



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 2023



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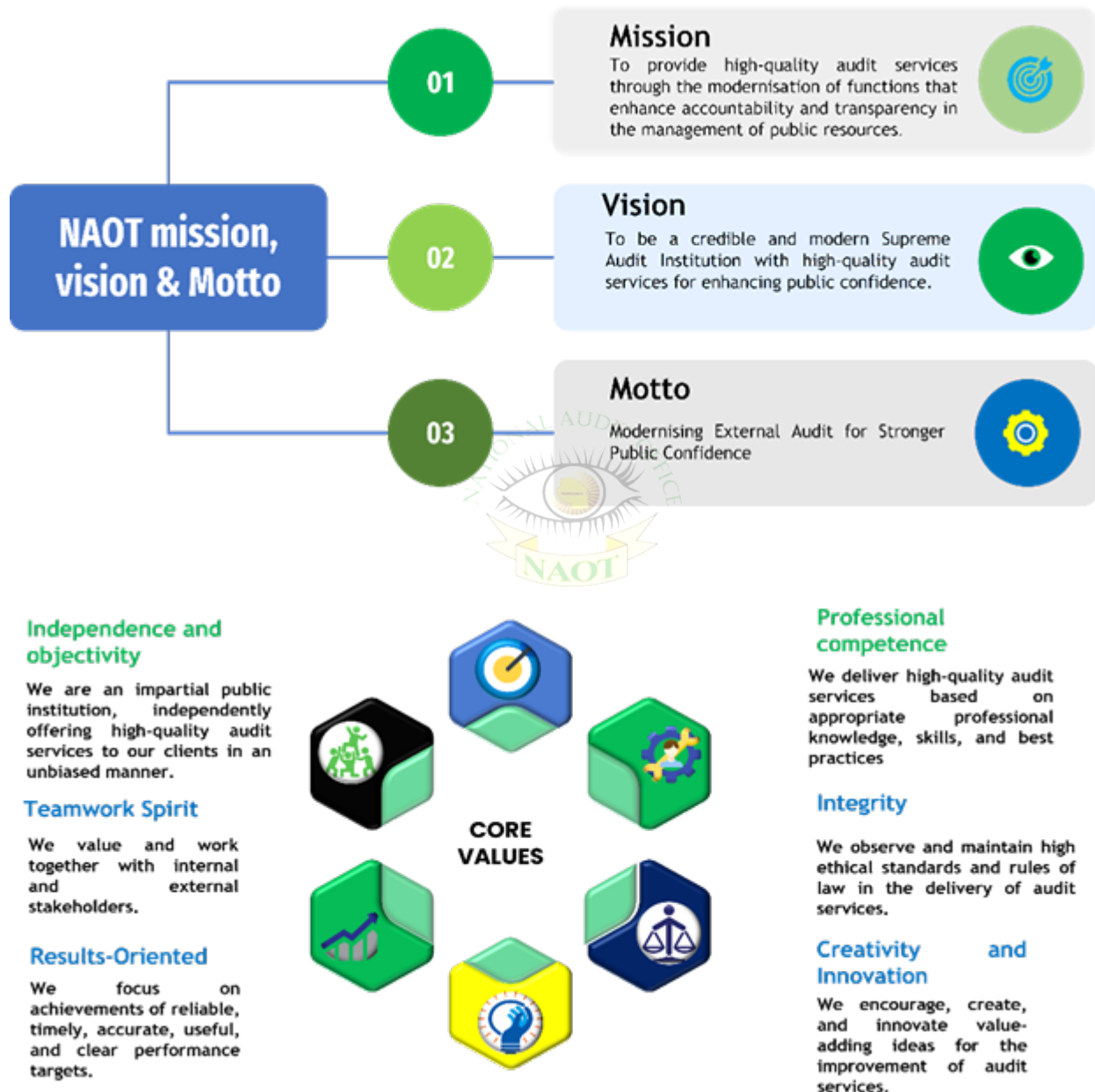
March 2024

AR/PA/TMDA/2022/23

About the National Audit Office

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 [R.E 2021]



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Abbreviations

ACPA	Associate Certified Public Accountant
ARMC	Audit and Risk Management Committee
CAG	Controller and Auditor General
COVID-19	Corona Virus Disease of 2019
CPA	Certified Public Accountant
EDCTP	European and Developing Countries Clinical Trials Partnership
FIFO	First in first out
GMP	Good Manufacturing Practice
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
MOH	Ministry of Health
MSD	Medical Store Department
NHIF	National Health Insurance Fund
PPE	Property, Plant and Equipment
PSSSF	Public Sector Social Security Fund
TBS	Tanzania Bureau of Standards
TFDA	Tanzania Food and Drugs Authority
TFRS 1	Tanzania Financial Reporting Standards 1
TMDA	Tanzania Medicines and Medical Devices Authority
TZS	Tanzania 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 2023, and the statement of financial performance, statement of changes in net assets and 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 2023, 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 responsibilities of the ministerial advisory board, Declaration by the Head of Finance, and any other information included in the entity'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 [R.E 2021] 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 [R.E 2022] 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 (TMDA) for the financial year 2022/23 as per the Public Procurement laws.

Conclusion

Based on the audit work performed, I state that, except for the matter described below, the procurement of works, goods, and services of Tanzania Medicines and Medical Devices Authority (TMDA) is generally in compliance with the requirements of the Public Procurement laws.

- **Absence of justification for using single-source procurement method**

My review of procurement management noted that, the tender board approved the use of single-source procurement method worth TZS 63,551,652 without documented justification contrary to the requirement of Section 257 (2) and Eleventh Schedule of the PPA, 2016.

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 the Tanzania Medicines and Medical Devices Authority (TMDA) for the financial year 2022/23 as per the Budget Act and other Budget Guidelines.

Conclusion

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

Charles E. Kichere
Controller and Auditor General,
Dodoma, United Republic of Tanzania.
March 2024

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 1 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 be the leading Regulatory Authority in ensuring safe, quality and effective, medicines, medical devices, diagnostics and other health related products for all.

Mission

To protect and promote public health by ensuring quality, safety 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. TMDA shall strive to balance the interests of our stakeholders without compromising quality, safety and effectiveness of medicines, medical devices and diagnostics by managing the Authority with utmost professionalism. TMDA is committed to comply with the requirements of ISO 9001:2015 Standard and continually improve the effectiveness of the Quality Management System. It shall manage and provide resources for continuous improvement of services to ensure customer satisfaction.

2.2 LOCATION OF THE OFFICES

TMDA Headquarters is located at Plot No. 56/1, Block E, Kisasa B, Centre, Swaswa Road, Adjacent to Martin Luther School, 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 THE 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 1 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 (DMD), Directorate of Laboratory Services (DLS) and Directorate of Business Support (DBS) whereas the seven (7) Units are Internal Audit, Quality and Risk Management, Legal Services, ICT and Statistics, Procurement, Accounts and finance, Communication and Public education. Zone offices are directly responsible to the Director General through the Zone Managers who oversee TMDA functions in the respective zones. Distribution of zones and their respective regions is as indicated in table below: -

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 TMDA OPERATING MODEL (CONTINUED)

2.5.1 Inputs

(a) Human Capital

The Authority had 352 (311 permanent and 41 temporary) employees as on 30 June 2023 (350 on 30 June 2022). The employees have adequate skills and competence to ensure the delivery of quality regulatory services. The employees are well trained, motivated and perform their duties responsibly and in an 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 and 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 nurtured a good working relationship among employees through cultivating trust and respect and ensuring views of each employee are 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 and 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 conducts 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 of 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, the 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 several activities in converting inputs into regulatory services. The operating activities are divided into three major groups;

(a) Regulation of Medical and Complimentary 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 ensuring that tobacco products circulating in the market are appropriate for the protection of public health.

(b) Regulation of Medical Devices and Invitro-Diagnostics

The activity involves overseeing assessment for the performance of medical devices, diagnostics and laboratory equipment prior to marketing authorization, coordinate quality audits of domestic and foreign manufacturing premises of medical devices and diagnostics overseeing issuance of import and 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 Medical and Complimentary Products

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

- 2,478 applications for registration of human medicines were received;
- 2,223 applications were evaluated;
- 757 human medicines were approved and registered;
- 281 applications for registration of veterinary were received;
- 271 veterinary applications were evaluated;
- 52 human medicines were approved and registered
- 1,030 applications for registration of premises were received;
- 908 Premises were approved and registered;
- 1,020 business premises for medical products were inspected;
- 908 premises were found to comply with the needed standard; and
- 7,475 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:

- 280 applications for registration of medical devices and 145 for applications for registration of diagnostics were received;
- 275 applications of medical devices and 141 for applications of diagnostics were evaluated; and
- 157 applications of medical devices and 69 for applications of diagnostics were approved

(c) Laboratory Analytical services

Under this function, the Authority had the following outputs:

- 2,076 samples of medical products were received;
- 1,989 samples were analysed;
- 1976 were passed and complied;

2.5.4 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)

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 30 June 2023, the Authority had its Head Office in Dodoma, eight (8) zone offices and total of 352 employees (30 June 2022 350 employees). The employees are highly motivated and 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 19 May 2020 and its three-year tenure ended on 19 May 2023. The composition of the board member is as hereunder:

S/N	Name	Position	Age	Qualification/ Discipline	Nationality
1.	Mr. Eric Shitindi	Chairperson	64	Masters Degree in Economics	Tanzanian
2.	CPA Zaina Thabit	Member	53	Associate Certified Public Accountant (ACPA-T), MBA- Corporate Management, Diploma in IPSAS and Risk Management	Tanzanian
3.	Prof. Said Shebe Aboud	Member	56	Doctor of Philosophy (PhD) in Infection Biology	Tanzanian
4.	Mr. Adam Fimbo	Secretary	48	Masters Degree in Clinical Trials, Masters Degree in Pharmaceutical Services and Medicines Control	Tanzanian
5.	Mr. Daudi Msasi	Member	45	MBA in Human Resources Management, Bachelor Degree in Pharmacy	Tanzanian
6.	Prof. Apolinary A.R. Kamuhabwa	Member	57	Doctor of Philosophy (PhD) in Pharmacology and Therapeutics	Tanzanian
7.	Ms. Emma Lekashingo Msuya	Member	55	Masters Degree in Public Health (MPH)	Tanzanian

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The new MAB was appointed on 18 August 2023. The composition of the board members is as hereunder.

S/N	Name	Position	Age	Qualification/ Discipline	Nationality
1	Mr. Eric Shitindi	Chairperson	64	Masters Degree in Economics	Tanzanian
2	CPA Chiku Thabit Yusuf	Member	53	Associate Certified Public Accountant (ACPA-T), MBA - Corporate Management (MBA - CM), and Advanced Diploma in Certified Accounting	Tanzanian
3	Adv. Patricia Maganga	Member	60	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
4	Mr. Adam Fimbo	Secretary	48	Masters Degree in Clinical Trials, Masters Degree in Pharmaceutical Services and Medicines Control	Tanzanian
5	Mr. Daudi Msasi	Member	45	MBA in Human Resources Management, Bachelor Degree in Pharmacy	Tanzanian
6	Prof. Apolinary A.R. Kamuhabwa	Member	57	Doctor of Philosophy (PhD) in Pharmacology and Therapeutics	Tanzanian
7	Mrs. Mariam G. Mwanilwa	Member	57	Postgraduate Diploma in Law, Mediation & Arbitration, Master's Degree in Public Administration, and Advanced Diploma in Public Administration	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
- 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 2023, the Board conducted four ordinary meetings as tabulated below.

