TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

20 YEARS

OF REGULATING MEDICINES, MEDICAL DEVICES AND DIAGNOSTICS;

MILESTONES ATTAINED

2003 - 2023

TABLE OF CONTENTS

LETTER OF TRANSMITTAL

Hon. Mohamed Omary Mchengerwa (MP)
Minister for Health
P.O. Box 743
Dodoma

Dr. Seif Shekalaghe
Permanent Secretary Ministry of Health
P. O. Box 743
Dodoma

Hon. Minister,

I am greatly honored to present to you the Tanzania Medicines and Medical Devices Authority (TMDA) 20th Anniversary Book. The Book presents historical background on product regulation in the country since the establishment of Tanzania Food and Drugs Authority in 2003. The milestones attained in controlling and regulating medicines, medical devices, diagnostics, and other health related products in the country between July 2003 and June 2023 are presented.

The book also outlines the challenges TMDA has faced over the period of 20 years in its pursuit of excellence in implementing its mandate.

I submit,

Shekalaghe

Dr. Seif Shekalaghe
Permanent Secretary,
Ministry of Health - Tanzania

ACKNOWLEDGEMENTS

> **“This publication represents not only a historical reflection but also a celebration of collective commitment, visionary leadership, and unwavering dedication to public health ”**

As we commemorate two decades of dedicated service since the establishment of the Tanzania Medicines and Medical Devices Authority (TMDA), originally founded as the Tanzania Food and Drugs Authority (TFDA) in 2003, I take this opportunity to express my deepest gratitude to all who contributed to the successful realization of this book.

This publication represents not only a historical reflection but also a celebration of collective commitment, visionary leadership, and unwavering dedication to public health. Its completion would not have been possible without the invaluable input and collaborative spirit of numerous individuals and teams within the Authority.

I extend my sincere appreciation to the TMDA Directors for their strategic oversight, valuable insights, and support throughout the crafting and design of this book. These include: Dr. Yonah Hebron, Director of Human and Veterinary Medicines; Dr. Danstan Shewiyo, Director of Laboratory Services; Dr. Kissa Mwamwitwa, Director of Medical Devices and Diagnostics; and Mr. Chrispin Severe, Director of Business Support. Their leadership and guidance have been instrumental in shaping the success of this publication.

Moreover, special recognition is extended to the dedicated team of Communication and Public Education Department namely Mr. Edward Bora, Mr. Sigfrid Mtey, and Ms. Njuu Kapwera, and to the TMDA Managers, including CPA. Adam Kimetelo, CPA. Godian Ngamesha, Mr. Ambele Mwafula, Ms. Grace Shimwela, Ms. Martha Malle, Ms. Donata Koko, and Mr. Moses Magoma, whose hard work, creativity, and commitment were instrumental in bringing this commemorative book to life.

Of highest note, I thank the Chief Editor, Dr. Adam M. Fimbo, who also serves as the Director General, for his exceptional editorial leadership, attention to detail, and dedication to excellence, as well as for his dynamic leadership, tireless supervision, and steadfast support throughout the development and refinement of this publication.

Furthermore, I am grateful to the TMDA Management and Members of the Ministerial Advisory Board (MAB) for their final endorsement and approval, ensuring that this book meets the highest standards of institutional integrity and impact.

As we reflect on our past and look to the future, TMDA remains committed to protecting and promoting public health. We continue to recognize the importance of informed stakeholders in maintaining the safety, quality, and efficacy of medical products. We encourage our readers to stay informed, engaged, and share feedback and suggestions that can help us continue to improve.

All stakeholders and the general public are invited to explore this book with pride and enthusiasm—knowing it is a product of dedication, collaboration, and our shared commitment to a healthier Tanzania.

Enjoy your reading!

Gaudensia Simwanza
Manager, Communication and Public Education

STATEMENT OF CHAIRPERSON – MINISTERIAL ADVISORY BOARD

> **“Over the past two decades, TMDA has emerged as a regional and continental leader in regulatory systems strengthening. It has achieved numerous milestones...”**

It is with great pride and deep appreciation that I present this statement on behalf of the Ministerial Advisory Board in commemoration of the 20-year journey of the Tanzania Medicines and Medical Devices Authority (TMDA), formerly known as the Tanzania Food and Drugs Authority (TFDA). This milestone marks not only a passage of time but a profound transformation in regulatory excellence, institutional maturity, and service to public health in Tanzania.

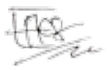
Since its establishment in 2003 under the Tanzania Food, Drugs and Cosmetics Act, TMDA has played a critical role in safeguarding and promoting the health of the Tanzanian people through the regulation and control of medicines, medical devices, diagnostics, and other health-related products. The journey from TFDA to TMDA in 2019 was more than a change of name—it reflected a strategic shift, a broader mandate, and an unwavering commitment to quality, safety, and innovation in health product regulation.

Over the past two decades, TMDA has emerged as a regional and continental leader in regulatory systems strengthening. It has achieved numerous milestones, including becoming a World Health Organization (WHO) Maturity Level 3 institution—a recognition of its advanced and well-functioning regulatory system. The Authority has also been instrumental in harmonizing regulatory practices across the East African Community and beyond, ensuring that Tanzanians and East Africans in general have timely access to quality-assured medicines and medical devices.

The Ministerial Advisory Board commends the visionary leadership, professionalism, and dedication exhibited by the Authority's management and staff throughout this journey. We also acknowledge the continued support of the Government of the United Republic of Tanzania, development partners, healthcare providers, industry stakeholders, and the Tanzanian public—whose trust and collaboration have been vital to TMDA's success.

As we look to the future, we are confident that TMDA will continue to evolve and strengthen its regulatory framework to respond to emerging public health challenges, advances in science and technology, and the growing demands of our healthcare system. The Board reaffirms its commitment to providing strategic guidance and oversight to ensure TMDA remains a beacon of regulatory excellence in Africa.

On behalf of the Ministerial Advisory Board, I extend heartfelt congratulations to TMDA for two decades of impactful service. May the next 20 years be marked by even greater achievements in protecting and advancing the health of our nation.



Mr. Eric Shitindi
Chairperson (MAB)

PREFACE

The Tanzania Medicines and Medical Devices Authority (TMDA) marks 20 years of service since its establishment in 2003, reflecting on significant milestones achieved in protecting public health through regulation of medical products. From its inception, the Authority has evolved into one of Africa's leading regulators, recognized globally for its capacity, systems, and commitment to safety, quality, and efficacy.

TMDA was created in response to the need for a stronger, unified institution capable of handling increasing complexities in health product regulation amidst rapid technological advances and liberalized markets. Originally founded as the Tanzania Food and Drugs Authority (TFDA) under the Tanzania Food, Drugs and Cosmetics Act, Cap 219, its transformation to TMDA in 2019 shifted regulatory responsibility for food and cosmetics to the Tanzania Bureau of Standards (TBS). This restructuring solidified TMDA's focus on medicines, medical devices, diagnostics, and other health-related products.

The Authority's legal mandate, derived from the Medicines and Medical Devices Act, has been progressively strengthened, positioning TMDA among the most capable regulators in Africa. In 2018, it became the first national medicines regulatory agency in Africa to be recognized by the World Health Organization (WHO) as a Maturity Level 3 institution only one level before attaining full maturity (Level 4). This achievement underscored its credibility as an independent, science-driven, and transparent agency committed to international best practices.

Over two decades, TMDA has introduced and refined robust systems for product registration, inspection, post-marketing surveillance, and laboratory analysis. Pharmacovigilance and clinical trial oversight frameworks have also been established to safeguard Tanzanians from unsafe or ineffective products. To support these systems, TMDA invested in developing a Quality Management System (QMS), earning ISO 9001:2008 certification in 2008/09, and has consistently maintained it through annual audits.

The introduction of the Client's Service Charter (CSC) in 2006, revised periodically in 2012, 2016, and 2020, improved service standards and reduced turnaround times for regulatory applications. These gains were made possible

by investment in digital infrastructure, including the internally developed Regulatory Information Management System (RIMS). RIMS has enhanced transparency, efficiency, and customer satisfaction by streamlining engagement with stakeholders.

A cornerstone of TMDA's success has been the establishment of its Quality Control Laboratory (QCL), which has become a benchmark in Africa. The QCL earned WHO prequalification in 2011, reached WHO Maturity Level 4 for pharmaceutical testing, and achieved accreditation under ISO/IEC 17025:2005 by the Southern African Development and Accreditation System (SADCAS). Its state-of-the-art facilities, advanced equipment, and skilled personnel provide confidence in the quality assurance of health products.

To expand access and strengthen oversight, TMDA established eight zonal offices and port-of-entry inspection units. This decentralization has improved stakeholder access to services and enhanced the Authority's ability to intercept substandard and falsified medicines.

Beyond regulation, TMDA has played a catalytic role in promoting domestic pharmaceutical manufacturing. By offering technical guidance, capacity building, and regulatory incentives, it has supported the growth of Good Manufacturing Practices (GMP)-compliant facilities, improving local access to quality-assured medical products.

Regionally and internationally, TMDA has positioned itself as a key player. It is a founding member of the African Medicines Regulatory Harmonization (AMRH) initiative and actively contributed to the establishment of the African Medicines Agency (AMA). Such partnerships have fostered regulatory convergence, reduced duplication of processes, and accelerated access to essential products across the continent.

Governance has been strengthened through five successive Strategic Plans (SPs), aligned with national frameworks such as Tanzania Development Vision 2025 and sectoral health strategies. These SPs guided the development of annual business plans and budgets, improving revenue collection from internal and external sources and supporting sustainability. TMDA has consistently received clean audit reports from the Controller and Auditor General, reflecting transparency and sound financial management.

However, the journey has not been without challenges. Limited resources, particularly financial and technical, have at times slowed progress. Emerging technologies such as biologics, biosimilars, and digital health products demand ongoing adaptation of regulatory frameworks. Falsified medicines, proliferating especially through informal markets and online platforms, remain a persistent threat. Balancing strict regulatory standards with timely access to medicines is another continuing challenge, particularly evident during emergencies like the COVID-19 pandemic.

Despite these hurdles, TMDA's progress is attributed to the professionalism and dedication of its staff, strong leadership, guidance from the Ministerial Advisory Board, collaboration with other government ministries, and partnerships with international organizations such as WHO, the Global Fund, EDCTP, and BMF. Support from Tanzanian citizens has also been vital.

Looking forward, TMDA commits to building upon its strong foundation, embracing innovation, and aligning with global health agendas. Continued investment in human capital, infrastructure, and research will ensure responsiveness to emerging regulatory needs. The Authority remains dedicated to its mission of protecting and promoting public health by ensuring access to safe, effective, and quality medical products.

As TMDA celebrates 20 years, it emphasizes the importance of shared responsibility and collaboration in strengthening regulatory systems, aiming to inspire continued progress for Tanzania and beyond.

Dr. Adam M. Fimbo

Director General

Reflections on TMDA by former Director Generals

Margareth Ndomondo-Sigonda (PhD, MBA, MSc, BPharm), The first Director General, Tanzania Food and Drugs Authority (TFDA)

The Tanzania Food and Drugs Authority (TFDA) was established as a merger between the Pharmacy Board and the National Food Control Commission. This merger was necessitated by the Public Service Reforms Program (2000-2007), which, among others, aimed to improve accountability, transparency, and resource management for service delivery, as well as introduce client orientation and results-oriented management. As the first Director General of the Tanzania Food and Drugs Authority (TFDA), transitionally operating as a semiautonomous agency under the Executive Agencies Act, of 1997, I entered into an agreement with the Permanent Secretary, Ministry of Health and Social Welfare, to ensure efficient and effective delivery of services, through a framework document which provided a clear vision, mission and strategic objectives. I worked under the technical guidance of the Management Team and Technical Committee while strategically seeking guidance from the Ministerial Advisory Board, Chaired by the Permanent Secretary, Ministry of Health and Social Welfare.

During my tenure as the Chief Executive Officer (CEO) of TFDA, I had the privilege of providing technical leadership in the

overhaul of the Food Control of Quality Act, and the Pharmacy and Poisons Act, both of 1978 and subsequent enactment of the Food and Drugs Act, and the Pharmacy Act, in 2003, to establish the Tanzania Food and Drugs Authority and the Pharmacy Council, respectively. While the former was responsible for the regulation of the quality, safety (for food and cosmetics), and efficacy (for medicines, the latter was responsible for regulating the pharmacy profession).

The TFDA's vision was to become the leading agency in the regulation of quality, safety and/ or effectiveness of food, drugs, medical devices and cosmetics in Africa. One of the first initiatives we pursued was strengthening the regulatory frameworks through the development of regulations and guidelines for undertaking various regulatory functions such as registration and marketing authorization, inspection of manufacturing sites, and clinical trials oversight, just to mention a few.

In addition, we embarked on an investment in the implementation of quality management systems in line with the International Standards Organization (ISO) 9001: 2008 certification scheme. Furthermore, we invested in capacity building - both in terms of infrastructure and human resources so that TFDA could effectively enforce regulations and respond to emerging public health challenges.

In order to ensure customer satisfaction with the service offered, a client services charter was developed and officiated in 2006 as an agreement between TFDA and its customers, with clear timelines for service delivery. This included developing stringent protocols and procedures for the approval, inspection, and surveillance of medical products and the quality of products circulating on the market, which had far-reaching impacts on patient safety.

TFDA leadership instilled a sense of commitment for staff to uphold the following values: transparency, accountability, quality, creativity, teamwork, integrity and customer focus. One of my proudest achievements was enhancing the transparency and accountability of TFDA's operations. Prior to my tenure, public perception of regulatory bodies in many African countries, including Tanzania, was often clouded by suspicion of corruption and inefficiency.

We implemented quality management systems for greater transparency in decision-making. Established clear lines of accountability and made the approval processes more accessible to the public through the implementation of a robust information management system. Engaging with stakeholders became a priority. It was not enough for TFDA to simply regulate; we had to do so in a way that fostered trust and understanding.

In the face of global health challenges, including the ongoing battle with infectious diseases, the Ministry of Health entrusted TFDA to spearhead the national strategy for the promotion of local production of

medical products to ensure that Tanzania becomes self-sufficient in its medical needs, as enshrined in the national medicines policy. While Tanzania has a strong tradition of health innovation, the country has historically depended on imports to meet its medical needs.

Through strategic partnerships with the private sector and international health organizations, we supported local manufacturers in meeting TFDA's rigorous standards, encouraging them to produce quality products. This not only boosted the local economy but also enhanced the resilience of Tanzania's healthcare infrastructure. Our belief was that investing in local manufacturing would lead to more affordable access to medical products for Tanzanians, while also positioning the country as a regional leader in health products production.

Between 2000 to 2003, I played a pivotal role in piloting and subsequently establishing Accredited Drug Dispensing Outlets (ADDOs) in rural and peri-urban areas. These communities faced persistent shortages of basic and essential medicines, largely because the private sector was reluctant to invest in such areas due to limited commercial viability. Through the ADDO initiative, we actively engaged both the public and the business community, introducing targeted incentives that encouraged investment in rural and peri-urban settings. This approach not only improved access to essential medicines but also strengthened the role of the private sector in supporting public health.

Looking back on my time as CEO of TFDA, the most important lesson I learned was the need for continual adaptation. Healthcare is a dynamic sector, and regulatory agencies must evolve alongside medical advancements and societal changes.

One of the key recommendations I have for the future of TMDA is to continue investing in human capital and innovations, not just in terms of how the products are being regulated, but also in how TMDA operates. The future of medicines and medical devices will rely heavily on staff who are competent in regulatory science, artificial intelligence, data analytics, cross-border collaborations, harmonization of regulatory standards and reliance.

Tanzania's contribution through TMDA in the regional regulatory harmonization initiatives for medical products, such as the East African Community (EAC) and the Southern African Development Community (SADC) and as a state Party to the African Medicines Agency (AMA), is pivotal in advancing the African Union agenda for research and development and local production of medical products.

TMDA has come a long way, and I am proud of the work done during my time as the CEO and subsequent leadership that has ensured continuity of the TFDA values. The Authority is now a cornerstone of not only Tanzania's but also regional and continental healthcare landscape, ensuring the quality and safety of the medicines, vaccines and medical devices that millions rely on.

Mr. Hiiti Baran Sillo

The second Director General, Tanzania Food and Drugs Authority (TFDA), 2010 to 2018

Strong and visionary leadership is central for effective, efficient, transparent, agile and accountable regulatory oversight to facilitating access to safe, effective and quality assured health products. Between May 2010 and January 2018, I had the great honour and privilege to serve as the second Director General of the Tanzania Food and Drugs Authority (TFDA), the predecessor of the Tanzania Medicines and Medical Devices Authority (TMDA). During the early days of my leadership, the TFDA set the vision of becoming the leading regulatory body in Africa for regulation and control of quality, safety and effectiveness of health products as well as quality and safety of food and cosmetics. Realizing this dream required a well-articulated strategic plan with concrete objectives and deliverables including well-defined monitoring and evaluation tools to measure progress, identify challenges and addressing them.

Some of the challenges facing the TFDA at the time included limited number of skilled staff to undertake regulatory activities across the country, limited regulations supporting enforcement of the law across product streams, weak quality management system, weak information management system, proliferation of substandard and

falsified medical products, lack of public awareness on the role of a regulatory body for health products, limited engagement in regional and global regulatory harmonization initiatives and few zone offices and port of entry inspectors.

To address these challenges, and with support and guidance of the Ministerial Advisory Board (MAB), unwavering political will and Government support, stakeholder buy-in and dedicated and committed management and staff of the TFDA; the Authority was able to record major achievements and milestones. Some of these include increase in number of staff by over 50% from 180 in 2010 to 290 in the beginning of 2018; established autonomous and sustainable financing mechanism, WHO Prequalification of the quality control laboratory for pharmaceuticals and accreditation to ISO 17025 of food testing laboratory; establishment and implementation of a robust Integrated Management Information System (IMIS) and Laboratory Information Management System (LIMS) linked to quality management systems (now modelled across Africa under the African Medicines Regulatory Harmonization (AMRH) Imitative; investment in public awareness and education on the functions of the Authority; expansion of zone offices from 4 in 2010 to 7 in 2017; construction and commissioning of a modern Lake Zone Office and Laboratory facility. Other milestones include track record and certification on implementation of principles of good governance in managing the Authority, enhanced public trust on the operations of the agency and particularly in curbing substandard and falsified products and alerting the public in a transparent and accountable manner.

During this period, the TFDA championed regional and global regulatory collaboration particularly in harmonization and convergence of regulatory requirements, processes and procedures in Africa, leading its piloting in East Africa and roll out across the Regional Economic Communities (RECs) under the coordination of the World Health Organization (WHO) and AUDA-NEPAD. As of the beginning of 2018, the TFDA was represented in various regional and global regulatory activities including the African Medicines Regulatory Harmonization (AMRH) Programme, WHO Member State Mechanism on Substandard Falsified Medical Products, International Council on Harmonization (ICH) of Registration of Pharmaceutical Products for Human Use, the Global Harmonization Working Party (GHWP) for Medical Devices, African Vaccines Regulatory Forum, and the African Union Task Team for Establishment of the African Medicines Agency.

By end of 2017, the Authority had established a strong, transparent, efficient and effective, accountable regulatory system for medicines,

vaccines, medical devices, cosmetics and food safety. The assessment in 2016 using the newly established global tool for assessing regulatory systems for medical products; WHO Benchmarking Tool (GBT) identified areas of focus in the new strategic plan towards fast-tracking the vision of becoming a leading agency on the continent of Africa. This set a firm foundation for the TFDA becoming the first regulatory body in Africa to be recognized by the WHO as a stable, well-functioning and integrated regulatory system (WHO Maturity Level 3) for medicines and imported vaccines towards the end of 2018. It is also on record that for the first in the history of regulation of health products in Tanzania, the Head of State, the fourth President of the United Republic of Tanzania, H.E Dr. Jakaya Mrisho Kikwete visited the Authority in 2013 during the inauguration of quality control laboratory.

Looking into the future of regulatory landscape for medical products in a rapidly changing global health, TMDA needs to ensure it holds the historical breakthrough of championing effective and efficient regulation of medical products, particularly with the establishment of the African Medicines Agency (AMA). Regulatory collaboration, work-sharing and reliance is "smart regulation" and the 21st century regulatory tools. The expertise and trust built over the years would need to be leveraged to serve other countries in Africa by effectively contributing to the work of the AMA and the Regional Economic Communities (RECs). TMDA should aspire to become the first ML 3 regulatory authority in Africa to become the WHO Listed Authority (WLA) – the global list of trusted and highly performing regulatory authorities.

Ms. Agnes Sitta Kijo
The third Director General, Tanzania Food and Drugs Authority (TFDA)

I had the honour of serving as the third Director General of the Tanzania Food and Drugs Authority (TFDA) from January to September 2018, succeeding Mr. Hiiti Sillo.

Despite my brief tenure, I played a crucial role in advancing TFDA's mission to safeguard public health through the regulation of medicines, medical devices, cosmetics and food safety. My leadership focused on sustaining the momentum of modernization and improving TFDA's regulatory services.

A key aspect of my tenure was the emphasis on effective leadership through professionalism, technological reforms, integrity, and accountability. Building upon the foundation set by my predecessor, I ensured that TMDA remained on its trajectory of growth and reform. My commitment to transparency, consistency, and integrity positioned the organization as one of the top government agencies in Tanzania and earned recognition at both continental and global levels.

I also championed improvements in regulatory processes, prioritizing digital transformation and enhancing staff welfare. Under my leadership, TFDA pursued key initiatives, including the aspiration to attain Maturity Level 3 through assessment by the World Health Organization (WHO), the expansion and retention of certification for the Quality Control Laboratory, the operationalization of a new laboratory in the Lake Zone including

purchasing of equipment, and the recruitment of staff, particularly at border points.

Additionally, I oversaw the acquisition of vehicles to strengthen inspection activities and planning for the construction of TFDA offices in the capital, Dodoma. These contributions were instrumental in advancing TMDA toward greater efficiency, transparency, and responsiveness as a regulatory authority.

Another critical focus of my leadership was fostering regional and international cooperation through the East African Community, African Medicines Regulatory Harmonization (AMRH) Initiatives, and WHO. Recognizing the global challenges posed by substandard and falsified products, I reinforced TFDA's role in cross-border regulatory collaboration. My efforts to align TFDA's regulations with international standards helped strengthen Tanzania's position in the global market and enhanced public health protections throughout East Africa and Africa at large.

One of my most notable achievements was leading TFDA to attain Maturity Level 3 through the WHO's Global Benchmarking Tool assessment, making it the first regulatory authority in Africa to reach this milestone. This achievement laid the groundwork for future advancements and positioned TFDA as a reference authority in the regulation of pharmaceutical products. Additionally, I played a pivotal role in establishing and strengthening the regulation of medical devices, including in vitro diagnostics, making TFDA one of the top agencies in this area of work in Africa and in setting up a new laboratory for testing selected medical devices, one of the few of its kind in the Continent. This initiative provided a strong foundation for regulatory benchmarking in this sector.

Every organization faces challenges, and TFDA was no exception. Some key challenges included inadequate human and financial resources, and the cultural shift required during preparations for the WHO benchmarking assessment.

As TMDA, the successor of TFDA marks 20 years of existence, it must continue addressing emerging health challenges, particularly in regulating new healthcare technologies. The rapid rise of digital health solutions and innovative medical devices necessitates the continuous development of updated regulations and guidelines. TMDA must remain agile, adapting its frameworks to keep pace with medical advancements while ensuring the safety and efficacy of healthcare products.

In conclusion, while my time as Director General of TFDA was short, it was marked by significant achievements in regulatory modernization, international collaboration, and institutional strengthening. To sustain its progress, TMDA must continue prioritizing innovation, investing in human resources (both in quantity and quality), reinforcing global partnerships, and adopting smart regulatory concepts such as reliance and balanced innovation. By doing so, TMDA can maintain public trust and effectively respond to evolving health and technology challenges. I am proud of the strides we made, and I remain committed to supporting TMDA's mission in any way I can.

Reflections on TMDA by MAB Chairperson

Ambassador Dr. Ben Moses
Long Serving MAB Chairperson: (2010–2020)

Serving as Chair of the Ministerial Advisory Board (MAB) for the Tanzania Food and Drugs Authority (TFDA) from 2010 to 2019 and later the Tanzania Medicines and Medical Devices Authority (TMDA) from 2019 to 2020 has been one of the most fulfilling chapters of my public service journey. Leading three consecutive Boards over a decade was both a privilege and a profound responsibility—one I carried with great humility and dedication.

During this period, TMDA evolved significantly—growing from a young regulatory institution into a nationally and regionally respected Authority. I take pride in having contributed to shaping its strategic direction, supporting sound governance, and strengthening its capacity to safeguard public health through the regulation of medicines, medical devices, diagnostics, biocidals, and tobacco products.

Our journey was not without its challenges, but with collective determination, strong leadership, and the unwavering support of the Ministry of Health and Development Partners, TMDA made remarkable strides. I witnessed the development and implementation of critical policies, improved stakeholder engagement, and enhancement of regulatory systems that continue to serve the country today.

