA services ii. Collaboration/ cooperation iii. Transparency	i. Bad mouthing and inadequate collaboration ii. Negative image of TMDA to the public; iii. Poor feedback on malpractice and product performance in the market; and iv. Demands for government interventions.	Medium
16.	International Organizations and Development Partners	i. Transparency and Cooperation; ii. Effective implementation of supported projects/ interventions; iii. Progress reports for supported projects; iv. Information and education; and v. Technical advice on respective development projects.	i. Bad mouthing and poor collaboration; ii. Failure to attain targets; iii. Withdraw of supports; and iv. Intervention from higher authorities that may negatively affect TMDA.	Medium
17.	Law Enforcers	i. Technical support; ii. Regulations and guidelines; iii. Information and education; and iv. Transparency and cooperation.	i. Inadequate collaboration and bad mouthing; ii. Negative image of TMDA; and iii. Intervention from higher authorities that may negatively affect TMDA.	Medium
18.	Local Government Authorities	i. Regulations and guidelines; ii. Information and education; iii. Transparency and cooperation; iv. Recognition; v. Resources; and vi. Technical support.	i. Inadequate collaboration and bad mouthing; ii. Negative image of TMDA; and iii. Inefficient implementation of delegated powers and functions.	Medium
19.	Other Government Institutions	i. Transparency, information sharing and cooperation; and ii. Technical advice.	i. Bad mouthing and poor image of TMDA to the public; and ii. Inadequate collaboration.	Low

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
20.	Parliamentary Committees	i. Effective implementation of TMDA function; ii. Proper management and utilization of resources; iii. Performance reports; and iv. Education and information.	i. Bad mouthing and negative image of TMDA to the public; ii. Political interventions that may negatively affect TMDA; and iii. Limited support.	High
21.	Religious institutions	1. Information and education.	1. Bad mouthing and negative image of TMDA to the public; 2. Limited support.	Low
22.	Employees	1. Equitable remuneration; 2. Clear working guidelines and staff regulations; 3. Capacity building and career development; 4. Adequate working tools; 5. Harmonious working relationship; 6. Staff welfare and support; and 7. Participation in decision making.	1. Low morale; 2. Sabotage; 3. Low performance; 4. Unethical practices; 5. High staff turnover rate; 6. Increased complaints from staff; 7. Increased labor disputes and litigations; and 8. Government interventions to rectify the situation that might impact negatively TMDA.	High

2.7 SWOC Analysis

In the development of this Strategic Plan, Strengths, Weaknesses, Opportunities and Challenges (SWOC) analysis was conducted to understand the current situation of the Institution both internally and externally. The analysis is used to measure performance of overall TMDA operations and functions, build on achievement and address challenges and minimize anticipated risks. The analysis will further help the Authority to make well informed decisions. Outcome of analysis is presented in **Table 10.**

Table 10: SWOC Analysis

Area	Strength	Weakness
Human Resources Management	a) Effective and visionary leadership; b) Existence of Human Resource Plan (HRP); c) Existence of active MAB and Technical Committees; d) Existence of staff training and development programs e) Presence of Scheme of Service f) Existence of Succession Plan	a) Inadequate implementation of HRP; b) Inadequate remuneration and motivation schemes; c) Inadequate gender mainstreaming strategies; d) Insufficient competence in regulation of medical devices, diagnostics and herbal medicines; e) Ineffective staff orientation and mentoring system.
	Opportunities	**Challenges**
	a) Presence of qualified labour force in the market; b) Commitment of central government on career development; c) Presence of health training institutions (local and international); d) Presence of qualified personnel at LGA that can be appointed to perform TMDA functions.	a) Delays in recruitment of staff due to centralized recruitment processes; b) Inadequate skilled labour for medical devices, diagnostics and laboratory equipment maintenance.
Systems and Processes	**Strength**	**Weakness**
	a) Presence of Organization Structure; b) Existence of eight (8) TMDA Zone offices c) Existence of legislations, regulations, programmes and guidelines;	a) Inadequate M&E of TMDA functions; b) Overambitious plans and unrealistic indicators; c) Inadequate capacity in regulation of medical devices and diagnostics;

Area	Strength	Weakness
Systems and Processes	d) Presence of Quality Management System (QMS); e) Presence of quality assurance centers; f) Being EAC Center of excellence for medicines evaluation and registration; g) Presence of computerized systems (e.g., RIMS, LIMS, MUSE, PLANREP, HCMIS, e-Office and GePG); h) Availability of new technologies such as the use of smart phones in product verifications; i) Presence of office buildings and facilities j) Attainment of WHO Maturity Level 3 and pre-qualified laboratory.	d) Lack of dedicated unit to deal with estate matters; e) Underutilization of available laboratories; f) TMDA documents are in English language which cannot be comprehended by stakeholders; g) Weak systems for control of promotion and advertisement of regulated products; h) Unclear instructions for special imports i) Narrow scope of revenue sources attributed to over reliance of imported goods
	Opportunities	**Challenges**
	a) Presence of supportive government policies, legislation and national framework guidelines and strategies b) Strong political will and support c) National Five-Year Development Plan III which promotes pharmaceutical industrialization d) International and Regional frameworks related to regulated products (conventions e.g., African Medicines Agency (AMA) Treaty, cooperation e.g., EAC and initiatives e.g., ZAZIBONA).	a) Dependence on DPP office on the investigation and prosecution of TMDA cases b) High pace of change in technologies c) Unauthorized borders d) Lack of approved sites to dispose hazardous waste products e) Absence of national steering committee for regulated products f) Bureaucratic approval of laws and reviews g) Over-reliance on imported products hence high chance of falsified and substandard products h) Risks of cybercrime acts i) Unreliable network from service providers

Area	Strength	Weakness
Customer Care	a) Existence of Clients' Service Charter (CSC) b) Existence of Communication and Public Education Strategy c) Presence of IEC materials for various procedures and requirements for TMDA services available in hard and soft copies. d) Existence of complaints handling mechanisms e) Customers feedback mechanisms such as exit interviews and Service Delivery Surveys f) Presence of customer care desks g) Existence of TMDA website, online portal, social media accounts and toll-free hotline 0800110084 h) Presence of whistleblowing policy	a) Weak implementation of Communication and Public Education Strategy b) Inadequate responsiveness to customer expectations c) Absence of TMDA offices at regional and district levels d) Limited branding and visibility
	Opportunities	**Challenges**
	a) Increasing growth for regulatory products business which entails demands for TMDA services b) Increased consumers' demand for safe, quality, effective and performing products c) Technological advancement d) Existence of diverse media platforms	a) Low voluntary compliance among dealers b) Low literacy level among members of public
Stakeholders Participation and Engagement	a) The presence of mutual and strategic partnerships with internal and external regulatory bodies (e.g. TBS, PC,VCT, MUHAS, NMRI, ZFDA and Rwanda FDA) b) Good reputation within and outside the country c) Presence of technical committees d) Mandate to delegate powers and functions to other bodies	a) Lack of formal stakeholders' forum to discuss regulatory issues b) Inadequate coordination between TMDA and PO-RALG on delegated functions c) Limited lobbying and advocacy

Area	Strength	Weakness
Stakeholders Participation and Engagement	Opportunities	Challenges
	a) Presence of LGAs and other law enforcers. b) Existence of private providers for goods and service c) Existence of Development Partners to support TMDA functions d) Existence of CSOs interested in TMDA functions e) International and regional integration initiatives	a) Undefined demarcation of roles and responsibilities among key players of regulated products b) Inadequate domestic suppliers for reagents, chemicals, equipment and technical services c) Inadequate collaboration from some law enforcers d) Dependence on GPSA for clearance of imported laboratory chemicals and consumables.

2.8 Recent Initiatives

A number of initiatives have been recently undertaken to address some of the institutional weaknesses and challenges as described in sub-sections 2.7.1- 2.7.2.

2.8.1 Major activities expected to be completed in the year 2021/22

The following major activities have been planned to be completed in the financial year 2021/22:-

(a) Automation of TMDA services;

(b) Sustaining Accreditation and WHO pre-qualification of Dar es Salaam laboratory;

(c) Review of the Organizational Structure;

(d) Sustaining ISO 9001:2015 certification; and

(e) Implementation of ASCEND projects which aim at strengthening pharmacovigilance systems.

2.8.2 Accomplished Milestones

The following major milestones have been accomplished during past four-year Strategic Plan

(a) Construction of TMDA office building in Dodoma;

(b) Sustaining ISO 9001:2015 certification;

(c) Attaining WHO Maturity Level 3;

(d) Equipping Lake Zone laboratory;
(e) Sustaining WHO pre-qualification for Dar es Salaam Laboratory;
(f) Equipping laboratory for testing medical devices, antiseptics and disinfectants;
(g) Conducting Services Delivery Survey (SDS);
(h) Attaining unqualified financial audit opinion;
(i) Reviewing and implementing Scheme of Service; and
(j) Conducting Institutional self-assessment.

2.9 Critical Issues

Based on the thorough situational analysis, the following issues were identified as critical for the future TMDA performance improvement and if not addressed they may affect organizational performance.

(a) Implementation of the newly approved organizational structure;
(b) Inadequate human resources, infrastructures and working facilities;
(c) Centralized accredited and prequalified laboratory services;
(d) Inadequate leverage of ICT usage in service provision;
(e) Insufficient systems for control of tobacco products;
(f) Inadequate competence in regulating medical devices and diagnostics;
(g) Inadequate facilitation and support of domestic manufacturers of regulated products;
(h) Inadequate stakeholders' participation and engagement;
(i) Inadequate public awareness, branding, visibility lobbying and advocacy; and
(j) Inadequate coverage of TMDA services at regional and district levels.

CHAPTER 3

THE PLAN

3.1 Introduction

This chapter presents five-year plan for executing TMDA functions in line with other National goals and priorities. The plan will be implemented from 2021/22 - 2025/26. This chapter provides for the vision, mission, policy statements for quality, risk and fraud risks management, core values, objectives, strategies, targets and key performance indicators.

3.2 Linkage with National Polices, Development Planning Frameworks and Strategies

This Strategic Plan has Nine (9) Strategic Objectives. These objectives are aligned to The Tanzania Development Vision 2025, National Five-Year Development Plan -FYDP III (2021/22 – 2025/26), and the CCM Election Manifesto (2020 – 2025). Equally, the SP is aligned to the National Health Policy, 2007 as well as Health Sector Strategic Plan V – HSSP V (2021 – 2026). A summary of issues pertaining to the alignment of the SP with National Planning Frameworks is appended as **Annex II.**

3.3 Vision Statement

"To achieve regulatory excellence in ensuring safe, quality and effectiveness of medicines, medical devices, diagnostics and other health related products".

3.4 Mission Statement

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

3.5 Core Values;

In pursuit of its Vision and Mission, TMDA is guided by seven (7) core values that define its desired organizational culture and hence embraces and institutionalizes them to ensure satisfaction and expectation of stakeholders.

The Authority's employees are committed to upholding the following values as character of identity: -

(a) Transparency: Operate in a fully transparent manner and communicate openly and timely to the relevant stakeholders.

(b) Accountability: Accountable for actions and outcomes.

(c) Customer focus: Always treat customers and colleagues with courtesy and be responsive, timely and proactive to meet their public health needs.

(d) Creativity Embrace innovation in service delivery.

(e) Teamwork: Support one another, work cooperatively and respect one another's views.

(f) Integrity: To uphold highest standards of conduct and commitments while acting in the best interest of the country.

(g) Quality: Strive to deliver the best services to the customers with utmost professionalism.

3.6 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 or performance of medicines, medical devices and diagnostics including minimizing harmful effects of tobacco products by managing the Authority with utmost professionalism.

We commit ourselves to comply with requirements of the ISO 9001:2015 standard and continually improve effectiveness of Quality and Risk Management System. We shall manage and provide resources for continuous improvement of our services to ensure customer satisfaction".

3.7 Risk Management Policy Statement

TMDA is committed to provide resources for implementation and continuous improvement of risk management activities in order to achieve strategic objectives. Management has integrated risk management practices at all levels of operation so as to provide reasonable assurance in implementation of Regulatory functions.

We identify and manage among the risks and opportunities in a systematic manner using principles set out in the guidelines. We will continually monitor and review implementation to mitigate risks and pursue opportunities in delivering regulatory services while protecting and promoting public health.

3.8 Fraud Risk Management Policy Statement

TMDA is committed to, and places the high priority on managing its fraud risks strategically and systematically. Fraud risk management will apply tone at a top approach. The Authority will maintain robust control mechanisms to prevent and detect fraud. The effectiveness of controls will be subject to periodic reviews by the Authority Internal Auditors.