(a) Number of MAB Meetings for the year under review

S/N	Meeting	MAB	ARMC	LTC
1	Ordinary Meeting	3	3	3
2	Adhoc/Special Meeting	-	2	-
3	Any other meeting	-	-	-
Total		3	5	3

(b) MAB members' attendance to MAB meetings and committee meetings

S/N	Name	MAB	ARMC	LTC
1	Mr. Eric Shitindi	3	N/A	N/A
2	CPA Zaina Thabit	3	4	N/A
3	Prof. Said Shebe Aboud	3	N/A	3
4	Mr. Adam Fimbo	3	5	3
5	Mr. Daudi Msasi	3	N/A	1
6	Prof. Apolinary A.R. Kamuhabwa	3	5	2
7	Ms. Emma Lekashingo Msuya	3	5	3

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

- Annual progress report for the financial year 2022/23;
- Incentive scheme of 2022;
- Annual Revised Budget for the Year 2022/23;
- Annual action plan and budget for the year 2022/23;
- Quarterly progress reports for year 2022/23;
- Building project for TMDA Central Zone Building;
- Renovation of TMDA Buildings (Tarakea and Horohoro) and building of fence for Namanga

- Building;
- h. Building of Incinerators of Pwani and Dodoma;
- i. Discussion of Government directive on staff transfer to Dodoma.
- j. WHO Rebenchmarking audit;
- k. Discussion on TMDA Journal version 11;
- l. Working Plan and audit fee for 2021/22.
- m. CAG Annual Audit Report for the year ended 30 June 2022;
- n. Quarterly Internal Audit, Legal and Risk reports;
- o. Approval of TMDA Budget of 2023/2024;
- p. Adverse effect on Bupivacaine medicine;
- q. Procurement plan of 2023/2024;
- 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 (ARMC)

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

S/N	Name	Position	Qualification/Discipline	Nationality	Date Appointed/ Resigned
1.	CPA Zaina Thabit	Chairperson	Associate Certified Public Accountant (ACPA-T), MBA-Corporate Management, Diploma in IPSAS and Risk Management	Tanzanian	Appointed 19 May 2020
2.	Emma Lekashingo Msuya	Member	Master's Degree in Public Health (MPH)	Tanzanian	Appointed 25 June 2020

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S/N	Name	Position	Qualification/Discipline	Nationality	Date Appointed/ Resigned
4.	Prof. Appollinary A.R. Kamuhabwa	Member	Doctor of Philosophy (PhD) in Pharmacology and Therapeutics	Tanzanian	Appointed 19 May 2020

2.9.2 Legal and Technical Committee (LTC)

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

S/N	Name	Position	Qualification/Discipline	Nationality	Date Appointed/ Resigned
1.	Prof. Said Shebe Aboud	Chairperson	Doctor of Philosophy (PhD) in Infection Biology	Tanzanian	Appointed 19 May 2020
2.	Emma Lekashingo Msuya	Member	Master's Degree in Public Health (MPH)	Tanzanian	Appointed 25 June 2020
3.	Mr.Daudi Msasi	Member	MBA in Human Resources Management, Bachelor Degree in Pharmacy	Tanzanian	Appointed 19 ay 2020

2.10 CAPITAL STRUCTURE

The capital structure of the Authority for the year ended 30 June 2023 is shown below on a comparable basis:

SOURCES	2022/23 TZS	2021/22 TZS
Capital fund	1,139,932,800	1,139,932,800
Accumulated surplus	41,722,881,419	44,613,546,724
TOTAL	42,862,814,219	45,753,479,524

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.

2.10.1 Office of the Director General

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

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).

2.10.2 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.

2.10.3 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, 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.

2.10.4 Directorate of Medical Devices

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.

2.10.5 Directorate of Medical Products 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 FINANCIAL PERFORMANCE FOR THE YEAR 2022/23

During the Financial year ended 30 June 2023, Revenue earned from internal sources (Fees and charges and other income) increased by 7% from TZS 36.0 billion (2021/22) to TZS 38.52 billion (2022/23) due to enhanced controls over collection of revenue through the usage of Government electronic Payment Gateway (GePG) and removal of COVID-19 restrictions which allowed more inspection and registration activities.

Donors' Grants carried forward to the financial year 2022/23 was TZS 0.43 billion, amount received was TZS 2.40 billion and a total of TZS 0.14 billion utilized during the year under review. Un-utilized fund of TZS 2.5 billion was carried forward. Government grants in respect of Personal emoluments were TZS 4.170 billion in 2022/23 from TZS 4.58 billion in 2021/22.

2.12 RISK MANAGEMENT AND INTERNAL CONTROL

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:

- a. The effectiveness and efficiency of operations;
- b. The safeguarding of the Authority's assets;
- c. Compliance with applicable laws and regulations;
- d. The reliability of accounting records;
- e. Business sustainability under normal as well as adverse conditions; and

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 30 June 2023 and is of the opinion that they met accepted criteria.

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 POLITICAL AND CHARITABLE DONATIONS

The Authority did not make any political donations during the year ended 30 June 2023. Donations were made as part of corporate social responsibility to institutions and charitable organizations to acknowledge the Authority's responsibility to community social needs.

2.15 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.

2.15.1 Principal Risks and Uncertainties**Table: 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	Failure to manage Authority's assets effectively. Impact: 1. Under/over stating the Authority's property value and financial statements 2. Assets' misappropriation and misuse 3. Underutilization of assets	TMDA is conducting timely verification of assets both fixed and inventories. TMDA also updates assets register and this information is part of progress reports.

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S/N	Category	Risk and Impact	Mitigation
	its objectives.	<p>4. Assets' duplication 5. Financial loss 6. Qualified audit report</p> <p>Failure of the MAB to execute its functions effectively.</p> <p>Impact:</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 governance innings.</p>
		<p>Gender imbalanced decisions.</p> <p>Impact:</p> <ol style="list-style-type: none"> 1. Gender biased decisions 2. Failure to comply with requirements of National Strategy for Gender Development 3. Reduced staff morale 4. Less attraction of physically challenged persons to seek services and opportunities rendered by TMDA 	<p>The Authority developed and implemented the gender mainstreaming strategy. TMDA Training program provides for special training about management to women each financial year has co-opted female staff as part of management.</p>
2	<p>Operational Risks: These are risks of losses to TMDA due to failed processes or systems.</p>	<p>Circulation of falsified, substandard and unauthorized products on the market.</p> <p>Impact:</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 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. Staff are continuously recruited to address the current shortage including providing regular training on inspection of medical products. 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 developed and uses electronic tools for collection of ADRs and AEs reports. The Authority enforces the Pharmacovigilance Regulations including requiring Marketing Authorization Holders to appoint Qualified Persons for Pharmacovigilance (QPPV)</p>

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S/N	Category	Risk and Impact	Mitigation
		<p>Leakage of TMDA information.</p> <p>Impact:</p> <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 	<p>TMDA has developed and implements Document and Records Management Guidelines. All TMDA systems used in service provision has audit trail which are regularly checked to verify users' activities.</p> <p>Staff are trained on code of ethics, records management and TMDA communication guidelines to transferred staff, interns, researchers and field students.</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>Unavailability of ICT Services.</p> <p>Impact:</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 developed and regularly performs testing of ICT Disaster Recovery Plan.</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>Impact:</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>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>Approval of non-existing or non GMP compliant manufacturing facilities</p> <p>Impact:</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>
		<p>Low public awareness on TMDA functions</p> <p>Impact:</p> <ol style="list-style-type: none"> 1. Non adherence to legal requirements 2. Institutional bad reputation 3. Panic and public health endangered 	<p>TMDA has recruited Public Education and Communication Officers at Southern Zone. TMDA has also conducted end term evaluation of its Communication and Public Education Strategy.</p>

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S/N	Category	Risk and Impact	Mitigation
		Underperformance, delays or failure of TMDA projects Impact: 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	For all project implemented at TMDA, the Authority has appointed focal persons to oversee operations of such projects.
		Loss of Product samples, exhibits or dossiers Impact: 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	Staff are regulatory trained on how to handle product samples as well as exhibits. The storage rooms for products samples and exhibits are under lock and key with a register of products under TMDA custody.
3	Financial and Systems Risks: This is any circumstance if materialized, may compromise the financial control systems of TMDA.	Loss of revenues to sustain TMDA activities. Impact: 1. Failure to implement strategic objectives 2. Loss of national and international credibility 3. Institutional instability 4. Decreased staff morale	As part of mitigation the Authority has reviewed and published the Fees and charges regulations. 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. Each Zone Offices has appointed staff 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. Impact: 1. Loss of time and financial resources 2. Litigations 3. Incomplete projects 4. Failure to deliver services Not sustaining ISO certifications, WHO Maturity Level 3 and Prequalification Impact:	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. 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.

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S/N	Category	Risk and Impact	Mitigation
		<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 	
		<p>Non-compliance to Legal requirements.</p> <p>Impact:</p> <ol style="list-style-type: none"> 1. Qualified audit reports. 2. Litigations against TMDA. 3. Financial loss. 4. Impaired reputation. 5. Public health compromised. 	<p>TMDA compliance to laws and regulations is now a permanent agenda in MAB meetings.</p> <p>TMDA staff are regularly sensitized on the code of ethics and law, regulations and guidelines to enhance compliance for TMDA operations.</p>

Source: TMDA Institutional Risk Registers.

2.16 PREJUDICIAL ISSUES

According to TFRS 1 (Paragraph 54); Entities shall report all issues which were outside the control of the respective entity in achieving their objectives. During the financial year 2022/23 there were no any prejudicial issues.

2.17 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 2022/23 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.

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.

