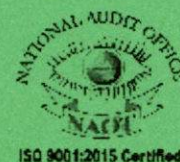




THE UNITED REPUBLIC OF TANZANIA

NATIONAL AUDIT OFFICE



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

REPORT OF THE CONTROLLER AND AUDITOR GENERAL ON THE FINANCIAL AND COMPLIANCE AUDIT
FOR THE FINANCIAL YEAR ENDED 30 JUNE 2024

Controller and Auditor General,
National Audit Office,
Audit House
Mahakama Road
P.O. Box 950
41104 Tambukareli
Dodoma, Tanzania.
Tel.: 255 (026) 2161200-9 E-mail: ocag@nao.go.tz
Website: www.nao.go.tz

March 2025

AR/PA/TMDA/2023/24

REPORT OF THE CONTROLLER AND AUDITOR GENERAL



THE UNITED REPUBLIC OF TANZANIA

NATIONAL AUDIT OFFICE



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

REPORT OF THE CONTROLLER AND AUDITOR GENERAL ON THE FINANCIAL AND COMPLIANCE AUDIT
FOR THE FINANCIAL YEAR ENDED 30 JUNE 2024

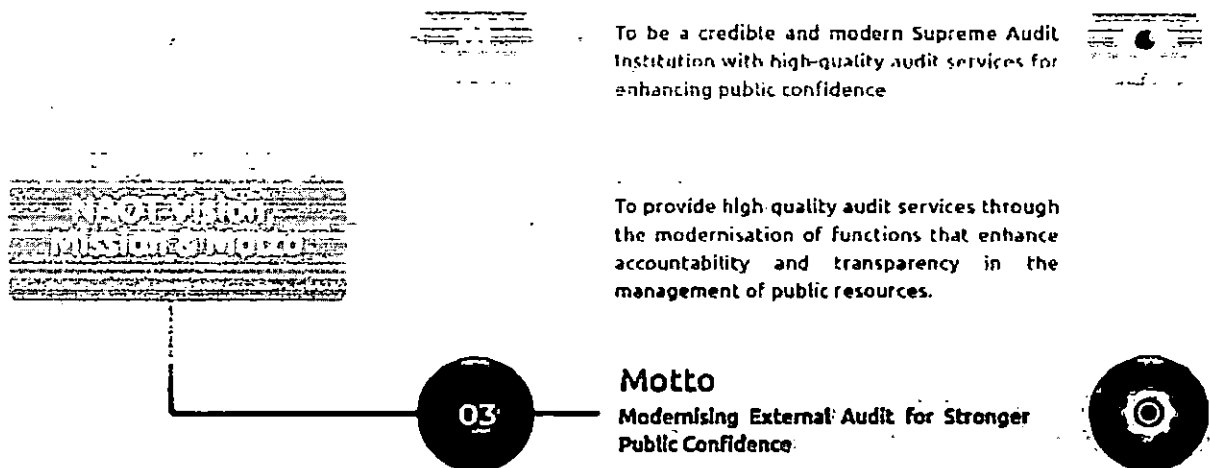
Controller and Auditor General,
National Audit Office,
Audit House
Mahakama Road
P.O. Box 950
41104 Tambukareli
Dodoma, Tanzania.
Tel.: 255 (026) 2161200-9 E-mail: ocag@nao.go.tz
Website: www.nao.go.tz

March 2025

AR/PA/TMDA/2023/24

Mandate

The statutory mandate and responsibilities of the Controller and Auditor-General are provided for under Article 143 of the Constitution of the United Republic of Tanzania of 1977 and in Section 10 (1) of the Public Audit Act, Cap. 418.



Independence and objectivity

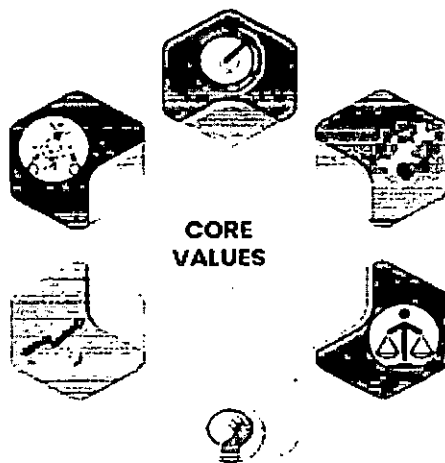
We are an impartial public institution, independently offering high-quality audit services to our clients in an unbiased manner.

Teamwork Spirit

We value and work together with internal and external stakeholders.

Results-Oriented

We focus on achievements of reliable, timely, accurate, useful, and clear performance targets.



Professional competence

We deliver high-quality audit services based on appropriate professional knowledge, skills, and best practices

Integrity

We observe and maintain high ethical standards and rules of law in the delivery of audit services.

Creativity and Innovation

We encourage, create, and innovate value-adding ideas for the improvement of audit services.

© This audit report is intended to be used by the Tanzania Medicines and Medical Devices Authority (TMDA) and may form part of the annual general report, which once tabled to National Assembly, becomes a public document; hence, its distribution may not be limited.

TABLE OF CONTENTS

ABBREVIATIONS.....	iii
1.0 INDEPENDENT REPORT OF THE CONTROLLER AND AUDITOR GENERAL	1
1.1 REPORT ON THE AUDIT OF FINANCIAL STATEMENTS	1
1.2 REPORT ON COMPLIANCE WITH LEGISLATIONS	4
1.2.1 Compliance with the Public Procurement laws	4
1.2.2 Compliance with the Budget Act and other Budget Guidelines	4
2.0 THE REPORT BY THOSE CHARGED WITH GOVERNANCE.....	5
3.0 STATEMENT OF RESPONSIBILITY BY THOSE CHARGED WITH GOVERNANCE...	41
4.0 DECLARATION OF THE HEAD OF FINANCE.....	42
5.0 FINANCIAL STATEMENTS	43

ABBREVIATIONS

ACPA	Associate Certified Public Accountant
ARMC	Audit and Risk Management Committee
CAG	Controller and Auditor General
CDC	Center for Disease Control
CPA	Certified Public Accountant
DCEA	Drug Control and Enforcement Authority
EDCTP	European and Developing Countries Clinical Trials Partnership
EAC	East African Community
FIFO	First in first out
GEPG	Government Electronic Payment Gateway
GMP	Good Manufacturing Practice
HR-MIS	Human Resource Management Information System
IPSAS	International Public Sector Accounting Standards
IPSASB	International Public Sector Accounting Standards Board
ISO	International Organization for Standardization
LPO	Local Purchase Order
LTC	Legal and Technical Committee
MAB	Ministerial Advisory Board
MBA	Master of Business Administration
MD	Doctor of Medicine
MOH	Ministry of Health
MUHAS	Muhimbili University of Health and Allied Sciences
MSD	Medical Store Departments
NAO	National Audit Office
NHIF	National Health Insurance Fund
PAA	Public Audit Act No. 11 of 2008
PPA	Public Procurement Act, 2011
PPE	Property, Plant and Equipment
PhD	Doctor of Philosophy
PSSSF	Public Sector Social Security Fund
SADC	Southern African Development Community
TBS	Tanzania Bureau of Standards
TAPSA	Tanzania Pharmaceutical Student's Association
TAGCO	Tanzania Association for Government Communication Officers
TFDA	Tanzania Food and Drugs Authority
TMDA	Tanzania Medicines and Medical Devices Authority
TZS	Tanzanian Shilling
WHO	World Health Organization
WIP	Work in Progress

1.0 INDEPENDENT REPORT OF THE CONTROLLER AND AUDITOR GENERAL

Chairperson of the Ministerial Advisory Board,
Tanzania Medicines and Medical Devices Authority,
P.O. Box 1253,
Dodoma, Tanzania

1.1 REPORT ON THE AUDIT OF FINANCIAL STATEMENTS

Unqualified Opinion

I have audited the financial statements of Tanzania Medicines and Medical Devices Authority (TMDA), which comprise the statement of financial position as at 30 June 2024, the statement of financial performance, statement of changes in net assets, cash flow statement and the statement of comparison of budget and actual amounts for the year then ended, as well as the notes to the financial statements, including a summary of significant accounting policies.

In my opinion, the accompanying financial statements present fairly in all material respects, the financial position of Tanzania Medicines and Medical Devices Authority (TMDA) as at 30 June 2024, and its financial performance and its cash flows for the year then ended in accordance with International Public Sector Accounting Standards (IPSAS) Accrual basis of accounting and the manner required by the Public Finance Act, Cap. 348

Basis for Opinion

I conducted my audit in accordance with the International Standards of Supreme Audit Institutions (ISSAIs). My responsibilities under those standards are further described in the section below entitled "Responsibilities of the Controller and Auditor General for the Audit of the Financial Statements". I am independent of Tanzania Medicines and Medical Devices Authority (TMDA) in accordance with the International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants (IESBA Code) together with the National Board of Accountants and Auditors (NBAA) Code of Ethics, and I have fulfilled my other ethical responsibilities in accordance with these requirements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Key Audit Matters

Key audit matters are those matters that, in my professional judgment, were of most significance in my audit of the financial statements of the current period. I have determined that there are no key audit matters to communicate in my report.

Other Information

Management is responsible for the other information. The other information comprises the Report by those charged with governance, statement of mana responsibility, Declaration by the

Head of Finance and any other information included in the TMDA's annual report but does not include the financial statements and my audit report thereon which I obtained prior to the date of this auditor's report.

My opinion on the financial statements does not cover the other information, and I do not express any form of assurance conclusion thereon.

In connection with my audit of the financial statements, my responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements, or my knowledge obtained in the audit, or otherwise appears to be materially misstated.

If, based on the work I have performed on the other information that I obtained prior to the date of this audit report, I conclude that there is a material misstatement of this other information, I am required to report that fact. I have nothing to report in this regard.

Responsibilities of Management and Those Charged with Governance for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with IPSAS and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the entity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the entity or to cease operations or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the entity's financial reporting process.

Responsibilities of the Controller and Auditor General for the Audit of the Financial Statements

My objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error and to issue an audit report that includes my opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISSAIs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISSAIs, I exercise professional judgment and maintain professional skepticism throughout the audit. I also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and

obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control;
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management;
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the entity's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my audit report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my audit report. However, future events or conditions may cause the entity to cease to continue as a going concern; and
- Evaluate the overall presentation, structure, and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

I communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

I also provide those charged with governance with a statement that I have complied with relevant ethical requirements regarding independence and to communicate with them all relationships and other matters that may reasonably be thought to bear on my independence, and where applicable, related safeguards.

From the matters communicated with those charged with governance, I determine those matters that were of most significance in the audit of the financial statements of the current period and are, therefore, the key audit matters. I describe these matters in my audit report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, I determine that a matter should not be communicated in my report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest of such communication.

In addition, Section 10 (2) of the Public Audit Act, Cap. 418 requires me to satisfy myself that the accounts have been prepared in accordance with the appropriate accounting standards.

Further, Section 48(3) of the Public Procurement Act, Cap. 410 requires me to state in my annual audit report whether or not the audited entity has complied with the procedures prescribed in the Procurement Act and its Regulations.

1.2 REPORT ON COMPLIANCE WITH LEGISLATIONS

1.2.1 Compliance with the Public Procurement laws

Subject matter: Compliance audit on procurement of works, goods, and services

I performed a compliance audit on the procurement of works, goods, and services in the Tanzania Medicines and Medical Devices Authority for the financial year 2023/24 as per the Public Procurement laws.

Conclusion

Based on the audit work performed, I state that procurement of goods, works and services of Tanzania Medicines and Medical Devices Authority is generally in compliance with the requirements of the Public Procurement laws in Tanzania.

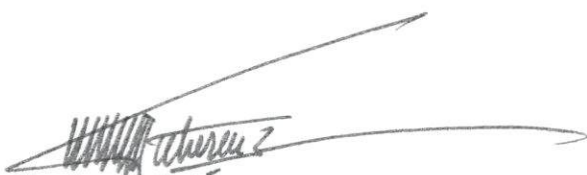
1.2.2 Compliance with the Budget Act and other Budget Guidelines

Subject matter: Budget formulation and execution

I performed a compliance audit on budget formulation and execution in Tanzania Medicines and Medical Devices Authority for the financial year 2023/24 as per the Budget Act and other Budget Guidelines.

Conclusion

Based on the audit work performed, I state that Budget formulation and execution of Tanzania Medicines and Medical Devices Authority is generally in compliance with the requirements of the Budget Act and other Budget Guidelines.



Charles E. Kichere
Controller and Auditor General,
United Republic of Tanzania.
March, 2025



2.0 THE REPORT BY THOSE CHARGED WITH GOVERNANCE

2.1 ESTABLISHMENT

Tanzania Medicines and Medical Devices Authority (TMDA) was established as a semi-autonomous regulatory body under the Ministry of Health which is responsible for protecting and promoting public health by ensuring safety, quality and effectiveness of medicines, medical devices and diagnostics. TMDA formerly TFDA became operational on the 1st July, 2003 as the Tanzania Food and Drugs Authority or its acronym TFDA. This name was changed into a new acronym of TMDA following the amendment of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 through the Finance Act, No. 8 of 2019 which apart from changing the name of the Act into Tanzania Medicines and Medical Devices Act, Cap 219, it also transferred the functions of regulating the quality and safety of food and cosmetics to the Tanzania Standard Act, Cap 130 which is under the Tanzania Bureau of Standards (TBS).

Vision

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

Mission

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

Philosophy

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

Quality Policy

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

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

2.2 LOCATION OF HEAD QUARTERS OFFICE

TMDA Headquarters is located at Plot No. 56/1, Block E, Kisasa B, Centre, Hombolo Road, Adjacent to Martin Luther Schools, P.O Box 1253, Dodoma, Tanzania; Telephone: +225 26 2320156/2450751 /2452108; Fax: +255 22 2450793; Email Address: info.dodoma@tmda.go.tz.

2.3 NATURE OF OPERATIONS

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

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

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

TMDA is managed by the Director General who is accountable to the Permanent Secretary of the Ministry responsible for Health. The Authority has a Ministerial Advisory Board (MAB) that advises the Minister responsible for health on the Authority's Strategic issues. The Director General is responsible for daily operations and proper management of the Authority's resources and functions. The Director General is assisted by four (4) Directors, seven (7) Heads of Units and eight (8) Zone Managers.

TMDA functions are executed through four (4) Directorates namely Directorate of Human and Veterinary Medicines (DMC), Directorate of Medical Devices and Diagnostics Control (DMD), Directorate of Laboratory Services (DLS) and Directorate of Business Support (DBS) whereas the seven (7) Units are Internal Audit, Quality and Risk Management, Legal Services, Information Communication Technology and Statistics, Procurement Management, Finance and Accounting, Communication and Public education. Zone offices are directly responsible to the Director General through the Zone Managers who oversee TMDA functions in the respective zones. Distribution of zones and their respective regions is as indicated in table below: -

Table 1: Distribution of Zone Offices and their respective locations

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

Due to limited capacity, the Authority has delegated some of its functions and powers to the Local Government Authorities vide the Delegation of Powers and Functions Order, 2015 in order to improve service delivery and ensure that its services are accessed and available at all levels

2.4 PRINCIPAL ACTIVITIES

Pursuant to the Tanzania Medicines and Medical Devices Act, Cap 219, TMDA discharges the following functions: -

- a) Regulating the manufacturing, importation, distribution and selling of medicines, medical devices, diagnostics, biocidals and tobacco products
- b) Prescribing standards of quality, safety and effectiveness for medicines, medical devices, diagnostics, biocidals and tobacco products;
- c) Inspecting manufacturing industries and business premises dealing with regulated products and make sure the standards required are attained;
- d) Evaluating and registering medicines, medical devices, diagnostics, biocidals and tobacco products so as to reach the required standards before marketing authorization;
- e) Issuance of business permits for premises dealing with regulated products;
- f) Assessing the quality, safety and efficacy of controlled drugs;
- g) Conducting laboratory investigations for regulated products to ascertain their quality specifications;
- h) Conducting pharmacovigilance of medical products and vigilance of medical devices, diagnostics, biocidals and tobacco products circulating on the market;
- i) Promoting rational use of medicines, medical devices, diagnostics, biocidals;
- j) Educating and sharing accurate and reliable information to stakeholders and the general public on regulatory matters; and
- k) To ensure that Tobacco products circulating in the market are appropriate for the protection of public health.

2.5 TMDA OPERATING MODEL

The Authority's operating model is the system of transforming inputs, through its operating activities, into outputs and outcomes that aims to fulfil TMDA's strategic purposes and create value over the short, medium and long term. The TMDA Operating Model is explained below: -

2.5.1 Inputs

(a) Human Capital

The Authority had 350 (349 permanent and 1 temporary) employees as on 30th June 2024 (352 on 30th June, 2023). The employees have adequate skills and competence to ensure delivery of quality regulatory services. The employees are well trained, motivated and perform their duties responsibly and in ethical manner.

(b) Financial Capital

Financial capital comprises of financial resources obtained from regulatory activities as provided under Section 12(1) of the Executive Agency Act CAP 245. The resources come mainly from services provided by the Authority for regulation of medical products. Such services include licencing and market authorization of premises, product registration, import and Export, laboratory services and inspection of Goods Manufacturing practices. Apart from fees collected under the Act, other funds come from donation & grants and monies received from disposal of Assets.

(c) Manufactured (Tangible) Capital

TMDA has acquired tangible assets such as motor vehicles, computers, ICT and accessories, machines, plots and buildings. The assets enable the Authority to efficiently provide regulatory services while the use of ICT reduces resource use thus enhancing both efficiency and sustainability of regulatory services.

(c) Social and Relationship Capital

The Authority has created good working relationships with both internal and external stakeholders. Internally, the Authority has natured a good working relationship among employees through cultivating trust and respect and ensuring views of each employee is considered in the decision-making process. This is achieved through regular meetings such as worker's council in collaboration with trade union. Further, the Authority has good standing with platforms such as Associations of Pharmaceutical Manufacturers, Importers and Private & public Hospitals whereby all decisions passed with regard to quality of service comments are always sought from those Stakeholders and communications. To facilitate communications, staff are provided with computers and airtime.

TMDA has also established transparent relationship with the Government and its institutions, customers, suppliers including of regulated services, policy makers and the society in general. The Authority conduct stakeholders' meetings to provide awareness and receive feedback on various issues. In order to respond effectively to community social needs, the Authority developed Client Service Charter to provide assurance and timeline of services offered by the Authority.

(d) Intellectual Capital

The Authority has sufficient knowledge of regulatory regime and has gained trust and respect from the regulated customers. To ensure effective and efficient provision of regulatory services, the Authority has offered all services online. TMDA customers have been used to electronic transactions for regulatory services as opposed to paper based-conventional services which proved inefficiency. That being the case, installation of e-communication is being intensified by ensuring that ICT technology is invested in every financial year.

