

STRATEGIC PLAN

2026/27 - 2030/31



Safeguarding Public Health
through Regulatory Excellence

CORE VALUES

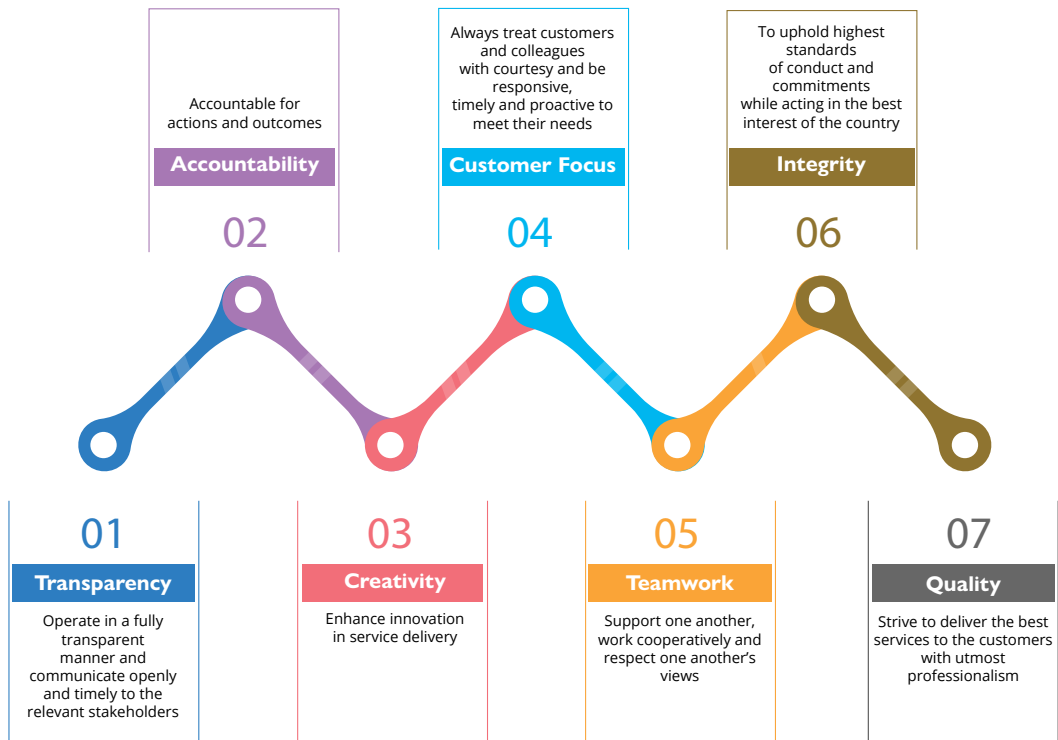


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LIST OF ABBREVIATIONS AND ACRONYMS

AEFI	- Adverse Event Following Immunization
AIDS	- Acquired Immune Deficiency Syndrome
AMA	- African Medicines Agency
AMR	- Antimicrobial Resistance
AU	- African Union
AWPB	- Annual Work Plans and Budgets
CAPA	- Corrective Action and Preventive Action
CCM	- Chama Cha Mapinduzi (Ruling Party)
CIA	- Chief Internal Auditor
CPE	- Communication and Public Education
CRP	- Collaborative Registration Procedure
CSC	- Clients' Service Charter
CSO	- Civil Society Organization
DBS	- Directorate of Business Services
DG	- Director General
DIRA 2050	- Tanzania Development Vision 2050
DLS	- Directorate of Laboratory Services
DMC	- Directorate of Human and Veterinary Medicines
DMD	- Directorate of Medical Devices and Diagnostics
DPP	- Director of Public Prosecutions
EAC - MRH	- East African Community - Medicines Regulatory Harmonization
ETE	- End-Term Evaluation
FSCA	- Field Safety Corrective Action
FYDP	- Five Year Development Plan
GARI-ITS	- Government Audit Recommendations Implementation Information Tracking System
GBT	- Global Benchmarking Tool
GCP	- Good Clinical Practice
GCLP	- Good Clinical Laboratory Practice
GDP	- Gross Domestic Product
GMP	- Good Manufacturing Practices
GPSA	- Government Procurement Services Agency
GSDP	- Good Storage and Distribution Practice
HBV	- Hepatitis B Virus

HIV	- Human Immunodeficiency Virus
HRP	- Human Resource Plan
IA	- Internal Audit
IAU	- Internal Audit Unit
ICH	- International Council for Harmonization
ICT	- Information and Communication Technology
IEC	- Information, Education and Communication
IMDRF	- International Medical Devices Regulators Forum
ISO	- International Organization for Standardization
ISO 9001	- Quality Management Systems – Requirements
ISO/IEC 17025	- General Requirements for the Competence of Testing and Calibration of Laboratories
KII	- Key Informant Interview
LAN	- Local Area Network
LGAs	- Local Government Authorities
LIMS	- Laboratory Information Management System
LSU	- Legal Service Unit
MA	- Marketing Authorization
MAB	- Ministerial Advisory Board
MDAs	- Ministries, Departments and Agencies
MNAP II	- Multisectoral Nutrition Action Plan II
MOH	- Ministry of Health
MUHAS	- Muhimbili University of Health and Allied Sciences
NACSAP IV	- National Anti-Corruption Strategy Action Plan IV
NCDs	- Non-Communicable Diseases
NIMR	- National Institute for Medical Research
OECD - DAC	- Organization for Economic Cooperation and Development - Development Assistant Committee
OSHA	- Occupational Health and Safety Authority
OTR	- Office of Treasury Registrar
PC	- Planning Commission
PEPMIS	Public Employees Performance Management Information System
PESTEL	- Political, Economic, Social, Technological, Environmental and Legal
PIC/S	- Pharmaceutical Inspection Co-operation Scheme
PIPMIS	- Public Institution Performance Management Information System
PMPA	- Pharmaceutical Manufacturing Plan for Africa
PME	- Planning Monitoring and Evaluation

PMS	- Post-Marketing Surveillance
PMU	- Procurement Management Unit
PoE	- Port of Entry
PO-PSMGG	- President's Office - Public Service Management and Good Governance
PO-RALG	- President's Office – Regional Administration and Local Government
PPRA	- Public Procurement Regulatory Authority
PQ	- Prequalification
PV	- Pharmacovigilance
QA	- Quality Assurance
QMS	- Quality Management System
QRM	- Quality and Risk Management
RBM	- Result Based Management
RIMS	- Regulatory Information Management System
SADC	- Southern Africa Development Community
SAE	- Serious Adverse Event
SDGs	- Sustainable Development Goals
SDS	- Service Delivery Survey
SF	- Substandard and Falsified
SO	- Strategic Objective
STI	- Sexually Transmitted Infection
SWOC	- Strengths, Weaknesses, Opportunities and Challenges
TBS	- Tanzania Bureau of Standards
TDV 2025	- Tanzania Development Vision 2025
TFDA	- Tanzania Food and Drugs Authority
TMDA	- Tanzania Medicines and Medical Devices Authority
UDI	- Unique Device Identification
USSD	- Unstructured Supplementary Service Data
WAN	- Wide Area Network
WHO	- World Health Organization
WLA	- WHO-Listed Authority
ZAZIBONA	- Zambia-Zimbabwe-Botswana-Namibia Medicines Regulatory Harmonization Initiative
ZFDA	- Zanzibar Food and Drugs Agency
ZOLGAC	- Zone Offices and Local Government Authorities Coordinator

STATEMENT OF THE CHAIRPERSON OF THE MINISTERIAL ADVISORY BOARD (MAB)



I am pleased to present the Tanzania Medicines and Medical Devices Authority (TMDA) Strategic Plan for the period of 2026/27–2030/31. This Strategic Plan provides a clear, forward-looking framework to guide the Authority in fulfilling its statutory mandate of regulating medicines, medical devices, diagnostics and tobacco products.

The development of this Strategic Plan comes at a critical moment in Tanzania's development trajectory, marked by a national shift towards a long-term, people-centered development vision under the National Development Vision (DIRA) 2050. Within this context, the role of TMDA as a trusted and competent regulator is increasingly important in safeguarding patient safety, strengthening confidence in health products and enabling a well-regulated and competitive market that supports industrial growth and innovation.

In formulating this Strategic Plan, due consideration was given to national development priorities, emerging regulatory risks, lessons learned from the implementation of the outgoing Strategic Plan, and the need to strengthen institutional effectiveness, accountability and responsiveness. The Plan reflects a deliberate effort to align TMDA's regulatory interventions with evolving public health needs, technological advancements, regional and international regulatory developments and expectations for efficient and transparent public service delivery.

The MAB is satisfied that this Strategic Plan provides a realistic and coherent strategic direction for the Authority. It articulates clear strategic objectives and priorities that will guide Management and staff in delivering measurable results, while strengthening governance, risk management and performance oversight. The Plan also reinforces TMDA's commitment to good governance, integrity, environmental and social responsibility and collaboration with stakeholders across the public and private sectors.

The successful implementation of this Strategic Plan will require collective efforts and sustained commitment from the TMDA Management, staff, regulated stakeholders and partners. The MAB pledges its full support in providing strategic oversight, policy guidance and accountability to ensure that the objectives of the Plan are achieved and that TMDA continues to uphold the highest standards of regulatory excellence.

On behalf of the MAB, I commend the Management, staff and all stakeholders who contributed to crafting of this Strategic Plan. I am confident that its effective implementation will strengthen TMDA's contribution to public health protection, market integrity and Tanzania's long-term socio-economic development.

A handwritten signature in black ink, appearing to read 'Eric Shitindi', with a stylized flourish underneath.

Mr. Eric F. Shitindi
MAB CHAIRPERSON

FOREWORD



The Tanzania Medicines and Medical Devices Authority (TMDA) is mandated to regulate the quality, safety, and effectiveness of medicines, medical devices, diagnostics and tobacco products to protect and promote public health. Within Tanzania's transition to a long-term development framework under the National Development Vision (DIRA) 2050, this mandate represents a unique institutional contribution to the realization of a healthy society, strong and accountable institutions, and a competitive and industrialized economy. In an operating environment characterized by increasing complexity of health products, growth in local manufacturing, expanding regional and international trade and rapid technological advancement, the Authority requires a clear and comprehensive strategic direction to effectively discharge its mandate and respond to emerging regulatory risks and opportunities.

It is against this background that the formulation, implementation, and continuous review of Strategic Plans remain integral to good governance, sound management and effective public service delivery at TMDA. Experience from implementing previous Strategic Plans, demonstrates that institutional stability, performance improvement and sustainable growth are achieved through disciplined execution of well-articulated strategies. In the same spirit, I am confident that the implementation of this Strategic Plan will further strengthen TMDA's regulatory effectiveness and institutional performance, thereby reinforcing its contribution to public health protection, market integrity and Tanzania's long-term development aspirations under DIRA 2050.

This five-year TMDA Strategic Plan for the period 2026/27–2030/31 is guided by the Authority's Vision of ***"Improved health and wellbeing for all Tanzanians through regulatory excellence that meets global standards"*** and its Mission ***"to protect and promote public health by ensuring quality, safety and effectiveness of medicines, medical devices, diagnostics and other related health products."*** In line with the National Planning Guidelines, the Vision was refined from the previous statement "To be the leading Regulatory Authority in ensuring safe, quality and effective medicines, medical devices, diagnostics and other health-related products for all" developed under Tanzania Development Vision 2025 to align with the long-term, outcome-oriented aspirations of Tanzania Development Vision 2050 (DIRA 2050), placing greater emphasis on beneficiaries while anchoring TMDA's role in regulatory excellence. Together, the Vision and Mission provide a clear and coherent strategic compass for guiding priorities, decisions and actions during the Plan period.

In line with this Vision and Mission, the Strategic Plan defines seven (7) Strategic Objectives to guide execution of TMDA's mandate during the Plan period. These objectives focus on: reducing HIV/AIDS, sexually transmitted infections, Hepatitis B and non-communicable diseases (NCDs) and improving related services; enhancing and sustaining implementation of the National Anti-Corruption Strategy; mainstreaming gender and improving the environmental ecosystem; Assuring the quality, safety and effectiveness of medicinal products and tobacco standards; assuring the quality, safety

and performance of medical devices and diagnostics; improving and maintaining laboratory services; and improving the Authority's capacity to deliver regulatory services. Collectively, these Strategic Objectives provide a coherent framework for addressing public health issues and institutional challenges.

Achievement of the Strategic Objectives set out in this Plan will depend on the Authority's capacity to deliver services effectively and efficiently. In this regard, Management is fully committed to providing strong leadership, mobilizing and optimally utilizing resources, strengthening staff capacity and fostering a culture of accountability, innovation and continuous improvement throughout the implementation of the Plan.

I would like to express my sincere appreciation to the MAB for its strategic guidance and oversight, to TMDA staff for their professionalism and dedication and to our stakeholders and partners for their continued cooperation and support. I am confident that, through collective effort and shared responsibility, the effective implementation of this Strategic Plan will further enhance TMDA's contribution to public health protection, regulatory excellence and Tanzania's long-term socio-economic development.



Dr. Adam M. Fimbo
DIRECTOR GENERAL

ACKNOWLEDGMENTS



The development of the TMDA Five-Year Strategic Plan is the result of collective efforts and valuable contributions from various individuals, institutions and a comprehensive review of key policy, legal and strategic documents.

The process was guided by the National Planning Guidelines of 2025 and drew on evidence from the End-Term Evaluation of the outgoing Strategic Plan (2021/22 - 2025/26), the Service Delivery Survey (SDS) Report and National development frameworks including the Tanzania Development Vision 2050 (DIRA 2050), Long-Term Perspective Plan, the Fourth Five-Year Development Plan (FYDP IV) and the CCM Election Manifesto of 2025. In addition, the Strategic Plan was aligned with relevant global and continental commitments, including the Sustainable Development Goals (SDGs) and the African Union Agenda 2063, as well as sector-specific guidance provided under the National Health Policy. I sincerely appreciate all those who participated in and supported this important process.

First and foremost, I wish to convey my gratitude to the staff of the Planning, Monitoring and Evaluation (PME) Section for their dedication, professionalism and tireless efforts throughout the planning process. In particular, I acknowledge the valuable contributions of Mr. William Nkondokaya, Mr. John Mwingira, Dr. Seif Magayane, Ms. Esther Mwera, Ms. Johari Mirambo, Ms. Loyce Mapunda, Mr. Imani Simba and Mr. John Makombo whose commitment and technical inputs were instrumental in the initial drafting, compilation, analysis and finalization of this Strategic Plan.

I also sincerely acknowledge the contributions and active participation of TMDA Directors and Managers, as well as the constructive comments, critiques and insights provided by members of the TMDA Workers Council. Their engagement significantly enriched the Plan, particularly in refining its strategic objectives, implementation strategies and results focus.

Finally, I would like to express my heartfelt appreciation to the Members of the Ministerial Advisory Board (MAB) for their strategic guidance, constructive inputs and eventual approval of this Strategic Plan.

A handwritten signature in blue ink, appearing to read 'Chrispin M. Severe'.

Chrispin M. Severe
DIRECTOR OF BUSINESS SUPPORT

CHAPTER ONE

INTRODUCTION



CHAPTER ONE:

INTRODUCTION

This chapter introduces the Tanzania Medicines and Medical Devices Authority (TMDA) Strategic Plan for the period 2026/27–2030/31. It provides the institutional, legal and strategic context within which the Plan has been developed, including TMDA's background, mandate and functions and the rationale for preparing a new Strategic Plan. The chapter also outlines the approach and methodology adopted in the planning process and explains the overall structure and organization of the document, thereby setting the foundation for the subsequent analytical and strategic chapters.

1.1 Background Information

The Tanzania Medicines and Medical Devices Authority (TMDA) is a semi-autonomous Government Executive Agency under the Ministry of Health (MoH), established under the Executive Agency Act (Cap. 245, Revised Edition 2009). TMDA, formerly known as the Tanzania Food and Drugs Authority (TFDA), was established in 2003 following the enactment of the Tanzania Food, Drugs and Cosmetics Act, Cap 219, by Parliament. This Act was later amended in 2019 to the Tanzania Medicines and Medical Devices Act, Cap 219, following the transfer of food and cosmetics regulation to the Tanzania Bureau of Standards (TBS). The change in legislative framework which was done through the Finance Act, No. 8 of 2019 also resulted into the change of name to TMDA.

TMDA is responsible for regulating the quality, safety and effectiveness of medicines, medical devices and diagnostics. In addition, under Section 18 of the Tobacco Products (Regulation) Act, Cap 121, the Minister for Health designated TMDA as an inspector for the purposes of carrying out inspections, enforcement and regulation of tobacco products.

TMDA operates within the National health system as a key regulatory institution, supporting Government efforts to ensure access to safe, effective and quality health products. Effective regulation of these products is critical for disease prevention and control, rational use of medicines and medical devices, patient safety and the overall functioning of the health system at all levels.

The regulatory environment in which TMDA operates has continued to evolve due to increased volumes of imported and locally manufactured health products, growth in the pharmaceutical and medical device industries, technological advancements and expanding regional and international trade.

These developments have increased the complexity of the health products market and heightened the risk of substandard, falsified, unsafe, or ineffective products entering the supply chain, thereby necessitating a strong, responsive and risk-based regulatory system.

In response to these dynamics, TMDA has progressively strengthened its regulatory systems, institutional capacity and service delivery approaches in line with National policies, legal requirements and international best practices. The TMDA Strategic Plan (2026/27–2030/31) has been developed to provide a clear medium-term strategic direction for the Authority, building on lessons learned from the implementation and evaluation of the preceding Strategic Plan and aligning TMDA's regulatory priorities with National development frameworks, including the National Development Vision (DIRA) 2050, the Fourth Five-Year Development Plan (FYDP IV) and the CCM Election Manifesto (2025–2030).

The Tanzania Medicines and Medical Devices Authority (TMDA) Strategic Plan is aligned with the National development framework articulated in DIRA 2050 and the Fourth Five-Year Development Plan (FYDP IV). These frameworks provide the strategic road map for Tanzania's socio-economic transformation through institutional reforms, industrial development, strengthened human capital and improved service delivery systems.

The FYDP IV, whose theme is "Reforms for Inclusive Economic Growth and Employment Creation," focuses on



strengthening institutional capacity, improving service delivery, accelerating digitalization, promoting private sector participation and supporting value chain development across key sectors of the economy.

Within the health sector, the Plan emphasizes strengthening health systems, improving access to safe and effective medicines and medical technologies, enhancing digital health systems and promoting domestic production of health commodities. These priorities aim to advance universal health coverage, improve population health outcomes and strengthen the resilience of the National health system.

In this context, TMDA plays a critical role in supporting the implementation of these National priorities. As the National regulatory authority responsible for medicines, medical devices and other regulated health products, TMDA ensures that products circulating in the country comply with established standards of safety, quality and efficacy. Through its regulatory functions including product registration, inspections, pharmacovigilance and post-market surveillance, the Authority contributes to safeguarding public health and strengthening confidence in the National health system.

Furthermore, TMDA supports the National agenda by strengthening regulatory efficiency, facilitating access to quality medical products, supporting the growth of local pharmaceutical manufacturing and enhancing regulatory oversight across the pharmaceutical supply chain. These efforts contribute to improved availability of safe and effective health commodities and reinforce the broader health system strengthening objectives articulated in FYDP IV.

1.2 Mandate and Functions

1.2.1 Mandate

TMDA is mandated to regulate medicines, medical devices, diagnostics and tobacco products in Tanzania to ensure they meet the required standards of quality, safety and effectiveness throughout their life cycle. This mandate covers the regulation of activities related to manufacturing, importation, exportation, distribution, storage, sale, use and post-marketing surveillance of regulated products, as provided for under the relevant laws and regulations.

In executing its mandate, TMDA contributes directly to FYDP IV priorities by strengthening health security, promoting industrial competitiveness through efficient and predictable regulatory processes and facilitating safe cross-border trade in regulated health products

1.2.2 Functions

Pursuant to the Tanzania Medicines and Medical Devices Act, Cap 219 and Tobacco Products (Regulations) Act Cap, 121, TMDA discharges the following functions: -

- (a) regulate all matters relating to quality and safety of drugs, herbal drugs, medical devices and poisons;
- (b) regulate in accordance with this Act, the importation, manufacture, labeling, marking or identification, storage, promotion, sell of drugs, herbal drugs and medical devices or any materials or substances used in the manufacture of products regulated under this Act.
- (c) ensure that evidence of existing and new adverse events, interactions and information about pharmacovigilance of products being monitored, analyzed and acted upon;
- (d) ensure that, clinical trials on drugs, medical devices and herbal drugs are being conducted in accordance with prescribed standards;
- (e) foster co-operation between the Authority and other institutions or organizations and other stakeholders;
- (f) approve and register products regulated under this Act, manufactured within or imported into and intended for use in the United Republic;
- (g) examine, grant, issue, suspend, cancel and revoke certificates and licenses or permits issued under this Act;
- (h) appoint inspectors and order inspection of any premises;
- (i) promote rational use of drugs, medical devices and herbal drug;
- (j) establish and maintain the Tanzania National Formulary and Tanzania Pharmacopoeia;
- (k) provide the public with unbiased information on products regulated under this Act;
- (l) maintain registers prescribed under this Act;
- (m) be responsible for its human resource management and development;
- (n) promote, monitor and ensure successful implementation of the provisions of this Act;
- (o) attend to and, where possible, take legal measures on complaints made by consumers against manufacturers of products regulated under this Act;
- (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 products regulated under this Act; and
- (q) 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 under this Act

In executing its mandate, TMDA plays a strategic role in advancing National development priorities under FYDP IV by strengthening health security systems, promoting industrial competitiveness through efficient and predictable regulatory processes and facilitating safe cross-border trade in regulated products. This linkage positions regulation not only as a compliance function but as a catalyst for economic transformation and public health protection.

1.3 Rationale of the Plan

Tanzania has entered a new phase in its National development trajectory, marked by a deliberate shift towards a long-term, people-centered development framework articulated in the National Development Vision (DIRA) 2050. This shift reflects a National consensus on the need to advance a healthy society, industrialization, technological advancement, environmental sustainability and strong, accountable institutions as the foundation for inclusive and resilient socio-economic transformation. Within this evolving development context, the regulation of medicines, medical devices, diagnostics, biocidals and tobacco products has assumed greater strategic importance in safeguarding population health, strengthening trust in public institutions and enabling a well-regulated, competitive health products market.

At the same time, the regulatory environment in which TMDA operates has become increasingly complex. Expansion of local pharmaceutical and medical device manufacturing, growing volumes of imports and exports, rapid technological change and deeper regional and international market integration have heightened the risks associated with substandard, falsified, unsafe, or ineffective health products.

These dynamics, coupled with rising public and stakeholder expectations for efficient, transparent and accountable regulatory services, underscore the need for a clear, coherent and forward-looking strategic framework to guide TMDA's regulatory and institutional interventions over the medium term.

Therefore, in order to define and operationalize TMDA's unique regulatory contribution to public health protection, industrial growth and socio-economic transformation within the new National development paradigm, the TMDA Strategic Plan (2026/27–2030/31) has been developed. The Plan provides a structured and results-oriented framework for translating National development aspirations into measurable regulatory outcomes within TMDA's statutory mandate, while strengthening the Authority's role in public health protection, market integrity and industrial competitiveness.

**TMDA Strategic Plan
(2026/27–2030/31)
provides a structured
and results-oriented
framework for
translating National
development
aspirations...**

On reflection, this strategic approach is justified for two reasons. First, the Strategic Plan is firmly anchored in DIRA 2050, which calls upon public institutions to act with determination, foster a culture of execution, embrace innovation and uphold accountability in the delivery of their mandates. An effective and credible health products regulatory system is essential to achieving these aspirations, as it underpins disease prevention and control, universal health coverage, consumer protection and the sustainable growth of local pharmaceutical and medical device manufacturing and innovation. The Plan also aligns with the CCM Election Manifesto (2025–2030), which emphasizes improved healthcare quality, strengthened regulation and enhanced governance across public institutions.

Second, the Strategic Plan ensures strong coherence with cross-cutting National priorities, including good governance and anti-corruption, environmental protection, gender equality and social inclusion, HIV/AIDS and non-communicable diseases and the digital transformation of public services. In addition, it aligns with relevant global, continental and regional frameworks such as the Sustainable Development Goals, the African Union Agenda 2063 and East African Community (EAC) and Southern African Development Community (SADC) regulatory harmonization initiatives. This coherence strengthens regional cooperation, supports safe cross-border trade in health products and enhances Tanzania's standing within regional and international regulatory systems.

Overall, the TMDA Strategic Plan positions the Authority as a modern, results-driven regulatory institution that goes beyond compliance enforcement to actively support public health protection, market integrity, industrial growth, environmental and social sustainability and good governance.

By clearly linking regulatory challenges to strategic responses and aligning TMDA's statutory mandate with the National shift towards a long-term development vision, the Plan provides a credible and practical road map for sustained regulatory excellence and meaningful contribution to Tanzania's development agenda under DIRA 2050.

1.4 Approach and Methodology

Preparation of TMDA Strategic Plan (2026/27–2030/31) followed a systematic, evidence-based and participatory methodology, consistent with National strategic planning guidelines and good practice in results-based management. The methodology was designed to ensure that the Strategic Plan is responsive to institutional performance realities, aligned with National development priorities and owned by key stakeholders.

The process integrated the End-Term Evaluation (ETE) of the outgoing Strategic Plan with forward-looking strategic planning, enabling lessons learned, performance trends and emerging risks to directly inform strategic choices. A mixed-methods approach was applied, combining desk reviews,

performance analysis, stakeholder consultations, institutional self-assessment, benchmarking and structured validation processes.

To ensure clarity, transparency and accountability, the methodology was implemented through six sequential and interlinked phases, covering preparation and initiation, situational analysis, strategy formulation and results framework development, internal review and refinement, validation and approval and dissemination and roll-out of the Strategic Plan. Each phase had clearly defined objectives, activities, outputs, time lines and responsible actors. Table 1 provides a summary of the phases and key actions undertaken during the Strategic Plan development process.

Table 1. Methodology Used to Prepare TMDA's Strategic Plan

Sn	Phase	Actions Undertaken
1.	Phase 1: Preparatory and Initiation Phase	This phase focused on establishing a strong institutional, technical and operational foundation for the development of the TMDA Strategic Plan (2026/27–2030/31), including preparation for and undertaking of the ETE of the outgoing Strategic Plan. The phase commenced with an inception meeting involving TMDA Management, the Planning Team and the External Facilitator to establish a shared understanding of the assignment, confirm the scope of work, clarify expectations and agree on the methodology, planning approach and implementation arrangements for both the ETE and the new Strategic Plan. Following the inception meeting, a comprehensive concept note was prepared outlining the background, objectives, methodology, stakeholder engagement approach, work plan and governance arrangements for the ETE and Strategic Plan development processes. Key internal and external stakeholders were identified and mapped, including regulatory directorates, laboratories, zonal offices, regulated entities, MDAs and development partners. A detailed work plan and timetable were developed in line with the approved road map. Roles and responsibilities were clearly defined, including the engagement of an External Facilitator to provide independent technical guidance. Data-collection tools were developed and teams for Key Informant Interviews (KIIs) and Focus Group Discussions (FGDs) were oriented to ensure readiness and effective coordination.
2.	Phase 2: Situational and Environmental Analysis	The phase commenced with a review of National development and policy frameworks to establish the strategic context for the new Plan, including the National Development Vision 2050, Fourth Five-Year Development Plan, the CCM Election Manifesto (2025–2030), relevant National health policies and applicable international regulatory standards. This review was complemented by a focused assessment of the ETE report on the outgoing Strategic Plan, undertaken to identify performance gaps, implementation challenges, institutional strengths and weaknesses and priority areas requiring strategic attention and corrective action in the new Plan.

Sn	Phase	Actions Undertaken
		Additional inputs to the analysis included desk reviews of institutional, sectoral and regulatory documents; analysis of administrative and performance data; and institutional self-assessments. Benchmarking against comparable National and regional medicines regulatory authorities was also conducted to inform strategic positioning and institutional strengthening. The analytical process was supported by the application of established tools, including PESTEL, SWOC, stakeholder analysis and regulatory risk assessment across the health products life cycle.
3.	Phase 3: Strategy Formulation and Results Framework Development	This phase focused on translating the findings of the situational and environmental analysis into a coherent and results-oriented Strategic Plan framework, in line with the prescribed National Strategic Plan format. TMDA reviewed and confirmed its Vision, Mission and Core Values, guided by evidence from the situational analysis and alignment with higher-level National and sectoral frameworks. Strategic priorities were identified and articulated into clearly defined Strategic Objectives, supported by appropriate strategies, targets and outcome indicators. Emphasis was placed on the development of results-based planning architecture, including formulation of the Results Framework and Results Chain, definition of beneficiaries and establishment of output and outcome indicators aligned with Annex III and IV respectively. The phase also included preliminary resource planning to assess human, financial and technological requirements and to ensure the feasibility and implementability of the proposed Strategic Objectives and Strategies.
4.	Phase 4: Internal Review and Refinement	An internal review retreat was conducted to critically assess the draft Strategic Plan. The review focused on strategic coherence, alignment with TMDA's mandate, feasibility of proposed interventions, clarity and measurability of results and indicators and consistency with National planning and budgeting frameworks. Feedback from Management and the Planning Team was systematically consolidated and incorporated to produce an improved Draft Strategic Plan.
5.	Phase 5: Validation, Finalization and Approval	The refined Draft Strategic Plan was presented to TMDA Management, the MAB and the Workers' Council for review, guidance and internal validation. A broader stakeholders' validation workshop was also conducted, bring together regulated entities, MDAs, professional bodies and other key stakeholders to ensure ownership and alignment with stakeholder expectations. All comments and recommendations were systematically reviewed and incorporated, followed by final quality assurance. The Strategic Plan was subsequently approved by the MAB and formally adopted for implementation.

Sn	Phase	Actions Undertaken
6.	Phase 6: Dissemination and Roll-out of the Strategic Plan	This phase focused on the dissemination and institutionalization of the approved Strategic Plan to ensure shared understanding, ownership and effective implementation. The Strategic Plan was disseminated to Management, staff, zonal offices, laboratories, the Workers' Council, the MAB, regulated entities, key MDAs and other stakeholders through internal briefings, stakeholder forums and electronic and printed communication channels. The dissemination process emphasized communication of strategic priorities, roles and responsibilities, performance indicators and implementation arrangements. Linkages were established between the Strategic Plan, Annual Work Plans and Budgets (AWPBs), performance management systems and the Monitoring and Evaluation framework to ensure alignment between planning, budgeting, implementation and reporting. This phase ensured that the Strategic Plan transitioned from a policy document into an operational management tool.

The planning process explicitly incorporated implementation feasibility, sequencing of reforms and financial sustainability considerations to ensure that proposed interventions are realistic, prioritized and aligned with FYDP IV delivery principles.

1.5 Layout of the Plan

This Strategic Plan is organized into five chapters and accompanying annexes, structured in line with the National Planning Guidelines for Public Institutions issued by the Planning Commission. The chapters are sequenced to progressively guide the reader from an understanding of TMDA's institutional context and mandate, through analysis of the operating environment, articulation of strategic choices and priorities, definition of implementation and resource arrangements and finally to the monitoring, evaluation and reporting framework. Sections (a) to (e) below summarize the focus and content of each chapter.

(a) Chapter One:

Introduction

This chapter provides the foundational elements of the Plan, including the background of the Authority, its mandate and functions, the rationale for developing the Strategic Plan, the approach and methodology used in the planning process and the overall layout of the document.

(b) Chapter Two:

Situational Analysis

This chapter presents an in-depth assessment of TMDA's internal and external environment. It includes the context analysis, review of the current Vision, Mission and Core Values, performance assessment of the existing Strategic Plan, PESTEL and SWOC ANALYSIS, stakeholder analysis, recent initiatives undertaken by the Authority and the identification of key challenges, opportunities and Critical Issues that inform the strategic direction.

(c) Chapter Three:**The Plan**

This chapter outlines TMDA's strategic direction for the 2026/27–2030/31 planning period. It includes the revised Vision, Mission and Core Values, as well as the Strategic Objectives, their rationale and the corresponding strategies, targets and key performance indicators. It also introduces the cascading of strategies and targets across Directorates, Sections and Units.

(d) Chapter Four:**Resources for the Plan**

This chapter provides an overview of the financial and non-financial resources required to implement the Strategic Plan. It outlines projected resource needs, resource mobilization strategies and mechanisms for ensuring effective use of resources in support of planned interventions.

(e) Chapter Five:**Results Framework**

This chapter presents the M&E framework for tracking implementation progress, assessing performance and ensuring accountability. It includes the results framework, reporting arrangements, performance indicators, evaluation processes and institutional M&E responsibilities.

(f) Annexes

The annexes provide supporting materials to the Strategic Plan, comprising the TMDA Organizational Structure (Annex I) Indicator Reference Sheets for the Results Framework (Annex II), Monitoring Framework for Output Indicators (Annex III), and Evaluation Framework for Outcome Indicators (Annex IV). Together, these annexes provide the technical and operational details required to support implementation, monitoring and evaluation of the Strategic Plan.

Subsequent chapters of this Plan demonstrate how TMDA's strategic objectives, interventions and results framework contribute to the achievement of DIRA 2050 aspirations and FYDP IV strategic priorities.

CHAPTER TWO

SITUATIONAL AND ENVIRONMENTAL ANALYSIS



CHAPTER TWO:

SITUATIONAL AND ENVIRONMENTAL ANALYSIS

This chapter presents a comprehensive situational and environmental analysis of the Tanzania Medicines and Medical Devices Authority (TMDA) to inform the formulation of the Strategic Plan. The analysis examines both internal and external factors that influence TMDA's performance, mandate execution and strategic positioning within the national, regional and global regulatory landscape. By systematically assessing institutional capacities, governance arrangements, regulatory systems and the broader political, economic, social, technological, legal and environmental context, the chapter provides evidence-based insights into the opportunities, challenges, risks and constraints facing the Authority. The findings of this analysis form a critical foundation for defining strategic priorities, objectives and interventions for the 2026/27 – 2030/31 planning period.

This analysis is structured across four strategic lenses: public health protection, industrial development, digital transformation, governance and accountability to ensure comprehensive alignment with National and sectoral priorities.

2.1 Assessment of endogenous and exogenous factors affecting the performance

The performance of the TMDA is shaped by a combination of internal institutional conditions and external environmental dynamics. Internally, TMDA benefits from a strong legal mandate, established regulatory systems aligned with international standards, accredited laboratories and experienced technical staff, which enhance regulatory credibility and effectiveness. However, increasing regulatory demand, skills gaps in emerging regulatory areas, capacity constraints and financial sustainability pressures continue to affect operational efficiency.