Authority's Objectives, Targets and Key Performance Indicators

Objective	Target for 2022/23	Key Performance Indicator (KPI)	Implementation Status 30 June 2023
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, 2023	80% of staff sensitized on HIV/AIDS	71% of staff were sensitized on HIV/AIDS
		80% of staff sensitized on NCDs	71% of staff were sensitized on NCDs
		80% 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, 2023.	80% of staff sensitized on Anti-Corruption Strategy and Public Service Code of Ethics and Conduct	71% 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
	Public Service Code of Ethics and Conduct instilled to staff by June, 2023	100% of new staff signing integrity pledge forms	100% of new staff signed integrity pledge forms
		4 areas prone to corruption identified and mitigated	4 areas prone to corruption were identified and mitigation plan were put in place and implemented
		78% of conformity to FIFO in registration and issuance of permits	All applications were attended in conformity with FIFO
Gender and environmental issues improved	Women staff empowered at all levels by June, 2023;	No woman trained on leadership and management among senior women staff	No woman was trained on leadership and management among senior women staff
	Infrastructures to support physically challenged persons provided by June, 2023; and		
		Infrastructures for physically challenged persons in place	Infrastructures for physically challenged

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Objective	Target for 2022/23	Key Performance Indicator (KPI)	Implementation Status 30 June 2023
			persons are in place
	Facilities for handling and disposal of waste and unfit products in place by June, 2023.	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, 2023;	98% of received applications for product registration of human medicines assessed within specified time as per CSC	92% of received applications for product registration of human medicines were assessed within specified time as per CSC
	Surveillance and vigilance of medicines and biocidal products conducted by June, 2023;	95% of received applications for registration of veterinary medicines assessed within specified time as per CSC	97% of received applications for registration of veterinary medicines were assessed within specified time as per CSC
	Medicines and biocidal products registered by June, 2023; and Clinical trials approved and inspected by June, 20223	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
		95% 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
		99% 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

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Objective	Target for 2022/23	Key Performance Indicator (KPI)	Implementation Status 30 June 2023
		100% of registered outlets for medicines inspected	100% of registered outlets for medicines were inspected
		100% of planned PMS samples for human medicines collected	95% of planned PMS samples for human medicines were collected
		100% of planned PMS samples for veterinary medicines collected	95% of planned PMS samples for veterinary medicines were collected
		100% of applications for authorization of clinical trials evaluated	100% of applications for authorization of clinical trials were evaluated
		70% of approved clinical trials inspected	100% of approved clinical trials were inspected
		100% of received field safety reports assessed	100% of received field safety reports were assessed
		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
		60% of overseas pharmaceutical manufacturing facilities inspected for GMP	24% of overseas pharmaceutical manufacturing facilities were inspected virtually due to COVID-19 restrictions
		100% of received import applications processed	94% of received import applications were processed

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Objective	Target for 2022/23	Key Performance Indicator (KPI)	Implementation Status 30 June 2023
		100% of received export applications processed	94% of received export applications were processed
		100% of approved consignments inspected at the Ports of Entry (PoEs);	66% of approved consignments were inspected
		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, 2023;	100% of received applications for registration of medical devices assessed	98% of received applications for registration of medical devices were assessed
	Surveillance and vigilance of medical devices and diagnostics conducted by June, 2023; and	100% of received applications for registration of diagnostics assessed	89% of received applications for registration of diagnostics were assessed
	Medical devices and diagnostics registered by June, 2023.	100% of received applications for registration of premises for medical devices and diagnostics processed;	93% 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
		100% of planned PMS samples for medical devices collected;	100% of planned PMS samples for medical devices were collected;

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Objective	Target for 2022/23	Key Performance Indicator (KPI)	Implementation Status 30 June 2023
		100% of planned PMS samples for diagnostics collected	100% 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 by using desk review method
		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.	100% of approved consignments were inspected at the PoEs.
		100% of received field safety reports assessed	100% of received field safety reports were assessed
Control of Tobacco Products strengthens	Premises dealing in tobacco products registered and inspected by June, 2023;	50% of received applications for notification of tobacco products assessed	50% of received applications for notification of tobacco products were assessed
	Surveillance and vigilance of tobacco products conducted by June, 2023; and	50% of planned surveillance samples for tobacco products collected	50% of planned surveillance samples for tobacco products were collected

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Objective	Target for 2022/23	Key Performance Indicator (KPI)	Implementation Status 30 June 2023
	Tobacco products notified/registered by June, 2023.	50% of domestic tobacco products manufacturing facilities inspected;	50% of domestic tobacco products manufacturing facilities were inspected;
Laboratory services improved	TMDA laboratories strengthened by June, 20;	100% of regulatory samples of medicines tested	100% of regulatory samples of medicines were tested
		100% of regulatory samples for herbal medicines tested	100% of regulatory samples for herbal medicines were tested
	Samples of medicines, medical devices, diagnostics, tobacco and complementary products tested by June, 2023;	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 and operationalized by June, 2023; and	100% of regulatory samples of diagnostics tested	100% of regulatory samples of diagnostics were tested
		9 analytical methods accredited for Dar es Salaam laboratory	9 analytical methods were accredited for Dar es Salaam laboratory
	Operational and applied researches on regulatory functions conducted by June, 2023.	95% of received non-regulatory samples from external customers tested	100% of received non-regulatory samples from external customers were tested
		1,550 medicines samples screened at all Quality Assurance (QA) Centres	1,989 medicines samples were screened at all Quality Assurance (QA) Centres

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Objective	Target for 2022/23	Key Performance Indicator (KPI)	Implementation Status 30 June 2023
		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, 2023;	Percentage of planned types of IEC materials developed, printed and disseminated	100% of planned types of IEC materials were developed, printed and disseminated
		Percentage of employees sensitized on customer care, core values and code of ethics and conduct	100% of employees were sensitized on customer care, core values and code of ethics and conduct
	Public awareness on TMDA functions and customer satisfaction raised by June, 2023;	Percentage of received customer complaints attended and resolved	100% of received customer complaints were attended and resolved
		Percentage compliance to external Clients' Service Charter	100% compliance to external Clients' Service Charter
	Stakeholders' engagement and participation plan developed and implemented by June, 2023.	Percentage of received whistle blower alerts and concerns attended and closed.	100% of received whistle blower alerts and concerns were attended and closed.
		95% of planned information updates uploaded on TMDA website	100% of planned information updates were uploaded on TMDA website
		800 information updates uploaded on TMDA social media platforms	533 information updates were uploaded on TMDA social media platforms
		35,000 followers on TMDA social media platforms	265,610 followers on TMDA social media platforms

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Objective	Target for 2022/23	Key Performance Indicator (KPI)	Implementation Status 30 June 2023
		95% of staff sensitized on customer care	100% of staff were sensitized on customer care
		95% of planned TV and radio programmes developed and aired	100% of planned TV and radio programmes were developed and aired
		95% of planned exhibitions participated	100% of planned exhibitions were participated
		95% of planned outreach campaigns conducted	100% of planned outreach campaigns were conducted
		99% of whistle blowers provided with feedback	99% of whistle blowers were provided with feedback
Institutional capacity to deliver regulatory services enhanced	Infrastructures, working facilities and tools provided and maintained by June, 2023;	Percentage of projected revenue collected from own source	106% of projected revenue collected from own source
	Annual Procurement Plans developed and implemented by June, 2023;		
	Internal Audit plans developed and implemented by June, 2023;		
	Financial resources properly managed by June, 2023;		
	Human resources properly managed by June, 2023;		
	Professional and career development programmes implemented by June, 2023;		

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Objective	Target for 2022/23	Key Performance Indicator (KPI)	Implementation Status 30 June 2023
	Zone offices operations coordinated by June, 2023;		
	Planning, budgeting and their implementation coordinated by June, 2023;		
	Institutional plans and programmes monitored and evaluated by June, 2023;		
		Percentage of projected revenue collected from all sources	106% of projected revenue collected from all sources
	Quality and Risk Management Systems improved by June, 2023;	Percentage of planned internal audits conducted	100% of planned internal audits were conducted
		Percentage implementation of planned work plans	100% implementation of planned work plans
	ICT usage enhanced by June, 2023;	Percentage implementation of the HR plan	100% implementation of the HR plan
		Percentage implementation of training programme	94% implementation of training programme
	Legal Services timely provided by June, 2023;	Percentage of service processes automated	95% of service processes automated
		Percentage implementation of the procurement plan	78% implementation of the procurement plan
	Administrative services provided by June, 2023;	Percentage of planned quality audits conducted	100% of planned quality audits conducted
		Percentage mitigation of identified risks	100% mitigation of identified risks
	Regional and international collaboration and harmonization initiatives for regulated	Percentage of staff sensitized on quality risk management	80% of staff sensitized on quality risk management

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Objective	Target for 2022/23	Key Performance Indicator (KPI)	Implementation Status 30 June 2023
	products facilitated by June, 2023.		

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

2.18 STATEMENT OF COMPLIANCE

The Report by Those Charged with Governance is prepared in compliance with the new Tanzania Financial Reporting Standard No. 1 (TFRS No. 1) as issued by the National Board of Accountants and Auditors (NBAA) and became effective from 1 January 2021. The Authority's financial statements have been prepared in compliance with the International Public Sector Accounting Standards (IPSASs) accrual basis as issued by the International Public Sector Accounting Standards Board (IPSASB).

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 2022/23. 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 which if allowed existing would impair the ability to discharge duties fairly.

2.19.2 Training

During the financial year ended 30 June 2023, the Authority's budget for Staff training amounted to TZS 917,586,831 as compared to TZS 1,336,221,451 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. In the financial year ended 30 June 2023 Staff training spent were TZS 901,936,831 as compared to TZS 1,129,264,770 in the previous year this reduction was caused by the transfer from Dar es Salaam to Dodoma.

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 2023, TMDA staff were deducted a total of TZS 259,666,080 for NHIF contribution as compared to TZS 254,877,780.00 for previous year.

In addition, the Authority covers for any medical expenses not covered by NHIF. During the year ended 30 June 2023 the authority paid for employee's medical expenses not covered by NHIF to

the tune of TZS 36,883,516.32 as compared to TZS 68,708,500.00 paid in the previous year. The decrease attributed by new health scheme whereby the Authority entered in agreement with NHIF to pay TZS 253,000,000 as a supplementary package.

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.

2.19.4 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.

2.19.5 Employees Benefit Plan

During the financial year that ended 30 June 2023, 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 401,514,300 (2022/23) as compared to TZS 371,053,434 (2021/22) due to fact that number of Employees was increased.

2.20 GENDER

As at 30 June 2023 the Authority had 312 permanent employees and 40 contract employees. Out of 312 permanent employees 197 are male and 115 are female. Out of 40 contract employees 28 are male and 12 are female (For the year ended 30 June 2022, the Authority had 307 employees out of which 203 are male and 104 are female. As indicated below:

Gender	2022/23			2021/22	
	No.	%		No.	%
Male	225	64%		203	66%
Female	127	36%		104	34%
Total	352	100%		307	100%

2.21 CORPORATE SOCIAL RESPONSIBILITY

The Authority has developed a marketing plan, which includes corporate social responsibility activities. To execute these activities a total of TZS 90,000,000 was set as budget in the financial year 2022/23. During the financial year 2022/23 the Authority spent TZS 34,350,000 compared to TZS 28,500,000 spent in 2021/22 to support a number of social and economic development

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

initiatives implemented throughout the country. The list of beneficiaries on corporate social responsibilities funds for the financial year 2022/23 is provided under Table below:

S/N	Beneficiary's Name	Amount (TZS)	Purpose
1.	National Blood Transfusion Service	1,250,000	Blood donation campaign
2.	Tanzania Disabled Community	1,500,000	Walking sticks and sunscreen oil
3.	Pharmaceutical Society of Tanzania (PST)	5,000,000	Support of the Annual Scientific conference
4.	Ministry of Health	10,000,000	Support of the National Mental Health Week commemoration
5.	Ministry of Health	6,000,000	Support of the World Anti-Microbial Resistance Week commemoration
6.	Tanzania Government Communication Officers Association (TAGCO)	2,000,000	Support of the Annual conference
7.	Muhimbili University of Health and Allied Sciences (MUHAS)	2,600,000	Support of learn and win events, best student academic awards
8.	Association of Certified Fraud Examiners (ACFE)	2,000,000	Support OF Anti-Fraud event
9.	e-Government Agency	2,000,000	Support of the Annual stakeholders conference
10.	Muhimbili Orthopaedic Institute (MOI)	2,000,000	Support treatment of children with hydrocephalus and spina bifida
Total		34,350,000	

2.22 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.