2.5.2 Operating Activities

The Authority implements a number of activities in converting inputs into regulatory services. The operating activities are divided into three major groups;

(a) Regulation of Medicinal and Tobacco Products

This activity focuses on regulating the manufacturing, importation, distribution and selling of medicines biocidals and tobacco products, Inspecting manufacturing industries and business premises dealing with medicines biocidals and tobacco products and making sure the standards require are attained, Evaluating and registering medicines, biocidals and tobacco products so as to reach the required standards before marketing authorization, Issuance of business permit for premises dealing with medicines biocidals and tobacco products, assessing the quality safety and efficacy of controlled drugs. Conducting pharmacovigilance of medical products and vigilance of biocidals and tobacco products circulating on the market, promoting rational use of medicines biocidals and tobacco products and to ensure that tobacco products circulating in market are appropriate for the protection of public health.

(b) Regulation of Medical Devices & Invitro-Diagnostics

Activity involves to overseeing assessment for performance of medical devices, diagnostics and laboratory equipment prior to marketing authorization, to coordinate quality audits of domestic and foreign manufacturing premises of medical devices and diagnostics oversee issuance of import export permits of medical devices, diagnostics laboratory equipment's blood and blood products, To monitor field safety updates on the performance and use of medical device and diagnostics, To supervise applied research undertaking on regulatory functions related to medical devices diagnostics and laboratory equipment supervise evaluation of the quality, safety and efficacy of blood and blood products and to supervise hemo vigilance activities for blood and blood products, To foster cooperation with regional and international bodies including harmonization initiatives related to medical devices and diagnostics.

(c) Laboratory Analytical services

This service done through laboratory analysis of medicines, medical devices, diagnostics and tobacco products for enhancing decision making within the Authority. It supervises chemical, physical and microbiological analysis of regulated products and overseeing testing of regulated products at quality assurance centres and mini-laboratories which are stationed at Zone offices, Referral hospitals and Ports of Entries (POEs).

It is also responsible for calibration and maintenance of laboratory equipment, develop, implement and review laboratory quality policy and maintenance and implementation of laboratory standards as per ISO/IEC 17025:2015. Furthermore, the Directorate implements laboratory Quality Management System (QMS) to maintain the WHO pre-qualification certification, coordinating and conduction of scientific research.

2.5.3 Outputs

(a) Regulation of Medicinal and Tobacco Products

In this regulatory role, the Authority had the following outputs:

- 1,609 applications for registration of human medicines were received;
- 1,322 applications were evaluated;
- 796 human medicines were approved and registered;
- 163 applications for registration of veterinary were received;
- 138 veterinary applications were evaluated;
- 120 Veterinary medicines were approved and registered
- 596 applications for registration of premises were received;
- 589 Premises were approved and registered;
- 13,376 business premises for medical products were inspected;
- 10,776 premises were found to comply with the needed standard; and
- 25,566 adverse reactions were reported and corrective actions were taken

(b) Regulation of Medical Devices and Invitro-Diagnostics

In this function, the Authority had the following outputs:

- 631 applications for registration of medical devices and 259 for applications for registration of diagnostics were received;
- 627 applications of medical devices and 254 for applications of diagnostics were evaluated; and
- 237 applications of medical devices and 88 for applications of diagnostics were approved

(c) Laboratory Analytical services

Under this function, the Authority had the following outputs:

- 2,214 samples of medical products were received;
- 2,209 samples were analysed;
- 2,209 were passed and complied;

Outcomes

The following were notable outcomes:

- Increased compliance with safety, quality and effectiveness of medicines for consumers;
- Enhanced quality of medical devices and diagnostics;
- Improved quality of regulatory services;
- Increased compliance among regulated customers;
- Improved safety and quality standards;
- Decreased number of defaulters and violators of the Act;

- Growth on investment on pharmaceutical business such as Industries;
- Increased operational efficiency of inspection and licensing; and
- Increased customers and stakeholders' satisfaction.

2.6 STAKEHOLDERS' RELATIONSHIP

The Authority believes that the stakeholders and customers are what make the Authority exist. Several measures have been taken to institute a responsible behaviour towards members of the Authority and other stakeholders. These measures include, but not limited to, holding interactive meetings, seminars and workshops; provide education through media and improving customer services at our offices.

In this regard, the Authority has identified four (4) categories of stakeholders; the Government, employees, regulated customers, society and policy-makers. Before making its decisions, the Ministerial Advisory Board considers the interests of the stakeholders and ensures that engagement with stakeholders is deliberate and planned and that communication is always transparent and effective.

2.6.1 The Government

The Government established the Authority with specific objectives and functions for medical products regulation. The motive behind establishment of TMDA is to ensure the protection of public health against the use of medical products.

(a) Key concerns

The Government's concerns to the Authority include the following:

- Enhance safety in the use of medical products;
- Receive 15% of gross revenue contribution quarterly and 70% of surplus funds at year ends by remittance to the Government Consolidated Fund;
- Effective and comprehensive regulation of medical products;
- Existence of mechanism for handling complains and resolving disputes in the regulated products; and
- Availability of regulated services to all consumers.

(b) Value we create

- Enhanced safety in the use of medical products;
- Remittance of 15% gross revenue contribution within every quarter to the Government Consolidated Fund;
- Effective and comprehensive regulation of medical products in the country;
- Handling complaints once received and resolving within the shortest possible time; and
- Effective availability of regulated services to all consumers.

2.6.2 Employees

Employees are key to make the Authority great place to work. They should find working for TMDA an inspiring and a place for elevating personal experience and consequently accepts co-responsibility for the development of each employee to the full potential. Career progress is based on the individual initiative towards the fulfilment of their responsibilities complemented by the Authority.

(a) Key concerns

Employees want friendly, safe and conducive working environment, defined career progression, better salary and benefits, motivation, recognition and opportunities to contribute to the society.

(b) Value we create

- Transforming into an inclusive society through employment equity and gender equality;
- We focus on developing our employee through targeted training programs and skills upgrading to further their career and improve our services;
- Rewarding employees for the value they add;
- Motivating and energizing our work force;
- Supporting employees in fulfilling of their professional membership obligations; and
- Timely payments of employees' entitlements.

2.6.3 Regulated Customers

Regulated customers have important roles in the social economic development specifically in the provision of the regulated services.

(a) Key concerns

The regulated service providers' key concerns to the Authority includes the following:

- Timely receiving of their approvals upon submission of genuine applications;
- Existence of supply and distribution of registered of medical products;
- Promotion of their investments especially for pharmaceutical industries; and
- Frequent engagement with the Authority to discuss medical product issues.

(b) Value we create

- Timely grant of their approvals upon submission of genuine applications;
- Ensure supply and distribution of registered of medical products;
- Promote investments in pharmaceutical industries; and
- Frequent engagement with the Authority to discuss medical product issues.
- Implementation of stakeholders' views and providing awareness and dissemination workshop.

2.6.4 Society

The Authority acknowledges its responsibility to respond to community social needs. The Corporate Social Responsibility (CSR) interventions included commitment to active participation in environment protection and promotion of socio-economic development of our society through extension of financial support to implementation of community activities.

(a) Key Concerns

- Supporting social development programs organized by the communities for socio-economic development;
- Awareness on TMDA functions and applicable legislation; and
- Compliance with environmental, social and governance matters.

(b) Value we create

- Supporting social community programs using donation and other sources of funds; and
- Providing awareness on TMDA functions and environmental protection.

2.6.5 Policy makers

The Authority implements its Act and complies with sector legislation, resolutions, directives and guidelines which are issued from time to time by the Government entities including Ministry of Health, National Environmental Management Council, Ministry of Finance, President's office-Public Service Management, Ministry of Home Affairs, Attorney General's Office, Tanzania Revenue Authority, Office of Treasury Registrar and Tanzania Parliamentary Committees (Community development and public Health, Budget Committee and Parliamentary Accounts Committee).

(a) Key Concerns

Authority complies with the relevant legislation, guidelines and supporting employees on fulfilling of their professional membership obligations.

(b) Value we create

- Facilitation of contributions to professional bodies and other National Organization;
- Operating within the scope of the respective policies, legislation, directives and guidelines; and
- Complying by paying membership fees and be active members.

2.7 RESOURCES

The Authority's key strengths which assist in the performance of its functions to achieve its objectives are pegged on a well-composed Ministerial Advisory Board (MAB), effective Management, competent human resources, deployed ICT systems and documented standard operating procedures (SoPs). These strengths continuously create value to the Authority. In terms of resources, the Authority has tangibles and intangibles, which include intellectual

resources, human resources, social and relationship resources, natural resources, financial resources and other resources. These are explained below: -

(a) Intellectual Resources

The Authority intellectual resources include ICT application systems which has automated and modernized operations, thus, improved provision of regulatory services and business operations. The Authority's ICT systems in operations include the following: -

- Regulatory Information Management System (RIMS);
- Laboratory Information Management System (LIMS);
- Mfumo wa Uhasibu Serikalini (MUSE);
- Enterprise Resource Management Suite (ERMS);
- Safety and Quality Reporting Tool (SQRT);
- File Management System (e-Office);
- Mfumo wa Malalamiko, Mapendekezo, Maulizo na Pongezi (eMrejesho);
- Budget and Planning System (PLANREP);
- Auditing System (ACL);
- National e-Procurement System of Tanzania (NeST);
- Public Employees Performance Management Information System (PEPMIS); and
- Government Assets Management Information System (GAMIS).

In general, implementation of ICT application systems improves the Authority's service delivery process and enhances efficiency. The Authority shall continue with its initiative to automate business operations to enhance efficiency and reduce costs of business operations. Factors that may affect availability, quality and affordability of intellectual resources include fast technological changes, Government legislative changes, systems hackers where access controls and firewalls are weak, and unexpected power outage. However, the Authority is organized to cope with future changes and expects intellectual resources will continuously be available to meet future demand.

(b) Human Resources

The Authority has skilled, committed, motivated and competent employees dedicated to the provision of quality services that meet and exceed customers' expectations. Management adheres to the principles of good governance and promotes good working environment and labour relations. In addition, the Authority has continually invested on human resource development focusing on training, staff wellness, staff recognition, competitive remuneration and career growth.

By 30th June, 2024, the Authority had its Head Office in Dodoma, eight (8) zone offices and total of 350 employees (30 June, 2023 352 employees). The employees are being supported by the Authority to continuously working with the Authority and meet future demand.

(c) Social and relationship resources

The Authority social and relationship resources is composed of ethical and transparent relationship with its customers, regulated service providers, suppliers, regulatory bodies, Government and the general public who are internal and external stakeholders by establishing a harmonious relationship. The Authority's creates shared value strategy relating to social development initiatives such as education and leadership development, financial inclusion, health and safety facilities which are delivered to the communities in the areas of operations.

During the year under review, stakeholders from both the regulated products and the medicines, medical devices business areas extended required cooperation and support to the Authority's activities. In addition, the Authority had established and maintained good working relationships with local entities within the country and maintained international networking with relevant organs including WHO, USAID, CDC, EAC and SADC.

(d) Financial resources

The Authority enhances its financial sufficiency by improving management of its resources through prioritization of initiatives, implementing initiatives within the available financial resources to generate adequate revenue for timely implementation of planned activities. The Authority Sources of finance is derived from the mandate it has been given through Section 7(1) (a) and 7(1)(b) of the establishment Act "Tanzania Medicines and Medical Devices Act, Cap. 219 R.E 2021" and its Regulations namely "The Tanzania Medicines and Medical Regulations (Fees and Charges Regulations):-

- Import fees from various applications;
- Registration fees of various products being regulated by TMDA;
- Charges from laboratory samples analysis for various parties;
- Inspection fees for various manufacturing premises;
- Income from rent received from the investment property;
- Proceeds from disposal of the TMDA's fixed assets;
- Proceeds from sale of various publications; and
- Income from various donors and development partners

2.8 COMPOSITION OF THE MINISTERIAL ADVISORY BOARD (MAB)

The MAB served during the year under review was appointed on 18th August, 2023 and its three-year tenure will end on 17th August, 2026. The composition of the board member is as hereunder:

Table 2: Composition of the Ministerial Advisory Board

S/N	Name	Position	Age	Qualification/ Discipline	Nationality
1	Mr.Eric F. Shitindi	Chairperson	64	Master's Degree in Economics	Tanzanian
2	Prof. Appolinary A.R. Kamuhabwa	Member	58	Doctor of Philosophy (PhD) in Pharmacology and	Tanzanian
Controller and Auditor General				AR/PA/TMDA/2023/24	

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

S/N	Name	Position	Age	Qualification/ Discipline	Nationality
				Therapeutics	
3	CPA Chiku Thabit Yusuf	Member	54	Associate Certified Public Accountant (ACPA-T), MBA - Corporate Management (MBA-CM), Advanced Diploma in Certified Accountancy and Women's Leadership Programme Certificate-Uongozi Institute.	Tanzanian
4	Adv. Patricia M.K. Maganga	Member	61	Bachelor Degree in Law LL. B (hons.), Master's degree of Arts Public Policy and Administration (MA-PPA), and Post Graduate Diploma in Health Care Law.	Tanzanian
5	Mrs. Mariam G. Mwanilwa	Member	58	Postgraduate Diploma in Law, Mediation & Arbitration, Master's Degree in Public Administration, and Advanced Diploma in Public Administration	Tanzanian
6	Dr. Adam M. Fimbo	Secretary	49	Doctor of Philosophy (PhD) in Pharmacovigilance	Tanzanian
7	Mr. Daudi Msasi	Member	46	MBA in Human Resources Management, Bachelor Degree in Pharmacy	Tanzanian

2.9 CORPORATE GOVERNANCE

The MAB of the Ministry of Health to the TMDA consists of 7 members including the Director General who is the Secretary to the Board.

Functions of the MAB

The functions of the Board are to advise the Minister on:

- The development and maintenance of a strategic framework;
- The objectives of the Authority;
- The acceptability of the Chief Executive's plans and associated budgets;
- The setting of priorities and annual performance targets for the Authority;
- The Authority Annual Reports and Accounts;
- The evaluation of the Authority performance;
- The salaries, wages and allowances of the employees of the Authority; and

- h. Any other matter in the promotion and furtherance of the objectives and functions of the Act.

The Board is also responsible for ensuring that a comprehensive system of internal control policies and procedures is operative, and for compliance with sound corporate governance principles. The Board is required to meet at least four times a year. The day-to-day management of the authority is vested to Director General assisted by Management team. The Management attends Board meetings to facilitate the effective control of all the Authority's operational activities, acting as a medium of communication and coordination between all various business units. The Authority is committed to the principles of effective corporate governance. The MAB also recognize the importance of integrity, transparency and accountability.

Meetings of MAB

The Board is required to meet at least four times a year. The Board meetings are held once quarterly with additional meetings convened as and where necessary. During the financial year ended 30 June 2024, the Board conducted four ordinary meetings as tabulated below.

Table 3: Number of MAB Meetings for the year under review

S/N	Meeting	MAB	ARMC	LTC
1	Ordinary Meeting	4	3	3
2	Adhoc/Special Meeting	-	-	-
3	Any other meeting	-	-	-
Total		4	3	3

Table 4: MAB members' attendance to MAB meetings and committee meetings

S/N	Name	MAB	ARMC	LTC
1	Mr. Eric F. Shitindi	4	N/A	N/A
2	CPA Chiku Thabit Yusuf	4	3	-
3	Adv. Patricia M.K Maganga	4	3	3
4	Dr. Adam M. Fimbo	4	3	3
5	Mr. Daudi Msasi	3	2	2
6	Prof. Appolinary A.R. Kamuhabwa	4	-	3
7	Mrs. Mariam G. Mwanilwa	4	3	3

Some of the significant issues for deliberations during the MAB and committee meetings were as follows:

- Annual progress implementation report for the year 2022/23;
- Annual Revised Budget for the Year 2023/24;
- Approval of TMDA Budget of 2024/2025;
- Annual action plan and budget for the year 2024/25;
- Quarterly progress implementation reports for year 2023/24;

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

- f. Proposed Incentive Scheme for TMDA employees;
- g. Building of TMDA Headquarter-Vertical Extension of HQ Office at Plot N. 56/1 Block E Kisasa B Dodoma;
- h. Renovation of TMDA Buildings (Tarakea and Horohoro) and building of fence for Namanga Building;
- i. Construction Basic Infrastructure of TMDA Incinerator on Plot No. 828 at NALA Area in Dodoma;
- j. WHO Re-benchmarking of Medicines Regulatory System;
- k. Implementation of Risk Management Activities;
- l. Quality Management Systems;
- m. Implementation of TMDA Communication and Customer Service Strategy;
- n. Working Plan and audit fee for 2022/23.
- o. CAG Annual Audit Report for the year ended 30 June 2023;
- p. Quarterly Internal Audit, Legal and Risk reports;
- q. Procurement plan of 2024/2025;
- r. MSD long term outstanding loan;
- s. Action Plan of promoting TMDA laboratory;
- t. Three years performance report of MAB; and
- u. Other matters on staff welfare.

The Board has two subcommittees formed to facilitate deliberations and ensure the highest standard of corporate governance. The Ministerial Advisory Board Sub-committees convene meetings before commencement of the full Board. That means, every ordinary Board meeting is preceded by a respective subcommittee meeting. The tenure of the subcommittees is similar to that of the Board. The composition of the committee's members is as follows:

Committees of MAB

The Board has two subcommittees formed to facilitate deliberations and ensure the highest standard of corporate governance. The Ministerial Advisory Board Sub-committees convene meetings before commencement of the full Board. That means, every ordinary Board meeting is preceded by a respective subcommittee meeting. The tenure of the subcommittees is similar to that of the Board. The composition of the committee's members is as follows:

2.9.1 Audit and Risk Management Committee

The committee is responsible for financial and operational issues. The following were the members of the committee

Table 5: audit and Risk management committee

S/N	Name	Position	Qualification/Discipline	Nationality	Appointment Date
1.	CPA Chiku Thabit Yusuf	Chairperson	Associate Certified Public Accountant (ACPA-T), MBA - Corporate Management (MBA - CM), Advanced Diploma in Certified	Tanzanian	24 October, 2023

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

S/N	Name	Position	Qualification/Discipline	Nationality	Appointment Date
			Accountancy and Women's Leadership Programme Certificate-Uongozi Institute.		
2.	Adv. Patricia M.K Maganga	Member	Bachelor Degree in Law LL. B (hons.), Master's degree of Arts Public Policy and Administration (MA-PPA), and Post Graduate Diploma in Health Care Law.	Tanzanian	24 October, 2023
3.	Mrs. Mariam G. Mwanitwa	Member	Postgraduate Diploma in Law, Mediation & Arbitration, Master's Degree in Public Administration, and Advanced Diploma in Public Administration	Tanzanian	24 October, 2023
4.	Mr. Daudi Msasi	Member	MBA in Human Resources Management, Bachelor Degree in Pharmacy	Tanzanian	24 October, 2023

2.9.2 Legal and Technical Committee

This subcommittee is responsible for legal and technical issue. The following were the members of the committee.