3.9 Philosophy

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

3.10 Strategic Objectives

To achieve TMDA's Vision and Mission, nine (9) Strategic Objectives and respective rationales have been developed. For each objective, a number of strategies, targets and performance indicators have been identified. The Strategic Objectives are;

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 and biocidal products assured;
E. Quality, safety and performance of medical devices and diagnostics assured;
F. Control of Tobacco Products strengthened;
G. Laboratory services improved;
H. Public education and customer services improved; and
I. Institutional capacity to deliver regulatory services enhanced.

3.10.1 Strategic Objective A: HIV/AIDS and Non-Communicable Diseases (NCDs) Reduced and Services Improved

3.10.1.1 Rationale

HIV/AIDS is a major development crisis that affects all sectors in Tanzania. It has spread relentlessly affecting people in all walks of life including people at work places. The increasing number of HIV/AIDS related absenteeism from workplaces and deaths hence causing reduction in productivity and increasing poverty. Given the current HIV prevalence (4.7 %) in the society, TMDA is therefore not immune to this epidemic thus necessitating taking concerted efforts to combat it.

National Policy on HIV/AIDS (2001) directs all employers to safeguard the rights of people living with HIV/AIDS so as to improve the quality of their lives and minimize stigma. Further, the Policy puts emphasis that people living with HIV/AIDS are entitled to all basic needs and all civil, legal, and human rights without any discrimination based on gender differences or sero-status.

TMDA shall ensure that all staff living with HIV/AIDS receive staff rights without any discrimination and shall avail all the necessary information in relation to HIV/AIDS or counseling, treatment and care. Recruitment, training and career development will be treated equally to all staff without discrimination on grounds of HIV/AIDS status. TMDA management and staff will strive to maintain positive attitude towards staff living with HIV/AIDS and shall provide facilities for HIV prevention measures, care and treatment.

On the other hand, NCDs pose a great threat to health and lives in the community. 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. In Tanzania like many developing countries the burden of NCDs has been increasing steadily. WHO country estimates of 2010 showed that NCDs account for 27% of all deaths in Tanzania.

Socio-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 TMDA, the burden is related to reduce productivity as NCDs cause repeated absenteeism and reduced individual capacity to work. The individual is affected both health wise and economically as big part of his or her budget is spent on medical services. Therefore, the Authority shall devise and implement various interventions to address NCDs, associated risk factors and prevention activities in order to manage the problem at its workplaces.

3.10.1.2 Strategies

(a) Effective implementation of the National Guidelines for Management of HIV/AIDS and NCDs in public service in force.

3.10.1.3 Targets

(b) Awareness, care and support on HIV/AIDS and NCDs to TMDA staff provided by June, 2026.

3.10.1.4 Key Performance Indicators

Outcome Indicators

(a) Percentage of sensitized staff who turn up for voluntary health check-ups for HIV/AIDS; and

(b) NCDs incidence rate among TMDA staff.

Output Indicators

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

(b) Percentage of staff living with HIV/AIDS and NCDs supported;

(c) Percentage of staff sensitized on wellness programme; and

(d) Percentage of sensitized staff attending wellness programme.

3.10.2 Strategic Objective B: National Anti-Corruption Strategy Effectively Implemented and Sustained

3.10.2.1 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 highly prone to corruption; corrupt practices if not prevented 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 continues to put in place initiatives to prevent and control corruption at place of work and in delivery of services by improving transparency on TMDA procedures, automation of services, handling of customer complaints, enforcement of compliance guidelines, presence of integrity committee, defining service standards as provided in the Client Service Charter and sensitization of staff to refrain from corruption practices.

3.10.2.1 Strategies

(a) Promote good governance, integrity and ethical values;

(b) Leverage ICT usage in service delivery; and

(c) Strengthen internal control systems

3.10.2.2 Targets

(a) Anti-corruption Strategy and Good Governance enforced to TMDA staff by June, 2026; and

(b) Public Service Code of Ethics and Conduct instilled to staff by June, 2026.

3.10.2.3 Key Performance Indicators

Outcome Indicators

(a) Level of staff awareness on corruption prevention; and

(b) Number of corruption allegations against TMDA staff.

Output Indicators

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

(b) Percentage of staff signing declaration of conflict-of-interest forms;

(c) Percentage of new staff signing integrity pledge forms;

(d) Number of areas prone to corruption identified and mitigated; and

3.10.3 Strategic Objective C: Gender and Environmental Issues Improved

3.10.3.1 Rationale

Proportion of women amongst TMDA staff as of June, 2021 stands at 30% against that of men staff which constitute 70% of the total workforce whereas the composition of top management of TMDA is not gender sensitive as all the directors are men. At managerial level, out of 22 managers, seven (7) were women and 15 were men. To date TMDA has not employed any person with disability and has user friendly infrastructures 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.

Some of the Authority activities and operations are likely to have impact on the environment. Such activities include disposal of unfit regulated products and laboratory wastes might lead into environmental degradation. The authority has taken initiatives of providing temporary storage facilities for laboratory chemical waste; 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. TMDA will sustain these initiatives and embark on new interventions such as construction of incinerators for safe disposal of unfit products is required to conserve the environment.

3.10.3.2 Strategies

(a) Mainstream gender issues in Authority plans; and

(b) Integrate environment management practices in TMDA activities.

3.10.3.3 Targets

(a) Women staff empowered at all levels by June, 2026;

(b) Infrastructures to support physically challenged persons provided by June, 2026; and

(c) Facilities for handling and disposal of waste and unfit products in place by June, 2026.

3.10.3.4 Key Performance Indicators:

Outcome Indicators

(a) Proportion of women at managerial positions.

Output Indicators

(a) Proportion of women trained on leadership and management among senior women staff;

(b) Infrastructures for physically challenged persons in place; and

(c) Facilities for handling and disposal of waste and unfit products in place.

3.10.4 Strategic Objective D: Quality, Safety and Effectiveness of Medicines and Biocidal Products Assured

3.10.4.1 Rationale

Quality, safety and effectiveness of medicines are of paramount importance for effective treatment and management of diseases in any society. Further, trust and confidence of the public with the regulatory Authority depends on strong systems of medicines regulation that assures quality, safety and effectiveness. Such systems shall ensure that products approved for market authorization meet the prescribed standards and early detection of substandard and falsified products in the market.

Tanzania like any other developing countries is prone to infiltration of substandard falsified medicines and biocidal products thus posing a high health risk to consumers. Recent data and records show that Tanzania imports about 80% of the medicines for both private and public supply chains. This phenomenon calls for strong medicine import control and concerted efforts to promote more domestic production of these products. Currently, there are 17 functional domestic manufacturing facilities and eight (8) are at different stages of construction under TMDA supportive supervision.

In view of the above status, TMDA will continue to streamline its regulatory systems to ensure a favourable, predictable and supportive environment for domestic production of quality, safe and effective medicines and biocidal products and control of imports.

3.10.4.2 Strategies

(a) Strengthen and streamline systems for regulation of medicines and biocidal products; and

(b) Facilitate and support domestic manufacturers and SMEs dealing in medicines and biocidal products to comply with legal and regulatory requirements.

3.10.4.2 Targets

(a) Premises dealing in medicines and biocidal products inspected by June, 2026;

(b) Surveillance and vigilance of medicines and biocidal products conducted by June, 2026;

(c) Medicines and biocidal products registered by June, 2026; and

(d) Clinical trials approved and inspected by June, 2026.

3.10.4.3 Key Performance Indicators

Outcome Indicators

(a) Percentage of applications for registration of medicines approved/rejected within a specified time period as per CSC;

(b) Percentage of applications for registration of biocidal products approved/ rejected within a specified time period as per CSC;

(c) Percentage of PMS human and veterinary medicines complying with quality requirements;

(d) Percentage of domestic pharmaceutical manufacturing facilities compliant with GMP requirements;

(e) Percentage of clinical trials compliant with GCP and GCLP requirements; and

(f) Percentage of inspected medicines selling outlets complying with requirements.

Output Indicators

(a) Percentage of product applications for registration of medicines and biocidal products assessed within specified time period as per CSC;

(b) Percentage of applications for registration of premises for medicines and biocidal products processed within specified time period as per CSC;

(c) Percentage of registered outlets for medicines inspected;

(d) Percentage of planned PMS samples for medicines collected;

(e) Percentage of applications for authorization of clinical trials evaluated;

(f) Percentage of approved clinical trials inspected;

(g) Percentage of domestic pharmaceutical manufacturing facilities inspected for GMP;

(h) Percentage of domestic biocidal manufacturing facilities inspected;

(i) Percentage of overseas pharmaceutical manufacturing facilities inspected for GMP;
(j) Percentage of received import/ export applications processed;
(k) Percentage of approved consignments inspected at the Ports of Entry (PoEs);
(l) Percentage of planned Adverse Drug Reactions (ADRs) reports received;
(m) Percentage of received ADR reports assessed;
(n) Percentage of received ADR reports uploaded to Vigiflow database;
(o) Percentage of planned Adverse Events following Immunization (AEFIs) reports received;
(p) Percentage of received AEFIs reports assessed; and
(q) Percentage of received AEFIs reports uploaded to Vigiflow database.

3.10.5 Strategic Objective E: Quality, Safety and Performance of Medical Devices and Diagnostics Assured

3.10.5.1 Rationale

Medical devices and diagnostics are very important components of health service delivery systems. They are used in diagnosis, prevention, aiding treatment and vaccination against diseases and restoration of normal function of the body. The use of medical devices and diagnostics of acceptable quality and safety is important for the well-being of any society. The desired health benefits are highly attributed to the quality, safety and performance of medical devices and diagnostics.

Diagnosis of diseases is the most critical part of the treatment and prevention in health care provision which entails the need to have stringent and robust regulatory systems to ensure the quality, safety and performance of these products. Success in prevention and good treatment outcomes depend on the right diagnosis and application of appropriate medical devices and diagnostics. Some of the medical devices are highly sophisticated characterized by fast changing technology that poses a big challenge to their regulation and control that calls for highly trained, skilled and dedicated staff and modern working tools.

TMDA has inadequate number of competent staff to cater for regulation of medical devices and diagnostics. This is aggravated by inadequate testing facilities and limited institutions that offer specialized trainings in such fields. Presently, there are 24 functional medical devices manufacturing facilities and 22 medical gas plants producing a very limited scope of products whereas there is no local production for diagnostics. This puts Tanzania at a high risk of importing substandard and falsified medical devices and diagnostics because it is almost a net importer of these goods which calls for immediate promotion of local production capacity and strengthening regulation of imports.

In view of the above facts, the Authority will enhance its capacity for regulation of medical devices and diagnostics and shall continue facilitating domestic production of these products in order to reduce dependence on importation.

3.10.5.2 Strategies

(a) Strengthen and streamline systems for regulation of medical devices and diagnostics; and

(b) Facilitate and support domestic manufacturers dealing in medical devices and diagnostics to comply with legal and regulatory requirements.

3.10.5.3 Targets

(a) Premises dealing in medical devices and diagnostics inspected by June, 2026;

(b) Surveillance and vigilance of medical devices and diagnostics conducted by June, 2026; and

(c) Medical devices and diagnostics registered by June, 2026.

3.10.5.4 Key Performance Indicators

Outcome Indicators

(a) Percentage of applications for registration of medical devices and diagnostics approved/rejected within a specified time period (as per CSC)

(b) Percentage of PMS medical devices and diagnostics complying with performance requirements;

(c) Percentage of domestic medical devices and diagnostics manufacturing facilities complying with the quality system; and

(d) Percentage of inspected medical devices and diagnostics outlets complying with requirements.

Output Indicators

(a) Percentage of product applications for registration of medical devices and diagnostics assessed within specified time period as per CSC;

(b) Percentage of product applications for notification of medical devices and diagnostics assessed within specified time period as per CSC;

(c) Percentage of applications for registration of premises for medical devices and diagnostics processed within specified time period as per CSC;

(d) Percentage of registered outlets for medical devices and diagnostics inspected;

(e) Percentage of planned PMS samples for medical devices and diagnostics collected;

(f) Percentage of domestic medical devices and diagnostics manufacturing facilities inspected for the quality management system;

(g) Percentage of overseas manufacturing facilities for medical devices and diagnostics inspected for the quality management system;

(h) Percentage of received import/ export applications processed;
(i) Percentage of approved consignments inspected at the PoEs;
(j) Percentage of large hospitals equipment assessed through PMS;
(k) Percentage of planned incidents reports received;
(l) Percentage of planned incidents reports assessed;
(m) Percentage of planned field safety reports received; and
(n) Percentage of received field safety reports assessed;

3.10.6 Strategic Objective F: Control of Tobacco Products Strengthened

3.10.6.1 Rationale

In recognizing the health risks associated with the use of tobacco products and to separate tobacco farming and regulation of products, the Tobacco Products (Regulation) Act, Cap, 121 was enacted in 2003. The Act provided for regulation of the manufacture, distribution, sale, promotion, advertising and use of tobacco products. To further streamline and interpret the regulatory process, the Tobacco Products Regulations were developed in 2014. Nevertheless, despite the existence of the Act and Regulations in force, the institutional framework to oversee the national control and coordination mechanism was not established. In view of this, TMDA was mandated to regulate tobacco products vide Government Notice No. 360 of 30th April, 2021.