2.23 IMPACT OF COVID-19

As widely reported COVID-19 pandemic continues to affect countries and businesses globally. Risks to businesses arising from the pandemic could include market, services and supply chain disruptions, unavailability of key people resources, locations being quarantined, among others. Government of the United Republic of Tanzania, Business communities and Societies in general are taking appropriate preventive and remedial measures to combat the pandemic.

At the time of issuing these financial statements, the Board continues to assess that, whereas concerted preventive measures have been instituted to mitigate the possible negative impact of the pandemic to the Authority's operations, it was impracticable to determine, quantify and disclose the extent of the possible future direct or indirect impact of the pandemic to the Authority's operations. It is reasonably possible that certain assumptions, estimates, and judgements used in preparation of the financial statements may be affected in the future by the possible negative impact and hence the carrying amounts of assets and liabilities reported in these financial statements.

2.24 RELATED PARTY TRANSACTIONS

A related party transaction is a transfer of resources, services or obligations between related parties, regardless of whether a price is charged. Related parties are those who have the ability, authority and responsibility for planning, directing and controlling the activities or exercise significant influence in making financial and operating decisions. For the Authority, the MAB members and Key Management Personnel are related parties in this case. This includes any Director. Specifically, they involve members of MAB and Key Management Personnel (Directors, Head of Units and Managers).

Details of the related party transactions and balances are disclosed in **Note 31** to the financial statements.

2.25 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 2023. 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 2023.

MAB accepts responsibility for the integrity of the Financial Statements, the information they contain and their compliance with IPSAS accrual basis of accounting. 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.

2.26 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 Mazars Tanzania was authorized to carry out audit of the TMDA for the year ended 30 June 2023.

3.0 STATEMENT OF RESPONSIBILITY BY THOSE CHARGED WITH GOVERNANCE

MAB accept responsibility for the maintenance of accounting records which may be relied upon in the preparation of the financial statements. Furthermore, MAB accept responsibility for the financial statements which have been prepared using appropriate accounting policies supported by reasonable and prudent judgments and estimates, in conformity with the International Public Sector Accounting Standards (IPSAS) accrual basis of accounting and NBAA's pronouncements.

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.

BY ORDER OF THE BOARD

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

Eric F. Shitindi
CHAIPERSON OF THE BOARD

DATE: _____

Chrispin M. Severe
Ag. DIRECTOR GENERAL

DATE: _____

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 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 30 June 2023 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 KIMETELO

SIGNATURE: _____

POSITION: CHIEF ACCOUNTANT

NBAA MEMBERSHIP NUMBER: **ACPA 5315**

DATE: _____

5.0 FINANCIAL STATEMENTS

STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2023

DETAILS		2022/23	2021/22
ASSETS	NOTE	TZS	TZS
CURRENT ASSETS			
Cash and Cash Equivalents	18	8,482,215,923	5,132,524,041
Receivables	19	35,240,982,562	35,683,696,965
Loan Receivables	20	892,043,246	1,046,914,212
Prepayments	21	495,154,744	224,930,460
Inventories	22	627,577,180	1,680,730,944
Total Current Assets		45,737,973,655	43,768,796,622
NON-CURRENT ASSETS			
Investment Property	23	1,359,572,023	1,390,321,685
Property, Plant and Equipment	24	32,934,619,068	27,809,683,982
Intangible Assets	25	-	212,846,668
Work in Progress	26	19,868,000	7,367,062,692
Total Non-Current Assets		34,314,059,091	36,779,915,027
TOTAL ASSETS		80,052,032,746	80,548,711,649
LIABILITIES			
CURRENT LIABILITIES			
Payable and Accruals	27	554,757,564	319,304,395
Provisions	28	33,607,389,638	33,605,119,638
Deferred Income	29	3,027,071,325	871,018,092
Total Current Liabilities		37,189,218,527	34,795,232,125
NET ASSETS		42,862,814,219	45,753,479,524
NET ASSETS			
Capital fund		1,139,932,800	1,139,932,800
Accumulated Surpluses		41,722,881,419	44,613,546,724
TOTAL NET ASSETS		42,862,814,219	45,753,479,524

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

Eric F. Shitindi
CHAIRPERSON OF THE BOARD

Chrispin M. Severe
Ag. DIRECTOR GENERAL

DATE: _____

DATE: _____

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

STATEMENT OF FINANCIAL PERFORMANCE FOR THE YEAR ENDED 30 JUNE 2023

		2022/23	2021/22
		TZS	TZS
REVENUE	NOTE		
Revenue From Exchange Transactions	5	20,035,668,920	19,051,921,416
Levies	6	384,899,820	240,530,618
Fees, Fines, Penalties and Forfeits	7	14,131,055,056	13,257,997,901
Fair value Gain on Assets and Liabilities	8	163,176,544	-
Other Revenue	9	3,970,571,721	3,175,409,292
Subvention from other Government Entity	10	4,616,096,743	4,790,199,007
TOTAL REVENUE		43,301,468,804	40,516,058,234
EXPENSES AND TRANSFERS			
Wages, Salaries and Employee Benefits	11	16,173,312,771	15,526,068,531
Use of Goods and Service	12	17,711,768,469	12,463,005,883
Maintenance Expenses	13	1,060,507,701	1,173,184,036
Depreciation of investment property	23	30,749,662	30,749,662
Depreciation of Property, Plant and Equipment (<i>Note 48</i>)	24	2,256,610,305	2,310,932,844
Impairment of Intangible Assets	25	212,846,668	212,846,667
Loss on Disposal of Assets	14	10,038,341	112,618,744
Other Expenses	15	1,186,870,480	582,593,849
Social Benefits	16	289,883,516	3,510,000
Total Expenses		38,932,587,913	32,415,510,216
Transfer			
Other Transfers	17	5,720,594,355	5,592,244,625
TOTAL EXPENSE AND TRANSFERS		44,653,182,268	38,007,754,841
SURPLUS / (DEFICIT)		(1,351,713,464)	2,508,303,393

Eric F. Shitindi
CHAIRPERSON OF THE BOARD

DATE: _____

Chrispin M. Severe
Ag. DIRECTOR GENERAL

DATE: _____

STATEMENT OF CHANGES IN NET ASSET AND EQUITY FOR THE PERIOD ENDED 30 JUNE 2023

	NOTE	CAPITAL FUND TZS	ACCUMULATED SURPLUS/(DEFICIT) TZS	TOTAL TZS
YEAR ENDED 30 JUNE 2023				
Balance as at 01 July 2022		1,139,932,800	44,613,336,724	45,753,269,524
Prior year adjustment	48		(1,138,741,841)	(1,138,741,841)
Capital Redemption			(400,000,000)	(400,000,000)
Surplus for the Year			(1,351,713,464)	(1,351,713,464)
Closing Balance as at 30 June 2023		1,139,932,800	41,722,881,419	42,862,814,219
YEAR ENDED 30 JUNE 2022				
Balance as at 01 July 2021		1,139,932,800	42,316,195,205	43,456,128,005
Prior year adjustment		-	(211,161,874)	(211,161,874)
Surplus for the Year		-	2,508,303,393	2,508,303,393
Balance as at 30 June 2022		1,139,932,800	44,613,336,724	45,753,269,524

Eric F. Shitindi
CHAIRPERSON OF THE BOARD

DATE: _____

Chrispin M. Severe
Ag. DIRECTOR GENERAL

DATE: _____

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

CASH FLOW STATEMENT FOR THE PERIOD ENDED 30 JUNE 2023

	NOTE	2022/23 TZS	2021/22 TZS
CASH FLOW FROM OPERATING ACTIVITIES			
RECEIPTS			
Subvention from other Government entities	40	4,171,135,320	4,580,191,490
Revenue from exchange transactions	35	20,035,668,921	19,051,921,417
Other Revenue	39	3,970,571,721	3,175,409,292
Levies	36	384,899,820	240,530,618
Increase in Deposit		194,909,345	219,750,432
Fees, Fines, Penalties and Forfeits	37	14,015,623,324	13,257,997,901
Total Receipts		42,772,808,451	40,525,801,149
PAYMENTS			
Wages, Salaries and Employee Benefits	41	16,070,350,270	15,526,068,531
Use of goods and service	42	16,510,778,886	12,179,682,295
Social benefits	44	289,883,516	3,510,000
Other Transfers	46	5,720,594,356	5,592,244,625
Other Expenses	45	1,270,350,268	432,615,561
Maintenance Expenses	43	1,060,507,701	1,173,184,035
International Contribution		-	-
Interest Expenses		-	-
Decrease in Deposit		194,489,344	219,960,432
Advance and Loans Payment made to other part	33	(628,984,618)	-
Total Payments		40,341,521,989	35,127,265,478
NET CASH FLOW FROM OPERATING ACTIVITIES		2,684,838,728	5,398,535,672
CASH FLOW FROM INVESTING ACTIVITIES			
Payment for Work in Progress	34	364,858,098	880,311,892
Advance payment for acquisition of PPE	32	248,749,287	92,346,913
Acquisition of PPE	47	725,925,871	1,413,675,031
NET CASH FLOW FROM INVESTING ACTIVITIES		1,339,533,256	2,386,333,836
CASH FLOW FROM FINANCING ACTIVITIES			
Receipts from Govt Subvention-Foreign	18	2,404,386,409	-
Excess Capital recall		-	-
NET CASH FLOW FROM FINANCING ACTIVITIES		2,404,386,409	-
Net Increase		945,305,472	3,012,201,836
Cash and cash equivalent at beginning of period		5,132,524,041	2,120,322,205
Cash and cash equivalent at end of period		8,482,215,923	5,132,524,041

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Eric F. Shitindi
CHAIRPERSON OF THE BOARD