Externally, TMDA operates within a dynamic policy, economic, technological and public health environment. National and regional commitments to public health protection, industrialization and regulatory harmonization, coupled with growth in local manufacturing, expanding imports and exports, technological innovation and evolving disease patterns, have intensified regulatory expectations. At the same time, challenges such as substandard and falsified products, cross-border trade risks and environmental pressures increase the complexity of regulatory oversight.

This assessment provides a critical foundation for subsequent SWOC and PESTEL analysis and informs the identification of key challenges, opportunities and critical issues that shape TMDA's strategic direction for the 2026/27–2030/31 planning period.

This situational analysis is structured across four strategic lenses namely; public health protection, industrial development, digital transformation and governance and accountability to ensure comprehensive alignment with National priorities and sectoral expectations

2.2 Analysis of Vision, Mission and Core Values

The review of TMDA's Vision Statement was conducted based on the criteria provided in the National Planning Guidelines, which require an effective Vision to be future-centered, inspirational, concise, driven by the National Development Vision and aligned with institutional values. The previous Vision Statement, *"To achieve regulatory excellence in ensuring safe, quality and effective medicines, medical devices, diagnostics and other health-related products for all,"* clearly expresses TMDA's mandate and ambition to lead in regulatory functions. However, the assessment revealed several areas for improvement.

While the previous Vision was clear and concise, it was more descriptive of TMDA's operational role than of its long-term aspiration. It did not fully describe the intended impact of the authority's functions on the stakeholders. Moreover, the previous Vision was developed to translate the health aspirations of Tanzania's development vision which has been superseded by DIRA 2050.

To address these gaps, a revised Vision Statement was proposed using the structural format preferred by TMDA and aligned with the National Planning Guidelines. The previous Vision: *"Improved health and wellbeing for all Tanzanians through regulatory excellence that meets global standards"* offers a clearer expression of the future state. The Vision statement is concise, easy to communicate and strongly aligns with DIRA 2050's aspirations, it also reflects TMDA's core values. This revised Vision better positions TMDA to inspire stakeholders and guide the Authority's strategic direction over the next five years.

... nevertheless, it was more descriptive of TMDA's operational role than of its long-term aspiration.

TMDA Vision:
"Improved health and wellbeing for all Tanzanians through regulatory excellence that meets global standards"

The analysis of TMDA's Vision was undertaken to assess their continued relevance, aspirational strength and alignment with National development priorities and institutional mandates. This review was guided by the National Planning Guidelines and the prescribed qualities of a good Vision Statement, namely: being future-centered, inspirational, concise, driven by the National Development Vision and aligned with organizational core values.

With regard to the Mission and Core Values, the review established that both remain relevant, clear and fully aligned with TMDA's statutory functions and strategic role. The Mission continues to accurately define TMDA's core purpose and regulatory approach, while the Core Values consistently reflect the principles guiding the Authority's conduct, decision-making and service delivery. The situational analysis did not identify any material gaps, inconsistencies, or misalignment with National development frameworks or emerging regulatory priorities. Consequently, it was concluded that there was no justification for revising the Mission and Core Values and they were therefore retained unchanged to ensure continuity, institutional stability and sustained organizational identity.

In this context, TMDA is strategically positioned to evolve into a trusted regional regulatory authority that supports innovation, enhances export readiness of locally manufactured health products and contributes to the competitiveness of Tanzania's pharmaceutical and health products industry within Regional and Global markets.

TMDA Mission continues to accurately define TMDA's core purpose and regulatory approach, while the Core Values consistently reflect the principles guiding the Authority's conduct, decision-making and service delivery.

2.3 Performance review of the fifth TMDA SP (2021/22 – 2025/26)

This section reviews TMDA’s performance during the implementation of the outgoing Strategic Plan, drawing on findings from the End-Term Evaluation and fourth-year performance data. The review assesses progress achieved against planned objectives, identifies persistent gaps and highlights lessons that inform the strategic direction of the new Strategic Plan. Detailed performance results are presented in sections 2.3.1



2.3.1 Achievement of Planned Outcomes

2.3.1.1 Strategic Objective A:

HIV/AIDS and Non-Communicable Diseases (NCDs) Reduced and Services Improved

This Strategic Objective aimed to enhance the prevention, management and control of HIV/AIDS and Non-Communicable Diseases (NCDs) among TMDA staff through effective implementation of National workplace health guidelines. The objective focused on increasing staff participation in voluntary HIV/AIDS health check-ups and reducing the incidence of NCDs among employees as key measures of improved health outcomes and institutional wellness.

Performance under this objective was assessed using two outcome indicators, namely: the percentage of TMDA staff participating in voluntary HIV/AIDS health check-ups and the incidence rate of NCDs among TMDA staff. Table 2 presents a comparison of baseline performance (2021/22) and fourth-year performance (2024/25), alongside the corresponding targets, to assess progress made over the Strategic Plan period and the likelihood of achieving end-term targets.



Table 2: Performance Towards Improving HIV/AIDS and NCDs Prevention and Services among TMDA Staff

Sn.	Indicator	Baseline 2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance	
1.	Percentage of staff participation in voluntary HIV/AIDS health check-ups	52	80	67	Participation in voluntary HIV/AIDS health check-ups increased from 52 percent at baseline to 67 percent by the fourth year of implementation, reflecting a 15-percentage-point improvement over the Strategic Plan period. However, when assessed against the end-year target of 80 percent, the fourth-year performance indicates that the target has not yet been achieved. TMDA remains 13 percentage points below the planned end-term target, implying that additional effort is required in the final year to close this gap.
2.	Percentage of NCDs incidence rate among TMDA staff	5	2	15	Despite the planned reduction of NCDs incidence from the baseline level of 5 to a fourth-year target of 2 percent, the actual performance in 2024/25 deteriorated sharply to 15 percent. This represents a substantial reversal from the baseline and indicates a significant worsening of NCDs incidence among TMDA staff. When assessed against the end-year target of 1 percent, the fourth-year performance is 14 percentage points above the intended level, demonstrating that TMDA is very far from achieving the end-term target. The result points to ineffective preventive interventions and underscores the need for urgent, intensified workplace wellness and behavior-change measures in the final year of the Strategic Plan.

Performance under Strategic Objective A was mixed. While participation in voluntary HIV/AIDS health check-ups among staff improved steadily over the Strategic Plan period, performance by FY 2024/25 remained below the end-term target, indicating the need for continued sensitization and service uptake initiatives. Conversely, the incidence of Non-Communicable Diseases among TMDA staff increased significantly compared to

the baseline, deviating substantially from the intended reduction trajectory. This trend highlights weaknesses in workplace wellness and preventive health interventions and underscores the need for a more comprehensive and institutionalized staff health program in the new Strategic Plan.

2.3.1.2 Strategic Objective B:

National Anti-Corruption Strategy Effectively Implemented and Sustained

This Strategic Objective aimed to promote good governance, integrity and ethical values within TMDA through effective implementation of the National Anti-Corruption Strategy. The objective focused on strengthening internal control systems, leveraging ICT in service delivery and institutionalizing the Public Service Code of Ethics and Conduct among staff, with the ultimate goal of improving staff awareness on corruption prevention and ensuring zero incidence of corruption within the institution.

Table 3: Performance Towards Strengthening Integrity and Anti-Corruption

Sn	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance	
1.	Percentage of level of staff awareness on corruption prevention	40	90	77	The level of staff awareness on corruption prevention increased substantially from 40 percent at baseline to 77 percent by the fourth year of implementation, representing a 37-percentage-point improvement over the Strategic Plan period. This demonstrates clear progress attributable to sustained ethics sensitization and governance strengthening initiatives. However, when assessed against the end-year target of 100 percent, the fourth-year performance remains 23 percentage points below the planned level, indicating that full institutional coverage has not yet been achieved and additional targeted sensitization efforts are required in the final year.
2.	Percentage of number of corruption allegations against TMDA staff	0	0	0	The number of corruption allegations against TMDA staff remained at zero from baseline through the fourth year of implementation. When compared against the end-year target of zero allegations, the fourth-year performance indicates that the target has been fully met and sustained throughout the Strategic Plan period. This reflects the effectiveness of internal control systems, enforcement of ethical standards and a strong institutional culture of integrity

As shown in Table 3, TMDA recorded strong performance in strengthening integrity systems and ethical conduct. Staff awareness on corruption prevention improved substantially over the Strategic Plan period, reflecting effective sensitization and internal governance initiatives, although full institutional coverage had not yet been achieved by the fourth year. Notably, zero corruption allegations were recorded throughout the implementation period, demonstrating robust internal controls and a strong culture of integrity. These results suggest that governance and accountability mechanisms are well established and should be sustained and further institutionalized in the new Strategic Plan.

2.3.1.3 Strategic Objective C:

Gender and Environmental Issues Improved

This Strategic Objective focused on strengthening gender equality and environmental management within TMDA by mainstreaming gender and environmental considerations across institutional plans, policies and operational practices. The objective emphasized increasing women’s representation in managerial and decision-making positions as a key measure of progress toward inclusive governance and equitable institutional development.

Performance under this objective was assessed using the proportion of women in managerial positions as the primary outcome indicator. Table 4 presents a comparison of baseline performance (2021/22) and fourth-year performance (2024/25), together with the corresponding targets, to assess progress made over the Strategic Plan period and the likelihood of achieving the end-term target.



Table 4: Performance towards improving Gender Equality in TMDA Management

Sn	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance	
1.	Percentage of proportion of women at managerial positions	15	35	35	The proportion of women in managerial positions increased significantly, achieving the intended target and reflecting effective gender mainstreaming and inclusive leadership practices within TMDA.

Performance under Strategic Objective C was strong (Table 4). The proportion of women in managerial positions increased significantly from the baseline and achieved the intended target by FY 2024/25. This reflects effective gender mainstreaming and inclusive leadership practices within TMDA. The key strategic consideration going forward is sustaining these gains and integrating broader gender and environmental considerations more systematically across regulatory functions.

2.3.1.4 Strategic Objective D:

Quality, Safety and Effectiveness of Medicines and Biocidal Products Assured

This Strategic Objective focused on safeguarding public health by ensuring that medicines and biocidal products circulating in the country meet required standards of quality, safety and effectiveness. Progress under this objective was measured using outcome indicators covering regulatory efficiency, post-marketing surveillance, manufacturing compliance, clinical trial oversight and compliance of medicines-selling outlets. These indicators collectively assessed TMDA's effectiveness in regulating products across the entire life cycle, from registration and manufacturing to distribution and post-marketing monitoring.

Table 5 presents a comparison of baseline performance (2021/22) and fourth-year performance (2024/25) for key outcome indicators under Strategic Objective D. The table highlights progress achieved over the Strategic Plan period, assesses fourth-year performance against annual and end-term targets and provides an indication of the likelihood of achieving final-year targets.



Table 5: Performance towards ensuring Quality, Safety and Effectiveness of Medicines and Biocidal Products

Sn.	Outcome Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance	
1.	Percentage of applications for registration of medicines processed within CSC time lines	80	85	85	Performance improved from the baseline level of 80 percent to 85 percent by the fourth year, fully meeting the annual target and demonstrating strengthened regulatory efficiency. However, when assessed against the end-year target of 90 percent, the fourth-year performance remains 5 percentage points below the planned level. Given the positive upward trend and the relatively small remaining gap, achievement of the final-year target is likely, provided current process efficiency gains are sustained.
2.	Percentage of applications for registration of biocidal products processed within CSC time lines	90	94	90	Performance remained unchanged at 90 percent from baseline through the fourth year, indicating stagnation and failure to meet the fourth-year target of 94 percent. Compared to the end-year target of 95 percent, the fourth-year performance remains 5 percentage points below the planned level. Given the absence of measurable improvement over time, achievement of the final-year target calls for targeted process improvements are implemented.
3.	Percentage of PMS samples of human medicines complying with quality requirements	100	100	81	Compliance declined from 100 percent at baseline to 81 percent by the fourth year, representing deterioration in performance. Given the negative performance trend and the magnitude of the remaining gap, achievement of the final-year target is unlikely without substantial corrective measures, including strengthened risk-based surveillance and enforcement activities.

Sn.	Outcome Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance	
4.	Percentage of PMS samples of veterinary medicines complying with quality requirements	100	100	N/D	Although the baseline and target values were set at 100 percent, no data were available for the fourth year. As a result, performance against both the fourth-year and end-term targets could not be assessed. The absence of data indicates a reporting gap in veterinary medicines post-marketing surveillance that requires corrective action.
5.	Percentage of domestic pharmaceutical manufacturers complying with GMP requirements	50	60	88	Compliance with GMP requirements increased substantially from a baseline of 50 percent to 88 percent by the fourth year, exceeding the annual target of 60 percent. This reflects strong regulatory enforcement and improved industry compliance. Compared to the end-term target of 60 percent, the indicator has already surpassed the planned level by 28 percentage points, indicating performance well ahead of target.
6.	Percentage of clinical trials compliant with GCP and GCLP requirements	100	100	94	Compliance declined from the baseline level to 94 percent by the fourth year, representing deterioration of regulatory oversight of clinical trials. However, when assessed against the end-year target of 100 percent, the fourth-year performance remains 6 percentage points below the planned level. Given the negative performance trajectory and the narrow remaining gap, achievement of the final-year target is unlikely without substantial corrective measures including enforcement and monitoring activities.
7.	Percentage of inspected medicines-selling outlets complying with requirements	88	90	100	Compliance increased from 88 percent at baseline to 100 percent by the fourth year, exceeding both the annual and end-year targets. This over achievement indicates highly effective inspection and enforcement mechanisms. The end-year target has already been achieved and sustained performance is very likely.

Results summarized in Table 5 indicate generally positive regulatory performance whereby significant improvements were recorded in medicines registration time lines, GMP compliance among domestic manufacturers, clinical trial oversight and compliance of medicines-selling outlets, with several indicators meeting or exceeding their planned targets. However, performance in post-marketing surveillance of human medicines declined and progress in some biocidal product regulatory processes stagnated. These mixed results highlight the need for the new Strategic Plan to consolidate gains in pre-market regulatory efficiency while strengthening post-marketing surveillance, risk-based inspections and enforcement mechanisms.

2.3.1.5 Strategic Objective E:

Quality, Safety and Performance of Medical Devices and Diagnostics Assured

This Strategic Objective focused on strengthening the regulation of medical devices and diagnostics to ensure that products available on the market meet required standards of quality, safety and performance. The objective emphasized regulatory efficiency, post-marketing surveillance, manufacturing compliance and distribution-level inspections as key measures of effective oversight in response to the increasing complexity and volume of medical technologies.

Performance under this objective was assessed using outcome indicators related to the timeliness of application processing, compliance of post-marketing surveillance samples with performance requirements, adherence of domestic manufacturers to Quality Management System (QMS) standards and compliance of inspected outlets. Table 6 presents a comparison of baseline performance (2021/22) and fourth-year performance (2024/25), together with the corresponding targets, to assess progress achieved during the Strategic Plan period and the likelihood of attaining end-term targets.



Table 6: Performance Towards Ensuring Quality, Safety and Performance of Medical Devices and Diagnostics

Sn	Outcome Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
1.	Percentage of applications for registration of medical devices and diagnostics processed within CSC time lines	87	94	82	Performance declined from the baseline level of 87 percent to 82 percent by the fourth year, indicating a deterioration in regulatory timeliness. Given the negative performance trend, achievement of the final-year target is unlikely without significant improvements in work flow efficiency and application processing systems.
2.	Percentage of applications for notification of medical devices and diagnostics processed within CSC time lines	87	94	88	Performance improved modestly from the baseline level of 87 percent to 88 percent by the fourth year, demonstrating limited progress in notification processing. However, when compared to the end-year target of 94 percent, the fourth-year performance remains 6 percentage points below the planned level. Given the slow pace of improvement, achievement of the final-year target is uncertain unless targeted process optimization measures are implemented.
3.	Percentage of PMS samples of medical devices and diagnostics complying with performance requirements	55	80	76	Compliance with performance requirements increased substantially from 55 percent at baseline to 76 percent by the fourth year, reflecting strengthened post-marketing surveillance activities. Nevertheless, when assessed against the end-year target of 80 percent, the fourth-year performance remains 4 percentage points below the intended level. Given the positive upward trend and the narrow remaining gap, achievement of the final-year target is likely, provided current surveillance efforts are sustained.
4.	Percentage of domestic medical device and diagnostics manufacturing facilities complying with QMS requirements	0	30	79	Compliance with Quality Management System requirements increased dramatically from zero at baseline to 79 percent by the fourth year, far exceeding the fourth-year target of 30 percent. Compared to the end-year target of 40 percent, performance is 39 percentage points above the planned level. This indicates that the end-year target has already been exceeded and sustained compliance is highly likely.

Sn	Outcome Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
5.	Percentage of inspected medical devices and diagnostics outlets complying with requirements	57	80	95	Compliance among inspected outlets improved markedly from 57 percent at baseline to 95 percent by the fourth year, exceeding both the annual target of 80 percent and the end-year target of 80 percent. This strong over achievement demonstrates effective inspection and enforcement mechanisms and sustained performance at or above the end-year target is very likely.

As indicated in Table 6, TMDA made notable progress in regulating medical devices and diagnostics, particularly in improving compliance among domestic manufacturers and compliance of inspected outlets, both of which exceeded end-term targets. Post-marketing surveillance compliance also improved and is approaching the planned end year target.

However, performance in medical device and diagnostic registration time lines declined, leaving a notable gap against end-term targets. This suggests the need for targeted process re-engineering, digitalization and capacity enhancement in medical devices regulatory work-flows under the new Strategic Plan.

2.3.1.6 Strategic Objective F:

Control of Tobacco Products Strengthened

This Strategic Objective aimed to strengthen the regulation and control of tobacco products through the establishment and operationalization of systems for notification, registration, inspection, surveillance and enforcement. The objective focused on ensuring that tobacco products are properly regulated throughout their life cycle, including compliance with safety standards and regulatory requirements by domestic manufacturers, with the ultimate goal of reducing public exposure to health risks associated with tobacco use.



Performance under this objective was assessed using outcome indicators related to the timeliness of processing applications for notification or registration of tobacco products, compliance of surveillance samples with safety standards and compliance of domestic tobacco manufacturing facilities with regulatory requirements. Table 7 presents a comparison of baseline performance (2021/22) and fourth-year performance (2024/25), together with the corresponding targets, to assess progress made over the Strategic Plan period and the likelihood of achieving end-term targets.

Table 7: Performance Towards Strengthening Control of Tobacco Products

Sn	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
1.	Percentage of applications for notification/registration of tobacco products approved or rejected within the specified time period (as per CSC)	0	95	0	No applications were processed within the reporting period, indicating that regulatory systems for tobacco product registration were not operationalized.
2.	Percentage of surveillance samples for tobacco products complying with safety standards	0	97	0	No testing result for surveillance samples were recorded, reflecting limited implementation of testing activities for tobacco products.
3.	Percentage of domestic tobacco manufacturing facilities complying with regulatory requirements	0	97	0	No available records for domestic tobacco manufacturing facilities assessed, indicating a gap in enforcement activities.

Performance under Strategic Objective F was limited (Table 7). By 2024/25, key regulatory systems for tobacco products had not been fully operationalized and no measurable progress was recorded against planned indicators.

Nevertheless, the Authority through its zone offices consented on inspection of tobacco wholesaler and retail business outlets and public areas including hotels, bars/ restaurants, to ensure compliance with tobacco product regulations. This indicates structural and implementation challenges that constrained achievement of the objective. Addressing these gaps will require clearer regulatory frameworks, defined institutional responsibilities and strengthened enforcement arrangements in the new Strategic Plan period.

2.3.1.7 Strategic Objective G:

Laboratory Services Improved

This Strategic Objective aimed to strengthen TMDA's laboratory services to support effective regulation of medicines, medical devices, diagnostics and other regulated products. The objective focused on improving turnaround time for laboratory results, sustaining internationally recognized accreditations and prequalification, expanding laboratory capacity through decentralization to zonal offices and strengthening applied laboratory research as key measures of laboratory effectiveness and credibility.

Performance under this objective was assessed using outcome indicators related to turnaround time for laboratory results, attainment and sustenance of ISO/IEC 17025 accreditation and WHO prequalification, customer satisfaction with laboratory services and publication of planned laboratory-related research outputs. Table 8 presents a comparison of baseline performance (2021/22) and fourth-year performance (2024/25), together with the corresponding targets, to assess progress made during the Strategic Plan period and the likelihood of achieving end-term targets.



Table 8: Performance Towards Improving Laboratory Services

Sn	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
1.	Percentage of laboratory results for medicines released within CSC turnaround time	100	100	100	Timely release of laboratory results for medicines was sustained at 100 percent from baseline through the fourth year, consistently meeting both the annual and end-term targets. This indicates stable operational efficiency and effective work flow management. Given the sustained performance trend, maintenance of the end-year target is highly likely.
2.	Percentage of laboratory results for medical devices released within CSC turnaround time	86	100	100	Turnaround time performance improved from 86 percent at baseline to 100 percent by the fourth year, fully achieving the annual target. Compared to the end-term target of 100 percent, the indicator has already reached the planned level. Given the strong upward trajectory and full compliance achieved, sustained attainment of the final-year target is very likely.
3.	Level of customer satisfaction in relation to laboratory services	100	100	N/D	Although a target of 100 percent was set, no data were available for the fourth year to assess performance. As a result, progress toward the end-term target cannot be determined. In the absence of measurable data, the likelihood of achieving the final-year target is uncertain, underscoring the need to operationalize customer satisfaction measurement mechanisms.
4.	ISO/IEC 17025 accreditation for Dar es Salaam laboratory	1	1	1	ISO/IEC 17025 accreditation for the Dar es Salaam laboratory was sustained from baseline through the fourth year, meeting the end-term target. This demonstrates continued compliance with international quality standards. Given the sustained accreditation status, continued achievement of the final-year target is highly likely.

Sn	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
5.	ISO/IEC 17025 accreditation for Mwanza laboratory	0	1	0	Despite a baseline of zero and an end-term target of accreditation, the Mwanza laboratory had not attained ISO/IEC 17025 accreditation by the fourth year. This indicates no measurable progress toward the end-term target. Given the absence of advancement by the fourth year, achievement of the final-year target is unlikely without accelerated investment in infrastructure, equipment and accreditation readiness.
6.	ISO/IEC 17025 accreditation for Dodoma laboratory	0	N/A	0	Accreditation was not achieved for the Dodoma laboratory by the fourth year, reflecting no progress toward the end-term target. Similar to Mwanza, capacity and readiness constraints persist. Given the lack of progress to date, achievement of the final-year target is unlikely without substantial corrective measures.
7.	WHO prequalification for Dar es Salaam laboratory	1	1	1	WHO prequalification for the Dar es Salaam laboratory was sustained throughout the Strategic Plan period, fully meeting the end-term target. This reinforces the credibility and international recognition of TMDA laboratory services. Sustained achievement of the final-year target is very likely.
8.	WHO prequalification for Mwanza laboratory	0	1	0	WHO prequalification was not achieved for the Mwanza laboratory by the fourth year, indicating no progress toward the end-term target. Given the absence of advancement and existing capacity constraints, achievement of the final-year target is unlikely without targeted capacity strengthening and technical support.
9.	WHO prequalification for Dodoma laboratory	0	1	0	WHO prequalification was not achieved for the Dodoma laboratory by the fourth year, reflecting limited readiness and capacity gaps. With no progress recorded to date, achievement of the final-year target is unlikely unless substantial investments and technical interventions are implemented.

Sn	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
10.	Percentage of planned laboratory-related researches output published	100	100	100	All planned laboratory-related research outputs were published at both baseline and the fourth year, fully meeting the annual and end-term targets. This demonstrates strong and sustained performance in applied laboratory research. Continued achievement of the final-year target is highly likely.

As summarized in Table 8, laboratory services recorded strong and sustained performance in several core areas. Turnaround time for laboratory results for medicines and medical devices consistently met or exceeded targets and the Dar es Salaam laboratory sustained both ISO/IEC 17025 accreditation and WHO prequalification status. However, progress toward accreditation and WHO prequalification for Mwanza and Dodoma laboratories remained limited. These results point to the need for focused investment in laboratory decentralization, infrastructure and capacity development in the new Strategic Plan.

2.3.1.8 Strategic Objective H:

Public Education Strengthened and Customer Services Improved

This Strategic Objective aimed to enhance public education and customer service delivery through effective implementation of TMDA's Communication and Customer Service Strategy. The objective focused on improving public awareness of TMDA's mandate, strengthening internal and external customer satisfaction, increasing awareness of the whistle-blowing policy and promoting behavior change related to tobacco use as key measures of effective communication, accountability and public engagement.

Performance under this objective was assessed using outcome indicators related to public awareness of TMDA functions, internal and external customer satisfaction, awareness of the whistle-blowing policy and tobacco-related knowledge and behavior change. Table 9 presents a comparison of baseline performance (2021/22) and fourth-year performance (2024/25), together with the corresponding targets, to assess progress achieved over the Strategic Plan period and the likelihood of attaining end-term targets.



Table 9: Baseline vs Fourth-Year Performance for Strategic Objective H

Sn.	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
1.	Percentage level of general public awareness on TMDA functions	88	90	56	The measured level of general public awareness on TMDA functions declined from 88 percent at baseline to 56 percent by the fourth year, indicating a significant deterioration in performance. When assessed against the end-year target of 90 percent, the fourth-year result remains 34 percentage points below the planned level. Given the downward trend and the magnitude of the gap, achievement of the final-year target is unlikely without substantial improvements in communication strategies, outreach coverage and consistency of measurement approaches.
2.	Percentage level of internal customer satisfaction	75	90	89	Internal customer satisfaction increased from 75 percent at baseline to 89 percent by the fourth year, reflecting a 14-percentage-point improvement and demonstrating enhanced service delivery and responsiveness. However, when compared to the end-year target of 90 percent, the fourth-year performance remains 1 percentage point below the planned level. Given the strong positive trend and the very small remaining gap, achievement of the final-year target is highly likely.
3.	Percentage level of external customer satisfaction	80	90	82	External customer satisfaction improved modestly from 80 percent at baseline to 82 percent by the fourth year, indicating incremental progress in stakeholder engagement and service quality. When assessed against the end-year target of 90 percent, the fourth-year performance remains 8 percentage points below the planned level. Given the slow rate of improvement, achievement of the final-year target is uncertain unless more targeted customer engagement and service improvement measures are implemented.

Sn.	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
4.	Level of general public awareness on whistle-blowing policy	0	70	N/D	Although an end-year target of 70 percent was established, no data were available for the fourth year to assess performance. Consequently, progress toward the end-term target cannot be determined. In the absence of measurable results and with limited evidence of systematic awareness activities, achievement of the final-year target is uncertain, highlighting the need to strengthen data collection and targeted public education initiatives.
5.	Proportion of the population understanding health hazards of smoking	92	100	0	Despite a high baseline level of 92 percent and an end-year target of 100 percent, the fourth-year result was reported as zero, indicating a breakdown in measurement or implementation rather than actual population awareness. As a result, performance against the end-year target cannot be reliably assessed. Given the absence of credible fourth-year data, the likelihood of achieving the final-year target is uncertain, underscoring the need for improved data collection and coordination of tobacco-related awareness programmes.
6.	Percentage of proportion of smokers quitting smoking	91	97	0	Although the baseline value was high at 91 percent and the end - year target set at 97 percent, no measurable progress was recorded by the fourth year. In the absence of reliable data and evidence of effective behavior-change outcomes, progress toward the end-term target cannot be confirmed. Given the lack of observed results to date, achievement of the final-year target is unlikely without intensified behavior-change communication and inter-sectoral interventions.

Performance under Strategic Objective H varied tremendously as indicated in Table 9. Internal customer satisfaction improved significantly close to achieving the planned target, indicating improved internal service delivery. External customer satisfaction improved modestly but remained below target. In contrast, public awareness of TMDA functions declined and data gaps were observed in whistle-blowing awareness and tobacco-related behavior change indicators. These findings call for an improved outreach and results measurement activities, through a more structured public education and stakeholder engagement strategy in the new Strategic Plan.

2.3.1.9 Strategic Objective I:

Institutional Capacity to Deliver Regulatory Services Enhanced

This Strategic Objective aimed to strengthen TMDA's institutional capacity to effectively deliver its regulatory mandate through improved governance, financial sustainability, human resource management, legal compliance and adoption of quality management and occupational safety standards. The objective focused on ensuring institutional stability, accountability and operational excellence as critical enablers of effective regulation.



Performance under this objective was assessed using outcome indicators related to financial sustainability, audit performance, staff retention, institutional governance ranking, legal case outcomes and attainment and sustenance of institutional certifications and maturity standards. Table 10 presents a comparison of baseline performance (2021/22) and fourth-year performance (2024/25), together with the corresponding targets, to assess progress achieved over the Strategic Plan period and the likelihood of attaining end-term targets.

Table 10: Baseline vs Fourth-Year Performance for Strategic Objective I

Sn.	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
1.	Percentage budgetary contribution from internal sources	87	90	89	Internal budgetary contribution increased from 87 percent at baseline to 89 percent by the fourth year, reflecting improved financial sustainability and enhanced internal revenue generation capacity. When assessed against the end-year target of 90 percent, the fourth-year performance remains marginally below the planned level by 1 percentage point. Although the target was not fully achieved, the positive upward trend suggests that the Authority is on a credible trajectory toward financial self-reliance, provided current financing strategies are sustained and further optimized.

Sn.	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
2.	Unqualified audit report attained	1	1	1	TMDA consistently attained an unqualified audit opinion from baseline through the fourth year of implementation, indicating sustained compliance with public financial management requirements. This performance reflects strong internal controls, effective financial governance and adherence to accountability standards. The maintenance of an unqualified audit opinion demonstrates institutional stability and effective stewardship of public resources.
3.	Percentage of staff retention	100	100	100	Staff retention remained at 100 percent from baseline through the fourth year, fully meeting the planned target. This sustained performance indicates a stable and motivated workforce, effective human resource management practices and a conducive working environment that supports institutional continuity and operational effectiveness.
4.	Position of TMDA in administration and human resource management in the public service	2	1	1	TMDA improved its position from second place at baseline to first place by the fourth year, achieving the planned target. This improvement reflects strengthened administrative systems, enhanced human resource management practices and improved institutional governance relative to peer public institutions.
5.	Percentage of cases decided in favour of TMDA	60	100	100	The proportion of legal cases decided in favour of TMDA increased from 60 percent at baseline to 100 percent by the fourth year, fully achieving the end-year target. This improvement indicates strengthened legal capacity, effective case management and improved compliance with regulatory and legal frameworks.

Sn.	Indicator	Baseline (2021/22)	2024/25		Performance Interpretation
			Target Value	Actual Performance Value	
6.	ISO certification sustained	1	1	1	ISO certification was sustained throughout the Strategic Plan period, indicating continued adherence to quality management system standards. This performance reflects institutional commitment to operational excellence, process standardization and continuous quality improvement.
7.	OSHA certification acquired and sustained at all TMDA offices	1	1	1	OSHA certification was acquired and sustained across all TMDA offices, meeting the planned target. This demonstrates effective implementation of occupational health and safety standards and reinforces TMDA's commitment to staff welfare and safe working environments.
8.	Maturity Level Four (4) certification attained	N/A	1	0	The intended attainment of Maturity Level Four certification was not achieved by the fourth year. This indicates gaps in advanced enterprise-wide systems integration, performance management maturity and institutional benchmarking. Failure to achieve this target suggests the need for deeper organizational reforms, digital transformation and structured capacity-building interventions in the next Strategic Plan.

As shown in Table 10, TMDA recorded consistently strong institutional performance across core governance and management dimensions. The Authority sustained unqualified audit opinions throughout the review period, maintained full staff retention, achieved complete success in legal cases and continued to comply with ISO and OSHA certification requirements.

These results indicate robust financial governance, effective human resource management and stable institutional systems. Notwithstanding these strengths, there was notable limited progress towards attainment of advanced institutional maturity certification, signaling persistent gaps in enterprise-wide systems integration and organizational performance maturity. Addressing these gaps, particularly through strengthened institutional systems and digital transformation will therefore constitute a key strategic priority in the forthcoming Strategic Plan.

2.3.2 Performance Drivers and Constraints

This section synthesizes key factors that influenced performance during implementation of the outgoing Strategic Plan (2021/22–2024/25) and highlights lessons that inform the design and prioritization of interventions in the new Strategic Plan. The analysis draws on findings from the End-Term Evaluation and fourth-year performance data and focuses on underlying drivers and constraints rather than on target achievement alone.



2.3.2.1 Performance Drivers

Implementation experience indicates that TMDA's strongest performance areas were underpinned by sound institutional foundations and systems maturity. Strong leadership commitment and effective governance arrangements enhanced accountability, ensured adherence to quality standards and supported timely decision-making across core regulatory functions. These factors contributed to sustained performance in institutional governance, financial management, laboratory services, medicines regulation and medical devices oversight.

Digitalization and automation of regulatory and support processes emerged as a critical enabler of performance. The use of integrated information systems particularly RIMS and LIMS improved efficiency, transparency and service turnaround times, particularly in application processing, laboratory services and revenue management. Automation also strengthened data availability for routine monitoring and operational control.

Performance was also higher in objectives closely aligned with TMDA's core statutory mandate and routine operational responsibilities. Regulatory functions that fall within TMDA's direct control benefited from established procedures, skilled personnel and predictable work-flows, enabling consistent implementation over the Strategic Plan period.

In addition, high staff retention and the availability of core technical competencies supported operational continuity and institutional memory, reinforcing performance stability in key regulatory and support functions.

2.3.2.2 Performance Constraints

Despite the strengths in performance drivers, several constraints limited achievement across selected strategic objectives. Weaknesses in PMS systems, including limited specialized skills and uneven capacity across zones, constrained effective monitoring of product quality and safety, particularly for veterinary medicine.

Outcome-level monitoring and data systems also posed a challenge while output tracking was generally strong. Gaps in outcome measurement and inconsistent data collection reduced the ability to assess behavioral and awareness-related results, notably in public education, whistle-blowing awareness and tobacco control interventions. This led to limited evidence-based adaptation of strategies during implementation.

Objectives that required behavior change, multi-sectoral coordination or policy leadership beyond TMDA's direct control recorded comparatively weaker performance. Limited influence over external actors and reliance on broader system responses constrained progress in areas such as tobacco control, public awareness and staff wellness initiatives.

Capacity disparities across zonal offices further affected performance. Differences in ICT infrastructure, logistics, equipment availability and maintenance constrained service timeliness and surveillance coverage in some zones.

Finally, external policy and resource constraints, including outdated sector policies, rising operational costs and limited availability of external financing mechanisms, reduced flexibility to scale resource-intensive interventions and respond to emerging regulatory priorities.

2.3.2.3 Implications for the New Strategic Plan

The performance drivers and constraints identified underscore the need for the new Strategic Plan to consolidate gains in governance, digitalization and core regulatory delivery while deliberately addressing systemic weaknesses. Strategic priorities should emphasize on strengthening post-marketing surveillance, improving outcome-level monitoring and data use, enhancing zonal capacity and adopting realistic approaches to objectives requiring multi-actor coordination and behavior change. These considerations will guide the formulation of focused, implementable and results-oriented strategies under the new Strategic Plan.