Tanzania's Global Adult Tobacco Survey (GATS) was conducted in 2018 by the National Bureau of Statistics (NBS) and the Office of Chief Government Statistician of Zanzibar (OCGS), in collaboration with the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) and the Ministry of Health Zanzibar (MOHZ). The survey which involved 2.6 million adult respondents, sought to provide statistics at the national level on adult tobacco use and important tobacco control measures that are comparable across the country. The survey findings show that 14.6% and 3.2% of men and women, respectively were on tobacco use in Tanzania. These statistics demonstrate the magnitude of the problem and thus call for intervention to regulate these products.

The Authority will regulate the use of tobacco products by

controlling their manufacturing, distribution, promotion, advertisement and sale of tobacco products. Since tobacco products have no reported health benefits, the main focus will be to minimize their use and public exposure.

3.10.6.2 Strategies

Establish and strengthen systems for control of usage of tobacco products

3.10.6.3 Targets

(a) Premises dealing in tobacco products registered and inspected by June, 2026;
(b) Surveillance and vigilance of tobacco products conducted by June, 2026; and
(c) Tobacco products notified/registered by June, 2026.

3.10.6.4 Key Performance Indicators

Outcome Indicators

(a) Percentage of applications for notification/registration of tobacco products approved/rejected within a specified time period (as per CSC);
(b) Percentage of surveillance samples for tobacco products complying with safety standards; and
(c) Percentage of domestic tobacco manufacturing facilities complying with requirements.

Output Indicators

(a) Percentage of product applications for notification/registration of tobacco products assessed;
(b) Percentage of applications for registration of premises dealing in tobacco products processed;
(c) Percentage of planned surveillance samples for tobacco products collected;
(d) Percentage of domestic tobacco products manufacturing facilities inspected; and
(e) Percentage of planned public places with designated smoking areas.

3.10.7 Objective G: Laboratory Services Improved

3.10.7.1 Rationale

Section 14(1) of the Tanzania Medicines and Medical Devices Act, Cap 219 provides for establishment of a laboratory under TMDA to cater for analysis of medicines, medical devices, diagnostics, complementary products 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 Authority has three laboratories located in Dar es Salaam, Mwanza and Dodoma. The laboratories are well equipped with state of the art equipment and facilities whereby the Dar es Salaam laboratory has been pre-qualified by the WHO.

Despite the international recognition of TMDA laboratories, more interventions are required to build capacity of staff in conducting analysis of regulated products especially medical devices, diagnostics, biocidal and tobacco products. Further, TMDA needs to acquire more modern equipment to cope with the changing technology. End term evaluation report shows that the capacity to test received medicines and medical devices samples grew from 96% (2017/18) to 100% (2020/21). Similarly, compliance to Client Service Charter (CSC) for the time to release laboratory results improved from 64% to 129% whereas level of customers' satisfaction for laboratory services rose from 63% to 105% in the same period under review.

The laboratories are mainly constrained by inadequate staff for specialized area such as testing of medical devices, diagnostics and tobacco products, shortage of local suppliers of reagents and equipment, lack of local capacity for equipment maintenance and technical services as well as centralized clearance services of imported laboratory goods.

The Authority will continue to improve the laboratory capacities in order to acquire accreditation and sustain pre-qualification status for Dar es Salaam. Likewise, efforts are underway to accredit and pre-qualify the other two laboratories. More efforts will be deployed to market the laboratory services to attract customers beyond Tanzania especially from member countries of regional blocs such as East African Community (EAC), Southern African Development Community (SADC) and other countries.

3.10.7.2 Strategies

(a) Decentralize laboratory services to zone offices;

(b) Ensure availability of laboratory consumables and maintenance of equipment;

(c) Acquire accreditation under ISO/IEC 17025 Standard and sustain WHO prequalification for Dar es Salaam laboratory;

(d) Acquire accreditation and prequalification for Mwanza and Dodoma laboratories; and

(e) Establish laboratories for testing vaccines, selected diagnostics, herbal medicines, biocidal and tobacco products.

3.10.7.3 Targets

(a) TMDA laboratories strengthened by June, 2026;

(b) Samples of medicines, medical devices, diagnostics, complementary and tobacco products tested by June, 2026;

(c) Laboratories for testing biocidals, herbal medicines and tobacco products designated and operationalized by June, 2026; and

(d) Operational and applied researches on regulatory functions conducted by June, 2026.

3.10.7.4 Key Performance Indicators

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) ISO/IEC 17025 accreditation for Dar es Salaam and Mwanza laboratories attained and sustained;

(d) WHO pre-qualification for Dar es salaam laboratory sustained;

(e) WHO pre-qualification for Mwanza and Dodoma laboratories attained and sustained; and

(f) Percentage of planned researches published.

Output Indicators

(a) Percentage of regulatory samples of medicines, medical devices, diagnostics and complementary products tested;

(b) Percentage of research applications received and processed;

(c) Number of analytical methods accredited for Dar es Salaam and Mwanza laboratories;

(d) Percentage of received non-regulatory samples from external customers tested;

(e) Number of medicines samples screened at all Quality Assurance (QA) Centers; and

(f) Percentage of laboratory equipment calibrated/maintained as per approved schedule.

3.10.8 Strategic Objective H: Public Education and Customer Services Improved

3.10.8.1 Rationale

Public education and customer services are critical components of the organizational performance and efficiency. This is because organizational performance and efficiency in this case TMDA to a big extent depend not only on the perceptions but also the interactions, behaviours and actions of the general public and customers/ stakeholders. With this regard, it is expected that improved public education and customer services will have a direct influence on compliance to law and rational use of regulated products.

TMDA Service Delivery Survey report, 2020 indicates that internal and external customers' satisfaction rate in 2020 stands at 75% and 80% respectively, whereas the level of public awareness on TMDA functions was 47%. Further, results from the end - term evaluation of the previous Strategic Plan noted inadequate Institutional branding and visibility, lobbying, advocacy, stakeholders' participation and engagement.

In order to address the above observed issues the Authority plans to improve public education and customer services by reviewing the previous targets in order to improve areas with low performance. The main benefit of improved public education and customer services is raised public awareness, customer satisfaction, and organizational reputation, reduction of enforcement costs and ultimately protection and promotion of public health.

3.10.8.2 Strategies

(a) Enhance implementation of comprehensive Communication and Customer Service Strategy;

(b) Improve stakeholders' engagement and participation in matters related to TMDA functions;

(c) Monitor implementation of the CSCs; and

(d) Provide public education and awareness programmes on effects and reduction of tobacco use among members of the public.

3.10.8.3 Targets

(a) Communication and Customer Service Strategy reviewed and implemented by June, 2026;

(b) Public awareness on TMDA functions and customer satisfaction raised by June, 2026;

(c) Anti-smoking awareness programmes developed and implemented by June, 2026; and

(d) Stakeholders' engagement and participation plan developed and implemented by June, 2026.

3.10.8.4 Key Performance Indicators

Outcome Indicators

(a) Percentage level of general public awareness on TMDA functions;

(b) Percentage level of external and internal customer satisfaction;

(c) Level of general public awareness on whistleblowing policy;

(d) Proportion of the population understanding health hazards of smoking; and

(e) Proportion of smokers quitting smoking.

Output Indicators

(a) Percentage of planned types of IEC materials developed, printed and disseminated;

(b) Percentage of employees sensitized on customer care, core values and code of ethics and conduct;

(c) Percentage of received customer complaints attended and resolved;

(d) Number of SDS conducted;

(e) Percentage implementation of the public education and customer service strategy;

(f) Percentage compliance to external Clients' Service Charter;

(g) Percentage compliance to internal Clients' Service Charter;

(h) Number of stakeholders sensitized on whistleblowing policy; and

(i) Percentage of received whistleblower alerts and concerns attended and closed.

3.10.9 Strategic Objective I: Institutional Capacity to Deliver Regulatory Services Enhanced

3.10.9.1 Rationale

Availability of adequate funding, competent human resources, infrastructures, working facilities and systems are important factors for performance of any organization including regulatory functions. For the past two (2) years, the Authority managed to increase internal revenue collection from 30.21 billion in 2019/20 to 31.38 billion in 2020/21, which is equivalent to 4% increase. In the same period the Authority received Unqualified Audit reports and staff retention rate increased from 98% in 2019/20 to 100% in 2020/21.

Despite the mentioned notable achievements, TMDA still faces shortage of staff at zone offices and ports of entry, and working facilities including office space as the six (6) zone offices are still in rented buildings. Further the idea of opening TMDA offices in zones was to extend services closer to the people, however these offices have not been able to serve the respective regions effectively which calls for more expansion. Moreover, the additional scope of regulatory functions which has recently included tobacco products justifies the need for additional resources.

For TMDA to remain relevant and vibrant there is a need to improve its capacity to discharge the mandated functions through broadening the scope of revenue sources, cost control, recruitment of more staff, construction of new office buildings, acquiring equipment, enhance monitoring and evaluation, vigorous risk and quality management and ICT usage in service provision.

3.10.9.2 Strategies

(a) Provide adequate human and financial resources, working facilities and tools;
(b) Strengthen financial and procurement management systems;
(c) Enhance human resource capacity, development and utilization;
(d) Strengthen zone offices' operations;
(e) Strengthen capacity for Monitoring and Evaluation;
(f) Strengthen ICT usage, Quality and Risk Management;
(g) Improve legal and administrative services; and
(h) Engage and maintain regional collaboration and international harmonization initiatives for regulated products.

Targets

(a) Infrastructures, working facilities and tools provided and maintained by June, 2026;
(b) Annual procurement plans developed and implemented by June, 2026;
(c) Internal Audit plans developed and implemented by June, 2026;
(d) Financial resources properly managed by June, 2026;
(e) Human resources properly managed by June, 2026;
(f) Professional and career development programmes implemented by June, 2026;
(g) Zone offices operations coordinated by June, 2026;
(h) Planning, budgeting and their implementation coordinated by June, 2026;
(i) Institutional plans and programmes monitored and evaluated by June, 2026;
(j) Quality and Risk Management Systems improved by June, 2026;
(k) ICT usage enhanced by June, 2026;
(l) Legal services timely provided by June, 2026;
(m) Administrative services provided by June, 2026; and
(n) Regional and international collaboration and harmonization initiatives for regulated products facilitated by June, 2026.

3.10.9.3 Key Performance Indicators

Outcome Indicators: -

(a) Percentage budgetary contribution from internal sources;
(b) Unqualified Audit Report attained;
(c) Percentage of staff retention;
(d) Position of TMDA in administration and human resource management in the public service;
(e) Percentage of cases decided in favor of TMDA;
(f) ISO certification sustained;

(g) OSHA certification acquired and sustained at all TMDA offices; and
(h) Maturity level four (4) or WHO Listed Authorities certification attained.

Output Indicators

(a) Percentage implemention of planned work plans;
(b) Percentage of projected revenue collected;
(c) Percentage implementation of the procurement plan;
(d) Percentage implementation of the HR plan;
(e) Percentage of planned quality audits conducted;
(f) Percentage of planned internal audits conducted;
(g) Percentage of processes and procedures reviewed;
(h) Completion level of construction of TMDA Offices in Mbeya;
(i) Percentage of service delivery processes automated;
(j) Percentage mitigation of identified risks;
(k) Percentage of staff sensitized on risk management;
(l) Percentage implementation of training programme;
(m) Revised Scheme of Service and Salary Structure in place;
(n) Revised Internal Staff and Financial Regulations in place; and
(o) Percentage of TMDA inspectors trained on investigation and evidence gathering.

3.11 Financial Sustainability Strategy

This section presents strategy for financing implementation of this Strategic Plan and outlines various sources for resource mobilization and sustainability as described in sub-sections 3.11.1 – 3.11.4.

3.11.1 Fees and Charges

Fees and charges constitute the major source of revenue in financing TMDA budgets. The Authority will strengthen collection of fees and charges for service rendered as mandated by the TMDA Fees and Charges Regulations, 2015 and its amendments. Automation of service delivery processes and use of Government Electronic Payment Gateway (GePG) will facilitate optimal collection of revenues.