DATE: _____

Chrispin M. Severe
Ag. DIRECTOR GENERAL

DATE: _____

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

STATEMENT OF THE COMPARISON BUDGET AND ACTUAL FOR THE YEAR ENDED 30 JUNE 2023

	Original Budget	Reallocations /Adjustments	Final Budget (B)	Actual Amount on Comparison Basis (A)	Different Final Budget and Actual (B-A)	Notes
RECEIPTS						
Subvention from other Government entities	4,409,824,000	-	4,409,824,000	4,472,982,792	(63,158,792)	a
Revenue from Exchange Transactions	18,372,739,139	-	18,372,739,139	20,035,668,920	(1,662,929,781)	b
Other Revenue	3,970,571,721	-	3,970,571,721	3,970,571,721	-	
Levies	405,212,332	-	405,212,332	384,899,820	20,312,512	c
Fees, Fines, Penalties and Forfeits	12,610,305,043	-	12,610,305,043	14,131,055,056	(1,520,750,013)	d
External Assistance	143,113,951	-	143,113,951	143,113,951	-	e
Total Receipts	39,911,766,186	-	39,911,766,186	43,138,292,260	(3,226,526,074)	
PAYMENTS						
Wages, Salaries and Employee Benefits	14,771,067,682	82,209,094	14,853,276,776	16,173,312,771	(1,320,035,995)	f
Use of Goods and Service	15,014,755,934	(638,300,374)	14,376,455,560	17,711,768,469	(3,335,312,909)	g
Other Transfers	5,325,291,328	-	5,325,291,328	5,720,594,355	(395,303,027)	h
Other Expenses	1,370,350,267	(18,200,459)	1,352,149,808	1,186,870,480	165,279,328	i
Maintenance Expenses	1,072,337,539	574,291,739	1,646,629,278	1,060,507,701	586,121,577	j
Advance Payment for Acquisition of Property Plant and	400,000,000	-	400,000,000	341,096,200	58,903,800	k
Acquisition of Property, Plant and Equipment	1,957,963,436	-	1,957,963,436	1,137,456,469	820,506,967	l
Total Payment	39,911,766,186	-	39,911,766,186	43,331,606,445	(3,419,840,259)	
Net receipt/payments				(193,314,185)	(193,314,185)	

Eric F. Shitindi
CHAIRPERSON OF THE BOARD

DATE: _____

Chrispin M. Severe
Ag. DIRECTOR GENERAL

DATE: _____

EXPLANATION OF VARIANCES OF FINAL BUDGET VS ACTUAL AMOUNTS

- a. A Variance of -0.33 billion shows that the government disbursed more amount for personnel emoluments than the budgeted amount because there was a salary increment and transfer of new staff.
- b. A Variance of -1.93 authority collected more than budgeted amount due to the strengthening of regulatory activities hence revenue increment.
- c. A variance of 0.00 billion explain the facts that in the financial year under review (2022/23) the authority collected as expected.
- d. A variance of 0.02 billion shows that the authority did not get tenants as expected.
- e. A variance of 0.068 billion indicates decrease of deposits as compared to the previous year.
- f. A variance of 0.1 indicates that the financial year under review (2022/23) the authority collected as expected
- g. A variance of 0.00 billion indicates that the authority amortized only what met the condition under the year reviewed.
- h. A variance of 1.00 billion indicates that wages, salaries and employee benefits expenses increase due to increments in salary and incentives, new staff and transfer costs during a year under review.
- i. The variance of 0.31 billion decreased in social benefits due to the fact that there was a change in the GFS Code resulting from new mapping of the accounting system for financial reporting.
- j. The variance of 0.29 billion was a result of the increase in transfer to the consolidated fund due to excess collection.
- k. The variance of 0.10 billion indicates the decrease in other expenses accelerated by normal operation expenses including Head Office relocation.
- l. A variance of 0.01 billion indicates decrease of Maintenance expenses due to budget control compared to the previous year.
- m. A variance of 0.63 billion indicates the net cash inflow with respect of staff loan amount repaid during a year.
- n. A variance of 0.36 billion indicates the amount paid in respect of the Dodoma building.

- o. A variance of 0.06 billion explains the saving in respect of amount paid for procuring three motor vehicles

6.0 NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2023

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

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 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 at 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	6.7%
Furniture, fittings and equipment	20%
Motor vehicles	10%
Computers	25

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 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 2023 in connection with the construction of Office Building in Dodoma. The building has reached its final stage of completion but will be available for use after completion and handed 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 fairvalue 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 33.33%.

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 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 was 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 2023 the authority had unliquidated commitments (Open LPOs) totalling TZS 203,013,997.00 for Services/Goods which were not received by the end of the financial year 2021/22.

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 2023.

6.18 Impact of COVID-19

As widely reported COVID-19 pandemic continues to affect countries and businesses globally. Risks to businesses arising from the pandemic could include market, services and supply chain disruptions, unavailability of key people resources, locations being quarantined, among others. Government of the United Republic of Tanzania, business communities and societies in general are taking appropriate preventive and remedial measures to combat the pandemic.

At the time of issuing these financial statements, those charged with governance have assessed that, whereas concerted preventive measures have been instituted to mitigate the possible negative impact of the pandemic to the Authority's operations, it was impracticable to determine, quantify and disclose the extent of the possible future direct or indirect impact of the pandemic to the Authority's operations. It is reasonably possible that certain assumptions, estimates, and judgements used in preparation of the financial statements may be affected in the future by the possible negative impact and hence the carrying amounts of assets and liabilities reported in these financial statements.

6.19 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 obligation recognised as a liability in respect of an inflow of resources from a non-exchange 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.

5. REVENUE FROM EXCHANGE TRANSACTIONS

	2022/23	2021/22
	TZS	TZS
Import Fee	19,940,257,599	18,783,711,917
Laboratory charges	58,451,403	211,735,177
Receipt from sale of Publications	832,351	56,474,322
Registration Fees	36,127,567	-
TOTAL	<u>20,035,668,920</u>	<u>19,051,921,416</u>

During the year revenue from exchange transactions increased by 5% to the tune of TZS 20.04 billion as compared with TZS 19.05 billion (2021/22) due to the enhanced controls over collection of revenue including the use of Government electronic payment gateway (GePG) and decrease of COVID-19 restriction.

6. LEVIES

Renting Space/ Houses	384,899,820	240,530,618
TOTAL	<u>384,899,820</u>	<u>240,530,618</u>

During the reporting period revenue renting space (Investment Property) increased by 46% to 0.38 billion as compared with 0.24 billion (2021/22), the increase has been accelerated by the increase in number of tenants.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

7. FEES, FINES, PENALTIES AND FORFEITS

	2022/23	2021/22
	TZS	TZS
Bail	-	1,951,418,827
Fines	3,647,561,755	-
Receipt from Annual Fees	324,399,473	317,770,275
Registration Fees	10,159,093,828	10,988,808,799
TOTAL	14,131,055,056	13,257,997,901

During the year revenue from Fees, Fines, Penalties and Forfeits increased by 7% to the tune of TZS 14.13 billion as compared with TZS 13.26 billion (2021/22) due to the enhanced controls over collection of revenue including the use of Government electronic payment gateway (GePG).

8. FAIR VALUE GAINS ON ASSETS AND LIABILITIES

Foreign exchange differences (Gain)	163,176,544	-
TOTAL	163,176,544	-

During the year under review, foreign exchange gain increased from TZS 0 to TZS 0.16 billion (2022/23). The increase was attributed to favourable foreign exchange fluctuations.

9. OTHER REVENUE

Miscellaneous Receipts	15,002,918	69,385,186
Rent Fee	29,345,000	47,325,000
Retention fee for logging	3,926,223,803	3,058,699,106
TOTAL	3,970,571,721	3,175,409,292

During the reporting period Other revenue increased by 25% to TZS 3.97 billion from 3.18 billion. The major change has been attributed by the increase in collection from retention fee due to enhancement in collection system and the increase in number of customer applying for retention of Medicines and medical devices.

10. SUBVENTION FROM OTHER GOVERNMENT ENTITIES

Government Grant Development Foreign	143,113,951	284,843,324
Non-monetary Revenue-Capital	312,059,979	-
Subvention for Personal Emolument	4,160,922,813	4,505,355,683
TOTAL	4,616,096,743	4,790,199,007

During the reporting period, Subvention from Other Government entities decreased by 4% from TZS 4.79 billion to TZS 4.62 billion (2022/23).

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

11. WAGES, SALARIES AND EMPLOYEE BENEFITS

	2022/23	2021/22
	TZS	TZS
Civil Servants	8,841,182,555	8,830,044,038
Extra-Duty	1,694,828,605	1,307,953,532
Food and Refreshment	8,341,359	1,217,501,133
Furniture	42,000,000	246,000,000
Gratuities	286,168,750	177,450,870
Honoraria	213,824,386	164,742,000
Housing Allowance	1,045,444,348	1,521,016,810
Leave Travel	720,389,615	696,193,012
Moving Expenses	1,283,035,488	42,944,650
National Health Insurance Scheme (NHIF)	-	2,309,813
Non-Civil Servant Contracts	14,999,999	-
Outfit Allowance	3,000,000	3,775,002
Responsibility Allowance	32,000,000	0
Risk Allowance	97,195,000	79,000,000
Sitting Allowance	395,888,000	366,445,640
Statutory Contributions	20,113,779	12,002,942
Subsistence Allowance	503,426,487	13,054,600
Transport	944,074,400	-
Transport Allowance	-	805,634,489
Uniform Allowance	27,400,000	40,000,000
TOTAL	<u>16,173,312,771</u>	<u>15,526,068,531</u>

Wages, Salaries and employee benefits increased to a tune of TZS 16.17 billion as compared to TZS 15.53 billion in the previous year due to fact that in the financial year under review there was a salary and incentive increment, new staff, shifting cost from Dar es salaam to Dodoma.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

12. USE OF GOODS AND SERVICE

	2022/23	2021/22
	TZS	TZS
Accommodation	58,047,401	53,570,448
Advertising and publication	69,722,201	107,629,800
Air travel tickets	918,393,534	485,489,925
Books, reference and periodicals	9,435,822	20,968,358
Computer supplies and accessories	54,825,492	-
Conference facilities	198,615,716	240,575,545
Consumable medical supplies	252,141,059	72,405,850
Courier services	5,140,004	1,725,733
Diesel	846,851,591	640,578,156
Drugs and medicines	-	68,708,500
Electricity	332,050,303	325,418,182
Entertainment	23,118,400	21,080,000
Exhibition, festivals and celebrations	32,218,994	50,736,144
Food and refreshments	1,258,458,920	-
Fumigation	8,924,094	8,718,565
Gifts and prizes	79,300,000	54,609,605
Ground transport (Bus, train, water)	1,630,000	400,000
Ground travel (bus, railway taxi, etc)	288,538,024	238,355,524
Health Insurance	5,923,905	648,300
Internet and Email connections	364,692,017	309,832,771
Laboratory Supplies	347,269,260	678,371,412
Lodging/Accommodation	10,445,400	14,736,000
Medical Gases and Chemicals	566,285,593	486,750
Mobile Charges	19,240,000	12,640,825
News Services Fees	325,259,125	406,238,618
Newspapers and Magazines	12,814,963	17,036,211
Office Consumable(paper)	882,518,666	568,984,979
Outsourcing costs	318,935,392	236,874,108
Per Diem-Domestic	7,163,788,893	6,413,525,711
Per Diem- Foreign	1,618,503,277	100,456,855
Petrol	9,195,000	7,609,300
Posts and Telegram	29,523,750	67,725,967
Printing and Photocopy	200,355,147	85,645,807
Programs Transmission	5,896,500	-
Publicity	13,751,003	3,500,000
Remuneration of Instructors	24,275,000	-
Rent- Office Accommodation	490,067,279	466,013,166
Rent of Private vehicles	13,330,000	7,810,000

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

	2022/23	2021/22
	TZS	TZS
Rent of Vehicle and Craft	9,293,296	18,873,525
Research and Dissertation	14,003,285	5,135,000
Software License Fees	44,000,000	6,016,400
Special Foods (diet food)	-	2,475,000
Sporting Supplies	14,100,000	-
Subscription Fees	260,871,231	172,125,000
Technical Service Fees	89,999,999	81,074,170
Telephone Charges (Land lines)	52,868,954	50,853,547
Training Allowances	-	17,681,037
Training Materials	11,502,500	9,710,000
Tuition fees	226,267,921	237,273,509
Uniforms and Ceremonial Dresses	42,300,000	31,350,950
Upkeep Allowances	28,818,237	-
Visa Application Fees	5,677,226	176,508
Water and Waste Disposal (Garbage)	6,120,000	-
Water Charges	46,464,095	41,154,122
TOTAL	<u>17,711,768,469</u>	<u>12,463,005,883</u>

During the financial year that ended 30 June 2023 use of goods and Service have increased by 42% to TZS 17.71 billion as compared to TZS 12.46 billion in the previous year, the reason behind being increase in Air travelling tickets, per diem foreign, purchases of medical gases and chemicals, Per diem domestic, and ground travel. During the year under review mostly of Medicines and medical devices manufacturing industries were inspected, resulting to the increase in air travel ticket and per diem foreign.