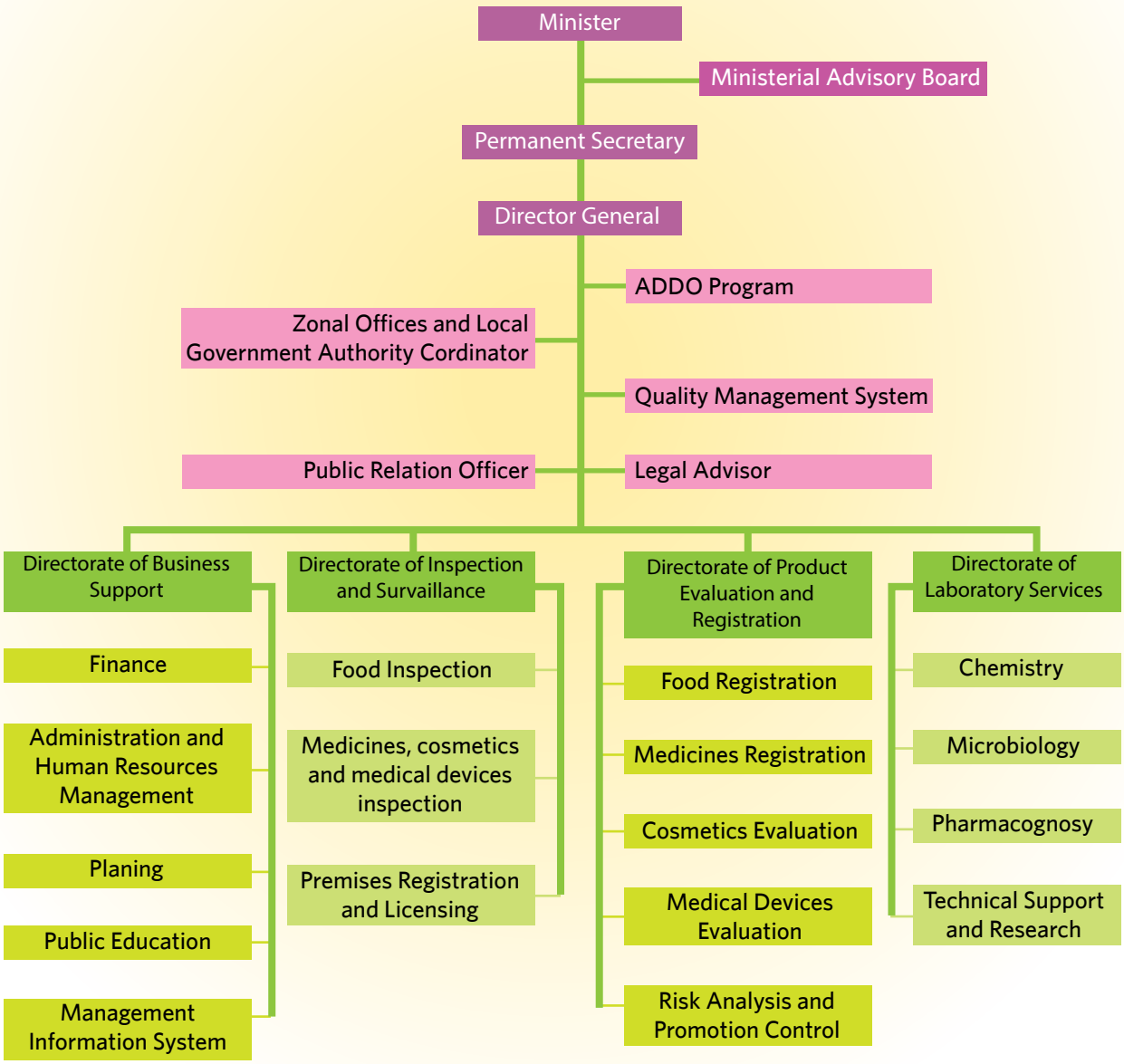
I am deeply grateful to the TMDA Management and staff for their professionalism, dedication, and tireless efforts throughout my tenure. My sincere thanks also go to my fellow Board members for their integrity, wisdom, and collaboration in steering the Authority forward.

As I reflect on these 10 years, I am proud of what we achieved together. I remain confident that TMDA will continue to build on this foundation and move steadily towards its vision of becoming a leading regulatory authority in Africa.

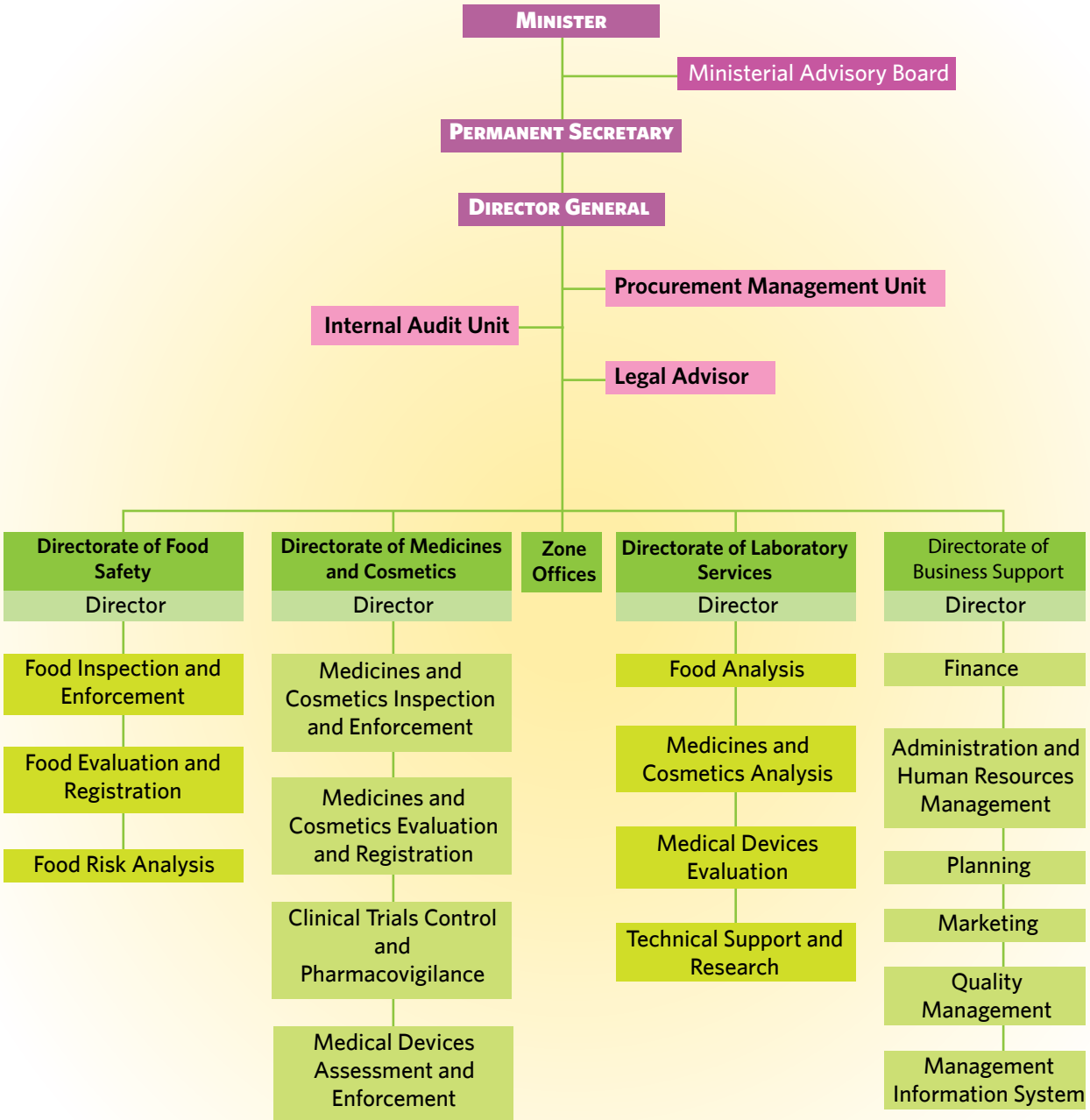
I leave this role with a heart full of gratitude and a continued commitment to support TMDA's mission wherever possible.

ORGANIZATIONAL STRUCTURES

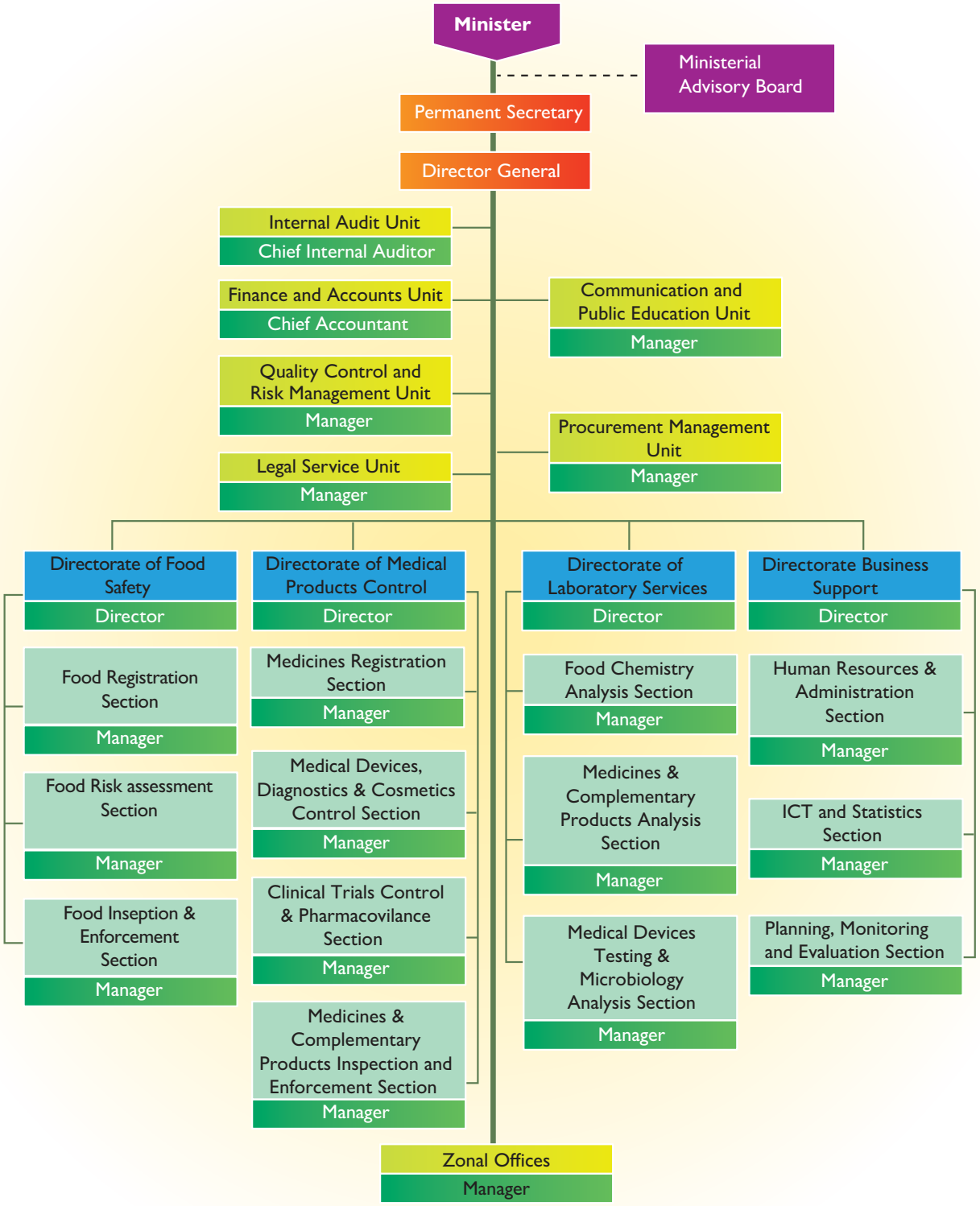
The First Organizational Structure of TFDA (2003-2008)



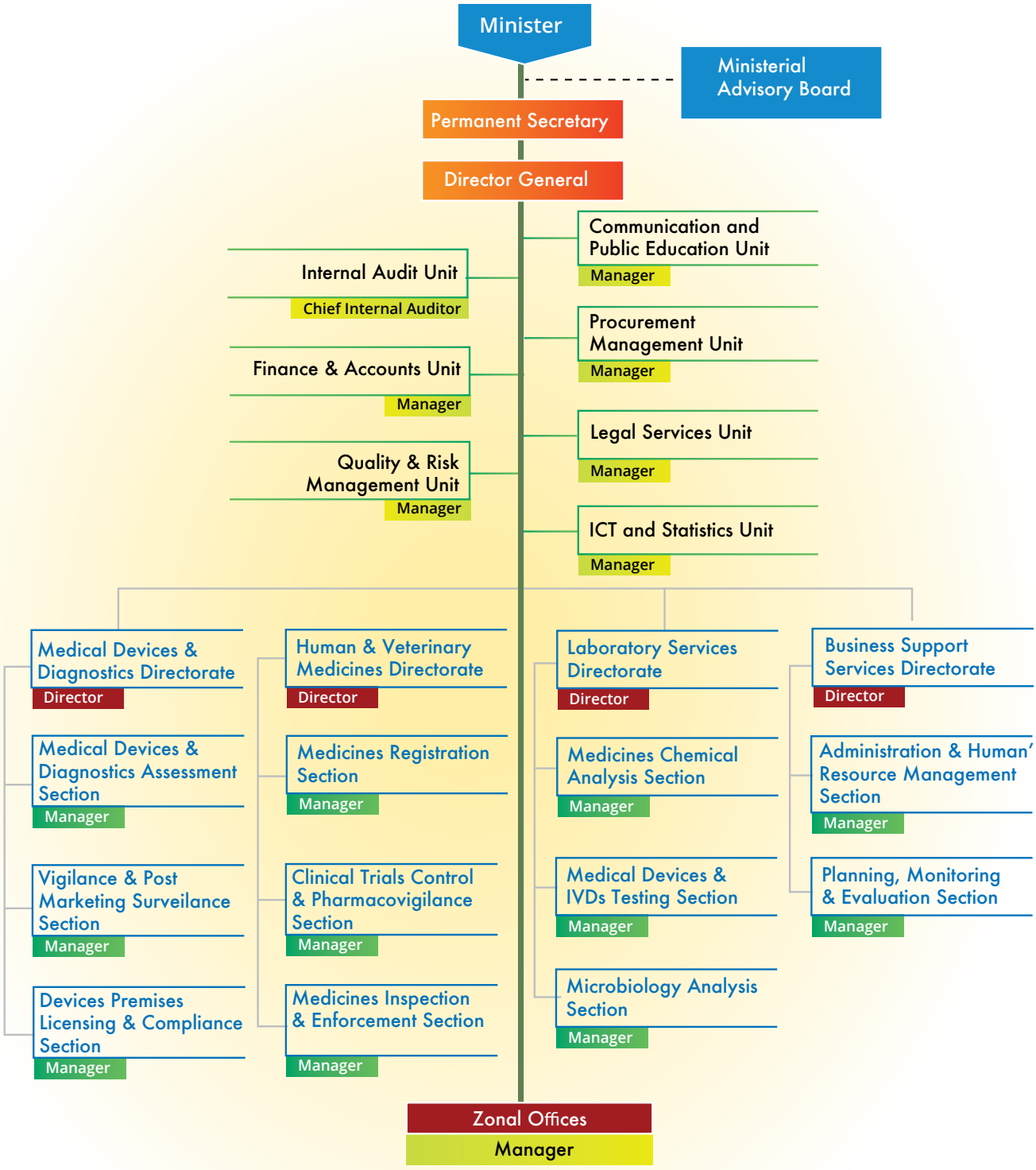
The Second Organizational Structure of TFDA (2008-2013)



The Third Organizational Structure of TFDA (2013-2019)



The Fourth Organizational Structure of TMDA (2019-2023)



MISSION, VISON, PHILOSOPHY AND CORE VALUES

VISION

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

TMDA
Tanzania Medicines & Medical Devices Authority

MISSION STATEMENT

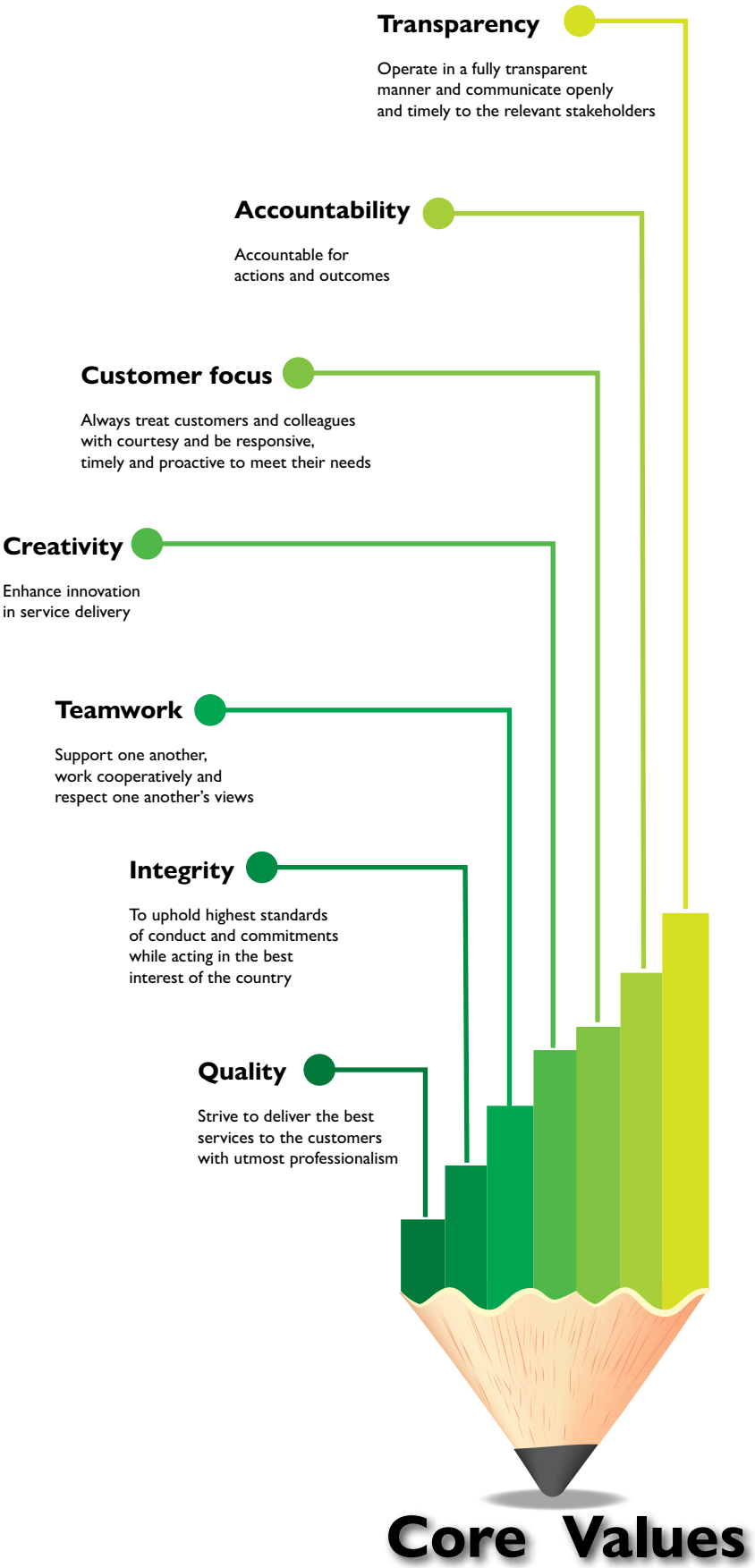
To protect and promote public health by ensuring quality, safety and effectiveness of medicines, medical devices, diagnostics and other health related products.

TMDA
Tanzania Medicines & Medical Devices Authority

PHILOSOPHY

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

TMDA
Tanzania Medicines & Medical Devices Authority


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

CHAPTER - 1

Ministerial Advisory Board and Management

1.1 Introduction

This chapter provides an overview of the structure, roles, and responsibilities of the Ministerial Advisory Board (MAB) and the Management Team in guiding and overseeing TMDA's strategic and operational functions.

TMDA, as an Executive Agency, operates within the framework of the Executive Agencies Act, Cap 245. Ministerial Advisory Board (MAB) was established under this Act, together with Section 9 of the Tanzania Medicines and Medical Devices Act, Cap. 219. MAB members, including the chairman, are appointed by the Minister responsible for health. The main role of MAB is to advise the Minister on strategic and operational matters of TMDA.

1.2 Ministerial Advisory Board Members

The Chairman and other Members of MAB serve for a tenure of three years and are eligible for re-appointment.

Table No. 1: Members of Ministerial Advisory Board (MAB) July 2003- May 2023

Period	Chairperson	Members
2003-2006	Ms.Mariam Mwafisi	Dr. Gabriel Upunda
2006-2007	Ms. Hilda H. Gondwe	Dr. Deo Mtasiwa
2007-2008	Mr. Wilson Mukama	Ms. Tabu Chando
2008-2010	Ms. Blandina Nyoni	Mr. Abraham Nyanda Mr. G. Nanyaro Ms. Sia B. Mrema Dr. Malik A. Juma Mr. John Mngondo Mr. Mick Kiliba Ms. Christine Kilindu Dr. D.G. Ndossi Mr. Charles Ekelege Dr. W.C. Mleche Mr. S. Nyimbi Ms. Margareth Ndomondo-Sigonda
2010-2013	Hon. Ambassador Dr. Ben Moses	Prof. Bendantunguka Tiisekwa Prof. Olipa Ngassapa Dr. Joseph Mhando Dr. Subilaga Kazimoto Adv. John Mponela Mr. Hiiti B. Sillo
2013- 2016	Hon. Ambassador Dr. Ben Moses	Prof. Bendantunguka Tiisekwa Prof. Olipa Ngassapa Dr. Joseph Mhando Dr. Subilaga Kazimoto Adv. John Mponela Mr. Hiiti B. Sillo
July 2016-Jan 2018	Hon. Ambassador Dr. Ben Moses	CPA. Zaina Thabit Prof. Said Aboud Dr. Maulid Walid Mwatawala Dr. Vincent Assey Adv. John Mponela Mr. Hiiti B. Sillo

January 2018-October 2018	Hon. Ambassador Dr. Ben Moses	CPA. Zaina Thabit Prof. Said Aboud Dr. Maulid Walid Mwatawala Dr. Vincent Assey Adv. John Mponela Agnes S. Kijo
October 2018-May 2020	Hon. Ambassador Dr. Ben Moses	CPA. Zaina Thabit Prof. Said Aboud Dr. Maulid Walid Mwatawala Dr. Vincent Assey Adv. John Mponela Mr. Adam M. Fimbo
May 2020-June 2022	Mr. Eric Shitindi	CPA. Zaina Thabit Prof. Said Aboud Mr. Mick Kiliba Mr. Daudi Msasi Prof. Appolinary A.R. Kamuhabwa Mr. Adam M. Fimbo
June 2022-May 2023		CPA. Zaina Thabit Prof. Said Aboud Mr. Daudi Msasi Prof. Appolinary A.R. Kamuhabwa Mrs. Emma L. Msuya Dr. Adam M. Fimbo

MEMBERS OF MAB

2003 - 2006

Ms. Mariam J. Mwafisi
Chairperson

Ms. Margareth Ndomondo-Sigonda
Member

Dr. W. C. Mleche
Member

Mr. Mick Kiliba
Member

Mr. G. Nanyaro
Member

Mr. Abraham Nyanda
Member

Mr. Charles Ekelege
Member

Ms. Christine Kilindu
Member

Ms. Sia B. Mrema
Member

Mr. S. Nyimbi
Member

Dr. Deo Mtasiwa
Member

Dr. D. G. Ndossi
Member

Ms. Tabu Chando
Secretary

Mr. John Mngondo
Member

Dr. Malik A. Juma
Member

MEMBERS OF MAB

2006 - 2010

Ms. Hilda A. Gondwe
Chairperson - 2006-2007

Wilson C. Mukama
Chairperson - 2007-2008

Ms. Blandina S. J. Nyoni
Chairperson - 2008-2010

Ms. Margareth Ndomondo-Sigonda
Member

Dr. W. C. Mleche
Member

Mr. Mick Kiliba
Member

Mr. G. Nanyaro
Member

Mr. Abraham Nyanda
Member

Mr. Charles Ekelege
Member

Ms. Christine Kilindu
Member

Ms. Sia B. Mrema
Member

Mr. S. Nyimbi
Member

Dr. Deo Mtasiwa
Member

Dr. D. G. Ndossi
Member

Ms. Tabu Chando
Secretary

Mr. John Mngondo
Member

Dr. Malik A. Juma
Member

MEMBERS OF MAB

2010 - 2013

Dr. Subilaga Kazimoto
Member

Ambassador Dr. Ben Moses
Chairperson

Prof. Bendantunguka Tiisekwa
Member

Mr. John Mponela
Member

Mr. Hiiti B. Sillo
Secretary

Dr. Joseph Mhando
Member

Prof. Olipa Ngassapa
Member

MEMBERS OF MAB

July 2013 - Jan 2016

Adv. John Mponela
Member

Ambassador Dr. Ben Moses
Chairperson

CPA Zaina Thabit
Member

Dr. Maulid Walid Mwatawala
Member

Prof. Said Aboud
Member

Mr. Raynald Mrope
Member

Mr. Hiiti B. Sillo
Member - Secretary

MEMBERS OF MAB

July 2016 - Jan 2018

Adv. John Mponela
Member

Ambassador Dr. Ben Moses
Chairperson

CPA Zaina Thabit
Member

Dr. Maulid Walid Mwatawala
Member

Ms. Agnes S. Kijo
2017 - 2018
Member - Secretary

Prof. Said Aboud
Member

Dr. Vincent-Assey
Member

Mr. Hiiti B. Sillo
2016 - 2017
Member - Secretary

MEMBERS OF MAB

October 2018 - May 2020

Adv. John Mponela
Member

Ambassador Dr. Ben Moses
Chairperson

Prof. Said Aboud
Member

Dr. Maulid Walid Mwatawala
Member

CPA Zaina Thabit
Member

Dr. Vincent-Assey
Member

Mr. Adam Mitangu Fimbo
Secretary

MEMBERS OF MAB

May 2020 - June 2022

Adv. John Mponela
Member

Mr. Eric Shitindi
Chairperson

Prof. Said Aboud
Member

Dr. Maulid Walid Mwatawala
Member

CPA Zaina Thabit
Member

Dr. Vincent-Assey
Member

Mr. Adam Mitangu Fimbo
Secretary

MEMBERS OF MAB

June 2022 - May 2023

Mr. Daudi Msasi
Member

Mr. Eric Shitindi
Chairperson

Prof. Said Aboud
Member

Prof. Appolinary A.R. Kamuhabwa
Member

CPA Zaina Thabit
Member

Mrs. Emma L. Msuya
Member

Dr. Adam Mitangu Fimbo
Secretary

1.3 Management Team

Section 11 (4) of the Tanzania Medicines and Medical Devices Act, Cap 219 provides for establishment of the Management Team to advise the Director General on functions and management of TMDA

> "the Director General (DG) is the chief executive officer and in charge of all day to day operations"

1.3.1 Director General

According to the approved organizational structure, the Director General (DG) is the chief executive officer and in charge of all day to day operations. The DG is answerable to the Permanent Secretary, Ministry responsible for health. From 2013 to 2023 the Authority was headed by the following personnel at the capacity of DG;

Table No. 2: List of names of Director Generals that have served TMDA for the period between 2003 to date

S/N	Name	Duration (Year)
1.	Ms. Magreth Ndomondo - Sigonda	July 2003 - April, 2010
2.	Mr. Hiiti B. Sillo	May 2010 - January 2018
3.	Ms. Agnes S. Kijo	Jan 2018 - September 2018
4.	Dr. Adam M. Fimbo	September 2018 - Todate

1.3.2 Directors

Table No. 3: Directors of various Directorates for the period between 2003 to 2023

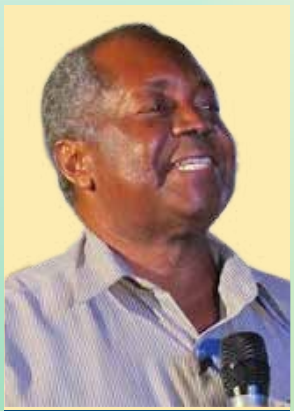
Directorate	Director's Name	Period
Inspection and Surveillance	Mr. Octavius M. Soli	Jul 2003 - Jan 2005
	Bi. Ollympia Kowero	Feb 2005 - Feb 2008
Laboratory Services	Ms. Ollympia Kowero	Jul 2003 - Jan 2005
	Ms. Charys Ugullum	Feb 2005 - Jan 2018
	Dr. Danstan Shewiya Hipolite	Jan 2018- To date
Food Safety	Mr. Raymond N. Wigenge	March 2008 - Jan 2018
	Mr. Justin D. Makisi	Jan 2018-Jul 2018
	Dr. Candida P. Shirima (Ms)	Jul 2018- June 2019
Business Support	Dr. Sikubwabo S. Ngendabanka	Jul 2003 - Dec 2015
	Mr. Bryceson P. Kibassa	Jan 2016 - Jul 2016
	Mr. Chrispin M. Severe	Aug 2016 – To date
Evaluation and Registration	Mr. Legu R. Mhangwa	Jul 2003 - Feb 2008
Medicines and Cosmetics	Mr. Hiiti B. Sillo	March 2008 - April 2010
	Dr. Adam M. Fimbo	May 2010-Dec 2014
Medicines and Complementary Products	Dr. Adam M. Fimbo	Jan 2015 - Sep 2018
	Mr. Akida Khea	Sep 2018 - Feb 2021
	Dr. Yonah H. Mwalwisi	March 2021 – Jan 2022
Human & Veterinary Medicines	Dr. Yonah H. Mwalwisi	Jan 2022 – To date
Medical Devices & Diagnostics	Dr. Kissa W. Mwamwitwa	Jan 2022 – To date

TFDA Directors - 2003

Ms. Margreth Ndomondo - Sigonda
Director General

Dr. Sikubwabo S. Ngendabanka
Director, Business Support

Mr. Octavius M. Soli
Director, Inspection and Surveillance

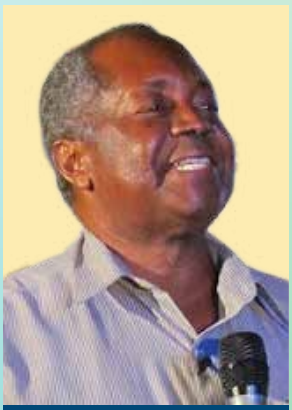


Mr. Legu R. Mhangwa
Director, Product Evaluation and Registration

Mrs. Ollympia Kowero
Director, Laboratory Services

TFDA Directors - 2005

Ms. Margreth Ndomondo - Sigonda
Director General



Mr. Legu R. Mhangwa
Director, Product Evaluation and Registration

Mrs. Ollympia Kowero
Director, Inspection and Survaillance

Dr. Sikubwabo S. Ngendabanka
Director, Business Support

Mrs. Charys N. Ugullum
Director, Laboratory Services

TFDA Directors - 2008

Ms. Margreth Ndomondo - Sigonda
Director General

Dr. Sikubwabo S. Ngendabanka
Director, Business Support

Mrs. Charys N. Ugullum
Director, Laboratory Services

Mr. Hiiti B. Sillo
Director, Medicines and Cosmetics

Mr. Raymond Wigenge
Director, Food Safety

TFDA Directors - 2013

Mr. Hiiti B. Sillo
Director General

Mr. Raymond Wigenge
Director of Food Safety

Ms. Charys N. Ugullum
Director of Laboratory Services

Mr. Adam M. Fimbo
Director of Medicines and Cosmetics

Dr. Sikubwabo S. Ngendabanka
Director of Business Support

TMDA Directors - 2023

Dr. Adam M. Fimbo
Director General

Dr. Danstan H. Shewiyo
Director of Laboratory Services

Dr. Yonah H. Mwalwisi
Director of Human and Veterinary Medicines

Mr. Chrispin M. Severe
Director of Business Support

Dr. Kissa W. Mwamwitwa
Director of Medical Devices and Diagnostics

1.3.3 Managers

Table No. 4: List of TMDA Managers between 2003 and 2023.