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

In developing this Strategic Plan, Strengths, Weaknesses, Opportunities and Challenges (SWOC) analysis was conducted to assess the current situation of the Institution both internally and externally. The analysis is used to evaluate the overall performance of TMDA operations and functions, build on successes, address challenges and reduce potential risks. It will also help the Authority make well-informed decisions. The results of the analysis are presented in Table 11.

Table 11: SWOC Analysis

Area	Strengths	Weaknesses
Human Resources Management	(a) Strong, visionary and results - oriented leadership;	(a) Limited implementation of the Human Resource Plan (HRP);
	(b) Existence of Human Resource Plan (HRP);	(b) Insufficient staffing levels given the increasing scope and volume of TMDA's regulatory duties.
	(c) Existence and support from the Ministerial Advisory Board (MAB);	(c) Challenges in keeping highly skilled professionals;
	(d) Trained human capital and development programs	(d) Skills gaps in
	(e) Presence of a functional Scheme of Service	(e) Skills gaps among TMDA staff in emerging regulatory areas, including medical devices, diagnostics and herbal medicines, as well as advanced competencies such as intelligence gathering, ICT programming and cybersecurity, analytical techniques, laboratory equipment maintenance, methods development and IT auditing.
	(f) Existence of an established Succession Plan	
	(g) Enhanced staff professionalism and organizational stability.	
	(h) Dedicated and motivated staff	
	Opportunities	Challenges
	(a) A growing pool of qualified professionals in the labor market provides opportunities to strengthen TMDA's workforce capacity;	(a) Inadequate human resource capacity in relation to workload and volume of assigned activities.
	(b) Strong government commitment to career development supports continuous staff growth and skill enhancement;	(b) High risk of attrition of skilled and experienced staff to international and better-remunerated organizations.

Area	Strengths	Weaknesses
	(c) Availability of local and international training institutions enables advanced professional and regulatory training; (d) Presence of health training institutions (local and international); (e) Presence of qualified personnel within Local Government Authorities (LGAs) offers opportunities for effective delegation of regulatory functions.	(c) Shortage of specialized experts in medical devices, diagnostics and laboratory equipment maintenance affects regulatory effectiveness. (d) Competition for experts in clinical trials, device regulation and quality assurance
Systems and Processes	Strengths (a) Presence of a clear and functional organizational structure; (b) Attaining global standards of medical products regulation (WHO Maturity Level 3) (c) Presence of eight (8) TMDA Zonal offices (d) Enactment of the Act and Regulations; (e) Presence of a well-established Quality and Risk Management Systems; (f) Recognition as the East African Community (EAC) Centre of Excellence for medicines evaluation and registration (g) Recognition as the East African Community (EAC) Centre of Excellence for vaccines oversight (h) Existence of electronic systems such as RIMS and LIMS; (i) Presence of office buildings and physical facilities; (j) Accreditation with international standards (ISO 9001 and ISO/IEC 17025) (k) Existence of WHO prequalified laboratories.	Weaknesses (a) Underutilization of existing laboratory capacity; (b) Inadequate mechanisms for follow-ups of approved promotion and advertisement of regulated products; (c) Inadequate monitoring and evaluation of TMDA functions; (d) Unexplored sources of revenues
	Opportunities (a) Advancing toward WHO Maturity Level 4; (b) Integration of AI/data analytics for surveillance and PV (c) Supportive National policies, legislation and strategic frameworks provide a strong foundation for regulatory advancement.	Challenges (a) Limited institutional control over investigations and prosecutions due to dependence on the DPP (b) Failure to comprehensively regulate promotional activities (c) Limited revenue generation from TMDA laboratory services

Area	Strengths	Weaknesses
	Opportunities	Challenges
	(d) Strong political support for strengthening health regulation and improving access to safe, quality and effective medical products. (e) National Five-Year Development Plan III prioritizes pharmaceutical industrialization (f) Growing regional and international regulatory initiatives, such as the African Medicines Agency (AMA), EAC harmonization and ZAZIBONA, enable collaboration, reliance and shared expertise	(d) Existence of porous borders that has contributed to smuggling of unregistered and substandard and falsified products in the market. (e) Limited availability of approved National facilities for safe disposal of hazardous regulated products. (f) Absence of a National steering committee for regulated products (g) Bureaucratic approval of laws and reviews (h) Supply chain disruptions affecting testing and surveillance (i) Risks of Cybersecurity threats (j) Unreliable network connectivity from service providers (k) Risk of regulatory gaps arising from fast-paced technological innovation in product manufacturing (l) Pilferage
Customer Care	Strengths	Weaknesses
	(a) Existence of a well-established Clients' Service Charter (CSC) and responsive communication channels (b) Existence of Communication and Public Education Strategy (c) Availability of user-friendly Information, Education and Communication (IEC) materials in both digital and print formats (d) Functional complaints-handling mechanism that support timely resolution of customer concerns. (e) Active customer feedback system, including exit interviews and service delivery surveys, that inform continuous improvement.	(a) Weak implementation of the Communication and Public Education Strategy (b) Inadequate responsiveness to customer expectations in some service areas (c) Absence of TMDA offices at regional and district levels, limiting access for local stakeholders (d) Insufficient branding and visibility of TMDA services, especially in rural and under-served areas.

Area	Strengths	Weaknesses
Customer Care	(f) Presence of dedicated customer care desks that provide direct support to stakeholders	(e) Inadequate mechanisms to reach out to the wider community to educate them on regulated products
	(g) Presence of multiple communication channels such as TMDA website, online portals, social media platforms and a toll-free hotline 0800110084	
	(h) Existence of a whistle-blowing policy that promotes transparency and accountability	
	Opportunities	Challenges
	(a) Rapid growth in the regulated products sector increases demand for TMDA services and engagement	(a) Low voluntary compliance among some dealers, affecting customer interactions and enforcement.
	(b) Rising consumer awareness and demand for safe, quality and effective medical products.	(b) Irrational use of medicines that has contributed to the emergency antimicrobial resistance.
	(c) Continuous technological advancement creates opportunities for digital customer service innovations	(c) Limited public awareness and understanding of quality and safety issues for regulated products .
	(d) Use of mobile platforms and USSD for customer engagement	(d) Emergence of digital and e-commerce channels for regulated products requiring enhanced regulatory controls
Stakeholders Participation and Engagement	Strengths	Weaknesses
	(a) Strong strategic partnerships with key regulatory and health institutions (TBS, PC, VCT, MUHAS, NMRI, ZFDA, Rwanda FDA and others).	(a) Lack of a formal platform for stakeholders to regularly discuss regulatory issues and provide structured feedback.
	(b) A positive institutional reputation Nationally and internationally	(b) Incomplete coordination between TMDA and PO-RALG on delegated regulatory functions at LGA level.
	(c) Presence of technical committees that provide expert input into regulatory decisions and	(c) Limited lobbying, advocacy and strategic communication aimed at influencing policy and stakeholder engagement
	(d) Legal mandate to delegate regulatory powers and functions to other competent bodies.	

Area	Strengths	Weaknesses
Stakeholders Participation and Engagement	Opportunities	Challenges
	(a) Availability of Local Government Authorities (LGAs) and enforcement agencies that can support regulatory operations (b) Growing number of private-sector providers of goods and services who can collaborate with TMDA (c) Presence of development partners interested in supporting regulatory strengthening initiatives (d) Involvement of civil society organizations (CSOs) in health and community education (e) Regional and international integration efforts (EAC, AMA, ZAZIBONA) enhance harmonization and cooperation	(a) Failure of the majority of domestic manufacturers of regulated products to comply with minimum GMP and quality standards. (b) Unclear division of roles and responsibilities among key regulatory stakeholders (c) Limited domestic suppliers of reagents, chemicals, equipment and technical services, increasing dependency on imports. (d) Unreliable collaboration or weak enforcement support from some law enforcement bodies. (e) Borderline regulatory control of food supplements and cosmeceuticals requiring coordinated oversight between TMDA and TBS. (f) Dependence on GPSA for clearance of imported laboratory chemicals and consumables, causing delays

2.5 PESTEL Analysis

A PESTEL Analysis was conducted to examine the external environment shaping TMDA's regulatory mandate and strategic direction. The analysis assesses the political, economic, social, technological, environmental and legal factors that influence TMDA's ability to ensure the quality, safety and efficacy of health products in Tanzania. These factors highlight external opportunities, risks and systemic conditions that were considered when designing this Strategic Plan.

Particular emphasis has been placed on technological transformation, including digital regulatory systems, advanced medical technologies and data-driven regulation. The analysis also highlights the growing importance of cross-border trade and regional regulatory harmonization in shaping regulatory requirements and market access. These issues underscore the need for adaptive regulatory systems capable of responding to rapid technological change and increasing regional and global integration.

Table 12 summarizes the key PESTEL issues and outlines their implications for TMDA's regulatory functions and institutional performance.

Table 12: PESTEL Analysis

Sn.	Factor	Key Issues in the External Environment	Implications for TMDA
1.	Political	(a) Strong National commitment to health product safety under DIRA 2050, DIRA 2050: FYDP IV and CCM Election Manifesto (2025-2030). (b) Government prioritization of digital transformation in public institutions. (c) Ratification of the AMA Treaty to strengthen continental cooperation. (d) Increased political focus on combating substandard and falsified medical products. (e) Government supports local pharmaceutical and medical devices manufacturing.	(a) Strengthen regulatory systems and vigilance. (b) Modernize digital regulatory platforms. (c) Participate actively in AMA structures. (d) Enhance enforcement against substandard/ falsified products. (e) Support regulatory pathways for local manufacturing.
2.	Economic	(a) Growth in local manufacturing requires strong GMP oversight. (b) National Industrialization Agenda, increasing demand for regulatory support. (c) Economic constraints affect affordability of essential medicines and diagnostics. (d) Limited public sector resources affect regulatory capacity and laboratory modernization. (e) Pressure to facilitate timely market access to cost-effective products.	(a) Improve resource efficiency and adopt reliance pathways. (b) Enhance GMP inspections and regulatory support for industry. (c) Ensure affordable, quality-assured products enter the market quickly. (d) Strengthen lab capacity and optimize spending.
3.	Social	(a) Growing population and expanded healthcare needs. (b) High burden of NCDs, HIV/AIDS, Hepatitis-B and other infectious diseases increasing demand for quality health products. (c) Rising public expectations for product safety and transparency. (d) Increasing use of diagnostics and self-care medical technologies. (e) Need for greater health literacy to prevent medicines misuse. (f) Irrational use of medicines leading to an upsurge of antimicrobial resistance (AMR).	(a) Strengthen vigilance and PMS. (b) Improve public engagement and communication. (c) Ensure availability of reliable diagnostics and NCDs products. (d) Enhance responsiveness to safety concerns.

Sn.	Factor	Key Issues in the External Environment	Implications for TMDA
4.	Technological	(a) Rapid evolution of new medical technologies, including advanced diagnostics and digital health tools. (b) Increased use of e-submissions, data-driven and AI-assisted regulatory decision-making and digital surveillance. (c) Need for inter-operable systems aligned with the National Digital Health Strategy. (d) Expansion of anti-counterfeit technologies (e.g., track-and-trace).	(a) Modernize regulatory information systems. (b) Strengthen digital regulatory systems' capacity. (c) Adopt AI/advanced analytics for decision-making. (d) Improve digital inspections and real-time surveillance.
5.	Environmental	(a) Climate-sensitive diseases increasing demand for diagnostics and medicines (b) Global and National push for environmentally safe pharmaceutical waste disposal. (c) Climate change is disrupting health supply chains. (d) Increased attention to sustainable laboratory and manufacturing practices.	(a) Strengthen oversight of environmentally sensitive products. (b) Promote green labs and eco-friendly manufacturing compliance. (c) Ensure supply chain resilience in regulatory planning.
6.	Legal	(a) Continental and regional harmonization expectations under AU Model Law, AMA, EAC MRH and SADC frameworks. (b) Evolving National laws on health, digital governance, medicines and devices. (c) A need to align with WHO, ICH and IMDRF global standards. (d) Increased legal demands for accountability and transparency (NACSAP IV). (e) Need for clear regulation of emerging medical technologies.	(a) Review and update regulatory instruments. (b) Strengthen enforcement and transparency. (c) Enhance reliance mechanisms and harmonization. (d) Update guidance for advanced technologies and digital health innovations.

2.6 Stakeholders Analysis

A stakeholders' analysis was carried out to identify key TMDA stakeholders, their expectations, potential impacts and influence within the regulatory ecosystem with the aim of devising ways to serve them and mobilize their support during the implementation of this Strategic Plan.

The analysis considered wide range of TMDA stakeholders in order to reflect the evolving regulatory landscape and the need for broader engagement to support innovation, compliance and knowledge exchange. Strengthened collaboration with these stakeholders will be essential for enhancing regulatory effectiveness, promoting industrial development and supporting digital transformation.

The results of the stakeholders' analysis are summarized in Table 13.



Table 13: TMDA Potential Stakeholders

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
1.	Consumers and general public	(i) Safety, quality and effectively regulated products; and (ii) Transparent information about medicines, devices and safety (e.g., adverse event reporting)	(i) Increased risks associated with regulated product consumption; and (ii) Increased customer complaints.	High
2.	Ministry responsible for Health	(i) Effective and efficient implementation of the health policy. (ii) Full execution of the TMDA mandate. (iii) Technical advice and information on regulated products; and (iv) Timely submission of Performance reports.	(i) Inadequate support from the Ministry; (ii) Decline in trust and confidence with TMDA; and (iv) 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 related to veterinary products.	(i) Inadequate support from the Ministry; (ii) Diminished trust in TMDA; and (iii) Ministry interventions to enforce corrective measures.	High

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
4.	Ministries responsible for Industry, Trade and Investment	(i) Trade facilitation for regulated products; (ii) Investments in regulatory products facilitated; (iii) Information and education; (iv) Technical guidance to domestic pharmaceutical and medical device manufacturers.	(i) Inadequate support from the Ministry; (ii) Diminished trust in TMDA; (iii) Ministry interventions to enforce corrective measures; and (iv) Existence of non-compliant industries for medicines and medical devices.	High
5.	Ministries responsible for Finance and Planning	(i) Effective and efficient implementation of National Development Plans; (ii) Timely submission of Information and performance reports; (iii) Full execution of the 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
6.	President's Office Public Service Management and Good Governance	(i) Effective and efficient public service delivery; (ii) Financial self-reliance; (iii) Timely submission of information and performance reports; (iv) Full execution of the TMDA mandate; and (vi) Compliance with Public Service Legislation and guidelines	(i) Limited support available; (ii) Lack of confidence and trust in TMDA; and (iii) Ministry intervention to rectify the situation	High
7.	Office of the Treasury Registrar	(i) Adherence to Registrar's directives; (ii) Timely submission of Information and Performance reports; (iii) Efficient Collection of fees and charges; and (iv) Financial prudence	(i) Limited support available; (ii) Lack of confidence and trust with TMDA; and (iii) Registrar's intervention to rectify the situation	High

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
8.	Office of the Attorney General	(i) Effective and efficient implementation of Attorney General's directives; and (ii) Full execution of the 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 Prosecutions	(i) Effective and efficient implementation of the Director of Public Prosecution's directives; and (ii) Collaboration and support	(i) Inadequate support and collaboration; and (ii) Lack of confidence and trust in TMDA.	High
10.	Manufacturers and dealers of the regulated products	(i) Timely approval and certification; (ii) Clear and streamlined service procedures; (iii) Effective management of complaints and quick responses. (iv) Regular forums to discuss regulatory issues; and (v) Information and education. (vi) Guidance and support on GMP compliance	(i) Inadequate compliance with regulated products. (ii) Decline in revenue collection; (iii) Increased number of complaints; (iv) Intervention from higher authorities that could negatively impact TMDA. (v) Increased enforcement costs; and (vi) Circulation of substandard and falsified products in the market.	High
11.	Media houses	(i) Information, transparency and cooperation; and (ii) Timely payments for service provided.	(i) Misinformation and disinformation about TMDA; (ii) Poor collaboration; and (iii) Negative image of TMDA to the public.	High
12.	Practitioners, Researchers/ Research institutions and Innovators	(i) Timely approval and certification; (ii) Fairness and transparency; (iii) Information and education; (iv) Timely feedback on reported adverse events; and (v) Continuous collaboration, cooperation and support	(i) Negative image of TMDA to the public; (ii) Misinformation and disinformation; and (iii) Poor feedback on malpractice. (iv) Missing evidence-based data for decision making	Medium

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
13.	Training Institutions & Higher Learning Institutions	(i) Technical support. (ii) 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) Ensuring fairness and transparency in services provided. (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
15.	Civil Society Organizations (CSOs), NGOs, Faith Based Organization (FBOs), Professional Bodies and Associations	(i) Information on TMDA services (ii) Collaboration/ cooperation (iii) Transparency	(i) Misinformation and disinformation; and (ii) Negative image of TMDA to the public.	Medium
16.	International Organizations and Development Partners	(i) Transparency and Cooperation; (ii) Effective implementation of supported projects/ interventions; (iii) Timely progress reports for supported projects; (iv) Technical advice on respective development projects.	(i) Misinformation and Disinformation; (ii) Poor collaboration; (iii) Failure to attain targets; and (iv) Withdraw of supports.	Medium
17.	Law Enforcers	(i) Technical support; (ii) Regulations and guidelines; (iii) Information and education; and (iv) Transparency and cooperation.	(i) Inadequate collaboration; (ii) Negative image of TMDA; and (iii) Intervention from higher authorities may negatively affect TMDA.	Medium
18.	Local Government Authorities	(i) Regulations and guidelines; (ii) Information and education; (iii) Transparency and cooperation; (iv) Resources; and Technical support.	(i) Inadequate collaboration; (ii) Negative image of TMDA; and (iii) Inefficient implementation of delegated powers and functions.	Medium

SN	Stakeholder	Expectations from TMDA	Potential Impacts (if expectation not met)	Priority
19.	Parliamentary Committees	(i) Effective implementation of the TMDA function; (ii) Proper management and utilization of resources; and (iii) Information.	(i) Misinformation and Disinformation; (ii) Negative image of TMDA to the public; (iii) Political interventions that may negatively affect TMDA; and (iv) Limited support.	High
20.	Employees	(i) Equitable remuneration; (ii) Clear working guidelines and staff regulations; (iii) Capacity building and career development; (iv) Adequate working tools and environment; and (v) Harmonious working relationship; (vi) Staff welfare and support; and (vii) Participation in decision making.	(i) Low morale; (ii) Sabotage; (iii) Low performance; (iv) Unethical practices; (v) High staff turnover rate; (vi) Increased complaints from staff; (vii) Increased labor disputes and litigations; and (viii) Government interventions to rectify the situation that might impact negatively TMDA.	High

2.7 Recent initiatives for improving performance

In recent years, the Tanzania Medicines and Medical Devices Authority (TMDA) has implemented a series of institutional, regulatory and systems-strengthening initiatives aimed at enhancing organizational performance, improving regulatory effectiveness and responding to emerging public health and market challenges. These initiatives reflect TMDA's commitment to continuous improvement, results-based management and alignment with National and international regulatory standards.

(a) Strengthening Regulatory Systems and Processes

TMDA has enhanced its core regulatory functions by strengthening evaluation, inspection and post-marketing surveillance processes and expanding the use of electronic regulatory systems, improving efficiency, transparency and tracking of regulatory decisions.

(b) Quality Management and International Recognition

The Authority has maintained international quality management certifications, including ISO 9001 and ISO/IEC 17025 and attained WHO Maturity Level 3, reinforcing its credibility and role in regional and international regulatory harmonization initiatives.

(c) Enhancing Laboratory Capacity and Surveillance

TMDA has strengthened laboratory analytical testing through accreditation, proficiency testing, preventive maintenance and improved post-marketing surveillance and pharmacovigilance systems for medicines, vaccines, medical devices and diagnostics.

(d) Human Resource Development and Institutional Capacity

Efforts have focused on staff training, professional development and performance management to enhance regulatory competencies and institutional effectiveness in line with evolving regulatory requirements.

(e) Customer Care, Public Engagement and Transparency

The Authority has strengthened customer care and public education through implementation of the Client Service Charter, expanded communication channels and use of feedback mechanisms to improve service delivery and public trust.

(f) Governance, Financial Management and Accountability

TMDA has enhanced internal governance, financial management, risk management and internal audit systems to promote accountability, efficient resource utilization and institutional sustainability.

2.8 Review of relevant information

Relevant information, including National policies, sectoral strategies, evaluation reports and international regulatory frameworks, confirms strong alignment between TMDA's mandate and broader development priorities.

The analysis highlights explicit linkages with DIRA 2050 aspirations, particularly in achieving high-quality livelihoods, a competitive industrial economy and strong institutional capacity. Similarly, alignment with FYDP IV is evident in areas related to health security, industrialization, digital transformation and trade facilitation.

These linkages reinforce the relevance of TMDA's strategic direction and underscore the importance of integrating regulatory functions within the broader National development agenda. The review further provides a basis for ensuring that strategic objectives and interventions are responsive to both National priorities and global regulatory trends.

2.8.1 Policy and Development Frameworks

TMDA operates within a broad set of global, continental, regional, National and cross-cutting frameworks that guide the regulation of medicines, vaccines, diagnostics, medical devices and other health products in Tanzania. These frameworks outline the standards, commitments and policy directions that shape TMDA's mandate and influence the Authority's strategic priorities for the next planning cycle.

The review of frameworks was undertaken to ensure that TMDA's Strategic Plan is fully aligned with international regulatory expectations, continental harmonization initiatives, regional cooperation mechanisms and National development policies. The analysis helps identify the regulatory obligations, system reforms and capacity requirements that TMDA must consider remaining effective, efficient and credible as a National regulatory authority.

2.8.1.1 Global Frameworks

Global frameworks provide overarching international standards, commitments and normative guidance that shape TMDA's regulatory mandate and institutional performance expectations. These frameworks articulate agreed global priorities on public health protection, access to quality-assured health products and the effectiveness of National regulatory systems. Within the situational analysis, global frameworks are therefore examined as structured reference points that define both regulatory obligations and strategic reform imperatives for TMDA.



The key global frameworks and the associated strategic issues relevant to TMDA are outlined below:

(a) United Nations Sustainable Development Goals (SDGs)

The SDGs provide a global policy framework that links health, governance and sustainable development. In relation to TMDA, SDG 3 emphasizes access to safe, effective, quality and affordable essential medicines and health products, while SDG 16 underscores the importance of effective, accountable and transparent public institutions. A key issue arising from this framework is the expectation that National regulators ensure both access and quality assurance in support of universal health coverage.

TMDA's Strategic Plan prioritizes risk-based regulation, efficient product evaluation and registration processes and strengthened post-market surveillance systems to directly support SDG targets, while embedding transparency and accountability measures consistent with SDG 16.

(b) World Health Organization (WHO) Global Regulatory Frameworks

The World Health Organization provides the primary global normative framework for regulation of medical products through instruments such as the Global Benchmarking Tool and associated guidance on regulatory system maturity. A central issue highlighted under this framework is the variability in regulatory capacity and maturity across countries, which affects regulatory credibility, international reliance and public health outcomes.

TMDA's Strategic Plan incorporates regulatory system strengthening as a core pillar, with targeted interventions to improve governance, quality management systems, inspection capacity, pharmacovigilance, laboratory services and regulatory digitalization, aligned with WHO benchmarks.

In summary, the situational analysis confirms that TMDA's strategic context is primarily shaped by global development and regulatory frameworks that emphasize access to quality health products and institutional regulatory maturity. The Strategic Plan responds by translating these global expectations into context-specific strategic objectives, institutional reforms and performance targets that strengthen TMDA's ability to fulfill its regulatory mandate effectively and sustainably.



2.8.1.2 Continental Frameworks

Continental frameworks set Africa-wide priorities for regulatory harmonization, manufacturing development, digital transformation and public health protection. These frameworks guide TMDA in aligning with continental expectations, participating in joint regulatory mechanisms and strengthening its systems to meet Africa’s regulatory integration agenda. Table 14 presents the core continental frameworks and highlights their implications for TMDA’s regulatory work and strategic direction.

Table 14: Continental Frameworks and Implications

Sn.	Framework	Key Commitments / Provisions	Implications for TMDA
1.	AU Model Law on Medical Products Regulation	Provides a harmonized legal and regulatory template for African countries. Strengthens transparency, enforcement, vigilance and cross-border regulatory actions.	Align National legislation; enhance transparency; modernize regulatory functions; support mutual recognition; strengthen enforcement and vigilance.
2.	African Medicines Agency (AMA) Treaty	Establishes a continental body for joint assessments, joint inspections, regulatory cooperation, safety monitoring and reliance mechanisms.	Participate in joint regulatory activities; share intelligence; adopt reliance; align with continental standards; strengthen regulatory science and PV capacity.
3.	Pharmaceutical Manufacturing Plan for Africa (PMPA)	Promotes local manufacturing, GMP compliance, technology transfer and reduced reliance on imports.	Strengthen GMP inspection; support manufacturers; streamline registration; build regulatory pathways for export-ready products.
4.	African Digital Transformation Strategy	Encourages digitalization, data systems, cybersecurity, innovation and adoption of advanced technologies across public institutions.	Improve interoperability; adopt digital inspections, real-time tracking, analytics; upgrade ICT capacity; enhance digital governance.

2.8.1.3 Regional Frameworks

Regional frameworks provide harmonized technical requirements and collaborative mechanisms among East African and Southern African countries. They support joint assessments, joint inspections, reliance mechanisms and coordinated safety actions. For TMDA, these frameworks are essential for improving efficiency, reducing duplication and enhancing regulatory coherence within the region. Table 15 outlines the key regional frameworks and their implications for TMDA's regulatory responsibilities.

Table 15: Regional Frameworks and Implications

Sn	Framework	Key Commitments / Provisions	Implications for TMDA
1.	EAC Medicines Regulatory Harmonization (MRH)	Harmonized guidelines for MA, GMP, QMS and PMS. Promotes joint assessments, joint inspections and reliance.	Adopt harmonized standards; participate in joint regulatory activities; strengthen QMS; reduce duplication; accelerate registration time lines.
2.	EAC PV & Medical Devices Guidelines	Standardized reporting, vigilance, PMS, device safety monitoring and risk management across EAC.	Strengthen PV systems; enhance device vigilance; coordinate regional recalls; integrate regional safety intelligence.
3.	SADC Medicines Harmonization Framework	Promotes regional regulatory cooperation, shared intelligence, joint inspections and aligned standards.	Expand reliance; align with regional guidelines; participate in joint inspections; strengthen oversight of substandard and falsified products.



2.8.1.4 National Frameworks

National frameworks reflect Tanzania's development priorities, health sector goals and regulatory expectations. They guide TMDA's mandate in ensuring access to safe, effective and quality health products while supporting digital transformation, industrial growth and public health outcomes. Table 16 summarizes the National frameworks reviewed and sets out their implications for TMDA's strategic and operational functions.

Table 16: National Frameworks and Implications

Sn	Framework	Key Commitments / Provisions	Implications for TMDA
1.	Tanzania Development Vision (DIRA 2050)	Tanzania's Development Vision (DIRA 2050) is structured around three development pillars, with Pillar Two focusing on Human Development and Social Well-Being and "A Healthy Society" identified as one of its core attributes. Under Section 4.2.2 A Healthy Society, the Vision aspires to build "a nation of resilient individuals and communities committed to health promotion, disease prevention and the maintenance of healthy lifestyles, with the capacity to mitigate the impact of pandemics and environmental and climate-related health risks" (p. 33). It further envisions "a healthy society where every individual enjoys affordable, comprehensive and equitable access to quality healthcare" and protection from "harmful substances" (p. 33). In addition, DIRA 2050 advances industrial and innovation ambitions by positioning Tanzania as "a regional hub for the manufacturing of healthcare products, ensuring equitable access to high-quality but affordable healthcare goods," and by promoting the use of modern technologies, including artificial intelligence, to strengthen disease prediction and management (p. 33). Beyond the health pillar,	TMDA's mandate directly contributes to the realization of Pillar Two of DIRA 2050 by safeguarding public health through effective regulation of medicines, medical devices, diagnostics, vaccines and related products. In response to Vision's A Healthy Society aspiration, TMDA will strengthen science-based and risk-based regulatory systems, enhance pharmacovigilance and post-marketing surveillance and protect the population from harmful, substandard and falsified products. In line with Section 4.1.4 on Enabling Business Environment and Investment Climate, TMDA will adopt proportionate, predictable and facilitative regulatory approaches that reduce unnecessary compliance costs, eliminate duplicative approvals, streamline licensing and inspection processes and avoid revenue-driven regulatory practices. To support DIRA 2050's ambition of establishing Tanzania as a regional hub for healthcare manufacturing, TMDA will provide efficient and internationally aligned regulatory pathways for local pharmaceutical and medical device manufacturers. Furthermore, reflecting Vision's emphasis on innovation and artificial intelligence, TMDA will expand digital and data-driven regulatory systems, apply advanced analytics for risk profiling and regulatory decision-making and strengthen regulatory transparency and responsiveness to foster both public health protection and a competitive investment climate.

Sn	Framework	Key Commitments / Provisions	Implications for TMDA
		Section 4.1.4: Enabling Business Environment and Investment Climate explicitly identifies over-regulation as a critical challenge, citing high compliance costs, duplicative approvals, excessive taxes, levies, fees and penalties, weak harmonization of laws and overlapping regulatory mandates and calls for streamlined, transparent, proportionate and business-enabling regulatory frameworks.	
2.	FYDP IV	Imports of essential health commodities reduced by 20% by June 2031 Establish fiscal, monetary and regulatory incentives for local industries producing basic and advanced health technologies by June 2031 Streamline regulatory approvals and customs clearance for pharmaceutical inputs to reduce delays by June 2028	
3.	CCM Election Manifesto (2025–2030)	The CCM Election Manifesto (2025–2030) prioritizes improvement of people's welfare and social well-being, with strong emphasis on public health protection, reduction of preventable diseases and deaths and access to quality healthcare products. The Manifesto emphasizes the importance of ensuring availability of safe, effective and affordable medicines, medical devices, diagnostics and other health-related products as a cornerstone of a strong health system. It further emphasizes the application of science, technology and digital transformation to improve efficiency, transparency and accountability in public service delivery. In line with National industrialization objectives, the Manifesto promotes domestic production and value addition, including manufacturing of health-related products, to enhance self-reliance, affordability and sustainability.	The CCM Manifesto positions TMDA as a key institution for safeguarding public health and supporting National welfare objectives by effectively regulating health products. TMDA will strengthen quality assurance and quality control systems, enhance pharmacovigilance and post-marketing surveillance and intensify enforcement against substandard and falsified medicines and medical devices. To support the Manifesto's industrial development agenda, TMDA will facilitate efficient, transparent and predictable regulatory pathways for local pharmaceutical and medical device manufacturers while maintaining internationally recognized standards. The Manifesto's emphasis on science, technology and digital public services reinforces TMDA's strategic focus on expanding digital regulatory systems, including e-registration, e-licensing, e-inspection and data-driven regulatory decision-making, to improve efficiency, access and public trust.

Sn	Framework	Key Commitments / Provisions	Implications for TMDA
4.	National Health Policy (2007)	The National Health Policy aims to ensure equitable access to quality health services, with strong emphasis on patient safety, effectiveness of health technologies and reliable availability of essential medicines, vaccines, diagnostics and medical devices. The Policy recognizes regulation, surveillance and evidence-based decision-making as critical pillars for protecting public health and improving health outcomes.	TMDA operationalizes the National Health Policy by ensuring that all regulated health products meet required standards of quality, safety and effectiveness throughout their life cycle. The Authority will strengthen regulation of medicines, medical devices, diagnostics and related products, enhance pharmacovigilance and post-marketing surveillance systems and strengthen laboratory testing capacity. TMDA will also support timely access to essential and priority health products while safeguarding patient safety.
5.	National Drug Policy (1997)	The National Drug Policy provides guidance on pharmaceutical governance, focusing on access to essential medicines, quality assurance, rational use, local production and effective regulation of the pharmaceutical sector. It emphasizes strong regulatory institutions, efficient registration systems, GMP compliance and collaboration with health programs and stakeholders.	In alignment with the Policy, TMDA will strengthen marketing authorization, GMP inspection, pharmacovigilance and surveillance systems to ensure the integrity of the medicines supply chain. The Authority will streamline registration, variation and import and export control processes while maintaining regulatory rigor. TMDA will collaborate with National health programs and stakeholders to promote rational use of medicines and a well-regulated, sustainable pharmaceutical sector.

2.8.2 Cross-Cutting Frameworks

Cross-cutting frameworks provide governance, integrity, health and workplace-related obligations that influence TMDA's institutional practices and regulatory environment. These frameworks strengthen ethical conduct, promote healthy workplaces and enhance system transparency. Table 17 presents the cross-cutting policies and outlines their relevance and implications for TMDA's regulatory responsibilities and institutional culture.

Table 17: Cross-Cutting Frameworks and Implications

Sn	Framework	Key Commitments / Provisions	Implications for TMDA
1.	NACSAP IV	Strengthens integrity, transparency, internal controls, digitalization and accountability.	Improve internal controls; enhance transparency; expand digital workflows; promote ethical culture; strengthen audit readiness.
2.	National HIV/AIDS Policy	Promotes prevention, nondiscrimination, care and reliable access to HIV-related products.	Ensure quality of HIV medicines/diagnostics; maintain safe workplace; collaborate with National HIV programs; support surveillance.
3.	National NCDs Strategy (2008)	Guides prevention and management of major NCDs; promotes access to essential NCDs products.	Strengthen oversight of NCDs medicines/devices; improve vigilance of diagnostics; promote staff wellness and awareness.

2.8.3 Review of Service Delivery Survey 2024

As part of the situational analysis, TMDA reviewed findings from the Service Delivery Survey conducted to assess customer perceptions, service accessibility, efficiency, responsiveness and overall satisfaction with regulatory services. The survey covered both internal and external customers and provides critical evidence on how TMDA's services are experienced by stakeholders across different regulatory functions.

Overall, the survey results indicate that TMDA has made notable progress in improving service delivery, particularly in areas related to clarity of procedures, professionalism of staff and availability of information through established communication channels. The presence of a Client Service Charter, multiple customer engagement platforms and structured complaint-handling mechanisms were positively acknowledged by respondents, reflecting the Authority's commitment to transparency and customer orientation.

However, the survey also highlights areas requiring further improvement. These include timeliness of service delivery in some regulatory processes, consistency in responsiveness across service points and accessibility of services for stakeholders located outside Dar es Salaam. Limited physical presence at the regional and district levels and varying levels of public awareness of TMDA's mandate and procedures were identified as factors affecting the customer experience. The findings further suggest the need to strengthen mechanisms for utilizing feedback to ensure that customer concerns consistently inform service improvements.