13. MAINTENANCE EXPENSES

Air conditioners	15,558,300	20,000,000
Cement, Bricks and Building Materials	2,315,620	16,428,990
Cement, bricks, and construction materials	3,600,000	-
Computers, printers, scanners, and other computer related equipment	37,445,385	40,357,771
Electrical and other cabling materials	14,987,488	212,400
Fire Protection Equipment	-	38,146,210
Medical and Laboratory equipment	154,669,785	143,577,600
Motor Vehicles and Watercraft	418,002,469	352,081,634
Outsource maintenance contract services	389,443,798	548,047,261
Small Tools and Implements	9,367,630	4,989,727
Telephones and Office PABX systems	15,117,226	9,342,443
TOTAL	<u>1,060,507,701</u>	<u>1,173,184,036</u>

During the year under review maintenance expenses have decreased by 10%, from 1.17bill to 1.06 billion. This has been attributed by the decrease in operational cost from Dar es salaam to Dodoma.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

14. LOSS ON DISPOSAL OF ASSETS

	2022/23	2021/22
	TZS	TZS
Foreign exchange differences (Losses)	-	29,251,544
Losses on disposal of property, plant and equipment	10,038,341	83,367,200
	<u>10,038,341</u>	<u>112,618,744</u>

15. OTHER EXPENSES

Agency Fees	66,699,309	31,856,784
Audit Fees	204,800,000	176,993,200
Bank Charges and Commissions	3,687,032	134,211
Burial Expenses	24,960,000	500,000
Consultancy fees	739,169,949	154,663,410
Director's fee	-	8,000,000
Freight Forwarding and clearing Charges	60,000,000	109,794,740
Honorariums (expert opinion)	-	7,000,000
Other Payments	2,229,650	3,640,100
Sundry Expenses	82,489,540	90,011,404
Witnesses Expenses	2,835,000	-
TOTAL	<u><u>1,186,870,480</u></u>	<u><u>582,593,849</u></u>

Other expenses increased to TZS 1.19 billion for the reporting period ending 30 June 2023, as compared to TZS 0.58 billion for the previous year, the increase has been attributed by consultancy fees cost, the mapping movement of GFS Code from Consultancy expense Code to Consultancy Fee Movement accelerated the increase.

16. SOCIAL BENEFITS

Settlement of Medical Treatment Claims	289,883,516	3,510,000
TOTAL	<u><u>289,883,516</u></u>	<u><u>3,510,000</u></u>

During the year under review social benefits increased to TZS 0.29 bill from 0.003 bill, the increase have been attributed to the payment of Supplementary package to NHIF and the increase in international travel that require health insurance and vaccination.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

17. OTHER TRANSFERS

	2022/23 TZS	2021/22 TZS
Contribution to CF (15%)	5,320,594,355	5,092,244,625
Capital Redemption	400,000,000	500,000,000
TOTAL	5,720,594,355	5,592,244,625

Contribution of 15% from raw collection to Consolidated Fund increased from TZS 5.1 billion in financial year 2021/22 to TZS 5.32 billion in a year under review. Excess capital remitted decreased to 0.40 billion in a year under review compared to 0.50 billion of previous year. Amount remitted was TZS 5.48 billion and TZS 0.19 billion has been provided for payment due to actual excess revenue collected.

18. CASH AND CASH EQUIVALENTS

BOT Own source Collection Account	714,428,955	2,038,103,547
Deposit Account USD	-	228,700,000
Deposit General Cash Account	-	237,078,000
Own source Collection Account - CRDB	495,329,956	63,717,908
Own source Collection Account - NBC	10,000,000	9,888,469
Own source Collection Account - NMB	99,376,973	11,721,190
Own source Collection Account - CRDB-USD	45,782,324	537
Own source Collection Account - NBC-USD	34,913	34,648
TMDA Global Fund Account NMB-TZS	2,404,386,409	-
Own source Development Expenditure	97,568,926	-
Own source Recurrent Expenditure GF	240,262,347	(198,387,048)
USD BOT Collection Account	4,157,285,348	2,523,907,018
USD Recurrent Expenditure	217,759,772	217,759,772
TOTAL	8,482,215,923	5,132,524,041

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 2023. The Cash and cash equivalents increased by 63% from TZS 5.13 billion (30 June 2022) to TZS 8.37 billion (30 June 2023) due to increase of revenue collection and receipt of 2.29 billion from Global fund at the end of the last month.

19. RECEIVABLES

Imprest Receivable	32,325,569	2,279,300
Receivables-Exchange Transaction (Staff Loans)	1,649,626,957	2,123,740,609
Trade Receivables	33,559,030,036	33,557,677,056
TOTAL	35,240,982,562	35,683,696,965

The amount of trade receivable is TZS 33.56 billion long outstanding debts the authority owed by MSD in respect of services that was enjoyed with the agreement that payments shall be made

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

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 0.16 billion refers to rent receivable, TZS 1.65 billion Receivable from Exchange transactions refers to Long term staff loan, TZS 0.032 billion refers to Staff outstanding imprest and TZS 0.16 billion is accrued rent income.

20. LOAN RECEIVABLES

	2022/23 TZS	2021/22 TZS
Staff Loan (current receivable)	892,043,246	1,046,914,212
TOTAL	892,043,246	1,046,914,212

21. PREPAYMENTS

Prepayments- Expenses	154,058,544	132,583,547
Prepayment- Assets	341,096,200	92,346,913
TOTAL	495,154,744	224,930,460

Prepayments comprise of TZS 0.34 billion paid in advance for purchase of three Motor vehicles, which until the date of the report was not delivered. TZS 0.15 billion refers to office rent accommodation paid in advance.

22. INVENTORIES

Consumables	627,577,180	1,680,730,944
TOTAL	627,577,180	1,680,730,944

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.

23. INVESTMENT PROPERTY COST

Balance as at 1 July	1,537,483,078	1,455,146,660
Additions during the year	-	82,336,418
Balance as at 30 June 2022	1,537,483,078	1,537,483,078
DEPRECIATION		
Balance as at 1 July	147,161,393	116,411,731
Depreciation during the year	30,749,662	30,749,662
Balance as at 30 June 2023	177,911,055	147,161,393
Net Book Value	1,359,572,023	1,390,321,685

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24. PROPERTY, PLANT AND EQUIPMENT

DESCRIPTION	LAND	BUILDINGS	MOTOR VEHICLES	PLANT and MACHINERIE S	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	8,540,363,910
Transfers	-	-	(351,226,185)	-	-	-	-	(351,226,185)
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	6,365,953,401	621,222,161	3,565,162,732	2,572,317,921	11,346,741,443	50,756,805,988
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	-	-	-	-	(10,467,591)	(9,271,135)	(152,179,266)	(170,417,992)
As At 30 June 2023	-	2,571,118,904	4,365,513,505	338,417,606	1,655,041,511	1,333,933,295	7,558,162,098	17,822,186,920
NET BOOK VALUE	2,321,973,500	21,392,315,925	2,000,439,896	282,804,556	1,910,121,221	1,238,384,626	3,788,579,345	32,934,619,068

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

COMPARABLE ASSET REGISTER 2021/22

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 2022								
COST								
As At 1 July 2021	2,255,394,500	16,587,830,109	6,440,138,847	551,887,468	2,273,921,466	2,374,743,317	11,382,203,367	41,866,119,074
Additions	66,579,000	-	184,693,826	-	807,766,944	261,077,950	115,044,099	1,435,161,821
Reclassification	-	(82,336,418)	-	-	-	-	-	(82,336,418)
Disposal	-	-	-	-	(32,995,784)	(192,643,674)	(247,125,359)	(472,764,818)
As At 30 June 2022	2,321,973,500	16,505,493,691	6,624,832,673	551,887,468	3,048,692,626	2,443,177,593	11,250,122,107	42,746,179,659
ACCUMULATED DEPRECIATION								
As At 1 July 2021	-	1,595,977,098	3,224,075,512	293,296,208	1,159,684,820	1,260,343,162	7,046,517,571	13,006,785,448
Charge For the Year	-	488,394,267.36	915,624,923.18	22,468,717.51	236,174,999	60,482,044	587,787,893	2,310,932,844
Adjustment	-	(1,646,729)	-	-	-	-	-	(1,646,729)
Disposal	-	-	-	-	(32,995,784)	(183,120,954)	(165,105,880)	(381,222,616)
As At 30 June 2022	-	2,082,724,636	4,139,700,435	315,764,926	1,362,864,035	1,137,704,252	5,896,090,661	14,936,495,677
NET BOOK VALUE	2,321,973,500	14,422,769,055	2,485,132,238	236,122,542	1,685,828,591	1,305,473,341	5,354,031,448	27,809,683,982

25. INTANGIBLE ASSETS

	2022/23 TZS	2021/22 TZS
COST		
Balance as at 1 July	971,611,748	971,611,748
Additions during the year	-	-
Balance as at 30 June	<u>971,611,748</u>	<u>971,611,748</u>
AMORTIZATION		
Balance as at 1 July	758,765,0810	545,918,413
Amortization during the year	212,846,668	212,846,667
Balance as at 30 June	<u>971,611,748</u>	<u>758,765,080</u>
Net Book Value	<u>-</u>	<u>212,846,668</u>

26. WORK IN PROGRESS

Balance as at 1 July	7,367,062,692	6,486,750,802
Additions during the year	364,858,098	880,311,890
Transfer to PPE	(7,712,052,790)	
Balance as at 30 June	<u>19,868,000</u>	<u>7,367,062,692</u>

Work in progress of TZS 0.02 billion represents the extent to which cost of work has been incurred as at 30 June 2023 in connection with the construction of office Building in Tarakea. Costs of TZS 7.71 billion was transferred to PPE after completion of Dodoma Building during the year under review.