Table 6: Legal and Technical committee

S/N	Name	Position	Qualification/Discipline	Nationality	Appointment Date
1.	Prof. Appolinary A.R. Kamuhabwa	Chairperson	Doctor of Philosophy (PhD) in Pharmacology and Therapeutics	Tanzanian	24 October, 2023
2.	Adv. Patricia M.K Maganga	Member	Bachelor Degree in Law LL. B (hons.), Master's degree of Arts Public Policy and Administration (MA-PPA), and Post Graduate Diploma in Health Care Law.	Tanzanian	24 October, 2023
3.	Mrs. Mariam G. Mwanitwa	Member	Postgraduate Diploma in Law, Mediation & Arbitration, Master's Degree in Public Administration, and Advanced Diploma in Public Administration	Tanzanian	24 October, 2023
4.	Mr. Daudi Msasi	Member	MBA in Human Resources Management, Bachelor Degree in Pharmacy	Tanzanian	24 October, 2023

2.10 CAPITAL STRUCTURE

The capital structure of the Authority for the year ended 30 June, 2024 is shown below on a comparable basis:

SOURCES	2023/24	2022/23
	TZS	TZS
Capital fund	1,139,933,337	1,139,933,337
Accumulated surplus	40,102,176,323	43,954,452,424
TOTAL	41,242,109,660	45,094,385,761

2.11 MANAGEMENT

The Management of the Authority is under the Director General and is organized into four directorates, eight zone offices, and seven independent units under the office of the Director General.

2.11.1 Office of the Director General

The office of the Director General is comprised of seven (7) independent units; Legal Services, Finance and Accounting, Internal Audit, Communication and Public Relations, Procurement Management, Information Communication Technology and Statistics and Quality & Risk Management.

There are Eight (8) operational Zone Offices which report directly to the Director General. The Eastern Lake Zone at Mwanza, serving Mwanza, Mara and Simiyu Regions, Western Lake Zone at Geita covering Geita, Kagera, and Shinyanga Regions, Northern Zone at Arusha for Manyara, Arusha and Kilimanjaro Regions; Southern Highland Zone at Mbeya offering services within Mbeya, Songwe, Rukwa and Njombe Regions; Southern Zone at Mtwara charged for service at Mtwara, Lindi and Ruvuma Regions, Central Zone at Dodoma serving Dodoma, Iringa, Morogoro and Singida regions, Easter Zone at Dar es Salaam standing for Pwani, Tanga and Dar es Salaam regions and Western Zone at Tabora covering Tabora, Katavi and Kigoma regions.

(i) Finance and Accounts Unit

This unit is responsible for managing the financial resources by ensuring maintenance of proper books of accounts and advising Director General on proper use of Authority's resources. It is also, responsible for implementing annual budget and preparing annual financial statements.

(ii) Internal Audit Unit

This unit is responsible for conducting internal audits and advising on effectiveness of existing internal financial controls and performance of the Authority. It is also, responsible for preparing and implementing annual audit plans; coordinating audit programs for internal and external audits.

(iii) Procurement Management Unit

This unit is responsible for provision of technical assistance and support services in the area of procurement and disposal of assets as stipulated in the Public Procurement Act No. of 2011 (amended 2016) and its regulations of 2013(amended 2016).

(iv) Legal Services Unit

The unit is responsible for advising the Director General on legal matters to ensure that TMDA operates within the legal framework. It provides legal expertise to directorates for drafting regulations and other legal documents pertaining to operations and procedures for handling all operations within the legal framework including investigation and prosecuting cases involving TMDA operations.

(v) Quality and Risk Management Unit

This unit is responsible for coordination and monitoring development, implementation and maintenance of quality management system and risk management throughout the organization.

(vi) Communication and Public Relations Unit

The unit is responsible for effective and efficient discharge of communication and public relations functions of the Authority and its organs to ensure that public awareness is enhanced, and good public image is portrayed.

(vii) Information Communication Technology and statistics

To coordinate preparation and implementation of ICT policy ,ICT strategic plan , ICT guidelines and procedures in line with National ICT policy, Advice management on matters pertaining to policies related to ICT and e-government implementation, Design and maintain ICT infrastructure and application systems, Coordinate provision of technical advice and support to TMDA on ICT data management ,Monitor the use of e-government in TMDA, To coordinate development of ICT Standards for software and hardware acquisition at TMDA, To coordinate development of ICT enterprise ,application network/technology and security architecture ,To coordinate training needs assessment on MIS and ICT and prepare capacity building plan ,Supervise the implementation of risk management pertaining to ICT infrastructure and management information system, To coordinate maintenance of ICT systems(application and infrastructure, TMDA wide and local area network).

2.11.2 Directorate of Laboratory Services

The Directorate is responsible for laboratory analysis of medicines, medical devices, diagnostics and tobacco products for enhancing decision making within the Authority. It supervises chemical, physical and microbiological analysis of regulated products and overseeing testing of regulated products at quality assurance centres and mini-laboratories which are stationed at Zone offices, Referral hospitals and Ports of Entries (POEs).

It is also responsible for calibration and maintenance of laboratory equipment, develop, implement and review laboratory quality policy and maintenance and implementation of laboratory standards as per ISO/IEC 17025:2015. Furthermore, the Directorate implements laboratory Quality Management System (QMS) to maintain the WHO pre-qualification certification, coordinating and conduction of scientific research.

2.11.3 Directorate of Business Support

Provides and enhances good management of resources of the authority to enhance the provision of regulatory services. It is responsible for coordinating the preparation and implementation of the Authority's strategic and business plans and compilation of relevant institutional progress reports in line with overseeing monitoring and evaluation of institutional performance. The Directorate also supervises the recruitment of appropriate human resources and manages staff welfare, health, safety, training, capacity building and development. It manages office facilities, buildings, working tools, security services and station upkeep. It also coordinates and facilitates cooperation with local government authorities, national, regional and international bodies.

2.11.4 Directorate of Human and Veterinary Medicines Control

Regulating the manufacturing, importation, distribution and selling of medicines biocidals and tobacco products, Inspecting manufacturing industries and business premises dealing with medicines biocidals and tobacco products and making sure the standards require are attained, Evaluating and registering medicines, biocidals and tobacco products so as to reach the required standards before marketing authorization, Issuance of business permit for premises dealing with medicines biocidals and tobacco products, assessing the quality safety and efficacy of controlled drugs. Conducting pharmacovigilance of medical products and vigilance of biocidals and tobacco products circulating on the market, promoting rational use of medicines biocidals and tobacco products and to ensure that tobacco products circulating in market are appropriate for the protection of public health.

2.11.5 Directorate of Medical Device and diagnostics Control

To oversee assessment for performance of medical devices, diagnostics and laboratory equipment prior to marketing authorization, to coordinate quality audits of domestic and foreign manufacturing premises of medical devices and diagnostics oversee issuance of import export permits of medical devices, diagnostics laboratory equipment's blood and blood products, To monitor field safety updates on the performance and use of medical device and diagnostics, To supervise applied research undertaking on regulatory functions related to medical devices diagnostics and laboratory equipment supervise evaluation of the quality, safety and efficacy of blood and blood products and to supervise hemo vigilance activities for blood and blood products, To foster cooperation with regional and international bodies including harmonization initiatives related to medical devices and diagnostics.

2.12 FINANCIAL PERFORMANCE FOR THE YEAR 2023/24

For the Financial year ended 30 June 2024, Revenue earned from internal sources (fees and charges and other income) increased by 3% from TZS 38.41 billion (2022/23) to TZS 40.51 billion (2023/24) due to enhanced controls over collection of revenue, domestic and international business growth, conducive investment environment, and strengthened controls at ports of entries.

Donors' Grants carried forward from financial year 2022/23 was TZS 2.52 billion, amount received was TZS 1.38 billion and a total of TZS 3.65 billion utilized during the year under review. Un-utilized fund of TZS 0.25 billion was carried forward. Government grants in respect of Personal emoluments were TZS 5.13 billion in 2023/24 from TZS 4.16 billion in 2022/23

2.13 SOLVENCY

The Board confirms that applicable accounting standards have been followed and that the financial statements have been prepared on a going concern basis. The Board has reasonable expectation that the Authority has adequate resources to continue in operational existence for the foreseeable future.

2.14 PREJUDICIAL ISSUES

During the Financial year ended 30 June 2024 there were no prejudicial issues.

2.15 STATEMENT OF SERVICE PERFORMANCE INFORMATION

The statement of service performance information is intended to provide insight into the operations of the Authority for the financial year 2023/24 and enable users to assess the extent to which Those Charged with Governance have been able to use the available resources in achieving targets which were set for that financial year. The targets were derived from the Authority's Five Years Corporate Strategic Plan 2021/22 - 2025/26. Hence, attainment of the targets is a step towards achieving the Authority's strategic objectives.

Table 7: Service performance Information

Input:	The financial, human, and material resources used during the completion of an activity. Inputs are frequently measured in terms of financial costs.
Objective:	A broad statement of what is to be achieved and the improvements to be made. An objective describes an intended outcome or impact and summarizes why a series of actions have been undertaken.
Outcome:	The likely or achieved short-term and medium-term effects of an intervention's outputs. A direct, but intermediary change or improvement in the welfare of the customer or beneficiary as a result of the use of a service (or output). Examples include improved health after visiting a dispensary, or increased knowledge after completing school.
Output:	The products, goods and services which result from an intervention; may also include changes (usually of an immediate nature) resulting from the intervention which are relevant to the achievement of outcomes.
Performance:	The degree to which an intervention or an implementer operates according to specific criteria/ standards/guidelines or achieves results in accordance with stated objectives or plans.

Table 8: Authority's Objectives, Targets and Key Performance Indicators

Objective	Target for 2023/24	Key Performance Indicator (KPI)	Implementation Status 30 June 2024
On HIV/AIDS infections and Non-Communicable diseases reduced and supportive services improved	Awareness, care and support on HIV/AIDS and NCDs to TMDA staff provided by June, 2024	90% of staff sensitized on HIV/AIDS	75% of staff were sensitized on HIV/AIDS
		90% of staff sensitized on NCDs	75% of staff were sensitized on NCDs
		100% of staff living with HIV/AIDS and NCDs supported	100% of staff living with HIV/AIDS and NCDs were supported
National Anti-Corruption Strategy effectively implemented and sustained	Anti-corruption Strategy and Good Governance enforced to TMDA staff by June, 2024.	100% of staff sensitized on Anti-Corruption Strategy and Public Service Code of Ethics and Conduct	76% of staff were sensitized on Anti-Corruption Strategy and Public Service Code of Ethics and Conduct
		100% of staff signing declaration of conflict-of-interest forms	100% of staff signed declaration of conflict of interest
		0 areas prone to corruption identified and mitigated	0 areas prone to corruption were identified
	Public Service Code of Ethics and Conduct instilled to staff by June, 2024	100% of new staff signing integrity pledge forms	100% of new staff signed integrity pledge forms
Gender and environmental issues improved	Women staff empowered at all levels by June, 2024;	Number of women trained on leadership and management among senior women staff	Three (3) Senior women staff out of five (5) were trained on leadership and management
	Infrastructures to support physically challenged persons	Infrastructures for physically challenged persons in place at all TMDA buildings	Infrastructures for physically challenged persons are in place in two (2) out of three (3) buildings

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Objective	Target for 2023/24	Key Performance Indicator (KPI)	Implementation Status 30 June 2024
	provided by June, 2024		
	Facilities for handling and disposal of waste and unfit products in place by June, 2024.	Facilities for handling and disposal of waste and unfit products in place	Facilities for handling and disposal of waste and unfit products are available at all TMDA offices
Quality, safety and effectiveness of medicines and biocidal products assured	Premises dealing in medicines and biocidal products inspected by June 2024	100% of received applications for registration of premises for medicines processed within specified time as per CSC	100% of received applications for registration of premises for medicines were processed within specified time as per CSC
		100% of registered outlets for medicines inspected	104% of registered outlets for medicines were inspected
		100% of domestic pharmaceutical manufacturing facilities inspected for GMP	100% of domestic pharmaceutical manufacturing facilities were inspected
		100% of domestic biocidal (antiseptics and disinfectants) manufacturing facilities inspected	100% of domestic biocidal manufacturing facilities were inspected
		100% of overseas pharmaceutical manufacturing facilities inspected for GMP	151% of overseas pharmaceutical manufacturing facilities were inspected
		100% of received import applications processed	100% of received import applications were processed
		100% of received export applications processed	100% of received export applications were processed
		100% of approved consignments inspected at the Ports of Entry (PoEs);	76% of approved consignments were inspected
	Medicines and biocidal products registered by June, 2024	100% of received applications for product registration of human medicines assessed within specified time as per CSC	82% of received applications for product registration of human medicines were assessed within specified time as per CSC
		100% of received applications for product registration of biocidal (antiseptics and disinfectants) assessed within specified time as per CSC	100% of received applications for product registration of biocidal were assessed within specified time as per CSC

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Objective	Target for 2023/24	Key Performance Indicator (KPI)	Implementation Status 30 June 2024
		100% of received applications for registration of veterinary medicines assessed within specified time as per CSC	85% of received applications for registration of veterinary medicines were assessed within specified time as per CSC
		100% of received applications for registration of Herbal medicines assessed within specified time as per CSC	100% of received applications for registration of Herbal medicines were assessed within specified time as per CSC
	Clinical trials approved and inspected by June, 20223	100% of applications for authorization of clinical trials evaluated	100% of applications for authorization of clinical trials were evaluated
		100% of approved clinical trials inspected	90% of approved clinical trials were inspected
		100% of received field safety reports assessed	100% of received field safety reports were assessed
	Quality, safety and effectiveness of medicines and biocidal products assured	100% of received ADR reports, assessed	100% of received ADR reports were assessed
		100% of received ADR reports uploaded to Vigiflow database.	100% of received ADR reports were uploaded to Vigiflow database.
		100% of received AEFIs reports assessed;	100% of received AEFIs reports were assessed;
		100% of received AEFIs reports uploaded to Vigiflow database	100% of received AEFIs reports were uploaded to Vigiflow database
Quality, safety and performance of medical devices and diagnostics assured	Premises dealing in medical devices and diagnostics inspected by June, 2024;	100% of received applications for registration of premises for medical devices and diagnostics processed;	100% of received applications for registration of premises for medical devices and diagnostics were processed
		100% of registered outlets for medical devices and diagnostics inspected;	100% of registered outlets were inspected
	Medical devices and diagnostics registered by June, 2024.	100% of received applications for registration of medical devices assessed	99% of received applications for registration of medical devices were assessed
		100% of received applications for registration of diagnostics assessed	98% of received applications for registration of diagnostics were assessed
	Surveillance and vigilance of medical	Surveillance and vigilance of medical devices and diagnostics products conducted by June, 2024;	103% of planned PMS samples for medical devices were collected;

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Objective	Target for 2023/24	Key Performance Indicator (KPI)	Implementation Status 30 June 2024
	devices and diagnostics conducted by June, 2024;	100% of planned PMS samples for diagnostics collected	70% of planned PMS samples for diagnostics were collected
		100% of domestic medical devices and diagnostics manufacturing facilities inspected for QMS	100% of domestic medical devices and diagnostics manufacturing facilities were inspected
		100% of overseas manufacturing facilities for medical devices and diagnostics inspected for QMS	100% of overseas manufacturing facilities for medical devices and diagnostics were inspected
		100% of received import applications processed	100% of received import applications were processed
		100% of received export applications processed	100% of received export applications were processed
		100% of approved consignments inspected at the PoEs.	73% of approved consignments were inspected at the PoEs.
		100% of received field safety reports assessed	100% of received field safety reports were assessed
Laboratory services improved	TMDA laboratories strengthened by June, 2024;	100% of regulatory samples of medicines tested	100% of regulatory samples of medicines were tested
		100% of regulatory samples for herbal medicines tested	No samples were received
	Samples of medicines, medical devices, diagnostics, tobacco and complementary products tested by June, 2024;	100% of regulatory samples for biocidal tested	100% of regulatory samples for biocidals were tested
		100% of regulatory samples medical devices tested	100% of regulatory samples medical devices were tested
	Laboratories for testing biocidals, herbal medicines and tobacco products designated	100% of regulatory samples of diagnostics tested	100% of regulatory samples of diagnostics were tested
		11 analytical methods accredited for Dar es Salaam laboratory	12 analytical methods were accredited for Dar es Salaam laboratory

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Objective	Target for 2023/24	Key Performance Indicator (KPI)	Implementation Status 30 June 2024
	and operationalized by June, 2024		
	Operational and applied researches on regulatory functions conducted by June, 2024.	100% of received non-regulatory samples from external customers tested	98% of received non-regulatory samples from external customers were tested
		2,740 medicines samples screened at all Quality Assurance (QA) Centres	3,309 medicines samples were screened at all Quality Assurance (QA) Centres
		100% of laboratory equipment calibrated/maintained as per approved schedule.	100% of laboratory equipments were calibrated/maintained as per approved schedule.
Public education strengthened and customer services improved	Communication and Customer Service strategy reviewed and implemented by June, 2024;	Percentage of planned types of IEC materials developed, printed and disseminated	101% of planned types of IEC materials were developed, printed and disseminated
	Public awareness on TMDA functions and customer satisfaction raised by June, 2024;	Percentage of employees sensitized on customer care, core values and code of ethics and conduct	75% of employees were sensitized on customer care, core values and code of ethics and conduct
		Percentage of received customer complaints attended and resolved	100% of received customer complaints were attended and resolved
		Percentage compliance to external Clients' Service Charter	To be determined through Service Delivery Survey (SDS) to be conducted in 2024/25
	Stakeholders' engagement and participation plan developed and	Percentage of received whistle blower alerts and concerns attended and closed.	100% of received whistle blower alerts and concerns were attended and closed.
		99% of planned information updates uploaded on TMDA website	126% of planned information updates were uploaded on TMDA website

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Objective	Target for 2023/24	Key Performance Indicator (KPI)	Implementation Status 30 June 2024
	implemented by June, 2024.	1,500 information updates uploaded on TMDA social media platforms	1,187 information updates were uploaded on TMDA social media platforms
		45,000 followers on TMDA social media platforms	313,986 followers on TMDA social media platforms
		95% of staff sensitized on customer care	100% of staff were sensitized on customer care
		100% of planned TV and radio programmes developed and aired	100% of planned TV and radio programmes were developed and aired
		100% of planned exhibitions participated	100% of planned exhibitions were participated
		100% of planned outreach campaigns conducted	100% of planned outreach campaigns were conducted
		100% of whistle blowers provided with feedback	100% of whistle blowers were provided with feedback
Institutional capacity to deliver regulatory services enhanced	Planning, budgeting and their implementation coordinated by June, 2024;	Percentage implementation of planned work	100% implementation of planned work
	Institutional plans and programmes monitored and evaluated by June, 2024;	Developed M&E framework and reports	M&E framework and reports available
	Financial resources properly managed by June, 2024;	Percentage of projected revenue collected from all sources	95% of projected revenue collected from all sources
		Percentage of projected revenue collected from own source	103% of projected revenue collected from own source
	Annual	Percentage implementation of the	95% implementation of the

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Objective	Target for 2023/24	Key Performance Indicator (KPI)	Implementation Status 30 June 2024
	Procurement Plans developed and implemented by June, 2024;	procurement plan	procurement plan
	Quality and Risk Management Systems improved by June, 2024;	Percentage of staff sensitized on quality risk management	100% of staff sensitized on quality risk management
		Percentage mitigation of identified risks	100% mitigation of identified risks
	Internal Audit plans developed and implemented by June, 2024;	Percentage of planned internal quality audit conducted	100% of planned internal quality audits conducted
	ICT usage enhanced by June, 2024;	Percentage of service processes automated	86% of service processes automated
	Human resources properly managed by June, 2024;	Percentage implementation of the HR plan	100% implementation of the HR plan
	Professional and career development programmes implemented by June, 2024;	Percentage implementation of training programme	92% implementation of training programme

Source: TMDA Strategic Plan (2021/22-2025/26) and Annual Performance Reports.