Directorate	Unit/Section	Manager's Name	Period
DG's Office	Zone and Local Government Authorities Coordination	Hery Mkunda	2008 - 2015
		Dr. Sikubwako Ngendabanka	2015 - 2017
	ADDO Program Coordinators	Emmanuel Alphonce	2003 - 2006
		Mwemezi Ngemera	2006 - 2007
		Emmanuel Alphonce	2007 - 2008
		Elizabeth Shekalage	2008 - 2009
		Brycesson Kibassa	2009 - 2010
		Elizabeth Shekalage	2010 - 2011
	Public Relation	Gaudensia Simwanza	2006 - 2008
	Communication and Public Relations	Gaudensia Simwanza	2012 - 2017
	Communication and Public Education	Gaudensia Simwanza	2017 – To date
	Quality Management	Hiiti B. Sillo	2005 –2008
		Didas K. Mutabingwa	2008 – 2017
		Sunday Kisoma	2017 –2019
	Quality and Risk Management	Grace M. Shimwela	2019 – To date
	Legal Services	Adv. Iskari Fute	2005 – 2023
	Internal Audit	Cyriacus Katunzi	2007 - 2018
		CPA. Godian Ngamesha	2018 – To date
	Procurement Management	Anaeli Kaale	2021 - 2022
		Ally Nampair	2022 – To date
	Communication and Public Education	Gaudensia Simwanza	2021 – To date
	ICT and Statistics	Ambele Mwafula	2021 – To date
	Finance and Accounts	CPA. Paschal Makoye	2021 – 2022
Inspection and Surveillance	Food Inspection	Raymond Wigenge	2003 - 2008
	Medicines, Cosmetics and Medical Devices Inspection	Erasto Mosha	2003 - 2008
	Premises Registration and Licensing	Agnes Kijo	2009 - 2012
Product Evaluation and Registration	Food Registration	Martin E. Kimanya	2008 - 2012
	Medicines Registration	Dr. Nditonda B. Chukilizo	2008 – 2012
	Cosmetics Evaluation	Akida Khea	2014 - 2018

Laboratory Services	Chemistry	Zera Msuya	2003 - 2007
	Microbiology Analysis	Dr. Henry Irunde	
		Dr. Adelard Mtenga	2003 - 2023
	Pharmacognosy	Moses Nandonde	
	Technical Support and Research	Dr. Danstan H. Shewiyo	2008 - 2018
	Food Analysis	Moses Nandonde	2003 - 2007
		Rajab Mzirai	2008 - 2020
	Medicines and Cosmetics Analysis	Zera Msuya	2003 – 2007
		Dr. Yonah H. Mwalwisi	2008 - 2023
	Medicine Chemical Analysis	Siya A. Assey	2022 – To date
	Medical Devices and IVDs Testing	Catherine M. Luanda	2022 – To date
Food Safety	Food Inspection & Enforcement	Justin Makisi	2008 - 2018
	Food Evaluation & Registration	Gwantwa Samson	2008 - 2018
		Moses Mbambe	2018 - 2019
	Food Risk analysis	Candida Shirima	2008 - 2018
		Gwantwa Samson	2018 - 2019
Business Support	Finance	Sultan Mlandula	2003 – 2005
		CPA Sadi Kajuna	2005 – 2018
		CPA. Pascal Makoye	2018 – 2020
	Administration & Human Resources Management	Pius U. Matagi	2004 - 2017
		Gloria Kaaya	2017 - 2018
		Moses B. Magoma	2018 - To date
	Planning, Monitoring and Evaluation	Octavius Soli	2003 - 2008
		Nobeji Shija	2006 - 2008
		Olympia Kowero	2008 - 2013
		Brycesson Kibassa	2013 - 2015
		Damas Matiko	2016 - 2022
		William Nkondokaya	2022 – To date
	Management Information System	Mtumwa Simba	2004 - 2011
		Fausta Nguzo	2011 - 2013
	Information Communication Technology and Statistics	Ambele Mwafula	2013 – 2021
	Public Education	Henry Irunde	2003 - 2004
		Rehema Shemhina	2004 -2008
	Marketing	Chrispin Severe	2008 - 2013
	Public Education and Customer Care	Chrispin Severe	2013 - 2016
		James Ndege	2016 - 2017
	Procurement Management	Elizabeth Maleto	2003 - 2007
		Anael Kaale	2007 - 2021

Medicines and Cosmetics	Medicines and Cosmetics Inspection & Enforcement	Adonis Bitegeko	2015 – 2019
	Medicines and Cosmetics Evaluation & Registration	Akida Khea	2008 - 2014
	Clinical trials Control and Pharmacovigilance	Adam Fimbo	2008 - 2011
		Dr. Nditonda Chukilizo	2011 - 2014
	Medical Devices Assesment and Enforcement	Agnes Kijo	2012 - 2017
Medicines and Complementary Products	Human and Veterinary Medicines Registration	Akida Khea	2014 - 2018
	Medical Devices & Diagnostics Registration	Agnes Kijo	2017 - 2018
		Sunday Kisoma	2019 - 2022
	Cosmetics & Complementary Medicines Registration	Grace Shimwela	2018 - 2019
		Jeniva J. Kyaruzi	2017 - 2017
	Clinical Trials Control & Pharmacovigilalnce	Kissa Mwamwitwa	2014 - 2021
	Medicines and Complimentary Products Inspection & Enforcement	Adonis Bitegeko	2015 - 2019
		Emmanuel A. Nkiligi	2019 – To date
Human & Veterinary Medicines	Medicines Registration	Felchism Apolnary	2018 - 2023
	Medicines Control Inspection and Enforcement	Emmanuel A. Nkiligi	2019 – To date
	Clinical Trials Control and Pharmacovigilance	Mtani Njegere	2021 - 2022
		Damas Matiko	2022 – To date
Medical Devices & Diagnostics	Medical Devices Assessment	Rehema Mariki	Jan 2021 - June 2023
	Medical Devices Premises Licensing and Compliance	Brycesson Kibassa	
	Vigilance and Post Marketing Surveillance	Mary Masanja	

CHAPTER - 2

Regulation of Food and Cosmetics

2.1 Introduction

This chapter explores the regulation of food and cosmetics under the former Tanzania Food and Drugs Authority (TFDA), highlighting the legal frameworks, enforcement strategies, and measures implemented to ensure the safety and quality of these products.

Food is anything eaten or drunk by humans as food except drugs, tobacco and cosmetics. Food control is carried out in order to ensure that quality and safe food reaches the consumers. TFDA put in place food control systems in the country as detailed in this chapter.

2.2 Regulation of Food Products

2.2.1 Registration of Food

Section 28 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap. 219 prohibits any person from manufacturing, importing,

distributing and selling pre–packaged food in the country before being registered by the Authority. Food products that are required to be registered are those processed and pre–packaged in containers, tins or bottles ready for sale directly to consumers or to be used as an ingredient for food preparation.

Food products that are not pre-packaged such as fruits, beans, cereals and groundnuts are non registrable instead they are controlled through different procedure that involves inspection, collection of samples for laboratory analysis and assessment of health risks that may arise as a result of food consumption.

Food is classified into various types as outlined in Table No.5

Table No. 5: Food classification

S/N	Food category
1.	Meat and Meat Products
2.	Fish and Fish Products
3.	Cereals and Cereals Products
4.	Fruits, Vegetables and their Products
5.	Milk and Milk Products
6.	Eggs and Eggs Products
7.	Tea, Coffee and Cocoa
8.	Food Supplements
9.	Confectionery/Baked Products
10.	Oils
11.	Drinking water
12.	Sugar and Honey
13.	Salt and Spices
14.	Soft Drinks and Beverages
15.	Infant Food formula and Weaning foods

The procedure for food registration included the following;

i. Evaluation of scientific information on safety and quality of food ingredients, and additives used;

ii. Packaging materials;

iii. Laboratory food analysis;

iv. Evaluation of information on food labels; and

Inspection of manufacturing systems at the premises where food was being processed in accordance with Good Processing Practices such as; GMP, GHP, HACCP.

From the year 2003 when TFDA was established to June 2019 the Authority managed to register 18,544 foods. Table No.6 shows breakdown of food registered between July 2003 and June 2019. It should also be noted that there was an increase in the number of applications for the registration of food products over the years. From July 2019 the responsibility for control of food was transferred to Tanzania Bureau of Standards (TBS).

Table No.6: Food Registration (2013-June 2019)

Year	Received Applications	Evaluated Applications	Registered Foods	Rejected Applications
2013/14	3,157	2,320	1,650	0
2014/15	3,524	3,029	2,627	0
2015/16	3.066	2,682	1,792	384
2016/17	3,174	3,053	1,577	167
2017/18	2,462	2,329	2,104	84
2018/19	3,286	3,353	2,876	140
Total	**30,358**	**28,023**	**18,544**	**2,440**

It should be noted that food registration system significantly improved. Moreover, it can be seen from the graph that, a number of registered foods was increasing on an annual basis. The food registration system helped TFDA to improve the quality and safety of food sold in the Tanzanian market. It also helped to improve food manufacturing systems in the country.

2.2.2 Premises Registration

Sections 18 and 20 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap. 219 prohibited anyone to manufacture, store, distribute and sell food in premises that were not registered by TFDA. Premises registered by TFDA included; food manufacturing, warehouses, butchery shops, hotels, restaurants, wholesale and retail shops, food carrying vehicles and slaughter houses.

The registration of food premises included the following procedures;

i. Receiving applications for premises registration;

ii. Evaluating received applications;

iii. Conducting inspection of respective premises and

iv. Registering premises.

Until 2013 TFDA had registered 7,373 food premises and the number was been increasing over years.

The system of premises registration assisted TFDA in identifying premises that were used for food processing, storage, distribution and sale. The system helped TFDA in ensuring that all food premises complied with prescribed standards in accordance with the then applicable laws, regulations and procedures.

2.2.3 Food Inspection

Sections 5(1) (h) and 106 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap. 219 empowered TFDA to inspect all premises that were involved in food businesses. Premises inspected included; manufacturing premises, wholesale and retail shops, hotels, restaurants, slaughter houses, food carrying vehicles and markets.

Inspection activities were carried out any time to evaluate the condition of the premises, production systems, environment, distribution, storage, sale and food quality of the food. Inspectors were appointed by the Director General and gazetted in the Government Gazette as per Section 105 of Tanzania Food, Drugs and Cosmetics Act 2003; Cap 219.

TFDA strengthened inspection functions by increasing the number of inspectors and number of operations. These steps greatly improved the control of quality and safety of food products in the country.

2.2.4 Control of Food at Ports of Entry

Sections 36 and 38 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap. 219 empowered TFDA to control imports and to register food importers in the country. Moreover, section 5(1)(l) provided for the control of food exports.

TFDA developed and implemented import and export control systems for food products at ports of entry (PoE). There were 32 official PoE where food inspections were carried out as shown in Table No. 7

Table No. 7: Official Port of Entry Recognized by TFDA

No.	Name of Ports of Entry		
1.	Namanga	17.	Dar es Salaam Airport
2.	Sirari	18.	Kilimanjaro Airport
3.	Tunduma	19.	Kipili Port
4.	Holili	20.	Lindi Port
5.	Horohoro	21.	Mtwara Port
6.	Tarakea	22.	Mbamba Bay Port
7.	Rusumo	23.	Mwanza Port
8.	Mutukula / Kyaka	24.	Musoma Port
9.	Isaka	25.	Bagamoyo Port
10.	Kabanga	26.	Bukoba Port
11.	Kasumulu	27.	Dar es Salaam Port
12.	Mabamba	28.	Tanga Port
13.	Manyovu	29.	Itungi Port
14.	Mafia	30.	Kasesya Port
15.	Mwanza Airport	31.	Kemondo Port
16.	Kigoma Airport	32.	Kigoma Port

The procedure for issuing food import and export permit involved the following steps;

i. Receiving applications for registration of importers and food to be imported/ Exported;

ii. Evaluating applications;

iii. Carrying out laboratory analysis of respective food samples; and

iv. Issuing Import Permits or Health Certificates for exports where desired.

A total of 54,767 import permits were issued between July, 2013 and June, 2019. At the same time 10,874 export permits were issued. Breakdown of the issued permits is shown in Table No. 8

Table No. 8: Import and Export Permits (July 2013 – June 2019).

Year	Food Imports Applications		Food Exports Applications	
	Approved	Not Approved	Approved	Not Approved
2012/13	1824	177	592	0
2013/14	4,690	318	156	415
2014/15	5,328	490	1,533	6
2015/16	1,402	12	500	0
2016/17	6,600	29	1,744	12
2017/18	8,375	3	2,324	6
2018/19	8,447	86	2,502	22
Total	**54,767**	**2,259**	**10,874**	**482**

2.2.5 Control of Food Advertisements

Sections 95 -98 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap. 219 prohibit any person to advertise food business without a permit granted by TFDA. The adverts include; photographs, films, bill boards, posters, leaflets, various publications, radio and TV advertisements.

The objective of instituting controls over advertisements was to protect the public from misleading information about the regulated products. Dealers were required to submit applications to TFDA for evaluation of promotional materials before a permit could be granted. Advertisements authorized for public consumption were only those approved and issued with a TFDA permit. The validity of which were aligned with the food circulation permit.

From year 2003 to June 2019, TFDA issued 180 permits for food adverts. During the same period; control of advertisements was strengthened whereby a number of approved adverts increased and misleading ones were removed from the market.

2.2.6 Post Marketing Surveillance

TFDA established Post Marketing Surveillance System (PMS) for monitoring food safety and quality in the market. The system included; taking of food samples in the market, conducting laboratory analysis, evaluation of laboratory test results and taking legal action. The remedial actions taken included; removal of unfit food from the market, issuance of warnings letters to food processors and distributors as well as educating them on the best ways to process, store and distribute foods.

The PMS in food products started in 2006/07. From that time upto June 2019, a total of 739 food samples were collected from the market and sent to the laboratory for analysis. The number of samples and types of food collected from the market and their respective test results were as shown in Table No. 9.

Table No. 9: Food Post Marketing Surveillance (2006/07 - 202012/13)

Year	Food type	Number of samples			
		Collected	Tested	Passed	Failed
2006/07	Mixed	157	117	88	29
2007/08		146	129	78	51
2008/09	-	-	-	-	-
2009/10	-	-	-	-	-
2010/11	-	-	-	-	-
2011/12	Water	98	98	96	2
	Cooking oil	30	30	28	2
2012/13	Beef	31	31		
	Fish	74	74		
	Eggs	72	72		
	Milk	83	83		
	Poultry meat	48	48		

Majority of the food samples taken from the market passed laboratory tests. Based on test results, various steps were taken by TFDA including; removal of products whose samples failed the tests and educating food processors especially small scale entrepreneurs on the importance of ensuring that their products comply with acceptable safety and quality standards.

Generally, PMS enabled TFDA to assess the state of food safety and quality in the market and identify risks that would have compromised the health of consumers. Likewise, the system also enabled TFDA to ensure that foods on the market continued to maintain safety and quality standards. Strategies were developed to ensure that substandard food products were removed from the Tanzanian market thereby protecting consumers from potential risks associated with their use.

2.2.7 Risk Assessment and Food Borne Disease Surveillance

TFDA put in place a system that monitored and analyzed potential risks that could arise from consumption of unfit food. The system was developed to enable TFDA identify potential health hazards to human beings that arise by consuming food contaminated with microorganisms, natural toxins, antimicrobials and pesticide residues and heavy metals.

The system involved the following steps;

- Distributing forms that were used to provide feedback on food borne diseases;

- Receiving reports on hazards associated with unsafe food;
- Evaluating received reports;
- Taking steps that included; prohibition of consumption of such foods and dissemination of information and education to the public.
- Reports on various health hazards that are associated with food consumption were received, evaluated and alert notice issued at different times between July, 2003 and June, 2019.

Reported health hazards included; diarrhoea, vomiting, typhoid, dysentery and allergy. TFDA also received death reports caused by consumption of contaminated and unsafe food.

2.2.8 Disposal of Food products unfit for human consumption

Section 6(c), 34, 35 and 99 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap. 219 empowered TFDA to prohibit and destroy food products not fit for human consumption. The system for disposal of condemned food was established and involved the following steps;

- Receiving requests for disposal of food;
- Inspecting the quantity and type of food to be disposed;
- Conducting valuation of the food consignment to be disposed;
- Disposing condemned food at the expense of the owner;
- Issuing disposal certificate.

Disposal of solid wastes took place at dump sites owned by City, Municipal, and Town or District councils. The disposal exercise involved an inspector from TFDA, representatives from the National Environment Management Council (NEMC), Police Force and the hosting Council.

Between July 2003 and June 2019, TFDA managed to oversee the disposal of condemned food stuffs worth TZS. 20.1 billion as shown in Table No.10;

Table No. 10: Disposal of Sub-Standard and Counterfeit food products

Year	Value of Disposed Goods
July 2003 – June 2008	2,384,542,386
July 2008 – June 2009	1,265,846,620
July 2009 – June 2010	2,718,429,788
July 2010 – June 2011	2,197,488,982
July 2011 – June 2012	1,353,186,185
July 2012 – June 2013	1,958,400,300
July 2013-June 2014	148,798,941
July 2014-June 2015	909,299,003
July 2015-June 2016	2,298,861,849.70
July 2016-June 2017	321,241,916.90
July 2017- June 2018	1,597,135,635
Total	**20,151,014,477.6**

20.1 Billion
worth of food stuffs disposed between July 2003 and June 2019

Disposal methods for food unfit for human consumption depend on the type of condemned food. The disposal of unfit food product helped preventing the same from reaching consumers. The inclusion of NEMC official in the team enabled TFDA to get proper advices on disposal without polluting the environment.

2.2.9 Harmonizing Food Control Systems

TFDA participated in discussions on harmonization of food control systems within the East African Community (EAC) and the Southern African Developing Countries (SADC). The systems aimed at harmonizing procedures for registration, transportation across borders and sale of food among member countries. Among issues that have been harmonized include; Sanitary and Phytosanitary Protocol, EAC - Food Standards Law and some food standards.

2.2.10 Setting of Food Standards

TFDA participated in setting various standards of food quality and safety. TFDA experts participated in different technical committees for setting national and international standards such as Tanzania Standards, EAC Standards and Codex Standards.

2.2.11 Researches

Since its establishment till 2019,the then TFDA conducted various researches on food safety and quality including;

i. Pesticide residues in food (2003 – 2006);

ii. Identification and assessment of food processing industries in the country (2005 - 2006);

iii. Evaluation of extent of poisonous fungus (aflatoxin) in the grains and children's food;

iv. Effects of poisonous fungus on human being 2011.

v. Post-harvest reduction of poisonous fungus in grains (2012 – 2019);

vi. Assessment of pesticide residues in tomatoes (2012).

These researches assisted TFDA in setting up food standards and making decisions on the quality and safety of food. The researches also contributed greatly in broadening TFDA staff knowledge on food science and technology.

2.2.12 Regulations for Food Control

On the part of food safety control, until 2018 before the transfer of the regulation of food and cosmetics to TBS, TFDA had published 16 enabling regulations for the control of food and one (1) regulation for control of cosmetics. See Table No. 11

Table No. 11: List of 16 regulations for food control

No.	Name of the Regulation
1	The Food (Control of Quality) (Slaughter Houses, Slaughtering and inspection of Meat) Regulations, 1993 were applicable under cap 219
2	The Food (Control of Quality) (Edible Palm Oils and Fats) Regulations, 1998 were applicable under cap 219
3	The Food (Control of Quality) (Food Additives) Regulations, 1998 were applicable under cap 219
4	The Tanzania Food, Drugs and Cosmetics (Transport of Meat) Regulations 2006(GN No 112 of 2006)- revoked and replaced the use of The Food (control of Quality) (Transport of Meat) Regulations of 1994.
5	The Tanzania Food, Drugs and Cosmetics (Importation and Exportation) Regualtions 2006 (GN No 113 of 2006) - revoked and replaced the use of Food (control of Quality) (Imporatation) Regulations of 1982
7	The Tanzania Food, Drugs and Cosmetics (Food Hygene) Regulations 2006 (GN No 114 of 2006) -revoked and replaced The Food (control of Quality) (Food Hygene) Regulations of 1982
8	The Tanzania Food, Drugs and Cosmetics (Food Labelling) Regulations 2006(GN No 115 of 2006-revoked and replaced The Food (control of Quality) (Food Labelling) Regulations of 1989
9	The Tanzania Food, Drugs and Cosmetics (Treatment and disposal of Unfit Food) Regulations 2006(GN No 116 of 2006)- revoked and replaced The Food (control of Quality) (Treatment and disposal of Unfit Food) Regulations of 1994
10	The Tanzania Food, Drugs and Cosmetics (Iodated Salt) Regulations, 2010
11	Tanzania Food, Drugs and Cosmetics (Control of Food Promotion) Regulation 2010
12	The Food (Control of Quality) (Transport of Meat) Regulations 2010
13	Tanzania Food, Drugs and Cosmetics (Marketing of Breast- Milk Substitutes and Designated Products) Regulations, 2011
14	Tanzania Food, Drugs and Cosmetics (Food Registration) Regulation 2011
15	Tanzania Food, Drugs and Cosmetics (Food Fortification) Regulation 2011
16	Tanzania Food, Drugs and Cosmetics (Premise Registration) Regulation 2011

2.2.13 Preparation of Guidelines

In order to improve the Authority's performance; transparency in service delivery procedures and various guidelines were developed. Some of the prepared guidelines were;

i. Food Registration Guidelines 2004 (Reviewed 2006, 2009 and 2011);

ii. Food Premises Registration Guidelines 2011;

iii. Food Import and Export Guidelines 2011;

iv. Food Risk Assessment and Control of Food Hazards Guidelines 2011;

v. Food Fortification Guidelines 2011; and

vi. Good Manufacturing Practice (GMP) Inspection Guidelines 2013

2.3 Regulation of Cosmetics

Cosmetics is anything that can be applied on the skin or any part of the human body by smearing, washing or spraying for the purpose of cleaning, beautification, decoration, skin enlightenment or change in appearance. Cosmetics are not supposed to be used in diagnosis of diseases, treatment or preventing diseases and when applied they are not supposed to impair the normal functions of the skin or body.

Cosmetics are manufactured in different forms such as; lotions, creams, perfumes (liquid and spray), nail polish, hair removal, powder, bathing soap, artificial hair products, etc.

> **“Harmful cosmetics ingredients were prohibited for use under Section 87 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap. 219.”**

They are also manufactured using different ingredients. Some ingredients used in manufacturing cosmetics are safe and others are not safe to users. Therefore, TFDA's had the responsibility to prohibit use of cosmetics manufactured with harmful ingredients. Prohibited ingredients are listed in Table No. 12.

Table No. 12: Prohibited Cosmetics Ingredients that are Poisonous and Harmful

S/N	Compound
1.	Mercury
2.	Chlorofluorocarbons
3.	Steroids
4.	Hydroquinone
5.	Bithionol
6.	Hexachlorophene
7.	Vinyl Chloride
8.	Zirconium
9.	Chloroform Propellants
10	Methyl Chloride
11.	Halogenated Salicylanilides

Harmful cosmetics ingredients were prohibited for use under Section 87 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap. 219.