27. PAYABLES AND ACCRUALS

Other payables	66,498,500	149,978,288
Supplies of goods and services	326,713,750	115,011,664
Staff claim	102,962,500	0
VAT Payable	67,344,430	50,941,598
Withholding tax payable	(8,761,616)	3,372,845
TOTAL	<u>554,757,564</u>	<u>319,304,395</u>

The amount of payable and Accruals comprises Unremitted 15% contribution to Consolidated Fund, Gratuity, PAYE, VAT an WCF and Withholding tax for the year ended 30 June 2022

28. PROVISIONS

Other Expenses	204,800,000	202,530,000
Provision for Bad and Doubtful debts-MSD debt	33,402,589,638	33,402,589,638
TOTAL	<u>33,607,389,638</u>	<u>33,605,119,638</u>

The amount of Audit fee provided has increased by 1% from TZS 202,530,000 in financial year 2021/22 to TZS 204,800,000 in the financial year 2022/23.

29. DEFERRED INCOME

	2022/23	2021/22
	TZS	TZS
Donor grants	2,515,758,035	426,215,437
GMP deferred income	511,313,290	444,802,655
TOTAL	3,027,071,325	871,018,092

Deferred income includes TZS 2.40 billion from Global Fund, TZS 0.04 from WHO, TZS 0.11 billion from EDCTP Donors and TZS 0.51 billion for uninspected manufacturers for the financial year 2022/23. Deferred income has increased from TZS 0.87 billion in the previous year 2021/22 to TZS 3.03 billion due to the receipt of TZS 2.29 billion from the Global fund end of the financial year 2022/23.

30. RECONCILIATION OF NET CASH FLOWS FROM OPERATING ACTIVITIES TO SURPLUS/(DEFICIT) FOR THE PERIOD ENDED 30 JUNE 2023

Surplus for the Period	(1,457,106,854)	1,359,523,210
Adjustment for Non-Cash Items		
Impairment of Intangible Assets	212,846,668	212,846,667
Depreciation of Investment Property	30,749,662	30,749,662
Depreciation of Property, Plant and equipment	2,256,610,305	3,459,713,027
Loss on Disposal of Assets	-	112,618,749
Non-Monetary Revenue-Capital	(312,059,979)	-
Fair value Gains on Assets and Liabilities	(161,822,965)	-
Add/(Less) Change in Working Capital		
Deferred Income	(132,901,444)	(210,007,517)
Deposit	420,000	
Inventories	1,053,153,764	136,343,907
Payables and Accruals	218,839,800	128,429,863
Prepayments	(21,474,998)	170,807,404
Receivables	597,585,369	(2,279,299)
Net Cash Flow from Operating Activities	2,284,838,728	5,398,535,672

31. RELATED PARTY TRANSACTIONS

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 2023. The following shows the related transaction for the financial year ended 30 June 2023.

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S/N	DETAILS	No. of people	2022/23	2021/22
			TZS	TZS
1	Director's Fee to Board Members	7	8,000,000	8,000,000
2	End of Term	7	24,000,000	-
Sub Total			32,000,000	8,000,000
3	Remuneration to Key Management Personnel	11	874,765,800	573,600,000
Sub Total			874,765,800	573,600,000
4	15% Contribution to Government		5,720,594,355	5,592,244,625
5	Capital Redemption		400,000,000	500,000,000
Sub Total			6,120,594,355	6,092,244,625
6	Governmental entities transaction		12,384,782,547	-
GRAND TOTAL			19,412,142,702	6,673,844,625

During the financial year ended 30 June 2023 all Members of the Board were paid TZS 0.02 billion as their annual fees and End of term, TZS 0.08 billion as Director's Fee, TZS 0.87 billion to Key management personnel as their remunerations. In addition, the Authority contributed to the Government a total of TZS 5.89 billion for the year ended 30 June 2023 as compared to TZS 5.59 billion contributed in the previous year. Inter-governmental entities transactions were TZS 12.38 billion for the year ended June 2023.

NOTES- CASH FLOW STATEMENT FOR THE PERIOD ENDED 30 June2023

32. ADVANCE PAYMENT FOR ACQUISITION OF PROPERTY PLANT AND EQUIPMENT

Prepayments-Assets	248,749,287	92,346,913
TOTAL	248,749,287	92,346,913

33. ADVANCE AND LOANS PAYMENTS MADE TO OTHER PART

Loan issued during the year	499,502,472	1,247,245,101
Loan repayment during the year	(1,128,487,090)	(1,347,885,132)
TOTAL	(628,984,618)	100,640,031

34. PAYMENT FOR WORK IN PROGRESS

Building other than dwellings-WIP	364,858,098	880,311,892
TOTAL	364,858,098	880,311,892

35. REVENUE FROM EXCHANGE TRANSACTIONS

	2022/23	2021/22
	TZS	TZS
Import fee	19,940,257,599	18,783,711,917
Laboratory Charges	58,451,403	211,735,177
Receipt from sales of Publications	832,351	56,474,323
Registration Fees	36, 127,567	-
TOTAL	20,035,668,920	19,051,921,417

36. LEVIES

Renting space/ Houses	384,899,820	240,530,618
TOTAL	384,899,820	240,530,618

37. FEE, FINE, PENALTIES AND FORFEIT

Bail	-	1,951,418,827
Fines	3,532,130,023	0
Receipts from annual Fees	324,399,473	317,770,275
Registration fee	10,159,093,828	10,988,808,799
TOTAL	14,015,623,324	13,257,997,901

38. EXTERNAL ASSISTANCE

European Union (EU)	-	-
TOTAL	-	-

39. OTHER REVENUE

Miscellaneous Receipts	15,002,918	69,385,186
Rent Fee	29,345,000	47,325,000
Retention Fee for logging	3,926,223,803	3,058,699,106
TOTAL	3,970,571,721	3,175,409,292

40. SUBVENTION FROM OTHER GOVERNMENT ENTITIES

	2022/23	2021/22
	TZS	TZS
Government Grant Development Foreign	143,113,951	284,843,324
Non- Monetary Revenue - Capital	48,295,206	0
Subvention for Personal Emolument	4,160,922,813	4,505,355,683
TOTAL	4,616,096,743	4,790,199,007
 Add/Less (Change in Working Capital)		
Deferred Subvention Capital	-	-
Deferred Subvention Current	(132,901,444)	(210,007,517)
Non-Monetary Revenue-Capital	(48,295,206)	-
	(181,196,650)	(210,007,517)
TOTAL	4,171,135,320	4,580,191,490

41. WAGES, SALARIES AND EMPLOYEE BENEFITS

Civil Servants	8,841,182,555	8,830,044,038
Electricity	-	-
Extra Duty	1,694,828,605	1,307,953,532
Food and Refreshment	8,341,359	1,217,501,133
Furniture	42,000,000	246,000,000
Gratuities	286,168,750	177,450,870
Honoraria	213,824,386	164,742,000
Housing allowance	1,045,444,348	1,521,016,810
Leave travel	720,389,615	696,193,012
Moving Expenses	1,283,035,488	42,944,650
National Health Insurance Scheme (NHIF)	-	2,309,813
Non-Civil Servant Contracts	14,999,999	-
Outfit Allowance	3,000,000	3,775,002
Responsibility Allowance	32,000,000	-
Risk Allowance	97,195,000	79,000,000
Sewage Charges	-	-
Sitting Allowance	395,888,000	366,445,640
Statutory Contributions	20,113,779	12,002,942
Subsistence Allowance	503,426,487	13,054,600
Transport Allowance	944,074,400	805,634,489
Uniform Allowance	27,400,000	40,000,000
	16,173,312,771	15,526,068,531
 Add/Less (Change in Working Capital)		
Staff Claim	(102,962,500)	-
	(102,962,500)	-
Payment	16,070,350,271	15,526,068,531

42. USE OF GOODS AND SERVICE

	2022/23	2021/22
	TZS	TZS
Accommodation	58,047,401	53,570,448
Advertising and publication	69,722,201	107,629,800
Air travel tickets.	918,393,534	485,489,925
Books, reference, and periodicals	9,435,822	20,968,358
Computer supplies and accessories	54,825,492	-
Conference facilities	198,615,716	240,575,545
Consumable medical supplies	252,141,059	72,405,850
Courier services	5,140,004	1,725,733
Diesel	846,851,591	640,578,156
Drugs and medicines	-	68,708,500
Electricity	332,050,303	325,418,182
Entertainment	23,118,400	21,080,000
Exhibition, festivals and celebrations	32,218,994	50,736,144
Food and refreshments	1,258,458,920	-
Fumigation	8,924,094	8,718,565
Gift and prizes	79,300,000	54,609,605
Ground Transport (Bus, Train, Water).	1,630,000	400,000
Ground travel (bus, railway, taxi, etc)	288,538,024	238,355,524
Health Insurance	5,923,905	648,300
Internet and email connections	364,692,017	309,832,771
Laboratory supplies	347,269,260	678,371,412
Lodging/ accommodation	10,445,400	14,736,000
Medical gases and chemical	566,285,593	486,750
Mobile charges	19,240,000	12,640,825
News services fees	325,259,125	406,238,618
Newspapers and magazines	12,814,963	17,036,211
Office Consumables (Papers, pencils, pens and stationaries)	882,518,666	568,984,979
Outsourcing Costs (includes cleaning and security services)	318,935,392	236,874,108
Per diem- domestic.	7,163,788,893	6,413,525,711
Per diem- foreign.	1,618,503,277	100,456,855
Petrol	9,195,000	7,609,300
Posts and telegraphs	29,523,750	67,725,967
Printing and photocopying Costs	200,355,147	85,645,807
Programs transmission Fees	5,896,500	-
Publicity	13,751,003	3,500,000

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Renumeration of instructors	24,275,000	-
Rent- Office accommodation	490,067,279	466,013,166
Rent of private vehicles	13,330,000	7,810,000
Rent of vehicles and crafts	9,293,296	18,873,525
Research and Dissertation	14,003,285	5,135,000
Software License Fees	44,000,000	6,016,400
Special Foods (diet food)	-	2,475,000
Sporting Supplies	14,100,000	-
Subscription Fees	260,871,231	172,125,000
Technical Service Fees	89,999,999	81,074,170
Telephone Charges (Land lines)	52,868,954	50,853,547
Training Allowances	-	17,681,037
Training Materials.	11,502,500	9,710,000
Tuition Fees	226,267,921	237,273,509
Uniforms and Ceremonial Dresses	42,300,000	31,350,950
Upkeep Allowances	28,818,237	-
Visa Application Fees	5,677,226	176,508
Water and Waste Disposal (Garbage)	6,120,000	-
Water Charges	46,464,095	41,154,122
Expense	17,711,768,469	12,463,005,883
Add/Less (Change in Working Capital)		
Consumables	(1,053,153,764)	(136,343,907)
Imprest Receivable	30,046,270	2,279,299
Prepayment- Expenses	21,474,998	(170,807,404)
Supplies of good and services	(211,702,086)	24,257,255
Withholding Tax	27,677,439	-
Withholding Tax Payable	(15,996,456)	(2,708,830)
	(1,200,989,583)	(283,323,587)
Payment	16,510,778,886	12,179,682,296
43. MAINTENANCE EXPENSES		
Air Conditioners	15,558,300	20,000,000
Cement, Bricks and Building Materials	2,315,620	16,428,990
Cement, Bricks and Construction materials	3,600,000	-
Computers, Printers, Scanners, and other computer related	37,445,385	40,357,771
Electrical and Other Cabling Materials	14,987,488	212,400
Fire Protection Equipment	-	38,146,210