2.16 RISK MANAGEMENT AND INTERNAL CONTROLS

The Board accepts final responsibility for the risk management and internal control systems of the Authority. It is the task of the Management to ensure that adequate internal financial and operational control systems are developed and maintained on an ongoing basis in order to provide reasonable assurance regarding:

- The effectiveness and efficiency of operations;
- The safeguarding of the Authority's assets;
- Compliance with applicable laws and regulations;
- The reliability of accounting records;

- e. Business sustainability under normal as well as adverse conditions;
- f. Responsible behaviours towards all stakeholders.

The efficiency of any internal control system is dependent on the strict observance of prescribed measures. There is always a risk of non-compliance of such measures by staff. Whilst no system of internal control can provide absolute assurance against misstatement or losses, the Authority system is designed to provide the Board with reasonable assurance that the procedures in place are operating effectively. The Board assessed the internal control system throughout the financial year ended 30th June 2024 and is of the opinion that they met accepted criteria.

2.17 POLITICAL AND CHARITABLE DONATIONS

During the year ended 30th June, 2024, donations were made as part of corporate social responsibility to institutions and charitable organizations to acknowledge the Authority's responsibility to community social needs. During the period under review, the Authority spent TZS-289,770,681 to support a number of social and economic development initiatives implemented throughout the country. The list of beneficiaries on corporate social responsibilities funds for the financial year 2023/24 is provided under Table below:

Table 9: Political and charitable donations

S/N	Beneficiary's Name	Amount (TZS)	Purpose
1.	Ministry of Health	10,000,000	Supporting Public Health programs on in Tanga City
2.	TAPSA and School of Pharmacy - MUHAS	1,800,000	Support of the School of Pharmacy and TAPSA pharma Expo and Walkathon Week 2023
3.	Ministry of Health	6,000,000	To support for conducting commemoration of World AMR Awareness Week (WAAW)
4.	Kijiji cha Kenyamonta	2,000,000	Top support construction of Kenyamonta dispensary
5.	Tanzania Association for Government Communication Officers (TAGCO)	5,000,000	To support of the Annual conference
6.	Tanzania Pharmaceutical Students' association (TAPSA)	3,000,000	To support of The National Pharmacy Week Conference
7.	Drug Control and Enforcement Authority (DCEA)	3,000,000	Support of The National Anti - Drugs week
8.	TAPHATA	1,000,000	To support AGM Meeting
9.	Tanzania Gastroenterology and Endoscopy Society	5,000,000	To Support Scientific Conference
10.	Medical Association of Tanzania	2,000,000	To support AGM meeting
11.	National Institute of Medical Research (NIMR)	11,000,000	To support Traditional Medicines Scientific Conference
12.	Pharmaceutical Society of Tanzania	5,000,000	To support AGM meeting
13.	REHAB Health	3,000,000	To support Rehabilitation Summit Meeting

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

S/N	Beneficiary's Name	Amount (TZS)	Purpose
14.	Maafa PMO office	15,000,000	To support the victims of the Hanang disaster
15.	RAS Kilimanjaro	3,000,000	To support Uhuru Torch Ceremony
16.	Ministry of Health	1,050,000	To support different interventions under Ministry of Health
17.	Prison dispensaries	212,920,681	
Total		289,770,681	

Also, during the year under review, medicines valued at TZS 209,273,101 and medical device products valued at TZS 3,647,580 which were confiscated from the market due to non-compliance with laws and regulations, were donated to various prison dispensaries across the country.

2.18 PRINCIPAL RISKS, UNCERTAINTIES AND OPPORTUNITIES

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

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

2.18.1 Principal Risks and Uncertainties

Table 10: Key Authority's Risks, Impacts and Mitigation

S/N	Category	Risk and Impact	Mitigation
1	Strategic Risks: These are risks that could obstruct TMDA from achieving its objectives.	Leakage of TMDA information. <u>Impact:</u> <ol style="list-style-type: none"> 1. Loss of confidentiality 2. Institutional bad reputation 3. Loss of customers' confidence 4. Loss of current and future clients 	TMDA regularly conducts awareness trainings on Document and Records Management. Conflict of interest and confidentiality policy is enforced to all TMDA staff, external experts, members of the committees, researchers and filed students. Biometric and Key card-controlled access has been affected in TMDA HQ premises. E-office is also used to handle files and other correspondences. Staff are trained on code of ethics, records management and TMDA communication guidelines to transferred staff, interns, researchers and field students.
		Gender imbalanced decisions. <u>Impact:</u> <ol style="list-style-type: none"> 1. Gender biased decisions 2. Failure to comply with requirements 	The Authority developed the gender mainstreaming strategy. The Mentorship guidelines is also in place. Gender inclusion in the Management has also been implemented effectively including

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

S/N	Category	Risk and Impact	Mitigation
		<p>of National Strategy for Gender Development</p> <p>3.Reduced staff morale</p> <p>4.Less attraction of physically challenged persons to seek services and opportunities rendered by TMDA</p>	<p>at zone offices.</p>
		<p>Underperformance, delays or failure of TMDA projects</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Loss of time and financial resources 2. Impaired business services 3. Failure to achieve strategic objectives 4. Disruption/incomplete/failure of project 5. Qualified audit reports 	<p>TMDA project are implemented and highest consideration is on the compliance to the procurement law and its regulations. For all project implemented at TMDA, the Authority has appointed focal persons to oversee operations of such projects.</p>
		<p>Failure of the MAB to execute its functions effectively.</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Under achievement of institutional objectives 2. Noncompliance to Good Governance Practices 3. Qualified audit report 4. Tarnishing image 5. Dissolution of the board and management 	<p>The MAB is adequately advising the minister in compliance with policies and laws. The MAB also is well equipped with key TMDA documents and regular trainings on governance.</p>
2	Operational Risks: These are risks of losses to TMDA due to failed processes or systems.	<p>Circulation of falsified, substandard and unauthorized products on the market.</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Public health compromised 2. Institutional bad reputation 3. Failure to meet the legal mandate of the organization 4. Loss of revenue 	<p>TMDA regularly receives new staff via recruitment or transfer from other public institution to address staff gap as per HRP. TMDA conducts stakeholder sensitization meetings to provide awareness on TMDA laws, regulations and guidelines. TMDA also enforces Good Storage and Distribution Practices Regulations. TMDA collaborates with other law enforcement agencies to address these risks.</p> <p>Trainings on intelligence gathering is regularly provided to inspectors. Ongoing trainings on evaluation of complex medical products and capacity building for analysts in a quality control laboratory is also implemented. The AMA treaty has also been ratified. Risk inspection approach is implemented in</p>

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

S/N	Category	Risk and Impact	Mitigation
			<p>GMP, GSDP, GCP and GVeP Inspections to objectively attains the set targets. Large equipment/medical devices PMS program and Special risk-based PMS program is also implemented to further monitor the quality of the medical products in the market.</p> <p>TMDA has signed MoU with Pharmacy Council of Tanzania to collaborate in regulations of medical products.</p>
		<p>Missing of safety signals of products circulating on the market.</p> <p>Impact:</p> <ol style="list-style-type: none"> 1. Loss of life 2. Chronic disease conditions 3. Low productivity 4. Disabilities 5. Financial loss 6. Institutional bad reputations 7. Prolonged hospitalizations which may lead to increased costs 	<p>The Authority conducts regular sensitization to Health care workers, Importers and distributors and general public on reporting of adverse events reaction or incidents. The Authority has introduced Vigiglow and developed SQRT for collection of ADRs, AEFI, incidents and AEs reports.</p> <p>The Authority enforces the Pharmacovigilance Regulations including requiring Marketing Authorization Holders to appoint Qualified Persons for Pharmacovigilance (QPPV).</p> <p>TMDA has also coordinated the appointment and facilitate the ongoing training of district investigations teams across the country.</p>
		<p>Failure to manage Authority's assets effectively.</p> <p>Impact:</p> <ol style="list-style-type: none"> 1. Under/over stating the Authority's property value and financial statements 2. Assets' misappropriation and misuse 3. Underutilization of assets 4. Assets' duplication 5. Financial loss 6. Qualified audit report 	<p>TMDA is conducting timely verification of assets both fixed and inventories. TMDA also updates assets register and this information is part of progress reports.</p> <p>Estate management guidelines has also been developed and currently implemented.</p>
		<p>Loss of information integrity.</p> <p>Impact:</p> <ol style="list-style-type: none"> 1. Incorrect transactions 2. Wrong reports due to wrong data/information in the system 3. Loss of original data 4. Qualified audit reports 	<p>The Authority has been providing training to ICT staff on malware attacks and other non-ICT staff are trained on usage of modules of Regulatory Information Management System. ICT policy has been developed and TMDA staff are regularly sensitized about it.</p> <p>The Authority now has developed Validation Master Plan for TMDA</p>

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

S/N	Category	Risk and Impact	Mitigation
			computerized system.
		<p>Unavailability of ICT Services.</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Interruption in service delivery 2. Financial loss 3. Loss of data 4. Impaired Business Continuity 	<p>The Authority has revised the ICT Disaster Recovery Plan and aligned with the BCP.</p> <p>Backup power system has been installed to support Servers in case of power shortage. Maintenance of TMDA generators are regularly conducted as per maintenance schedule.</p>
		<p>Fire outbreak</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Interruption in service delivery 2. Damage and loss of properties, documents and records. 3. Injury or loss of lives 4. Impaired business continuity 	<p>All TMDA premises have been inspected and certified by OSHA. Periodic maintenance services for fire detection, suppression and fighting systems are conducted at TMDA buildings in Mwanza, Dar es Salaam and Dodoma.</p> <p>Staff are provided with fire drilling exercise in each financial year.</p>
		<p>Low public awareness on TMDA functions</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Non-adherence to legal requirements 2. Institutional bad reputation 3. Panic and public health endangered 	<p>Adequate financial resources have been allocated to support the TMDA programs for TV and radio. TMDA has also conducted end term evaluation of its Communication and Public Education Strategy.</p>
		<p>Existence of incompetent or unethical staff</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Bad reputation or image. 2. Compromised quality of services 3. Compromised TMDA culture 4. Failure to achieve objectives 5. Financial loss 	<p>Newly recruited and transferred staff are oriented upon joining TMDA by HRA Unit and later by the respective offices. Probation is implemented and feedback communicated to staff for improvement</p>
		<p>Staff turnover</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Under achievement of institutional objectives. 2. Replacement cost. 3. Burden to remaining workforce 4. Competence loss 5. Tarnishing image 6. Failure to attract more 	<p>TMDA has reviewed Internal Financial Regulations 2012 to improve the incentives and welfare for staff. Management also is currently on process of supporting Trade union (TUGHE) to develop Mkataba wa Hali Bora as part of improving staff welfares. Staff are given trainings as per training program following thoroughly and inclusive training needs assessment. 360 feedback for leaders is regularly conducted and</p>

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

S/N	Category	Risk and Impact	Mitigation
		<p>employees from labour market</p> <p>7. Brain drainage</p>	<p>timely staff promotion is also implemented.</p>
		<p>Loss of Product samples, exhibits or dossiers</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Delays or failure in making regulatory decisions 2. Tarnish institutional image 3. Public safety compromised 4. Financial loss due to compensation 5. Discredit of evidence 	<p>Staff are regularly trained on how to handle product samples as well as exhibits.</p> <p>The storage rooms for products samples and exhibits are under lock and key with a register of products under TMDA custody.</p>
		<p>Staff injury and occupational health hazards</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Loss of life or permanent disability 2. Loss of work force 3. Financial loss for uncovered insurance 4. Low productivity 5. Bad reputation 	<p>TMDA has sensitized staff on the role and benefits of workers Compensation Fund. Appropriate chairs are provided to staff including certification of TMDA premises (working places) by OSHA. Staff are periodically sensitised on wellness including non-communicable diseases. In addition to that TMDA has provided subscription to staff for gym activities. TMDA sport clubs are also supported to enhance promotion of physical fitness to all staff members.</p>
		<p>Approval of non-existing or non GMP compliant manufacturing facilities</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Public health compromised 2. Institutional bad reputation 3. Loss of public confidence 4. Loss of revenue 	<p>TMDA has trained GMP inspectors on desk review and visual inspection. TMDA has also resumed with GMP Inspection of local and overseas manufacturing facilities.</p>
3	<p>Financial and Systems Risks:</p> <p>This is any circumstance if materialized, may compromise</p>	<p>Lack of sufficient revenues to sustain TMDA activities.</p> <p><u>Impact:</u></p> <ol style="list-style-type: none"> 1. Failure to implement strategic objectives 2. Loss of national and international credibility 3. Institutional instability 4. Decreased staff morale 	<p>As part of mitigation the Authority has reviewed and published the Fees and charges regulations.</p> <p>The Authority has also reviewed HS codes for all medical devices and are included in TeWS - Single window to ensure all devices imported into the country are tracked effectively.</p> <p>Each Zone Offices has appointed staff</p>

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

S/N	Category	Risk and Impact	Mitigation
	the financial control systems of TMDA.		who is responsible for making follow up on outstanding debts and invoices.
4	Compliance Risks: These are risks which may compromise TMDA compliance to various laws and regulations.	Failure to implement annual procurement plan. <u>Impact:</u> <ol style="list-style-type: none"> 1. Loss of time and financial resources 2. Litigations 3. Incomplete projects 4. Failure to deliver services 	TMDA has revised procedures for finance and accounts to align with current financial system of MUSE which is critical component in procurement process. The Authority has developed procedure for management of contract and has appointed contract managers for all ongoing contracts.
		Not sustaining ISO certifications, WHO Maturity Level 3 and Prequalification <u>Impact:</u> <ol style="list-style-type: none"> 1. Loss of international recognition 2. Loss of reputation 3. Inconsistent service delivery and decreased customer satisfaction 4. Financial loss 	The Authority regularly conducts QMS awareness trainings to TMDA staff at least once per year. TMDA has conducted self-assessment of medicines regulatory system using WHO - Global Benchmarking Tool. In addition to that TMDA in collaboration with Paul-Ehrlich-Institut (PEI) is also conducting benchmarking of blood and blood products regulatory system.
		Non-compliance to Legal requirements. <u>Impact:</u> <ol style="list-style-type: none"> 1. Qualified audit reports. 2. Litigations against TMDA. 3. Financial loss. 4. Impaired reputation. 5. Public health compromised. 	TMDA compliance to laws and regulations is now a permanent agenda in MAB meetings. TMDA staff are regularly sensitized on the code of ethics and law, regulations and guidelines to enhance compliance for TMDA operations.

Source: TMDA Institutional Risk Registers.

2.19 EMPLOYEES' WELFARE

2.19.1 Management and Employees' Relationship

A harmonious relationship existed between employees, trade union and the management for the financial year 2023/24. The Authority is an equal opportunity employer. To this end, TMDA gives equal access to employment opportunities and ensures that the right person is appointed to a given position free from discrimination of any kind and without regard to factors like gender, marital status, nepotism, religion, and disability. The emphasis on equal opportunity and non-discrimination highlights the organization's commitment to fairness and inclusivity. The approach not only fosters good relationship among employees, trade unions and management but also enhances overall productivity and morale.

2.19.2 Training

During the financial year ended 30th June, 2024, the Authority's budget for Staff training amounted to TZS 956,260,521.00 as compared to TZS 917,586,831 for the preceding year. The objective is to improve knowledge and skills of existing and newly recruited staff. Therefore, training programs are being developed to ensure that employees at all levels have the right knowledge and skills to enable them to discharge their duties in a professional manner.

2.19.3 Medical Services

Employees and their families are provided with medical services under the NHIF where both the employee and the employer contribute 3% each of the employee's monthly salary to the NHIF (total monthly contribution is 6%). During the financial year ended 30 June, 2024, TMDA staff were deducted a total of TZS 277,013,220.00 for NHIF contribution as compared to TZS 259,666,080.00 for previous year.

In addition, the Authority entered in agreement with NHIF to pay TZS 253,000,000.00 as a supplementary package to cover for any medical expenses not covered by normal NHIF scheme.

2.19.4 Financial Assistance to Staff

The Management guarantees employees to take loans from financial institutions for the purpose of promoting their welfare. Also, the Management has facilitated the establishment of the Staff Loans Scheme and TMDA Workers' Savings and Credit Co-operative Society which provides loans to employees hence assisting them to solve their financial problems.

2.19.5 Persons with Disabilities

Applications for employment by disabled persons are always considered, bearing in mind the aptitude of the applicant concerned. In the event of staff members becoming disabled, every effort is made to ensure that their employment with the Authority continues and appropriate training is arranged. It is the policy of the Authority that training, career development and promotion of disabled persons should, as far as possible be identical to that of other employees.