2.3.1 Health Risks of Harmful Ingredients

Harmful ingredients used in manufacturing of cosmetics, may lead to various health risks to the users. Among health effects resulting from use of harmful cosmetics include;

i. Skin allergy;

ii. Skin diseases and skin irritation when exposed to the sun;

iii. Skin becomes softer and prone to infections such as fungus and bacterial diseases;

iv. Harmful effects to babies in the mother's womb when expectant mothers use cosmetics that have mercury;

v. Skin and lung cancer due to the use of cosmetics with Vinyl Chloride and Zirconium;

vi. Skin irritation and pigment orientations that cause dark and light spots on the skin due to the use of Hydroquinone; and

vii. Economic burden due to financial implications associated with treatment costs and loss of workforce when the user gets reactions from the harmful cosmetics.

2.3.2 Illicit Cosmetic Concoctions (Mikorogo)

Due to the fact that prices of modern cosmetics are very high, some people have opted to make their own concoctions of local or homemade cosmetics. Some of these local cosmetics especially those made from plants generally regarded as, are safe as they have no health risks to the users. However, other local cosmetics concocted by mixing unsafe substances are harmful to human beings. These illicit cosmetics concoctions popularly known as "Mikorogo" are available in different names as shown in Table No. 13.

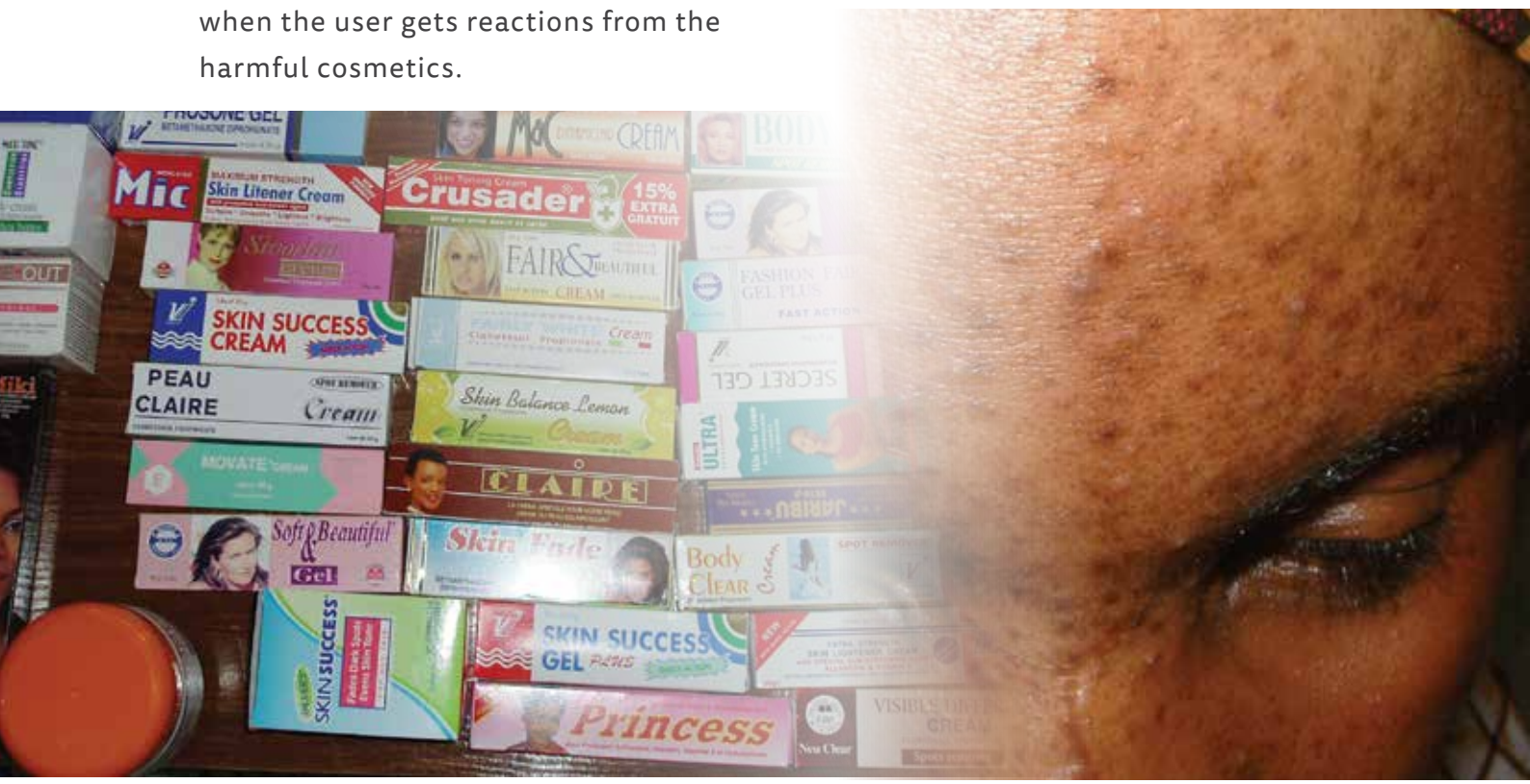


Table No. 13: Various Types of illicit Cosmetic concoctions

No.	Local Cosmetics Name	Mixing Formulae and Its Preparations	Usage / Application
1.	Mkorogo Special	Boil Jaribu Soap then add Jaribu Cream + tube of Colgate (Toothpaste) + (Bleach) JIK + Any type of lotion (Mix Vigorously)	Apply twice per day
2.	ITV Special	Add Hamira Lotion + Hamira Cream (Boil for a long time)	Apply twice per day
3.	Saloon Special	Add any steroid cream (especially Dermotave) + Any lotion + Water + Hydrogen Peroxide	Apply at any convenient time
4.	Mkorogo	Add Demortave + Revlon + (Bleach)JIK + (Washing Powder) OMO detergents	Apply twice per day
5.	Mambo yote	Add Grounded soap in a bath + (Bleach) JIK + White cement (Mix for a reasonable time)	Take a bath in the tub for several minutes
6.	N/A	Add Cocoa butter + Boiled RICO soap + White Rose cream + Jaribu cream	Apply at any time convenient
7.	N/A	Add Movate cream + Dermotave cream + Mekako soap	Apply at any time Convenient

2.3.3 Misuse of Medicines as Cosmetics

Among the prohibited ingredients used in cosmetics is steroid which basically is a medicine. Examples of such medicines with steroids as ingredients include; 'Clobetasol' and 'Betamethasone' which are traded as Movate, Betacort -N, Diproson, Gentrisone, etc. These products are dispensed as ''prescription only medicines" and are only applied to the patient's skin subject to a doctor's prescription and dispensed by a pharmacist. They are not allowed to be used as cosmetics despite of misuse by some people due to skin bleaching effects.

Other substances that have been prohibited for use as cosmetics are those claimed for hip, penis and breast enlargement. These substances are believed to have harmful effects that may trigger cancer or other adverse health effects to users.

Due to health and economic risks associated with the use of unsafe cosmetics, TFDA instituted control systems in order to ensure that cosmetics that were available in the country were of good quality and safe to the users.

This ensured that cosmetics circulating in the Tanzanian market contained no prohibited ingredients that could be harmful to users, some of them are shown in Table No. 14.

Table No. 14: Prohibited ingredients in Cosmetics

S/N	Ingredient
1	Mercury
2	Chlorofluorocarbons
3	Steroids
4	Hydroquinone
5	Bithionol
6	Hexachlorophene
7	Vinyl Chloride
8	Zirconium
9	Chloroform Propellants
10	Methyl Chloride
11	Halogenated Salicylanilides

The control systems of cosmetics that were in place included; registration of cosmetics, import and export control, inspection and surveillance, and issuance of business permits as indicated hereunder.

2.3.4 Registration of Cosmetics

Sections 86 -90 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap 219 prohibits anyone from selling and distributing cosmetics that are not registered by TFDA and which could be harmful to users. The law requires that all those engaged in the distribution and selling of cosmetics in the country to register their cosmetic products.

The process for registration of cosmetics includes;

i. Receiving and evaluating information on the ingredients contained in the cosmetics;

12,374

Total registered cosmetics from year 2013/14 to year 2018/19

ii. Conducting laboratory analysis of cosmetic samples, and

iii. Evaluating product information including labels

Before the registration procedure was introduced, a system for notification of cosmetics was put in place between July 2003 and February 2008. Until June 2019, TFDA had notified and registered a total of 12,374 cosmetics as highlighted in Table No. 15.

Table No. 15: Notified and Registered Cosmetics by TFDA (2013-2019)

Year	Received Applications	Evaluated Applications	Approved Cosmetics
2013/14	839	745	617
2014/15	1,453	1,063	865
2015/16	1,704	1,488	2,213
2016/17	1,523	1,410	1,413
2017/18	1,862	1,862	1,136
2018/19	2,196	2,196	2,162
Total	**17,080**	**15,540**	**12,374**

The system for registration of cosmetics significantly improved and the number of cosmetics registered had increased. The system has assisted TFDA to bolster its performance in terms of ensuring that cosmetics that are in the Tanzanian market are safe and of good quality and those with prohibited ingredients do not penetrate the market.

2.3.5 Registration of Premises

Sections 86 -90 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap 219 prohibits anyone from manufacturing, storing, distributing and selling cosmetics in premises not registered by TFDA. Registered premises include manufacturing facilities, warehouses, wholesale and retail cosmetic outlets.

Procedures for premises registration involve the following steps;

i. Receiving applications;

ii. Verifying the received applications;

iii. Inspecting premises;

iv. Issuing registration certificates; and

v. Issuing business permits.

Up to 2019, TMDA registered a total number of 1,223 premises that are involved in cosmetics business. These premises include; 7 manufacturing facilities, 3 warehouses and 1,213 wholesale and retail cosmetics shops.

2.3.6 Inspection of cosmetics

Section 5 (1) (h) of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap 219 provide for TFDA to inspect all premises that are used for cosmetics business. Premises inspected include manufacturing facilities, warehouses, wholesale and retail shops and vehicle/vessels that are used to transport cosmetics.

Between July 2003 and June 2019, TFDA inspected 4,164 business premises as shown in Table No. 16.

Table No. 16: Inspected Cosmetics Business Premises (2003-2013)

Type of premises	**Financial Year**						**Total**
	2003/04	2008	2009	2010	2011	2012	
	-	-	-	-	-	-	
	2007/08	2009	2010	2011	2012	2013	
Wholesale and Retail Shops	706	142	905	1,049	871	475	4,148
Manufacturers and Warehouses	3	2	3	3	3	2	16
Total	**709**	**144**	**908**	**1,052**	**874**	**477**	**4,164**

Regulatory actions were taken against violators of cosmetics regulations which included issuing warning letters, prohibiting their products from reaching the market, denying business permits, closing down of their businesses, educating and or instituting legal actions.

2.3.7 Import and export control of cosmetics

Section 86 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap 219 mandated TFDA to control importation of cosmetics into the country whereas, Section 5(1) (l) specified the requirements for export control of cosmetics.

TFDA put in place systems for control of importation and exportation of cosmetics in the country. The procedures for importation and exportation of cosmetics involved the following steps;

i. Receiving application for registration of the imported and specifying details of intended cosmetics to be dealt with;

ii. Reviewing the applications, and

iii. Issuing import or export permits.

From 2003 to 2019, TFDA managed to issue 914 import permits and 155 export permits for cosmetics. The import and export control system for cosmetics has been strengthened over the years, especially after implementing the requirement for all cosmetics to be registered before market authorization came into force. The system assisted the Authority to prevent the importation of harmful cosmetics into the country and thereby protecting the general public health.

2.3.8 Disposal of cosmetics

Sections 6 (c), 34, 35, and 99 of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 gave mandate to TFDA to confiscate and dispose all products including cosmetics with prohibited ingredients. The disposal procedure were set up and involved the following steps:

i. Receiving applications for disposal of cosmetics;

ii. Conducting inspection of the quantity and type of cosmetics to be disposed off;

iii. Estimating the value of cosmetics to be disposed off;

iv. Disposing cosmetics at the expense of the applicant; and

v. Issuing Disposal Certificates.

The actual disposal process took place at the sites registered by the government. The process involved Inspectors from TFDA and representatives from NEMC, Police force and respective Councils.

2.3.9 Regulations and Guidelines

In order to improve the Authority's efficiency and transparency specific regulations for control of cosmetics were developed in 2010 as required by the Tanzania Food, Drugs and Cosmetics Act, Cap 219. They included guidelines for Registration of Cosmetics. In July 2019, the control of Cosmetics was moved to TBS.

Section 86 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap 219 mandated TFDA to control importation of cosmetics into the country

Section 5(1) (l) specified the requirements for export control of cosmetics

Sections 6 (c), 34, 35, and 99 of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 gave mandate to TFDA to confiscate and dispose all products including cosmetics with prohibited ingredients.

914
import permits for cosmetics issued by TFDA between 2003 to 2019

155
export permits for cosmetics issued by TFDA between 2003 to 2019

CHAPTER - 3

Regulation of Medicines

3.1 Introduction

This chapter covers the regulation of medicinal products from July 2003 to June 2023. During this period, the responsible directorate's name changed in accordance with approved organizational structures to enhance regulatory oversight. A list of the directors who led these directorates is provided in Table No. 17 below.

> **"TMDA has become a regional leader in product registration and marketing authorization."**

Table No. 17: Directors of Medicines Regulation Directorates between 2003 to 2023

Directorate	Director's Name	Period
Product Evaluation and Registration	Mr. Legu R. Mhangwa	Jul 2003 - Feb 2008
Medicines & Cosmetics	(1) Mr. Hiiti B. Sillo	March 2008 - April 2010
	(2) Dr. Adam M. Fimbo	May 2010-Dec 2014
Medicines & Complementary Products	(2) Dr. Adam M. Fimbo	Jan 2015 - Sep 2018
	(2) Mr. Akida Khea	Sep 2018 - Feb 2021
	(3) Dr. Yonah H. Mwalwisi	March 2021 - Jan 2022
Human & Veterinary Medicines	Dr. Yonah H. Mwalwisi	Jan 2022 - To date
Medical Devices & Diagnostics	Dr. Kissa W. Mwamwitwa	Jan 2022 - To date

The Tanzania Medicines and Medical Devices Act, Cap. 219, defines a medicine as any substance or mixture of substances intended for:

a. Diagnosis, treatment, or prevention of disease in humans or animals;

b. Restoring, correcting, or modifying body or mental functions;

c. Disinfection of premises or equipment used for medical or veterinary purposes.

Medicines are classified into human, veterinary, herbal, traditional, vaccines, biologicals, antiseptics, and disinfectants. TMDA's mandate is to ensure that these products are safe, efficacious, and of acceptable quality before and after entering the market.

3.2 Registration and Marketing Authorization of Medicines

The section responsible for the registration and licensing of premises that handle medicinal products has been led by various managers between 2003 and 2023. Their names and respective tenures are provided in Table No. 18 below.

Table No. 18: Medicines Registration Section Managers between 2003 to 2023

Section	Manager's Name	Period
Medicines Registration Section	Dr. Nditonda Chukilizo	Jul 2003 – Feb 2012
Evaluation & Registration of Medicines and Cosmetics	Mr. Akida Khea	March 2012 – Oct 2018
Medicines Registration Section	Apolinary Felchism	Oct 2018 – To date

Marketing Authorization (MA) is the official government approval for a medicinal product to be marketed in Tanzania. Before approval, every product undergoes a rigorous pre-marketing assessment of its safety, quality, and efficacy, supported by scientific data in a Common Technical Document (CTD).

A total of 9,037 medicinal products were registered, of which 7,741 remain valid today, as highlighted in Table 20 below. Registered products include 6,765 human pharmaceuticals and biologicals, 634 veterinary medicines, 48 herbal products, and 294 biocidal products.

Introduction of the Regulatory Information Management System (RIMS 2.0) in 2016 streamlined applications, reducing timelines from 240 to 180 days for imports and from 120 to 60 days for local products.

Priority medicines now receive accelerated approval in 90 days. Development of over 44 regulatory documents (19 standard operating procedures, 19 guidelines, and six (6) regulations) strengthened transparency and compliance with the Tanzania Medicines and Medical Devices Act, Cap. 219. TMDA has become a regional leader in product registration and marketing authorization, supporting other African National Regulatory Authorities (NRAs) to attain WHO Maturity Level 3. This included Namibia, Rwanda, Burundi, South Sudan, Mozambique, Botswana, Zambia, Uganda and Ethiopia.

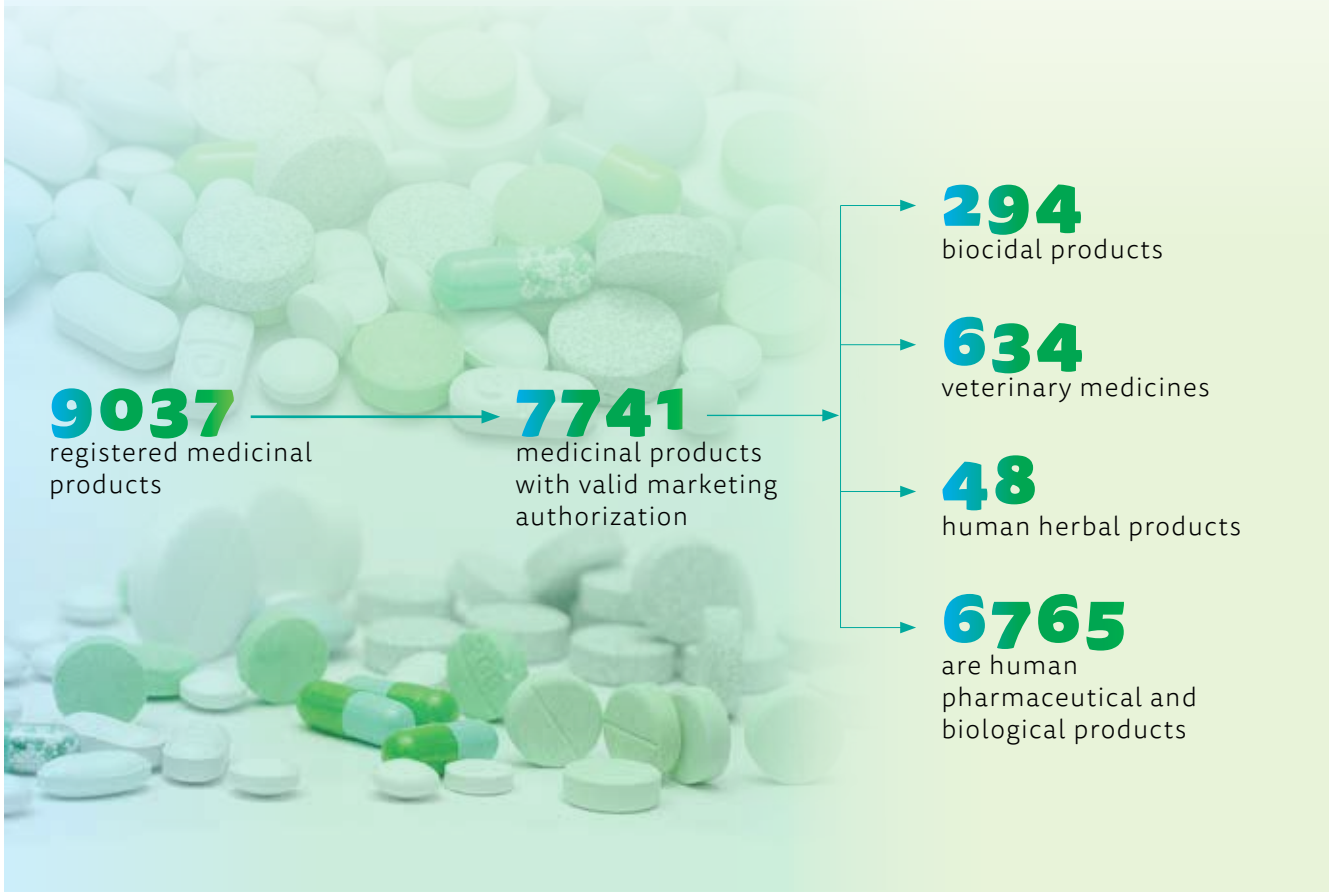


Table No. 19: The number of medicinal and biocidal products granted marketing authorisation for the period between July 2003 and June 2023

Year	Received	Evaluated	Registered
2003/04 - 2012/13	10,271	9,548	4,782
2013/2014	510	450	300
2014/2015	671	600	439
2015/2016	921	844	426
2016/2017	685	641	303
2017/2018	726	654	316
2018/2019	817	719	336
2019/2020	715	704	531
2020/2021	845	788	551
2021/2022	1,193	1,037	462
2022/2023	1,151	1,054	591
Total	**18,505**	**17,039**	**9,037**

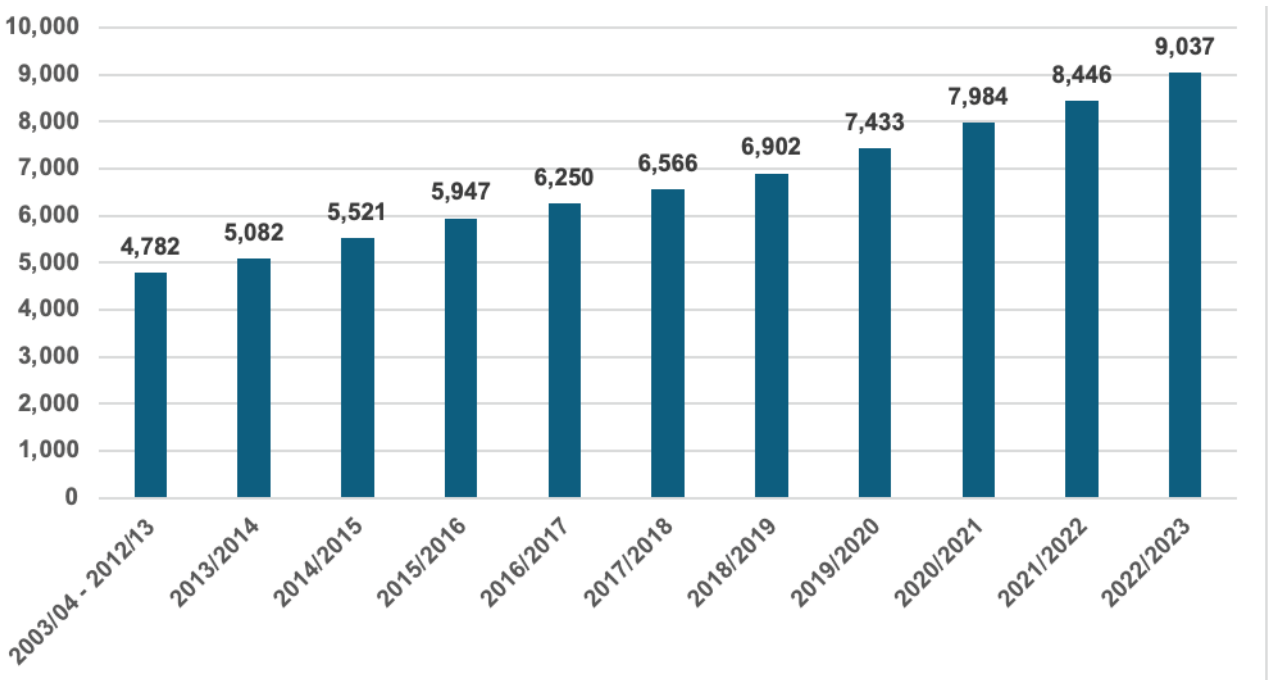


Figure 1: Number of medicinal products registered for the period between July 2003 - June 2023

3.3 Registration and Licensing of Premises

The section responsible for the registration and licensing of premises that handle medicinal products has been led by various managers between 2003 and 2023. Their names and respective tenures as indicated in Table No. 20 below.

Table No. 20: Medicines premises Registration and Licensing Section Managers between 2003 to 2023

Section	Manager's Name	
Premises Registration & Licensing Section	Mr. Emmanuel A. Nkiligi	Jul 2003 – July 2008
Medicines & Cosmetics Inspection and Enforcement Section	(1) Mr. Emmanuel A. Nkiligi	July 2008 – Dec 2012
	(2) Mr. Adonis A. Bitegeko	Dec 2012 – March 2019
Medicines Inspection & Enforcement Section	Mr. Emmanuel A. Nkiligi	April 2019 – To date

For the period between its inception in 2003 to 2013, TMDA (formally TFDA) was responsible for registration and licensing of all pharmaceutical premises, including manufacturers, warehouses, wholesale, and retail pharmacies.

However, after the enactment of the Pharmacy Act, Cap 311, in 2013 the regulation of retail and wholesale pharmacies was transferred to the Pharmacy Council, while TMDA retained responsibility of regulating manufacturering, import and export of pharmaceuticals

The registration and licensing premises is intended to ensure that premises dealing in pharmaceutical products comply with the Good Manufacturing, Storage, and Distribution Practices requirements.

From 2003/04 to 2012/13, 17013 premises were registered, and from 2013/14 to 2022/23 a total of 4428 premises were registered as shown in Table No. 21 below.

Table No. 21: Number of pharmaceutical premises registered and licensed between 2003/04 to 2022/23

Financial Year	Manufacturing Facilities	Pharmacy	Warehouses	Part II Poison Shops	ADDOs	Total
2003/04 – 2012/13	367	2,397	105	3,872*	10,332	17,073
2013/14	8	96	18	-	67	189
2014/15	7	138	38	-	114	297
2015/16	2	116	72	-	326	516
2016/17	5	108	40	-	317	470
2017/18	7	201	142	-	417	767
2018/19	16	351	32	-	218	617
2019/20	2	275	31	-	95	403
2020/21	0	194	39	-	2	235
2021/22	17	258	117	-	0	392
2022/23	0	503	39	-	0	542
Total	**431**	**4,637**	**673**	**3,872**	**11,888**	**21,501**

3.4 Control of Promotional Materials and Activities

To safeguard the public from misleading claims, TMDA regulates advertisements and promotional materials in line with Section 96 (1) of the Tanzania Medicines and Medical Devices Act, Cap 219 and the Medicines and Medical Devices (Control of Promotion) Regulations, 2010.

According to Section 97 of Act, Advertisements include every form of advertising, whether in a publication, or by the display of any notice or by means of any catalogue, price list, letter, whether circular or addressed to a particular person, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting, or television or any other means of communication.

Applications for approval of promotional materials are received and reviewed through RIMS. Approved promotions are closely monitored via Media and online surveillance, inspections at trade shows and conferences, and periodic audits of online sales platforms. This ensures that only truthful, evidence-based promotional materials reach the public.

A total of 3,909 applications for the approval of promotional materials were received and approved as provided under Table No. 22 below.