The Service Delivery Survey findings align with the broader SWOC analysis, particularly with respect to customer care weaknesses and emerging challenges such as increasing service demand, digital service expectations and the growth of online marketing and sale of regulated products. The insights from the survey therefore provide a strong empirical basis for prioritizing interventions related to customer care, public education, decentralization of services, digitalization and performance monitoring.

In response to these findings, the Strategic Plan incorporates targeted strategies aimed at strengthening customer care and complaints-handling systems, maintaining public education programs, improving internal and external customer satisfaction and enhancing service efficiency and accessibility. Continued use of service delivery surveys and customer feedback mechanisms will remain an important tool for monitoring performance and guiding continuous improvement throughout the Strategic Plan period.

2.8.4 Adoption of Artificial Intelligence (AI)

Artificial Intelligence (AI) and advanced data analytics are increasingly transforming regulatory systems globally. Modern medicines regulatory authorities are adopting AI-enabled analytical tools to support pharmacovigilance signal detection, regulatory intelligence, inspection risk profiling and analysis of large volumes of regulatory data. These technologies enhance the efficiency, accuracy and timeliness of regulatory decision-making.

In line with the National digital transformation agenda articulated in DIRA 2050 and the Fourth Five-Year Development Plan (FYDP IV), public institutions are encouraged to adopt advanced digital technologies to strengthen service delivery, institutional performance monitoring and evidence-based decision-making. Integration of AI-supported analytics within TMDA's regulatory and monitoring systems will therefore provide opportunities to enhance detection of substandard and falsified medical products, strengthen post-market surveillance and improve efficiency of regulatory operations.

2.9 Key Challenges and Opportunities

The review of TMDA's operating environment, regulatory performance, stakeholder expectations and development frameworks revealed several challenges and opportunities that influence the Authority's ability to achieve its mandate. These factors are critical inputs for shaping the strategic priorities and interventions for the next planning cycle.

2.9.1 Key Challenges

(a) Rapid evolution of medical technologies

The increasing complexity of medicines, medical devices and diagnostics including biologics, digital health products, advanced diagnostics and innovative medical device technologies, poses challenges in regulatory science, evaluation capacity and staff competencies.

(b) Growing workload with limited resources

Demand for regulatory services continues to increase with population growth, expanded healthcare needs, rising NCDs burden and growth in the pharmaceutical and medical devices industry. However, TMDA still faces constraints in staffing, infrastructure and financial resources.

(c) Inadequate digital integration and interoperability

Despite progress in digitalizing regulatory services, gaps persist in interoperability with National digital health systems, real-time surveillance, data governance and cyber-attack. Manual processes remain in some processes affecting regulatory efficiency.

(d) Increasing threat of substandard and falsified products

Weaknesses in supply chains, illicit trade routes and mushrooming of porous borders increase the risk of substandard and falsified health products in the market.

(e) Evolving legal, regional and continental regulatory obligations

Harmonization requirements under the AMA Treaty, AU Model Law, EAC MRH, SADC frameworks and WHO GBT maturity level expectations require TMDA to continuously update guidelines, QMS processes and regulatory instruments.

(f) Environmental and supply chain vulnerabilities

Climate change, disasters, pandemics and global supply chain disruptions expose vulnerabilities in access to essential health products and require immediate and effective regulatory decision-making.

G) Public expectations and trust pressures

Demand for transparency, availability of health products, quick market access and efficient regulatory processes continue to grow, putting pressure on TMDA to deliver high-quality services consistently.

2.9.2 Key Opportunities

- (a) **Strong government commitment to digital transformation and health system strengthening**
DIRA 2050, FYDP IV and the CCM Manifesto prioritize digital public services, health security, innovation and regulatory strengthening, creating an enabling environment for TMDA's modernization.
- (b) **Tanzania's ratification of the AMA Treaty**
AMA opens opportunities for joint assessments, joint inspections, shared regulatory intelligence and reliance mechanisms, reducing workload and strengthening regulatory effectiveness.
- (c) **Growth of the pharmaceutical and medical devices industry**
Expanding local manufacturing under the PMPA, DIRA 2050 and National industrialization initiatives provides opportunities for TMDA to support domestic production and advance regulatory reforms.





- (d) Strengthening regional harmonization platforms**
 EAC MRH, SADC frameworks and other regional mechanisms enable TMDA to adopt harmonized guidelines, reduce duplication, share resources and improve regulatory efficiency.
- (e) Advancements in regulatory technologies**
 Digital tools, AI, track-and-trace systems, e-submissions, digital inspections and advanced laboratory technologies offer opportunities to improve regulatory effectiveness, transparency and decision-making.
- (f) Increasing complexity of medical products**
 The increasing complexity of medicines, medical devices and diagnostics present opportunities for TMDA to strengthen regulatory science, adopt innovative regulatory approaches and enhance its role in supporting emerging health technologies, including digital regulatory services.
- (g) Expanded stakeholder collaboration**
 Partnerships with MOH, public health programs, research institutions, manufacturers and development partners create opportunities to improve regulatory capacity and achieve better public health outcomes.
- (h) Rising societal awareness and demand for quality products**
 Increased public health literacy and consumer awareness provide an opportunity for TMDA to strengthen risk communication, vigilance reporting and public engagement.

(i) **Potential for strengthened resource mobilization**

Participation in continental and regional structures, reliance mechanisms and donor-funded initiatives creates room for resource expansion, capacity building and modernization of TMDA systems.

(j) **Political commitment to promote domestic industrialization for health products**

The FYDP IV targets to reduce the importation of essential health commodities by 20% by June 2031. These create opportunity for TMDA to incentivize local production of health commodities by developing strategies to guide and support domestic manufacturers.



2.10 Critical Issues

The identified critical issues are categorized under four strategic dimensions namely; public health protection, industrial development, digital transformation and governance and accountability. To ensure consistency with the situational analysis and strategic response framework, they can be further be re-categorized into the following 12 dimensions that ought to be properly addressed in this SP ;-

(a) **Strengthening institutional capacity and resource mobilization**

Financial resources, staffing level and technical expertise affect the Authority's ability to effectively deliver on its mandate. Strengthening institutional capacity, including workforce development and sustainable financing mechanisms is essential for improving performance and ensuring long-term sustainability.

(b) Enhancing digital transformation and data integration

Gaps in digital integration, interoperability and data management systems limit the efficiency and responsiveness of regulatory operations. Strengthening digital regulatory services including electronic submissions, integrated information systems and real time data analytics will improve service delivery, support evidence-based decision-making and advance digital transformation.

(c) Improving efficiency of regulatory processes and service delivery

Delays in regulatory approval processes and increasing demand for services necessitate improvements in efficiency, predictability and transparency. Enhancing regulatory time lines and streamlining processes will support industrial development by facilitating timely market entry of quality products and improving the business environment for pharmaceutical and medical device manufacturers.

(d) Strengthening laboratory capacity and infrastructure

Limited laboratory capacity, including infrastructure, equipment and geographical coverage, constrains the Authority's ability to ensure timely detection of substandard and falsified products and provide reliable analytical support for regulatory decision-making. Addressing these issues will enhance regulatory effectiveness and support both public health protection and industrial development.



(e) Growing regulatory workload unmatched by human and financial resources

Demand for regulatory services continues to rise due to increasing population needs, expanding local manufacturing, product diversification and heightened public expectations. Current staffing levels, inspection capacity and financial resources do not fully match this growing workload.

(f) Continuous regulatory support for domestic pharmaceutical and medical devices manufacturing

The National industrialization agenda and PMPA create opportunities for domestic manufacturing. TMDA needs to continuously support the growth of domestic manufacturers through GMP oversight, regulatory pathways, pre-submission guidance, streamlining regulatory procedures, industry support mechanisms and collaboration with other players.

(g) Increased risks of substandard and falsified health products

Mushrooming of porous border, expanding informal markets, telemedicine and global supply chain disruptions increase irrational use and risk of unsafe medical products in the country. TMDA must strengthen enforcement, risk communication, joint operations and surveillance systems.



(h) Strengthening regional and international regulatory collaboration

Increasing obligations under regional and continental regulatory frameworks require enhanced coordination, harmonization and alignment with international standards. Strengthening participation in regional regulatory initiatives will facilitate cross-border trade, promote mutual recognition and enhance the global acceptance of medical products. TMDA must continuously update its regulatory instruments, guidelines and processes to meet the requirements of the AMA Treaty, AU Model Law, ICH, PICs, IMDRF, GHWP, EAC and SADC harmonization frameworks and WLA expectations.

(i) Limited stakeholder engagement, communication and public awareness on regulatory issues

Public expectations for transparency and timely information are increasing, yet current communication, risk messaging and stakeholder platforms require enhancement to build trust and support compliance across the regulated value chain.

(j) Enhancing governance and accountability

To meet DIRA 2050, FYDP IV and NACSAP IV expectations, there is a need to improve internal controls, process transparency, audit readiness, institutional integrity systems, monitoring, evaluation and learning (MEL) systems and aligning institutional performance with National frameworks.

(k) Strengthening Tobacco Control to protect human health

The continued use and marketing of tobacco products pose significant risks to public health, contributing to the burden of non-communicable diseases and preventable morbidity and mortality. Strengthening regulatory oversight, enforcement, public awareness and compliance with tobacco control measures is essential to safeguard human health and align with National and international public health commitments.



(l) Enhance utilization of advanced digital technologies

Although TMDA has made progress in digitalizing regulatory services, utilization of advanced analytical technologies such as Artificial Intelligence remains limited. Increasing volumes of regulatory data generated from product registration systems, pharmacovigilance reporting, laboratory testing and inspections require modern analytical tools capable of supporting predictive analysis and regulatory intelligence. Without the integration of AI-supported analytics, the Authority may face challenges in efficiently analyzing regulatory datasets and identifying emerging safety and compliance risks.

Strengthening the adoption of Artificial Intelligence technologies will enhance regulatory intelligence, improve efficiency of performance monitoring systems and support evidence-based regulatory decision-making.



**MAMLAKA YA DAWA NA
VIFAA TIBA**



**WASILIANA
NASI**



**Toa taarifa ya maudhi yatokanayo na
matumizi ya dawa**

CHAPTER THREE

THE PLAN



CHAPTER THREE:

THE PLAN

This chapter outlines TMDA's strategic direction for the 2026/27–2030/31 planning period. It presents vision, mission, core values and strategic objectives that address the critical issues identified in the situational analysis. It also introduces the strategies, targets and performance indicators that will guide implementation across all Directorates, Units, Sections and Zone Offices.

The chapter is structured around three pillars that define the Authority's priority focus areas. The first pillar, Public Health Protection, focuses on strengthening regulatory systems to ensure that all medicines, medical devices and diagnostics meet required standards of quality, safety and efficacy, thereby protecting the health of the population. The second pillar, Industrial Development Support, underscores TMDA's role in fostering an enabling regulatory environment that promotes local production, enhances competitiveness of Tanzanian manufacturers and facilitates access to regional and international markets. The third pillar, Institutional Modernization, emphasizes the need to enhance organizational effectiveness through digital transformation, human resource development and strengthened governance and accountability systems. Together, the three pillars provide a coherent pathway for achieving Vision while aligning TMDA's mandate with National development priorities under DIRA 2050 and FYDP IV.

3.1 Vision Statement



Improved health and well-being for all Tanzanians through regulatory excellence that meets global standards.

3.2 Mission Statement



To protect and promote public health by ensuring quality, safety and effectiveness of medicines, medical devices, diagnostics and other related health products in an efficient, transparent and technology-enabled manner.

3.3 Core Values



The core values that guide TMDA, collectively represented by the acronym TACCTIQ, influence the Authority's institutional culture, decision-making and services delivery.

Figure 1: TMDA's Core Values



3.4 Objectives, Strategies, Targets and Key Performance Indicators

3.4.1 Strategic Objectives

In alignment with its Vision and Mission, the Tanzania Medicines and Medical Devices Authority (TMDA) has defined seven (7) Strategic Objectives to guide the execution of its mandate during the 2026/27–2030/31 Strategic Plan period as follows:

- (a) **Strategic Objective A:** HIV/AIDS, Hepatitis B and Non-Communicable Diseases (NCDs) reduced and services improved
- (b) **Strategic Objective B:** National Anti-Corruption Strategy implementation enhanced and sustained
- (c) **Strategic Objective C:** Gender mainstreamed and environmental ecosystem improved
- (d) **Strategic Objective D:** Quality, safety and effectiveness of medicinal products and tobacco standards assured
- (e) **Strategic Objective E:** Quality, safety and performance of medical devices and diagnostics assured
- (f) **Strategic Objective F:** Laboratory services improved and maintained
- (g) **Strategic Objective G:** Capacity to deliver regulatory services improved and sustained

The implementation of TMDA's strategic objectives is anchored in five (5) Key Result Areas (KRAs) that translate strategic priorities into measurable outcomes. Table 18 presents the alignment between the KRAs, Strategic Objectives, and Expected Outcomes to support results-based monitoring and performance tracking.

Table 18: Alignment of KRAs, Strategic Objectives, and Expected Outcomes

SN	Key Result Area (KRA)	Strategic Objective	Expected Outcome
1	Institutional Health, Governance and Integrity	SO A: HIV, Hepatitis B and Non-Communicable Diseases reduced and services improved	Reduced prevalence of HIV, Hepatitis B and non-communicable diseases and improved staff health outcomes
			Increased staff awareness, knowledge and practices on HIV and related conditions
		SO B: National anti-corruption strategy implementation enhanced and sustained	Improved institutional integrity, transparency and accountability
			Strengthened implementation of audit recommendations and internal controls
		SO C: Gender mainstreamed and environmental ecosystem improved	Increased gender equity in leadership and decision-making
			Improved compliance with environmental sustainability standards
2	Medicines and Tobacco Regulation	SO D: Quality, safety and effectiveness of medicinal products and tobacco standards assured	Increased access to safe, effective and quality-assured medicines and tobacco products
			Reduced prevalence of substandard and falsified medicines and tobacco products
			Improved compliance with good manufacturing practices (GMP)
			Reduced time lines for product registration and market authorization
3	Medical Devices and Diagnostics Regulation	SO E: Quality, safety and performance of medical devices and diagnostics assured	Increased access to safe, effective and quality-assured medical devices and diagnostics
			Reduced prevalence of substandard medical devices and diagnostics
			Improved compliance among manufacturers and distributors
			Reduced time lines for registration of medical devices and diagnostics
4	Laboratory Systems Strengthening	SO F: Laboratory services improved and maintained	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions
			Improved timeliness of laboratory testing and result reporting
			Increased number of laboratories accredited to international standards

SN	Key Result Area (KRA)	Strategic Objective	Expected Outcome
5	Regulatory Capacity and Institutional Modernization	SO G: Capacity to deliver regulatory services improved and sustained	Improved efficiency, transparency and digitalization of regulatory services
			Increased digital delivery of regulatory services and data-driven decision-making
			Improved customer satisfaction and service delivery experience
			Achieved globally recognized regulatory maturity level (WHO Maturity Level 4 or Listed Authority status)
			Strengthened financial sustainability and internal revenue mobilization
			Improved compliance with statutory financial obligations and reduced fiscal risk

3.4.2 Targets and Key Performance Indicators

The detailed rationale, targets and Key Performance Indicators (KPIs) for each Strategic Objective are further elaborated in subsections 3.4.2.1 to 3.4.2.7.

3.4.2.1 Strategic Objective A:

HIV/AIDS, Hepatitis B and Non- Communicable Diseases (NCDs) reduced and services improved

(a) Rationale

Within public institutions, these conditions contribute to increased morbidity, absenteeism, reduced staff performance and rising health-related costs, thereby affecting service continuity and institutional efficiency. Findings from the TMDA Strategic Plan Evaluation indicate that while the Authority has implemented workplace sensitization, wellness and support interventions, performance has been uneven, with significant year-to-year fluctuations and gaps in institutionalization. Although sensitization and support services for staff living with HIV/AIDS and NCDs improved over time, outcomes related to actual disease reduction, particularly for NCDs, remain suboptimal.

Preventive service coverage remains inadequate. Workplace health assessments and National adult health patterns indicate that routine screening for STIs and HBV among employees commonly ranges between 40–60%, while HBV vaccination completion among adults is often below 50% in the absence of structured institutional programmes. Furthermore, the incidence of NCDs among TMDA staff remains high and as an inverse indicator, elevated incidence levels signify poor performance and increased disease burden, reflecting insufficient prevention, early detection and sustained risk-reduction interventions.

For TMDA, whose mandate requires highly skilled personnel, sustained regulatory vigilance, field inspections and timely decision-making, the health and wellbeing of staff is a critical enabler of institutional performance. TMDA staff largely fall within the working-age group most vulnerable to HIV/AIDS, STIs, HBV and lifestyle-related NCDs. Weak workplace-level prevention programmes, limited access to routine screening and vaccination and inconsistent wellness participation heighten operational risks that may undermine the Authority's ability to effectively discharge its regulatory responsibilities.

Establishing a dedicated strategic objective on HIV/AIDS, STIs, Hepatitis B and NCDs is therefore essential to strengthen TMDA's human resource capacity, protect institutional productivity and ensure sustainable delivery of regulatory services. This objective provides a structured framework for institutionalizing workplace health promotion, prevention, screening, referral and support interventions, in line with National policies on cross-cutting issues applicable to all public institutions. By reducing preventable illness and improving access to essential health services, the objective directly contributes to a healthier, more resilient workforce capable of supporting TMDA's core mandate of safeguarding public health through effective regulation of medicines, medical devices, diagnostics and related products.

This objective aligns with National development priorities under DIRA 2050 and FYDP IV, which emphasize human capital development, productivity and resilience of public institutions as key drivers of socio-economic transformation. A healthy workforce is essential for sustaining regulatory efficiency, improving service delivery outcomes and ensuring institutional performance.

(b) Strategies

Prevention and management of HIV/AIDS, STIs, Hepatitis B and NCDs

(c) Targets

- (i) Prevalence of non-communicable diseases reduced by 30% by June 2031
- (ii) At least 90% of staff demonstrate adequate knowledge and practices on HIV and related conditions by June 2031

(d) Key Performance Indicators

- (i) Prevalence rate of non-communicable diseases
- (ii) Proportion of staff with adequate knowledge and practices

3.4.2.2 Strategic Objective B:

National Anti-Corruption Strategy Implementation Enhanced and Sustained

(a) Rationale

National governance statistics indicate that corruption remains a significant and persistent challenge in Tanzania's public sector. According to Transparency International's Corruption Perception Index (CPI), Tanzania's score has consistently ranged between 30 and 40 out of 100 in recent years, placing the country below the global average and indicating continued risks related to transparency, accountability and integrity in public institutions. These National indicators underscore that corruption remains a systemic governance issue despite ongoing reforms.

National anti-corruption assessments further highlight that corruption risks continue to undermine public trust, distort decision-making processes and compromise the efficient use of public resources. Within public institutions, such risks commonly manifest through conflicts of interest, unethical conduct, weak internal controls, limited transparency and inadequate accountability mechanisms, all of which negatively affect service delivery, organizational performance and public confidence.

For TMDA, which exercises regulatory authority over medicines, medical devices, diagnostics, tobacco products and other health-related commodities, exposure to corruption risks poses direct threats to public health, regulatory credibility and institutional reputation. TMDA's core functions including product evaluation, licensing, inspections, enforcement and post-marketing surveillance involve high-impact regulatory decisions that are particularly vulnerable to undue influence if governance and integrity systems are not sufficiently robust. Perceptions of corruption within regulatory processes may reduce compliance among regulated entities and erode confidence in the Authority's oversight role.

Strengthening and sustaining implementation of the National Anti-Corruption Strategy and Action Plan (NACSAP) is therefore critical to enhancing governance, accountability and ethical conduct within TMDA. This Strategic Objective provides a structured framework for mainstreaming anti-corruption principles across institutional systems, processes and human resource practices, including prevention, detection, reporting, investigation and enforcement mechanisms. Effective implementation will reinforce institutional integrity, safeguard regulatory decision-making and ensure that TMDA delivers its mandate in a transparent, accountable and credible manner, in line with DIRA 2050 aspirations and FYDP IV which emphasize good governance, transparency, accountability and efficient public service delivery as foundational pillars for socio-economic transformation.

(b) Key Strategies

Enhance Implementation of NACSAP-IV

(c) Targets

- (i) Corruption perception improved by 30% by June 2031
- (ii) At least 95% of audit recommendations implemented within agreed time lines by June 2031

(d) Key Performance Indicators

- (i) Corruption perception index
- (ii) Level of implementation of audit recommendations

3.4.2.3 Strategic Objective C:

Gender mainstreamed and environmental ecosystem improved

(a) Rationale

Environmental degradation and ecosystem disruption remain critical cross-cutting challenges in Tanzania, driven by factors such as improper waste management, pollution, climate variability, unsustainable resource use and uneven compliance with environmental safeguards across sectors. These challenges pose direct risks to public health, environmental sustainability and socio-economic development, while also increasing institutional exposure to regulatory, operational and climate-related risks. For public institutions, weak environmental management translates into higher operational costs, inefficient resource use, occupational health hazards and heightened risk of non-compliance with National environmental laws and standards.



Performance data for 2021/22–2024/25 indicate that TMDA has made tangible progress in strengthening environmental management within its operations, while also revealing areas requiring sustained attention. The Authority consistently maintained full compliance (100%) in the establishment and operation of facilities for handling and disposal of waste and unfit products, demonstrating a strong institutional commitment to safe waste management and environmental protection. This performance is particularly significant given TMDA's regulatory functions involving laboratories, inspections, storage, transportation and disposal of medical and pharmaceutical products, all of which carry inherent environmental and public health risks if not properly managed.

At the same time, the data highlight persistent infrastructure-related constraints. The proportion of infrastructures accessible to physically challenged people across TMDA buildings averaged approximately 84%, indicating progress towards inclusive and environmentally responsive infrastructure design, but also signaling remaining gaps in achieving full compliance. These gaps reflect broader challenges in retrofitting older facilities and integrating universal design and environmental sustainability considerations across all institutional premises, which are essential for long-term operational resilience and compliance with cross-cutting government directives.

Environmental management under this Strategic Objective is closely linked with gender and social inclusion, which form part of Tanzania's cross-cutting development priorities. Performance data show significant progress in gender mainstreaming within leadership and management. The proportion of women trained on leadership and management skills among senior staff increased substantially, with average performance exceeding 160% of targets and the proportion of women in managerial positions reaching 35% by 2024/25, compared to a baseline of 15%. These gains demonstrate that TMDA is increasingly integrating gender considerations into institutional capacity and decision-making structures, which strengthens environmental governance, accountability and sustainability outcomes.

The combined evidence underscores that effective environmental and ecosystem management is not limited to technical waste handling alone, but also depends on inclusive leadership, compliant infrastructure and institutional culture that values sustainability and risk management. While TMDA has achieved strong performance in waste management systems and made notable gains in gender inclusion, remaining gaps in infrastructure accessibility and the need to sustain gender balance at managerial levels point to the importance of continued investment and institutionalization of cross-cutting practices.

This Strategic Objective is aligned with DIRA 2050 and FYDP IV which emphasize environmental sustainability, climate resilience, gender equality and inclusive development as key drivers of long-term socio-economic transformation.

(a) Key Strategies

- (i) Strengthen institutional systems, policies and practices for effective gender mainstreaming in planning, HR management, leadership and service delivery
- (ii) Strengthen environmental management systems for sustainable operations and safe disposal

(b) Targets

- (i) At least 40% of managerial positions held by women by June 2031
- (ii) Environmental compliance reaches at least 95% by June 2031
- (iii) Environmental Issues mainstreamed in TMDA operations by June, 2031

(c) Key Performance Indicators

- (i) Proportion of women in leadership positions
- (ii) Compliance with environmental standards
- (iii) Percentage of unfit medical products (by weight) disposed of through approved eco-friendly methods

3.4.2.4 Strategic Objective D:***Quality, safety and effectiveness of medicinal products and tobacco standards assured*****(a) Rationale**

National and regulatory evidence demonstrates that the circulation of unregistered, substandard, falsified, unsafe, or ineffective medicinal products, and non compliant tobacco products remains a persistent regulatory and public health concern in Tanzania. While global estimates by the World Health Organization indicate that approximately 10% of medicines circulating in low- and middle-income countries are substandard or falsified, Tanzania's Post-marketing Surveillance (PMS) data show a lower but still material prevalence, with about 2% of sampled products failing quality specifications. Although this reflects progress in regulatory effectiveness, the expanding scale and increasing complexity of the health products market mean that even relatively low non-compliance rates continue to pose significant risks to patient safety, treatment outcomes and public confidence.



TMDA's regulatory performance data for the 2021/22–2024/25 indicate generally strong but not uniform efficiency in core regulatory processes. On average, approximately 90% of applications for registration of medicines, medical devices, diagnostics and veterinary medicines were processed within the prescribed time lines, against a target of 100%. This performance reflects a functional regulatory system supported by established procedures and institutional capacity. However, the remaining gap highlights persistent pressure arising from increasing application volumes, growing product complexity and variability in the quality of submitted applications. Delays at the registration stage create downstream regulatory risks, including the potential for market entry of non-compliant products through informal channels and the accumulation of regulatory backlogs.

With respect to premises registration and inspection, including pharmacies, ADDOs, health facilities and manufacturing sites, TMDA achieved an average performance of approximately 94% over the same period. While this demonstrates relatively strong oversight capacity, variations across years and facility types point to ongoing operational constraints, particularly in inspection coverage, follow-up inspections and enforcement consistency. Incomplete or delayed oversight of premises increases the risk of improper storage, handling and distribution of regulated products, which directly undermines product quality and compromises patient safety.

PHARMACOVIGILANCE DATA

19,702



TMDA ADR Reports - 2024/25

12,000



**WHO's recommended benchmark
of ADR reports per year**

Pharmacovigilance data show significant strengthening of post-marketing safety monitoring, particularly in recent years. Over much of the review period, TMDA consistently received and processed ADR reports in line with or above annual targets, reflecting improved reporting systems, increased awareness among healthcare workers and enhanced data management capacity. Notably, in 2024/25, TMDA received 19,702 ADR reports, exceeding the WHO's recommended benchmark of 12,000 ADR reports per year. This performance signals that the National pharmacovigilance system for medicines has reached and surpassed internationally recognized standards.

Adverse Events Following Immunization (AEFI) reporting, which had previously remained comparatively weak, also demonstrated substantial improvement in 2024/25. While earlier years recorded low average reporting levels, TMDA received a total of 7,017 AEFI reports during the year, exceeding the WHO-recommended benchmark of 6,000 reports annually.

This improvement reflects strengthened integration of pharmacovigilance into immunization programmes, increased awareness among healthcare workers and improved coordination between TMDA, health facilities and local government authorities. The sharp increase in both ADR and AEFI reports, while positive from a surveillance perspective, also implies increased demand for advanced signal detection, causality assessment, regulatory decision-making and effective risk communication to ensure that reported data translate into timely public health actions.

Taken together, the evidence indicates that while TMDA has achieved high efficiency in regulatory application processing and has made substantial gains in pharmacovigilance performance, structural regulatory risks persist, particularly in inspection coverage, premises oversight and the preventive control of product quality and safety risks. As Tanzania's health products market continues to expand through increased local manufacturing, higher import and export volumes and the introduction of more complex and technology-intensive products, even modest performance gaps can translate into significant public health exposure. A small shortfall in registration or inspection coverage may result in a large absolute number of products or premises operating outside full regulatory control.

Strengthening regulatory oversight under this Strategic Objective is therefore essential to close remaining efficiency gaps in product registration, achieve full coverage in premises registration and inspection, sustain and effectively manage the high volume of ADR and AEFI reports recorded in 2024/25 and ensure that expanded surveillance outputs are systematically translated into evidence-based regulatory actions. This approach is fully aligned with DIRA 2050 and FYDP IV which emphasizes strong health systems, promoting industrialization and enhancing Tanzania's participation in regional and global trade.

(b) Strategies

- (i) Streamline medicines evaluation processes
- (ii) Strengthen post-marketing surveillance and pharmacovigilance of regulated medicines
- (iii) Strengthen market control and enforcement

(c) Targets

- (i) Average time for product registration reduced by 30 to 40% by June 2031
- (ii) Compliance of pharmaceutical manufacturing facilities with good manufacturing practice (GMP) reaches at least 90% by June 2031
- (iii) Substandard and falsified (SF) medicinal products reduced to atmost 50% of the baseline level by June 2031
- (iv) At least 95% of evaluated applications for tobacco products listed by June 2031

- (v) Annual volume of Adverse Drug reactions (ADR) and Adverse Events Following Immunization (AEFI) reports maintained above WHO recommended minimum pharmacovigilance benchmark of 12,000 ADR report and 6,000 AEFI reports per year by June 2031

(d) Key Performance Indicators

- (i) Average time taken to complete registration of medicinal products
- (ii) Percentage of evaluated applications for medicinal products registered
- (iii) Percentage of evaluated applications for clinical trials authorized
- (iv) Percentage of processed applications licensed
- (v) Prevalence of falsified medicinal products detected in the market (%)
- (vi) Prevalence of substandard medicinal products detected in the market (%)
- (vii) Prevalence of unregistered medicinal products detected in the market (%)
- (viii) Percentage of pharmaceutical manufacturing facilities compliant with Good Manufacturing Practices (GMP)
- (ix) Percentage of medicine distribution and wholesale outlets compliant with Good Storage and Distribution Practices (GSDP)
- (x) Percentage of inspected clinical trials compliant with Good Clinical Practice (GCP) requirements
- (xi) Percentage of evaluated applications of tobacco products listed
- (xii) Percentage of controlled drugs abused in the market (%)
- (xiii) Incidence rate of medicine-related harms
- (xiv) Percentage of medication errors reported
- (xv) Percentage of unfit and expired medicinal products in health facilities
- (xvi) Percentage reduction in lack of efficacy of selected registered medicinal products
- (xvii) Percentage of highly utilized medicinal products in health facilities
- (xviii) Number of Adverse Drug Reaction (ADR) report received annually
- (xix) Number of Adverse Events Following Immunization (AEFI) reports received annually

3.4.2.5 Strategic Objective E:

Quality, safety and performance of medical devices and diagnostics assured

(a) Rationale

Medical devices and diagnostics play a critical role in disease prevention, diagnosis, treatment and monitoring across all levels of the health system. However, the circulation of medical devices and diagnostics that do not meet established quality, safety and performance standards continues to pose significant risks to patient safety, clinical decision-making and the effectiveness of healthcare delivery. Inadequate regulation of these products can lead to misdiagnoses, treatment failure, preventable injuries and loss of public confidence in the health system.

The regulatory environment for medical devices and diagnostics is becoming increasingly complex due to rapid technological advancement, digital and software-based medical technologies, increased importation, local assembly and manufacturing and expanding regional and global trade. These dynamics heighten regulatory risks and require robust, adaptive and risk-based regulatory oversight to ensure that products placed on the market perform as intended throughout their life cycle.

Regulatory enforcement records over the past five years indicate the continued detection of unregistered, substandard and adverse events/incidents related to medical devices through routine market surveillance...

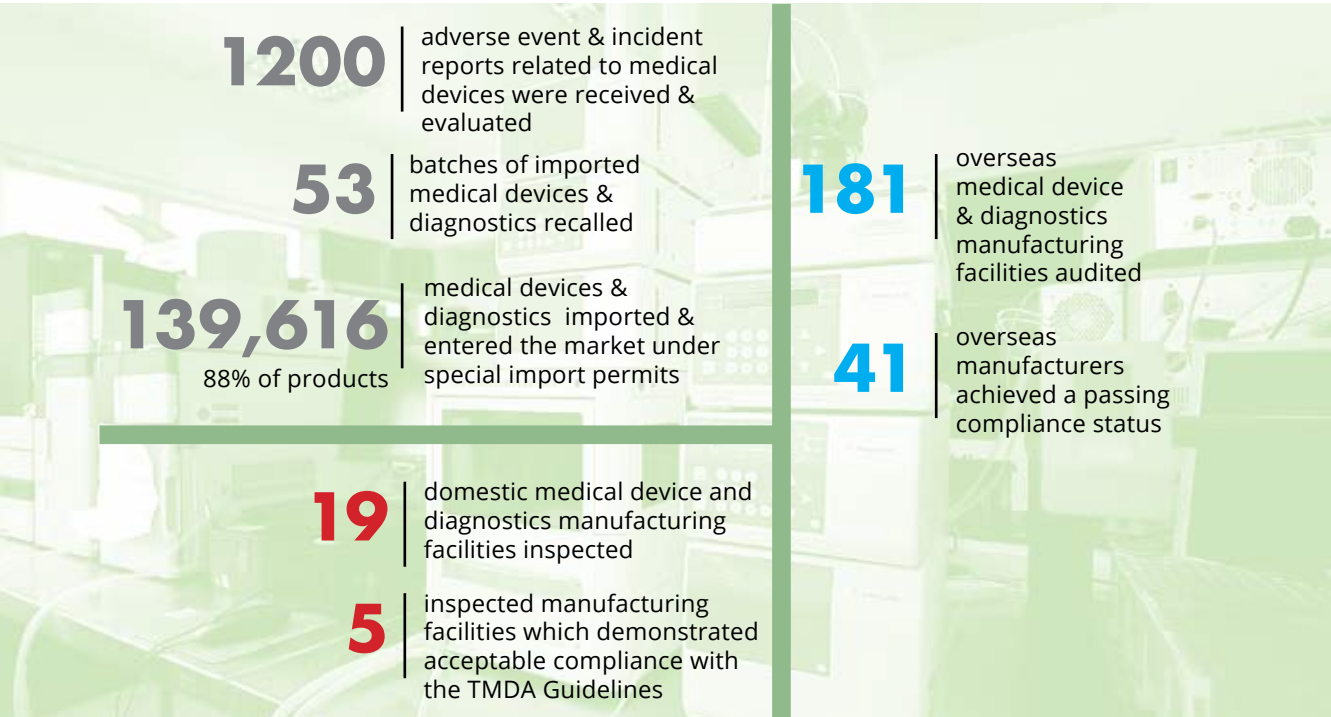


This Strategic Objective is directly aligned with DIRA 2050, which emphasizes improved quality of life through access to reliable health services, the application of science, technology and innovation in healthcare and effective regulation of strategic sectors to support National development. Ensuring the quality, safety and performance of medical devices and diagnostics contributes to accurate diagnosis, effective treatment, patient safety and strengthened health system performance, which are central to DIRA 2050 aspirations.

The objective also aligns with the CCM Election Manifesto, which prioritizes strengthening healthcare service delivery, promoting the use of modern medical technologies, supporting local production and innovation and improving regulatory oversight to ensure safety and reliability of health products. Effective regulation of medical devices and diagnostics supports these commitments by ensuring that innovations entering the health system meet required standards and deliver intended health benefits.