3.11.2 Government Subvention

TMDA budget will also be funded by the central Government through subvention of 55.1% of Personnel Emolument (PE) budget. This arrangement is expected to be sustained till the end of this Plan.

3.11.3 Development Partners

The Authority will continue to collaborate with development partners in discharging regulatory functions. It is anticipated that they will financially and technically support some of the interventions. Various project proposals will be developed to solicit funding from Development Partners. The potential partners include the Global Fund, World Bank, European Developing Countries Clinical Trials Partnership (EDCTP), WHO, Bill and Melinda Gates Foundation (BMGF), Clinton Foundation, UNICEF, GIZ, JICA and AMREF International, USAID and UNIDO.

3.11.4 Other Sources

Other sources of collections include office rental fee from its buildings in Mwanza and Namanga.

CHAPTER 4

MONITORING AND EVALUATION PLAN

4.1 Introduction

Monitoring and evaluation plan is a critical element for effective implementation of intervention including strategic plans. This chapter therefore, provides guidance and roadmap on how execution of this Strategic Plan will be monitored and evaluated. The chapter consists of overall Development Objective which is basically the general impact of TMDA interventions; the beneficiaries of services; Results Chain; the Monitoring and Evaluation Framework, planned reviews, reporting plan and evaluation studies. The M&E plan is expected to answer the following key questions: -

(a) Information needs: What, who and why?;

(b) Information source: Methods, frequency, location of data to be collected?;

(c) Who is responsible for Monitoring, Evaluation and Reporting (MER)?;

(d) What indicators should be used to measures and Monitor each stage of the Strategic Plan implementation?;

(e) How should the information be collected?;

(f) How to assess the perception of stakeholders on TMDA's services?;

(g) How and when to communicate the findings to different stakeholders?;

(h) How effective and efficient was the Plan?; and

(i) How will benefits and changes/impacts of the Strategic Plan be assessed?.

4.2 Development Objective

The overall objective of TMDA is to ensure safety, quality and effectiveness of medicines, medical devices and diagnostics. This goal represents the highest level of results envisioned by TMDA.

4.3 Beneficiaries of 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 institutions that receive technical advice and information from TMDA.

4.4 Results Chain

The results chain is an explicit expression of the different levels of results expected from particular strategies and in this case, the Fifth TMDA Strategic Plan. It shows linkage between the input, activities, outputs, outcomes and impacts. The basic assumption is that, there is causal linkage in the various elements of the chain i.e., utilization of resources will lead to accomplishment of the activities, which will lead to achievement of outputs. Attainment of targets will lead to achievement of objectives/outcomes that will contribute to realization of TMDA's development objective (impact). This chain of results justifies TMDA use of resources for various interventions and thus contributes to the protection and promotion of public health and national development at large. Development of this result chain is based on the nine (9) Strategic Objectives as illustrated in **Figure 2**. A Detailed linkage of different levels of the result chain is detailed in the Strategic Plan Matrix attached as **Annex III.**

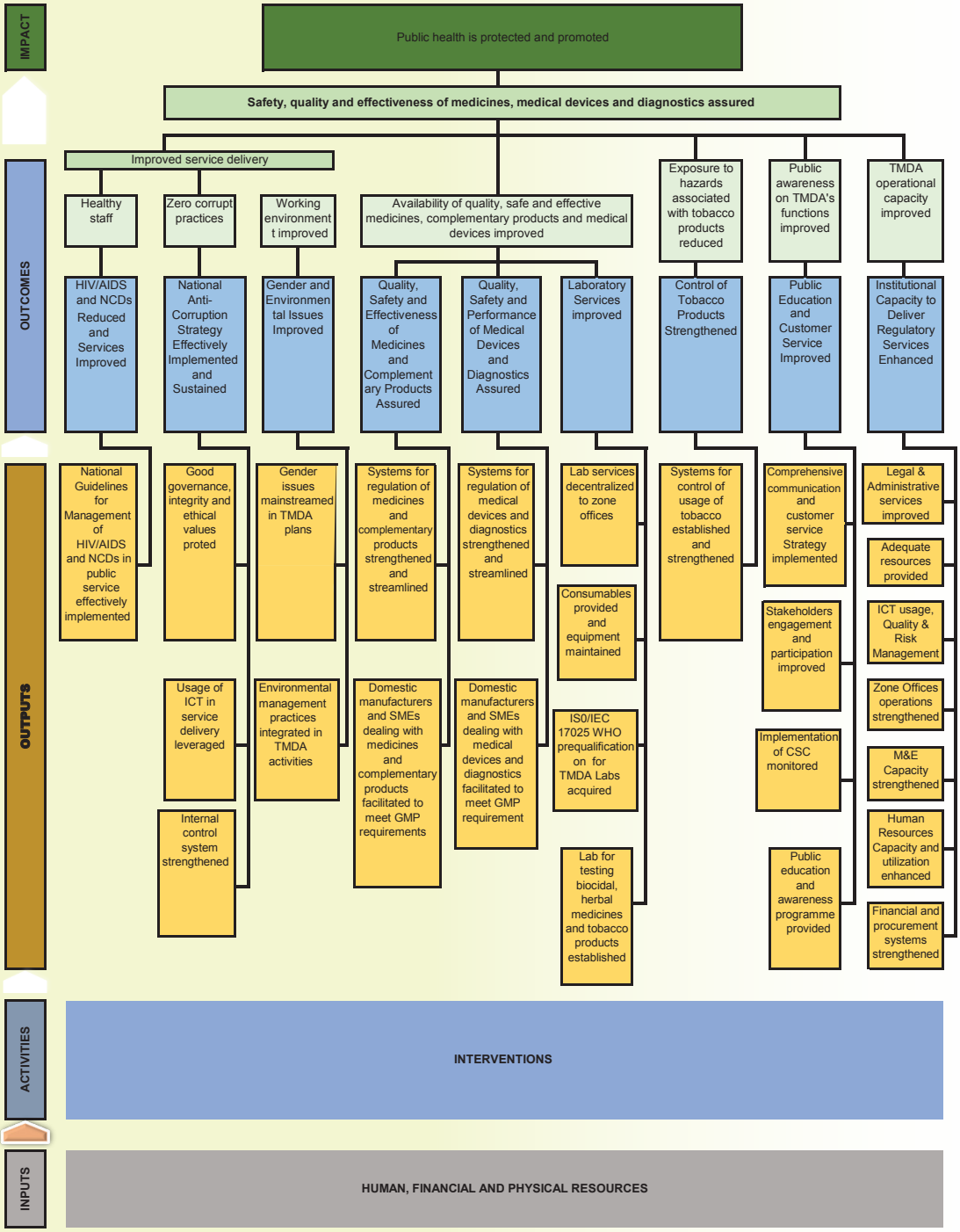

Figure 2: Results Chain for the fifth TMDA Strategic Plan

4.5 Relationship between Results Chain and Reporting Arrangements

4.5.1 Level 1: Inputs

The first level of the Results Chain tracks the allocation and use of resources in various activities. Resources availability will be reviewed on weekly, fortnightly or monthly basis and will be reported on respective implementation reports. At this level, indicators will focus on funds and number of human resources available for various tasks, amount of time dedicated to tasks by staff, information flow between various levels, time spent on resolving problems, quality and timeliness of decisions as well as predictability of resource flows.

4.5.2 Level 2: Activities

The second level of the Results Chain focuses on realization of activities and linkage between activities and outputs. At this level, indicators will focus on activities programming and timeliness of implementation. Activities will be reviewed on weekly and monthly basis and will be reported upon their completion in the same period. The reports will focus on quality and timeliness of the activities implemented and will inform corrective action if the activities are not being conducted on time, to the expected quality and if are not contributing to outputs.

4.5.3 Level 3: Outputs

The third level of the Results Chain tracks the realization of outputs that are produced and attributed solely to TMDA activities. The outputs at this level will be measured by output Indicators and milestones. Data collection and analysis will be done on quarterly, biannual and annual basis. The reports will focus on how the outputs produced are delivering the outcomes and will inform corrective action if the outputs are not being delivered effectively or are not contributing to outcomes.

4.5.4 Level 4: Outcomes

The fourth level tracks realization of intermediate outcomes specified for each objective, though achievement of these outcomes may not be attributed to TMDA alone as there will be several players contributing to these outcomes. These intermediate outcomes will be measured through outcome indicators whose data

collection and analysis be done during annual and end-term reviews. Indicators at this level are reported through the annual, self-assessment and end term evaluation reports.

4.6 M&E Framework

M&E Framework for TMDA Strategic Plan consists of indicator name, baseline and indicator target values, data collection tools and methods of analysis, indicator reporting frequencies and the officers who will be responsible for data collection. It spells out a set of indicators that will be used to measure performance /results at all levels of the Strategic Plan implementation and results hierarchy i.e., inputs, activities, outputs, outcomes and impacts. Details of the Result Framework for output-based indicators and outcome-based indicators are presented in Annex IV and V respectively.

4.7 Monitoring, Reviews and Evaluation Plan

M&E Framework establishes the basis on how interventions will be executed during implementation of the Strategic Plan will be monitored leading to accomplishment of the Development Objective. It also demonstrates how various interventions will be monitored, what types of reviews will be conducted over time, and what types of evidence-based evaluation studies will be conducted to demonstrate that the interventions have either led to or are leading to the achievement of the intended outcomes. Finally, it shows how the indicators and progress of various interventions will be reported and to which stakeholders.

4.7.1 Reporting Plans

This subsection details both the internal and external reporting plans. The reporting plan cycle 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.

4.7.1.1 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 MoH, MoFP, OTR, 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**.

Table 11: Internal Reporting Plan

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

4.7.1.2 External Reporting Plan

The external reporting plan is for those reports intended for public consumptions which include Annual Audited and Performance Reports. The reports will be prepared at the end of each financial year in accordance with the TMDA guidelines, standards (IPSAS) and other statutory requirements as directed by Government. Such reports will be disseminated through various platforms such as website (www.tmda.go.tz), public exhibitions and trade fairs.

4.7.2 Planned Reviews

Five (5) formal reviews will be conducted during the implementation of the Strategic Plan. The Management will lead the review process. The reviews will track progress on achievement of targets, identify implementation problems/challenges and use the findings to adjust implementation strategies whenever necessary in the subsequent years. The reviews will focus on the tracking indicator targets specified in Annex IV and V. Likewise, the reviews will provide necessary information for the Management and MAB on whether a particular milestone is on track, off track or at risk.

Director General will be generally responsible for the execution and completion of the Strategic Plan. The milestones which will be monitored and reported in the course of implementation of the SP are presented in **Table 12**.

Table 12: Planned Reviews Matrix

S/N	Objective Code	Milestones	Expected Accomplishment Date	Responsible Person
1	C	Construction of incinerator at Kibaha	December, 2022	DMC
2		Construction of incinerator in Dodoma	June, 2023	DMC
3	D & E	Strategy for promotion of domestic manufacturing of medicines, medical devices and diagnostics developed	December, 2022	DMC
4	F	Tobacco products registration/ notification commenced	December, 2022	DMC
5		Public education and awareness programme on tobacco products control developed	June, 2023	MCPE
6	G	Accreditation for medical devices laboratory in Dar es Salaam	June, 2024	DLS
7		Accreditation and Prequalification of Mwanza laboratory	June, 2025	DLS
8	H	Service Delivery Survey (SDS) conducted	June, 2024	MCPE
9	I	Scheme of service and salary structure reviewed	June, 2024	DBS
10		Internal Staff and Financial Regulations reviewed	June, 2023	DBS
11		Fees and charges Regulations reviewed	June, 2023	DBS
12		Office buildings in Mbeya constructed and equipped	June, 2026	DBS
13		Maturity level four (4) or WLA certification attained	June, 2026	MQR

4.8 Evaluation Studies

This consists of different evaluation studies to be carried out during the entire life time of the Strategic Plan, description of each study, evaluation questions, methodology, time frame and the responsible person. Four (4) 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 **ANNEX III**).