Table No. 22: Number of promotional materials received and processed between 2003 – 2023/24

Year	Received	Evaluated	Approved	Rejected
2003/04 - 2007/08	387	386	345	41
2007/08	92	86	86	0
2009/10	196	190	175	15
2010/11	116	91	79	12
2011/12	100	118	118	0
2012/13	62	56	56	6
2015/16	195	193	179	10
2016/17	249	246	191	52
2017/18	194	174	143	12
2018/19	493	448	285	4
2019/20	336	334	325	0
2020/21	393	376	378	0
2021/22	508	504	454	54
2022/23	588	559	464	0
Total	**3,909**	**3,761**	**3,278**	**206**

3.5 Medicines inspection

Pursuant to Section 5(1) (l) and 106 of the Tanzania Medicines and Medical Devices Act, Cap 219 TMDA is mandated to inspect all premises involved in the medicine supply chain from manufacturers and importers to pharmacies, hospitals, veterinary outlets, transporters, as well as open markets and trade fairs.

Pharmaceutical manufacturing facilities are inspected to ensure compliance with the TMDA Good Manufacturing Practices (GMP) requirements as prescribed in GMP Guidelines. From July 2003 to June 2023 a total of 1,149 foreign and local manufacturing sites were inspected as shown in Table No. 23.

Table No. 23: Number of domestic and foreign manufacturing facilities inspected between July 2003 to June 2023

Financial Year	Number of facilities inspected
July 2003 – June 2012/13	367
July 2013 - June 2014	72
July 2014 – June 2015	61
July 2015 - June 2016	68
July 2016 - June 2017	116
July 2017 - June 2018	103
July 2018 - June 2019	119
July 2019 - June 2020	74
July 2020 - June 2021	0
July 2021 - June 2022	53
July 2022 - June 2023	116
Total	**1,149**

Similarly, pharmaceutical distribution premises were inspected to ascertain whether medicines circulating in the markets were registered and stored in compliance with the requirements prescribed in Good Storage and Distribution Practices (GSDP) Guidelines. In the same period, a total of 21,500 premises were inspected.

Inspection is carried out by inspectors who are appointed by the Director General and gazetted in the Government Gazette as per mandate provided by section 105 of the Tanzania Medicines and Medical Devices Act 2003; Cap 219.

3.6 Import and Export Control

In line with Section 73 of the Tanzania Medicines and Medical Devices, Cap 219, TMDA allows importation and exportation of the regulated health products through 16 official ports of entry shown in Table 24. Products are cleared for importation or export only if they comply with legal requirements for import or export of the respective product.

Table No. 24: The list of official medicines port of entry

S/N	Ports of Entry
1.	Namanga
2.	Sirari
3.	Tunduma
4.	Holili
5.	Horohoro
6.	Kasumulu
7.	Dar es Salaam Airport
8.	Kilimanjaro Airport
9.	Dar es Salaam Seaport
10.	Tanga Seaport Tanga
11.	Mwanza South Port
12.	Mwanza Airport
13.	Bukoba Seaport
14.	Tarakea
15.	Mutukula
16.	Rusumo

From July 2003 to June 2023 a total of 61,343 import and 1,752 export permits of medicines were issued as shown in Table No. 25.

Inspection of consignments at ports of entry has been strengthened, thereby enabling TMDA to curb the importation of substandard and falsified medicines.

Table No. 25: Import and Export Permits of Medicines Issued 2003-2023

Financial Year	Applications for Importation		Applications for Importation	
	Approved	Rejected	Approved	Rejected
2003 – 2012/13	20,233	961	539	0
2013/14	2,972	300	79	0
2014/15	3,262	56	122	67
2015/16	2,503	0	90	0
2016/17	3,044	4	70	0
2017/18	4,548	37	105	5
2018/19	5,069	52	115	12
2019/20	4,650	0	153	0
2020/21	5,591	0	201	0
2021/22	5,422	0	127	0
2022/23	4,049	0	151	0
Total	**61,343**	**1,410**	**1,752**	**84**

3.7 Post-Marketing Surveillance

Since 2009, TMDA has implemented a structured Post Market Surveillance (PMS) system to monitor medicines quality in the market. Samples of targeted products were collected in selected regions and then subjected to quality control testing in the TMDA quality testing laboratories.

A total of 6,366 samples of antimalaria, antibiotics, anti-tuberculosis, antiretrovirals, antihypertensives, antidiabetics, as well as various types of veterinary products were collected and tested from 2009–2023. Whenever detected, substandard products are promptly removed from the market. For the reported period, 3,912 out of 5,372 tested samples complied with the investigated parameters as shown in Table 26. PMS enabled TMDA to take regulatory action against poor quality antibiotics medicines thereby protecting public health.

Table No. 26: Results of the PMS program for the period between 2009 to 2023

Financial YR	Number collected	Number tested	Number complied	Number not complied
2009/10	281	130	100	30
2010/11	59	9	9	0
2011/12	58	22	20	2
2012/13	379	154	76	0
2013/14	467	308	260	48
2014/15	270	184	170	14
2015/16	383	207	171	36
2016/17	322	253	245	146
2017/18	466	539	539	0
2018/19	626	511	511	0
2019/20	1,839	1,839	591	0
2020/21	779	779	779	0
2021/22	437	437	441	4
Total	**6,366**	**5,372**	**3,912**	**280**

3.8 Pharmacovigilance

Pharmacovigilance ensures the understanding, detection, reporting, collection, and assessment of Adverse Drug Reactions (ADRs) as well as Adverse Event Following Immunization (AEFI). Pharmacovigilance systems have been implemented in Tanzania since 1989 and are continuously improved and strengthened with time. TMDA is mandated under Section 5(1) (a) and (c) of the TMDA Act Cap. 219 to regulate and oversee all matters relating to the safety of medicines and vaccines

The section responsible for the Pharmacovigilance and Clinical Trial has been led by various managers between 2003 and 2023. Their names and respective tenures are provided as indicated in Table No. 27 below.

Table No. 27: PV & Clinical Trial Section Managers between 2003 to 2023

Section Name	Manager's Name	Period
Product Analysis, Safety monitoring & Promotional Control	Dr. Henry Irunde	Jul 2003 – Feb 2012
Clinical Trials Control and Pharmacovigilance	Dr. Nditonda B. Chukilizo	Jan 2013 - April 2014
Clinical Trials Control and Pharmacovigilance	Kissa W. Mwamwitwa	July 2014 - Jan 2021
Pharmacovigilance & Clinical Trials	Mr. Mtani Njegere	July 2021 - Jan 2022
Pharmacovigilance & Clinical Trials	Mr. Damas N. Matiko	Jan 2022 - To date

There are two major pharmacovigilance reporting systems in Tanzania, namely the spontaneous or passive reporting and active surveillance systems. Passive reporting involves unsolicited reporting of adverse events by patients/community and healthcare workers. Active surveillance means that active measures are taken to find adverse events.

Spontaneous reporting mechanisms implemented included the Yellow and Green forms, which are continuously distributed to all health facilities in the country; Unstructured Supplementary Service Data (USSD) Code *152*00#; SQRT App; SQRT Web-based: sqrt.tmda.go.tz; Website: www.tmda.go.tz (adverse reaction reporting tool); Toll-Free call: 0800 110 084; and online platforms (Vigimobile, SQRT App, TMDA website).

The reporting rate of ADR has increased from 2,263 reports for the period between 2003 – 2013 to 10,921 in 2022/23 as shown in Figure 2 below.

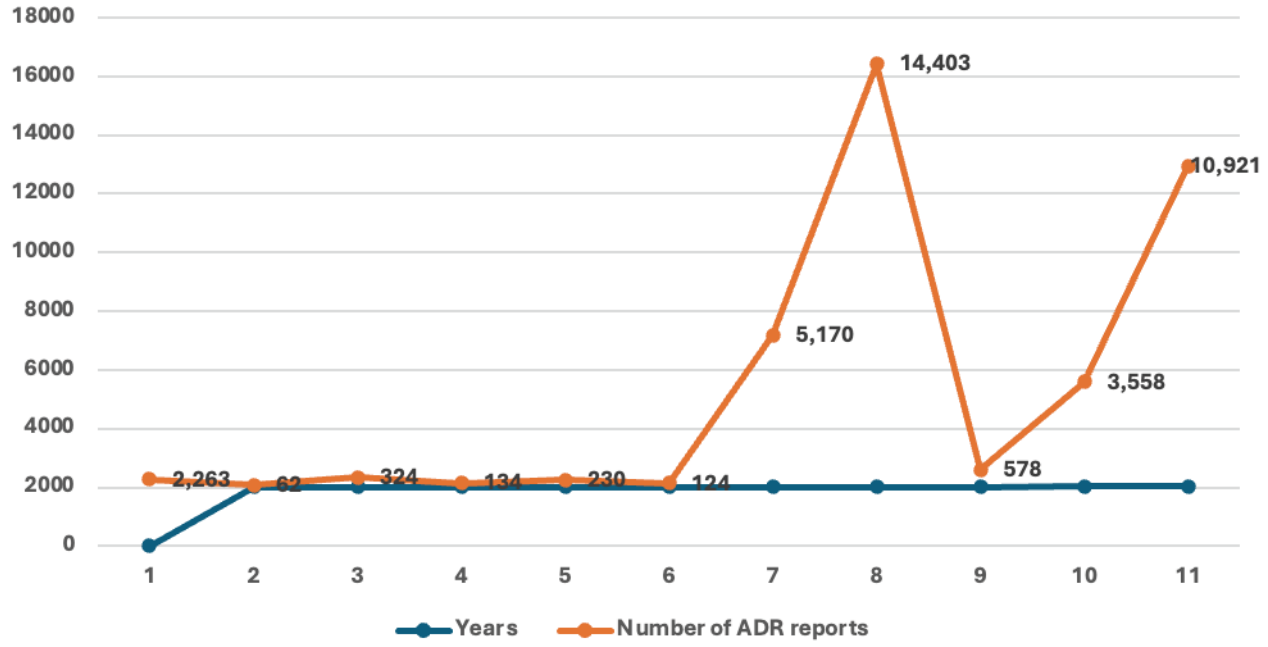


Figure 2: Number of Adverse Drug Reactions (ADRs) collected and assessed

Similarly, the number of reported AEFI increased from 2,263 in July 2003 to 10,921 in June 2023, as provided under Table 29 below. The reporting rate of 14,403 in the years 2018 enabled the Authority to attain the WHO ADR/AEFI reporting annual targets of at least 12,000 ADRs and 1,200 AEFI reports, respectively, in line with the population of 59,517,754 in Tanzania Mainland.

The improvement in the reporting rate was attributed to the use of both paper and electronic reporting systems, the establishment of PV centres at all zonal and referral hospitals, and the appointment of ADR/AEFI investigations teams (All 184 councils and 37 referral hospitals have appointed investigation teams).

Three (3) Active Safety Monitoring of Artemether/Lumefantrine tablets, Janssen COVID-19 Vaccines, and Dolutegravir tablets were executed between 2019 and 2022/23. The outcome of safety monitoring of Artemether/Lumefantrine and Dolutegravir tablets studies were published in peer-reviewed journals and can be accessed by using the following link: -

a. Fimbo AM et.al. Incidence and determinants of adverse events in individuals with HIV commencing Dolutegravir-based antiretroviral therapy in mainland Tanzania. Sci Rep. 2024 Jan 5;14(1):615. doi: 10.1038/s41598-023-51144-7. PMID: 38182720; PMCID: PMC10770041. https://pubmed.ncbi.nlm.nih.gov/38182720/

b. Mssusa AK et.al. A Cohort Event Monitoring Study in Public Health Facilities in Tanzania. Clin Drug Investig. 2016 May;36(5):401-11. doi: 10.1007/s40261-016-0385-z. PMID: 26951203. https://pubmed.ncbi.nlm.nih.gov/26951203/

In addition, pharmacovigilance inspections of 44 Marketing Authorization Holders between 2013 – 2023, and over 641 Periodic Safety Reports (PSURs), 85 Periodic Benefit-Risk Evaluation Reports (PBRERs), and 104 Risk Management Plans reports (RMPs) were received and assessed by TMDA. Regulatory actions taken included safety alerts, label changes, and product recalls.

3.9 Control of Clinical Trials

Sections 61- 67 of the Tanzania Medicines and Medical Devices Act, Cap 219, empower TMDA to control medicines and medical devices, including in vitro diagnostics and clinical trials in the country. The enforcement of these legal requirements has enabled the Authority to regulate the conduct of clinical trials in the country and protect human rights and the well-being of study subjects.

From July 2003 to June 2023 a total of 262 clinical trials of medicines, vaccines, medical devices, including in vitro diagnostics applications, were approved, of which 208 (79.3%) were medicine-related trials.

In carrying out this function, TMDA collaborated with the National Institute for Medical Research (NIMR) and the Animal Diseases Research Institute (ADRI). NIMR is responsible for the issuance of ethical clearance for trials involving humans as study subjects, while ADRI regulates the conduct of clinical trials in animals when veterinary medicines are used.

3.10 Control of Narcotics and Psychotropic Substances

Under Sections 78(1-3) of The Medicines and Medical Devices Act, Cap 219, the TMDA is mandated to

regulate the use of narcotics and psychotropic products in hospitals, with a focus on managing severe pain in terminally ill patients.

Recognizing the potential for addiction, abuse, and diversion, the Authority enforces a strict control framework. This framework covers all stages, including manufacturing, distribution, and disposal. For enforcement, the TMDA works closely with the Drug Control and Enforcement Authority (DCEA), as outlined in the Drugs and Prevention of Illicit Traffic in Drugs Act, 1995.

The importation of these controlled substances is limited to the Medical Stores Department (MSD), which subsequently distributes them to approved public and private health facilities. To ensure proper use, approved facilities are required to submit quarterly consumption reports to TMDA, which uses these reports to monitor usage and authorize subsequent supply.

Finally, TMDA compiles the national data and submits a comprehensive report to the International Narcotics Control Board (INCB) in Vienna, Austria, fulfilling Tanzania's international obligations.

From July 2003 to June 2023 a total of 1232 import permits for controlled drugs were issued by TMDA, as highlighted in Table No. 28 and 29 below.

Table No. 28: Import permits issued for medical narcotics, July 2003 to June 2023

2003- 2012/13	371	371
2013/14	33	33
2014/15	39	39
2015/16	45	45
2016/17	54	54
2017/18	66	66
2018/19	87	87
2019/20	74	74
2020/21	75	75
2021/22	100	100
2022/23	73	73
Total	**1,017**	**1,017**

Table No. 29: Import permits issued for Psychotropic substances, July 2003 to June 2023

2003 - 2012/13	124	124
2013/14	8	8
2014/15	8	8
2015/16	8	8
2016/17	12	12
2017/18	18	18
2018/19	10	10
2019/20	7	7
2020/21	5	5
2021/22	8	8
2022/23	7	7
TOTAL	**215**	**215**

In addition to issuing import permits to authorized dealers, the TMDA grants permits to health facilities for stocking and using controlled medicines. These facilities must meet requirements specified in the Tanzania Medicines and Medical Devices Act (Cap 219), the Tanzania Medicines and Medical Devices (Good Storage and Distribution Practices) Regulations, 2021, and the Guidelines for Dealing in Controlled Drugs (Third Edition, January 2021).

A total of 453 health facilities have been authorized to stock and use controlled medicines as provided in the Table No. 30 below.

Table No. 30: Number of Health facilities authorized to stock and use controlled medicines, July 2003 to June 2023

Dispensaries	0
Health Centre	196
Hospital	225
Regional Referral Hospitals	27
Zonal Referral Hospitals	4
National hospital	1
Total	**453**

3.11 Recall and Disposal of Unfit Products (Introducing incinerator)

In accordance with Section 99 of the Tanzania Medicines and Medical Devices Act, Cap 219, the TMDA is authorized to seize, condemn, and destroy unfit products. These powers are exercised to prevent the diversion of substandard or condemned medicines back into the market. Between July 2013 and June 2023, TMDA oversaw the disposal of unfit medicines valued at approximately TZS 55,141,448,996, as detailed in Table No. 31.

Table No. 31: Value of unfit medicines disposed, July 2013 - March 2023

Financial Year	Value in TZS
2013/2014	459,474,518
2014/2015	1,978,024,576
2015/2016	2,782,914,232.59
2016/2017	1,429,623,162.81
2017/2018	147,578,533
2018/2019	7,533,026,199
2019/2020	6,204,687,289.00
2020/2021	6,204,687,289.00
2021/2022	25,187,856,391.40
2022/2023	3,213,576,805.10
Total	**55,141,448,996**

3.12 Harmonization of Regulatory Requirements

Tanzania is a member of the East African Community (EAC) and the Southern African Development Community (SADC). As part of the implementation of the African Medicines Regulatory Harmonization (AMRH) programme, which started in 2009, these two regional economic communities have been implementing

the programme to harmonise regulation requirements of medicines in the region. The harmonization process began with the preparation of technical requirements for the manufacture and registration of medicines followed by joint training and carrying out joint inspections of manufacturing facilities and joint evaluation of dossiers.

TMDA has been participating in the EAC-MRH program since 2012. Through the program, a number of applications for marketing authorization in the EAC or SADC countries using Common Technical Document (CTD) which were then jointly assessed and respective manufacturing facilities jointly inspected to verify for GMP compliance. This has fast- tracked the marketing authorization process. Under this scheme a total of 266 applications were received and 225 approved.

3.13 WHO Benchmarking and Attaining Maturity Level 3

The implementation of the GBT in Africa is a key component of the World Health Organization (WHO)'s Regulatory Systems Strengthening program. Tanzania was the first African country to achieve Maturity Level 3 status for its medicines regulatory system, a milestone confirmed by the WHO in December 2018.

The core purpose of achieving a WHO Maturity Level 3 is to establish a stable and well-functioning regulatory system. This guarantees that all medical products in the market, whether locally manufactured or imported, meet international standards. This is critical for detecting and preventing substandard and falsified medicines from entering the market, thereby protecting the public from harm. It has also significantly boosted the TMDA's credibility on the global stage. This recognition translates into increased trust from international bodies and other countries.

The ML3 status for TMDA, along with the WHO Maturity Level 4 for its Quality Control Laboratory, provides a strong endorsement of the quality of medicines produced in Tanzania. This has enabled domestic manufacturers to meet the stringent quality requirements of international markets.

Tanzanian domestic pharmaceutical manufacturers became more capable of exporting their products to regional markets, such as the EAC and SADC, largely due to the confidence generated by TMDA's WHO-recognised regulatory standards.

3.14 Promotion of Domestic Manufacturers

The pharmaceutical manufacturing sector in Tanzania has seen significant growth, particularly since 2015. This expansion is a result of concerted efforts by the government and its regulatory body, the Tanzania Medicines and Medical Devices Authority (TMDA), to promote domestic production.

From 1961, the year of independence, until 2015, only nine facilities were established to manufacture medicinal products in Tanzania. The first of these was Mansoor Daya Chemicals Limited, founded in 1962. During the first eight years of TMDA's operations (2015–June 2023), the number of manufacturing facilities in the country nearly doubled. Eight new facilities were constructed and became operational, bringing the total number of operational facilities to 17.

As of June 2023, human medicinal products: 11 facilities (2 of which produce sterile products) and Veterinary medicinal products: 6 facilities (1 of which produces sterile vaccines) as shown in Table No. 32.

Table No. 32: List of operational domestic pharmaceutical manufacturing facilities

No.	Facility name	Facility Category	Dosage forms
1.	Zenufa Laboratories (T) Limited, Dar es Salaam.	Human Medicines	Oral solids & Liquids
2.	Shelys Pharmaceuticals Limited, Dar es Salaam.	Human Medicines	Oral solids & Liquids
3.	Prince Pharmaceuticals Ltd, Mwanza.	Human Medicines	Oral solids & Liquids
4.	Kairuki Pharmaceuticals Industry Ltd, (KPIL), Coast Region.	Human Medicines	Large volume parenterals
5.	Mansoor Daya Chemical Industries, Dar es Salaam.	Human Medicines	Oral solids & Liquids
6.	Keko Pharmaceuticals (1997) Limited, Dar es Salaam.	Human Medicines	Oral solids & Liquids
7.	Alfa Pharmaceuticals Limited, Dar es Salaam, Tanzania	Human Medicines	Large volume parenterals
8	Katwaza Pharmaceuticals Industry Ltd, Kibaha, Pwani	Human Medicines	Oral solids & Liquids
9.	A.A Pharmaceuticals Ltd, Dar es Salaam.	Human Medicines	External preparations
10.	Sri Balaj Pharmaceuticals Ltd, Dar es Salaam	Human Medicines	External preparations

No.	Facility name	Facility Category	Dosage forms
11.	Bhanji Pharmaceuticals Ltd, Keko, Dar es Salaam.	Human Medicines	External preparations
12	Hester Biosciences Africa Ltd, Dar es Salaam	Veterinary Medicines	Vaccines-Veterinary
13	Novel Vaccines and Biological Company Ltd (NOVABI), Kihonda, Morogoro	Veterinary Medicines	Vaccines-Veterinary
14	Farmers Centre, Veterinary Pharmaceutical, Dar es Salaam.	Veterinary Medicines	Oral powder and Liquids
15	TVI (Tanzania Vaccines Industries),Kibaha, Pwani	Veterinary Medicines	Vaccines-Veterinary
16	Farm Access Limited, Arusha Tanzania.	Veterinary Medicines	Oral powder & Liquids
17	Biotec Laboratories Ltd, Lulanzi, Kibaha, Coast Region.	Veterinary Medicines	Oral solids & Liquids

An additional 10 facilities are currently under construction, nine (9) facilities for manufacturing human medicines and one (1) facility for manufacturing veterinary medicines (Table No. 33).

Table 33: List of domestic manufacturing facilities for medicinal products under construction

S/N	Facility Name	Category	Proposed dosage forms
1.	Roll Agrovet (T) Ltd, Arusha	Veterinary Medicines	Oral Liquids & Oral Powder
2.	Dhzambo Tiba Company Ltd, Tanga	Human Medicines	Herbal Medicines
3	Resha Pharmaceutical Ltd, Mwanza	Human Medicines	External preparations (ointments and creams) and oral liquids
4.	Boka Pharmaceutical Industries, Dar es Salaam	Human Medicines	External preparations (ointments and creams), oral tablets and oral liquids
5.	Emedics Pharmaceuticals Ltd, Coastal Region	Human Medicines	External preparations (ointments and creams), oral tablets and oral liquids
6.	Vine Vision Infusion Ltd, Arusha	Human Medicines	Sterile Eye drops
7.	National Institute of Medical Research (NIMR), Dar es Salaam	Human Medicines	Herbal Medicines
8.	Medical Store Department (MSD), Dar es Salaam	Human Medicines	Oral tablets and Capsules
9.	Medical Store Department (MSD), Dar es Salaam	Human Medicines	Oral tablets and Capsules
10.	Polai (TZ) Company Limited, Dar es Salaam	Human Medicines	Collection of urine for production of hormonal medicinal products

A number of pharmaceutical manufacturing facilities are at different stages of construction.. Upon completion of all projects in pipeline, Tanzania is projected to have a total of 27 pharmaceutical manufacturing facilities.. The surge in manufacturing is a direct result of government policy and TMDA initiatives, demonstrating a strong political commitment to strengthening domestic production.

The Health Sector Strategic Plan 5 (HSSPV) (2021–2026) prioritizes strengthening domestic manufacturing of pharmaceuticals , including research and development. The TMDA action plan (ending 2025/26 aligns itself with the HSSPV and the National Industrialization Agenda – 2025 to address the challenges faced by local manufacturers.

To promote growth, TMDA, through its action plan to promote domestic medicinal products manufacturing

facilities, has established several incentives throughout the lifecycles of a facilities , from construction to full operation.

a. Fee exemptions: Waived fees on import permits for machine parts, packaging materials, and raw materials used for trial and validation studies.

b. Expedited processes: Timely issuance of import permits and assistance with customs clearance.

c. Dedicated support: A dedicated desk at both the Tanzania Investment Centre (TIC) and TMDA Head Offices to expedite all approval processes.

d. Incentives for marketing authorisation: Reduced fees and timelines: TMDA has eliminated or reduced some registration fees and accelerated processing times for new submissions, variations, and renewals as highlighted in Table No. 34 below.

Table No. 34: Comparison of timelines for marketing authorization of products between domestic and overseas facilities

Services	Domestic facilities	Imported facilities
Marketing Authorization of products	90 Days	180 Days
Renewal of marketing Authorization, including antiseptics (After 5 years)	20 Days	30 Days
Registration of Antiseptics and Disinfectants	30 Days	60 Days
Variation (Major)	45 Days	45 Days
Variation (Minor)	30 Days	30 Days
Approval of promotional materials for medicines	10 Days	10 Days

Table No. 35: Comparison of the timeline for GMP inspection between domestic and overseas facilities

Service	Domestic Facility	Overseas Facility
Sending GMP inspectors for inspection of the domestic facility for medicines and medical devices	5 Days	45 Days
Sending the GMP inspection report after the last date of conducting the inspection	5 Days	45 Days
Issuance of the GMP certificate/GMP approval letter after compliance	3 Days	45 Days

Table No. 36: Comparison of fee structures between domestic and overseas products

Services	Domestic facilities	Imported facilities
Registration Fees for human and veterinary pharmaceuticals	1,000,000 TZS	2000USD
Registration Fees for human and veterinary biological products and vaccines	1,000,000 TZS	3000 USD
Renewal of registration (after 5 years)	1,000,000 TZS	2000-3000 USD
Retention fees (Paid Annually)	Exempted	300 USD
Major Variation on Registered Medicine	200,000 TZS	1000 USD
Minor Variation on Registered Medicine	100,000 TZS	300 USD
Change of Local technical representative (LTR)	Exempted	2000 USD
Fees applicable for marketing authorization of Antiseptics and Disinfectants		
Registration of Antiseptics from Large-Scale Manufacturers	100,000 TZS	300 USD
Registration of Antiseptics from Small-scale and Medium-scale Manufacturers	50,000 TZS	300 USD

Renewal for Registration	100,000 TZS	300 USD
Variation on registered Antiseptics	Exempted	100 USD
Retention fees	Exempted	80 USD
Fees applicable for marketing authorization of Tobacco Products		
New registration	300,000 TZS	300 USD
Renewal of registration	300,000 TZS	300 USD
Retention fees	00.00	00.00
Variation-Major	100,000 TZS	100USD
Variation-Minor	50,000 TZS	50USD
Fees applicable for approval of Promotional Materials and advertisements, Permit of Medicines		
Promotional Materials Permits	50,000 – 100,000 TZS	50-100 USD
Fees applicable for GMP inspection		
GMP inspection	Exempted	4000 -7500USD

These incentives have contributed to a significant increase in registered domestically produced products: As of June 2023, TMDA had expedited the registration of 259 products from domestic facilities (Human medicinal products: 171; Veterinary products: 43; and Biocidal products: 45 (antiseptics and disinfectants).