2.19.6 Employees Benefit Plan

During the financial year that ended 30 June, 2024, TMDA contributed to PSSSF as 5% employee contributions for the purpose of ensuring that employees are able to benefit from such scheme after their retirement. During the year under review total contributions increased to TZS 461,688,700.00 (2023/24) as compared to TZS 401,514,300.00 (2022/23) due to fact that under the year of review more employee joined the Authority.

2.20 GENDER

As at 30 June, 2024 the Authority had 349 permanent employees and 1 contract employees as compared to 311 permanent and 41 temporary employees as at 30th June, 2023. Distribution of male and female employees for the two financial years is as indicated below:

Table 11: Gender

Gender	2023/24		2022/23	
	No.	%	No.	%
Male	217	62	225	64
Female	133	38	127	36
Total	350	100	352	100

2.21 ENVIRONMENTAL CONTROL PROGRAMME

The Authority continued to enforce safety procedures and measures for disposal of unfit medicines, medical devices and diagnostics by providing technical assistance to both government entities and individual persons required to dispose such products.

2.22 RELATED PARTY TRANSACTIONS

A related party transaction involves the transfer of resources, services, or obligations between parties that have a close relationship, irrespective of whether a price is charged. Related parties include individuals who have significant influence or authority over financial and operational decisions. In the context of an Authority, members of the Management and Advisory Board (MAB) and Key Management Personnel, such as Directors, Heads of Units, and Managers, are considered related parties. This relationship is essential for understanding potential conflicts of interest and ensuring transparency in financial reporting.

2.23 STATEMENT OF COMPLIANCE

These financial statements have been prepared by the management of the TMDA in accordance with the requirements of IPSAS accrual basis of accounting.

MAB confirms that relevant accounting policies have been used and applied consistently, and reasonable and prudent judgment and estimates have been made in the preparation of the financial statements for the year ended 30 June 2024. The board also confirm that IPSAS has been followed and that the financial statements have been prepared on the going concern basis to the best of the board knowledge, the internal control system has operated adequately throughout the reporting period and the accounting and underlying records provide a reasonable basis for the preparation of the financial statements for the year ended 30 June 2024.

The statement indicates that MAB is responsible for ensuring the integrity and compliance of the Financial Statements with IPSAS on an accrual basis. Additionally, it asserts that the board has no reason to believe that TMDA will not continue to operate as a going concern for at least the next twelve months. This suggests confidence in TMDA's financial health and operational viability.


2.24 AUDITORS

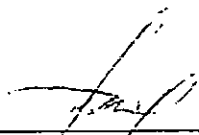
The Controller and Auditor General is the statutory auditor of Tanzania Medicines and Medical Devices Authority (TMDA) by virtue of the provisions of Article 143 of the Constitution of the United Republic of Tanzania and Section 10 of the Public Audit Act No.11 of 2008. However, in accordance to section 33 (1) of the Public Audit Act (PAA), M/s Forvis Mazars was authorized to carry out audit of the TMDA for the year ended 30th June, 2024.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

BY ORDER OF THE BOARD

Approved by the Ministerial Advisory Board (MAB) on _____ and signed on its behalf by:


Eric F. Shitindi
CHAIRPERSON OF THE BOARD


Dr. Adam M. Fimbo
DIRECTOR GENERAL

Date 12/3/2025

3.0 STATEMENT OF RESPONSIBILITY BY THOSE CHARGED WITH GOVERNANCE

These financial statements have been prepared by the management of the TMDA in accordance with the requirements of IPSAS.

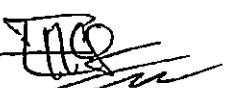
MAB is responsible for establishing and maintaining a system of effective internal control designed to give reasonable assurance that the transactions recorded in the financial statements are within the statutory requirement and that they contain the receipts and utilization of resources by the Authority.

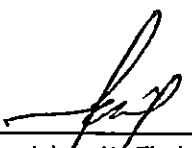
MAB is responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the Authority, and which enable them to ensure that the financial statements comply with the Executive Agencies Act, Cap 245. They are also responsible for safeguarding the assets of TMDA and hence for taking reasonable steps for the prevention and detection of fraud, error and other irregularities.

MAB confirms that relevant accounting policies have been used and applied consistently, and reasonable and prudent judgment and estimates have been made in the preparation of the financial statements for the year ended 30th June, 2024. The board also confirm that IPSAS has been followed and that the financial statements have been prepared on the going concern basis to the best of the board knowledge, the internal control system has operated adequately throughout the reporting period and the accounting and underlying records provide a reasonable basis for the preparation of the financial statements for the year ended 30th June, 2024.

MAB accepts responsibility for the integrity of the Financial Statements, the information they contain and their compliance with IPSAS. Nothing has come to the attention of the board to indicate that TMDA will not remain a going concern for at least the next twelve months from the date of the Statement.

Approved by the Board on _____ and signed on its behalf by:


Eric F. Shitindi
CHAIRPERSON OF THE BOARD


Dr. Adam M. Fimbo
DIRECTOR GENERAL

Date.....12/3/2025.....

4.0 DECLARATION OF THE HEAD OF FINANCE

The National Board of Accountants and Auditors (NBAA) according to the power conferred under the Auditors and Accountants (Registration) Act. CAP 286, requires financial statements to be accompanied with a declaration issued by the Head of Finance responsible for the preparation of financial statements of the entity concerned.

It is the duty of a Professional Accountant to assist the Board of Directors/Governing Body/Management to discharge the responsibility of preparing financial statements of an entity showing true and fair view of the entity's position and performance in accordance with applicable International Accounting Standards and statutory financial reporting requirements. Full legal responsibility for the preparation of financial statements rests with the Board of Directors/Governing Body as under Directors Responsibility statement on an earlier page.

I, CPA. Adam John Kimetelo being the Chief Accountant of TMDA, hereby, acknowledges my responsibility of ensuring that Financial Statements for the year ended 30th June, 2024 have been prepared in compliance with applicable Accounting Standards and Statutory Requirements.

I thus, confirm that the Financial Statements give a true and fair view position of TMDA as on that date and that they have been prepared based on properly maintained financial records.

SIGNED BY: CPA. ADAM JOHN KIMTELO

SIGNATURE: 

POSITION: CHIEF ACCOUNTANT


NBAA MEMBERSHIP NUMBER: ACPA 5315

DATE: 12 MARCH, 2025

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

5.2 STATEMENT OF FINANCIAL PERFORMANCE FOR THE YEAR ENDED 30 JUNE 2024

DETAILS	Note	2023/24 TZS	2022/23 TZS Restated
REVENUE			
Revenue			
Revenue from Exchange Transactions	7	19,364,317,463	20,035,668,920
Levies	8	365,915,987	384,899,820
Fees, Fines, Penalties and Forfeits	9	15,292,341,386	14,131,055,056
Fair value Gains on Assets and Liabilities	10	237,656,806	189,761,629
Other Revenue	11	5,254,306,325	3,970,571,721
Revenue Grants	12	8,171,969,062	4,304,036,764
Subvention from other Government entities	13	-	312,059,979
TOTAL REVENUE		48,686,507,029	43,328,053,889
EXPENSES AND TRANSFERS			
Expenses			
Wages, Salaries and Employee Benefits	14	20,436,348,000	16,173,312,771
Use of Goods and Service	15	18,172,749,907	15,755,705,126
Maintenance Expenses	16	1,196,209,134	1,060,507,701
Loss on Disposal of Assets	17	9,479,276	10,038,341
Other Expenses	18	1,196,831,807	1,186,900,480
Expected Credit Loss	19	-	6,583,904
Social Benefits	20	311,352,045	289,883,516
Depreciation of Investment Property	27	32,322,332	30,749,662
Depreciation of Property, Plant and Equipment	28	2,993,011,613	2,256,610,305
Impairment of Intangible Assets	29	63,854,000	63,854,000
Total Expenses		44,412,158,114	36,834,145,806
Other Transfer			
Contribution to CF (15%)	21	5,902,166,689	5,320,594,355
Capital redemption	21	2,224,458,329	400,000,000
Total Transfers		8,126,625,018	5,720,594,355
TOTAL EXPENSES AND TRANSFERS		52,538,783,132	42,554,740,161
Surplus /(Deficit) for the period		(3,852,276,103)	773,313,728


Eric F. Shitindi
CHAIRPERSON OF THE BOARD


Dr. Adam M. Fimbo
DIRECTOR GENERAL

DATE: 12/3/2025

DATE: 12/3/2025


TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

5.0 FINANCIAL STATEMENTS

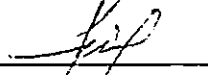
5.1 STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2024

DETAILS	Note	2023/24	2022/23
ASSETS		TZS	TZS
Current Asset			Restated
Cash and Cash Equivalents	22	4,254,392,426	8,479,848,325
Receivables	23	677,055,180	66,986,487
Loan receivables	24	1,640,078,354	2,513,177,439
Prepayments	25	384,024,277	495,154,744
Inventories	26	2,271,548,739	2,583,610,523
Total Current Asset		9,227,098,976	14,138,777,518
Non-Current Assets			
Investment Property	27	1,405,883,191	1,359,572,023
Property, Plant and Equipment	28	31,416,754,473	32,924,580,727
Intangible Assets	29	383,123,999	446,977,999
Work In Progress	30	2,126,264,728	19,868,000
Total Non-Current Assets		35,332,026,391	34,750,998,749
TOTAL ASSETS		44,559,125,367	48,889,776,267
LIABILITIES			
Current Liabilities			
Payables and Accruals	31	1,465,274,820	563,519,180
Provisions	32	204,800,000	204,800,000
Deferred Income	33	1,646,940,887	3,027,071,326
Total Current Liabilities		3,317,015,707	3,795,390,506
NET ASSETS		41,242,109,660	45,094,385,761
NET ASSETS/EQUITY			
Capital Contributed by:			
Taxpayers/Share Capital		1,139,933,337	1,139,933,337
Accumulated Surpluses / Deficits		40,102,176,323	43,954,452,424
TOTAL NET ASSETS/EQUITY		41,242,109,660	45,094,385,761

Notes form part of the financial statements which were approved by the Board and signed on its behalf:


Eric F. Shitindi
CHAIRPERSON OF THE BOARD

DATE: 12/3/2025



Dr. Adam M. Fimbo
DIRECTOR GENERAL

DATE: 12/3/2025

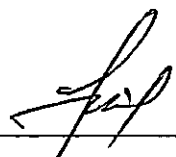
TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

5.3 STATEMENT OF CHANGES IN NET ASSET AND EQUITY FOR THE PERIOD ENDED 30 JUNE 2024

	Taxpayer's Fund TZS	Accumulated Surplus/(Deficit) TZS	Total TZS
YEAR ENDED 30 JUNE 2024			
Opening Balance as at 01 July 2023	1,139,933,337	43,954,452,426	45,094,385,763
Deficit for the Year	-	(3,852,276,103)	(3,852,276,103)
Balance as at 30 June 2024	1,139,933,337	40,102,176,323	41,242,109,660
YEAR ENDED 30 JUNE 2023			
Opening Balance as at 01 July 2022	1,139,933,337	43,283,153,366	44,423,086,703
Capital Redemption	-	(400,000,000)	(400,000,000)
Restated Overcharged impairment	-	297,985,332	297,985,332
Restated Surplus for the Year	-	773,313,728	773,313,728
Restated Balance as at 30 June 2023	1,139,933,337	43,954,452,426	45,094,385,763


Eric F. Shitindi
CHAIRPERSON OF THE BOARD

DATE: 12/3/2025



Dr. Adam M. Fimbo
DIRECTOR GENERAL

DATE: 12/3/2025


TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

5.4 CASH FLOW STATEMENT FOR THE PERIOD ENDED 30 JUNE 2024

		2023/24 TZS	2022/23 TZS
CASH FLOW FROM OPERATING ACTIVITIES			
RECEIPTS	Notes		
Revenue Grants	43	8,171,969,062	4,304,036,764
Revenue from Exchange Transactions	39	17,984,187,025	22,191,722,154
Other Revenue	42	5,254,306,325	3,970,571,721
Levies	41	365,915,987	384,899,820
Fees, Fines, Penalties and Forfeits	40	14,772,081,044	14,129,702,076
Loan repayment	44	1,603,432,750	1,128,487,090
Realise gain on exchange rates	10	187,230,144	163,176,544
Total Receipts		48,339,122,337	46,272,596,169
PAYMENTS			
Wages, Salaries and Employee Benefits	45	(20,477,528,000)	(16,070,350,270)
Use of Goods and Service	46	(16,892,571,148)	(16,570,251,862)
Social Benefits	49	(311,352,045)	(289,883,516)
Contribution to CF (15%)	50	(8,126,625,017)	(5,720,594,355)
Other Expenses	48	(1,263,330,307)	(1,270,380,267)
Maintenance Expenses	47	(1,196,209,134)	(1,060,507,702)
Loan disbursed	44	(721,100,000)	(499,502,472)
Total Payments		(48,988,715,651)	(41,481,470,444)
NET CASH FLOW FROM OPERATING ACTIVITIES		(649,593,314)	4,791,125,725
CASH FLOW FROM INVESTING ACTIVITIES			
Investing Activities			
Proceed from sale of PPE	52	26,232,074	
Payment for Work in Progress	38	(2,230,911,878)	(364,858,098)
Advance Payment for Acquisition of PPE	37	(238,317,998)	(248,749,287)
Acquisition of PPE	51	(1,055,285,359)	(828,311,119)
Acquisition of Investment Property	27	(78,633,500)	
NET CASH FLOW FROM INVESTING ACTIVITIES		(3,576,916,661)	(1,441,918,504)
Net change in cash and cash equivalents		(4,226,509,975)	3,349,207,221
Cash and cash equivalent at beginning of period		8,482,215,923	5,133,008,702
Cash and cash equivalent at end of period		4,255,705,948	8,482,215,923


Eric F. Shitindi
CHAIRPERSON OF THE BOARD

DATE: 12/3/2025


Dr. Adam M. Fimbo
DIRECTOR GENERAL

DATE: 12/3/2025


TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

5.5 STATEMENT OF THE COMPARISON BUDGET AND ACTUAL FOR THE YEAR ENDED 30 JUNE 2024

	Original Budget	Reallocations/ Adjustments	Final Budget (B)	Actual Amount on Comparison Basis (A)	Different Final Budget & Actual (B- A)	Notes
	TZS	TZS	TZS	TZS	TZS	
RECEIPTS						
Subvention from other Government entities (Govt Grants)	10,445,689,234	0	10,445,689,234	8,171,969,062	2,273,720,172	a
Revenue from Exchange Transactions	18,574,578,710	0	18,574,578,710	17,984,187,025	590,391,685	b
Other Revenue	5,000,000,000	0	5,000,000,000	5,254,306,325	(254,306,325)	c
Levies	346,599,608	0	346,599,608	365,915,987	(19,316,379)	d
Fees, Fines, Penalties and Forfeits	15,080,000,000	0	15,080,000,000	14,772,081,044	307,918,956	e
Total Receipts	49,446,867,552	0	49,446,867,552	46,548,459,443	2,898,408,109	
PAYMENTS						
Wages, Salaries and Employee Benefits	21,110,228,852	983,509,374	22,093,738,226	20,477,528,000	1,616,210,226	f
Use of Goods and Service	16,388,537,080	(546,268,785)	15,842,268,295	16,892,571,148	(1,050,302,853)	g
Social Benefits	300,000,000	(30,000,000)	270,000,000	311,352,045	(41,352,045)	h
Other Transfers	5,902,166,689	0	5,902,166,689	8,126,625,017	(2,224,458,328)	i
Other Expenses	2,106,230,760	(145,152,480)	1,961,078,280	1,263,330,307	697,747,973	j
Maintenance Expenses	1,691,968,237	(159,254,025)	1,532,714,212	1,196,209,134	336,505,078	k
Proceed from sale of PPE	0	0	0	(26,232,073)	26,232,073	l
Payment for Work in Progress	2,106,396,728	0	2,106,396,728	2,230,911,878	(124,515,150)	
Acquisition of PPE	1,625,366,500	(458,000,000)	1,167,366,500	1,055,285,359	112,081,141	m
Prepayment of assets	0	0	0	238,317,998	(238,317,998)	
Acquisition of Investment Property	78,633,500	0	78,633,500	78,633,500	0	
Total Payment	51,309,528,346	(355,165,916)	50,954,362,430	51,844,532,313	(890,169,883)	
Net Receipts/Payments	(1,862,660,794)	355,165,916	(1,507,494,878)	(5,296,072,870)	3,788,577,992	


Eric F. Shitindi
CHAIRPERSON OF THE BOARD

DATE: 12/3/2025


Dr. Adam M. Fimbo
DIRECTOR GENERAL

DATE: 12/3/2025

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

EXPLANATION OF VARIANCES OF FINAL BUDGET VS ACTUAL AMOUNTS

- a. A Variance of TZS 2.27 billion shows that the government and donor grants received less than the budgeted amount.
- b. A Variance of TZS 0.59 billion implies Authority collected more than projected revenue from exchange transactions.
- c. A variance of TZS 0.25 billion explain the change of revenue GFS code compared to previous year.
- d. A variance of TZS 0.02billion shows that Authority collected more revies revenue that its annual projections.
- e. A variance of TZS 0.03 billion implies Authority collected more than projected revenue from fees and charges.
- f. A variance of TZS 1.62 billion indicates decrease of personal emoluments expenses due cut of unnecessary staff expenses. -
- g. A variance of TZS 1.05 billion shows increment in Use of Goods due to change of budgetary GFS code compared to previous year.
- h. The variance of TZS 0.04 billion shows more expenses in social benefits due to the increase which has been attributed by big number of staff who enjoys supplement package.
- i. The variance of TZS 2.22 billion caused by excess capital redemption which was not previously budgeted.
- j. The variance of TZS 0.70 billion explains expenses cut down in operating activities during a year under review.
- k. The variance of TZS 0.34 billion explains expenses cut down in office maintenance activities during a year under review.
- l. The variance of TZS 0.03 refers to proceeds from sale of PPE which was not budgeted earlier.
- m. The variance of 0.12 billion shows more spending in acquisition of PPE than earlier budgeted amount due to increase in construction materials.

6.0 NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2024

6.1 Accounting Policies and Principles

The principal accounting policies adopted by the organization and used in the preparation and presentation of these financial statements are set out below;

6.2 Basis of Accounting

The financial statements have been prepared under the Accrual basis of accounting unless stated otherwise in the accounting policies. The Cash Flow Statement is prepared using direct method while the Statement of Comparison of Budget and Actual Amounts is prepared on a budgetary basis which is cash basis with the actual amounts being presented on comparable basis.