For TMDA, assuring the quality, safety and performance of medical devices and diagnostics is a core statutory responsibility and a key contribution to public health protection. Weak regulatory controls, limited post-marketing oversight, or ineffective enforcement increase the likelihood of unsafe or non-performing products reaching health facilities and patients, with serious public health and reputational consequences.

Regulatory enforcement records over the past five years indicate the continued detection of unregistered, substandard and adverse events/incidents related to medical devices through routine market surveillance, border inspections and targeted enforcement operations.



During this period, over 1200 adverse event and incident reports related to medical devices were received and evaluated and 53 batches of imported medical devices and diagnostics were recalled. This challenge is contributed by the fact that approximately 139,616 products (88%) of medical devices and diagnostics imported into the country entered the market under special import permits. This importation pathway has contributed to a steady increase in the circulation of falsified and substandard medical devices and diagnostics within the market.

Strengthening regulation of medical devices and diagnostics will contribute to improved diagnostic accuracy, effective treatment, patient safety

Compliance outcomes from manufacturing facility inspections further underscore these concerns. Of the 19 domestic medical device and diagnostics manufacturing facilities inspected, only five (26.32%) demonstrated acceptable compliance with the TMDA Guidelines for Submission of Documentation for Quality Audit of Medical Devices and Diagnostics Manufacturing Sites and the Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulations, 2015.

Similarly, among overseas medical device and diagnostics manufacturing facilities, only 41 out of 181 audited facilities (22.7%) achieved a passing compliance status, while the remaining facilities exhibited varying levels of non-conformities requiring corrective actions.

Considering that products from both domestic and foreign manufacturing facilities with identified compliance gaps continue to be imported and supplied to the local market, there is a critical need to strengthen post-marketing surveillance activities and enhance enforcement activities. These efforts should include intensified routine inspections, risk-based and targeted surveillance and stricter regulatory controls across both routine and special-case importation pathways to mitigate risks associated with substandard and falsified medical devices and diagnostics.

Through this Strategic Objective, TMDA will strengthen risk-based regulatory oversight across the medical devices and diagnostics life cycle, enhance inspection and surveillance mechanisms and improve regulatory processes in line with National laws, DIRA 2050, the CCM Election Manifesto and FYDP IV which emphasize improved quality of life, application of science and technology in healthcare, promotion of innovation and strengthening of regulatory systems to support industrial development. Strengthening regulation of medical devices and diagnostics will contribute to improved diagnostic accuracy, effective treatment, patient safety and overall health system performance.

In doing so, the Authority will contribute to improved patient safety, better clinical outcomes, increased public trust in medical technologies and sustainable health system development throughout the Strategic Plan period.

(b) Strategies

- (i) Strengthen inspection and certification systems
- (ii) Streamline device evaluation systems, improve regulatory processes, enhance work flow efficiency
- (iii) Strengthen device surveillance systems

(c) Targets

- (i) Average Turn Around Time to complete Marketing Authorization applications for medical devices manufacturing facilities maintained within CSC by June 2031
- (ii) Average Turn Around Time to complete quality audit applications for medical devices and diagnostics manufacturing facilities maintained within CSC by June 2031
- (iii) Compliance among manufacturers and distributors reaches at least 90% by June 2031
- (iv) Prevalence of substandard and falsified (SF) medical devices and diagnostics in the market reduced by at least 30% from the 2025 baseline by June 2031
- (v) Number of reported adverse events and incidents related to medical devices and diagnostics (including field safety issues) from health facilities, manufacturers and the general public reaches at least 1500 reports per year by June 2031

(d) Key Performance Indicators

- (i) Average Turnaround Time (in days) to complete Marketing Authorization applications for medical devices manufacturing facilities maintained within Customer Service Charter (CSC) time lines
- (ii) Average Turnaround Time (in days) to complete quality audit applications for medical devices and diagnostics manufacturing facilities maintained within Customer Service Charter (CSC) time lines
- (iii) Percentage of evaluated applications for medical devices and diagnostics registered
- (iv) Percentage of processed applications licensed

- (vi) Prevalence of falsified medical devices and diagnostics detected in the market
- (vii) Prevalence of substandard medical devices and diagnostics detected in the market
- (viii) Prevalence of unregistered medical devices and diagnostics detected in the market
- (ix) Percentage of medical devices manufacturing facilities compliant with Quality Audit requirements
- (x) Percentage of medical devices distribution and wholesale outlets compliant with Good Storage and Distribution Practices (GSDP)
- (xi) Incidence rate of medical devices and diagnostics -related harms
- (xii) Percentage of unfit and expired medical devices and diagnostics in health facilities

3.4.2.6 Strategic Objective F:

Laboratory services improved and maintained

(a) Rationale

Laboratory services are a critical pillar of effective regulation of medicines, medical devices, diagnostics and related products, as they provide the scientific evidence required to confirm product quality, safety and performance throughout the product life cycle. In Tanzania, the expanding health products market, increased use of diagnostics in clinical decision-making and growing volumes of imported and locally manufactured products have significantly increased demand for timely, reliable and internationally credible laboratory testing services. Strengthening laboratory capacity is therefore essential to support regulatory decision-making, protect public health and maintain confidence in the National regulatory system.



TMDA's performance data for 2021/22–2024/25 demonstrates generally strong laboratory service delivery, particularly in routine regulatory testing. The Authority consistently tested regulatory samples of medicines, biocidals and diagnostics at or near full coverage, with average performance levels of approximately 97% for medicines, 100% for biocidals and 100% for diagnostics. These results indicate a robust baseline capacity to support post-marketing surveillance and regulatory enforcement decisions. However, performance for testing of medical devices averaged about 94%, reflecting the increasing technical complexity of device testing and the need for specialized equipment, methods and expertise.

The data also shows mixed performance in testing of specific product categories. While herbal medicines testing achieved full coverage in most years, a sharp drop in performance in 2024/25 reduced the four-year average to about 75%, signaling operational disruptions or prioritization challenges that could weaken oversight of a product category widely used by the population. Such fluctuations underscore the need for resilient laboratory systems capable of maintaining consistent performance across all regulated product types.

**...the number of
medicine samples
screened at
Quality Assurance
Centres increased
substantially ...**

Beyond routine testing, laboratory system strengthening is closely linked to accreditation and method development. TMDA made notable progress in expanding the number of analytical methods accredited for the Dar es Salaam laboratory, achieving an average performance exceeding targets, which enhances the credibility, scope and international recognition of test results. In contrast, the Mwanza laboratory shows limited progress in accredited analytical methods, with performance remaining below desired levels. This imbalance constrains decentralization of testing services, increases turnaround time for samples from upcountry regions and places additional pressure on the Dar es Salaam laboratory.

Laboratory service demand is also increasing beyond regulatory surveillance. The number of samples received from external customers and tested by TMDA laboratories averaged about 98%, demonstrating strong responsiveness to stakeholder needs. At the same time, the number of medicine samples screened at Quality Assurance Centres increased substantially over the period, with average performance exceeding 130% of targets. While this reflects growing reliance on TMDA laboratory infrastructure and expertise, it also signals rising workload pressure that could affect turnaround times, staff capacity and equipment utilization if not matched with commensurate investments.

Operational sustainability of laboratory services depends heavily on equipment reliability and maintenance. The data shows consistently strong performance in calibration and maintenance of laboratory equipment, with average



performance of 100%, indicating effective asset management systems. However, the absence of processed research applications throughout the period suggests untapped potential for laboratories to contribute more systematically to regulatory science, innovation and evidence generation that could inform policy and regulatory reforms.

Improving and maintaining laboratory services under this Strategic Objective is therefore essential to consolidate existing strengths while addressing identified gaps in consistency, geographic coverage and advanced testing capacity. Priority areas include stabilizing performance across all product categories, expanding accredited analytical methods especially at the Mwanza laboratory, enhancing capacity for medical device testing and aligning rising testing demand with investments in human resources, equipment and infrastructure. This Strategic Objective aligns with DIRA 2050 and FYDP IV which emphasize the application of science, technology and innovation to strengthen health systems and regulatory effectiveness. By reinforcing laboratory services as a core regulatory function, TMDA will enhance evidence-based decision-making, improve detection of substandard and unsafe products and sustain public trust.

Furthermore, advancing laboratory accreditation and aligning with international standards will enhance TMDA's regulatory maturity, support regional harmonization efforts and facilitate mutual recognition of test results across borders. This is essential for promoting trade, improving efficiency in regulatory processes and reducing duplication of testing requirements.

(b) Key Strategies

- (i) Strengthen laboratory analytical testing systems to support risk-based regulatory decision-making and market surveillance
- (ii) Strengthen compliance with laboratory quality management systems

(c) Targets

- (i) Turn Around Time to release laboratory results maintained within CSC
- (ii) WHO prequalification status and ISO/IEC 17025 accreditation of TMDA laboratories sustained for Dar es Salaam and attained for Mwanza and Dodoma by June 2031.

(d) Key Performance Indicators

- (i) Percentage compliance to laboratory testing
- (ii) Accredited TMDA laboratories
- (iii) WHO prequalified TMDA laboratories
- (iv) Vaccines testing laboratory in place
- (v) Increased revenues from external customer services

3.4.2.7 Strategic Objective G:***Capacity to deliver regulatory services improved and sustained*****(a) Rationale**

Strengthening institutional capacity to deliver regulatory services is fundamental to the effective execution of TMDA's mandate in an increasingly complex and demanding regulatory environment. The rapid expansion of the health products market, rising volumes of applications and inspections, growing expectations for timely regulatory decisions and increasing reliance on risk-based and evidence-driven regulation all require a capable institution with robust systems, skilled personnel, adequate infrastructure and sustainable financing. Without deliberate investment in institutional capacity, gains achieved in regulatory outcomes cannot be sustained.



Performance data for 2021/22–2024/25 demonstrates that TMDA has established a strong operational foundation for institutional performance. Implementation of approved work plans and budgets remained consistently high, averaging about 99%, reflecting effective planning, coordination and financial discipline. Revenue collection performance was equally strong, with projected revenue from all sources averaging approximately 103% and revenue from own sources averaging about 106%, indicating improved cost recovery mechanisms, service demand growth and strengthened financial sustainability. These results provide a solid basis for financing regulatory operations and strategic investments.

At the same time, the data highlight areas where institutional systems require strengthening to ensure consistent service delivery. Implementation of procurement plans averaged about 94%, pointing to procedural bottlenecks, procurement cycle delays and capacity constraints that can affect timely acquisition of essential goods and services. Similarly, staff sensitization on quality risk management averaged about 90%, indicating that while progress has been made, a proportion of staff have yet to be fully equipped with risk-based regulatory approaches essential for modern regulation.

Risk management performance shows a mixed trajectory. While mitigation of identified risks reached full performance in 2024/25, the four-year average reflects variability across earlier years, suggesting that enterprise risk management systems were not consistently applied throughout the period. Sustained capacity strengthening is therefore required to institutionalize proactive risk identification, mitigation and monitoring as routine management practices rather than reactive measures.

Internal accountability and governance mechanisms show strong performance. Planned internal audits and quality audits were consistently conducted at 100%, demonstrating functional internal control systems and commitment to compliance and continuous improvement. However, automation of service processes averaged about 88%, indicating that a significant proportion of regulatory work-flows remain manual or partially digitized. This limits efficiency gains, increases operational risk and constrains TMDA's ability to respond quickly to rising service demand.

Human resource capacity remains a critical constraint. While implementation of the Human Resource Plan averaged about 88% and training program implementation averaged about 91%, the proportion of TMDA inspectors trained on investigation and evidence gathering averaged only about 26% over the period. This gap directly affects the quality of inspections, investigations and enforcement actions, particularly in complex cases involving falsified, substandard, or unsafe products.

In addition, delays in completion of TMDA offices in Mbeya, with zero performance recorded by 2024/25, constrain decentralization of regulatory services and increase operational pressure on existing offices.

Notwithstanding these constraints, TMDA made important structural advances in institutional strengthening. The revised Scheme of Service and Salary Structure and revised Internal Staff and Financial Regulations were fully put in place, providing a stronger foundation for staff motivation, retention, accountability and organizational governance. These reforms are essential enablers for long-term institutional performance but must be complemented by investments in skills development, infrastructure and digital systems.

Strengthening capacity to deliver regulatory services under this Strategic Objective is therefore essential to consolidate strong financial and planning performance while addressing critical gaps in human resource capacity, risk management institutionalization, service automation, infrastructure development, integration of information systems and adoption of data-driven decision-making will be critical for improving service delivery, reducing turnaround times and enhancing stakeholder experience. This will position TMDA as a modern, technology-enabled regulatory authority capable of responding to evolving regulatory demands.

This Strategic Objective is aligned with DIRA 2050 and FYDP IV which emphasizes capable public institutions, effective governance and the use of technology to enhance service delivery. By systematically strengthening institutional capacity, TMDA will improve efficiency, responsiveness and credibility of regulatory services, ensuring sustained protection of public health.

(b) Key Strategies

- (i) Digital transformation initiatives and system integration
- (ii) Strengthen data systems and analytics capacity
- (iii) Strengthen service delivery and customer feedback systems
- (iv) Strengthen regulatory systems and international benchmarking
- (v) Optimize collection from existing revenue sources by streamlining registration procedures; strengthen billing systems; enhance compliance enforcement; automate revenue collection processes; reduce revenue leakages
- (vi) Implement preventive maintenance systems; strengthen asset life cycle management; improve maintenance planning
- (vii) Strengthen contract management systems; improve invoice processing efficiency; enhance cash flow planning; enforce compliance with payment terms
- (viii) Strengthen reconciliation of tax accounts; implement arrears clearance plans; enhance coordination with tax authority
- (ix) Strengthen tax compliance systems; enforce timely remittance procedures; integrate tax obligations into cash flow planning

- (x) Promote incineration services through targeted awareness campaigns, stakeholder engagement and client sensitization; strengthen customer outreach and communication to increase uptake of services and voluntary compliance

(c) Targets

- (i) At least 80% of regulatory services are delivered through digital platforms by June 2031
- (ii) At least 80% of strategic indicators are tracked through digital dashboards and advanced analytics by June 2031
- (iii) Customer satisfaction reaches at least 90% by June 2031
- (iv) World Health Organization maturity level 4 or listed authority status attained by June 2031
- (v) Internal revenue from existing sources increased by 30% by June 2031
- (vi) Maintenance cost as a proportion of total asset value reduced by 30% by June 2031
- (vii) 100% of payments to contractors and service providers made within contractual time lines by June 2031
- (viii) Outstanding tax liabilities to Tanzania Revenue Authority reduced by 100% from baseline by June 2031
- (ix) At least 100% of current tax obligations settled within statutory time lines by June 2031
- (x) Revenue collection from incineration services increased by 30% by June 2031

(d) Key Performance Indicators

- (i) Level of digital service delivery
- (ii) Level of digital performance tracking
- (iii) Customer satisfaction index
- (iv) Regulatory maturity level attained
- (v) Total internal revenue collected annually compared to baseline
- (vi) Ratio of annual maintenance cost to total asset value

- (vii) Proportion of contractor and service provider payments made within agreed time lines
- (viii) Value of outstanding tax liabilities
- (ix) Proportion of tax payments made within statutory deadlines
- (x) Annual revenue collected from incineration services

3.5 Operationalization of the Plan

The Authority will operationalize the Strategic Objectives through its existing organizational structure, as described in Sections 3.5.1 to 3.5.6 by cascading strategies, performance indicators and targets from the corporate level to Directorates and Units in line with their respective mandates. Each Directorate and Unit is assigned clearly defined responsibilities, ensuring that strategic priorities are systematically translated into operational actions and that accountability for implementation is firmly established.

Through this cascading approach, the Strategic Plan is translated into concrete and measurable interventions that strengthen performance monitoring, enhance evidence-based decision-making and improve alignment between TMDA's regulatory functions and National health, industrial and trade priorities. This approach further ensures that TMDA's corporate priorities are coherently integrated across all Directorates and Units, enabling coordinated implementation and sustained progress toward the Authority's Development Objective.

3.5.1 Directorate of Business Support

The Directorate of Business Support (DBS) is responsible for providing institutional and administrative support services that enable TMDA to effectively implement its mandate. The Directorate oversees recruitment and management of human resources, staff welfare, health and safety, training and capacity development, as well as the management of office facilities, buildings, working tools, security services and station upkeep. It coordinates the preparation, implementation and review of the Strategic Plan, Business Plans and Budgets and leads the monitoring and evaluation of institutional performance and management of Authority statistics. In addition, the Directorate facilitates cooperation with National, regional and international bodies on cross-cutting institutional matters.

During the implementation of this Strategic Plan, the Directorate will be involved in the implementation of various strategies under Strategic Objectives A, B, C and G, as summarized in Table 19.

Table 19: Cascaded Strategies and Targets for DBS

Desired Impact	Key Strategies	Key Actions	Responsible Person
Strategic Objective A: HIV, Hepatitis B and Non-Communicable Diseases reduced and services improved			
A healthy workforce with reduced burden of HIV, Hepatitis B and Non-Communicable Diseases, supporting sustained institutional performance	Workplace wellness programmes, screening and prevention interventions	Design and implement workplace wellness programmes covering NCDs prevention, health promotion and staff wellbeing	MHRA
		Design and implement routine screening and vaccination programmes for NCDs risk factors, HIV/AIDS and Hepatitis B	MHRA
		Design and implement sensitization programmes on HIV/AIDS, Hepatitis B and NCDs prevention	MHRA
		Design and implement behavior change and awareness programmes to improve staff knowledge and practices	MHRA
Strategic Objective B: National Anti-Corruption Strategy Implementation Enhanced and Sustained			
An ethical and accountable institution capable of sustaining regulatory performance	Promote integrity	Design and implement anti-corruption and integrity sensitization programmes for staff	MHRA
		Design and implement Integrity Committee coordination mechanisms including planning and conduct of meetings	MHRA
		Design and implement NACSAP IV implementation Plan	MHRA
		Design and conduct corruption perception surveys to assess institutional integrity levels	MPME
Strategic Objective C: Gender mainstreaming and environmental sustainability improved			
An inclusive, gender-responsive and environmentally sustainable institution with safe and compliant working conditions that support effective regulatory service delivery	Gender mainstreaming policies and leadership programmes	Design and implement gender mainstreaming programmes to enhance gender balance in leadership and workforce participation	MHRA
		Design and implement gender sensitization and capacity-building programmes for staff	MHRA
	Environmental monitoring and enforcement systems	Design and implement programmes for eco-friendly disposal of unfit medical products and environmental compliance	MHRA

Desired Impact	Key Strategies	Key Actions	Responsible Person
Strategic Objective C: Gender mainstreaming and environmental sustainability improved			
An inclusive, gender-responsive and environmentally sustainable institution with safe and compliant working conditions that support effective regulatory service delivery	Occupational health and safety management systems	Design and implement occupational health and safety programmes including workplace risk assessments, inspections and corrective actions	MHRA
		Develop and implement systems for tracking occupational health and safety compliance of buildings and facilities	MHRA / MPME
Strategic Objective G: Institution Capacity to deliver regulatory services improved			
Efficient administrative support systems enabling effective implementation of zonal regulatory operations	Strengthen administrative support systems	Coordinate provision of administrative and operational support services within zones	MHRA

3.5.2 Directorate of Human and Veterinary Medicines Control

The Directorate of Human and Veterinary Medicines (DMC) is responsible for regulating human and veterinary medicines to ensure their quality, safety and efficacy prior to and after marketing authorization. The Directorate oversees assessment of product performance, evaluation of the quality, safety and efficacy of medicinal and tobacco products, coordination of quality audits of domestic and foreign manufacturing premises and issuance of import and export permits for medicines and related products. It supervises pharmacovigilance and hemovigilance activities, monitors field safety updates on the performance and use of medicines and overseas applied regulatory research related to human and veterinary medicines. In addition, the Directorate facilitates cooperation with regional and international regulatory bodies, including harmonization initiatives.



During the implementation of this Strategic Plan, the Directorate of Human and Veterinary Medicines will implement various strategies under Strategic Objectives C and D, as summarized in Table 20.

Table 20: Cascaded Strategies and Targets for DMC

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
SO C: Gender mainstreamed and environmental ecosystem improved				
Environmental compliance reaches at least 95% by June 2031	An environmentally sustainable regulatory system with safe and compliant disposal of unfit medical products, minimizing public health and environmental risks	Environmental compliance and safe disposal systems	Design and implement systems for safe disposal of unfit medical products using approved eco-friendly methods	MCIE
SO D: Quality, safety and effectiveness of medicinal products and tobacco standards assured				
Average time for product registration of medicinal products reduced by 30–40% by June 2031	A robust and efficient regulatory system supporting timely registration of medicinal products	Streamline product evaluation and regulatory processes	Design and implement streamlined processes for timely evaluation of applications for registration, renewal and variations of medicinal products	MMRE
			Design and implement processes for timely handling and resolution of queries and applications	MMRE
			Design and implement processes for timely publication of assessment reports and regulatory decisions	MMRE
Compliance of pharmaceuticals manufacturing facilities with Good Manufacturing Practice (GMP) reaches at least 90% by June 2031	A robust and efficient regulatory system ensuring quality, safety and effectiveness of medicinal products and tobacco	Strengthen inspection and enforcement system	Design and implement GMP inspection programmes for domestic and overseas facilities	MCIE

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
	A robust and efficient regulatory system ensuring quality, safety and effectiveness of medicinal products and tobacco	Strengthen inspection and enforcement system	Design and implement GMP inspection backlog reduction program to clear pending inspections	MCIE
Substandard and falsified medicinal products reduced to at most 50% of the baseline level by June 2031	A robust and efficient regulatory system ensuring quality, safety and effectiveness of medicinal products and tobacco	Strengthen inspection and enforcement system	Develop and implement enforcement processes including recalls, destruction and compliance actions	MCIE
			Develop and implement processes for tracking surveillance findings and compliance trends	MCIE
		Strengthen clinical trials, pharmacovigilance and post-market surveillance processes	Design and implement processes for authorization, monitoring and inspection of clinical trials	MCTPV
			Design and implement pharmacovigilance processes for ADR, AEFI and safety monitoring	MCTPV
			Design and implement PMS programmes for routine surveillance of medicinal products in the market	MCTPV
At least 95% of evaluated applications for tobacco products listed by June 2031	Improved regulatory control of tobacco products	Strengthened evaluation and listing of tobacco products	Evaluate applications for listing of tobacco products in accordance with regulatory requirement	MMRE
Substandard and falsified medicinal products reduced to at most 50% of the baseline level by June 2031	A robust and efficient regulatory system ensuring quality, safety and effectiveness of medicinal products and tobacco	Strengthen clinical trials, pharmacovigilance and post-market surveillance processes	Develop and implement processes for causality assessment, safety reporting and compliance monitoring	MCTPV
			Design and implement backlog management processes for clinical trial applications, PMS activities and safety assessments	MCTPV

3.5.3 Directorate of Medical Devices and Diagnostics

The Directorate of Medical Devices and Diagnostics (DMD) is responsible for regulating medical devices, diagnostics and medical laboratory equipment to ensure their quality, safety and performance before and after marketing authorization. The Directorate oversees assessment of product performance before marketing authorization, supervision of evaluation of the quality, safety and efficacy of blood and blood products and coordination of quality audits for domestic and foreign manufacturing premises of medical devices and diagnostics.

The Directorate also is concerned with the issuance of import and export permits for medical devices, diagnostics, laboratory equipment, blood and blood products, supervises vigilance activities and monitors field safety updates on the performance and use of medical devices and diagnostics. In addition, the Directorate oversees applied regulatory research related to medical devices and diagnostics, fosters cooperation with regional and international regulatory bodies including harmonization initiatives.

During the implementation of this Strategic Plan, DMD will be involved in the implementation of various strategies under Strategic Objectives C, E and G as summarized in Table 21.

Table 21: Cascaded Strategies and Targets for DMD

Strategies	Targets	Output Indicators	Responsible Person
Strategic Objective C: Gender mainstreamed and environmental ecosystem improved			
Strengthen environmental management systems for sustainable operations and safe disposal	Environmental and Gender Issues Mainstreamed in TMDA operations by June, 2031	Percentage of identified unfit medical devices and diagnostics disposed off through eco-friendly methods	MMDL
Strategic Objective E: Quality, safety and performance of medical devices and diagnostics assured			
Strengthen evaluation and marketing authorization of regulated products	Average turnaround time to complete Marketing Authorization applications for medical devices manufacturing facilities maintained within CSC by June, 2031	Percentage of available applications for registration of medical devices and diagnostics including devices related to blood and blood products evaluated within time line as per CSC	MMDA
		Percentage of available applications for advertisement of medical devices and diagnostics evaluated within time line as per CSC	MMDA

Strategies	Targets	Output Indicators	Responsible Person
Strengthen market control and enforcement	Average Turn Around Time to complete quality audit applications for medical devices and diagnostics manufacturing facilities maintained within CSC by June 2031	Percentage of overseas planned quality audits for medical devices and diagnostics manufacturing facilities inspected within time line as per CSC	MMDA
		Percentage of inspected medical devices and diagnostics manufacturing facilities with identified non-conformances that are issued with corrective and preventive actions (CAPA) within the specified time frame as per CSC	MMDA
		Percentage of received CAPA submissions processed within the prescribed time lines	MMDA
		Percentage of quality audit reports published on website	MMDA
	Prevalence of substandard and falsified (SF) medical devices and diagnostics in the market reduced by at least 30% from the 2025 baseline by June 2031	Percentage of available applications for licensing of manufacturing facilities dealing with medical devices and diagnostics including blood establishments processed within time line as per CSC	MMDL
		Percentage of registered domestic medical devices and diagnostics applications from the domestic manufacturing facilities inspected for quality audits within time line as per CSC	MMDL
		Percentage of available applications for import and export permits for medical devices and diagnostics processed	MMDL
Strengthen Post Marketing surveillance, vigilance and haemovigilance of regulated products.	Increase annual volume of reported adverse events and incidents related to medical devices and diagnostics (including field safety issues from health facilities, manufacturers and the general public to at least 1500 reports per year by June 2031.	Total number of adverse event and incident reports received from health facilities and consumers per year.	MMDV
		Total number of adverse event and incident reports received from manufacturers per year.	MMDV
		Total number of Field Safety Corrective Action (FSCA) reports received per year	MMDV

Strategies	Targets	Output Indicators	Responsible Person
		Percentage of serious events and incidents related to medical devices, diagnostics, blood and blood related devices investigated within regulatory time lines	MMDV
		Percentage of planned PMS activities successfully completed annually	MMDV
		Percentage of medical equipment in healthcare facilities that have undergone assessment	MMDV
Strategic Objective G: Capacity to deliver regulatory services improved			
		Percentage of registered medical devices and diagnostics for which the annual retention fee is paid in accordance with regulatory requirements	MMDA

3.5.4 Directorate of Laboratory Services

The Directorate of Laboratory Services (DLS) is responsible for providing laboratory testing and analytical services to support TMDA's regulatory mandate. The Directorate supervises chemical, physical and microbiological analysis of regulated products, oversees testing of products at quality assurance centers and mini-laboratories and ensures calibration and maintenance of laboratory equipment. It develops, implements and reviews laboratory quality policies, maintains and implements laboratory standards in accordance with ISO/IEC 17025:2015 and oversees management of zonal laboratories. In addition, the Directorate maintains WHO Prequalification certification and the Laboratory Quality Management System, fosters cooperation with regional and international bodies on laboratory-related matters and performs any other official duties as may be assigned by Management.



During the implementation of this Strategic Plan, the Directorate of Laboratory Services will be involved in implementing various strategies under Strategic Objective F, as summarized in Table 22.

Table 22: Cascaded Strategies and Targets for DLS

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
All laboratory results are released within the standard turnaround time by June 2031	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions	Strengthen laboratory information management systems and work-flows	Design and implement streamlined laboratory work-flows for timely receipt, analysis and release of laboratory results	MMCA / MMDT / MMBA
	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions		Design and implement processes for efficient sample tracking, analysis and reporting through LIMS	MMCA / MMDT / MMBA
	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions	Expand accreditation and quality assurance programmes	Design and implement accreditation programmes to meet international laboratory standards	MMCA / MMDT
	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions	Strengthen research and innovation	Design and implement operational research programmes within TMDA	MMBA
	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions	Strengthen laboratory governance and coordination systems	Design and implement Laboratory Technical Committee coordination processes	MMCA / MMDT
	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions	Strengthen laboratory equipment management processes	Design and implement preventive maintenance programmes for laboratory equipment	MMCA / MMDT / MMBA
	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions		Design and implement calibration processes for laboratory equipment	MMCA / MMDT / MMBA

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
At least 4 laboratories are accredited to international standards by June 2031	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions	Strengthen laboratory equipment management processes	Design and implement quality assurance systems including proficiency testing schemes and compliance monitoring	MMCA / MMDT / MMBA
	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions		Design and implement laboratory quality improvement programmes and standards compliance initiatives	MMCA / MMDT / MMDA
	Reliable, timely and internationally accredited laboratory services supporting regulatory decisions		Design and implement programmes for establishment of vaccine testing laboratories	MMCA / MMDA
Revenue from laboratory services increased by at least 30% from baseline by June 2031	Increased revenue collection from laboratory services through expanded utilization and enhanced customer engagement	Strengthen laboratory service delivery and outreach	Design and implement strategies to increase external customers utilizing laboratory services	MMCA / MMDT / MMBA

3.5.5 Zonal Offices

The Zonal Offices are responsible for implementing TMDA's regulatory functions at sub-national level to ensure effective oversight of regulated products, premises and practices. The Offices inspect regulated products and premises, control importation and exportation of regulated products, register, issue and renew permits for premises dealing with regulated products. They maintain and update registers of premises, control the demand, supply and use of narcotics, psychotropic substances, conduct post-marketing surveillance and vigilance activities for medicines and medical devices.

In addition, the Zonal Offices monitor advertising and promotional activities, manage office facilities, human and financial resources, coordinate delegated regulatory functions with Local Government Authorities, create public awareness on TMDA services, foster collaboration with local authorities and other stakeholders, support applied regulatory research and programs.

During the implementation of this Strategic Plan, the Zonal Offices will be involved in the implementation of various strategies under Strategic Objectives C, D and E as summarized in Table 23.

Table 23: Cascaded Strategies and Targets for Zone Offices

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
Strategic Objective C: Gender mainstreamed and environmental ecosystem improved				
Environmental and Gender Issues Mainstreamed in TMDA operations by June 2031	An environmentally sustainable and socially responsive regulatory system with safe disposal of unfit regulated products	Strengthen environmental management systems for sustainable operations and safe disposal	Coordinate disposal of unfit medical devices, diagnostics and medical products through approved eco-friendly methods	Zone Managers
Strategic Objective D: Quality, safety and effectiveness of medicinal products and tobacco standards assured				
Prevalence of substandard and falsified (SF) medicinal products in the market reduced to utmost 50% of the baseline level by June 2031	Improved market control systems ensuring availability of safe, quality and effective medicinal and tobacco products	Strengthen market control and enforcement systems	Process applications for licensing and registration of premises dealing in medicinal products within prescribed time lines	Zone Managers
		Strengthen market control and enforcement systems	Conduct routine and follow-up inspections of premises dealing in medicinal products	Zone Managers
		Strengthen market control and enforcement systems	Process import and export applications and inspect consignments at ports of entry	Zone Managers
		Strengthen market control and enforcement systems	Remove identified substandard and falsified medicinal products from the market	Zone Managers
	Strengthened pharmacovigilance systems supporting early detection and management of medicine and vaccine safety issues	Strengthen post-marketing surveillance and pharmacovigilance systems	Sensitize health care workers on ADR and AEFI reporting requirements and procedures	Zone Managers

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
Annual volume of Adverse Drug Reaction (ADR) and Adverse Events Following Immunization (AEFI) reports increased to levels exceeding WHO minimum pharmacovigilance requirements by June 2031	Strengthened pharmacovigilance systems supporting early detection and management of medicine and vaccine safety issues	Strengthen post-marketing surveillance and pharmacovigilance systems	Investigate reported Serious Adverse Events (SAEs) in accordance with approved procedures	Zone Managers
Strategic Objective E: Quality, safety and performance of medical devices and diagnostics assured				
Prevalence of substandard and falsified (SF) medical devices and diagnostics in the market reduced by at least 30% from the 2025 baseline by June 2031	Improved market control systems ensuring safety, quality and performance of medical devices and diagnostics	Strengthen market control and enforcement systems	Process applications for licensing of premises dealing with medical devices and diagnostics	Zone Managers
			Conduct routine and follow-up inspections of outlets and facilities dealing with medical devices and diagnostics	Zone Managers
			Process import and export permit applications for medical devices and diagnostics within prescribed time lines	Zone Managers
Increase the number of adverse events related to medicines, vaccines and medical devices reports received from health facilities and the public to at least 12,000, 1,200 and 1,500 reports per year respectively by June 2031	Strengthened vigilance systems supporting early detection and response to safety issues related to medicines, vaccines and medical devices	Strengthen post-marketing surveillance and vigilance systems	Sensitize health care workers and stakeholders on reporting adverse events and serious incidents related to medical devices and diagnostics	Zone Managers
		Strengthen post-marketing surveillance and vigilance systems	Investigate reported serious adverse events and field safety incidents in accordance with approved procedures	Zone Managers

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
		Strengthen post-marketing surveillance and vigilance systems	Monitor and document field safety reports received from health facilities and stakeholders	Zone Managers
Strategic Objective F: Laboratory services improved and maintained				
Turn Around Time to release laboratory results maintained within CSC by June 2031	Timely laboratory screening services supporting quality assurance of regulated products	Strengthen laboratory analytical testing systems	Conduct screening of planned medicine samples at QA Centers within approved turnaround time lines	Zone Managers
Strategic Objective G: Institution Capacity to deliver regulatory services improved				
Level of general public awareness on TMDA functions increased from 56% to 64% by June 2031	Increased public awareness and stakeholder engagement on TMDA functions and regulatory services	Strengthen customer care, public engagement and complaints handling systems	Conduct public education programmes and stakeholder awareness campaigns on TMDA services	Zone Managers
Level of general public awareness on TMDA functions increased from 56% to 64% by June 2031	Increased public awareness and stakeholder engagement on TMDA functions and regulatory services	Strengthen customer care, public engagement and complaints handling systems	Resolve customer complaints within approved service time lines and monitor response performance	Zone Managers
	Increased public awareness and stakeholder engagement on TMDA functions and regulatory services	Strengthen customer care, public engagement and complaints handling systems	Conduct coordination meetings between TMDA and Local Government Authorities (LGAs)	Zone Managers
Administrative services maintained at 100% by June 2031	Efficient administrative support systems enabling effective implementation of zonal regulatory operations	Strengthen administrative support systems	Coordinate provision of administrative and operational support services within zones	Zone Managers



3.5.6 Units

3.5.6.1 Legal Services Unit

The Legal Services Unit is responsible for providing legal advisory and litigation support services that ensure TMDA's operations are conducted in compliance with applicable laws, regulations and policies. The Unit develops, reviews and interprets legal documents and instruments to safeguard the Authority's legal interests and support effective execution of its regulatory mandate.