Fig. 4.11 (1a) Human medicinal products registered from domestic facilities

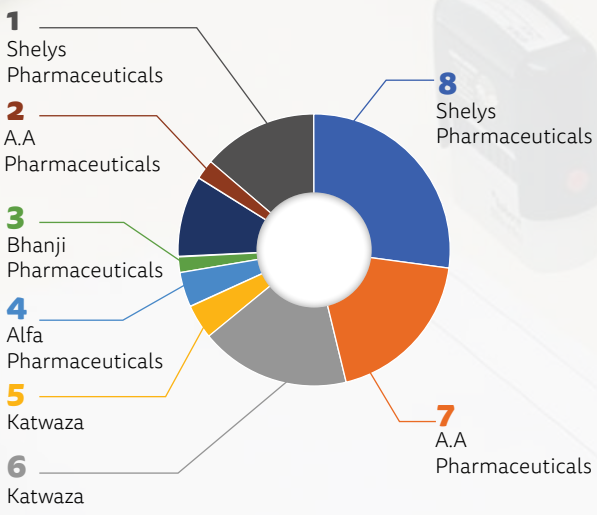
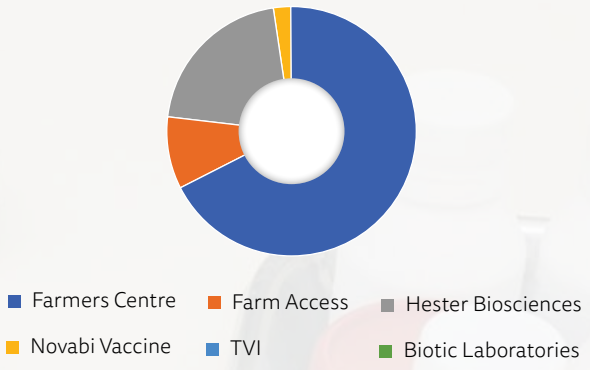


Fig. 4.11 (1b) Veterinary medicines registered from domestic facilities



CHAPTER - 4

Regulation of Medical Devices and Diagnostics

4.1 Introduction

This chapter discusses the regulation of medical devices and diagnostics in Tanzania, tracing the evolution of oversight, legal frameworks, and guidelines established to ensure their quality, safety, and performance in health service delivery.

Medical devices and diagnostics are very important components of health service delivery systems. They are used in diagnosis, prevention, aiding treatment and vaccination against diseases and restoration of normal function of the body. The desired health benefits are highly attributed to the quality, safety and performance of these products.

Regulation of medical devices started in 2008 by approval of proforma invoices for the devices imported in the country and later

on in 2012, registration of the same started. In 2015 the regulation of in vitro diagnostics was transferred to the then Tanzania Food and Drugs Authority (TFDA) from the Public Health Laboratory Board (PHLB). This transfer led to the review of the legal framework to have new regulations (Control of Medical Devices Regulations) for medical devices which included in vitro diagnostics. Several guidelines have been prepared to facilitate and enable users comply with the mentioned regulations. The guidelines are available and can be accessed from TMDA website www.tmda.go.tz

From 2008 to 2021 the responsibilities for regulating medical devices and diagnostics was undertaken by the Medical Devices Control Section under the TFDA Directorate of Medicines and Cosmetics. In 2019 TFDA was changed to TMDA through the Finance Act, No. 8 of 2019 which transferred responsibilities of food and cosmetics regulation to Tanzania Bureau of Standards (TBS). Consequently TMDA was reorganized and a directorate of Medical Devices and Diagnostics was formed following approval of TMDA first organization structure on 28th December, 2021. The directorate has three sections namely; Medical Devices and Diagnostics Assessment, Device Premises Licensing and Compliance, and Vigilance and Post Marketing Surveillance.

Regulation of medical devices and diagnostics involves three elements namely pre-marketing, marketing and post marketing controls. Pre-marketing control involves issuance of marketing authorization/ registration or notification and control of promotional materials. Marketing control involves licensing and registration of premises, issuance of import/export permits and enforcement. Post marketing control covers surveillance, investigations and taking regulatory action(s). Through these controls, TMDA has made a significant step in promoting the accessibility of these products in Tanzania while ensuring that their safety, quality and performance are maintained throughout their lifecycles.

4.2 Marketing authorization of medical devices and diagnostics

Marketing authorization is an official approval of a medical device or diagnostic for circulation on the market which involves premarket assessment followed by registration or notification. Section 51 of the Tanzania Medicines and Medical Devices Act, Cap 219 mandates TMDA to register devices before being allowed to circulate on Tanzanian market. The process of registration

includes receipt of applications for registration, screening for the purpose of classifying the device according to its associated risks, evaluation to ascertain conformance to quality, safety and performance requirements, and issuance of a registration certificates.

In 2009, the process of notifying medical devices started whereby a total of 3,500 devices were notified. In 2010, the first phase of registration of medical devices started with 16 selected devices namely syringes, surgical sutures, examination and surgical gloves, scalp vein sets, intravenous cannulas, catheters and tubes, condoms, needles and administration sets (blood giving and taking sets, blood lancets and intravenous giving sets). Others are blood collection bags, surgical dressings, internal prosthetic replacements, orthopaedic implants, bone cements, drug eluting stents and intraocular lenses. This was followed by registration of all types of medical devices, including in vitro diagnostics, in 2016.

A total of 2,804 medical devices were registered and 3 rejected between 2010 and 2023, as shown in Table No.41 below. In addition, 2,223 medical devices were notified.

Table No.37. Registered medical devices. July, 2010 – June, 2023

Year	Received applications	Evaluated applications	Registered application s	Rejected application s
2010/2013	96	96	96	-
2013/2014	218	173	15	-
2014/2015	261	232	79	-
2015/2016	235	235	124	-
2016/2017	549	442	76	-
2017/2018	561	489	165	3
2018/2019	528	470	115	-
2019/2020	468	439	1229	-
2020/2021	468	412	373	-
2021/2022	403	395	333	-
2022/2023	419	401	199	-
Total	**4,206**	**3,784**	**2,804**	**3**

4.3 Control of promotional materials and activities

Section 68 of the Tanzania Medicines and Medical Devices Act, Cap. 219, restricts the promotion and advertisement of medical devices, among other products, unless approved by the Authority. Advertisements refer to any information that can promote the sale or use of a medical device. Advertisements may include publication in newspapers, magazines, journals, news bulletins, display of posters or notices, circulars, brochures, pamphlets, books, fliers or free samples to healthcare professionals and announcements made orally or through producing or transmitting light or sound.

A total of 55 application for approval of promotional materials of medical devices and diagnostics were received and evaluated between 2010 – 2023. Out of 55, 50 were approved and 5 rejected as shown in Table No. 38 below.

55
promotional materials for medical devices and diagnostics received and evaluated between 2010 – 2023

50
promotional materials for medical devices and diagnostics approved

5
promotional materials for medical devices and diagnostics rejected

Table No. 38: Applications for approval of promotional materials of medical devices received and evaluated 2010-2023

Year	Received applications	Evaluated applications	Approved adverts	Rejected adverts
2010 – 2013	-	-	-	-
2013/14	-	-	-	-
2014/15	-	-	-	-
2015/16	-	-	-	-
2016/17	-	-	-	-
2017/18	6	6	5	1
2018/19	-	-	-	-
2019/20	1	1	1	-
2020/21	11	11	11	-
2021/22	12	12	8	4
2022/23	25	25	25	-
Total	**55**	**55**	**50**	**5**

4.4 Registration and licensing of premises

Section 18 of the Tanzania Medicines and Medical Devices Act, Cap 219 restricts the manufacture for sale, sell, supply or storage of medical devices, in vitro diagnostic devices and laboratory equipment unless the premises have been registered.

A total of 2,445 premises were registered between July 2013 to June, 2023 as shown in Table No.39 below. Premises registered included manufacturing facilities, retail and wholesale outlets, warehouses, medical device transport vehicles and medical gas outlets.

Table No. 39: Registered medical device and diagnostics premises (2013–2023)

Year	Premises						
	Overseas and domestic medical device manufacturing facilities	Whole sale Outlets	Ware houses	Retail outlets	Medical device transport vehicles	Medical gas outlets	Total
2013/14	-	-	-	-	-	-	-
2014/15	-	-	-	-	-	-	-
2015/16	0	96	0	0	0	-	96
2016/17	0	132	3	0	0	-	135
2017/18	1	246	1	0	0	-	248
2018/19	1	164	17	68	0	-	250
2019/20	66	390	2	9	0	-	467
2020/21	35	285	8	29	0	3	360
2021/22	33	277	35	12	6	-	363
2022/23	41	427	8	29	0	21	526
Total	**177**	**2,017**	**74**	**147**	**6**	**24**	**2,445**

4.5 Inspection of medical devices and diagnostics premises

Pursuant to Sections 5(1)(h) and 106 of the Tanzania Medicines and Medical Devices Act, Cap 219, TMDA is required to inspect all premises that are involved in the business of medical devices including diagnostics. Inspections are conducted to ascertain that medical devices and diagnostics circulating on the market comply with marketing authorization criteria and good storage and distribution practice regulations. There are five types of inspections namely routine, concise, follow-up, audit and special/ investigative inspection.

In addition to compliance with quality, safety and performance criteria during marketing authorization, medical devices and diagnostics manufacturing facilities are required to comply with requirements laid down in the current ISO 13485 standards and requirements prescribed by the Authority. Quality System audit is part of quality assurance, which ensures that medical devices are consistently produced and controlled to the quality standards appropriate for the intended use.

A total of 2,304 premises were inspected between July 2015 to June 2023 as shown in Table No. 40 below. The inspected premises included manufacturing facilities, warehouses, medical gas outlets, and wholesale and retail outlets.

Table No.40 Inspected medical devices premises (2015 - 2023)

Year	Premises						
	Overseas and domestic medical device manufacturing facilities	Wholesale outlets	Ware houses	Retail outlets	Medical device transport vehicle	Medical gas outlets	Total
2013/14	-	-	-	-	-	-	-
2014/15	-	-	-	-	-	-	-
2015/16	1	10	0	7	0	-	18
2016/17	12	162	8	5	0	-	18
2017/18	19	140	5	1	0	-	36
2018/19	27	24	0	93	0	-	72
2019/20	26	103	1	21	0	-	144
2020/21	40	66	25	0	0	45	288
2021/22	69	42	20	340	3	-	576
2022/23	65	443	10	31	0	26	1,152
Total	**259**	**990**	**69**	**498**	**3**	**71**	**2,304**

4.6 Import and Export Control

Importers and exporters of medical devices are required to obtain a permit for importation or exportation of medical devices from TMDA pursuant to Section 73 of the Tanzania Medicines and Medical Devices Act, Cap 219.

Between 2008 to 2023, a total of 48,385 import permits were approved and 2,599 rejected. In the same period, 3,846 export permits were issued and 60 rejected as shown in Table No.41 below.

Table 41: Issuance of medical device and diagnostic imports and export permits (2008 - 2023)

Year	Applications for imports		Applications for exports	
	Approved	Rejected	Approved	Rejected
2008/09	980	0	3	0
2009/10	340	0	-	-
2010/11	1,333	123	15	0
2011/12	337	92	1	0
2012/13	1,977	1,754	15	0
2013/14	1,611	415	21	-
2014/15	1,579	90	21	55
2015/16	1,681	25	23	-
2016/17	2,073	21	10	-
2017/18	4,919	6	142	4
2018/19	5,509	38	359	1
2019/20	5,479	35	331	-
2020/21	6,310	-	1,157	-
2021/22	8,049	-	1,075	-
2022/23	6,208	-	673	-
Total	**48,385**	**2,599**	**3,846**	**60**

Note: The Regulation of Medical Devices started in 2008/09

4.7 Post Marketing Surveillance

Post Marketing Surveillance (PMS) of medical devices and diagnostics is a methodology used to monitor the quality, safety and performance of these products circulating on the market. Monitoring is performed to ensure that medical devices and diagnostics on the market meet and maintain prescribed standards of quality, safety and performance.

Monitoring of quality and performance of medical devices and diagnostics in the market employs structured and unstructured approaches. The structured PMS is a three-year program which is implemented annually and involves planning, budgeting and implementation.

4.7.1 PMS Program for Simple and Single Use Medical Devices and Diagnostics

PMS programs for simple and single use medical devices and diagnostics commenced in the year 2012 with a pilot program that was implemented between 2012 and 2015. The first, second and third programs were implemented in the years 2015 to 2017, 2018 to 2020 and 2021 to 2023 respectively.

The implementation phases of each program involved training of sample collectors, collection of samples, product information review (PIR), laboratory testing, evaluation of results, report writing and regulatory actions. Regulatory actions included removing substandard or counterfeit medical devices and diagnostics from the market, issuing warning letters to the concerned parties, banning the devices and educating dealers where appropriate.

“Monitoring is performed to ensure that medical devices and diagnostics on the market meet and maintain prescribed standards of quality, safety and performance.”

Table No. 42 Results of PMS programs for simple and single use medical devices and diagnostics 2012 - 2023

PMS Program	Samples collection and PIR			Laboratory testing		
	Collected	Passed PIR	Failed PIR	Tested	Passed	Failed
Pilot Program 2012 - 2015	1,328	-	-	1,005	972	33
1st Program 2015 - 2017	312	-	-	309	275	34
2nd Program 2018 - 2020	590	524	66	590	582	8
3rd Program 2021 - 2023	1,038*	888	150	983*	890	93
Total	**3,268**	**1,412**	**2,16**	**2,887**	**2,719**	**168**

* 55 samples were not tested due to inability of the laboratory capacity to test glucose strips

4.7.2 PMS Program for Medical Equipment

Medical equipment are medical devices requiring calibration, maintenance, repair, user training and decommissioning. Medical equipment being part of medical devices are regulated by TMDA and therefore must comply with prescribed standards of quality, safety and performance.

The first PMS Program for Medical Equipment 2021/22 – 2023/24 was developed to systematically define how quality and performance of medical equipment could be monitored in health facilities. This program targeted surveillance of 16 types of selected medical equipment from different levels of health facilities namely national, regional and district levels.

A total of 494 medical equipment were inspected in private and public hospitals between 2022 to 2023 as shown in Table No. 43 below.

Table No. 43 Types and number of medical equipment inspected in each phase

S/N	Type of medical equipment	Year and number of inspected equipment			
		2021/22	2022/23	Total	(%)
1	Chemistry analyzers	34	24	58	12
2	Ultrasound Machines	36	22	58	12
3	Haematology analyzers	27	26	53	11
4	X-Ray machines	28	17	45	9
5	Blood Pressure (BP) machines	19	8	27	6
6	Patient monitors	21	25	46	9
7	Microscope	0	15	15	3
8	Anaesthesia machines	17	20	37	8
9	Infant incubators	24	10	34	7
10	Glucometers	0	11	11	2
11	Immunoassay analyzers	8	13	21	4
12	Pulse oximeter, line powered	0	4	4	1
13	Dialysis machines	12	9	21	4
14	Computerized Tomography (CT) scan	15	6	21	4
15	Ventilator machines	10	5	15	3
16	Magnetic Resonance Image (MRI)	6	4	10	2
17	ECG Machine*	6	0	6	1
18	Mammography*	3	0	3	0.6
19	Urine analyzers*	2	0	2	0.4
20	Gene Expert machine*	2	0	2	0.4
21	CD4 Count machine*	2	0	2	0.4
22	Steam sterilizer*	1	0	1	0.2
23	Diatherapy machine*	1	0	1	0.2
24	Water Treatment Plant (RO System)**	0	1	1	0.2
	Total	**274**	**220**	**494**	**100**

* Inspected equipment not included in the PMS Program for Medical Equipment 2021/22 – 2023/24

** Inspected equipment as part of dialysis machine

4.8 Vigilance

Vigilance is a system used to monitor adverse events and adverse incidents associated with the use of medical devices and diagnostics. It involves detecting, reporting, evaluating, understanding and preventing the dangerous adverse effects of medical devices and diagnostics. The vigilance system involves the use of ''Medical Devices and In Vitro Diagnostics Adverse Event/Incident Reporting Form for Consumers and Health Facilities'' also known as (Orange Forms) for voluntary reporting adverse events and incidents by healthcare workers and consumers. The forms have

been widely distributed to TMDA zones, hospitals, health centres and dispensaries country wide.

To enhance the reporting of adverse events and incidents associated with the use of medical devices and diagnostics TMDA conducts supportive supervision of pharmacovigilance centres across the countryto sensitizes healthcare workers in the health facilities to raise awareness and motivation for timely and accurate reporting.

From 2016 to 2023 a total of 7,272 healthcare workers in health facilities were sensitized on how to detect and report adverse events and incidents associated with the use of medical devices and diagnostics. The number of adverse event and incident reports received and evaluated during this period was 466 as shown in Table No.44 below.

Table No. 44 Healthcare workers sensitized and adverse event and incident reports received and evaluated, 2016 to 2023

Year	Number of sensitized healthcare workers	Number of adverse event / incident reports received and evaluated
2016/17	664	-
2017/18	1,031	24
2018/19	504	26
2019/20	781	15
2020/21	1,055	86
2021/22	1,369	130
2022/23	1,868	185
Total	**7,272**	**466**

4.9 Recall and Disposal of Unfit Products (Introducing incinerator)

Unfit medical device or diagnostic means products that have expired, improperly sealed, damaged, unexpired but improperly stored, improperly labelled, substandard, falsified, prohibited or unauthorized. Section 99 of the Tanzania Medicines and Medical Devices Act 2003, Cap 219 empowers TMDA to prevent and seize, forfeit, condemn and destroy unfit medical devices and diagnostics. In order to protect public health, TMDA has introduced various measures and strategies to detect and remove from the market unfit medical devices and diagnostics.

Between July, 2014 to June, 2023, TMDA has supervised the disposal of unfit medical devices worth around TZS 12,429,519,201 as shown in Table No.45 below.

Table No.45: Value of disposed medical devices July 2014 – June, 2023

Year	Weight (Tons)	Value of Disposed Goods
July 2014 - June 2015	0	0
July 2015 - June 2016	0	0
July 2016 - June 2017	0.006	240,000.00
July 2017 - June 2018	0	0
July 2018 - June 2019	0.021	15,110,000.00
July 2019 - June 2020	6,493.15	2,999,050,790.02
July 2020 - June 2021	6,493.15	2,999,050,790.02
July 2021 - June 2022	13,103.09	2,624,813,199.69
July 2022 - June 2023	19.55	3,791,254,421.45
Total	**26,108.967**	**12,429,519,201.18**

4.10 Promotion of Domestic Manufacturers

Domestic manufacturers of medical devices, diagnostics and laboratory equipment are categorized based on their production scale into small-scale manufacturers, medium-scale manufacturers and large-scale manufacturers. In order to promote domestic production of medical devices and diagnostics, several initiatives have been undertaken by the government through TMDA.

These initiatives included preparation of action plan aimed at promoting domestic medical device and diagnostic manufacturing during the period 2022/23–2026/27, establishment of a special desk officer to deal with issues of domestic medical device and diagnostic manufacturers, provision of technical support to domestic medical devices and diagnostics manufacturers through site visits, training to facilities' technical staff and preparation of IEC materials to encourage establishment of medical device and diagnostic manufacturers.

TMDA also offers a number of incentives to domestic medical devices and diagnostics manufacturers including; zero import duty for manufacturing equipment and raw materials, fast tracking registration applications, exemption of exportation fees for finished products, exemption of alteration fees for registered devices and diagnostics and zero cost for quality audit inspection.

Between 2010 to 2023, a total 82 domestic medical devices manufacturers were inspected and registered as shown in Table No.46 below.

Table No. 46: Number of domestic medical devices manufacturers registered in TMDA Zones

S/N	Summary	Medical device and diagnostic manufacturing facilities scale				Medical gas plant and hospital centres scale				Total
	Zone	Small	Medium	Large	Total	Small	Medium	Large	Total	
1.	Central Zone	2	0	0	2	1	3	0	4	6
2.	Eastern Zone	19	10	10	39	0	0	3	3	42
3.	Lake Zone East	3	0	1	4	0	2	3	5	9
4.	Lake Zone West	0	0	0	0	0	0	0	0	0
5.	Western Zone	0	0	0	0	0	1	0	1	1
6.	Southern Highland	2	0	1	3	5	0	0	5	8
7.	Southern Zone	0	0	0	0	3	0	0	3	3
8.	Northern Zone	7	1	0	8	2	2	1	5	13
Total		**33**	**11**	**12**	**56**	**11**	**8**	**7**	**26**	**82**

4.11 Harmonization of regulatory requirements

At regional level, TMDA collaborates with other neighbouring countries in regional economic community (REC) initiatives related to regulation of medical products. Tanzania is a member of the East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme as well as in the SADC. Under these regional initiatives, countries share information on substandard and falsified products, conduct joint assessment of applications for market authorization as well as joint inspections of manufacturing facilities.

At continental level, TMDA was the founder of Pan African Working Party (PAWP) in 2012 which later transitioned to African Medical Devices Forum (AMDF) and TMDA is still a member. The forum is under the Africa Medicines Harmonization programme (AMRH) of the AUDA-NEPAD, that offered opportunity for the Authority to participate in decision making on different issues pertaining to regulation of medical devices and in vitro diagnostics in the continent. TMDA is also a members of two (2) subcommittee technical working groups (for pre-market assessment and PMS) which facilitate discussions and development of policies and guidance documents.

Internationally, in 2014 we were the first country in Africa to join the Global Harmonization Working Group (GHWP). GHWP is a group of experts from the medical device regulatory Authorities and the medical device industries. GHWP goals are to study and recommend ways to harmonize medical device and in vitro diagnostic regulations globally. TMDA has representatives in Working Group 1 and Working Group 2 which discuss and recommend ways to harmonize regulations related to pre-market of medical devices and in vitro diagnostics respectively. Recently in 2024 TMDA became an affiliated member of International Medical Devices Regulators Forum (IMDRF).

TMDA also participates and implements the Collaborative Registration Procedure as designed and organized by WHO (WHO-CRP) for in vitro diagnostics since 2012. The programme provides the Authority with access to the assessment reports, manufacturing site inspection reports as well as performance evaluation reports of the products submitted for market authorization which already have undergone the prequalification process of WHO. By using the information obtained, TMDA has significantly reduced timelines for assessing and approving application for registration of medical devices and diagnostics and therefore promoting accessibility of the the products to the people of Tanzania.

4.12 Benchmarking and Capacity Building

Owing to its advanced and well-established regulatory systems for medical devices and invitro diagnostics TMDA has been a trusted hub and Regional Centre of Regulatory Excellence (RCORE) for learning and capacity building for different

National Regulatory Authorities within the East African Region, SADC region as well as the continent at large. TMDA has been a point of reference and conducted attachment training for staff from Botswana Medicines Regulatory Authority (BOMRA), The Autoridade Nacional Reguladora de Medicamentos (ANARME) of Mozambique, Zambia Medicines Regulatory Authority (ZAMRA), Ethiopian FDA, National Drug Authority of Uganda (NDA) as well as the Burundi National Medicines Regulatory Authority (ABREMA).

Also, under the support of Medicines Technologies and Pharmaceutical Services (MTaPs) programme of MSH TMDA hosted and facilitated official training for Maternal and Child Health (MNCH) medical devices for officers from Rwanda, South Africa, BurkinaFaso, Burundi, Botswana, Togo, Kenya, Ethiopia, Zambia, Nigeria, Ghana and Uganda.

Through these initiatives TMDA imparted knowledge and skills to participants to help them strengthen their country's regulatory systems and hence protecting their people from inferior, unsafe and non performing products.

4.13 Collaboration with development partners

The Authority in collaboration with The European and Developing Countries clinical Trials Partnership (EDCTP) has implemented a development project named Building Resilient Research ethics, Diagnostics and Medicines Regulatory Capacity during Routine and Public Health Emergency Periods". Also known as the "BREEDIME'

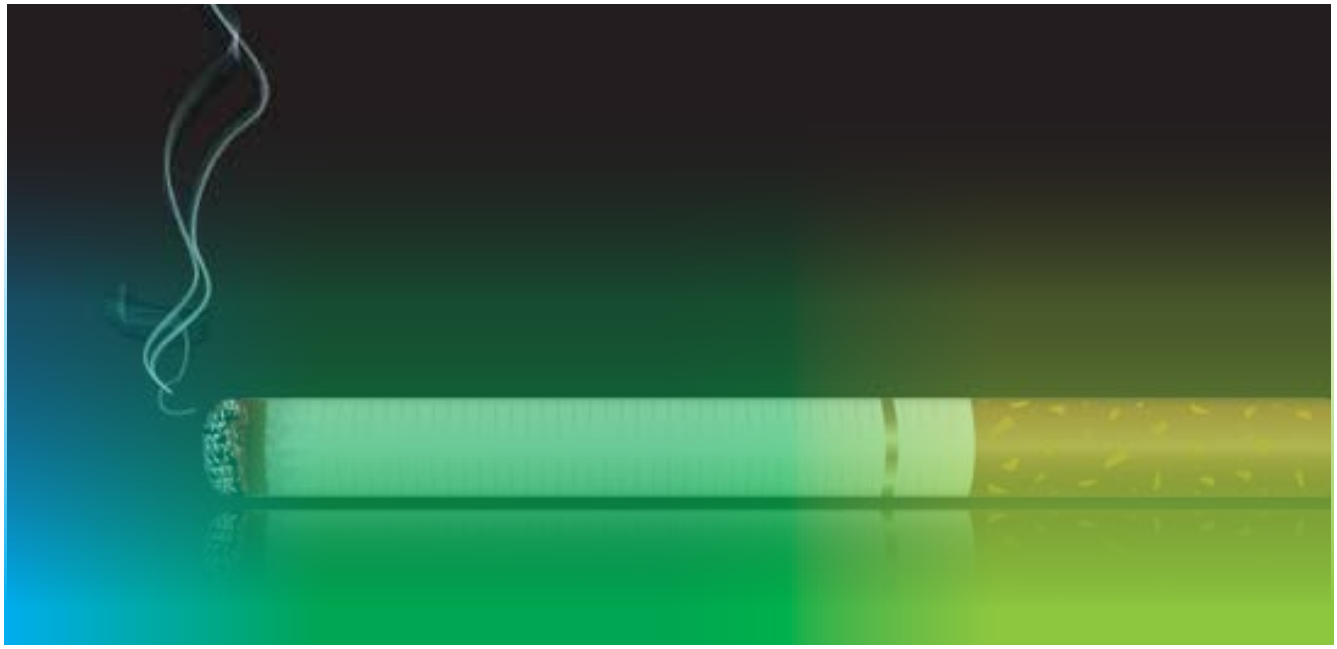
Under this project TMDA has developed guidelines to conduct performance evaluation of invitro diagnostic in the identified laboratories in Tanzania, the document outlines the requirements and procedures that an applicant or manufacturer requires in order to demonstrate the performance of the device both analytically and clinically. In connection with that six (6) protocols have been developed for use by the identified labs while conducting the evaluation, the idea is to harmonize the process in the country in to have reliable and accurate reports.

4.14 In-country performance evaluation

In-country performance evaluation is of paramount advantage to the end-user and will involve those IVDs which are not prequalified by WHO and currently will involve IVDs for six (6) diseases namely HIV,

CHAPTER - 5

Regulation of Tobacco Products



5.1 Introduction

This chapter presents TMDA's regulatory mandate over tobacco products, detailing its designation, legal framework, and roles in inspection, enforcement, and public health protection.