Further, endline evaluation to be conducted during the fifth year will focus on determining whether or not the planned outcomes over the five years period have been achieved against the set targets, and if not, what could have been the reasons for the under achievement. The evaluation will also assess the extent to which achieved targets have contributed towards realization of five year expected outcomes as well as challenges and lessons learnt over the five years period. Evaluation Plan Matrix for execution of the SP is detailed in **Table 13.**

Table 13: Evaluation Plan Matrix

S/N	Evaluation Study	Description	Evaluation Study Questions	Methodology	Timeframe	Responsible Person
1.	Baseline Studies	The studies aim at collecting baseline data which will form basis for the evaluation process	What are the baseline values for indicators listed in the Monitoring Plan I & II?	Review of relevant documents and interviews with Key Informants	January, 2022	DBS
2.	SDS	SDS measures level of public awareness on TMDA functions and customer satisfaction	(a) To what extent is the general Public aware on TMDA functions? (b) To what extent are TMDA customers satisfied? (c) Are services standards being met as per CSC?	Interviews and questionnaires	December, 2024	MCPE
3.	Institutional self-assessment completed	The assessment intends to determine institutional performance	Has TMDA achieved its objectives after three years of SP implementation?	Desk reviews, interviews and questionnaires	June, 2024	DBS
	End term evaluation	The evaluation will measure the extent to which the Authority has achieved its objectives. It is also expected to assess the success and challenges encountered during the implementation of the SP	(a) Are the Strategic Objectives in line with the National Development Plans/Policies? (b) Have the Strategic Objectives been achieved? (c) What were the challenges/gaps encountered in the course of implementing the SP?	Interviews, Questionnaires and desk reviews	September, 2025	DBS

S/N	Evaluation Study	Description	Evaluation Study Questions	Methodology	Timeframe	Responsible Person
			(d) What lessons can be learnt from the SP implementation? (e) How efficient has TMDA used its resources in contributing to the achievement of the Strategic Objectives? (f) How efficient was the SP in enhancing resource mobilization (capacity) and management? (g) Can TMDA sustain its operations from its financial internal sources? (h) Did the SP enable TMDA to sustain its operations?			

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 achieve.
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 realization 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.
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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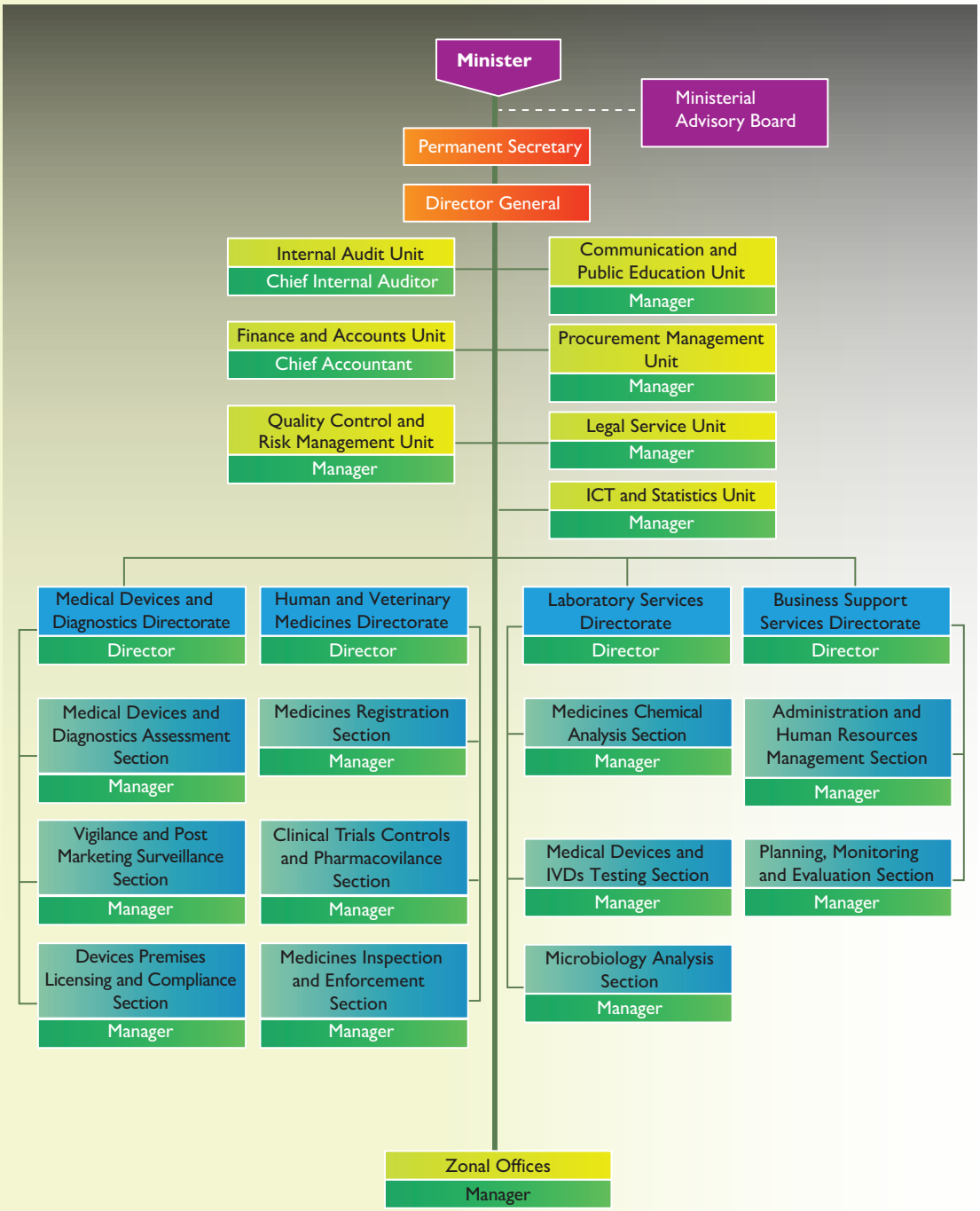
ANNEXES

Annex I: TMDA Organizational Structure (Approved by the President of United Republic of Tanzania on 28th December, 2021)



Annex II: Key issues (priority areas) in the National Development Plans/Policies that can be addressed in the fifth TMDA Strategic Plan

S/N	ISSUE/PRIORITY ARES	SECTION INCLUDING PAGE NUMBERS.	QUOTES
1.0	**The Tanzania Vision 2025**		
1.1	High quality livelihood: - (a) Gender mainstreaming (b) Quality health care	Section 1.2.1 (pg.3)	By 2025, racial and gender imbalances will have been addressed such that economic activities will not be identifiable by gender or race. All social relations and processes which manifest and breed inequalities, in all aspects of society (law, politics, employment, education, culture), will have been reformed.
		Section 3.1 (Pg.12)	(c) Gender equality and empowerment of women in all socio-economic and political relations and culture (d) Access to quality primary health care for all
1.2	Good governance	Section 1.2.3 (Pg.4)	By 2025, good governance should have permeated the national economic structure thereby ensuring a culture of accountability, rewarding good performance and effectively curbing corruption and other vices in society.
1.3	Good governance and the Rule of Law	Section 3.2 (Pg. 13)	Absence of corruption and other vices
2.0	**Five Years Development Plan III (2021/22 – 2025/26)**		
2.1	Key Interventions include; (ii) Ensure availability of medicine, medical supplies, reagents, vaccine and pharmaceutical equipment	Section 5.5.2 (Pg. 115)	FYDP III seeks to strengthen health management systems, service availability and delivery. The plan prioritizes the resolution of quality challenges in health service.
2.2	Good Governance	Section 4.5.2. (Pg. 61 & 62)	FYDP III will bank on the trust and public confidence that has been inspired by concrete good-governance and improvements in public services during the implementation of FYDP II. Firm steps taken during the period include stern court and other actions against corruption; removal of ghost workers from public service; Increased discipline at workplaces, including in the use of public finances on concrete projects and social programmes rekindled public goodwill.

S/N	ISSUE/PRIORITY ARES	SECTION INCLUDING PAGE NUMBERS.	QUOTES
2.3	Guiding Norms and Values: Application of digital capacities to curb corruption practices including minimizing corruption-prone person-to-person contacts in the course of such facilitation.	Section 4.3 (Pg. 55 & 56)	The FYDP III recognizes the paramount of national unity and social cohesion, rule of law, respect for human rights, equitable society and peace and security as prerequisites for sustainable and inclusive socio-economic development. Tied to these values are good governance, continued fight against corruption and proper use of the nation's natural and financial resources.
2.4	Establishing enabling environment for investment	H.E. Samia Suluhu Hassan Key note: Pg. vi	Efforts to improve the business and investment enabling environment will focus on shortening procedures and easing regulations for starting and operating businesses; simplifying investment procedures by establishing one stop service centers to reduce bureaucracy and corruption; reducing barriers for investors including work permits for specialized professionals;
2.5	Social Development (vii) Governance interventions (anti-corruption) (viii) Gender mainstream and (ix) Environment Protection	Section 4.5.4. (Pg. 71 & 72)	(vii) Public administration: to provide efficient services and reduce bureaucracy. Broad intervention areas to include law and order; specific governance interventions (anti-corruption) and peace and security. (viii) Gender mainstreaming: including, at the minimum, measures that address gender inequalities against women and girls; (ix) Protection of environment and climate change mitigation: including, at the minimum, proper land use and management, protection of water sources, use of water harvesting technologies, afforestation programmes, community-based natural resource management, enforcement of legislation against all forms of pollution, and against harmful extractive techniques; measures to mitigate against environmental disasters.
2.6	Manufacturing: Commercialization and Scaling-Up Technology (Design, Development and Commercialization of Medical Equipment)	Section 5:3:2 (Pg. 91-92)	Increasing demand for medical equipment and tools is an investment opportunity for local and Foreign entrepreneurs. On that basis, FYDP III will focus on creating an enabling environment to attract investment and technology transfer to this key sector.

S/N	ISSUE/PRIORITY ARES	SECTION INCLUDING PAGE NUMBERS.	QUOTES
3.0	**The National Health Policy**		
3.1	Mission and vision: (Improve health and health status of all Tanzanians)	Page 8	To have a healthy and prosperous society that contributes fully to the development of individuals, communities and the nation.
			Providing essential health services with geographical equity, acceptable quality standards that are affordable and sustainable.
3.2	Non-Communicable Diseases	Page 8 section 4.3.1(iii)	Prevent and control communicable and non- communicable diseases.
3.3	Public Education and awareness	Page 8 section 4.3.1(v)	Create awareness to citizens on responsibility for caring for their own health, that of their families and society at large.
3.4	Public Private Partnership/ Engagement	Page 9 section 4.1.3 (vi)	Improve partnership between public sector, private sector, religious institutions, civil society and community in provision of health services.
3.5	Capacity building strengthening	Page 9 section 4.1.3 (vii)	Plan, train, and increase the number of competent health staff.
4.0	**Health Sector Strategic Plan V (2021 – 2025)**		
4.1	**Mission and vision:** (Improve Health of the community)	Page xii section 2…. Mission and Vision	**The vision:** "To have a healthy and prosperous society that contributes fully to the development of individuals and the nation". **Mission:** "The health sector will provide sustainable health services with standards that are acceptable to all citizens without financial constraints, based on geographical and gender equity"
4.2	Improve Diagnostic services: quality assurance and accreditation systems for laboratory services	Page xv……...Paragraph 3	Effective and up-to-date diagnostic services, with equipment, supplies and consumables, will be created to support a functional referral system for health services. Government will maintain external quality assurance and accreditation systems for laboratory services.
4.3	Gender Mainstreaming in governance and human resource development and management.	Page xii Section 2….. last paragraph	HSSP V will promote gender equality not only in service delivery for the population, but also in governance and human resource development and management.
4.4	Awareness raising	Page xvii… Last paragraph	The MOH will stimulate awareness-raising and competency development among health staff at all levels, to include gender issues in health services and policies, also in pregraduate training. The health sector will enhance gender equality in decision making bodies.

S/N	ISSUE/PRIORITY ARES	SECTION INCLUDING PAGE NUMBERS.	QUOTES
4.5	Community engagement	Page xiii Section 2……. paragraph 1	HSSP V aims for improved health of the population through community empowerment and engagement through responsive community health systems. The community-based health service strategy will be implemented and community health workers and volunteers will be embedded in an integrated system aiming at health and wellbeing.
4.6	Health Education/Public Health	Page xiii Section 2……. paragraph 2	in collaboration with other sectors and private partners, community awareness on health and health literacy will be strengthened, leading to behaviors that improve nutrition, healthy lifestyles and health seeking behavior. Vulnerable groups in particular will be supported.
4.7	Environmental Health	Page xiii Section 2……. paragraph 4	Environmental Health is becoming increasingly important at home with safe housing, safe water and safe food, protection against pollution and hazardous products.
4.8	Infectious diseases	Page xiii Section 2……. paragraph 9	The health sector will achieve reduced morbidity and mortality due to communicable diseases through preventive measures, early detection and early treatment for communicable diseases of public health importance. In the coming years it is important to broaden the perspective of communicable diseases control beyond malaria, HIV and tuberculosis. Upcoming epidemics threaten the country
4.9	Non-Communicable Diseases (NCDs)	Page xiii…… last paragraph	The health sector aims to reduce morbidity and mortality from NCD. Increased attention is necessary due to the increase in life expectancy, nutrition, and changes in lifestyle.
4.10	Human Resources for Health	Page xiii…… paragraph 6	The government will continue to oversee and coordinate the training of human resources for health.
4.11	Partnership (Intersectoral collaboration)	Page xvii	In implementing this strategy, the MOH will collaborate with other ministries, institutions, religious organizations, social organizations, the private sector, and development partners. This collaboration will be intensified at decentralized levels during HSSP V.
4.12	Partnership/Engagement (International collaboration)	Page xvii… Paragraph 9	Government will collaborate with various countries and international organizations on matters of health that are of global and national interest. Government will coordinate with development partners on health sector plans that focus on national priorities.