The Unit conducts in-house litigation and manages legal proceedings involving the Authority, including liaison with the Director of Public Prosecutions (DPP) and other relevant legal institutions on matters arising from TMDA's operations. It maintains and regularly updates a comprehensive database of legal proceedings, including cases and legal outcomes, to support institutional learning, risk management and informed decision-making.

In addition, the Legal Services Unit coordinates the drafting, review and updating of legislation, regulations and regulatory guidelines to ensure they remain responsive to emerging regulatory needs and aligned with National legal frameworks.

During the implementation of this Strategic Plan, the Legal Services Unit will be involved in implementing strategies under Strategic Objective G, as summarized in Table 24.

Table 24: Cascaded Strategy and Target for LS Unit

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
Governance effectiveness and accountability strengthened by June 2031	A transparent, accountable and well-governed regulatory authority with effective legal frameworks, strong oversight systems and full compliance with statutory obligations	Strengthen legal and regulatory framework development systems	Design and implement processes for development, review and updating of regulations and guidelines	MLS
			Design and implement processes for legal drafting, approval and gazettment of new regulations	MLS
			Design and implement processes for coordination and conduct of Ministerial Advisory Board (MAB) meetings	MLS
	An efficient, transparent and globally recognized regulatory authority delivering high-quality services	Strengthen governance and board coordination systems	Design and implement processes for preparation and submission of MAB performance reports within prescribed time lines	MLS
	An efficient, transparent and globally recognized regulatory authority delivering high-quality services		Design and implement processes for appointment and gazettment of LGA inspectors	MLS
	An efficient, transparent and globally recognized regulatory authority delivering high-quality services		Design and implement processes for gazettment of TMDA inspectors and analysts	MLS
	An efficient, transparent and globally recognized regulatory authority delivering high-quality services		Design and implement processes for issuance and management of identification cards for gazetted inspectors	MLS

3.5.6.2 Quality and Risk Management Unit

The Quality and Risk Management Unit is responsible for coordinating, monitoring and strengthening quality and risk management systems across TMDA to ensure consistent, efficient and compliant delivery of regulatory services. The Unit oversees the development, implementation, maintenance and continuous improvement of the Authority's Quality Management System (QMS) in accordance with internationally recognized standards.

Specifically, the Unit coordinates the development and periodic review of the Quality Policy in line with ISO 9001 standards, ensures maintenance of ISO 9001 certification and prepares quality audit plans. It conducts internal quality audits and coordinates external audits and benchmarking assessments to ensure compliance, identify gaps and promote continuous improvement across all organizational units.

In addition, the Quality and Risk Management Unit coordinates the development, review and maintenance of institutional guidelines, manuals and Standard Operating Procedures (SOPs) to promote standardization, consistency and accountability in operations. The Unit also leads the development and enhancement of risk management policies, procedures and systems and coordinates organization-wide efforts to embed the risk management framework into institutional planning, operations and decision-making processes.

Furthermore, the Unit collates, reviews and monitors institutional risk registers to support proactive identification, assessment and mitigation of strategic, operational and compliance risks.



During the implementation of this Strategic Plan, the Quality and Risk Management Unit will be involved in implementing strategy under Strategic Objectives B and G, as summarized in Table 25.

Table 25: Cascaded Strategy and Target for QRM Unit

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
Strategic Objective B: National Anti-Corruption Strategy Implementation Enhanced and Sustained				
Zero corruption incidents sustained by June 2031	A transparent, accountable and corruption-free institution with strong compliance and integrity systems	Strengthen governance and anti-corruption compliance systems	Monitor compliance with internal control systems and enforce corrective actions for identified risks	MQR
Strategic Objective G: Capacity to deliver regulatory services improved				
Quality management systems strengthened and sustained by June 2031	A quality-driven, risk-informed and continuously improving regulatory authority with robust systems for compliance, performance and accountability	Strengthen quality management systems (QMS)	Conduct internal ISO 9001 audits in accordance with approved audit plans	MQR
Quality management systems strengthened and sustained by June 2031	A quality-driven, risk-informed and continuously improving regulatory authority with robust systems for compliance, performance and accountability	Strengthen quality management systems (QMS)	Coordinate external ISO 9001 audits and maintain certification requirements	MQR
		Strengthen quality management systems (QMS)	Convene management review meetings and document performance decisions	MQR
		Strengthen quality management systems (QMS)	Sensitize staff on ISO 9001 requirements and quality standards	MQR
		Strengthen quality management systems (QMS)	Track and ensure timely closure of non-conformities within agreed corrective action time lines	MQR

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
WHO maturity level 4 attained by June 2031	A globally recognized regulatory authority with advanced systems aligned to international standards and best practices	Strengthen regulatory benchmarking and continuous improvement systems	Conduct WHO GBT self-assessments for medicinal products and document implementation status	MQR
	A globally recognized regulatory authority with advanced systems aligned to international standards and best practices	Strengthen regulatory benchmarking and continuous improvement systems	Conduct WHO GBT self-assessments for medical devices and track progress toward compliance	MQR
WHO maturity level 4 attained by June 2031	A globally recognized regulatory authority with advanced systems aligned to international standards and best practices	Strengthen regulatory benchmarking and continuous improvement systems	Coordinate implementation of corrective actions required for WHO maturity level advancement	MQR
Risk management systems strengthened by June 2031	A risk-aware regulatory authority with effective systems for identifying, assessing and mitigating institutional risks	Strengthen risk management systems	Identify and assess institutional risks in accordance with approved frameworks	MQR
Risk management systems strengthened by June 2031	A risk-aware regulatory authority with effective systems for identifying, assessing and mitigating institutional risks	Strengthen risk management systems	Monitor implementation of risk mitigation actions and report on progress	MQR
Risk management systems strengthened by June 2031	A risk-aware regulatory authority with effective systems for identifying, assessing and mitigating institutional risks	Strengthen risk management systems	Conduct business continuity and disaster recovery tests and document outcomes	MQR
Governance and compliance systems strengthened by June 2031	A compliant and accountable institution with strong adherence to policies, standards and ethical practices	Strengthen governance and compliance systems	Monitor implementation of ESG policy and report on compliance status	MQR



3.5.6.3 ICT and Statistics Unit

The Information and Communication Technology (ICT) Unit is responsible for planning, developing, managing and maintaining ICT systems and infrastructure that support TMDA's regulatory and administrative operations. The Unit ensures the availability, reliability, security and optimal performance of ICT operating systems, applications and digital platforms used across the Authority. It provides technical support, guidance and assistance to staff in the effective use of ICT equipment and systems, including help desk services for routine ICT queries and complaints.

The ICT Unit prepares medium- and long-term ICT strategies, annual ICT plans and budgets and advises Management on appropriate ICT technologies, infrastructure and e-Government solutions in line with National standards. It manages ICT service contracts to ensure continuity, efficiency and value for money. The Unit is also responsible for administering and updating anti virus systems, firewalls, Intra net, Local Area Networks (LAN), Wide Area Networks (WAN) and Virtual Private Networks (VPN) and for maintaining secure network connectivity at Headquarters and Zonal Offices.

In addition, the ICT Unit serves as the custodian of the Authority's statistics and digital data, responsible for collecting, documenting, analyzing and interpreting institutional statistics and product-related metrics to support performance monitoring, reporting and evidence-based decision-making. The Unit develops, updates and maintains the Authority's portals and digital platforms in liaison with the e-Government.

During the implementation of this Strategic Plan, the ICT Unit will be involved in implementing the strategy under Strategic Objective G, as summarized in Table 26.

Table 26: Cascaded Strategy and Target for ICT and Statistics Unit

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
ICT systems security strengthened and sustained by June 2031	Secure, resilient and reliable ICT systems that safeguard institutional data and support uninterrupted regulatory operations	Strengthen ICT security systems	Conduct regular ICT security assessments including penetration testing and vulnerability analysis	MICT
			Address identified system vulnerabilities and enforce corrective security measures	MICT
Zero successful cyber-attack sustained by June 2031	A secure ICT environment with effective protection against cyber threats and unauthorized system access	Strengthen ICT security systems	Monitor ICT systems for threats and enforce preventive and response mechanisms	MICT
ICT data integrity and reliability strengthened by June 2031	Reliable, accurate and consistent data across ICT systems supporting regulatory decision-making	Strengthen ICT data governance and quality systems	Validate ICT systems to ensure data accuracy, consistency and reliability	MICT
	Reliable, accurate and consistent data across ICT systems supporting regulatory decision-making		Maintain data quality through routine data cleaning and system-wide data management practices	MICT
AI-enabled regulatory analytics integrated into key regulatory functions, with at least 50% of core regulatory functions supported by AI-enabled analytics by June 2031	A digitally enabled regulatory authority with strong governance frameworks and technical capacity for adoption of artificial intelligence	Strengthen AI governance and support systems	Establish and maintain institutional frameworks, policies and standards for adoption and use of AI technologies	MICT
	A digitally enabled regulatory authority with strong governance frameworks and technical capacity for adoption of artificial intelligence		Provide technical support and guidance for adoption and integration of AI-enabled solutions across regulatory systems	MICT
AI-enabled regulatory analytics integrated into key regulatory functions, with at least 50% of core regulatory functions supported by AI-enabled analytics by June 2031	A digitally enabled regulatory authority with strong governance frameworks and technical capacity for adoption of artificial intelligence	Strengthen AI governance and support systems	Facilitate integration and interoperability of ICT systems to support AI-enabled data use and analytics	MICT
	An integrated digital ecosystem supporting real-time monitoring, evaluation and evidence-based decision-making		Ensure availability, accessibility and quality of data to support AI-enabled decision-making and reporting	MICT

3.5.6.4 Communication and Public Education Unit

The Communication and Public Education Unit is responsible for coordinating and managing communication, public relations, customer care and public education functions to enhance public awareness, stakeholder engagement and trust within the Authority. The Unit advises Management on communication strategies, public relations, customer services and public education matters in support of TMDA's regulatory mandate.

The Unit manages media relations, including press releases, press conferences and other media engagements and coordinates organizational events such as official functions, public notices and preparation of speeches. It also oversees Corporate Social Responsibility (CSR) initiatives and communicates to the public on events and issues related to the Authority's operations.

In addition, the Unit develops and publishes TMDA's News Bulletin, updates and manages the Authority's website and handles emergency and crisis communications to ensure timely, accurate and consistent dissemination of information. The Unit educates and sensitizes the public on TMDA's functions and responsibilities and collects, ANALYSIS and disseminates information related to regulated products to promote safe and informed use.

The Unit develops and implements public education programmes and health promotion interventions, monitors advertisements and promotional materials for regulated products and manages library services to support information access and knowledge management. It also manages customer relations, including handling complaints and compliments.

During the implementation of this Strategic Plan, the Communication and Public Education Unit will be involved in implementing the strategy under Strategic Objective B and G, as summarized in Table 27.



Table 27: Cascaded Strategy and Targets for CPE Unit

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
SOB B:				
National Anti-Corruption Strategy Implementation Enhanced and Sustained				
Whistle-blowing awareness and compliance strengthened by June 2031	A transparent and accountable institution with increased awareness and utilization of whistle-blowing mechanisms	Strengthen whistle-blowing awareness and communication systems	Conduct staff sensitization programmes on whistle-blowing policy and reporting mechanisms	MCPE
			Conduct public sensitization and outreach campaigns on whistle-blowing policy through approved communication channels	MCPE
SOG:				
Capacity to deliver regulatory services improved and sustained				
Public awareness on TMDA functions increased by June 2031	An informed public with increased awareness and understanding of TMDA regulatory functions and services	Strengthen public communication and information dissemination systems	Publish and disseminate regulatory information through TMDA website and social media platforms	MCPE
			Develop, print and disseminate IEC materials through approved communication channels	MCPE
			Conduct public education programmes through media campaigns and approved broadcasting platforms	MCPE
			Conduct outreach campaigns and exhibitions to enhance public engagement on TMDA services	MCPE
			Establish and support school clubs to promote awareness on regulated products and TMDA functions	MCPE
Customer satisfaction strengthened by June 2031	A customer-centered regulatory authority delivering responsive and quality services to internal and external stakeholders	Strengthen customer care and service delivery systems	Conduct staff sensitization programmes on customer care and service standards	MCPE
		Strengthen customer care and service delivery systems	Conduct customer satisfaction surveys and monitor feedback on service delivery performance	MCPE
		Strengthen customer care and service delivery systems	Monitor adherence to customer service charter time lines for internal and external services	MCPE

3.5.6.5 Internal Audit Unit

The Internal Audit Unit provides independent and objective assurance and advisory services to Management and the MAB on the adequacy, effectiveness and efficiency of governance, risk management and internal control systems of the Authority. The Unit is responsible for preparing and implementing risk-based strategic and annual audit plans, reviewing and reporting on the proper control, utilization and safeguarding of financial and other resources and assessing compliance with applicable laws, policies, procedures and National and international standards.

The Unit evaluates the reliability and integrity of financial and operational information, reviews systems for asset protection, conducts performance and systems audits and assesses whether operations and programs are achieving intended objectives and value for money. It also follows up on the implementation of internal and external audit recommendations and provides assurance on controls embedded in computerized systems and development projects, thereby supporting accountability, transparency and continuous improvement across the Authority.



During the implementation of this Strategic Plan, the Unit will implement the strategy under Strategic Objective G, as summarized in Table 28.

Table 28: Cascaded Strategy and Target for IAU

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
Internal audit and assurance systems strengthened by June 2031	A transparent, accountable and well-controlled institution with effective internal audit and oversight systems	Strengthen internal audit and assurance systems	Conduct planned internal audits in accordance with approved annual audit plans	CIA
	A transparent, accountable and well-controlled institution with effective internal audit and oversight systems	Strengthen internal audit and assurance systems	Prepare and submit internal audit reports through GARI-ITS within prescribed time lines	CIA
	A transparent, accountable and well-controlled institution with effective internal audit and oversight systems	Strengthen internal audit and assurance systems	Monitor implementation of external audit recommendations and track compliance status	CIA
	A transparent, accountable and well-controlled institution with effective internal audit and oversight systems	Strengthen audit governance and oversight mechanisms	Convene audit and risk committee meetings and document resolutions and recommendations	CIA

3.5.6.6 Procurement Management Unit

The Procurement Management Unit is responsible for providing professional procurement and supply management services that ensure timely, efficient, transparent and value-for-money acquisition of goods and services required for the Authority's operations. The Unit advises Management on all matters pertaining to procurement in accordance with applicable procurement laws, regulations and institutional policies.

The Unit develops, implements and reviews Annual Procurement Plans to support effective implementation of the Strategic Plan and annual business plans. It procures, maintains and manages supplies and services to support the operational and administrative functions of the Authority, while ensuring proper inventory management and optimal utilization of resources.

In addition, the Unit manages procurement contracts and evaluates supplier and service provider performances to ensure compliance with contractual obligations and quality standards. The Unit maintains and regularly updates inventories of supplies and assets to support accountability and effective resource management. It also performs secretariat duties for the Tender MAB, ensuring proper documentation, coordination and compliance with procurement governance requirements.

During the implementation of this Strategic Plan, the Procurement Management Unit will be involved in implementing the strategy under Strategic Objective G, as summarized in Table 29.

Table 29: Cascaded Strategy and Target for PMU

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
Procurement management systems strengthened and sustained by June 2031	An efficient, transparent and accountable procurement system ensuring timely acquisition of goods, services and works	Strengthen procurement planning and processing systems	Coordinate submission of requisitions in accordance with time lines specified in the Annual Procurement Plan (APP)	MPM
			Process submitted requisitions in accordance with approved procurement procedures and time lines	MPM
			Convene Tender Board meetings and implement procurement decisions within prescribed time lines	MPM
			Issue procurement awards in accordance with the approved Annual Procurement Plan	MPM
Contract management systems strengthened by June 2031	Effective contract management systems ensuring timely implementation and delivery of procured goods, services and works	Strengthen contract management and compliance systems	Monitor implementation of awarded contracts and enforce compliance with contractual obligations	MPM
			Facilitate timely payment of contracts upon satisfactory delivery and verification of goods, services or works	MPM
Asset management systems strengthened by June 2031	Efficient and accountable asset management systems supporting optimal utilization and sustainability of institutional resources	Strengthen asset management and life cycle systems	Conduct useful life assessments for TMDA assets in accordance with approved asset management procedures	MPM
			Monitor asset depreciation and maintain updated asset valuation records	MPM
			Coordinate disposal of obsolete assets in accordance with approved disposal procedures and regulations	MPM

3.5.6.7 Finance and Accounts Unit

The Finance and Accounts Unit is responsible for the effective management, controlling and reporting of the Authority's financial resources in accordance with applicable financial laws, regulations and accounting standards. The Unit prepares accurate financial statements and management reports, including bank reconciliations and overseas day-to-day financial operations such as revenue collection, payments, receivables and payroll administration.

The Unit ensures proper custody and management of cash and cash equivalents, tracks the Authority's financial performance to support informed decision-making and advises Management on financial matters, compliance requirements and areas for efficiency improvement. It also coordinates and supports both internal and external audit processes and responds to audit queries, thereby promoting financial accountability, transparency and prudent use of public resources.

During the implementation of this Strategic Plan, the Finance and Accounts Unit will be involved in implementing the strategy under Strategic Objective G, as summarized in Table 30.

Table 30: Cascaded Strategy and Targets for Finance and Accounts Unit

Target	Desired Impact	Key Strategies	Key Actions	Responsible Person
Financial management and revenue systems strengthened by June 2031	A financially sustainable and accountable institution with efficient revenue collection, budget execution and financial control systems	Strengthen revenue collection and financial sustainability systems	Monitor collection of projected revenues from internal sources in accordance with approved financial plans	CA
	A financially sustainable and accountable institution with efficient revenue collection, budget execution and financial control systems	Strengthen revenue collection and financial sustainability systems	Monitor contribution of internally generated revenue to total institutional revenue	CA
	A financially sustainable and accountable institution with efficient revenue collection, budget execution and financial control systems	Strengthen budget execution and expenditure management systems	Monitor budget absorption and expenditure performance against approved budgets	CA
	A financially sustainable and accountable institution with efficient revenue collection, budget execution and financial control systems	Strengthen financial accountability and control systems	Conduct timely bank reconciliations and maintain updated financial records	CA
	A financially sustainable and accountable institution with efficient revenue collection, budget execution and financial control systems	Strengthen financial accountability and control systems	Monitor retirement of imprests within approved time lines and enforce compliance measures	CA
Government contribution compliance strengthened by June 2031	A compliant and accountable institution fulfilling statutory financial obligations to the Government Consolidated Fund	Strengthen statutory financial compliance systems	Monitor and facilitate timely remittance of contributions to the Government Consolidated Fund in accordance with statutory requirements	CA

CHAPTER FOUR

RESOURCES FOR THE PLAN



CHAPTER FOUR:

RESOURCES FOR THE PLAN

This chapter outlines the resources required to effectively implement the TMDA Strategic Plan for the period 2026/27–2030/31. It presents an assessment of human, financial and other critical resources needed to support the planned strategic interventions and ensure their sustainability. The chapter also highlights key resource mobilization considerations and efficiency measures aimed at strengthening TMDA's capacity to deliver regulatory services in a cost-effective and results-oriented manner throughout the Plan period.

4.1 Human Resources

Effective implementation of this Strategic Plan depends largely on the availability of adequate, competent and well-distributed human resources. TMDA therefore places strong emphasis on systematic human resource planning to ensure that staffing levels and competencies are aligned with its expanding regulatory mandate and strategic priorities.

An assessment of TMDA's staffing levels, as documented in the Human Resource Plan, indicates that while the Authority has made progress in establishing key technical and support positions, a staffing gap still exists. Against the approved establishment, TMDA has a total deficit of 288 staff, reflecting shortages across critical regulatory, technical and support functions. This gap poses a potential risk to efficient execution of core regulatory functions, particularly in areas requiring specialized competencies and sustained operational presence.

The Human Resource Plan provides a structured road map for addressing this deficit through phased recruitment, skills development and succession planning. It is anticipated that the identified staffing gaps will be progressively addressed during the Strategic Plan period, in line with approved recruitment plans, resource availability and evolving institutional priorities. This approach ensures that human resource growth remains realistic, sustainable and responsive to operational demands.

In addition to recruitment, the Strategic Plan emphasizes strengthening human capital through targeted capacity-building initiatives, deployment optimization and performance management. These measures are intended to maximize productivity of existing staff while gradually building a critical mass of skilled personnel required to deliver on TMDA's regulatory objectives.

Overall, human resource planning under this Strategic Plan is designed to enhance institutional capacity, improve service delivery and support achievement of planned results, while maintaining compliance with public service regulations and approved establishment ceilings.

The successful implementation of the Strategic Plan is contingent upon the availability of adequate, skilled and well-distributed human resources aligned with TMDA's evolving regulatory mandate. In this regard, the Authority will adopt a resource prioritization framework that distinguishes between (i) core regulatory operations and (ii) strategic modernization investments.

Core regulatory operations will focus on sustaining essential functions such as product registration, inspection and enforcement, licensing, pharmacovigilance, laboratory services and import and export control. These functions require stable staffing levels and continuous capacity development to maintain service delivery standards and regulatory reputation.

In parallel, strategic modernization investments will target critical areas to enhance regulatory effectiveness and long-term institutional performance. These include strengthening digital regulatory systems, expanding laboratory infrastructure, technical capacity and improving post-market surveillance systems. Human resource planning will therefore prioritize specialized competencies required to support these areas, including regulatory science, data management and advanced laboratory analysis.

To ensure optimal utilization of human resources, TMDA will also strengthen human resource planning, performance management systems and continuous professional development programs. This approach will enable the Authority to balance immediate operational demands with long-term strategic transformation, consistent with the principles of FYDP IV on efficiency, prioritization and results-oriented implementation.

4.2 Financial Resources

The successful implementation of the TMDA Strategic Plan (2026/27–2030/31) requires a clear, realistic and evidence-based estimation of the financial resources needed over the planning period. An assessment of the Authority's historical revenue performance shows that TMDA has maintained a strong, stable and growing internal revenue base, largely generated through regulatory fees, cost-recovery mechanisms and service-related charges.



4.2.1 Historical Financial Performance and Trend Analysis

An analysis of approved revenue targets and actual collections for the period 2020/21–2025/26 indicates a sustained upward trend in TMDA's financial resource capacity. As presented below, approved annual revenue increased from TZS 31.1 billion in 2020/21 to TZS 60.5 billion in 2025/26, representing an almost twofold increase within six years. Actual collections consistently met or exceeded approved targets from 2020/21 to 2024/25, demonstrating effective revenue administration, strengthened compliance and sound financial management.

For purposes of trend consistency and comparability, the approved annual revenue figure for 2025/26 has been used as the reference value, given that available collection data for the year reflects a mid-year position.

Figure 2: Trend Analysis of TMDA Revenue Performance (2020/21 - 2025/26)



The year-on-year revenue increases shown in Figure 2 indicate that TMDA experienced moderate and steady revenue growth between 2020/21 and 2023/24, followed by a significant structural increase in 2024/25. This increase reflects expansion of the regulatory scope, increased uptake of laboratory and regulatory services, improvements in cost-recovery mechanisms and enhanced enforcement and compliance. The relatively stable growth observed in 2025/26 indicates consolidation of these gains and provides a credible baseline for forward-looking projections.

4.2.2 Overall Revenue Performance for 2025/26

Overall revenue performance for the first six months of the 2025/26 Financial Year indicates that TMDA collected TZS 22.33 billion against a planned six-month revenue target of TZS 26.01 billion, achieving 85.8 percent. This performance level is consistent with historical collection patterns, where a substantial proportion of annual revenue is typically realized in the second half of the financial year. Accordingly, the mid-year performance provides reasonable assurance that the Authority is on track to achieve the approved annual revenue target for 2025/26 and supports the use of the annualized 2025/26 figure as the projection baseline.

4.2.3 Basis for Financial Projections

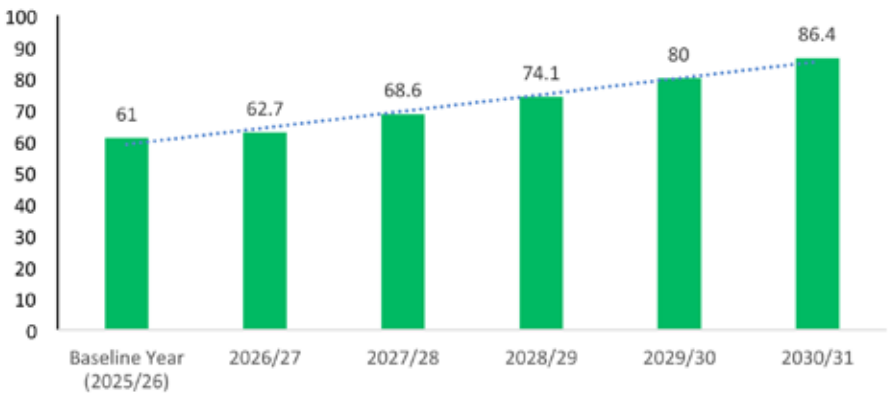
Building on the historical revenue trends presented in Figure 3 and taking into account strategic reforms envisaged under the new Strategic Plan, including further digitalization of regulatory services, expansion of regulatory scope to emerging products and technologies, strengthening of laboratory and post-marketing surveillance services, improved compliance enforcement and enhanced cost-recovery mechanisms. TMDA has adopted a conservative average annual revenue growth rate of 7.2 percent for the 2026/27–2030/31 planning period.

This growth assumption balances ambition with realism and aligns with historical performance trends and expected institutional capacity over the medium term.

4.2.4 Projected Financial Resources for the Strategic Plan Period

Applying the assumed growth rate to the 2025/26 baseline revenue of TZS 61.0 billion results in an estimated total financial resource envelope of approximately TZS 372.5 billion over the five-year Strategic Plan period. The projected annual financial resources available for implementation of the Strategic Plan are presented in Figure 3.

Figure 3: Projected Revenue for Implementation of the SP (TZS Billion)



The projected financial resources in Figure 3 establish a realistic and credible fiscal framework within which TMDA will plan, implement, monitor and evaluate its strategic interventions. The projections also provide a sound basis for annual budget preparation, resource allocation and performance monitoring during the Strategic Plan period.

NB: The 2025/26 baseline year is shown for reference and is excluded from the total projected resources for the 2026/27 to 2030/31 Strategic Plan period.

CHAPTER FIVE

RESULTS FRAMEWORK



CHAPTER FIVE:

RESULTS FRAMEWORK

This chapter presents the Results Framework and Monitoring and Evaluation (M&E) arrangements for tracking implementation of the TMDA Strategic Plan. It outlines the results chain, performance indicators, monitoring, evaluation and reporting mechanisms that will be used to measure progress, assess outcomes and support evidence-based decision-making. The chapter establishes clear linkages between planning, implementation, monitoring and reporting and defines institutional responsibilities to ensure accountability, learning and continuous performance improvement during the Plan period.

5.1 The Development Objectives

The Development Objective of this Strategic Plan is to enhance access to safe, quality and efficacious health products through strengthened regulatory efficiency, promotion of domestic pharmaceutical competitiveness and reinforcement of accountable and transparent governance systems.

Implementation of these objectives intend to contribute to the attainment of the high-level health outcomes, which include: -

- (a) To improve health care for all by ensuring access to safe, quality and efficacious health products;
- (b) To reduce importation of medical products through strengthening GMP and quality audit compliance for domestic manufacturers; and
- (c) To improve regulatory competence vide adoption of AI and emerging technologies in medical products.

5.2 Beneficiaries of TMDA Services

The Tanzania Medicines and Medical Devices Authority (TMDA) serve a wide range of direct and indirect beneficiaries whose health, safety, livelihoods and welfare depend on the availability of safe, quality and effective regulated health products. Through its regulatory mandate, TMDA's interventions generate public value across the health system, the economy and society at large.

5.2.1 Primary Beneficiaries

(a) General Public and Patients

The primary beneficiaries of TMDA services are Tanzanian citizens and other residents who use medicines, medical devices, diagnostics, vaccines and related health products. By ensuring that regulated products meet required standards of quality, safety and effectiveness,

TMDA protects patients from preventable harm, treatment failure, adverse health outcomes and financial loss associated with substandard or falsified products.

(b) Healthcare Providers and Health Facilities

Public and private healthcare facilities, health professionals and laboratories benefit from TMDA's regulatory oversight through access to quality-assured products and reliable regulatory guidance. Effective regulation supports accurate diagnosis, safe treatment, rational use of medicines and improved clinical outcomes across all levels of healthcare delivery.

(c) Manufacturers, Importers, Exporters and Distributors of Regulated Products

Pharmaceutical manufacturers, medical device and diagnostics producers, importers, exporters, wholesalers and retailers benefit from transparent, predictable and science-based regulatory processes. TMDA facilitates fair market access, supports compliance with National and international standards and contributes to a stable and competitive regulatory environment that supports investment, innovation and trade.

5.2.2 Secondary Beneficiaries

(a) Government and Public Institutions

Central and Local Government Authorities benefit from TMDA's regulatory functions through improved public health protection, reduced healthcare costs linked to ineffective or unsafe products and strengthened implementation of National health and industrial policies. TMDA also supports government accountability through regulatory data, surveillance information and evidence-based advice.

(b) Health Programs and Development Partners

National health programs, research institutions and development partners benefit from TMDA's regulatory systems, laboratory services and post-marketing surveillance data, which support program implementation, monitoring of health interventions and informed policy and investment decisions.

(c) Regional and International Regulatory Community

Through regulatory harmonization initiatives and collaboration with regional and international partners, TMDA contributes to improved regulatory coherence, shared learning and mutual confidence in regulatory decisions, indirectly benefiting populations beyond National borders.

5.2.3 Long-Term Societal Beneficiaries

By safeguarding public health, TMDA contributes to a productive workforce, reduces disease burden and improves quality of life. Effective regulation also supports local pharmaceutical and medical device manufacturing, trade facilitation and industrial development, thereby contributing to socio-economic growth and the realization of National development aspirations.

5.3 Linkage with FYDP IV

The TMDA Strategic Plan is aligned with the National development framework articulated in DIRA 2050 and the Fourth Five-Year Development Plan (FYDP IV). These frameworks provide the overarching strategic direction for Tanzania's socio-economic transformation through institutional reforms, industrial development, strengthened human capital and improved service delivery systems.

FYDP IV, themed *“Reforms for Inclusive Economic Growth and Employment Creation,”* prioritizes to strengthen institutional capacity, enhancing service delivery, accelerating digital transformation, promoting private sector participation and supporting value chain development across key sectors. Within the health sector, particular emphasis is placed on “Improved Health Care for All” (Strategic Area 3.4.6), which focuses on strengthening health systems, expanding access to safe and effective medicines and medical technologies, advancing digital health systems and promoting domestic production of health commodities. These priorities collectively aim to accelerate progress toward universal health coverage, improve population health outcomes and enhance the resilience of the National health system.

In this context, TMDA plays a central and distinct role in advancing these National priorities. As the National regulatory authority responsible for medicines, medical devices, diagnostics and other regulated health products, TMDA directly contributes to Strategic Area 3.4.6 (Improved Health Care for All) through its core mandate of ensuring that all regulated products meet established standards of safety, quality and efficacy. Through regulatory functions such as product registration, inspections, pharmacovigilance and post-market surveillance, the Authority safeguards public health, improves treatment outcomes and strengthens confidence in the National health system. This direct contribution, reflecting TMDA's core relevance to the health sector, is presented in Table 31.

Table 31: Alignment of the TMDA SP with FYDP IV

DIRA 2050 Aspiration	FYDP IV Strategic Direction	TMDA Strategic Objective	Contribution Pathway (Results Chain)	High Level Outcome
High-quality livelihood and well-being	Health for All – Building Human Capabilities and Social Development (3.4; Target: 3.4.6 Health Systems Strengthening)	A: HIV/AIDS, STIs, Hepatitis B and NCDs reduced and services improved	■ Regulatory support to prevention and treatment interventions ■ Improved access to quality-assured medicines ■ Reduced disease burden ■ Improved population health outcomes	Infant mortality (33-27); Under-five mortality (43-34); Life expectancy (68.3-70.4)
		D: Quality, safety and effectiveness of medicinal products and tobacco standards assured	■ Strengthened medicines regulation and surveillance ■ Increased availability of safe and effective medicines ■ Improved treatment outcomes ■ Reduced morbidity and mortality	Reduced disease burden; improved treatment outcomes
		E: Quality, safety and performance of medical devices and diagnostics assured	■ Strengthened regulation of diagnostics ■ Improved diagnostic accuracy ■ Better clinical decisions ■ Improved maternal and general health outcomes	Maternal mortality (104-85); Skilled birth attendance (84%-89.3%)
		F: Laboratory services improved and maintained	■ Strengthened laboratory systems ■ Improved testing accuracy and turnaround ■ Evidence-based healthcare ■ Improved service quality	Improved quality of healthcare services; increased access to diagnostics
Streamlined health care regulation for effective private sector participation	Health System Governance – Strengthening Regulatory Systems (3.4; Targets: 7.1 & 7.3 under 3.4.6)	G: Regulatory services improved and sustained	■ Streamlined regulatory processes ■ Improved efficiency and compliance ■ Increased access to services ■ Strengthened health system performance	Increased access to healthcare services; improved service delivery efficiency

Beyond its primary health sector mandate, TMDA also plays an important enabling role across multiple sectors of the economy, contributing to broader FYDP IV priorities. These include supporting industrialization and local pharmaceutical production (3.4.6 & 9.1–9.2) through regulatory facilitation and Good Manufacturing Practice (GMP) oversight; advancing digital transformation (3.7/8.1) through implementation of electronic regulatory systems; strengthening governance and accountability (3.6) through compliance and anti-corruption measures; and promoting environmental sustainability (3.5) through integration of environmental safeguards in regulatory processes. These cross-sectoral contributions demonstrate the coherence of the TMDA Strategic Plan within the wider National development agenda and are summarized in Table 32.