Due to an increase in tobacco products consumption and the corresponding increase in tobacco-related diseases, the Minister responsible for health has designated TMDA as the regulator of tobacco productsas part of broader efforts to promote and protect public health This mandate has been gazetted in the Tobacco Products (Regulations) (Designation of Inspectors) Notice, GN 360, which was published on 30/4/2021. pursuant to this designation, TMDA has assumed

these statutory responsibilities of inspection, enforcement and regulatory oversight of tobacco products.

TMDA has developed an action plan for the regulation of tobacco products. The Action Plan focuses on several evidence-based interventions drawing its principles from the provisions of the World Health Organization Framework Convention on Tobacco Control (WHO-FCTC). Furthermore, the guidelines for the listing of tobacco products was developed. These guidelines prescribed the minimum requirements for listing of tobacco products

5.2 Listing of Tobacco Products

The Authority has established an online system for Tobacco Products Listing which came into effect on 1st November, 2023. Companies and business people intending to market their tobacco products in Tanzania are required to submit applications for listing of tobacco products in the format prescribed in the Guidelines for Tobacco Products Listing. Any tobacco product not listed in the Authority Register shall not be allowed to be marketed in Tanzania. By June, 2023, TMDA has notified 106 tobacco products, The list of notified medicinal tobacco products is publicly available on TMDA website www.tmda.go.tz

CHAPTER - 6

Laboratory Services

6.1 Introduction

This chapter outlines the establishment, evolution, and current status of the TMDA Quality Control (QC) Laboratory, emphasizing its regulatory foundation, historical development, and alignment with international quality standards.

TMDA has a Quality Control (QC) laboratory for analyzing medicines, medical devices and diagnostics. This laboratory was established in-line with the provisions of Section 14(1) of Tanzania Food, Drugs and Cosmetics Act, Cap 219. The laboratory began operating in 1996 under the auspices of the then Pharmacy Board, and continued with its operations

under Tanzania Food and Drugs Authority (TFDA) which was established in 2003. In 2009, the TFDA QC laboratory was expanded and upgraded to cope with advances in science and technology and to prepare it for accreditation as per requirements of international quality standards. The Laboratory is currently referred to as TMDA QC Laboratory following the change of name of the Authority from TFDA to the Tanzania Medicines and Medical Devices Authority (TMDA) in 2019.

During era of the Pharmacy Board, the supervisor of the laboratory held the tittle "Head of Laboratory". The first head was Mr. Erasto Theobald Mosha. Later Mr. Legu Ramadhani Mhangwa and Ms. Olympia Mbatia Kowero followed as heads of the laboratory at different short periods. The title of the head of laboratory changed to Director of Laboratory Services (DLS) under the newly established TFDA in 2003. The first DLS was Ms. Charys Kahurunanga Ugullum (2003 – 2016) followed by Dr. Danstan Hipolite Shewiyo (2018 todate).

The Qualiity Control Laboratory conducts analysis of medicines, medical devices and diagnostics samples to ascertain their quality attributes thereby facilitating evidence-based regulatory decisions. Analysis is conducted in accordance with national and international standards, evidence-based regulatory decisions. Analysis is conducted in accordance with national and international standards, using modern equipment and trained analysts. Some of the equipment is listed in Table No. 47.

Table No. 47: List of some Equipment

S/N	Type of Equipment
1.	High Performance Liquid Chromatography (HPLC) -7 with UV/Vis, Diode array, Fluorescence, Refractive Index, Detectors
2.	Atomic Absorption Spectrophotometer (AAS) with Graphite furnace, Flame Photometer, Hydride Vapour Generator
3.	High Performance Thin Layer Chromatography (HPTLC)
4.	Fourier transformed infra-red (FTIR)
5.	Stability Chambers (2)
6.	Near Infrared 3600 Ultraviolet/ Visible Spectrophotometer
7.	Ultraviolet/Visible Spectrophotometer (3)
8.	Cryoscope
9.	Incubators Five (5)
10.	Dissolution Machines two (2)
11.	Disintegration Machine
12.	Digital Polarimeter
13.	Kjeldahl Apparatus
14.	Digital Microwave Digester Apparatus
15.	Freeze Dryer
16.	Sterility Testing Apparatus
17.	Bio Safety Cabinet (4)
18.	Autoclaves two (2)

6.2 Organization of the laboratories

TMDA has three (3) laboratories as follows:

a) Main Laboratory located in Dar es Salaam

b) Lake Zone Laboratory located in Mwanza

c) Newly established Laboratory located in the TMDA headquarter's building in Dodoma

These full-fledged laboratories conduct full monograph testing of samples and selected tests as per customer requirements. They also carry out research, analytical methods development and optimization, validations and verifications.

In order to ensure laboratory services were closer to the community, TMDA stationed 25 Mini - Laboratory Kits in some of its Zonal Ofiices, Ports of Entries (PoE) and Regional Referal Hospitals across the country. These stations are referred to as Quality Assurance Centers (QA centers). TheQA centers conduct screening testing of selected groups of medicines to ensure their quality at all times. These medicines are those prone to falsification due to their importance in treating deceases of public interest (selected antibiotics, antituberculosis, anti malarials and antiretrovirals).

The Full-fledged laboratories have the following organization;

a) Main laboratory located in Dar es Salaam is organized into two sections one for Physico-chemical testing of medicines, medical devices and diagnostics testing and another section for microbiological testing of all products

b) Lake Zone laboratory located in Mwanza organized into physico-chemical testing section and microbiological testing section

c) The Dodoma Laboratory has wet chemistry and instrument room and physico-chemical testing sections. Analytical work performed by the laboratories above in the past 20 years is as described below:

6.3 Medicines Physico-Chemical Analysis

This section is in both laboratories. Analytical test parameters for medicines include dissolution, disintegration, identification, assay, related substances (impurities profiles), friability, pH, melting point, hardness, appearance, moisture content, etc.

For the past 20 years period from July 2003 to June 2023, a total of 22,661 samples of medicines, had been analysed, for different physico-

chemical parameters; out of which 22,424 (99%) passed the tests. In the initial 10 years between July 2003 and June 2013, a total of 6,497 samples were analysed and 6,163 samples passed As detailed in Table 48.

Table No. 48 indicating number of samples analysed annyally and their results for the period of 10 years covering July 2013 and June 2023.

Table 48: Yearly Summary of Samples Analyses and Results July 2013- June 2023

Year	Medicine		
	Tested	Pass	Fail
2013/14	1,462	1,435	27
2014/15	1,671	2,011	15
2015/16	2,142	2,090	52
2016/17	1,887	1,862	25
2017/18	1,305	1,272	33
2018/19	1,818	1,808	10
2019/20	1,665	1,635	30
2020/21	2,358	2,322	36
2021/22	1,310	1,302	8
2022/23	546	524	22
Total	**16,164**	**16,261**	**258**

6.4 Medical Devices and Diagnostics Testing

This section is located in the main laboratory in Dar es Salaam. Its main function is to test and assess medical devices quality parameters as per relevant ISO standards. It was established under the TMDA and during the initial 10 years (2003 – 2013), only 36 samples of medical Devices were tested or assessed, of which 35 samples passed laboratory testing. This period mainly used to develop testing capacities related to medical devices.

In the following 10 years period from 1st July, 2013 to 30th June 2023, a total of 4,456 samples of medical devices and diagnostics tested or assessed, of which 3,865 samples, equivalent to 87% were of acceptable quality as summarized in Table 49.

Table No. 49 Results of analyzed samples 2013 - 2023

Year	Medical Devices		
	Tested	Pass	Fail
2013/14	91	91	0
2014/15	53	51	2
2015/16	179	178	1
2016/17	58	52	6
2017/18	234	204	30
2018/19	274	269	5
2019/20	674	670	4
2020/21	1,129	760	369
2021/22	969	816	153
2022/23	759	739	20
Total	**4,420**	**3,830**	**590**

6.5 Tobacco Products Analysis

The analysis of tobacco products was carried out in the newly established laboratory in Dodoma. From 2022 to 2023, TMDA collected and tested 41 ordinary cigarette samples from the market and all of them (100% passed as shown in Table 50 below.

Table No. 50: Ordinary cigarttes samples tested and results 2022/2023

Year	Tobacco products analysis		
	Tested	Pass	Fail
2022/23	41	41	0
Total	**41**	**41**	**0**

6.6 Microbiology Analysis

Microbiology section operates at the main laboratory in Dar es Salaam and at the Lake Zone laboratory in Mwanza. It is responsible for microbiological analyses of samples. it has been in existence since the establishment of the quality control laboratory during the tenure of the then Pharmacy Board. The analytical parameters performed were part of the tests carried out for physico-chemical or medical devices samples. Hence, the number of samples indicated in table 34 and 35 above include microbiological testing.

Over the years the microbiology laboratory evolved from ordinary laboratory to a state of art laboratoryl. The Laboratory has acquired sophisticated equipment and installed sterile room for analysis of sterile products.

6.7 Laboratory Quality Management System and Certification status

Since 2009 TMDA laboratory has been implementing quality management system as per international standards for testing laboratories in order to ensure accuracy, reliability and timely release of analytical results for regulatory decisions and customer use. On the 17th January 2011, the laboratory under TFDA, became the fourth laboratory owned by a regulatory authority in Africa to attain WHO prequalification status. The status meant the laboratory met international standards for chemical testing of medicines, hence, could be used by United Nations agencies and other national regulatory authorities.

This demonstrated the laboratory's competence in generating reliable analytical results to support regulatory decision-making in the country and beyond.

On the 12th September, 2012 TFDA food laboratory attained Accreditation status based on ISO/IEC 17025:2005. On the 19th November, 2021, under TMDA, the laboratory maintained the WHO prequalification status after WHO inspection and Microbiology laboratory became WHO prequalified

6.8 Other Services Offered by TMDA Laboratory

Apart from testing samples for regulatory purposes, the laboratory also tests samples of regulated and non-regulated products submitted by different customers. Testing of non-regulated products was legalized in the Tanzania Medicines and Medical Devices (Laboratory Analysis of Medical and Non-Medical Products) Regulations, 2021. In addition, it conducts training on various areas of laboratory techniques for analysis of products to internal analysts and other analysts from national and international institutions. Types and training offered and their respective costs are provided in the TMDA Fees and Charges Regulations, 2021.

Some of the national regulatory authorities in Africa that have benefited from the testing and training services of by the Quality Control Laboratory during the 20 years of existence include those from Namibia, Rwanda, Botswana, Zanzibar, Mozambique, Lesotho, Ethiopia, Burundi, Kenya (MEDS

CHAPTER - 7

Quality Management Systems

7.1 Introduction

This chapter provides an overview of TMDA's Quality Management System (QMS), highlighting its development, certification history, continuous improvement efforts, and documentation in alignment with ISO 9001:2015 requirements.

TMDA consistently demonstrates its commitment to provide quality services that meet customer expectations and regulatory standards by implementing the principles of Quality Management System (QMS) as stipulated in the ISO 9001:2015 Quality Management Systems - Requirements.

This Unit since then was led by the following heads;

1. Mr. Baran H. Sillo 2005 - 2008
2. Mr. Didas N. Mutabingwa 2008 - 2017
3. Mr. Sunday Kisoma 2017 - 2019
4. Mrs. Grace M. Shimwela 2019 to date

TMDA's Quality Management system was first certified to ISO 9001: 2008 in the year 2009 and later recertified to ISO 9001:2015 in 2017. Since then, the systems have been consistently maintained and enhanced by continuous improvement. The systems are subjected to regular assessment, audits and management reviews to ensure sustained compliance to the standards . Comprehensive details of TMDA's Quality Management System are documented in the Quality Manual which outlines the Quality Policy Statement, Mission Vision and Quality Objectives among other key elements.

To ensure consistent provision of quality services TMDA implements a risk management system in accordance with National and International Guidelines to mitigate risks that may affect achievement of its objectives set out in the Strategic Plan. The Authority developed Risk Management Framework, Fraud Risk Management Framework and Business Continuity Plan (BCP) as guiding tools to address risks and respond to disasters that may impede performance and TMDA's ability to deliver its services.

Through its implementation of the quality management principles as stipulated in ISO 9001:2015 and risk management framework, TMDA has achieved notable milestones which include the following: -

- Enhanced customer satisfaction.
- Increased efficiency, productivity and profit.
- Improved internal management and decision making.
- Improved credibility and image.
- Global recognition as the first African Country to achieve WHO - Maturity Level 3 for its competence in regulation of medicines.
- Established continuous improvement culture.

7.2 Quality Management Policy

TMDA is committed to provide quality services in response to customer needs and expectations. It strives to balance the interests of its stakeholders without compromising quality, safety and effectiveness or performance of medicines, medical devices and diagnostics. Furthermore minimizing the harmful effects of tobacco products by managing the Authority with utmost professionalism. TMDA commits itself to comply with requirements of the ISO 9001:2015 standard and continuously improve its performance of the Quality and Risk Management Systems. It is committed to provide and manage resources for continuous improvement of its services to ensure customer satisfaction".

7.3 Risk Management Policy

TMDA is committed to provide resources for implementation and continuous improvement of risk management activities in order to achieve strategic objectives. Management has integrated risk management practices at all levels of operation so as to provide reasonable assurance in implementation of Regulatory functions Risks and opportunities are identified in a systematic manner using principles set out in the guidelines. Implementation is continuously monitored and reviewed to mitigate risks and pursue opportunities in delivering regulatory services while protecting and promoting public health.

7.4 Fraud Risk Management Policy

TMDA is committed to, and places high priority on managing its fraud risks strategically and systematically. TMDA's fraud risk management strategy adopts a 'tone at the top' approach. The Authority maintains robust control mechanisms to prevent and detect fraud. The effectiveness of controls are subjected to periodic reviews by the Authority Internal Auditors.

7.5 Attainment of ISO 9001

The introduction of QMS at TMDA was a result of self-assessment of its performance in 2005 which was done under the guidance of the Quality Assurance Officer.

The QMS system was implemented sequentially as follows:

- Conducting training to all staff on QMS principle;
- Developing a road map for QMS implementation;
- Developing quality policy;
- Developing quality manual;
- Development and documentation of processes;
- Developing Standard Operating Procedures (SOPs) for all services in all departments;
- Implementation of the system including conducting training of internal quality auditors during which 16 were trained and
- Establishing systems for conducting internal audits to identify gaps and rectify nonconformances.

In order to improve efficiency in implementing QMS, review of the TMDA organization structure was done in 2008 to create QMS department. In the period of 20 years, a total of 30 processes and 105 SOPs were developed.


TRUSTED FOR OUR STANDARDS

IAF

ACM

Certificate of Registration

This is to certify that the Quality Management System of

Tanzania Medicines and Medical Devices Authority
Mabibo External
P.O Box 77150
Dar es Salaam
Tanzania

Has been independently assessed and is compliant with the requirements of:

ISO 9001:2015

For the following scope of activities:

Regulatory body for the inspection, enforcement, testing, analysis, evaluation, and registration of medicines, medical devices and diagnostics; including companies importing, distributing and manufacturing medicines, medical devices and diagnostics in Tanzania. Also, clinical trials control & vigilance of regulated products.

Certificate Number: 0010170

Date of initial registration: 25th August 2009
Date of this certificate: 16th July 2021
Certificate expiry: 24th August 2024

Authorised Signatory

UKAS

Following successful implementation of QMS, in 2007 TMDA applied to ACM Limited (UK) for accreditation. After the audits, TMDA was accredited the ISO 9001:2008 after fulfilling the requirements and awarded an ISO certificate on 24th July 2009.

Since the ISO certificate is valid for three years, TMDA's quality systems were re -audited in May 2012 and the Authority retained the ISO certificate for three years.

TMDA aims to retain certification by continuously improving its service delivery and ensuring that the requirements of the QMS are met all the time.

The TMDA Quality Control Laboratory complies with the WHO Good Practices for Pharmaceutical Quality Control Laboratories. It is among the fifty-five (55) quality control laboratories having international recognition as competent laboratory for testing pharmaceutical products after being WHO prequalified in the year 2011.

7.6 Implementation of ISO 17025

The ISO/IEC 17025:2005 standard which provides for quality requirements for laboratories started to be implemented by TMDA in 2005. This came after the assessment of the TMDA laboratory conducted in 2004 and 2005 to identify service delivery gaps.

The outcome of the two assessments led to to introduction of robust measures aimed to enable the laboratory to offer reliable services to TMDA clients. Among the key strategies adopted was the implementation of ISO/IEC 17025:2005. The implementation of these QMS standards, involved the following steps:

- Developing a roadmap for implementing ISO/IEC 17025:2005
- Training of laboratory staff on QMS and implementation of ISO/IEC 17025:2005;
- Developing laboratory specific SOPs for all departments;
- Developing laboratory quality policy; and
- Developing laboratory quality manual.

For the implementation of ISO/ IEC 17025:2005, the laboratory has developed 22 SoPs.

CHAPTER - 8

Corporate and Legal Services

8.1 Introduction

This chapter outlines the roles and functions of the Corporate and Legal Services Unit, focusing on its contribution to TMDA's governance, compliance, and administrative support.

Before establishment of independent Legal Services Unit in 2005, TMDA legal services were provided directly by the office of Attorney General (OAG). Following the need to have close oversight and strengthening of corporate and legal services to its regulatory functions, a standalone unit was formally established in 2005.

The Unit was led by a Legal Counsel, Mr. Iskari Chotusinga Fute (2005 to 2023) and became housed under the office of the Director General.

The main function of the unit was to advise the Director General on key corporate and legal functions of the Authority on regulatory framework for food and medical products as was expounded by the then Tanzania Food, Drugs and Cosmetics Act, Cap 219. In a nutshell, the corporate functions which needed legal services were in two major folds as follows:

a) Food and food Products Regulations

The Unit was involved on daily and routine executions of duties related to the seven (7) statutory functions to regulate food products including preparing relevant regulations hinged on the following main areas: -

- Marketing Authorization or approvals of food products
- Licensing of Manufacturers, Importers, Exporters, Wholesalers and Distributors
- Surveillance and Safety Monitoring of foodborne diseases
- Regulatory Inspection and Enforcement
- Control of Promotion and Advertisement of Food Products
- Quality Control Laboratory
- Classification and Control of unfit Food Products

b) Medical Products Regulations

This area is the second part where the Unit was daily and fully involved in the oversight of compliance to laid down guidelines and drafting respective regulations. The eight (8) major functions for regulation of medical products are briefly outlined below: -

- Marketing Authorization or approvals of medical products
- Licensing of Manufacturers, Importers, Exporters, Wholesalers and Distributors
- Post-Marketing Surveillance and Safety Monitoring
- Regulatory Inspection and Enforcement
- Control of Clinical Trials of Medical Products
- Control of Promotion and Advertisement of Medical Products
- Quality Control Laboratory
- Scheduling, Classification and Control of Substandard and Falsified Medical Products

Therefore since 2005 to date the specific services of the unit has predominantly been on drafting of legal documents, handling of Ministerial Advisory Board, coordinating and handling of

litigations, drafting and vetting of contracts, coordinating investigations for violation under the Act, providing legal opinion and guidance on diverse matters as well as liaison with the office of Attorney General Chambers, Chief Parliamentary Draftsman, Solicitor General, National Prosecution Services, Police Force, Judiciary and other law enforcement agents at national, regional and international page.

8.2 Acts and Regulations

As alluded earlier, the major legal framework for the comprehensive regulation of food and medical products were based on the Tanzania Food, Drugs and Cosmetics Act, Cap 219 and its key technical regulations to support the mandatory functions of the Agency and the Executive Agency Act, Cap 245. Both legislations provided the legal status and framework of TMDA as an executive Agency. The enactment of the TMDA legal framework and its regulations may trace its history way back from 1937.

a) Enactment of the Act

The legislations for control of quality and food safety together with medical products have undergone several transitions since 1937 to date. It started from the Narcotic Control Medicine Act 1937, the Food and Drug Ordinance Cap, 93 which became applicable even after independence, the Pharmacy and Poisons Ordinance, Cap 416, which established the Drug Board, the Meat Hygiene Ordinance. Cap 432 passed in 1961, the Diary Industry Act, 1966, the Fisheries Act, 1970, the Bee Keeping Act, Cap 224 and the Standards Act, 1975. All these laws were administered by various Ministries until 1978.

In strengthening the legislations for regulation of Food and Medicine, two different laws became enacted in 1978 namely, The Pharmacy and Poison Act, 1978 which aimed at enhancing quality control of pharmaceuticals and professionals administered by the Pharmacy Board and the Food (Control of quality) Act, 1978, aimed at regulating the quality and safety of food in the country administered by the National Food Control Commission (NFCC) were enacted repealing and replacing the Food and Drug Ordinance Cap, 93.

In 2003 the Tanzania Food, Drugs and Cosmetics Act, Cap 219 which established TFDA with effect from 1st of July 2003 was enacted abolishing the former two legislations of 1978. Food control, drugs, cosmetics and medical devices were then placed under one Act. The objective of the Act was to set up an effective system for control of safety, quality

and effectiveness of food, medicine, cosmetics and medical devices with a view to protect the health of the people. This Act became part of key milestones in the implementation of the Executive Agency Act, Cap 245 particularly when focusing to the Public Service Reform Program (PSRP) of 1996 that aimed at improving service delivery levels, revenue collections; reduce administrative expenses by using qualified staff, staff competency and enhancing better achievement of public services.

However, it is imperative to note that, the two major legislations for the past 20 years have under gone two (2) significant changes as follows:

b) The Executive Agencies Act, Cap 245

From 1997 to 2009, TMDA as an Executive Agency under this Act was governed by the Ministerial Advisory Boards (MAB) chaired by Permanent Secretary from the Ministry responsible for health. Members of the MAB were all ex-officio that is representing specified institutions not accountable to their personal capacities while the Directors of Human Resources of the Ministry being Secretaries to the Boards. This type of governance was found challenging as MAB became not effective and was against the rules of governance to Executive Agencies that intended the Ministries to place their eyes on and hands off approach.

That being the case, in 2009 the Parliament passed a major amendment to the Executive Agencies Act, Cap 245 through the Executive Agencies (Amendment) Act No 13 of 2009. The Act abolished the statutory appointment of the designated chairperson and members of MAB including the Secretary to the Board.

The Amendment Act, among others brought a new and independent MAB whose content and context might be worthy to mention as a success to the governance of TMDA as herein overseen by the Legal Services Unit.

The composition of MAB became restricted in that Chief Executive Officers from Government, persons holding political post or a director and head of any department under which the Authority is established, were not allowed to be appointed as members of MAB. Substantively, the composition of the Board required the Chairperson to be appointed by the Minister together with other members not being more than five (5). The Secretary of the Board became the Director General who replaced the Directors of Human Resource of the Ministry.

For members to be appointed, they need to be well vested with the matters or functions in respect of which TMDA was established. The Chairperson should be appointed from outside the Ministry under which TMDA was established. Other members include:

i. An officer of a position of Assistant Director or above from the Ministry under which the Authority was established as an ex-officio member; and

ii. One member appointed from persons who are not in the public service as a representative of the interests of TMDA's customers.

The roles of MAB continued to be of mainly advisory to Minister on:

1) The development and maintenance of a strategic framework;

2) The objectives of the Authority;

3) The acceptability of the Chief Executive's Plans and associated budgets;

4) The setting of priorities and annual performance targets for the Authority;

5) The Authority Annual Reports and Accounts;

6) The evaluation of the Authority performance;

7) The salaries, wages and allowances of employees of the Authority;

8) Any other matter intended, aimed or geared towards the promotion and furtherance of the objectives and functions of the Act.

Apart from advising the Minister, MAB is also responsible for ensuring that a comprehensive system of internal control policies and procedures are operative for compliance with sound corporate governance principles. MAB meetings are conducted four times a year while recognising the importance of integrity, transparency and accountability.

c) The Tanzania Food, Drugs and Cosmetics Act, Cap 219

The Tanzania Medicines and Medical Devices Act, Cap 219 according to the Government Notice Number 160 of 2003, came into force on the 1st of July, 2003. This Act also has undergone a major turning point in 2019 where two major functions to regulate food products and cosmetics were transferred to the Tanzania Bureau of Standards (TBS).

It is paramount to mention that when the Finance Act No. 18 of 2019 was passed by the Parliament in 2019, the whole legal framework under the Act that provided for mandate to regulate

food and cosmetics were repealed and shifted to the Standards Act, Cap 30 proving same mandate to be executed by Tanzania Bureau of Standards-TBS from 1st of July 2019. Based on this amendment, the name of the Authority Tanzania Food and Drugs Authority –TFDA changed to Tanzania Medicines and Medical Devices Authority –TMDA. Consequently, all the technical regulations prepared by the former TFDA under the oversight of the Legal Service Unit regarding food and cosmetics were inherited by TBS for better functioning of food safety and cosmetics control.

d) Technical Regulations

One of the services that are offered by the Unit since 2005 has been the drafting of various legal documents and regulations. Until the year 2024, the Unit had significantly drafted and administered a total of 43 regulations. These regulations and documents were drafted after being satisfied that other related laws were not offended. Therefore, most of the drafting needed an extensive synoptic reference in order to avoid noncompliance with the existing laws. The other aspect in drafting of regulations and legal documents was the follow up of the implementation of the contents of the regulations or publication in the government Gazette. The Unit ensured that the regulations and other legal documents were fully disseminated before use to make them fully operational.

since 2005 to 2018 and 2024, in the light of the WHO – Global Benchmarking Tool (WHO-GBT) version VI and other relevant requirements particularly for having all the necessary regulations for all essential regulatory functions for medical products by TMDA, the Unit had drafted and published 27 regulations with at least one for each function. See Table A.

The 18 years of the Unit, its aggressiveness to ensure that necessary regulations are in place within the regulatory framework, the Unit became the 1st one to provide legal services to the National Medicine Regulatory Agency (NMRA) with Maturity Level 3 in Africa in 2018. It was later on benchmarked and followed by four (4) NMRAs Legal Services Units of Ghana, Egypt, South Africa and Nigeria.