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Medical and Laboratory Equipment	154,669,785	143,577,600
Motor Vehicle and Watercraft	418,002,469	352,081,634
Outsource maintenance contract services	389,443,798	548,047,260
Small Tools and Implements	9,367,630	4,989,727
Telephones and Office PABX systems	15,117,226	9,342,443
Expense	1,060,507,701	1,173,184,035
44. SOCIAL BENEFITS		
Settlement of Medical Treatment Claims	289,883,516	3,150,000
Expenses	289,883,516	3,150,000
45. OTHER EXPENSES		
Agency fees	66,699,309	31,856,784
Audit fees	204,800,000	176,993,200
Bank Charges and Commissions	3,687,032	134,211
Burial Expenses	24,960,000	500,000
Consultancy fees	731,169,949	154,663,410
Director's Fee	8,000,000	8,000,000
Freight Forwarding and Clearing Charges	60,000,000	109,794,740
Honorariums (Expert Opinion)	-	7,000,000
Other Payments	2,229,650	3,640,100
Sundry Expenses	82,489,540	90,011,404
Witness Expenses	2,835,000	-
	1,186,870,480	582,593,849
Add/Less (Change in Working Capital)		
Other payables	83,479,788	(149,978,288)
	83,479,788	(149,978,288)
	1,270,350,268	432,615,561
46. OTHER TRANSFERS		
Contribution to CF (15%)	5,720,594,356	5,592,244,625
Expenses	5,720,594,356	5,592,244,625

47. ACQUISITION OF PROPERTY, PLANT AND EQUIPMENT

	2022/23	2021/22
	TZS	TZS
Hardware: Servers and equipment	527,087,612	786,280,155
Laboratory equipment and instruments	39,730,870	-
Lease hold land	-	66,579,000
Motor vehicles	-	184,693,826
Office Furniture and Fittings	142,257,389	261,077,950
Other Office equipment	16,850,000	115,044,100
Payment	<u>725,925,871</u>	<u>1,413,675,031</u>

48. 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 2021/22) have been restated as narrated in the table below.

Restated as narrated in the table below.			
Item affected	Prior amount before restatement/reclassification	Amount after restatement /reclassification	Reason for restatements/reclassification
	TZS	TZS	
STATEMENT OF FINANCIAL POSITION			
Depreciation charge	3,459,713,027	2,310,932,844	<p>This was in respect of review of useful lives of all Property, Plant and Equipment which some were fully depreciated but still in use as at 30th June, 2023.</p> <p>The review has resulted in its estimated useful lives to change from previously estimated useful lives, the effect has been accounted for as an accounting error and the overcharged depreciation for previous years has been retrospectively recalculated as per the provisions of IPSAS 17 Property, Plant and Equipment.</p> <p>The opening carrying amounts of accumulated depreciation for 2021/2022 and retained earnings for the financial year 2021/2022 has been respectively restated by TZS 1,138,741,841 while the current depreciation has been posted in the current period.</p>

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Item affected	Prior amount before restatement/reclassification	Amount after restatement /reclassification	Reason for restatements/reclassification
	TZS	TZS	
			Also accumulated depreciation of TZS 10,038,342 regarding disposed PPE have been adjusted accordingly.
Receivables	3,328,021,539	35,683,696,965	<p>TZS 3,328,021,539 comprised of imprest receivable TZS 2,279,300, provision for bad and doubtful debts TZS (33,402,589,638), receivable TZS 33,402,589,638, rent income receivable TZS 155,087,418, long term staff loans receivable TZS 2,123,740,609 and short term staff loans TZS 1,046,914,212.</p> <p>Due to changes in GFS Code and application of MUSE system the presentation changed to respective sections</p>
Loan receivable	-	1,046,914,212	This was previously indicated in receivables as explained above, in 2022/23 due to changes in GFS Code and application of MUSE system, the loan receivable was shifted to its respective section of loans receivable
Provisions	202,530,000	33,605,119,638	In 2021/22 TZS 202,530,000 was the provision for audit fees. Due to change in GFS Codes and application of MUSE system provisions all provisions were presented in Note 28.
STATEMENT OF FINANCIAL PERFORMANCE			
Revenue From Exchange Transactions	316,092,779	19,051,921,416	In 2021/22 TZS 316,092,779 comprised of receipt from publications TZS 28,237,161 and rent fee TZS 287,855,618 while in 2022/23 TZS 19,051,921,416 comprised of import fees TZS 18,783,711,917, laboratory charges TZS 211,735,177, receipt from sale of publications TZS 56,474,322. Regrouping of the figures was

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Item affected	Prior amount before restatement/reclassification	Amount after restatement /reclassification	Reason for restatements/reclassification
	TZS	TZS	
			done due to changes in GFS code and report mapping.
Levies	-	240,530,618	Levies comprise of rent fees, the recategorization of the figures was done to enhance accurate comparatives inline with the GFS Codes when producing 2022/23 financial statements in MUSE system.
Fees, Fines, Penalties and Forfeits	35,356,203,499	13,257,997,901	In 2021/22 TZS 35,356,203,499 comprised of fines, penalties and forfeitures TZS 24,049,694,425, receipt from annual fees TZS 317,770,275 and registration fees TZS 10,988,738,799 while in the year 2022/23 it was reclassified into bail Y=TZS 1,951,418,827, receipt from annual fees TZS 317,770,275 and registration fees TZS 10,988,738,799 due to the changes in GFS codes in MUSE system.
Other Revenue	53,562,949	3,175,409,292	In the year 2021/22 TZS 53,562,949 comprised of miscellaneous incomes TZS 53,562,949 while in the year 2022/23 it was reclassified into miscellaneous receipts 69,385,186, retention fees for lodging TZS 3,106,024,106 due to changes in GFS Code in MUSE system.
Wages, Salaries and Employee Benefits	14,308,567,396	15,526,068,531	In the year 2022/23 TZS 1,217,501,133 for food and refreshment was reclassified to wages, salaries and employee benefits to make it TZS 15,526,068,531 due to changes in GFS codes in MUSE system.
Use of Goods and Service	13,680,507,014	12,463,005,883	TZS 1,217,501,133 for food and refreshment was reclassified to wages, salaries and employee benefits due to changes in GFS codes in MUSE system.

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Item affected	Prior amount before restatement/reclassification	Amount after restatement /reclassification	Reason for restatements/reclassification
	TZS	TZS	
Depreciation of investment property	-	30,749,662	TZS 30,749,662 was the depreciation amount for investment property which were reported together with PPE. In the year 2022/23 Investment property was reported separately.
Depreciation of Property, Plant and Equipment	3,490,462,688	3,459,713,027	Reclassification of TZS 30,749,662 of depreciation for investment property from PPE.
Loss on Disposal of Assets	83,367,200	112,618,744	TZS 29,251,549 was for foreign exchange losses, which was reclassified to loss on disposal due to changes in GFS codes
Other Expenses	611,845,398	582,593,849	TZS 29,251,549 was for foreign exchange losses, which was reclassified to loss on disposal due to changes in GFS codes
STATEMENT OF CASH FLOWS			
Subvention from other Government entities	4,357,035,183	4,580,191,490	There was an amortization of subvention from other government entities of TZS 210,007,517 which was deducted from the total subvention from other entities of TZS 4,790,199,007. Also, TZS 13,148,790 was the reclassification to the subvention from other government entities due to changes in GFS code
Revenue from exchange transactions	309,173,141	19,051,921,417	In 2021/22 TZS 316,092,779 comprised of receipt from publications TZS 28,237,161 and rent fee TZS 287,855,618 while in 2022/23 TZS 19,051,921,416 comprised of import fees TZS 18,783,711,917, laboratory charges TZS 211,735,177, receipt from sale of publications TZS 56,474,322. Regrouping of the figures was done due to changes in GFS code and report mapping.
Other Revenue	1,299,859,320	3,175,409,292	In the year 2021/22 TZS 53,562,949 comprised of

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Item affected	Prior amount before restatement/reclassification	Amount after restatement /reclassification	Reason for restatements/reclassification
	TZS	TZS	
			miscellaneous incomes TZS 53,562,949 while in the year 2022/23 it was reclassified into miscellaneous receipts 69,385,186, retention fees for lodging TZS 3,106,024,106 due to changes in GFS Code in MUSE system.
Levies	-	240,530,618	Levies comprise of rent fees, the recategorization of the figures was done to enhance accurate comparatives inline with the GFS Codes when producing 2022/23 financial statements in MUSE system.
Increase in Deposit	-	219,750,432	This was the contra entry which set offs on the receipts and payments sides. There was receipt of TZS 219,750,432 and payment of the same amount TZS 219,750,432. The figures arose due to changes in GFS codes in MUSE system however they net off within the financial statements.
Fees, Fines, Penalties and Forfeits	35,356,203,499	13,257,997,901	In 2021/22 TZS 35,356,203,499 comprised of fines, penalties and forfeitures TZS 24,049,694,425, receipt from annual fees TZS 317,770,275 and registration fees TZS 10,988,738,799 while in the year 2022/23 it was reclassified into bail Y=TZS 1,951,418,827, receipt from annual fees TZS 317,770,275 and registration fees TZS 10,988,738,799 due to the changes in GFS codes in MUSE system.
Wages, Salaries and Employee Benefits	14,308,567,396	15,526,068,531	In the year 2022/23 TZS 1,217,501,133 for food and refreshment was reclassified from other expenses to make it TZS 15,526,068,531 due to changes in GFS codes in MUSE system.
Use of goods and service	13,260,623,340	12,179,682,295	TZS 1,217,501,133 for food and refreshments was

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

Item affected	Prior amount before restatement/reclassification	Amount after restatement /reclassification	Reason for restatements/reclassification
	TZS	TZS	
			reclassified to wages, salaries and employee benefits and TZS 582,593,849 was reclassified to other expenses. Also, TZS 283,323,587 was the movement in working capital used to compute cash paid from use of goods and services. The reclassifications were brought by the changes in GFS codes in MUSE system.
Other Expenses	-	432,615,561	There was a movement of TZS 149,978,288 from the total other expenses of TZS 582,593,849. The existence of other expenses has been brought by the changes in the GFS Codes in MUSE system