Table 32: Alignment of the TMDA SP with FYDP IV demonstrating its contribution towards cross cutting issues

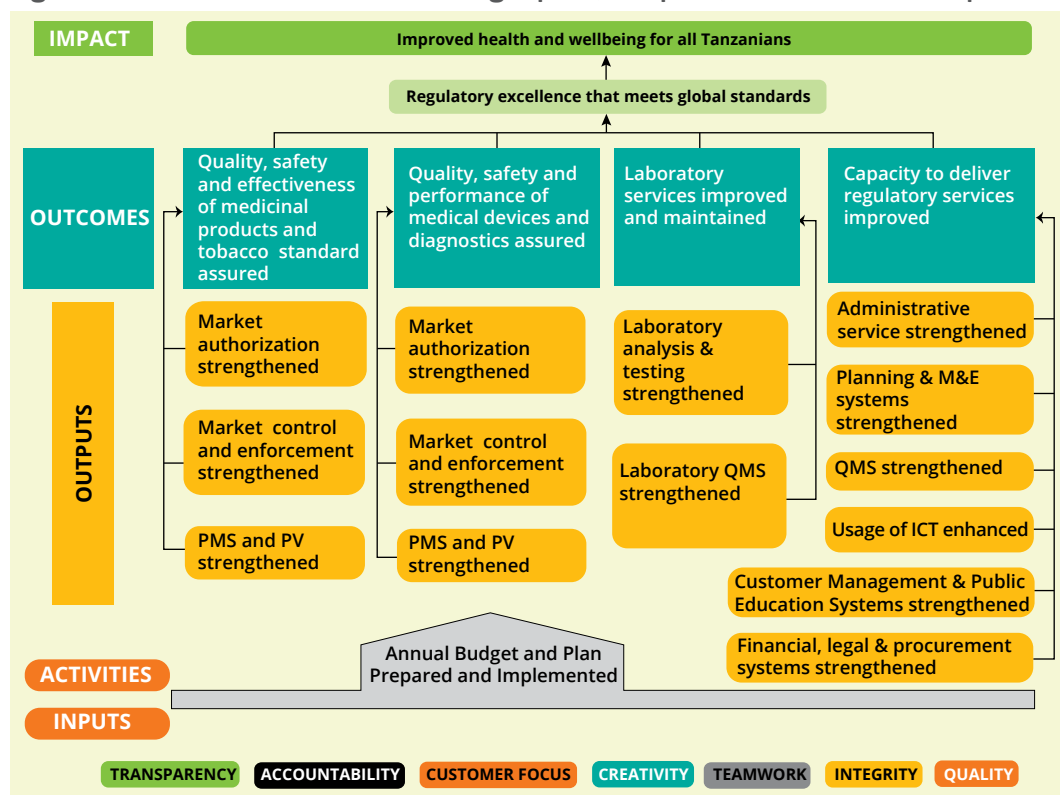
DIRA 2050 Aspiration	FYDP IV Strategic Direction	TMDA Strategic Objective	Contribution Pathway (Results Chain)	High Level Outcome
Competitive and industrialized economy	Industrialization for Health Commodities – Local Production and Supply Chain Strengthening (3.4.6 & 9.1–9.2)	D: Quality, safety and effectiveness of medicinal products and tobacco standards assured	- Regulatory facilitation, GMP compliance and streamlined approvals - Increased domestic pharmaceutical production - Improved supply chain resilience - Reduced import dependency	Reduced import dependency of health commodities; improved access to essential medicines
	Industrialization and Investment Promotion – Value Chain Expansion (3.3; incl. 3.3.13)	D: Quality, safety and effectiveness of medicinal products and tobacco standards assured	- Strengthened regulatory systems - Increased investment in pharmaceutical manufacturing - Expanded value chain - Improved access to medicines	Increased access to essential medicines; improved industrial output
Innovation-driven economy	Innovation and Health Technology Development (3.3 Innovation)	E: Quality, safety and performance of medical devices and diagnostics assured	- Strengthened regulatory frameworks for medical technologies - Increased adoption of safe innovations - Improved healthcare delivery	Improved health outcomes linked to diagnostics and devices
Inclusive economic growth	Formalisation and Business Environment Improvement (3.3.14)	G: Regulatory services improved and sustained	- Digital regulatory services - Increased formalisation and compliance - Improved efficiency of business processes	Increased formalisation; improved service delivery efficiency

DIRA 2050 Aspiration	FYDP IV Strategic Direction	TMDA Strategic Objective	Contribution Pathway (Results Chain)	High Level Outcome
Strong institutions and governance	Governance and Institutional Strengthening (3.6)	B: National Anti-Corruption Strategy Implementation Enhanced and Sustained	- Strengthened accountability and compliance systems - Reduced corruption - Improved institutional trust	Improved governance and accountability indicators
Environmental sustainability	Environmental Integrity and Climate Resilience (3.5; Target: 3.5.1 Environmental Integrity)	C: Gender mainstreamed and environmental ecosystem improved	- Integration of environmental protection measures - Sustainable regulatory practices - Reduced environmental risks	Increased compliance with environmental standards; improved environmental outcomes

5.4 Results Chain

The Results Chain for the TMDA Strategic Plan is illustrated in Figure 4 and presents the logical pathway through which TMDA's resources and interventions lead to measurable development results. The diagram shows how inputs are transformed into activities, outputs, intermediate outcomes and ultimately contribute to the Development Objective and National development impact.

Figure 4: TMDA Results Chain Linking Inputs, Outputs, Outcomes and Impact



At the base of the Results Chain (Figure 4), inputs and activities are consolidated under the preparation and implementation of the Annual Budget and Plan. This reflects the principle that all TMDA interventions are planned, financed and executed through the annual planning and budgeting cycle. Financial resources, human resources, infrastructure, systems and partnerships are mobilized and translated into regulatory, laboratory and corporate support activities through this mechanism, forming the operational foundation for the entire results chain.

Moving upward in the diagram, these activities generate a set of outputs, shown in the yellow boxes under each outcome area. As depicted in Figure 4, these outputs include strengthened market authorization systems, enhanced market control and enforcement, improved post-marketing surveillance and pharmacovigilance, strengthened laboratory analysis and quality management systems and improved corporate and support functions such as administration, ICT, planning and M&E, QMS, legal, finance, procurement, customer management and public education. These outputs represent immediate and directly attributable results of TMDA's interventions.

The outputs feed into four distinct but interrelated outcome areas, represented by the black boxes in Figure 4. These outcomes focus on assuring the quality, safety and effectiveness of medicinal and tobacco products; assuring the quality, safety and performance of medical devices and diagnostics; improving and sustaining laboratory services; and strengthening TMDA's capacity to deliver regulatory services. At this level, the diagram shows how strengthened systems and processes translate into improved regulatory performance rather than isolated activities.

As shown at the next level of the diagram, the combined achievement of these outcomes leads to an overarching regulatory result: regulatory excellence that meets global standards. This intermediate outcome reflects TMDA's alignment with international regulatory benchmarks, enhanced institutional credibility and ability to make science-based and risk-informed regulatory decisions. The upward arrows in emphasize that this level is achieved through the cumulative effect of all outcome areas rather than any single intervention.

At the top of the Results Chain, the ultimate impact is defined as improved health and wellbeing for all Tanzanians. This impact situates TMDA's regulatory mandate within the broader National health and development context. The diagram intentionally shows this impact as a shared result, acknowledging that while TMDA makes a critical contribution, impact-level change is achieved through the collective efforts of multiple actors within the health system.

Finally, as highlighted at the base of the diagram, TMDA's core values of transparency, accountability, customer focus, creativity, teamwork, integrity and quality cut across all levels of the Results Chain. These values guide how activities are implemented and how results are achieved, ensuring that progress along the results chain is ethical, professional and sustainable.

5.5 Results Framework Matrix

The Results Framework operationalizes the TMDA Results Chain by translating the Strategic Objectives, outcomes and outputs into measurable results with clearly defined indicators, targets, responsibilities and time lines. It provides a structured basis for planning, performance monitoring, evaluation and reporting throughout the implementation period of the Strategic Plan.

As illustrated in the Results Chain, TMDA's interventions follow logical progression from inputs and activities to outputs, intermediate outcomes and the Development Objective. The Results Framework Matrix Table 33: TMDA Results Framework Matrix Linking Strategic Objectives, Outcomes, Outputs and Performance Indicators) captures this logic systematically and measures it by aligning each level of results with appropriate performance indicators.

Detailed definitions, formulas, data sources and responsibilities for each indicator are provided in Annex II (Indicator Reference Sheets).

Table 33: TMDA Strategic Plan Results Framework

Desired Impact	Strategic Objective	Target at Outcome Level	Performance Outcome	Strategic Actions	Responsibility
KRA1: Institutional Health, Governance and Integrity					
A healthy, ethical and accountable institution capable of sustaining regulatory performance	SO A: HIV, Hepatitis B and Non-Communicable Diseases reduced and services improved	Prevalence of non-communicable diseases reduced by 30% by June 2031	Prevalence rate of non-communicable diseases	Workplace wellness programmes, screening and prevention interventions	DBS
		At least 90% of staff demonstrate adequate knowledge and practices on HIV and related conditions by June 2031	Proportion of staff with adequate knowledge and practices	Workplace awareness and sensitization programmes	
	SO B: Anti-corruption strategy implementation enhanced and sustained	Corruption perception improved by 30% by June 2031	Corruption perception index	Strengthen internal audit and compliance systems	CIA
		At least 95% of audit recommendations implemented within agreed time lines by June 2031	Level of implementation of audit recommendations	Strengthen audit follow-up and enforcement mechanisms	
	SO C: Gender mainstreaming and environmental sustainability improved	At least 50% of managerial positions held by women by June 2031	Proportion of women in leadership positions	Gender mainstreaming policies and leadership programmes	DBS
		Environmental compliance reaches at least 95% by June 2031	Compliance with environmental standards	Environmental monitoring and enforcement systems	Directors / MHRA / MQR

Desired Impact	Strategic Objective	Target at Outcome Level	Performance Outcome	Strategic Actions	Responsibility
KRA 2: Medicines and Tobacco Regulation					
Improved availability of safe, effective and quality-assured medicinal product and strengthened regulatory and control of tobacco products	SO D: Quality, safety and effectiveness of medicinal products and tobacco standard assured	Substandard and falsified medicinal products reduced to at most 50% of the baseline level by June 2031	Proportion of substandard products in the market	Strengthen post-market surveillance and enforcement	DMC
		Compliance of pharmaceuticals manufacturing facilities with good manufacturing practices (GMP) reaches at least 90% by June 2031	Level of of pharmaceuticals manufacturing facilities with GMP requirements	Strengthen inspection systems and regulatory enforcement	
		Average time taken to complete registration of medicinal products reduced by 30–40% by June 2031	Registration time lines for medicinal and tobacco products	Streamline product evaluation processes, strengthen dossier review systems, enhance regulatory work-flows	
		Atleast 95% of evaluated applications for tobacco products listed by June 2031	Percentage of evaluated application for tobacco products listed	Strengthened evaluation and listing of tobacco products	DMC
KRA 3: Medical Devices and Diagnostics Regulation					
Improved safety and performance of medical devices and diagnostics	SO E: Quality safety and performance of medical device and diagnostics assured	Substandard medical devices reduced to at most 60% of the baseline level by June 2031	Proportion of substandard devices	Strengthen device surveillance systems	DMD
		Compliance among manufacturers and distributors reaches at least 90% by June 2031	Compliance rate among manufacturers and distributors	Strengthen inspection and certification systems	
		Average time for registration of medical devices and diagnostics reduced by 30–40% by June 2031	Registration time lines for medical devices and diagnostics	Strengthen device evaluation systems, improve regulatory processes, enhance work flow efficiency	

Desired Impact	Strategic Objective	Target at Outcome Level	Performance Outcome	Strategic Actions	Responsibility
KRA 4: Laboratory Systems Strengthening					
Reliable, timely and internationally accredited laboratory services supporting regulatory decisions	SO F: Laboratory services improved and maintained	All laboratory results are released within the standard turnaround time by June 2031	Timeliness of laboratory results	Strengthen laboratory information management systems and work-flows	DLS
		At least 4 laboratories are accredited to international standards by June 2031	Number of accredited laboratories	Expand accreditation and quality assurance programmes	
KRA 5: Regulatory Capacity and Institutional Modernization					
An efficient, transparent and globally recognized regulatory authority delivering high-quality services	SO G: Capacity to deliver regulatory services improved and sustained	At least 80% of regulatory services are delivered through digital platforms by June 2031	Level of digital service delivery	Digital transformation initiatives and system integration	MICT
		At least 80% of strategic indicators are tracked through digital dashboards and advanced analytics by June 2031	Level of digital performance tracking	Strengthen data systems and analytics capacity	DBS
		Customer satisfaction reaches at least 90% by June 2031	Customer satisfaction index	Strengthen service delivery and customer feedback systems	MCPE
		World Health Organization maturity level 4 or listed authority status attained by June 2031	Regulatory maturity level attained	Strengthen regulatory systems and international benchmarking	MQR
Financial sustainability strengthened through efficient revenue mobilization	SO G: Capacity to deliver regulatory services improved and sustained	Internal revenue from existing sources increased by 30% by June 2031	Total internal revenue collected annually compared to baseline	Optimize collection from existing revenue sources by streamlining registration procedures; strengthen billing systems; enhance compliance enforcement; automate revenue collection processes; reduce revenue leakages	DBS / CA

Desired Impact	Strategic Objective	Target at Outcome Level	Performance Outcome	Strategic Actions	Responsibility
Financial sustainability strengthened through efficient revenue mobilization	SO G: Capacity to deliver regulatory services improved and sustained	Annual Maintenance cost as a proportion of total asset value reduced by 20–30% by June 2031	Ratio of annual maintenance cost to total asset value	Implement preventive maintenance systems; strengthen asset life cycle management; improve maintenance planning	MPM
		100% of payments to contractors and service providers made within contractual time lines by June 2031	Proportion of contractor and service provider payments made within agreed time lines	Strengthen contract management systems; improve invoice processing efficiency; enhance cash flow planning; enforce compliance with payment terms	MPM
Full compliance with statutory financial obligations and reduced fiscal risk		Outstanding tax liabilities to Tanzania Revenue Authority reduced by 100% from baseline by June 2031	Value of outstanding tax liabilities	Strengthen reconciliation of tax accounts; implement arrears clearance plans; enhance coordination with tax authority	CA
At least 100% of current tax obligations settled within statutory time lines by June 2031		Proportion of tax payments made within statutory deadlines	Strengthen tax compliance systems; enforce timely remittance procedures; integrate tax obligations into cash flow planning	CA	
Revenue collection from incineration services increased by 30% by June 2031		Annual revenue collected from incineration services	Promote incineration services through targeted awareness campaigns, stakeholder engagement and client sensitization; strengthen customer outreach and communication to increase uptake of services and voluntary compliance	DMC / DBS / CA / MCPE	

At the Development Objective level, the Results Framework focuses on high-level outcome indicators that measure TMDA's contribution to safeguarding public health and supporting socio-economic development through effective regulation of health products. These indicators reflect changes that occur as a result of the combined achievement of all Strategic Objectives and are monitored periodically to assess overall strategic performance.

At the Strategic Objective (Outcome) level, the Results Framework Matrix links each Strategic Objective (A–G) to a specific outcome statement and corresponding outcome indicators. These indicators measure medium-term changes such as improved regulatory effectiveness, enhanced integrity and governance, improved safety and quality of regulated products, strengthened laboratory-based decision-making and improved service delivery performance.

At the Output level, the Results Framework Matrix specifies tangible deliverables generated through the implementation of activities under each Strategic Objective. Output indicators measure the volume, coverage, timeliness and quality of regulatory services delivered, including evaluated applications, conducted inspections, implemented surveillance activities, laboratory analysis performed and strengthened governance and support systems.

The Results Framework Matrix further assigns baselines, annual and end-of-plan targets and responsible units for each indicator. This strengthens accountability and facilitates evidence-based management by clearly defining performance expectations and responsibilities.

Overall, the Results Framework serves as the critical link between strategy and implementation. While the Results Chain explains how change is expected to occur, the Results Framework Matrix defines what will be measured to confirm that the expected results are being achieved. Together, these tools provide a coherent system for tracking progress, learning, accountability and results reporting in line with National planning and monitoring requirements.

This integrated framework ensures that the implementation of the Strategic Plan consistently delivers on improved access to safe health products, enhanced regulatory efficiency, strengthened domestic industrial competitiveness and accountable governance, while maintaining alignment between planning, monitoring, evaluation and reporting functions.

5.6 Monitoring Plan

The implementation of TMDA's Strategic Plan (2025/26–2030/31) will be systematically monitored to ensure that it remains on course to achieve its strategic objectives and overall impact. Monitoring will involve continuous and structured collection, analysis and use of data to assess the performance of planned activities and progress toward set targets. This will enable the Authority to identify implementation gaps, inform strategic decision-making, enhance accountability and support learning and adaptive management. The monitoring process will answer key performance questions, such as:

- (a) Are the activities being implemented on time and within budget?
- (b) Are the outputs being achieved as planned and contributing to outcomes?
- (c) Are the resources (financial, human and technical) available and used effectively?
- (d) How do stakeholders, including beneficiaries, perceive TMDA's services?
- (e) What challenges or emerging issues require adaptive responses from management?

The list of indicators to be tracked is detailed in Annex III.

5.7 Plan Reviews

Effective implementation of the Strategic Plan requires systematic, structured and well-coordinated review mechanisms that enable TMDA to continuously track progress, identify implementation bottlenecks and make timely corrective decisions. Review meetings provide a formal platform for assessing performance against approved milestones, activities, outputs, targets and time lines, while also promoting accountability, strengthening coordination among Directorates, Units and Committees and ensuring that management decisions are evidence-based.

During the planning period, the Authority will conduct various categories of review meetings, rang from monthly to annual frequency, depending on the mandate, purpose and decision-making needs of each organ. Each review meeting will have a designated chairperson and clearly defined participants to ensure effective participation, follow-up and implementation of agreed actions. Table 34 summarizes the planned review meetings and their respective frequencies.

In addition to routine performance reviews, the Authority will track progress against critical strategic milestones, particularly for high-impact institutional outcomes. These include milestones for the attainment of WHO Maturity Level 4 (ML4) and WHO Listed Authority (WLA) status for medicinal products, which are time-bound and sequenced to guide implementation and oversight. Table 35 presents the key milestones and target time lines that will be systematically reviewed through the established governance and management review structures to ensure timely delivery of these strategic commitments.

Table 34: Planned Review Meetings

No.	Type of Meeting	Frequency	Designation of Chairperson	Participants
1.	Departmental/Unit and Zone Meeting	Monthly	Director/Head of Unit	Departmental/Unit staff
2.	Section Meetings	Every two weeks	Manager	Section staff
3.	Management Meeting	Monthly	Director General	Directors, Heads of Units
4.	Directors and Managers Meeting	Quarterly	Director General	Directors, Heads of Units and Managers
5.	Workers Council	Semi-Annually	Director General	Workers Council Members
6.	MAB Meeting	Quarterly	MAB Chairperson	MAB Members and Director General
7.	Budget Committee Meetings	Monthly	Director General	Budget Committee members
8.	Tender Board	On demand	Chairperson of the Tender Board	Tender Board Members

Table 35: Milestones for Attainment of WHO Maturity Level 4 and WHO Listed Authority (WLA)

Milestone	Target Time line
WHO Maturity Level 4 Attained (Medicinal Products)	
ML4-specific gap analysis completed and approved	April, 2027
Advanced regulatory functions (risk-based inspections, benefit–risk assessment, regulatory reliance) institutionalized	June, 2027
All ML4 WHO GBT indicators implemented and fully documented	June, 2029
WHO ML4 pre-benchmarking assessment conducted with satisfactory results	December, 2029
WHO benchmarking completed and ML4 status formally granted	June, 2030
WHO Listed Authority (WLA) Attained (Medicinal Products)	
WLA eligibility assessment and application prepared and approved	June, 2028
Regulatory reliance and recognition mechanisms operational and consistently applied	June, 2029
Evidence package demonstrating sustained ML4 performance submitted to WHO	June, 2030
WHO WLA evaluation mission completed with no critical gaps	June, 2030
WHO Listed Authority designation formally granted	June 2031
TMDA Central Zone Office Constructed (Morogoro)	
ESIA report conducted	December. 2026
Topographical survey completed	April, 2027
Technical design and design approved	June, 2027
Construction contract awarded and site works commenced	December, 2028
Structural works completed and building services installed	June, 2029
Office completed, furnished and operational	June 2031

5.8 Evaluation Plan

Evaluation is a core pillar of TMDA's Results-Based Management (RBM) approach and plays a critical role in strengthening accountability, institutional learning and evidence-based decision-making throughout the implementation of the Strategic Plan (2026/27–2030/31). Through systematic evaluation, TMDA will assess the performance, outcomes and longer-term effects of its regulatory interventions across medicines, medical devices, diagnostics, tobacco products, laboratory services, governance and institutional capacity.

In alignment with Government best practices and in accordance with the National Monitoring and Evaluation (M&E) Guidelines, TMDA will prepare and operationalize an M&E Strategy to guide the long-term institutionalization of results-based management. The M&E Strategy will strengthen organizational data systems, enhance performance measurement and reporting, promote learning and adaptive management and ensure full coherence with National M&E systems, standards and reporting requirements. The Strategy will serve as the overarching framework for monitoring, reporting, evaluation, learning and accountability processes across the Authority.

All evaluation activities will be guided by the Evaluation Framework and Evaluation Matrix presented in Annex IV, with a specific focus on outcome-level indicators aligned to the Strategic Objectives of the Strategic Plan. Evaluations will primarily assess changes in regulatory effectiveness, product quality and safety, service delivery performance, institutional integrity, laboratory efficiency, financial sustainability and stakeholder satisfaction. All formal evaluations will be inclusive, participatory and gender-responsive and will be conducted in accordance with the National Evaluation Manual and internationally recognized best practices, including the OECD-DAC evaluation criteria.

Evaluation findings will be systematically documented and disseminated through comprehensive evaluation reports, policy briefs, management review sessions and stakeholder engagement forums. The results will inform strategic and operational decision-making, support corrective actions where necessary and provide evidence to guide the preparation of subsequent strategic plans and regulatory reforms.

5.8.1 Rapid Appraisals

Rapid appraisals are targeted, time-bound assessments designed to generate timely and actionable evidence on TMDA's regulatory performance, service delivery efficiency and emerging operational risks. Unlike comprehensive evaluation studies, rapid appraisals focus on immediate performance issues and provide real-time insights to support adaptive management and prompt decision-making.

During the implementation of the Strategic Plan, TMDA will conduct two main types of rapid appraisals:

(a) Service Delivery and Satisfaction Surveys

These surveys will assess external customer satisfaction with TMDA's regulatory services as well as internal staff satisfaction with institutional systems and work processes. The surveys will focus on accessibility, quality, timeliness, transparency and responsiveness of services, using rapid data collection tools and short-cycle feedback mechanisms to identify emerging challenges requiring immediate management attention.

(b) Annual Performance Reviews

These are light-touch annual assessments conducted to track TMDA's progress toward achieving planned outputs and outcomes. The reviews will focus on key result areas, performance trends and early warning signals, using simplified methodologies and routinely generated monitoring data to provide timely performance updates to Management and the MAB.

5.8.2 Evaluation Studies

TMDA will undertake a set of formal evaluation studies to assess the implementation progress, effectiveness and longer-term outcomes of the Strategic Plan. These evaluation studies will include:

- (a) Baseline Assessment**, conducted at the beginning of the Plan period to establish benchmark data for key outcome indicators and institutional capacities prior to full implementation;
- (b) Mid-Term Evaluation (MTE)**, conducted at the midpoint of the Plan period to assess progress toward outcome achievement, identify implementation bottlenecks and recommend corrective actions;
- (c) End-Term Evaluation (ETE)**, conducted at the end of the Plan period to assess the overall achievements, contribution, impact and sustainability of the Strategic Plan; and
- (d) Special or Diagnostic Evaluations**, undertaken on an as-needed basis to address emerging regulatory, operational, or thematic issues that require in-depth analysis beyond routine monitoring and planned evaluations.

These evaluation studies, including their purpose, scope, methodologies and time lines, are summarized in Table 36.

Table 36: Summary of Evaluation Studies, Purpose and Time line

Sn	Evaluation	Description	Evaluation Questions	Methodology	Time frame
1	Baseline Assessment	Establishes baseline values for key outcome indicators prior to implementation of the Strategic Plan. The assessment provides a reference point for measuring progress and performance over the Plan period.	What is the baseline status of key outcome indicators under each Strategic Objective? What institutional capacities, systems and data gaps exist at the start of the Plan? What benchmarks will guide mid-term and end-term target setting?	Document review, administrative data analysis, baseline surveys, stakeholder consultations.	(Before Beginning of SP Implementation)
2	Mid-Term Evaluation (MTE)	Assesses progress toward achievement of outcomes at the midpoint of the Strategic Plan, identifies implementation bottlenecks and recommends corrective actions to improve performance during the remaining Plan period.	To what extent have planned outcomes been achieved by mid-term? What factors are enabling or constraining achievement of outcomes? Are regulatory interventions producing the intended results? What corrective measures are required to accelerate performance?	Mixed methods: outcome indicator trend analysis, key informant interviews, focus group discussions, performance reviews, selected field verifications.	Mid-Plan Period (Year 3)
3	End-Term Evaluation (ETE)	Determines the overall achievement of Strategic Plan outcomes, their contribution to TMDA's mandate and the sustainability of achieved results at the end of the Plan period.	To what extent were the Strategic Plan outcomes achieved? What contribution did TMDA interventions make toward public health protection and regulatory effectiveness? How sustainable are the outcomes achieved? What lessons should inform the next Strategic Plan?	Mixed methods: contribution analysis, outcome harvesting, trend analysis, stakeholder surveys, validation workshops.	End of Plan Period (Year 5)

Sn	Evaluation	Description	Evaluation Questions	Methodology	Time frame
4	Special / Diagnostic Evaluations	Conducted on an as-needed basis to address emerging issues, thematic priorities, or high-risk areas requiring in-depth analysis beyond routine monitoring and planned evaluations.	What specific regulatory, operational or thematic issue requires in-depth analysis? What corrective or improvement measures are most appropriate? How can emerging risks be mitigated effectively?	Rapid assessments, case studies, technical reviews, targeted field inspections.	As Needed
5.	Service Delivery Survey (SDS)	Conducted every two years to assess the quality, accessibility, efficiency and user satisfaction of TMDA regulatory services from the perspective of stakeholders, including industry, healthcare providers and the public.	What is the level of stakeholder satisfaction with TMDA services? How accessible and timely are regulatory services? What are the key service delivery gaps and bottlenecks? How responsive is TMDA to stakeholder needs and feedback? What improvements are required to enhance service quality and efficiency?	Structured surveys, stakeholder interviews, online feedback systems and data analysis of service delivery metrics	Every 2 years
6.	Self-Institutional Assessment (SIA)	Conducted every two years to assess institutional capacity, systems, processes and performance against regulatory standards and organizational objectives to inform continuous improvement and readiness for external benchmarking (e.g., WHO GBT).	To what extent are TMDA systems, structures and processes aligned with regulatory standards and best practices? What are the key institutional strengths and capacity gaps? How effective are internal systems in supporting regulatory performance and service delivery? What improvements are required to enhance institutional efficiency, governance and compliance? How prepared is TMDA for external assessments and international benchmarking (e.g., WHO maturity levels)?	Self-assessment tools, internal audits, document reviews, benchmarking against standards (e.g., WHO GBT) and stakeholder consultations	Every 2 years

5.9 Reporting Plan

Monitoring will be supported by both internal and external reporting mechanisms that align with government performance management frameworks and statutory obligations.

5.9.1 Internal Reporting Plan

An effective internal reporting system is essential for ensuring that TMDA remains accountable, transparent and responsive in its implementation of the Strategic Plan. The Internal Reporting Plan outlines the key reports that must be generated periodically to support evidence-based decision-making, strengthen oversight functions and enhance operational efficiency.

Under this plan, various technical, managerial and governance reports will be prepared on a weekly, quarterly, semiannual, annual or on-demand basis, depending on the required information. These reports provide updates on performance trends, emerging risks, audit observations and quality management issues that may influence the achievement of organizational objectives. The plan also guides responsible officers on when and to whom reports should be submitted, ensuring consistent and timely information flow across the Authority. Table 37 summarizes TMDA's Internal Reporting Plan for the planning period.

Table 37: Internal Reporting Plan

S/N	Type of Report	Recipient	Frequency	Responsible Person
1.	Quarterly Reports	Management, Directors, Managers Meeting and MAB	Quarterly	DG/DBS/MPME
2.	Mid-Year Reports	Management, Directors, Managers Meeting and MAB	Semi - annual	DG/DBS/MPME
3.	Annual Reports	Management, Directors, Managers Meeting and MAB	Annually	DG/DBS/MPME
4.	Internal Audit Reports	MAB	Quarterly	DG/CIA

These reports will provide data on activity implementation, budget execution and progress toward output-level results.

5.9.2 External Reporting Plan

The External Reporting Plan outlines the statutory and regulatory reports that TMDA must prepare and submit to external stakeholders in accordance with National laws, sector regulations and institutional accountability requirements. These reports ensure that TMDA remains transparent, compliant and responsive to oversight institutions, including the Ministry of Health (MoH), Parliament and the Office of the Treasury Registrar (OTR). External reporting serves several purposes:

- (a) Demonstrating TMDA's compliance with its regulatory mandate
- (b) Providing evidence of sector performance, emerging risks and operational challenges
- (c) Supporting National policy formulation, planning and resource allocation
- (d) Facilitating inter-agency coordination and accountability

The reports are prepared on a scheduled basis: quarterly, semi-annually, annually or as required by governing transport regulation. Table 38 provides a summary of TMDA's External Reporting Plan for the planning period.

Table 38: External Reporting Plan

S/N	Type of Report	Recipient	Frequency	Responsible Person
1.	Quarterly Reports	MoH/PO-PSMGG and OTR	Quarterly	DG/DBS/MPME
2.	Mid-Year Reports	MoH/PO-PSMGG and OTR	Semi-annual	DG/DBS/MPME
3.	Annual Reports	MoH/PO-PSMGG and OTR	Annually	DG/DBS/MPME
4.	NACSAP IV Implementation Report	Chief Secretary	Quarterly	DG/DBS/MHRA
5.	Parliamentary Committee	Parliamentary Committee	On demand	DG/DBS/CA
6.	Financial Statements	CAG	Annually	DG/CA
7.	Implementation of CCM Election Manifesto, 2025	Secretary General CCM	On demand	DG/Directors

All reports will adhere to the formats and schedules prescribed by National authorities and sector-specific guidelines.

5.10 Relationship between Results Framework, Results Chain, M&E and Reporting Arrangement

This Strategic Plan adopts an integrated Results-Based Management (RBM) approach that links the Results Framework, Results Chain, Monitoring and Evaluation (M&E) and Reporting Arrangements into a coherent performance management system for TMDA. This integrated approach ensures that TMDA's regulatory interventions are systematically planned, implemented, monitored and reported in a manner that promotes accountability, institutional learning and evidence-based decision-making throughout the Strategic Plan period.

The Results Framework is structured across five interrelated performance levels, namely Impact, Outcomes, Outputs, Activities and Inputs. This hierarchy provides a clear and logical structure for tracking progress from the utilization of resources to long-term public health and regulatory outcomes to which TMDA contributes through its statutory mandate.

At the Impact level, the Results Framework focuses on long-term improvements in public health protection and socio-economic wellbeing arising from access to safe, effective and quality medicines, medical devices, diagnostics and related products. These impact-level changes are aligned with National development priorities, health sector policies and international commitments. Given their long-term nature and the involvement of multiple actors within the health system, impact-level results are not attributable to TMDA alone. Performance at this level is assessed through periodic sector reviews, National health statistics, surveillance data and evaluative studies and is reported primarily through end-term evaluations and sector performance reports rather than routine monitoring.

At Outcome level (Strategic Objectives), the framework tracks the achievement of intermediate results associated with each Strategic Objective of the Plan. These outcomes reflect changes in regulatory performance, system effectiveness, service delivery, institutional capacity and stakeholder behavior that TMDA seeks to influence in collaboration with regulated entities, healthcare providers and other government institutions.

Outcome indicators are monitored on an annual basis and reported through annual performance reports and consolidated end-of-plan outcome assessments, drawing on regulatory databases, inspection and surveillance data, studies and National statistics. Reporting at this level focuses on the benefits delivered to the public, regulated stakeholders and the health system.

The Output level captures the tangible products and services delivered directly by TMDA and is fully attributable to the Authority. These include regulatory decisions, inspections conducted, laboratory tests performed, surveillance activities implemented, public education initiatives delivered and customer care services provided. Outputs are measured using clearly defined indicators and milestones, with data collection and analysis conducted quarterly. Quarterly reporting focuses on progress in delivering outputs and on assessing how these outputs contribute to achieving the intended outcomes.

At the Activity level, monitoring focuses on the implementation of planned regulatory, operational and support activities that generate outputs. Indicators at this level emphasize implementation progress, process quality, compliance with standards and timeliness. Activity performance is reviewed on a weekly, fortnightly, or monthly basis through routine implementation and management reports, enabling early identification of delays, operational risks and implementation bottlenecks.

The Input level tracks the allocation and utilization of financial, human and material resources required to implement activities. Monitoring at this level focuses on resource availability, predictability, alignment with planned activities and efficiency of use. Input-level performance is reviewed regularly through financial, procurement and administrative reports to support effective resource management, cost control and timely managerial decision-making.

The Results Chain provides the logical linkage across all five levels by clearly articulating how inputs enable activities, activities generate outputs, outputs contribute to outcomes and outcomes collectively contribute to long-term impact. This logic ensures coherence and alignment between strategic planning, implementation, monitoring, evaluation and reporting processes across TMDA.

Monitoring and Evaluation arrangements are operationalized through a comprehensive M&E Plan, which translates the Results Framework and Results Chain into practical monitoring and evaluation processes. The M&E Plan defines performance indicators at each level, establishes standardized data collection tools and procedures, specifies monitoring frequencies and clarifies roles and responsibilities across Directorates, Units and relevant stakeholders. It also provides capacity building, data quality assurance and structured stakeholder feedback mechanisms to strengthen use of evidence in decision-making.

Reporting arrangements consolidate information generated through monitoring and evaluation into structured performance reports, including routine implementation reports, quarterly and annual performance reports, mid-term reviews and end-term evaluations. These reports support management oversight, regulatory accountability, institutional learning and communication with oversight bodies and stakeholders.

Within this integrated RBM system, the Results Framework defines what TMDA seeks to achieve across all performance levels, the Results Chain explains how those results are expected to be achieved, Monitoring and Evaluation assess progress and performance and Reporting ensures systematic communication, accountability and learning. Together, these elements form a robust performance management system that supports effective delivery of TMDA's Strategic Plan and contributes to sustained protection of public health and regulatory effectiveness over the Plan period.