The Authority's financial statements have been prepared in compliance with IPSAS as issued by IPSASB.

The financial statements are presented in Tanzanian Shillings (TZS) which is the functional and reporting currency of the authority.

6.3 Transaction in Other Currencies

The organization earns revenues in Tanzania shillings and in United States Dollars; the majority of its transactions are in Tanzania shillings, so transactions in foreign currencies are converted to Tanzania shillings at the rate of exchange ruling at the date of the transaction. Exchange gains or losses on the translation of the foreign bank account balances at the end of reporting period are recognized in the statement of financial performance in the period in which they arise.

6.4 Comparative Figures

Previous year's balances have been regrouped/reclassified wherever necessary for comparison purposes and enhancement of understanding.

6.5 Financial Assets

Initial Recognition and Measurement

Financial assets within the scope of IPSAS 29 are classified as loans and receivables or held-to-maturity investments as appropriate. The Authority determines the classification of its financial assets at initial recognition. All financial assets are recognized initially at fair value.

The Authority's financial assets include cash and cash equivalents, trade and other receivables, staff loans and other receivables.

Subsequent Measurement

The subsequent measurement of financial assets depends on their classification as follows:

Cash and Cash Equivalents

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Cash and bank balances in the statement of financial position comprise cash at banks and in hand. For the purpose of the cash flow statement, cash and cash equivalents consist of cash and cash equivalents as defined above, net of outstanding bank overdrafts.

Loans and Receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. After initial measurement loans and receivables are carried at amortized cost using the effective interest method less any allowance for impairment.

Staff loans relate to housing and vehicle loans issued to staff of which will be recovered over a period of years. Long term loans advanced to staffs are initially recorded at the face value of the total amount advanced to staffs. Then, the recovery of loans (Loan repayments) from staffs reduces the carrying amount of long-term staff loan. Since the recovery of the staff loan (Cash inflows) are expected to be received during more than one accounting period then the loan term staff loan is classified under the Non-Current Assets. However, the recovery of loans which is expected to be realized during one accounting period shall be reclassified as Current Assets (Receivable).

Provision for Impairment

Provision for impairment of receivables is established when there is objective evidence that the Authority will not be able to collect all amounts due according to the original terms of specific receivables. The loss is charged to the statement of performance for the year in which the event has occurred. Furthermore, a provision in full amount of the debt can be made in case a specific total debt proves unrecoverable (Specific provision).

Derecognizing of Financial Assets

A financial asset (or, where applicable a part of a financial asset or part of a group of similar financial assets) is derecognized when:

- The rights to receive cash flows from the asset have expired;
- The Authority has transferred its rights to receive cash flows from the asset or has assumed obligation to pay the received cash flows in full without material delay to a third party under a 'pass-through' arrangement and either (a) the Authority has transferred substantially all the risks and rewards of the asset, or (b) the Authority has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

Where the Authority has transferred its rights to receive cash flows from an asset and has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the asset is recognized to the extent of the Authority's continuing involvement in the asset. Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Authority could be required to repay.

6.6 Budget information

TMDA prepares its budget on an accrual basis. As such, the budget and the financial statements are already on the same basis and further adjustments are not required to align the financial statements to

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

the budget. The Authority has the option to present this comparison either as a separate additional financial statement or as additional budget columns in the financial statements as required by IPSAS 24 *"Presentation of Budget Information in Financial Statements"*. The Authority has therefore chosen to present the comparison separately in the statement of comparison of budget and actual amounts. The explanations for the variances between budgeted amounts and actual amounts have been indicated below the statement.

6.7 Inventories

Inventories are valued at the lower of cost and current replacement cost determined FIFO method. Provision for impairment is made on the basis of actual costs of stocks found absolute or damaged. When there are objective evidences that the value of inventories is impaired either through damage and/or obsolescence, provision is made to that effect through the statement of performance for the year in which that event occurs.

6.8 Investment Property

Investment property (a part of a building) held to earn rentals or capital appreciations, other than for use in the provision or supply of services or for administrative purposes or sale in the ordinary course of operations is initially measured at its cost (transaction costs are included in the initial recognition). After initial recognition, investment property is subsequently measured a cost model (depreciated cost). However, the Fair value of the investment property is still disclosed.

6.9 Property, Plant, and Equipment

Property, Plant and Equipment are initially measured and recorded at cost less accumulated depreciation. After Initial Recognition, Property, Plant and Equipment's are carried at cost amount less any accumulated depreciation. Repair and maintenance expenditures are charged through statement of financial performance and major improvements and replacements that extend the useful life of an asset are capitalized. When each major inspection is performed, its cost is recognized in the carrying amount of asset as a replacement if the recognition criteria are satisfied. The capitalization threshold for items of PPE is TZS 100,000. PPE are depreciated on a straight-line method over their estimated useful lives.

The principal annual rates used for this purpose are:

Class of Assets	Percentage (%)
Buildings	2%
Plant and machinery	7%
Furniture, fittings and equipment	10%
Motor vehicles	10%
Computers	12.5%

Land is not depreciated because its value keeps on appreciating.

IPSAS 17 require useful life of an asset to be reviewed at least at each annual reporting date and, if expectations differ from previous estimates, the change(s) should be accounted for as a change in an

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

accounting estimate in accordance with IPSAS 3, "Accounting Policies, Changes in Accounting Estimates and Errors.

The assets' residual values, useful lives and depreciation method are reviewed at the end of each reporting period in accordance with the provisions of IPSA 17, *Property, Plant and Equipment* and adjusted prospectively in accordance to provisions of IPSA 3, *Accounting Policies, Changes in Accounting Estimates and Errors*, if appropriate. In addition, the Authority stops charging depreciation on an asset when carrying amount equals its residual value.

6.10 Work in Progress

Work in progress for TMDA represents the extent to which cost of work has been incurred as at 30 June 2024 in connection with the extension of office building in Dodoma. The construction is still on progress and will be available for use after completion and handled to the management. Costs incurred comprise of the consultancy fees for Structural Design, Works' supervision, Building Materials and Labour charges.

6.11 Intangible Assets

Intangible assets acquired are measured on initial recognition at cost. Following initial recognition, intangible assets are carried at devalued amount less any accumulated amortization and any accumulated impairment losses provided its fair value can be measured with reliability. Internally generated intangible assets are capitalized only if all the recognition criteria are met; otherwise, they are expensed to the Statement of Financial Performance in the year in which the expenditure is incurred.

The useful lives of intangible assets are assessed to be finite. Intangible assets with finite live are amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset are reviewed at least at each financial year-end. Changes in the expected useful life or the expected pattern of consumption of future economic benefits embodied in the asset is accounted for by changing the amortization period or method, as appropriate, and treated as changes in accounting estimates. The amortization expense on intangible assets is recognized in the statement of financial performance. Gains or losses arising from derecognizing of an intangible asset are measured as the difference between the net disposal proceeds and the carrying amount of the asset and are recognized in the statement of financial performance when the asset is derecognized. The principal annual rate used for this purpose is 10%.

6.12 Impairment of Non-Financial Assets

To comply with the requirement of IPSAS 21, TMDA assesses at each reporting date whether there is an indication that an asset may be impaired. If any such indication exists, or when annual impairment testing for an asset is required, the Authority makes an estimate of the asset's recoverable amount. An asset's recoverable amount is the higher of an assets or cash generating unit's fair value less costs to sell and its value in use and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. Where the carrying amount of an asset exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. Impairment losses of

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

continuing operations are recognized in the Statement of Financial Performance in those expense categories consistent with the function of the impaired asset. An assessment is made at each reporting date as to whether there is any indication that previously recognized impairment losses may no longer exist or may have decreased. If such indication exists, the recoverable amount is estimated.

A previously recognized impairment loss is reversed only if there has been a change in the estimates used to determine the asset's recoverable amount since the last impairment loss Recognized. If that is the case the carrying amount of the asset is increased to its recoverable amount.

That increased amount cannot exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years. Such reversal is recognized in the Statement of Financial Performance. After such a reversal the depreciation charge is adjusted in future periods to allocate the asset's revised carrying amount, less any residual value, on a systematic basis over its remaining useful life.

To fulfil the requirement of IPSAS 21, at the end of financial year 2021/22, TMDA subjected its assets for annual impairment testing and determined that they are not impaired.

6.13 Provisions

Provisions are recognized when the Authority has a present obligation (legal or constructive) as result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. Where the Authority expects some or all of a provision to be reimbursed, for example under an insurance contract, the reimbursement is recognized as a separate asset but only when the reimbursement is virtually certain. The expense relating to any provision is presented in statement of financial performance net of any reimbursement. If the effect of the time value of money is material, provisions are discounted using a current pre-tax rate that reflects, where appropriate, the Risk specific to the liability. Where discounting is used, the increase in the provision due to the passage of time is recognized as a finance cost.

6.14 Pensions and retirement benefits

The Authority operates defined contribution and benefit plans.

Pension Obligations

Under defined contribution plans, TMDA employees are members of state-owned pension scheme, namely the PSSSF, contributions to the funds are charged to the statement of financial performance in the year to which they relate at a rate of 5% of an employee's basic salary.

6.15 Capital

TMDA is a corporation 100% owned by the Government. It is an Executive Agency under the Ministry of Health, Community Development, Gender, Elderly and Children. TMDA initial capital is made up with Net Assets vetted from the then Pharmacy Board and National Food Control Commission (NFCC) under the Parliament Act No. 1 of 2003 as per approved opening balance sheet of 1 July, 2003.

6.16 Contractual Commitments and contingencies

Commitments

Reg. 21 (2) of Budget Regulation 2015 requires unliquidated contractual commitments (LPOs) issued for Services/Goods during the year and for which delivery of goods or performance of services have not been done as at the end of financial year should be carried forward to the next financial year in which payments will be made after Goods/Services have been received.

As at 30 June 2024 the authority had unliquidated commitments (Open LPOs) totalling TZS 297,850,759.32 for Services/Goods which were not received by the end of the financial year 2023/24.

6.17 Events after the reporting date

These are events which occur between the reporting date and the date when the financial statements are approved for issue. These events may require adjustments depending on whether conditions existed at the reporting date or after the reporting date.

There were no other events after the reporting period which requires adjustment or disclosure in the financial statements. The financial statements will be authorised by the Ministerial Advisory Board for issue in January 2025.

6.18 Revenue Recognition

Revenue from non-exchange transactions is recognized to the extent that it is probable that the economic benefits will flow to the Authority and the amount for which can be reliably measured. Income is measured at the fair value of the consideration received, excluding discounts, rebates, and sales taxes or duties. An inflow of resources from a non-exchange transaction recognized as an asset shall be recognized as revenue, except to the extent that a liability is also recognized in respect of the same inflow. As an entity satisfies a present transaction recognised as an asset, it shall reduce the carrying amount of the liability recognised and recognise an amount of revenue equal to that reduction.

The Amounts of Stationeries and Office Consumables comprise of stationery stock and printing materials for office use while Laboratory Supplies and Consumables comprise of laboratory gases and chemicals, Glassware and Reference Standards which remained unused at the end of the reporting period.

6.19 Financial Instruments Policy (IPSAS 41)

Financial instruments refer to any contract that gives rise to both a financial asset of one entity and a financial liability or equity instrument of another entity.

Financial asset

A financial asset is any asset that is, Cash or an equity instrument of another entity or a contractual right to receive cash or to receive financial asset from another entity; or to exchange financial assets or liabilities under conditions that are potentially favourable.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Financial liability

A financial liability is any liability that is a contractual obligation to deliver cash or to deliver another financial asset or to exchange financial assets or liabilities under conditions that are potentially unfavourable.

Equity Instrument

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities.

Recognition

Financial instrument shall be recognized in the statement of financial position when an entity becomes party to the contractual provisions of the instruments.

De-recognition

Financial instrument shall be derecognized in the statement of financial position when the contractual rights/ obligation to the cash flows from the financial asset/ liability expire or are waived or transferred.

Classification of Financial assets

Financial assets are classified as Measured at amortized cost, measured at fair value through net assets and Measured at Fair value through surplus or deficit (FVTSD)

Authority's financial assets are classified under Financial Assets Measured at Amortized cost because has passed the cashflow test and Management Modal test.

Classification of Financial liabilities

The Authority financial liability is measured at amortized cost.

Measurement

Shall be measured at its fair value plus transaction cost except short-term receivables which are measured at their original invoice. The Authority measures the financial assets at its invoice price

Subsequent Measurement

Shall be measured at amortized cost using the effective interest method

Measurement of Financial Liabilities measured at Amortized Cost Initially.

Impairment

The Authority shall recognize the expected loss credit loss allowance on financial assets measured at amortized cost.

The Authority shall measure expected credit losses over the remaining life of a financial instrument in a way that reflects:

- i. an unbiased and probability-weighted amount that is determined by evaluating a range of possible outcomes.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

- ii. the time value of money; and
- iii. reasonable and supportable information about past events, current conditions and reasonable and supportable forecasts of future events and economic conditions at the reporting date

Impairment model

The Authority impairment determination accounting model is the simplified impairment model which is applicable to receivables and contract assets without a significant financing component and short time to maturity. The Authority shall apply Simplified approach in determination of the expected credit loss by establishing the provisional matrix basing on information that is reasonably available, including information about past events, current conditions and reasonable and supportable forecasts of future events and economic conditions. The degree of judgment shall be used for the estimates depends on the availability of detailed information.

7. REVENUE FROM EXCHANGE TRANSACTIONS

	2023/24	2022/23
	TZS	TZS
Import Fee- Exchange	19,275,483,369	19,940,257,599
Laboratory Charges	67,402,226	58,451,403
Registration Fees- Exchange	-	36,127,567
Revenue from sales of Publications	21,431,868	832,351
Total	19,364,317,463	20,035,668,920

During the year revenue from exchange transactions decreased by 3% to the tune of TZS 19.36 billion as compared with TZS 20.04 billion (2022/23) due to change of MUSE system mapping system which has reclassified Registration fees to Note number 9

8. LEVIES

Levy -Renting Space / Houses	365,915,987	384,899,820
Total	365,915,987	384,899,820

During the reporting period revenue renting space (Investment Property) decreased by 4% to 0.37 billion as compared with 0.38 billion (2022/23), the decrease has been accelerated by the decrease in number of tenants.

9. FEES, FINES, PENALTIES AND FORFEITS

Fines	3,052,234,895	3,532,130,023
Registration Fees	11,868,501,491	10,274,525,560
Revenue from Annual Fees	371,605,000	324,399,473
Total	15,292,341,386	14,131,055,056

During the year revenue from Fees, Fines, Penalties and Forfeits increased by 8% to the tune of TZS 15.29 billion as compared with TZS 14.13 billion (2022/23) due to the enhanced controls over collection of revenue accelerated by the use of electronic means of payment through GePG platform.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

10. FAIR VALUE GAINS ON ASSETS AND LIABILITIES

	2023/24	Restated 2022/23
	TZS	TZS
Foreign currency exchange gain	187,230,144	163,176,544
Reversal of provision for impairment of Receivables (ECL)	50,426,662	26,585,085
Total	237,656,806	189,761,629

During the year under review, foreign exchange gain occurred due to USD volatility in the market than in previous year (2022/23). The increase was attributed to favourable foreign exchange fluctuations.

11. OTHER REVENUE

Miscellaneous Revenue	21,299,457	44,347,918
Retention Fee for logging	5,233,006,868	3,926,223,803
Total	5,254,306,325	3,970,571,721

During the reporting period other revenue increased by 32% to TZS 5.25 billion from 3.97 billion. The major change has been attributed by the increase in collection from retention fee due to enhancement in collection system, the increase in business volume and the increase in number of customers applying for retention of Medicines and medical devices.

12. REVENUE GRANTS

		Restated
Government Grant Personal Emolument	5,134,978,380	4,160,922,813
Government Grant Development Foreign	1,096,480,693	143,113,951
Government Grant Development Local	1,940,509,989	-
Total	8,171,969,062	4,304,036,764

During the reporting period, Subvention from Other Government entities increased from TZS 4.3 billion to TZS 8.17 billion (2023/24), the increase is attributed by the increase in number of staff and promotion.

13. SUBVENTION FROM OTHER GOVERNMENT ENTITIES

Non-Monetary Revenue - Capital	-	312,059,979
Total	-	312,059,979

During the year under review there was no subvention received from any other Government entities compared to previous year.

14. WAGES, SALARIES AND EMPLOYEE BENEFITS

	2023/24	2022/23
	TZS	TZS
Civil Servants	10,695,263,548	8,841,182,555
Extra-Duty	2,147,083,521	1,694,828,605
Food and Refreshment	1,768,868,392	8,341,359

Controller and Auditor General

AR/PA/TMDA/2023/24

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Furniture Expenses	77,223,586	42,000,000
Gratuities	147,995,000	286,168,750
Honoraria	359,954,585	213,824,386
Housing Allowance discretionary Expenses	1,889,716,818	1,045,444,348
Leave Travel	674,734,560	720,389,615
Moving Expenses	65,649,546	1,283,035,488
Non-Civil Servant Contracts	-	14,999,999
Outfit Allowance	10,327,500	3,000,000
Responsibility Allowance	28,480,000	32,000,000
Risk Allowance	156,600,000	97,195,000
Sitting Allowance	387,295,212	395,888,000
Statutory Contributions	-	20,113,779
Subsistence Allowance	29,124,000	503,426,487
Transport Allowance	1,978,203,492	944,074,400
Uniform Allowance	19,828,240	27,400,000
Total	20,436,348,000	16,173,312,771

Wages, Salaries and employee benefits increased to a tune of TZS 20.44 billion as compared to TZS 16.17 billion in the previous year due to fact that in the financial year under review there was a salary and incentive increment, new staff, reclassification of Food & Refreshment from note 15 (Use of Goods & Services) to this category.