Annex III: Strategic Plan Matrix

S/N	Strategic Objective Code	Strategic Objective Description	Strategies	Targets	Service outputs	Key Performance Outcome Indicators	Responsible Person
1	A	HIV/AIDS and Non-Communicable Diseases (NCDs) Reduced and Services Improved	Effective implementation of the National Guidelines for Management of HIV/AIDS and NCDs in public service in force.	Awareness, care and support on HIV/AIDS and NCDs to TMDA staff provided by June, 2026	(a) Increased awareness on HIV, AIDS and NCDs among TMDA staff; (b) Reduction of new cases of NCDs; (c) Improved health status for HIV/AIDS and NCDs patients	(a) Percentage of sensitized staff who turn up for voluntary health check-ups for HIV/AIDS; and (b) NCDs incidence rate among TMDA staff.	DBS
2	B	National Anti-Corruption Strategy Effectively Implemented and Sustained	(a) Promote good governance, integrity and ethical values; (b) Leverage ICT usage in service delivery; and (c) Strengthen internal control systems	(a) Anti-corruption Strategy and Good Governance enforced to TMDA staff by June, 2026; and (b) Public Service Code of Ethics and Conduct instilled to staff by June, 2026.	(a) Improved staff awareness on prevention and combating of corruption. (b) Zero corruption incidences; and	(a) Level of staff awareness on corruption prevention; and (b) Number of corruption allegations against TMDA staff.	DBS

S/N	Strategic Objective Code	Strategic Objective Description	Strategies	Targets	Service outputs	Key Performance Outcome Indicators	Responsible Person
3	C	Gender and Environmental Issues Improved	(a) Mainstream gender issues in Authority plans; and (b) Integrate environment management practices in TMDA activities.	(a) Women staff empowered at all levels by June, 2026; (b) Infrastructures to support physically challenged persons provided by June, 2026; and (c) Facilities for handling and disposal of waste and unfit products in place by June, 2026.	(a) Improved proportion of women at decision making level; (b) Improved gender mainstreaming in all TMDA plans; (c) Improved working conditions; and (d) Improved environmental conservation	Proportion of women at managerial positions.	DBS
4	D	Quality, Safety and Effectiveness of Medicines and Complementary Products Assured;	(a) Strengthen and streamline systems for regulation of medicines and complementary products; and	(a) Premises dealing in medicines and complementary products inspected by June, 2026; (b) Surveillance and vigilance of medicines and complementary products conducted by June, 2026;	Improved compliance to quality and safety requirements of medicines and complementary products	(a) Percentage of applications for registration of medicines and complementary products approved/ rejected within a specified time period (as per CSC);	DMC

S/N	Strategic Objective Code	Strategic Objective Description	Strategies	Targets	Service outputs	Key Performance Outcome Indicators	Responsible Person
			(b) Facilitate and support domestic manufacturers and SMEs dealing in medicines and complementary products to comply with legal and regulatory requirements.	(c) Medicines and complementary products registered by June, 2026; and (d) Clinical trials approved and inspected by June, 2026.		(b) Percentage of PMS human and veterinary medicines complying with quality requirements; (c) Percentage of domestic pharmaceutical manufacturing facilities compliant with GMP requirements; (d) Percentage of clinical trials compliant with GCP and GCLP requirements; and (e) Percentage of inspected medicines selling outlets complying with requirements.	

S/N	Strategic Objective Code	Strategic Objective Description	Strategies	Targets	Service outputs	Key Performance Outcome Indicators	Responsible Person
5	E	Quality, Safety and Performance of Medical Devices and Diagnostics Assured	(a) Strengthen and streamline systems for regulation of medical devices and diagnostics; and (b) Facilitate and support domestic manufacturers dealing in medical devices and diagnostics to comply with legal and regulatory requirements.	(a) Premises dealing in medical devices and diagnostics inspected by June, 2026; (b) Surveillance and vigilance of medical devices and diagnostics conducted by June, 2026; and (c) Medical devices and diagnostics registered by June, 2026.	Improved compliance to quality and safety requirements of medical devices and diagnostics	(a) Percentage of applications for registration of medical devices and diagnostics approved/rejected within a specified time period (as per CSC); (b) Percentage of applications for notification of medical devices and diagnostics approved/rejected within a specified time period (as per CSC); (c) Percentage of PMS medical devices and diagnostics complying with performance requirements;	DMD

S/N	Strategic Objective Code	Strategic Objective Description	Strategies	Targets	Service outputs	Key Performance Outcome Indicators	Responsible Person
						(d) Percentage of domestic medical devices and diagnostics manufacturing facilities complying with the quality system; and (e) Percentage of inspected medical devices and diagnostics outlets complying with requirements.	
6	F	Control of Tobacco Products Strengthened	Establish and strengthen systems for control of tobacco products	(a) Premises dealing in tobacco products registered and inspected by June, 2026; (b) Surveillance and vigilance of tobacco products conducted by June, 2026; and (c) Tobacco products notified/ registered by June, 2026.	Reduced public exposure to hazards associated with tobacco Products	(a) Percentage of applications for notification/ registration of tobacco products approved/rejected within a specified time period (as per CSC); (b) Percentage of surveillance samples for tobacco products complying with safety standards; and	DMC

S/N	Strategic Objective Code	Strategic Objective Description	Strategies	Targets	Service outputs	Key Performance Outcome Indicators	Responsible Person
						(c) Percentage of domestic tobacco manufacturing facilities complying with requirements.	
7	G	Laboratory Services improved	(a) Decentralize laboratory services to zone offices; (b) Ensure availability of laboratory consumables and maintenance of equipment; (c) Acquire accreditation under ISO/IEC 17025 Standard and sustain WHO prequalification for Dar es Salaam laboratory;	(a) TMDA laboratories strengthened by June, 2026; (b) Samples of medicines, medical devices, diagnostics, complementary and tobacco products tested by June, 2026; (c) Laboratory for testing tobacco products designated and operationalized by June, 2026; and	(a) Increased level of customer satisfaction on Laboratory services; (b) Increased capacity to test samples; and (c) Recognition and reputation of TMDA Laboratories.	(a) Percentage of laboratory results released within the turnaround time as per CSC; (b) Level of customers satisfaction in relation to laboratory services; (c) ISO/IEC 17025 accreditation for Dar es Salaam and Mwanza laboratories attained and sustained; (d) WHO pre-qualification for Dar es salaam laboratory sustained;	DLS

S/N	Strategic Objective Code	Strategic Objective Description	Strategies	Targets	Service outputs	Key Performance Outcome Indicators	Responsible Person
			(d) Acquire accreditation and prequalification for Mwanza and Dodoma laboratories; and (e) Establish laboratories for testing vaccines, selected diagnostics, herbal medicines, biocidals and tobacco products.	(d) Operational and applied researches on regulatory functions conducted by June, 2026.		(e) WHO pre-qualification for Mwanza and Dodoma laboratories attained and sustained; and (f) Percentage of planned researches published.	
8	H	Public Education Strengthened and Customer Services Improved	(a) Enhance implementation of comprehensive Communication and Customer Service Strategy; (b) Improve stakeholders' engagement and participation in matters related to TMDA functions; (c) Monitor implementation of the CSCs; and	(a) Communication and Customer Service Strategy reviewed and implemented by June, 2026; (b) Public awareness on TMDA functions and customer satisfaction raised by June, 2026;	(a) Improved public awareness on TMDA functions (b) Improved customer satisfaction (c) Reduced use of tobacco products	(a) Percentage level of general public awareness on TMDA functions; (b) Percentage level of external and internal customer satisfaction; (c) Level of general public awareness on whistleblowing policy; (d) Proportion of the population understanding health hazards of smoking; and	MCPE

S/N	Strategic Objective Code	Strategic Objective Description	Strategies	Targets	Service outputs	Key Performance Outcome Indicators	Responsible Person
			(d) Provide public education and awareness programmes on reduction of tobacco use among members of the public.	(c) Anti-smoking awareness programmes developed and implemented by June, 2026; and (d) Stakeholders' engagement and participation plan developed and implemented by June, 2026.		(e) Percentage of non - smokers compared to baseline.	
9	I	Institutional Capacity to Deliver Regulatory Services Enhanced	(a) Tools; (b) Strengthen financial and procurement management systems; (c) Enhance human resource capacity, development and utilization; (d) Strengthen zone offices' operations; (e) Strengthen capacity for Monitoring and Evaluation;	(a) Infrastructures, working facilities and tools provided and maintained by June, 2026; (b) Annual procurement plans developed and implemented by June, 2026; (c) Internal Audit plans developed and implemented by June, 2026;		(a) Percentage budgetary contribution from internal sources; (b) Unqualified Audit Report attained; (c) Percentage of staff retention; (d) Position of TMDA in administration and human resource management in the public service (e) Percentage of cases decided in favor of TMDA;	DBS

S/N	Strategic Objective Code	Strategic Objective Description	Strategies	Targets	Service outputs	Key Performance Outcome Indicators	Responsible Person
			(f) Strengthen ICT usage, Quality and Risk Management; (g) Improve legal and administrative services; and (h) Engage and maintain regional collaboration and international harmonization initiatives for regulated products.	(d) Financial resources properly managed by June, 2026; (e) Human resources properly managed by June, 2026; (f) Professional and career development programmes implemented by June, 2026; (g) Zone offices operations coordinated by June, 2026; (h) Planning, budgeting and their implementation coordinated by June, 2026;	Improved TMDA operational capacity	(f) ISO certification sustained; (g) OSHA certification acquired and sustained at all TMDA offices; and (h) Maturity level four (4) or WLA certification attained.	

S/N	Strategic Objective Code	Strategic Objective Description	Strategies	Targets	Service outputs	Key Performance Outcome Indicators	Responsible Person
				(i) Institutional plans and programmes monitored and evaluated by June, 2026; (j) Quality and Risk Management Systems improved by June, 2026; (k) ICT usage enhanced by June, 2026; (l) Legal services timely provided by June, 2026; (m) Administrative services provided by June, 2026; and (n) Regional and international collaboration and harmonization initiatives for regulated products facilitated by June, 2026.			