This integrated framework ensures that implementation and reporting remain aligned with the Plan's Development Objective of improving access to safe health products, enhancing regulatory efficiency, strengthening domestic pharmaceutical competitiveness and promoting accountable governance

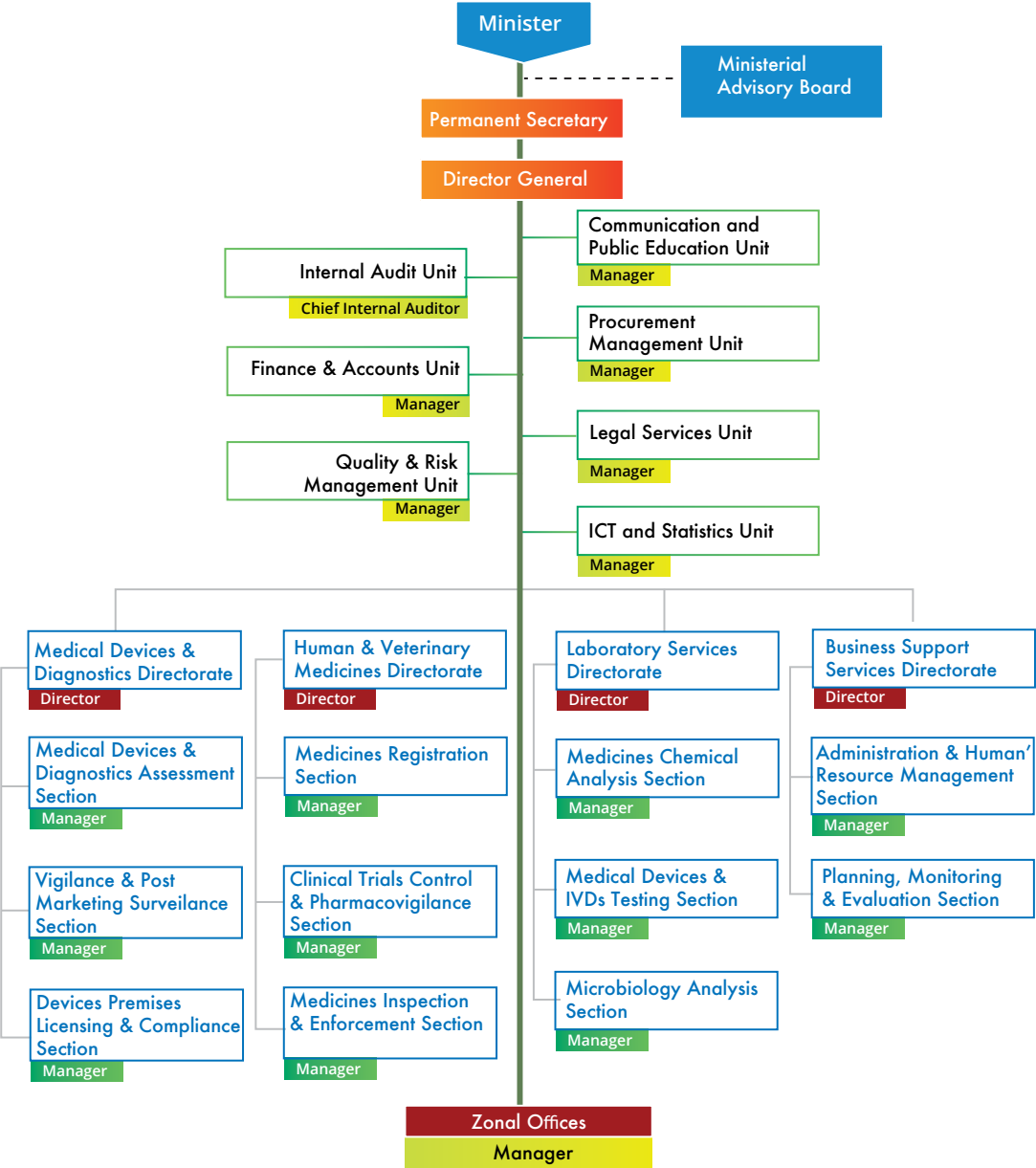


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ANNEXES

Annex I: TMDA Organizational Structure



Annex II: Indicator Reference Sheets for the Results Framework

Strategic Objective	Indicator	Definition	Formula
SO A	Prevalence rate of NCDs among TMDA staff	Proportion of staff diagnosed with NCDs	$(\text{NCD cases} \div \text{Total staff}) \times 100$
	% of staff with adequate HIV/STI knowledge and practices	Staff demonstrating correct knowledge and behavior	$(\text{Informed staff} \div \text{Total staff}) \times 100$
SO B	Corruption perception index	Stakeholder perception of integrity and transparency	Survey index (scored)
	% of audit recommendations implemented within time frame	Audit findings resolved within agreed time lines	$(\text{Implemented} \div \text{Total recommendations}) \times 100$
SO C	% of women in managerial positions	Representation of women in leadership roles	$(\text{Women managers} \div \text{Total managers}) \times 100$
	% compliance with environmental safety standards	Compliance with environmental regulations	$(\text{Compliant cases} \div \text{Total inspected}) \times 100$
SO D	% of substandard and falsified medicinal and tobacco products in the market	Proportion of sampled products failing quality standards	$(\text{Substandard} \div \text{Total sampled}) \times 100$
	% of facilities compliant with GMP/GSDP standards	Compliance of facilities with regulatory standards	$(\text{Compliant facilities} \div \text{Total inspected}) \times 100$
SO E	% of substandard medical devices and diagnostics in the market	Proportion of devices failing quality/performance standards	$(\text{Non-compliant} \div \text{Total sampled}) \times 100$
	% of compliant medical device manufacturers and distributors	Compliance level of operators	$(\text{Compliant} \div \text{Total assessed}) \times 100$
SO F	% of laboratory results released within standard turnaround time	Efficiency of laboratory result delivery	$(\text{Results on time} \div \text{Total results}) \times 100$
	Number of laboratories with ISO/IEC 17025 accreditation	Labs meeting international accreditation standards	Count
SO G	Average time for product registration (days)	Time taken from submission to approval	$\text{Total processing time} \div \text{Applications}$
	% of regulatory services delivered through digital platforms	Proportion of services delivered digitally	$(\text{Digital services} \div \text{Total services}) \times 100$
	% of strategic indicators tracked through digital dashboards and AI-enabled analytics	Indicators monitored using digital systems	$(\text{Digital indicators} \div \text{Total indicators}) \times 100$
	% customer satisfaction with regulatory services	Stakeholder satisfaction level	$(\text{Satisfied} \div \text{Total respondents}) \times 100$
	WHO GBT Maturity Level attained	Regulatory system maturity level	WHO external assessment

Annex III: Monitoring Framework (Output Indicators)

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
Strategic Objective A: HIV/AIDS, STI's, Hepatitis B and Non- Communicable Diseases (NCDs) reduced and services improved															
1.	Percentage of staff participating in wellness initiatives	2024/25	88	94	90	92	94	96	98	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MHRA
2.	Number of sports centres established and operationalized	2024/25	0	1	-	-	-	1	1	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
3.	Percentage of staff sensitized on HIV/AIDS, Hepatitis B and NCDs prevention	2024/25	75	81	77	79	81	83	85	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
4.	Percentage of staff screened for NCDs risk factors	2024/25	72	75	73	74	75	76	77	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
5.	Percentage of staff screened for HIV/AIDS	2024/25	30	45	35	40	45	50	55	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
6.	Percentage of staff screened for Hepatitis B	2024/25	37	50	40	45	50	55	60	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
7.	Percentage of staff vaccinated for Hepatitis B infection	2024/25	0	60	50	55	60	65	70	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
8.	Percentage of declared staff with HIV/AIDS and Hepatitis B provided with supportive services	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MHRA
Strategic Objective B: National Anti-Corruption Strategy Implementation Enhanced and Sustained															
9.	Percentage of staff sensitized on anti-corruption and integrity matters	2024/25	73	85	75	80	85	90	95	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
10.	Number of NACSAP IV implementation reports submitted to the Chief Secretary	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MHRA
11.	Number of Integrity committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MHRA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
12.	Number of Recruitment Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MHRA
13.	Number of Disciplinary Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MHRA
14.	Number of Loan Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MHRA
15.	Number of loan committee meetings conducted	2024/25	2	2	2	2	2	2	2	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MHRA
16.	Number of Budget committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MHRA
17.	Number of surveys conducted to measure experience or perception of corruption	2024/25	0	-	1	-	1	-	-	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MHRA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
18.	Number of corruption incidents detected	2024/25	0	0	0	0	0	0	0	Progress reports	Whistle blowers	Approved progress reports	Annually	Annually	MHRA
19.	Percentage of staff trained on artificial intelligence skills and techniques	2024/25	0	50	10	20	30	30	50	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MHRA
20.	Percentage of staff trained on ICT security features	2024/25	0	25	8	10	15	20	25	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MHRA
21.	Percentage of staff sensitized on whistle-blowing policy	2024/25	75	84	78	81	84	87	90	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCPE
22.	Number of sensitization events to the general public on whistle-blowing policy	2024/25	2	15	5	10	15	20	25	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCPE
Strategic Objective C: Gender mainstreamed and environmental ecosystem improved															
23.	Percentage of women and disabled employees within TMDA	2024/25	38	41	39	40	41	42	43	Progress reports	Document review	Approved quarterly progress reports	Annually	Annually	MHRA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
24.	Percentage of staff sensitized on gender mainstreaming	2024/25	62	75	65	70	75	80	85	Progress reports	Document review	Approved quarterly progress reports	Annually	Annually	MHRA
25.	Ratio of female to male staff on managerial positions	2024/25	1:2	1:1	1:2	1:2	1:2	1:1	1:1	Progress reports	Document review	Approved quarterly progress reports	Annually	Annually	MHRA
26.	Number of TMDA buildings complying with occupational health and safety standards	2024/25	2	3	3	3	3	3	3	Progress reports	Document review	Approved quarterly progress reports	Annually	Annually	MHRA
27.	Percentage of available unfit medicinal products disposed of through approved eco-friendly methods	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE
28.	Percentage of available unfit medical products (by weight) disposed of through approved eco-friendly methods	2024/25	0	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMDL / MCIE

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
Strategic Objective D: Quality, safety and effectiveness of medicinal products and tobacco standards assured															
29.	Percentage of available new applications for registration of medicines evaluated	2024/25	90	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMRE
30.	Percentage of available applications for renewal of registered medicines evaluated	2024/25	75	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMRE
31.	Percentage of available applications for variations (minor and major) completed	2024/25	80	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMRE
32.	Percentage of available applications for listing of tobacco products evaluated	2024/25	-	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMRE

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
33.	Percentage of available applications for advertisement of medicinal products evaluated	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMRE
34.	Percentage of received query responses for medicinal products processed	2024/25	92	95	93	94	95	96	97	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMRE
35.	Percentage of medicinal products of public assessment reports published within specified time lines	2024/25	94	97.2	95	96	97	98	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMRE
36.	Percentage of available applications for registration of pharmaceutical manufacturing facilities processed	2024/25	98	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE
37.	Percentage of falsified medicinal products detected on the market	2024/25	1	1	1	1	1	1	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
38.	Percentage of substandard medicinal products detected on the market	2024/25	2	1	1	1.5	1	1	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE
39.	Number of Human Medicines Registration Technical Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMRE
40.	Number of Veterinary Medicines Registration Technical Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMRE
41.	Percentage of unregistered medicinal products detected on the market	2024/25	28	19	25	22	19	16	13	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
42.	Percentage of available applications for import and export permits for medicines processed	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE
43.	Percentage of domestic pharmaceutical manufacturing facilities inspected for Good Manufacturing Practices (GMP)	2024/25	96	98.8	97	98	99	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE
44.	Percentage of planned overseas GMP inspections conducted	2024/25	TBE	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE
45.	Percentage of GMP inspection reports published on website	2024/25	TBE	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE
46.	Percentage of registered pharmaceutical products covered by the national Track and Trace system	2024/25	0	70	NA	35	60	65	70	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
47.	Number of GMP Technical committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE
48.	Overall percentage implementation of facilitation of promotion of domestic manufacturing action plan	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCIE
49.	Percentage of available applications for new clinical trials authorization evaluated	2024/25	TBE	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCTPV
50.	Percentage of available applications for clinical trials amendments evaluated	2024/25	TBE	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCTPV
51.	Percentage of approved and ongoing clinical trials inspected for GCP	2024/25	TBE	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCTPV

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
52.	Number of ADR reports received annually	2024/25	19702	≥ 19702	≥ 19702	≥ 19702	≥ 19702	≥ 19702	≥ 19702	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCTPV
53.	Number of AEFI reports received	2024/25	7007	≥ 7007	≥ 7007	≥ 7007	≥ 7007	≥ 7007	≥ 7007	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCTPV
54.	Percentage of field and safety reports assessed within specified time lines	2024/25	TBE	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCTPV
55.	Percentage of serious AEFI cases assessed for causality	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCTPV
56.	Percentage of SAEs assessed for causality	2024/25	TBE	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCTPV
57.	Percentage of Marketing authorization holders submitting periodic safety update reports	2024/25	TBE	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCTPV

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
58.	Number of PMS programmes completed timely	2024/25	1	1	1	1	1	1	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCTPV
59.	Number of Pharmacovigilance Technical Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MCTPV
60.	Number of Clinical Trials Technical Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MCTPV
61.	Number of PMS Technical Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Quarterly	MCTPV
62.	Percentage of processed new applications for registration of premises dealing with medicinal products processed	2024/25	80	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
63.	Percentage of registered premises dealing with medicinal products renewed	2024/25	86	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers
64.	Percentage of TMDA licensed premises inspected	2024/25	78	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers
65.	Percentage of TMDA unlicensed premises inspected	2024/25	75	60	65	70	75	80	85	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers
66.	Percentage of premises dealing in medicinal products licensed by other institutions inspected	2024/25	-	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers
67.	Percentage of received import and export applications for medicinal products processed	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
68.	Percentage of inspected consignments against import permits issued	2024/25	81	86	82	84	86	88	90	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers
Strategic Objective E: Quality, safety and performance of medical devices and diagnostics assured															
69.	Percentage of available new applications for registration of medical devices and diagnostics evaluated	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDA
70.	Percentage of available new applications for notification of medical devices and diagnostics evaluated	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDA
71.	Percentage of available applications for renewal of medical devices and diagnostics evaluated	2024/25	85	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
72.	Percentage of available applications for variations (minor and major) completed	2024/25	75	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDA
73.	Percentage of available applications for advertisement of medical devices and diagnostics evaluated	2024/25	80	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDA
74.	Percentage of received query responses for medical devices and diagnostics processed	2024/25	85	95	93	94	95	96	97	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDA
75.	Percentage of medical devices and diagnostics of public assessment reports published within specified time lines	2024/25	70	97.2	95	96	97	98	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
76.	Percentage of available applications for registration of medical devices and diagnostics manufacturing facilities processed	2024/25	98	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDL
77.	Percentage of falsified medical devices and diagnostics detected on the market	2024/25	1	1	0.5	0.5	0.5	0.5	0.5	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDL
78.	Percentage of substandard medical devices and diagnostics detected on the market	2024/25	5.1	5	4	3	2	1	0.5	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDL
79.	Percentage of unregistered medical devices and diagnostics detected on the market	2024/25	2.9	2.9	2	1	0.5	0.5	0.5	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDL

Sn	Indicator Name	Baseline		Target Value		Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31		
80.	Percentage of available applications for import and export permits for medical devices and diagnostics processed	2024/25	100	100	100	100	100	100	100	Progress reports	MMDL
81.	Percentage of domestic medical devices and diagnostics manufacturing facilities inspected for Quality Audit (QA)	2024/25	96	98	97	98	99	100	100	Progress reports	MMDL
82.	Percentage of planned overseas QA inspections conducted	2024/25	90	90	95	100	100	100	100	Progress reports	MMDL
83.	Percentage of QA inspection reports published on website	2024/25	0	0	80	85	90	95	100	Progress reports	MMDL
84.	Number of adverse events and incident reports from health facilities and consumers received	2024/25	300	300	400	500	600	700	800	Progress reports	MMDV

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
85.	Number of adverse events and incident reports from manufacturer received	2024/25	25	25	30	35	40	45	50	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDV
86.	Percentage of AE and incident reports evaluated annually	2024/25	90	90	95	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDV
87.	Percentage of serious AE and incident reports investigated annually	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDV
88.	Percentage of Field Safety Corrective Action (FSCA) reports assessed within specified time lines	2024/25	90	90	95	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDV
89.	Number of PMS programmes completed	2024/25	1	1	1	1	1	1	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDV

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
90.	Percentage of planned PMS activities successfully completed (Portable)	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDV
91.	Percentage of medical equipment in healthcare facilities that have undergone assessment under PMS (Large equipment)	2024/25	98	99.8	99	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDV
92.	Percentage of Marketing authorization holders submitting PMS reports	2024/25	80	80	85	90	95	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDV
93.	Number of Medical Devices Registration Technical Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDA
94.	Number of Device Vigilance and PMS Technical Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDV

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
95.	Number of Quality Audit Technical Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	MMDL
96.	Percentage of processed new applications for premises dealing in medical devices and diagnostics	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	Zone Managers
97.	Percentage of registered premises dealing with medical devices and diagnostics renewed	2024/25	80	80	85	90	95	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	Zone Managers
98.	Percentage of licensed premises dealing with medical devices and diagnostics inspected	2024/25	80	80	85	90	95	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	Zone Managers
99.	Percentage of unlicensed premises inspected	2024/25	70	70	75	80	85	90	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	Zone Managers

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
100.	Percentage of premises dealing in medical devices and diagnostics licensed by other institutions inspected jointly	2024/25	80	80	85	90	92	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	Zone Managers
101.	Percentage of received import and export applications for medicinal products processed	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	Zone Managers
102.	Percentage of inspected consignments against import permits issued	2024/25	81	86	82	84	86	88	90	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	Zone Managers
103.	Quantities of unfit products in health facilities	2024/25	350	200	300	250	200	150	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	Zone Managers
104.	Percentage of available unfit medical devices and diagnostics products disposed of through approved ecofriendly method	2024/25	50	50	60	65	70	80	90	Progress reports	Document review	Approved quarterly progress reports	Monthly	Progress reports	Zone Managers

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
Strategic Objective F: Laboratory services improved and strengthened															
105.	Percentage of received medicine samples analysed	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMCA/ MMBA
106.	Percentage of planned medicine samples screened at QA Centers	2024/25	TBE	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers
107.	Percentage of received medical device samples analyzed	2024/25	77	86	80	83	86	89	92	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMDT/ MMBA
108.	Percentage of received diagnostic samples tested	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMDT
109.	Percentage of laboratory equipment subjected to preventive maintenance	2024/25	TBE	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMCA
110.	Percentage of laboratory equipment calibrated	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMCA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
111.	Number of Laboratory Technical Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMCA
112.	Number of Laboratory QMS Management Review meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMCA
113.	Percentage of planned proficiency testing schemes implemented	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMCA MMDT MMBA
114.	Number of accredited TMDA laboratories	2024/25	2	1	2	2	2	3	3	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMCA MMDT MMBA
115.	Number of scientific papers published on peer review journals	2024/25	4	5	5	5	5	5	5	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMBA
116.	Percentage utilization of large laboratory equipment (i.e. LCMSMS, GCMSMS, HPLC etc)	2024/25	60	90	65	70	75	80	90	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMCA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
117.	Number of operational researches conducted within TMDA	2024/25	10	10	2	2	2	2	2	Progress reports	Document review	Approved quarterly progress reports	Quarterly	Annually	MMBA
118.	Number of laboratories for vaccines testing established	2024/25	0		-	-	1	-	-	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMCA
119.	Categories of medical devices analysed	2024/25	2	7	2	2	2	3	5	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMDT
120.	Categories of diagnostics analysed	2024/25	2	7	2	2	2	3	5	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MMDT
Strategic Objective G: Capacity to deliver regulatory services improved															
121.	Number of regional offices established and operational	2024/25	0	2	-	1	-	1	-	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	ZOLGAC
122.	Number of LGA inspectors appointed and gazetted	2024/25	915	1,065	965	1,015	1,065	1,115	1,165	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers

Sn	Indicator Name	Baseline		Target Value		Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31		
123.	Percentage of staff trained according to the annual training program	2024/25	96	98	96	97	98	99	100	Quarterly	MHRA
124.	TMDA staff loan recovery rate	2024/25	70	85	75	80	85	90	95	Quarterly	MHRA
125.	Number of TMDA buildings and plots valuated	2024/25	3	21	21	21	21	21	21	Quarterly	MHRA
126.	Percentage of planned maintenance completed on schedule	2024/25	70	86	75	80	85	90	100	Quarterly	MHRA
127.	Number of staff planned to be recruited	2024/25	488	554	510	532	554	576	600	Quarterly	MHRA
128.	Number of TMDA buildings complying with occupational health and safety standards	2024/25	2	3	3	3	3	3	3	Annually	MHRA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
129.	Overall performance of TMDA in PIPMIS	2024/25	86	90	90	87	88	89	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MHRA / MPME
130.	Percentage of new staff subjected to induction training timely	2024/25	60	91	80	85	90	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MHRA
131.	Percentage implementation of annual monitoring plan	2024/25	TBE	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPME
132.	Percentage implementation of evaluation plan	2024/25	TBE	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPME
133.	Number of progress report submitted timely to relevant authorities	2024/25	TBE	20	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPME
134.	Percentage implementation of signed MoUs	2025/26	0	80	70	75	80	85	90	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPME
135.	Percentage contribution to the Government Consolidated Fund	2024/25	70	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPME

Sn	Indicator Name	Baseline		Target Value					Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person	
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification			Frequency of Data collection
136.	Number of Budget Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPME
137.	Number of Directors and Managers meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPME
138.	Number of Workers Council meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MHRA
139.	Percentage of staff trained on use of large laboratory equipment	2024/25	5	15	6	8	10	12	15	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MHRA
140.	Percentage of planned public education programmes implemented	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers
141.	Percentage of received customer complaints resolved within approved service time line	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
142.	Percentage of complaints resolved within approved service time lines	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	Zone Managers
143.	Number of MAB meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MLS
144.	Number of new regulations developed	2024/25	1	2	2	2	2	2	2	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MLS
145.	Number of MAB performance reports submitted to the Office of the Treasury Registrar within the prescribed time lines	2024/25	1	1	1	1	1	1	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MLS
146.	Percentage of TMDA inspectors and analysts gazetted	2024/25	90	93	91	92	93	94	95	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MLS
147.	Percentage of gazetted TMDA inspectors with valid identification cards	2024/25	90	93	91	92	93	94	95	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MLS

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
148.	Number of internal ISO 9001 audits conducted	2024/25	2	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
149.	Number of ISO 9001 external audits conducted	2024/25	1	1	1	1	1	1	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
150.	Number of management review meetings conducted	2024/25	1	1	1	1	1	1	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
151.	Percentage of staff sensitized on ISO 9001 requirements	2024/25	45	60	50	55	60	65	70	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
152.	Percentage of non-conformities closed within agreed corrective action time lines	2024/25	70	85	75	80	85	90	95	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
153.	Percentage of WHO GBT ML3 sub-indicators for medicinal products self assessed as "implemented"	2024/25	100	100	100	-	100	-	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
154.	Percentage of WHO GBT ML4 sub-indicators for medicinal products self assessed as "implemented"	2024/25	90	96	92	94	96	98	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
155.	Percentage of WHO GBT ML3 sub-indicators for medical devices self assessed as "implemented"	2024/25	70	85	75	80	85	90	95	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
156.	Percentage of identified risks assessed	2024/25	80	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
157.	Percentage of planned risk mitigation actions completed	2024/25	70	85	75	80	85	90	95	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
158.	Number of BCP tests conducted	2024/25	0	1	1	1	1	1	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
159.	Number of ICT DRP tests conducted	2024/25	0	1	1	1	1	1	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MICT

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
160.	Number of penetration testing and vulnerability assessments for ICT systems conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MICT
161.	Percentage of identified ICT vulnerable areas resolved	2024/25	75	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MICT
162.	Percentage implementation of ESG policy	2024/25	0	54	0	40	60	80	90	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MQR
163.	Number of security attacks on ICT systems	2024/25	1	0	0	0	0	0	0	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MICT
164.	Number of ICT systems validated for data accuracy	2024/25	1	1	1	-	1	-	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MICT
165.	Percentage of modules subjected to data cleaning in all ICT systems	2024/25	TBE	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MICT

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
166.	Number of ICT Steering Committee meetings conducted	MICT	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MICT
167.	Number of information updates uploaded on TMDA website and social media platforms.	2024/25	1971	2740	90	80	2200	2500	2700	3000	3300	Approved quarterly progress reports	Monthly	Quarterly	MCPE
168.	Percentage of planned IEC materials developed, printed, and disseminated	2024/25	76	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCPE
169.	Percentage of planned outreach campaigns conducted	2024/25	80	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCPE
170.	Percentage of planned exhibitions conducted	2024/25	80	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCPE
171.	Number of new school clubs established	2024/25	200	50	50	50	50	50	50	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCPE

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
172.	Percentage of planned public education programmes designed and aired through approved media channels	2024/25	80	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCPE
173.	Percentage of staff sensitized on customer care services	2024/25	70	85	75	80	85	90	95	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCPE
174.	Number of customer satisfaction surveys conducted	2024/25	2	2	-	1	-	-	1	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCPE
175.	Number of Editorial Committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCPE
176.	Number of planned internal audits conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	CIA
177.	Number of internal audit reports submitted to GARI-ITS	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	CIA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis					Frequency of Reporting	Responsible Person
		Year	Value		Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
178.	Percentage of external audit recommendations implemented within prescribed time lines	2024/25	80	90	80	85	90	95	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	CIA	
179.	Number of audit and risk committee meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	CIA	
180.	Percentage of requisitions submitted to PMU in accordance with time lines specified in Annual Procurement Plan (APP)	2024/25	70	85	75	80	85	90	95	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPM	
181.	Percentage of submitted requisitions processed by PMU	2024/25	75	85	80	80	85	90	95	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPM	
182.	Number of Tender Board meetings conducted	2024/25	4	4	4	4	4	4	4	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPM	

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
183.	Percentage of awards issued according to App	2024/25	70	85	75	80	85	90	95	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPM
184.	Percentage implementation of awarded contracts	2024/25	95	98	96	97	98	99	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPM
185.	Percentage of contracts timely paid upon satisfactory delivery of goods, services or works	2024/25	50	80	60	70	80	90	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPM
186.	Percentage of TMDA assets subjected to useful life assessment	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPM
187.	Percentage of obsolete assets that have been dispose off	2024/25	90	96	92	94	96	98	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPM
188.	Percentage of reports submitted by contract managers timely	2024/25	50	80	60	70	80	90	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MPM

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
189.	Percentage of projected revenues collected from internal sources	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	CA
190.	Percentage contribution of internal revenue to total revenue	2024/25	85	85	85	85	85	85	85	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	CA
191.	Percentage budget absorption rate	2024/25	99	99	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	CA
192.	Number of bank reconciliations conducted timely	2024/25	12	12	12	12	12	12	12	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	CA
193.	Percentage of impress retired on time	2024/25	70	100	100	100	100	100	100	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	CA

Annex IV: Evaluation Framework (Outcome Indicators)

Sn	Indicator Name	Baseline		Target Value					Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person	
		Year	Value	Cumulative/Average Value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
Strategic Objective A: HIV/AIDS, Hepatitis B and Non- Communicable Diseases (NCDs) reduced and services improved															
1.	Prevalence of NCDs among TMDA staff	2024/25	50	20	40	35	30	25	20	Progress reports	Document review	Approved annual progress reports	Annually		MHRA
2.	Incidence rate of HIV/AIDS and Hepatitis-B among TMDA staff	2024/25	1	0	0	0	0	0	0	Progress reports	Document review	Approved annual progress reports	Annually		MHRA
3.	Percentage of TMDA staff demonstrating adequate KAP related to HIV and STIs	2024/25	50	90	65	75	80	85	90	Progress reports	Document review	Approved annual progress reports	Annually		MHRA
Strategic Objective C: Gender mainstreamed and environmental ecosystem improved															
4.	Corruption Perception Index score	2024/25	--	90	75	80	85	88	90	Progress reports	Document review	Approved annual progress reports	Annually		MHRA
5.	Incidences of fraud recorded	2024/25	0	0	0	0	0	0	0	Progress reports	Document review	Approved annual progress reports	Annually		MHRA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
6.	Percentage of women employees among TMDA staff	2024/25	37	45	38	40	42	43	45	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
7.	Percentage of women employees in managerial positions	2024/25	35	40	36	37	38	39	40	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
8.	Percentage of staff workload across TMDA	2024/25								Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MHRA
9.	Incidence of occupational hazards	2024/25	7	2		5	4	3	2	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
10.	Proportion of unfit and expired medical products disposed using eco- friendly methods	2024/25	-	100	90	95	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE / MMDL

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
11.	Percentage compliance to ESG policy	2024/25	10	90	40	75	80	85	90	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MQR / CIA
Strategic Objective D: Quality, safety and effectiveness of medicinal products and tobacco standards assured															
12.	Percentage of evaluated applications for medicinal products registered	2024/25	85	90	86	87	88	89		Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMRE
13.	Percentage of evaluated applications for clinical trials authorized	2024/25	85	90	86	87	88	89	85	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMRE
14.	Percentage of processed applications licensed	2024/25	85	90	86	87	88	89	85	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMRE
15.	Prevalence of falsified medicinal products detected on the market	2024/25	85	90	86	87	88	89	85	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
16.	Prevalence of substandard medicinal products detected on the market	2024/25	2	0.5	1.8	1.7	1.5	1	0.5	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE
17.	Prevalence of unregistered medicinal products detected on the market	2024/25	2	0.5	1.8	1.7	1.5	1	0.5	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE
18.	Percentage of pharmaceutical manufacturing facilities compliant with GMP	2024/25	88	95	90	92	93	94	95	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE
19.	Percentage of medicine distribution and wholesale outlets compliant with GSDP	2024/25	100	100	100	100	100	100		Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
20.	Percentage of inspected clinical trials compliant with GCP	2024/25	94	100	95	96	98	99		Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE
21.	Percentage of evaluated applications of tobacco products listed	2024/25	0	95	50	70	80	90		Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMRE
22.	Incidence rate of medicine-related harms	2024/25	-	5	Establish baseline	Baseline -5	Baseline -10	Baseline -15		Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCTPV
23.	Percentage of medication errors	2024/25	-	5	Establish baseline	Baseline -5	Baseline -10	Baseline -15		Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCTPV

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
24.	Percentage reduction in lack of efficacy of selected registered medicinal products	2024/25	-	50	45	40	30	32	25	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCTPV
25.	Percentage reduction in unfit and expired products in health facilities	2024/25	-	50	8	10	25	40	50	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE
26.	Percentage of controlled drugs abused on the market	2024/25	-	3	7	8	6	5	4	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE
27.	Percentage of highly utilized medicinal products in health facilities detected	2024/25	-	90	60	75	80	85	90	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
Strategic Objective E: Quality, safety and performance of medical devices and diagnostics assured															
28.	Percentage of evaluated applications for medical devices and diagnostics registered	2024/25	60.3	60	61	63	65	68	70	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDA
29.	Percentage of processed applications licensed	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDL
30.	Prevalence of falsified medical devices and diagnostics detected on the market	2024/25	0	0	0	0	0	0	0	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDL
31.	Prevalence of substandard medical devices and diagnostics detected on the market	2024/25	5.1	5	4	3	2	1	0.5	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDL

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/ Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
32.	Prevalence of unregistered medical devices and diagnostics detected on the market	2024/25	2.9	3	2	1	0.5	0.5	0.5	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDL
33.	Percentage of medical devices and diagnostics manufacturing facilities compliant with Quality Management Systems	2024/25	50	50	60	70	80	90	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDL
34.	Percentage of medical devices and diagnostics distribution and wholesale outlets compliant with GSDP	2024/25	70	70	75	80	85	90	98	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDL
35.	Incidence rate of medical devices- and diagnostics- related harms	2024/25	0.5	0.5	0.45	0.40	0.30	0.18	0.1	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDV

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
36.	Percentage of medical devices and diagnostics user errors	2024/25	5	5	4	3	2	1	0.5	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDV
37.	Percentage reduction in lack of performance of selected registered medical devices and diagnostics	2024/25	100	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDV
38.	Percentage reduction in unfit and expired products in health facilities	2024/25	70	70	75	80	85	90	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDL
39.	Percentage of highly utilized medical devices and diagnostics in health facilities	2024/25	95	95	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMDV

Sn	Indicator Name	Baseline		Target Value					Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person	
		Year	Value	Cumulative/ Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
Strategic Objective F: Laboratory services improved and strengthened															
40.	Percentage compliance to laboratory testing	2024/25	90	98	92	94	96	97	98	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMCA
41.	Accreditation status of TMDA laboratories	2024/25	0	0	0	0	0	0	0	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMCA
42.	WHO prequalification status of TMDA laboratories	2024/25	0	0	0	0	0	0	0	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMCA
43.	Vaccines testing laboratory establishment and operationalization status	2024/25	-	-	0	0	0	0	0	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMCA
44.	Percentage increase in revenue generated from external customer services	2024/25	0	3	5	7	8	9	10	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MMCA

Sn	Indicator Name	Baseline		Target Value		Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person			
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection	
Strategic Objective G: Capacity to deliver regulatory services improved														
45.	Level of general public awareness on TMDA functions	2024/25	56	80	60	65	70	75	80	Progress reports	Document review	Approved annual progress reports	Annually	MCPE
46.	Internal Customer Satisfaction Index	2024/25	89	95	90	91	93	94	95	Progress reports	Document review	Approved annual progress reports	Annually	MCPE
47.	External Customer Satisfaction Index	2024/25	82	90	84	85	87	89	90	Progress reports	Document review	Approved annual progress reports	Annually	MCPE
48.	Overall percentage implementation of Annual Procurement Plan	2024/25	85	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	MPM
49.	Overall percentage implementation of Annual Audit Plan	2024/25	87	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	CIA

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
50.	Percentage adherence to time lines as per CSC (Internal and external)	2024/25	85	70	75	80	85	90	95	Progress reports	Document review	Approved quarterly progress reports	Monthly	Quarterly	MCPE
51.	Overall percentage implementation of Communication and Customer Care Strategy	2024/25	75	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCPE
52.	Overall percentage implementation of Human Resources Plan	2024/25	80	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
53.	Overall percentage implementation of Risk Management Plan	2024/25	90	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MQR

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
54.	Overall percentage implementation of Fraud Risk Management Plan	2024/25	80	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MQR
55.	Overall percentage implementation of ICT Strategy	2024/25	80	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MICT
56.	Overall percentage implementation of Facilitation of Promotion of Domestic Manufacturing Action Plan	2024/25	90	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCIE
57.	Overall percentage adherence to Clients Service Charter time lines for all services	2024/25	80	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MCPE

Sn	Indicator Name	Baseline		Target Value						Data Collection and Methods of Analysis				Frequency of Reporting	Responsible Person
		Year	Value	Cumulative/Average value	2026/27	2027/28	2028/29	2029/30	2030/31	Source of Data	Data Collection methods and tools	Means of verification	Frequency of Data collection		
58.	Overall percentage implementation of TMDA Anticorruption Action Plan	2024/25	60	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
59.	Overall percentage implementation of Wellness Program	2024/25	75	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MHRA
60.	Overall percentage implementation of Whistle-blowing Policy	2024/25	80	100	100	100	100	100	100	Progress reports	Document review	Approved annual progress reports	Annually	Annually	MLS

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