15. USE OF GOODS AND SERVICE

	2023/24	2022/23
	TZS	TZS
		Restated
Accommodation Training - Domestic	70,500,000	58,047,401
Advertising and Publication - Communication & Information	34,720,242	69,722,201
Air Travel Tickets Training - Domestic	16,000,000	-
Air Travel Tickets Training - Foreign	219,054,338	136,032,000
Air Travel Tickets Travel - In - Country	979,295,554	753,349,910
Air Travel Tickets Travel Out Of Country	136,241,482	29,011,624
Books, Reference and Periodicals	2,789,303	9,435,822
Computer Supplies and Accessories	9,315,000	54,825,492
Conference Facilities	140,326,210	198,615,716
Consumable Medical Supplies	993,292,917	2,141,059
Courier Services	7,709,600	5,140,004
Diesel	765,030,137	846,851,591
Drugs and Medicines	2,400,000	0
Electricity - Utilities Supplies and Services	290,695,246	332,050,303
Entertainment - Hospitality Supplies and Services	39,811,900	23,118,400
Exhibition, Festivals and Celebrations	43,063,000	32,218,994
Food and Refreshments	28,630,952	1,258,458,920
Fumigation Expenses	3,211,585	8,924,094
Gifts and Prizes	121,446,500	79,300,000
Ground Transport (Bus, Train, Water)	1,320,000	1,630,000
Ground travel (bus, railway taxi, etc) Travel - In - Country	170,810,754	288,538,024
Ground travel (bus, railway taxi, etc) Travel Out Of Country	18,775,504	-

Controller and Auditor General

AR/PA/TMDA/2023/24

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

	2023/24 TZS	2022/23 TZS Restated
Health Insurance Training - Foreign	10,773,997	5,923,905
Internet and Email connections	405,294,818	364,692,017
Laboratory Supplies	193,398,641	-
Lodging/Accommodation Travel Out Of Country	31,000,000	10,445,400
Medical Gases and Chemicals	40,000,000	-
Mobile Charges	17,686,436	19,240,000
News Services Fees	17,591,808	325,259,125
Newspapers and Magazines	7,174,398	12,814,963
Expenditure-Use of Goods and Service	2,117,417,250	622,416,714
Office Consumables (papers, pencils, pens and stationaries)	328,345,424	205,471,908
Outsourcing Costs (includes cleaning and security services)	461,599,828	203,473,660
Per Diem - Domestic	7,199,197,431	6,541,372,179
Per Diem - Foreign	1,769,775,186	1,618,503,277
Petrol	11,150,000	9,195,000
Posts and Telegraphs	43,775,900	29,523,750
Printing and Photocopy paper	2,050,000	-
Printing and Photocopying Costs	115,245,090	200,355,147
Programs Transmission Fees	-	5,896,500
Publicity	22,000,002	13,751,003
Remuneration of Instructors	25,000,000	24,275,000
Rent - Office Accommodation	485,375,558	490,067,279
Rent of Private vehicles	18,782,000	13,330,000
Rent of Vehicles and Crafts	13,400,000	9,293,296
Research and Dissertation Training - Domestic	29,000,000	14,003,285
Software License Fees	20,874,672	44,000,000
Special Foods (diet food)	3,600,000	-
Sporting Supplies	-	14,100,000
Subscription Fees	216,903,403	260,871,231
Technical Service Fees	68,066,142	89,999,999
Telephone Charges (Land Lines)	39,186,191	52,868,954
Telephone Charges -Utilities Supplies and Services	500,000	-
Training Materials	14,700,000	11,502,500
Tuition Fees Training - Domestic	163,877,790	166,707,800
Tuition Fees Training - Foreign	113,781,000	59,560,121
Uniforms and Ceremonial Dresses	19,050,000	42,300,000
Upkeep Allowances	8,000,000	28,818,237
Visa Application Fees	11,271,130	5,677,226
Water and Waste Disposal (Garbage)	0	6,120,000
Water Charges	33,465,588	46,464,095
Total	18,172,749,907	15,755,705,126

During the financial year that ended 30 June 2024 use of goods and Service have increased to TZS 18.17 billion as compared by TZS 15.76 billion in the previous year due to reclassification of Food & Refreshment which have been presented in note number 13 (Wages, Salaries & Employees benefits).

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

16. MAINTENANCE EXPENSES

Air conditioners	4,020,000	15,558,300
Cement, Bricks and Building Materials	16,672,580	2,315,620
Cement, bricks and construction materials	3,194,000	3,600,000
Computers, printers, scanners, and other computer related equipment	15,255,645	37,445,385
Electrical and Other Cabling Materials - Water and Electricity Installations	10,121,179	14,987,488
Fire Protection Equipment	20,000,000	-
Medical and Laboratory equipment	331,377,909	154,669,785
Motor Vehicles and Water Craft	382,817,571	418,002,469
Outsource maintenance contract services - Buildings	38,572,700	288,687,798
Outsource maintenance contract services - Machinery, Equipment and Plant	268,849,896	-
Outsource maintenance contract services - Water and Electricity Installations	68,549,274	100,756,000
Small tools and implements - Buildings	22,900,000	3,750,000
Small tools and implements - Water and Electricity Installations	3,789,000	5,617,630
Telephones and Office PABX systems	10,089,380	15,117,226
Total	1,196,209,134	1,060,507,701

During the year under review maintenance expenses have increased from 1.06 bill to 1.20 billion. This has been attributed by the increase in operational cost.

17. LOSS ON DISPOSAL OF ASSETS

Losses on disposal of property, plant and equipment	9,479,276	10,038,341
Total	9,479,276	10,038,341

The Loss on disposal of property, plant and equipment refers to accounting losses in respect of disposed assets during a year.

18. OTHER EXPENSES

	2023/24 TZS	2022/23 TZS
Agency fees	101,809,862	66,699,309
Audit fees Expenses	204,800,000	204,800,000
Bank Charges and Commissions	-	3,687,032
Burial Expenses	66,650,000	24,960,000
Co-Location operational Expenses	1,523,750	2,229,650
consultancy fees	593,539,851	739,169,949
Freight Forwarding and Clearing Charges	55,948,200	60,000,000
Sundry Expenses	170,205,144	82,489,540
Transports posts - other expenses	1,000,000	-
Witnesses Expenses	1,355,000	2,835,000
Total	1,196,831,807	1,186,870,480

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Other expenses increased to TZS 1.20 billion for the reporting period ending 30 June 2024, as compared to TZS 1.19 billion for the previous year, the increase has been attributed by consultancy fees expenses which has been capitalized as work in progress.

19. EXPECTED CREDIT LOSS

Financial Asset	Opening balance	Prior Year ECL Adjustments		Prior Year balance	Current year ECL	
		2021/22	2022/23		2023/24	Current Year balance
Staff loans	-	22,152,981	6,339,782	28,492,764	(9,233,665)	19,259,099
Trade Receivable	33,402,589,638	157,366,718	(26,585,085)	33,533,371,271	(40,138,920)	33,493,232,351
Cash & Cash Equivalent	-	2,123,476	244,122	2,367,598	(1,054,077)	1,313,522
Total	33,402,589,638	181,643,175	(20,001,181)	33,564,231,633	(50,426,662)	33,513,804,972

20. SOCIAL BENEFITS

Settlement of Medical Treatment Claims	311,352,045	289,883,516
Total	311,352,045	289,883,516

During the year under review social benefits increased to TZS 0.31 billion from 0.29 billion, the increase has been attributed by increase in number of staff who enjoys supplement package.

21. OTHER TRANSFERS

Contribution to CF (15%)	5,902,166,689	5,320,594,355
Capital redemption	2,224,458,329	400,000,000
Total	8,126,625,018	5,720,594,355

Contribution of 15% from raw collection to Consolidated Fund increased from TZS 5.32 billion in financial year 2022/23 to TZS 5.90 billion in a year under review. Excess capital remitted increased to 2.22 billion in a year under review compared to 0.40 billion of previous year. Amount remitted was TZS 8.13 billion.

22. CASH AND CASH EQUIVALENTS

	2023/24	Restated 2022/23
	TZS	TZS
BOT Ownsource Collection Account	1,188,822,067	714,428,955
Cash in hand	-	4,000,000
Deposit Cash Account	39,475,782	2,404,146,409
Development Expenditure Cash Account	49,441,160	-
Development Revenue Account	-	45,782,324
Imprest Cash Account	32,677,150	(4,000,000)
Ownsource Collection Account - NBC	-	10,000,000
Ownsource Collection Account - NMB	8,542,250	99,376,973
Ownsource Collection Account - CRDB	-	495,329,956
Ownsource Collection Account NMB - USD	854,806	-
Ownsource Development Expenditure	293,537,556	97,568,926
Ownsource Recurrent Expenditure GF	788,891,587	240,262,347
Recurrent Expenditure Cash Account	3,482,740	240,000

Controller and Auditor General

AR/PA/TMDA/2023/24

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Redemption Cash Account	-	34,913
USD BOT Collection Account	1,494,187,976	4,157,285,348
USD Commercial Collection Account	355,792,874	217,759,772
Sub total	4,255,705,948	8,482,215,923
Less: Provision for ECL (Cash)	(1,313,522)	(2,367,598)
Total	4,254,392,426	8,479,848,325

Cash and cash Equivalents as defined under the IPSAS 29; Financial Assets, comprises of the Authority's cash at banks and cash in hand as at 30 June 2024. The Cash and cash equivalents decreased by 50% from TZS 8.48 billion (30 June 2023) to TZS 4.26 billion (30 June 2024) due to capital redemption and construction works payments.

23. RECEIVABLES

		Reclassified
Imprest Receivable - Staff	90,967,150	32,325,569
Withholding Tax	-	8,761,616
Trade Receivables	34,079,320,381	33,559,270,573
Sub total	34,170,287,531	33,600,357,758
Less: Provision for ECL (Trade receivables)	(33,493,232,351)	(33,533,371,271)
Total	677,055,180	66,986,487

Aging analysis

	0-30 days	30-60 days	60-90 days	90-180 days	180-360 days	Over 360 days	Total
Days							
30 June 2024							
Imprest Receivable	90,967,150	-	-	-	-	-	90,967,150
Trade Receivables	566,847,700	-	-	-	109,913,043	33,402,589,638	34,079,320,381
Provision for ECL	-	-	-	-	(90,642,713)	(33,402,589,638)	(33,493,232,351)
							677,055,180
30 June 2023							
Imprest Receivable	32,325,569	-	-	-	-	-	32,325,569
Withholding Tax	8,761,616	-	-	-	-	-	8,761,616
Trade Receivables	-	-	-	-	156,680,935	33,402,589,638	33,559,270,573
Provision for ECL	-	-	-	-	(130,781,633)	(33,402,589,638)	(33,533,371,271)
							66,986,487

The amount of trade receivable is TZS 33.40 billion long outstanding debts the authority owed by MSD in respect of services that was enjoyed with the agreement that payments shall be made later on, from 2013/2014 to June 2017. The debts have remained outstanding since then. Therefore, a specific provision for doubtful debt was made in the financial year 2016/2017. The debt have been verified by CAG to be written off. The amount of TZS 0.11 billion refers to rent receivable.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

24. LOAN RECEIVABLE

	2023/24	2022/23 Reclassified
Short term staff loans	932,440,011	892,043,246
Long term staff loans	726,897,442	1,649,626,957
	<u>1,659,337,453</u>	<u>2,541,670,203</u>
Less: Provision for ECL (Long term loans)	(19,259,099)	(28,492,764)
Total	<u>1,640,078,354</u>	<u>2,513,177,439</u>

Long term staff loans receivable refers to outstanding amounts advanced to Staffs which are expected to be recovered in a period of more than one year.

25. PREPAYMENTS

Prepayments- Expenses	145,706,279	154,058,544
Prepayment- Assets	579,414,198	341,096,200
Received Assets	(341,096,200)	-
Total	<u>384,024,277</u>	<u>495,154,744</u>

Prepayments comprise of TZS 0.15 billion refers to office rent accommodation paid in advance and 0.58 billion prepaid in Bank for NHC contract. Three motor vehicles to TZS 0.34 billion which were prepaid previous year were received in 2023/24.

26. INVENTORIES

		Restated
Consumables	2,271,548,739	2,583,610,523
Total	<u>2,271,548,739</u>	<u>2,583,610,523</u>

Consumables comprise of stationary stock and printing materials for office use, Laboratory Supplies and Consumables, chemicals, Glassware and Reference Standards, which remained unused at the end of the reporting period. The decrease in inventories has been attributed by the fact that most of consumables was utilized during the reporting period.

27. INVESTMENT PROPERTY

COST		
	2023/24	2022/23
Balance as at 1 July 2023	1,537,483,078	1,537,483,078
Additions during the year	78,633,500	-
Balance as at 30 June 2024	<u>1,616,116,578</u>	<u>1,537,483,078</u>
DEPRECIATION		
Balance as at 1 July 2023	177,911,055	147,161,393
Depreciation during the year	32,322,332	30,749,662
Balance as at 30 June 2024	<u>210,233,387</u>	<u>177,911,055</u>
Net Book Value	<u>1,405,883,191</u>	<u>1,359,572,023</u>

During a year under review, Authority's investment property located at Namanga Border was improved by construction of the surrounding wall costing TZS 0.08 billion.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

28. PROPERTY, PLANT AND EQUIPMENT

DESCRIPTION	LAND	BUILDINGS	MOTOR VEHICLES	PLANT and MACHINERIES	ICT EQUIPMENT	FURNITURE and FITTINGS	OFFICE LABORATORY EQUIPMENT	TOTAL
	TZS	TZS	TZS	TZS	TZS	TZS	TZS	TZS
YEAR ENDED 30 JUNE 2023								
COST								
As At 1 July 2023	2,321,973,500	23,963,434,829	6,355,915,060	621,222,161	3,565,162,732	2,572,317,921	11,346,741,443	50,746,767,646
Additions	601,117,450	45,881,650	401,386,800	-	419,224,163	52,686,646	-	1,520,896,709
Disposals	-	-	(357,113,492)	-	-	-	-	(357,113,492)
As At 30 June 2024	2,923,090,950	24,009,316,479	6,400,788,368	621,222,161	3,984,386,895	2,625,004,567	11,346,741,443	51,910,550,863
ACCUMULATED DEPRECIATION								
As At 1 July 2023	-	2,571,118,904	4,365,513,505	338,417,606	1,655,041,511	1,333,933,294	7,558,162,099	17,822,186,919
Charge For the Year	-	480,186,330	620,983,331	41,621,885	457,436,021	258,109,903	1,134,674,144	2,993,011,614
Disposals	-	-	(321,432,143)	-	-	-	-	(321,402,143)
As At 30 June 2024	-	3,051,305,234	4,665,094,693	380,039,491	2,112,477,532	1,592,043,197	8,692,836,243	20,493,796,390
NET BOOK VALUE	2,923,090,950	20,958,011,245	1,735,693,675	241,182,670	1,871,909,363	1,032,961,370	2,653,905,200	31,416,754,473

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

COMPARABLE ASSET REGISTER 2022/23

DESCRIPTION	LAND	BUILDINGS	MOTOR VEHICLES	PLANT and MACHINERIES	ICT EQUIPMENT	FURNITURE and FITTINGS	OFFICE LABORATORY EQUIPMENT	TOTAL
	TZS	TZS	TZS	TZS	TZS	TZS	TZS	TZS
YEAR ENDED 30 JUNE 2023								
COST								
As At 1 July 2022	2,321,973,500	16,505,493,691	6,624,832,673	551,887,468	3,048,692,626	2,443,177,593	11,250,122,108	42,746,179,659
Additions	-	7,457,941,138	92,346,913	69,334,693	527,087,612	139,431,389	254,222,164	8,540,363,909
Transfers	-	-	(351,226,185)	-	-	-	-	(351,226,185)
Prior year adjustment	-	-	(10,038,341)	-	-	-	-	(10,038,341)
Disposals	-	-	-	-	(10,617,506)	(10,291,061)	(157,602,829)	(178,511,396)
As At 30 June 2023	2,321,973,500	23,963,434,829	6,355,915,060	621,222,161	3,565,162,732	2,572,317,921	11,346,741,443	50,746,767,646
ACCUMULATED DEPRECIATION								
As At 1 July 2022	-	2,082,724,636	4,139,700,435	315,764,926	1,362,864,035	1,137,704,252	7,046,517,571	16,085,275,855
Charge for the Year	-	488,394,268	575,094,318	22,652,680	302,145,067	204,500,178	663,823,794	2,256,610,305
Transfers	-	-	(349,281,248)	-	-	-	-	(349,281,248)
Disposals	-	-	-	-	(9,967,591)	(8,271,136)	(152,179,266)	(170,417,993)
As At 30 June 2023	-	2,571,118,904	4,365,513,505	338,417,606	1,655,041,511	1,333,933,294	7,558,162,099	17,822,186,919
NET BOOK VALUE	2,321,973,500	21,392,315,925	1,990,401,555	282,804,555	1,910,121,221	1,238,384,627	3,788,579,344	32,924,580,727

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

29. INTANGIBLE ASSETS

	2023/24	2022/23
	TZS	TZS
COST		Restated
Balance as at 1 July	638,540,000	971,611,748
Derecognition of two softwares	0	(333,071,748)
Balance as at 30 June	<u>638,540,000</u>	<u>638,540,000</u>
AMORTIZATION		
Restated balance as at 1 July	191,562,001	340,554,668
Overcharged impairment	-	(212,846,667)
Amortization during the year	63,854,000	63,854,000
Balance as at 30 June	<u>255,416,001</u>	<u>191,562,001</u>
Net Book Value	<u>383,123,999</u>	<u>446,977,999</u>

Intangible Assets refers to LIMS software which is used in Laboratory operating activities. Derecognized assets include two software (HR-MIS and Accounting software-IFMIS Epicor) which are no longer in use since June 2021 with a total cost of TZS 0.33 billion.

30. WORK IN PROGRESS

	2023/24	2022/23
Balance as at 1 July	19,868,000	7,367,062,692
Additions during the year	2,230,911,878	364,858,098
Transfer to PPE	(124,515,150)	(7,712,052,790)
Balance as at 30 June 2024	<u>2,126,264,728</u>	<u>19,868,000</u>

Work in progress of TZS 2.13 billion represents the extent to which cost of work has been incurred as at 30 June 2024 in connection with the construction of Infrastructures in Nala and Extension of HQ Building in Dodoma. Completion of construction works with total cost of TZS 0.12 billion in respect of Namanga and Tarakea have been capitalized as Investment Property and Office Building respectively during a year under review.

31. PAYABLES AND ACCRUALS

	2023/24	2022/23
Other payables	-	66,498,500
Supplies of goods and services	597,885,480	326,713,750
Staff claim	61,782,500	102,962,500
VAT Payable	85,795,206	67,344,430
Withholding tax	719,811,634	
Total	<u>1,465,274,820</u>	<u>563,519,180</u>

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Aging analysis

Days	0-30 days	30-60 days	60-90 days	90-180 days	180-360 days	Over 360 days	Total
30th June, 2024							
Supplies of goods and services	597,885,480	-	-	-	-	-	597,885,480
Staff claim	61,782,500	-	-	-	-	-	61,782,500
VAT Payable	85,795,206	-	-	-	-	-	85,795,206
Withholding tax	719,811,634	-	-	-	-	-	719,811,634
Total	1,465,274,820	-	-	-	-	-	1,465,274,820
30th June, 2023							
Other payables	66,498,500	-	-	-	-	-	66,498,500
Supplies of goods and services	326,713,750	-	-	-	-	-	326,713,750
Staff claim	102,962,500	-	-	-	-	-	102,962,500
VAT Payable	67,344,430	-	-	-	-	-	67,344,430
Total	563,519,180	-	-	-	-	-	563,519,180

The amount of payable and Accruals comprises tax consultation fee, Supplement package due to NHIF, VAT, PAYE and Withholding tax for the year ended 30 June 2024.