Annex IV: Monitoring and Evaluation Framework (Output Based Indicators)

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE A: HIV/AIDS and Non- Communicable Diseases (NCDs) reduced and Services Improved;													
1.	Percentage of staff sensitized on HIV/AIDS	71	80	85	90	95	100	HRA Section	Document review	Annually	Progress Report	Annually	DBS
2.	Percentage of staff sensitized on NCDs	71	80	85	90	95	100	HRA Section	Document review	Annually	Progress Report	Annually	DBS
3.	Percentage of staff living with HIV/AIDS and NCDs supported	0	80	100	100	100	100	HRA Section	Document review	Quarterly	Confidential files	Annually	DBS
4.	Percentage of staff sensitized on wellness programme	71	73	75	80	85	90	HRA Section	Document review	Annually	Progress Report	Annually	DBS
5.	Percentage of sensitized staff attending wellness programme.	28	32	35	40	45	50	HRA Section	Document review	Quarterly	Progress Report	Quarterly	DBS
OBJECTIVE B: National Anti-Corruption Strategy effectively Implemented and Sustained;													
1.	Percentage of staff sensitized on Anti-Corruption Strategy and Public Service Code of Ethics and Conduct	75	80	85	100	100	100	HRA Section	Document review	Annually	Progress Report	Annually	DBS
2.	Percentage of staff signing declaration of conflict-of-interest forms	100	100	100	100	100	100	HRA Section	Document review	Annually	Progress Report	Annually	DBS
3.	Percentage of new staff signing integrity pledge forms	100	100	100	100	100	100	HRA Section	Document review	Quarterly	Progress Report	Annually	DBS
4.	Number of areas prone to corruption identified and mitigated	5	4	3	0	0	0	QRM Unit	Document review	Quarterly	Progress Report	Annually	MQR

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE C: Gender and Environmental Issues Improved													
1.	Proportion of women trained on leadership and management among senior women staff	10	50	60	70	80	90	HRA Section	Document review	Annually	Progress Report	Annually	DBS
2.	Iinfrastructures for physically challenged persons in place	√	√	√	√	√	√	HRA Section	Document review	Annually	Progress Report	Annually	DBS
3.	Facilities for handling and disposal of waste and unfit products in place	√	√	√	√	√	√	HRA Section	Document review	Annually	Progress Report	Annually	DBS
OBJECTIVE D: Quality, Safety and Effectiveness of Medicines and Biocidal Products Assured													
1.	Percentage of received applications for product registration of human medicines assessed within specified time as per CSC	94	98	100	100	100	100	MRE Section	Document review	Monthly	Progress Report	Quarterly	DMC
2.	Percentage of received applications for registration of veterinary medicines assessed within specified time as per CSC	91	95	100	100	100	100	MRE Section	Document review	Monthly	Progress Report	Quarterly	DMC
3.	Percentage of received applications for registration of Herbal medicines assessed within specified time as per CSC	100	100	100	100	100	100	MRE Section	Document review	Monthly	Progress Report	Quarterly	DMC

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE D: Quality, Safety and Effectiveness of Medicines and Biocidal Products Assured													
4.	Percentage of received applications for product registration of biocidal (antiseptics and disinfectants) assessed within specified time as per CSC	90	95	100	100	100	100	MRE Section	Document review	Monthly	Progress Report	Quarterly	DMC
5.	Percentage of received applications for registration of premises for medicines processed within specified time as per CSC	99	99	100	100	100	100	CIE Section/ Zones	RIMS review	Monthly	Progress Report	Quarterly	DMC/ZM
6.	Percentage of received applications for registration of premises for biocidal products processed within specified time as per CSC	99	99	100	100	100	100	CIE Section/ Zones	RIMS review	Monthly	Progress Report	Quarterly	DMC/ZM
7.	Percentage of registered outlets for medicines inspected	100	100	100	100	100	100	CIE Section	Document review	Monthly	Progress Report	Quarterly	DMC/ZM
8.	Percentage of planned PMS samples for human medicines collected	100	100	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC
9.	Percentage of planned PMS samples for veterinary medicines collected	100	100	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC
10	Percentage of applications for authorization of clinical trials evaluated	100	100	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE D: Quality, Safety and Effectiveness of Medicines and Biocidal Products Assured													
11.	Percentage of approved clinical trials inspected	42	70	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC
12.	Percentage of received field safety reports assessed	100	100	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC
13.	Percentage of domestic pharmaceutical manufacturing facilities inspected for GMP	69	100	100	100	100	100	CIE Section	Document review	Monthly	Progress Report	Quarterly	DMC
14.	Percentage of domestic biocidal (antiseptics and disinfectants) manufacturing facilities inspected	63	100	100	100	100	100	CIE Section	Document review	Monthly	Progress Report	Quarterly	DMC
15.	Percentage of overseas pharmaceutical manufacturing facilities inspected for GMP	41	60	100	80	90	90	CIE Section	Document review	Monthly	Progress Report	Quarterly	DMC
16.	Percentage of received import applications processed	92	100	100	100	100	100	CIE Section	RIMS review	Monthly	Progress Report	Quarterly	DMC/ZM
17.	Percentage of received export applications processed	93	100	100	100	100	100	CIE Section	RIMS review	Monthly	Progress Report	Quarterly	DMC/ZM
18.	Percentage of approved consignments inspected at the Ports of Entry (PoEs);	87	100	100	100	100	100	CIE Section	RIMS review	Monthly	Progress Report	Quarterly	DMC/ZM
19.	Percentage of planned Adverse Drug Reactions (ADRs) reports received	100	100	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC
20.	Percentage of received ADR reports assessed	100	100	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC
21.	Percentage of received ADR reports uploaded to Vigiflow database.	100	100	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE D: Quality, Safety and Effectiveness of Medicines and Biocidal Products Assured													
22.	Percentage of planned Adverse Events following Immunization (AEFIs) reports received;	100	100	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC
23.	Percentage of received AEFIs reports assessed;	100	100	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC
24.	Percentage of received AEFIs reports uploaded to Vigiflow database	100	100	100	100	100	100	CTP Section	Document review	Monthly	Progress Report	Quarterly	DMC
OBJECTIVE E: Quality, Safety and Performance of Medical Devices and Diagnostics Assured													
1.	Percentage of received applications for registration of medical devices assessed	86	100	100	100	100	100	DDA Section	RIMS review	Monthly	Progress Report	Quarterly	DMD
2.	Percentage of received applications for registration of diagnostics assessed	96	100	100	100	100	100	DDA Section	RIMS review	Monthly	Progress Report	Quarterly	DMD
3.	Percentage of received applications for registration of premises for medical devices and diagnostics processed;	100	100	100	100	100	100	DDA Section	RIMS review	Monthly	Progress Report	Quarterly	DMD
4.	Percentage of registered outlets for medical devices and diagnostics inspected;	100	100	100	100	100	100	DLC Section	Document review	Monthly	Progress Report	Quarterly	DMD/ZM
5.	Percentage of planned PMS samples for medical devices collected;	100	100	100	100	100	100	PMS Section	Document review	Monthly	Progress Report	Quarterly	DMD
6.	Percentage of planned PMS samples for diagnostics collected	100	100	100	100	100	100	PMS Section	Document review	Monthly	Progress Report	Quarterly	DMD

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE E: Quality, Safety and Performance of Medical Devices and Diagnostics Assured													
7.	Percentage of domestic medical devices and diagnostics manufacturing facilities inspected for QMS	100	100	100	100	100	100	DLC Section	Document review	Monthly	Progress Report	Quarterly	DMD
8.	Percentage of overseas manufacturing facilities for medical devices and diagnostics inspected for QMS	100	100	100	100	100	100	DLC Section	Document review	Monthly	Progress Report	Quarterly	DMD
9.	Percentage of received import applications processed	92	100	100	100	100	100	DLC Section	RIMS review	Monthly	Progress Report	Quarterly	DMD/ZM
10.	Percentage of received export applications processed	93	100	100	100	100	100	DLC Section	RIMS review	Monthly	Progress Report	Quarterly	DMD/ZM
11.	Percentage of approved consignments inspected at the PoEs.	87	100	100	100	100	100	DLC Section	RIMS review	Monthly	Progress Report	Quarterly	DMD/ZM
12.	Percentage of large hospitals equipment assessed through PMS	100	100	100	100	100	100	PMS Section	Document review	Monthly	Progress Report	Quarterly	DMD
13.	Percentage of planned incidents reports received	100	100	100	100	100	100	PMS Section	Document review	Monthly	Progress Report	Quarterly	DMD
14.	Percentage of planned incidents reports assessed	100	100	100	100	100	100	PMS Section	Document review	Monthly	Progress Report	Quarterly	DMD
15.	Percentage of planned field safety reports received	100	100	100	100	100	100	PMS Section	Document review	Monthly	Progress Report	Quarterly	DMD
16.	Percentage of received field safety reports assessed	100	100	100	100	100	100	PMS Section	Document review	Monthly	Progress Report	Quarterly	DMD

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE F: Control of Tobacco Products Strengthened													
1.	Percentage of received applications for notification of tobacco products assessed	0	50	100	100	100	100	MRE Section	Document review	Monthly	Progress Report	Quarterly	DMC
2.	Percentage of received applications for registration of tobacco products assessed;	0	50	100	100	100	100	MRE Section	Document review	Monthly	Progress Report	Quarterly	DMC
3.	Percentage of applications for registration of premises dealing in tobacco products processed;	0	50	100	100	100	100	CIE Section	Document review	Monthly	Progress Report	Quarterly	DMC/ZM
4.	Percentage of planned surveillance samples for tobacco products collected	0	50	100	100	100	100	PMS Section	Document review	Monthly	Progress Report	Quarterly	DMC
5.	Percentage of domestic tobacco products manufacturing facilities inspected;	0	50	100	100	100	100	CIE Section	Document review	Monthly	Progress Report	Quarterly	DMC
6.	Percentage of planned public places with designated smoking areas	0	50	100	100	100	100	CIE Section	RIMS review	Monthly	Progress Report	Quarterly	DMC/MCPE
OBJECTIVE G: Laboratory Services Improved													
1.	Percentage of regulatory samples of medicines tested	89	100	100	100	100	100	MCA Section	Document review	Monthly	Progress Report	Quarterly	DLS
2.	Percentage of regulatory samples for herbal medicines tested	100	100	100	100	100	100	MCA Section	Document review	Monthly	Progress Report	Quarterly	DLS

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
3.	Percentage of regulatory samples for biocidal tested	100	100	100	100	100	100	MCA Section	Document review	Monthly	Progress Report	Quarterly	DLS
4.	Percentage of regulatory samples medical devices tested	92	100	100	100	100	100	DIT Section	Document review	Monthly	Progress Report	Quarterly	DLS
5.	Percentage of regulatory samples of diagnostics tested	99	100	100	100	100	100	DIT Section	Document review	Monthly	Progress Report	Quarterly	DLS
6.	Percentage of research applications received and processed	100	100	100	100	100	100	DLS	Document review	Monthly	Progress Report	Quarterly	DLS
7.	Number of analytical methods accredited for Dar es Salaam laboratory	9	9	10	11	12	13	DLS	Document review	Monthly	Progress Report	Quarterly	DLS
8.	Number of analytical methods accredited for Mwanza laboratory	0	0	2	3	4	5	DLS	Document review	Monthly	Progress Report	Quarterly	DLS
9.	Percentage of received non-regulatory samples from external customers tested	88	95	100	100	100	100	DLS	Document review	Monthly	Progress Report	Quarterly	DLS
10.	Number of medicines samples screened at all Quality Assurance (QA) Centres	1,500	1,550	1,600	1,700	1,800	1,900	DLS	Document review	Monthly	Progress Report	Quarterly	DLS
OBJECTIVE G: Laboratory Services Improved													
1.	Percentage of laboratory equipment calibrated/ maintained as per approved schedule.	100	100	100	100	100	100	DLS	Document review	Monthly	Progress Report	Quarterly	DLS

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE H: Public Education Strengthened and Customer Services Improved													
1.	Percentage of planned types of IEC materials developed, printed and disseminated	90	95	100	100	100	100	CPE Unit	Document review	Quarterly	Progress Report	Quarterly	MCPE
2.	Percentage of employees sensitized on customer care, core values and code of ethics and conduct	75	80	85	100	100	100	CPE Unit	Document review	Quarterly	Progress Report	Annually	MCPE
3.	Percentage of received customer complaints attended and resolved	100	100	100	100	100	100	CPE Unit	Document review	Monthly	Progress Report	Quarterly	MCPE
4.	Number of SDS conducted	1	N/A	N/A	N/A	1	N/A	CPE Unit	Document review	Once	SDS Report	Once	MCPE
5.	Percentage compliance to external Clients' Service Charter	79	85	100	100	100	100	CPE Unit	Document review	Monthly	Progress Report	Quarterly	MCPE
6.	Percentage compliance to internal Clients' Service Charter	80	85	90	100	100	100	CPE Unit	Document review	Monthly	Progress Report	Quarterly	MCPE
7.	Number of stakeholders sensitized on whistleblowing policy	0	100	300	400	500	600	CPE Unit	Document review	Monthly	Progress Report	Quarterly	MCPE
8.	Percentage of received whistle blower alerts and concerns attended and closed.	0	100	100	100	100	100	CPE Unit	Document review	Monthly	Progress Report	Quarterly	MCPE
9.	Percentage of planned information updates uploaded in TMDA website.	90	95	99	99	99	100	TMDA	Review of TMDA Website	Quarterly	Progress Reports	Quarterly	MCPE

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
10.	Number of information updates uploaded in TMDA social media platform.	700	800	1,000	1,500	2000	3,000	TMDA	Review of TMDA Social media platform	Quarterly	Progress Reports	Quarterly	MCPE
11.	Number of followers on TMDA social media	30,000	35,000	40,000	45,000	50,000	55,000	TMDA	Review of TMDA social media accounts	Quarterly	Progress Reports	Quarterly	MCPE
12.	Percentage of received whistle blower complaints and concerns attended	100	100	100	100	100	100	TMDA	Whistle blower complaints register	Quarterly	Progress reports	Quarterly	MCPE
13.	Percentage of staff sensitized on customer care	90	95	95	95	95	95	TMDA	Training records	Annually	Progress Reports	Annually	MCPE
14.	Percentage of planned TV and radio programmes developed and aired	95	95	99	100	100	100	TMDA	Review of list of TV programmes aired	Annually	Progress Reports	Annually	MCPE
15.	Percentage of planned exhibitions participated	95	95	99	99	99	99	TMDA	Review of Exhibition reports	Annually	Progress Reports	Annually	MCPE
16.	Percentage of planned outreach campaigns conducted	95	95	99	99	99	99	TMDA	Review of progress reports	Annually	Progress Reports	Annually	MCPE
17.	Percentage of planned press conference conducted	95	95	99	99	99	99	TMDA	Review of press conference conducted	Annually	Progress Reports	Annually	MCPE
18.	Percentage of whistle blowers provided with feedback	95	99	100	100	100	100	TMDA	Review of whistle blower complaints register	Annually	Progress Reports	Annually	MCPE

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE I: Institutional Capacity to Deliver Regulatory Services Enhanced													
1.	Percentage of projected revenue collected from own source	100	100	100	100	100	100	Accounts Unit	Document review	Monthly	Progress Report	Quarterly	CA
2.	Percentage of projected revenue collected from all sources	100	100	100	100	100	100	Accounts Unit	Document review	Monthly	Progress Report	Quarterly	CA
3.	Percentage of planned internal audits conducted	100	100	100	100	100	100	Interna Audit Unit	Document review	Monthly	Progress Report	Quarterly	CA
4.	Percentage implementation of approved planned work plans and budgets	97	100	100	100	100	100	PME Section	Document review	Quarterly	Progress Report	Quarterly	DBS
5.	Percentage implementation of the HR plan	-	70	80	85	90	95	HRA Section	Document review	Monthly	Progress Report	Quarterly	DBS
6.	Percentage implementation of training programme	85	96	100	100	100	100	HRA Section	Document review	Monthly	Progress Report	Quarterly	DBS
7.	Revised Scheme of Service and Salary Structure in place	-	N/A	√	N/A	N/A	N/A	HRA Section	Document review	Monthly	Progress Report	Quarterly	DBS
8.	Revised Internal Staff and Financial Regulations in place	-	N/A	√	N/A	N/A	N/A	HRA Section	Document review	Monthly	Progress Report	Quarterly	DBS
9.	Percentage of service processes automated	67	70	80	85	90	100	ICT Unit	Document review	Monthly	Progress Report	Quarterly	MICT
10.	Percentage of TMDA inspectors trained on investigation and evidence gathering	40	60	70	80	90	100	Legal Unit	Document review	Quarterly	Progress Report	Quarterly	MLS
11.	Percentage implementation of the procurement plan	100	100	100	100	100	100	Procurement Unit	Document review	Monthly	Progress Report	Quarterly	MPM

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE I: Institutional Capacity to Deliver Regulatory Services Enhanced													
12.	Completion level of construction of TMDA Offices in Mbeya	N/A	N/A	N/A	N/A	50	100	Procurement Unit	Document review	Monthly	Progress Report	Quarterly	MPM
13.	Percentage of planned quality audits conducted	100	100	100	100	100	100	QRM Unit	Document review	Monthly	Progress Report	Quarterly	MQR
14.	Percentage of processes and procedures reviewed	100	100	100	100	100	100	QRM Unit	QMS Unit	QMS Unit	QMS Unit	Quarterly	MQR
15.	Percentage mitigation of identified risks	53	60	70	80	90	100	QRM Unit	Document review	Monthly	Progress Report	Quarterly	MQR
16.	Percentage of staff sensitized on quality risk management	90	95	100	100	100	100	QRM Unit	Document review	Monthly	Progress Report	Quarterly	MQR

KEY
N/A: Not Applicable

Annex V: Monitoring and Evaluation Framework (Outcome - Based Indicators)

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2021/22	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE A: HIV/AIDS and Non- Communicable Diseases (NCDs) Reduced and Services Improved;													
1.	Percentage of sensitized staff who turn up for voluntary health check-ups for HIV/AIDS	52	58	60	70	80	80	HRA Section	Document review	Quarterly	Progress Report	Annually	DBS
2.	NCDs incidence rate among TMDA staff	5	3	2	2	2	1	HRA Section	Document review	Quarterly	Progress Report	Annually	DBS
OBJECTIVE B: National Anti-Corruption Strategy Effectively Implemented and Sustained;													
1.	Level of staff awareness on corruption prevention	40	60	70	80	90	100	HRA Section	Min survey	Quarterly	Progress Report	Annually	DBS
2.	Number of corruption allegations against TMDA staff	0	0	0	0	0	0	Legal Unit	Document review	Annually	Progress Report	Annually	MLS
OBJECTIVE C: Gender and Environmental Issues Improved													
1.	Proportion of women at managerial positions	15	N/A	30	N/A	35	N/A	HRA Section	Document review	Biennially	Progress Report	Biennially	DBS
OBJECTIVE D: Quality, Safety and Effectiveness of Medicines and Biocidal Products Assured													
1.	Percentage of applications for registration of medicines approved/ rejected within a specified time period (as per CSC)	80	81	82	84	85	90	MRE Section	RIMS review	Quarterly	Progress Report	Annually	DMC

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2021/22	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE D: Quality, Safety and Effectiveness of Medicines and Biocidal Products Assured													
2.	Percentage of applications for registration of biocidal products approved/rejected within a specified time period (as per CSC)	90	90	90	92	94	95	MRE Section	RIMS review	Quarterly	Progress Report	Annually	DMC
3.	Percentage of PMS human medicines complying with quality requirements	100	100	100	100	100	100	PV Section	Document review	Quarterly	Progress Report	Annually	DMC
4.	Percentage of PMS veterinary medicines complying with quality requirements	100	100	100	100	100	100	PV Section	Document review	Quarterly	Progress Report	Annually	DMC
5.	Percentage of domestic pharmaceutical manufacturing facilities compliant with GMP requirements	0	20	40	45	50	60	MCIE Section	Document review	Quarterly	Progress Report	Annually	DMC
6.	Percentage of clinical trials compliant with GCP and GCLP requirements	61	65	70	100	100	100	PMS Section	Document review	monthly	Progress Report	Quarterly	DMC

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2021/22	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
7.	Percentage of inspected medicines selling outlets complying with requirements	88	90	90	90	90	90	MCIE Section	Document review	Monthly	Progress Report	Quarterly	DMC
OBJECTIVE E: Quality, Safety and Performance of Medical Devices and Diagnostics Assured													
1.	Percentage of applications for registration of medical devices and diagnostics approved/rejected within a specified time period (as per CSC)	87	90	90	92	94	98	MDA Section	RIMS review	Monthly	Progress Report	Quarterly	DMD
2.	Percentage of PMS medical devices and diagnostics complying with performance requirements	55	57	60	70	80	90	Vigilance Section	Document review	Quarterly	Progress Report	Annually	DMD
3.	Percentage of domestic medical devices and diagnostics manufacturing facilities complying with the quality system	0	6	10	20	30	40	DLC Section	Document review	Monthly	Progress Report	Quarterly	DMD

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2021/22	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE E: Quality, Safety and Performance of Medical Devices and Diagnostics Assured													
4.	Percentage of inspected medical devices and diagnostics outlets complying with requirements	57	60	60	70	80	90	DLC Section	Document review	Monthly	Progress Report	Quarterly	DMD
OBJECTIVE F: Control of Tobacco Products Strengthened													
1.	Percentage of applications for notification/ registration of tobacco products approved/ rejected within a specified time period (as per CSC)	0	50	70	90	95	100	MRE Section	Document review	Monthly	Progress Report	Quarterly	DMC
2.	Percentage of surveillance samples for tobacco products complying with safety standards	0	50	90	95	97	99	PMS Section	Document review	Quarterly	Progress Report	Annually	DMC
3.	Percentage of domestic tobacco manufacturing facilities complying with requirements	0	50	90	95	97	99	MCIE Section	Document review	Monthly	Progress Report	Quarterly	DMC

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2021/22	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE G: Laboratory Services Improved													
1.	Percentage of laboratory results for medicines released within the turnaround time as per CSC	100	100	100	100	100	100	LIMS Data Base	LIMS review	Monthly	Progress Report	Quarterly	DLS
2.	Percentage of laboratory results for medical devices released within the turnaround time as per CSC	86	90	100	100	100	100	LIMS Data Base	Document review	Monthly	Progress Report	Quarterly	DLS
3.	Level of customers satisfaction in relation to laboratory services	100	100	100	100	100	100	SDS Report	Document review	Once	Progress Report	Once	MCPE
4.	ISO/IEC 17025 accreditation for Dar es Salaam sustained	√	√	√	√	√	√	QRM Unit	Document review	Annually	Copy of Certificate	Annually	DLS
5.	ISO/IEC 17025 accreditation for Mwanza laboratory attained	X	N/A	N/A	√	N/A	N/A	QRM Unit	Document review	Annually	Copy of Certificate	Annually	DLS
6.	ISO/IEC 17025 accreditation for Dodoma laboratory attained	X	N/A	N/A	N/A	N/A	√	QRM Unit	Document review	Annually	Copy of Certificate	Annually	DLS
7.	WHO pre-qualification for Dar es salaam laboratory sustained	√	√	√	√	√	√	QRM Unit	Document review	Annually	Copy of Certificate	Annually	DLS

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2021/22	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
8.	WHO pre-qualification for Mwanza laboratory attained and sustained	X	N/A	N/A	√	√	√	QRM Unit	Document review	Annually	Copy of Certificate	Annually	DLS
9.	WHO pre-qualification for Dodoma laboratory attained and sustained	X	N/A	N/A	N/A	√	√	QRM Unit	Document review	Annually	Copy of Certificate	Annually	DLS
10.	Percentage of planned researches published.	100	100	100	100	100	100	DLS	Document review	Annually	Copy of Certificate	Annually	DLS
OBJECTIVE H: Public education strengthened and customer services improved													
1.	Percentage level of general public awareness on TMDA functions	88	N/A	N/A	N/A	90	N/A	SDS Report	Document review	Once	SDS Report	Once	MCPE
2.	Percentage level of internal customer satisfaction	75	N/A	N/A	N/A	90	N/A	SDS Report	Document review	Once	SDS Report	Once	MCPE
3.	Percentage level of external customer satisfaction	80	N/A	N/A	N/A	90	N/A	SDS Report	Document review	Once	SDS Report	Once	MCPE
4.	Level of general public awareness on whistleblowing policy	0	50	50	60	70	80	CPE Unit	Document review	Once	SDS Report	Once	MCPE
5.	Proportion of the population understanding health hazards of smoking	92	93	95	98	100	100	MCIE Section	Document review	Once	Survey Study Report	Once	DMC
6.	Proportion of smokers quitting smoking.	91	92	92	95	97	98	DMC	Document review	Once	SDS Report	Once	DMC

S/N	Indicator Name	Baseline	Indicator Target Values					Data Collection and Methods of analysis				Frequency of Reporting	Responsible Person
		2021/22	2021/22	2022/23	2023/24	2024/25	2025/26	Data source	Data collection instrument and methods	Frequency of data collection	Means of Verification		
OBJECTIVE I: Institutional capacity to deliver regulatory services enhanced OBJECTIVE I: Institutional capacity to deliver regulatory services enhanced													
1.	Percentage budgetary contribution from internal sources	87	88	88	90	90	90	FA Unit	Document review	Monthly	Progress Report	Quarterly	CA
2.	Unqualified Audit Report attained	√	√	√	√	√	√	FA Unit	Document review	Annually	Copy of the Report CAG	Annually	CA
3.	Percentage of staff retention	100	100	100	100	100	100	HRA Section	Document review	Quarterly	Progress Report	Annually	DBS
4.	Position of TMDA in administration and human resource management in the public service	2	1	1	1	1	1	HRA Section	Document review	Annually	Certificate of Appreciation	Annually	DBS
5.	Percentage of cases decided in favour of TMDA	60	100	100	100	100	100	Legal Unit	Document review	Monthly	Progress Report	Quarterly	MLS
6.	ISO certification sustained	√	√	√	√	√	√	QRM Unit	Document review	Annually	Copy of Certificate	Annually	MQR
OBJECTIVE I: Institutional capacity to deliver regulatory services enhanced OBJECTIVE I: Institutional capacity to deliver regulatory services enhanced													
7.	OSHA certification acquired and sustained at all TMDA offices	√	√	√	√	√	√	HRA Section	Document review	Annually	Progress Report	Annually	DBS
8.	Maturity level four (4) certification attained	N/A	N/A	N/A	N/A	N/A	√	QRM Unit	Document review	Annually	Copy of Certificate	Annually	MQR

Key: *N/A* = Not Applicable

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