32. PROVISIONS

	2023/24 TZS	2022/23 TZS Reclassified
Other expenses	204,800,000	204,800,000
Total	204,800,000	204,800,000

Provisions include an amount provided for audit fees for the audit of the Authority's financial statements amounted to TZS 0.20 billion.

33. DEFERRED INCOME

33 (a) Donor Grants

	2023/24	2022/23
Balance as at 1 July 2023	2,515,758,036	426,215,437
Grants received during the year	1,379,715,636	2,404,386,409
Grants utilized during the year	(3,649,301,053)	(314,843,810)
Subtotal	246,172,619	2,515,758,036

33 (b) Deferred GMP

	2023/24	2022/23
Balance as at 1 July 2023	511,313,290	444,802,655
GMP received during the year	2,949,058,164	2,903,391,431
GMP utilized during the year	(2,059,603,186)	(2,836,880,796)
Subtotal	1,400,768,268	511,313,290

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Grand total	<u>1,646,940,887</u>	<u>3,027,071,326</u>
--------------------	-----------------------------	-----------------------------

Deferred income includes TZS 0.25 billion remained for Global Fund which will be refunded back thereto and TZS 1.40 billion for uninspected manufacturers (GMP) for the financial year 2023/24.

34. RECONCILIATION OF NET CASH FLOWS FROM OPERATING ACTIVITIES TO SURPLUS/(DEFICIT) FOR THE PERIOD ENDED 30 JUNE 2024

		Restated
Surplus/ Deficit for the Period	(3,852,276,102)	773,313,728
Add/ (Less) Non-Cash Item		
Depreciation of Investment Property - Carried at Cost	32,322,332	30,749,662
Depreciation of Property, Plant and Equipment	2,993,011,613	2,256,610,305
Expected Credit Loss Impairment	(50,426,662)	(26,585,085)
Impairment of Intangible Assets	63,854,000	63,854,000
Loss on Disposal of Assets	9,479,276	10,038,341
Add/ (Less) Change in Working Capital		
Deferred Income	(1,380,130,438)	2,156,053,233
Loans receivables	882,332,750	623,323,451
Inventories	312,061,784	(912,917,920)
Staff claim	(41,180,000)	102,962,500
Imprest Receivable - Staff	(58,641,581)	(30,046,270)
Prepayment - Expenses	8,352,265	(21,474,998)
Supplies of goods and services	271,171,729	(211,038,071)
VAT Payable	18,450,776	(16,402,832)
Withholding tax	728,783,786	77,548,450
Other payables	(66,498,500)	(83,479,788)
Receivables	(520,260,342)	179,461
Net Cash Flow from Operating Activities	<u>(649,593,313)</u>	<u>4,792,688,167</u>

35. RELATED PARTY TRANSACTIONS DETAILS

The related party transactions include Director's fee paid to Board Members, Remuneration paid to key Management personnel, various Governmental entities transactions, Contribution to Government Consolidated Fund in the form of 15% of Gross Revenue and Excess Capital Redemption for the year ended 30 June 2024. The following shows the related transaction for the financial year ended 30 June 2024.

S/N	DETAILS	No. of people	2023/24 TZS	2022/23 Restated TZS
1	Director's Fee to Board Members	7	9,500,000	8,000,000
2	End of Term	7	-	24,000,000
	Sub Total		<u>9,500,000</u>	<u>32,000,000</u>
3	Remuneration to Key Management Personnel	11	959,184,000	874,765,800
	Sub Total		<u>959,184,000</u>	<u>874,765,800</u>

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

4	15% Contribution to Government	5,902,166,689	5,320,594,355
5	Capital Redemption	2,224,458,328	400,000,000
	Sub Total	8,126,625,017	5,720,594,355
6	Governmental entities transaction	6,979,090,311	12,384,782,547
	Sub Total	6,979,090,311	12,384,782,547
	GRAND TOTAL	16,074,399,328	19,012,142,702

TMDA related parties of TZS 16.07 billion include Government of Tanzania which is the ultimate controlling entity, other government entities, board of directors and key management personnel. During the financial year ended 30 June 2024 all Members of the Board TZS 0.01 billion as Director's Fee, TZS 0.96 billion to Key management personnel as their remunerations. In addition, the Authority contributed to the Government a total of TZS 8.13 billion for the year ended 30 June 2024 as compared to TZS 5.72 billion contributed in the previous year. Inter-governmental entities transactions were TZS 6.98 billion for the year ended June 2024.

36. DONOR GRANTS (EDCTP & GF)

	EDCTP	Global Funds (GF)	Total
Deferred donor grants as at 1 July 2023	111,371,625	2,404,386,409	2,515,758,034
Add: Funds received during the year	223,300,685	1,156,414,951	1,379,715,636
Total for the Year	334,672,310	3,560,801,361	3,895,473,671
Amortized Donor Grants for the Year	334,672,310	3,314,628,743	3,649,301,053
Deferred donor grants as at 30 June 2024	-	246,172,618	246,172,618
	1,004,016,930	10,682,404,082	11,686,421,012

NOTES- CASH FLOW STATEMENT FOR THE PERIOD ENDED 30 JUNE 2024

37. ADVANCE PAYMENT FOR ACQUISITION OF PROPERTY PLANT AND EQUIPMENT

	2023/24	2022/23
	TZS	TZS
Prepayments-Assets	238,317,998	248,749,287
TOTAL	238,317,998	248,749,287

38. PAYMENT FOR WORK IN PROGRESS

Buildings other than dwellings - WIP Monetary	2,230,911,878	364,858,098
Total	2,230,911,878	364,858,098

39. REVENUE FROM EXCHANGE TRANSACTIONS

Import Fee- Exchange	19,275,483,369	19,940,257,599
Laboratory Charges	67,402,226	58,451,403
Registration Fees- Exchange	-	36,127,567
Revenue from sales of Publications	21,431,868	832,351

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Subtotal	19,364,317,463	20,035,668,920
Add/Less (Change in Working Capital)		
Increase of Deferred income	(1,380,130,438)	2,156,053,234
Total	17,984,187,025	22,191,722,154

40. FEE, FINE, PENALTIES AND FORFEIT

Fines	3,052,234,895	3,532,130,023
Registration Fees	11,868,501,491	10,274,525,560
Revenue from Annual Fees	371,605,000	324,399,473
Subtotal	15,292,341,386	14,131,055,056

Add/Less (Change in Working Capital)

Trade receivables	(520,260,342)	(1,352,980)
Total	14,772,081,044	14,129,702,076

41. LEVIES

Levy -Renting Space / Houses	365,915,987	384,899,820
Total	365,915,987	384,899,820

42. OTHER REVENUE

Miscellaneous Revenue	21,299,457	15,002,918
Rent Fees	-	29,345,000
Retention Fee for logging	5,233,006,868	3,926,223,803
Total	5,254,306,325	3,970,571,721

43. REVENUE GRANTS

Government Grant Personal Emolument	5,134,978,380	4,160,922,813
Government Grant Development Foreign	1,096,480,693	143,113,951
Government Grant Development Local	1,940,509,989	-
Sub total	8,171,969,062	4,304,036,764

44. LOAN RECEIVABLES

	2023/24	2022/23
	TZS	TZS
Balance at start - short term	892,043,246	1,046,914,212
Balance at start - long term	1,649,626,957	2,123,740,609
Loan disbursed during the year	721,100,000	499,502,472
Subtotal	3,262,770,203	3,670,157,293
Less Loan repayment made	(1,603,432,750)	(1,128,487,090)
Balance at close	1,659,337,453	2,541,670,203

Closing balance - short term	932,440,011	892,043,246
------------------------------	-------------	-------------

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Closing balance - long term	726,897,442	1,649,626,957
	<u>1,659,337,453</u>	<u>2,541,670,203</u>

45. WAGES, SALARIES AND EMPLOYEE BENEFITS

Civil Servants	10,695,263,548	8,841,182,555
Extra-Duty	2,147,083,521	1,694,828,605
Food and Refreshment	1,768,868,392	8,341,359
Furniture Expenses	77,223,586	42,000,000
Gratuities	147,995,000	286,168,750
Honoraria	359,954,585	213,824,386
Housing Allowance discretionary Expenses	1,889,716,818	1,045,444,348
Leave Travel	674,734,560	720,389,615
Moving Expenses	65,649,546	1,283,035,488
Non-Civil Servant Contracts	-	14,999,999
Outfit Allowance	10,327,500	3,000,000
Responsibility Allowance	28,480,000	32,000,000
Risk Allowance	156,600,000	97,195,000
Sitting Allowance	387,295,212	395,888,000
Statutory Contributions	-	20,113,779
Subsistence Allowance	29,124,000	503,426,487
Transport Allowance	1,978,203,492	-
Transport Expenses	-	944,074,400
Uniform Allowance	19,828,240	27,400,000
Subtotal	<u>20,446,888,000</u>	<u>16,173,312,771</u>
Add/Less (Change in Working Capital)		
Staff Claim Addition	41,180,000	(102,962,500)
Total	<u>20,477,528,000</u>	<u>16,070,350,271</u>

46. USE OF GOODS AND SERVICE

	2023/24	2022/23
	TZS	TZS
Accommodation Training - Domestic	70,500,000	58,047,401
Advertising and Publication - Communication & Information	34,720,242	69,722,201
Air Travel Tickets Training - Domestic	16,000,000	-
Air Travel Tickets Training - Foreign	219,054,338	136,032,000
Air Travel Tickets Travel - In - Country	979,295,554	753,349,910
Air Travel Tickets Travel Out of Country	136,241,482	29,011,624
Books, Reference and Periodicals	2,789,303	9,435,822
Computer Supplies and Accessories	9,315,000	54,825,492
Conference Facilities	140,326,210	198,615,716
Consumable Medical Supplies	993,292,917	2,141,059
Courier Services	7,709,600	5,140,004

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

	2023/24	2022/23
	TZS	TZS
Diesel	765,030,137	846,851,591
Drugs and Medicines	2,400,000	-
Electricity - Utilities Supplies and Services	290,695,246	332,050,303
Entertainment - Hospitality Supplies And Services	39,811,900	23,118,400
Exhibition, Festivals and Celebrations	43,063,000	32,218,994
Food and Refreshments	28,630,952	1,258,458,920
Fumigation Expenses	3,211,585	8,924,094
Gifts and Prizes	121,446,500	79,300,000
Ground Transport (Bus, Train, Water)	1,320,000	1,630,000
Ground travel (bus, railway taxi, etc) Travel - In - Country	170,810,754	288,538,024
Ground travel (bus, railway taxi, etc) Travel Out Of Country	18,775,504	-
Health Insurance Training - Foreign	10,773,997	5,923,905
Internet and Email connections	405,294,818	364,692,017
Laboratory Supplies	193,398,641	-
Lodging/Accommodation Travel Out Of Country	31,000,000	10,445,400
Medical Gases and Chemicals	40,000,000	-
Mobile Charges	17,686,136	19,210,000
News Services Fees	17,591,808	325,259,125
Newspapers and Magazines	7,174,398	12,814,963
Expenditure-Use of Goods and Service	2,117,417,250	622,416,714
Office Consumables (papers, pencils, pens and stationaries)	328,345,424	205,471,908
Outsourcing Costs (includes cleaning and security services)	461,599,828	203,473,660
Per Diem - Domestic	7,199,197,431	6,541,372,179
Per Diem - Foreign	1,769,775,186	1,618,503,277
Petrol	11,150,000	9,195,000
Posts and Telegraphs	43,775,900	29,523,750
Printing and Photocopy paper	2,050,000	-
Printing and Photocopying Costs	115,245,090	200,355,147
Programs Transmission Fees	-	5,896,500
Publicity	22,000,002	13,751,003
Remuneration of Instructors	25,000,000	24,275,000
Rent - Office Accommodation	485,375,558	490,067,279
Rent of Private vehicles	18,782,000	13,330,000
Rent of Vehicles and Crafts	13,400,000	9,293,296
Research and Dissertation Training - Domestic	29,000,000	14,003,285
Software License Fees	20,874,672	44,000,000
Special Foods (diet food)	3,600,000	-
Sporting Supplies	-	14,100,000
Subscription Fees	216,903,403	260,871,231
Technical Service Fees	68,066,142	89,999,999
Telephone Charges (Land Lines)	39,186,191	52,868,954
Telephone Charges -Utilities Supplies and Services	500,000	-
Training Materials	14,700,000	11,502,500

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

	2023/24	2022/23
	TZS	TZS
Tuition Fees Training - Domestic	163,877,790	166,707,800
Tuition Fees Training - Foreign	113,781,000	59,560,121
Uniforms and Ceremonial Dresses	19,050,000	42,300,000
Upkeep Allowances	8,000,000	28,818,237
Visa Application Fees	11,271,130	5,677,226
Water and Waste Disposal (Garbage)	-	6,120,000
Water Charges	33,465,588	46,464,095
Total	18,172,749,907	15,755,705,126
Add/Less (Change in Working Capital)		
Consumables	(312,061,784)	912,917,920
Imprest Receivable - Staff	58,641,581	30,046,270
Prepayment - Expenses	(8,352,265)	21,474,998
Supplies of goods and services	(271,171,729)	(211,038,071)
VAT Payable	(18,450,776)	(16,402,832)
Withholding tax	(728,783,786)	77,548,450
Total	16,892,571,148	16,570,251,861

47. MAINTENANCE EXPENSES

	2023/24	2022/23
	TZS	TZS
Air conditioners	4,020,000	15,558,300
Cement, Bricks and Building Materials	16,672,580	2,315,620
Cement, bricks and construction materials	3,194,000	3,600,000
Computers, printers, scanners, and other computer related equipment	15,255,645	37,445,385
Electrical and Other Cabling Materials - Water and Electricity Installations	10,121,179	14,987,488
Fire Protection Equipment	20,000,000	-
Medical and Laboratory equipment	331,377,909	154,653,786
Motor Vehicles and Watercraft	382,817,571	418,002,469
Outsource maintenance contract services - Buildings	38,572,700	288,687,798
Outsource maintenance contract services - Machinery, Equipment and Plant	268,849,896	-
Outsource maintenance contract services - Water and Electricity Installations	68,549,274	100,756,000
Small tools and implements - Buildings	22,900,000	3,750,000
Small tools and implements - Water and Electricity Installations	3,789,000	5,617,630
Telephones and Office PABX systems	10,089,380	15,117,226

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

	2023/24 TZS	2022/23 TZS
Total	1,196,209,134	1,060,491,702

48. OTHER EXPENSES

Agency fees	101,809,862	66,699,309
Audit fees Expenses	204,800,000	204,800,000
Bank Charges and Commissions	-	3,687,032
Burial Expenses	66,650,000	24,960,000
Co-Location operational Expenses	1,523,750	2,229,650
consultancy fees	593,539,851	739,199,948
Freight Forwarding and Clearing Charges	55,948,200	60,000,000
Sundry Expenses	170,205,144	82,489,540
Transports posts - other expenses	1,000,000	-
Witnesses Expenses	1,355,000	2,835,000
sub total	1,196,831,807	1,186,900,479
Add/Less (Change in Working Capital)		
Other Payables	66,498,500	83,479,788
Total	1,263,330,307	1,270,380,267

49. SOCIAL BENEFITS

Settlement of Medical Treatment Claims	311,352,045	289,883,516
Total	311,352,045	289,883,516

50. OTHER TRANSFERS

Contribution to CF (15%)	5,902,166,689	5,320,594,355
Capital redemption	2,224,458,329	400,000,000
Total	8,126,625,018	5,720,594,355

51. ACQUISITION OF PROPERTY, PLANT AND EQUIPMENT

PPE - Addition	1,520,896,709	8,540,363,909
Transfer from Prepayment - Assets	(341,096,200)	-
Transfer from Work in progress	(124,515,150)	(7,712,052,790)
Total	1,055,285,359	828,311,119

52. PROCEED FROM SALE OF PPE

	2023/24 TZS	2022/23 TZS
Motor vehicles, Disposal	357,113,492	-
Motor vehicles, Depreciation Disposal	(321,402,143)	-
Subtotal	35,711,349	-
Proceeds	26,232,074	-
Losses on disposal of PPE	9,479,275	-

53. PRIOR YEAR ADJUSTMENT

Where necessary, comparative figures have been re-classified to conform to the current year's presentation.

Also, there are some of the comparative figures (Prior year 2022/23) have been restated as narrated in the table below.

Item affected	Prior amount before restatement/reclassification	Amount after restatement /reclassification	Reason for restatements/reclassification
	TZS	TZS	
Consumables-Inventory	627,577,180	2,583,610,523	Consumables (Inventory) value reported previous year included only unit cost. After review of previous report the discrepancy of TZS 1,956,033,343 was identified and recognized.
Intangible Asset	-	446,977,999	Adoption of new Government Asset Management guideline of 2024 which changed useful life from 3 to 10 years lead to recalculation of Software net book value hence re-recognition of LIMS software.
Impairment of Intangible Assets	638,540,000	191,562,001	Adoption of new Government Asset Management guideline of 2024 which changed useful life from 3 to 10 year lead to recalculation of Software impairment charge for the year hence restate charges. Review lead to decrease of Impairment charge by TZS 148,992,668 hence restatement of financials of previous year.
Expected Credit Loss (ECL) for previous years	33,402,589,638	33,564,231,633	Adoption of new IPSAS 41 lead to recalculations of ECL for two previous years starting June 2022. The total effect of TZS 161,641,995.07 lead to restating previous year financials accordingly.
Receivables	35,240,982,562	33,591,596,142	TZS 35,240,982,562 comprised of imprest receivable TZS 32,325,569 and Trade receivable of TZS 33,559,030,036 (MSD 33,402,589,638 and rent TZS 109,883,043).
Use of- Goods and Service	17,711,768,469	15,755,705,126	Consumables (Inventory) value reported previous year

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Item affected	Prior amount before restatement/reclassification	Amount after restatement /reclassification	Reason for restatements/reclassification
	TZS	TZS	
			included only unit cost. After review of previous report, the discrepancy of TZS 1,956,033.342.82 was identified. and financial performance (Use of goods & services) was restated to the tune of TZS 1,956,033,342.82.
Provisions	33,402,589,638	33,564.231.633	The changes of TZS 161,641,995 were due to inclusion of ECL of previous years.