Table Table No. 51: List of 27 regulations for medical products

No	Name of the regulations
1	Pharmaceutical and poisons (List of Human Drugs, Human Notified Drugs and Veterinary Drugs) Notification Orders, 2001
2	The Tanzania Medicines and Medical Devices (Control of Drug and herbal Drugs Promotion) Regulation 2010 GN. 159
3	Tanzania Food, Drugs and Cosmetics (Control of cosmetics) regulations, 2010
4	The Tanzania Medicines and Medical Devices (Clinical Trial Control) GN. 53 Regulation, 2013
5	The Tanzania Medicines and Medical Devices (Fees and Charges) GN. 464 Regulation, 2015 [Revoked]
6	The Tanzania Medicines and Medical Devices (Scheduling of Medicine) GN. 63 Regulation, 2015
7	The Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulation, 2015 GN. 315
8	The Tanzania Medicines and Medical Devices (The Recall, Handling and Disposal of Unfit Medicines and Cosmetics) Regulations, 2015 GN. 313
9	The Tanzania Medicines and Medical Devices (Registration of Premises, Importation and Exportation of Pharmaceutical Products and Raw Materials) Regulation 2015 GN. 312
10	The Tanzania Medicines and Medical Devices (Delegation of Powers and Functions) 2015 GN. 476,
11	The Tanzania Medicines and Medical Devices (Registration of Medicinal Product) Regulation 2015 GN. 314,
12	The Tanzania Medicines and Medical Devices (List of Registered Human Medicinal Product Veterinary Pharmaceutical and Medical Devices) Regulation, 2016 GN. 283
13	The Tanzania Medicines and Medical Devices (appointment of Inspectors) 2016 GN No. 275,
14	The Tanzania Medicines and Medical Devices (appointment of Analysts) 2016 GN. 270,
15	The Tanzania Medicines and Medical Devices (Delegation of Powers and Functions) 2017 GN. 19
16	The Tanzania Medicines and Devices (Orphan Drugs) Regulation, 2018 GN. 412
17	The Tanzania Medicines and Medical Devices (Good Manufacturing Practice Enforcement) Regulations, , 2018 GN. 295
18	The Tanzania Medicines and Medical Devices (Pharmacovigilance) Regulation, 2018 GN. 296
19	The Tanzania Medicines and Medical Devices (List of Registered Human, Veterinary and Withdrawn Medicinal Products), 2018 GN.160
20	The Tanzania Medicines and Medical Devices (List of Registered and Cancelled Medicines) 2020 GN. 187,
21	The Tanzania Medicines and Medical Devices (Appointment of Inspectors) Order, 2020 GN 257
22	The Tanzania Medicines and Medical Devices (Appointment of Inspectors) Order, 2020 GN. No. 191

23	The Tanzania Medicines and Medical Devices (Fees and Charges) Regulations, 2021 GN NO 686
24	The Tanzania Medicines and Medical Devices (Laboratory Analysis of Medical and Related Products) Regulations), 2021 GN No 686
25	The Tanzania Medicines and Medical Devices (Fees and Charges Amendment) Regulations, 2023 GN No 5
26	Tanzania Medicines and Medical Devices (Good Storage and Distribution Practices) Regulations, 2021. GN. 363
27	The Tanzania Medicines and Medical Devices (Laboratory Analysis of Medical and Related Products Amendment) Regulations), 2023 GN No 1

8.3 Law enforcement and Engagement of State Attorneys

The Legal service Unit at all material time, remained due and flexible to provide solid legal guidance to all actions to be taken during inspection and enforcement. The active and timely response of the unit to inspectors achieved holistic, ethical and sustainable actions to violators that did not negatively impact the reputations of the Authority.

The unit has been holding immense significance participation in enforcement of the law due to its role in shaping societal order, upholding justice, and providing framework governance for inspection of premises and regulatory actions taken to protect public health through routine in-house training to law enforcers.

The Legal Service unit collaborates with State Attorneys who either prosecute or handle TMDA related cases. That refers to lawyers employed under the Office of the Attorney General, Solicitor General or Director of Public Prosecution or law officers employed in the Public Service. This is because cases upon which the TMDA as a government agency is a party must be reported to the Office of the Attorney General or in the case of criminal cases, to the National Prosecution Office.

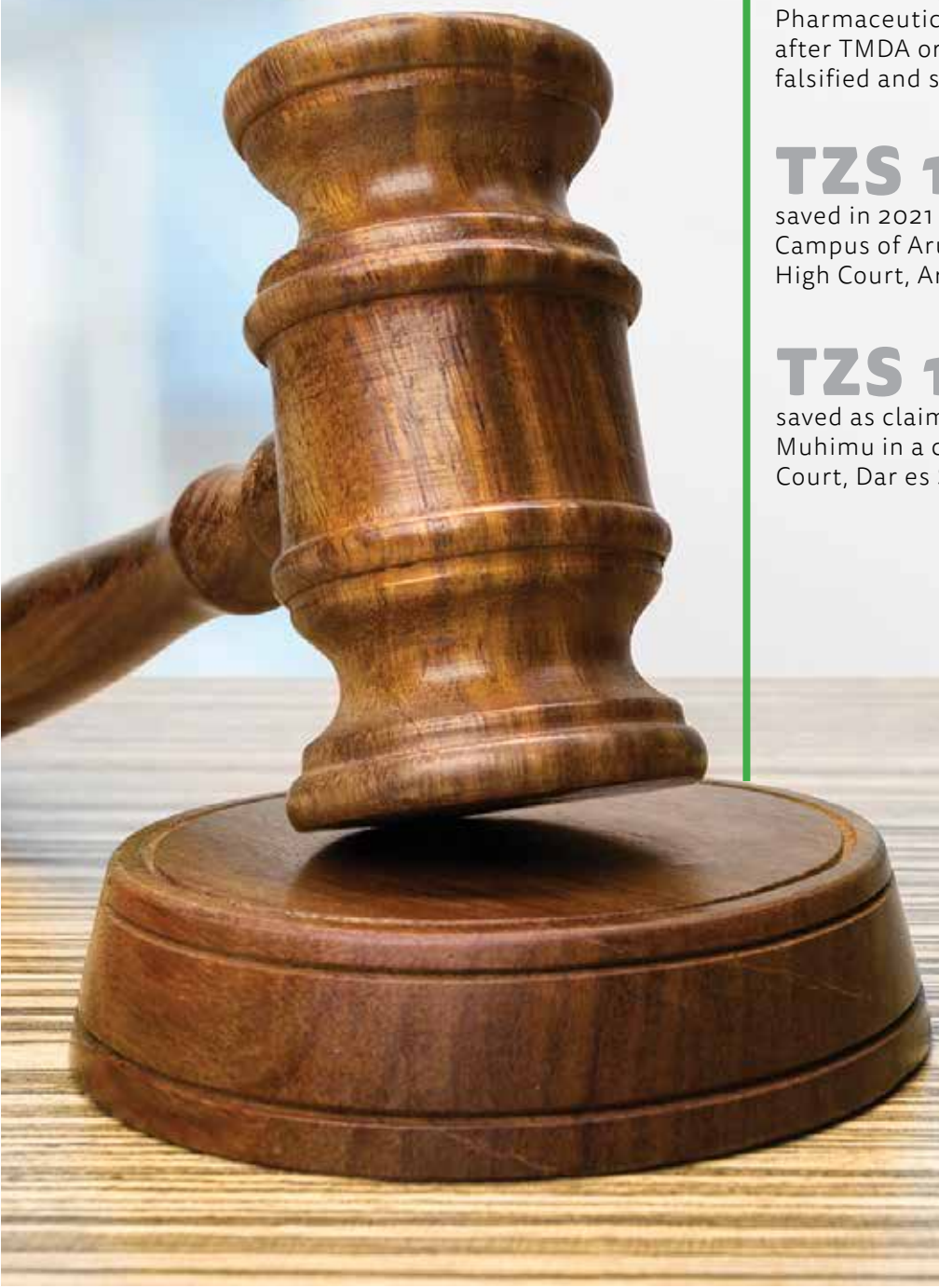
8.4 Case management

TMDA through the Legal Service Unit, developed a tailor-made database improved from time to time for case management. The data base provides for ongoing investigations as received from Zone Managers or inspectors who keep records of investigation or case filed during their routine inspection. The data base shows the name of the accused person, offence, Investigation Registry number and particulars of the offence, Police station and whether closed or pending.

For court cases the particulars include the name and number of the case, Court, status and offence charged, prosecution or defense case.

TZS 20 billions

The amount of money saved per annum from loss that could have been incurred



TZS 800 million

Legal Service Unit helped save from a high court case at Dar es Salaam. When the Authority was sued by one Sylvester Venance Kwembe and Yanglin Pharmaceuticals Ltd

TZS 210 billion

saved in 2022, which was to be paid to Tanzania Pharmaceuticals Industries-TPI as damages after TMDA ordered suspension of production of falsified and substandard medical products

TZS 100 million

saved in 2021 as damages claim by Tarangire Campus of Arusha through a case filled at the High Court, Arusha

TZS 100 million

saved as claimed by vendors of Maduka ya Dawa Muhimu in a case which was filed at the High Court, Dar es Salaam

Similarly for closed court cases the data base includes name and number of the case, offence charged and the verdict pronounced by court or where applicable disposition of exhibits if any.

8.5 Litigation and Court Proceedings

Since 2005, the Legal Service Unit has been devoted to defend the Authority when it was sued in various cases for monetary compensation. It is worthy to mention few significant cases whereby in 2008, the legal Service Unit worn a High court case at Dar es Salaam registry and saved a total of TZS 800,000,000 when the Authority was sued by one Sylvester Venance Kwembe and Yanglin Pharmaceuticals Ltd claiming to be paid damages for confiscated medical products.

Similarly, in 2022, the unit saved a total of TZS 210 billion which were claimed to be paid as damage to Tanzania Pharmaceuticals Industries-TPI before the High Court of Tanzania at Dar es Salaam Registry for suit for loss arising from TMDA order to suspend the production of falsified and substandard medical products.

Other remarkable cases for which the Unit saved money were TZS 100 million claimed as damage by Tarangire Campus of Arusha through a case filled at the High Court, Arusha registry in 2021, TZS 100 millions claimed by vendors of Maduka ya Dawa Muhimu in Dar es Salam which was filed at the High Court, Dar es Salaam registry, TZS 400,000,000 arising from tender for supply of office furniture (DSM office building) in 2008 and TZS 374,000,000 (Dodoma Office) in 2023 arising from tender for provision of catering services for TMDA as compensations from appeals bidders filed before the Public Procurement Appleals Authority.

In a nut shell it is worthy to note and underscore the silent role of the Unit in saving contigency money to the Authority where by a minimum of TZS 300 billions have been saved from being paid to litigants for the period of 15 years counted from 2008 to 2023. This amount is significant and a milestone to the Authority worthy to be proud of. When it is computed and apportioned consecutively for 15 years, the Unit has been saving TZS 20 billions per annum from loss that could have been incurred, an amount which is more than 50% of the operational budget for TMDA for the past 15 years.

CHAPTER - 9

Procurement of Goods/ Services and Works

9.1 Introduction

This chapter highlights the evolution and strategic importance of the Procurement Management Unit (PMU) in supporting TMDA's operations, infrastructure development, and commitment to efficient and accountable resources management.

Procurement has been a cornerstone in the institutional development of the TMDA. Over the two decades from 2003 to 2023, the Procurement Management Unit (PMU) played a critical role in ensuring that the Authority was adequately equipped with the infrastructure, goods, and services necessary to deliver on its regulatory mandate. The growth

of procurement activities not only mirrored the expansion of TMDA's services but also demonstrated the Authority's commitment to efficiency, accountability, and good governance in the management of public resources.

From its establishment, the Procurement Management Unit was guided by leaders whose stewardship ensured compliance with evolving procurement regulations and standards. Between 2003 and 2023, the Unit was headed by three Managers as shown in table no. 52.

Table No. 52: Procurement Management Unit Manager's between 2003-2023

Section Name	Manager's Name	Period
Procurement Section	Elizabeth Maleto	2003 - 2006
Procurement Management Unit	Anael Kaale	2007 - 2022
Procurement management Unit	Ally Nampair	2022 – 2023

TZS 1.45 B
Total procurement amount in 2003

TZS 10.87 B
Total procurement amount by 2023

Year 2018
The adoption of the Tanzania National Electronic Procurement System (TANePS) further strengthened transparency, accountability, and efficiency

Their leadership provided strategic direction, institutional discipline, and a governance framework that sustained accountability while enabling significant growth in procurement volume and complexity.

The volume and value of procurement activities expanded remarkably over the 20-year period. In 2003, total procurement amounted to Tsh 1.45 billion, while by 2023 the figure had risen to Tsh 10.87 billion, underscoring both the expansion of TMDA's operations and the increasing scope of regulatory services.

This growth was not merely numerical; it reflected an evolution in governance systems. Initially conducted manually, procurement processes transitioned into electronic systems following directives from the Public Procurement Regulatory Authority (PPRA) in 2005. The adoption of the Tanzania National Electronic Procurement System (TANePS) in 2018 further strengthened transparency, accountability, and efficiency. This digital transformation enabled TMDA to consistently achieve unqualified audit

reports from the Controller and Auditor General (CAG), a testament to sound governance and compliance with national procurement regulations.

Table No. 53: Value and number of contracts signed between 2003 - 2023

FINANCIAL YEAR	AMOUNT IN TSH	CONTRACTS SIGNED
2003/2004 -2012/13	1,453,069,680.26	26
2013/2014	1,255,391,329.95	18
2014/2015	6,422,047,437.00	55
2015/2016	8,922,952,829.34	52
2016/2017	4,854,654,111.41	28
2017/2018	9,593,569,216.97	48
2018/2019	11,632,937,000.00	46
2019/2020	10,137,856,459.69	36
2020/2021	3,393,363,396.67	31
2021/2022	4,897,643,760	59
2022/2023	4,655,529,014.62	56

The significant raise in procurement of works, goods and services signified growth and expansion of TMDA regulatory services.

On the other hand procurement of works, goods and services has evolved over the period of 20 years, from Manual operations to electronic system owing to Public Procurement Regulatory Authority (PPRA) directives since May 2005. It replaced the Central Tender Board (CTB), which was established under the Public Procurement Act, 2001.

9.2 Tender Boards

The effectiveness of the Procurement Unit has also been anchored in the oversight and guidance of the Tender Board, comprising seven members per tenure. Since 2003, there have been six Boards, each contributing to governance, accountability, and fairness in procurement decisions.

Chairs and members such as Mr. Legu Mhangwa, Ms. Charys Ugullum, Dr. Ngendabanka, Mr. Raymond Wigenge, and Dr. Dastan Hipolite exemplified professionalism and integrity, ensuring that procurement processes adhered to established laws while meeting the operational needs of TMDA. Their stewardship-maintained confidence in the Authority's use of public funds and reinforced the principles of good governance. tender board members between 2003-2023 were as mentioned in Table No. 54 - 58

Table No. 54: Tender Board Members 2003-2008

S/N	NAME	TITLE
1	Legu Mhangwa	Chairman
2	Olympia Kowero	Member
3	Charys Ugullum	Member
4	Iskari Fute	Member
5	Sadi Kajuna	Member
6	Octavius Soi	Member
7	Dr. S.S Ngendabanka	Member

Table No. 55: Tender Board Members 2008-2010

S/N	NAME	TITLE
1	Hiiti Sillo	Chairman
2	Raymond Wigenge	Member
3	Charys Ugullum	Member
4	Iskari Fute	Member
5	Sadi Kajuna	Member
6	Hery Mkunda	Member
7	Dr. S.S Ngendabanka	Member

Table No. 56: Tender Board Members 2010-2012

S/N	NAME	TITLE
1	Charys Ugullum	Chairman
2	Raymond Wigenge	Member
3	Hery Mkunda	Member
4	Iskari Fute	Member
5	Sadi Kajuna	Member
6	Adam Fimbo	Member
7	Dr. S.S Ngendabanka	Member

Table No. 57: Tender Board Members 2012-2014

S/N	NAME	TITLE
1	Raymond Wigenge	Chairman
2	Dr. Dastan Hipolite	Member
3	Hery Mkunda	Member
4	Iskari Fute	Member
5	Sadi Kajuna	Member
6	Akida Khea	Member
7	Dr. S.S. Ngendabanka	Member

Table No.58 Tender Board Members 2014 - 2016

S/N	NAME	TITLE
1	Adam M. Fimbo	Chairman
2	Dr. Danstan Shewiyo	Member
3	Iskari Fute	Member
4	Kandida Shirima	Member
5	Herry Mkunda	Member
6	CPA Sadi Kajuna	Member
7	Dr. Yonah H. Mwalwisi	Member

Table No. 59: Tender Board Members 2017-2020

S/N	NAME	TITLE
1	Dr. Dastan Hipolite	Chairman
2	Siya Augustine	Member
3	Dr. Yonah H. Mwalwisi	Member
4	Donesta Simon	Member
5	Paschal Makoye	Member
6	Chrispin Severe	Member
7	Kissa Mwamwitwa	Member

Table 60 Tender Board Members 2021 - 2023

S/N	NAME	TITLE
1	Dr. Danstan H. Shewiyo	Chairman
2	Chrispin Severe	Member
3	Dr. Yonah H. Mwalwisi	Member
4	Dr. Kissa Mwamwitwa	Member
5	CPA Adam Kimetelo	Member
6	Siya Augustine	Member
7	Adv. Martha Malle	Member

The evolution of procurement practices within TMDA reflects the broader story of institutional growth and resilience. Each milestone from manual systems to TANePS adoption, from modest budgets to multibillion-shilling operations was driven by the dedication of procurement professionals and the oversight of governance structures.

By ensuring that the Authority had access to timely, high-quality goods, works, and services timely, the Procurement Management Unit has directly supported TMDA's ability to regulate medicines, medical devices, diagnostics, and food safety. Its role in institutional strengthening cannot be overstated: procurement became both an enabler of service delivery and a guardian of public accountability.

9.3 Bidding Process and Tender Acquisition

TMDA that intends to commence competitive tendering proceedings prepare a tender notice inviting tenderers to submit priced offers for the goods, works, services or disposal of assets by tender through National Electronic Systems known as NeST.

The Procurement Management Unit shall submit to the Director General or tender board the invitation and the tender document for comments and approval, and shall, prior to publication of the invitation and issue of the tender document, incorporate any agreed amendments.

Invitations issued without the approval of Director General or the tender board shall not be considered valid and in such cases, TMDA shall be required to issue new invitations for tenders.

TMDA shall immediately after the publication of the tender notice, issue tender documents to all tenderers who have responded to the tender notice in accordance with the procedures and requirement specified in the invitation to tender.

The Procurement Management Unit shall, prior to submission of the documents to the Director General or tender board for approval, ensure that the time allowed for preparation of tenders is based on the magnitude and complexity of the intended procurement.

The tender period shall be approved by the Director General or tender board and shall be prescribed in the invitation to tender. TMDA shall prescribe the specific date and time for the submission of tenders. A potential tenderer shall, in the prescribed time and manner, submit the tender to the TMDA.

Tender shall be sealed by a digital signature during submission. The Procurement Management Unit shall coordinate opening of the tenders in accordance with the Public Procurement Regulations of 2024.

9.4 Tender Evaluation and Award

The Director General shall form a tender evaluation committee comprising of three or five members. In exceptional circumstances, the Director General may form an evaluation committee of more than five members depending on the value and complexity of the procurement provided there are justifiable reasons for such increase and an odd number of members is maintained.

The tender evaluation committee shall evaluate opened tenders on a common basis in order to determine the cost or price to TMDA in each tender and permit a comparison to be made between the tenders on the basis of the evaluated costs or prices.

The preliminary examination of the tenders to determine whether-

(a) each tender is substantially responsive to the requirements of the tender documents;

(b) the required securities have been provided;

(c) the documents have been properly signed; and

(d) the tenders are otherwise generally in order.

For the purpose of Public Procurement Regulation of 2024, a tender shall be considered to be substantially responsive if it conforms to all the terms, conditions and specifications of the tender document without material deviation or reservations. Examination, evaluation and comparison of tenders.

All tenders shall be checked for substantial responsiveness to the technical requirements of the tender documents and non-conformity to technical requirements, which amounts to justifiable grounds for rejection of a tenders shall include the following:

(a) failure to tender for the required scope of work as instructed in the tender documents and where such failure has been indicated as unacceptable;

(b) failure to quote for a major item in the package;

(c) failure to meet major technical requirements, such as offering completely different types of equipment or materials from the types specified, plant capacity well below the minimum specified, equipment not able to perform the basic functions for which it is intended; or

(d) presentation of absolutely unrealistic and inadequate implementation plans.

The TMDA's determination of a tender's responsiveness shall be based on the contents of the tender itself without recourse to extrinsic evidence, where a tender is not responsive to the tender document, it shall be rejected by the TMDA and may not subsequently be made responsive by correction or withdrawal of that deviation.

Except where it is otherwise provided in Public Procurement Regulation 162(1) and (2) shall, with minimum variations, apply to procurement conducted by means of request for proposals with consecutive negotiations. Proposals with technical, quality and performance characteristics which meet or exceed the relevant minimum requirements shall be considered to be responsive and the TMDA shall rank each responsive proposal in accordance with the criteria and procedure for evaluating proposals set out in the request for proposals.

The negotiations with the invited tenderer may not result in a procurement contract, the TMDA may terminate the negotiations and shall, thereafter, communicate to the tenderer its decision to terminate the negotiations. In the course of negotiations, TMDA shall not modify the subject matter of the procurement, qualification, or evaluation criterion, including any established minimum requirements, an element of the description of the subject matter of the procurement or term or condition of the procurement contract other than financial aspects of proposals which are subject to the negotiations as specified in the request for proposals.

The award of contract made by Director General and not approved retrospectively shall be valid, and the Director General who approved the award shall be liable as provided in Public Procurement Regulations of 2024.

9.5 Goods and Services Inspections and Acceptance

The Director General shall, in respect of each tender, appoint an inspection and acceptance committee for goods, works or services which shall comprise three members, one from the user department and the others with expertise in procurement matters or the subject matter of the project. Inspection and acceptance of goods shall be completed within the time frame specified in the contract.

9.6 Tender Execution and Contract Management

The Director General shall be responsible for the implementation and management of contracts for The Public Procurement Regulations of 2024.

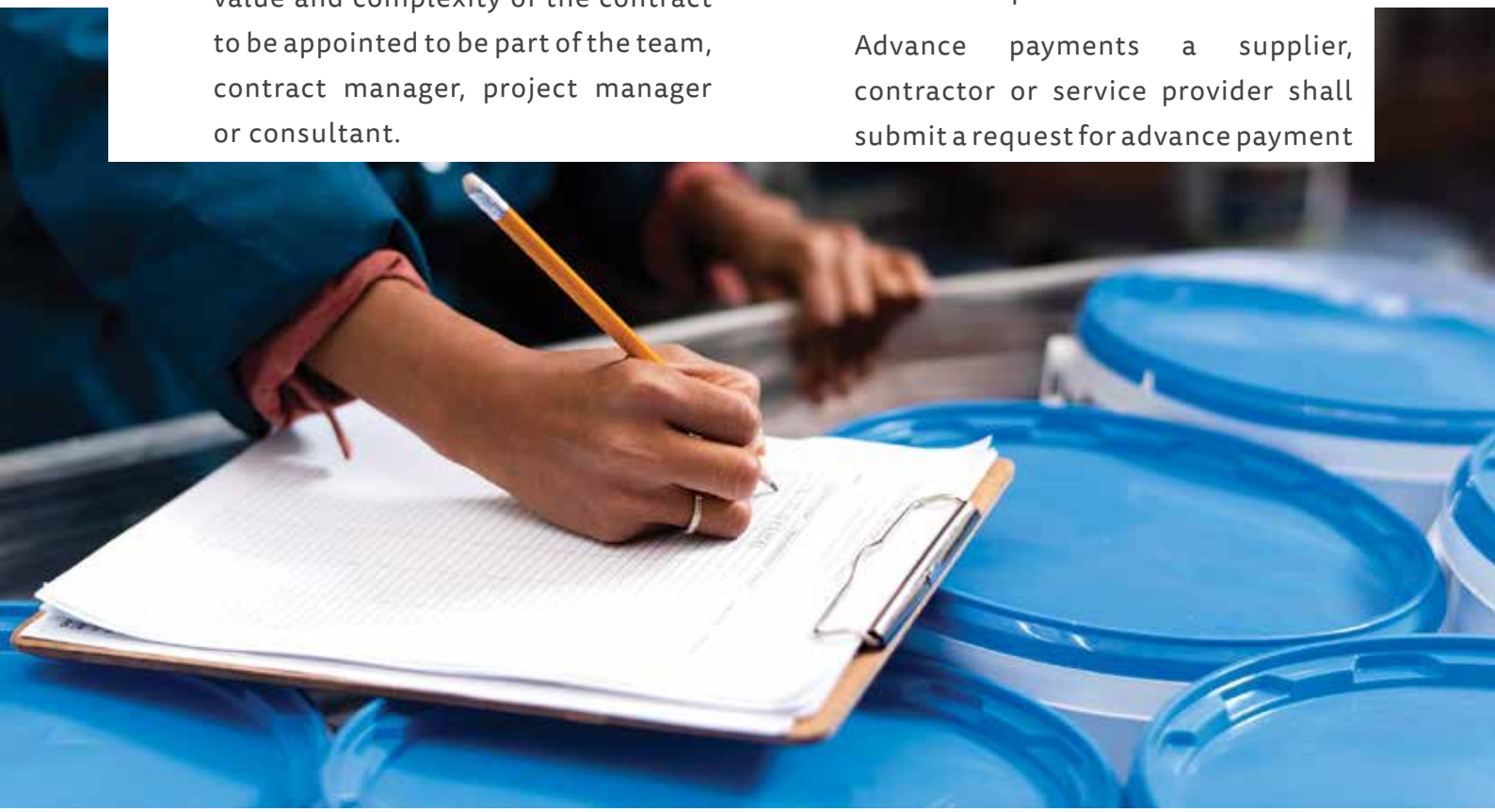
The appointment of contract manager, the Director General shall, for each contract, appoint a contract manager who shall be responsible for ensuring the implementation of the signed contract. The user department shall recommend to the Director General a member of the user department or any other person with appropriate level of expertise and experience, depending on the value and complexity of the contract to be appointed to be part of the team, contract manager, project manager or consultant.

The contract manager may be external to the procuring entity, where the required skills and experience are not available within the TMDA.

The Procurement Management Unit shall submit signed contracts to the user department responsible for overseeing the implementation of the contract.

The Suppliers, contractors or service providers shall ensure that they fulfill all contractual obligations before any payments are made by the TMDA. The supplier, contractor or service provider whose payment request is rejected shall be required to resubmit or rectify the payment request, which shall then be treated as a new request.

Advance payments a supplier, contractor or service provider shall submit a request for advance payment



to the TMDA using the prescribed form provided in the tender documents, if required and specified in the procurement contract.

Subject to section 95 of the Public Procurement Act of 2023, proposals for contract variations, including additions or deductions which are not incidental to the contract andwhich alter the scope or intention of the contract, shall be referred to the accounting officer or the tender board for approval before instructions are issued to the contractor.

TMDA intending to terminate a procurement contract shall, in writing, seek legal advice from the Attorney General. Termination of contract 320. Upon termination of a contract, the Director General shall notify the Authority and the Attorney General within fourteen days from the date of termination, for information and necessary actions.

The contract closure shall involve the following:

(a) ensuring that all goods, services and works have been completed and accepted;

(b) ensuring that all rights, including copyrights, and other intellectual and industrial property rights that were secured during the implementation of the contract are devolved to the ownership of the procuring entity;

(c) ensuring the return to the procuring entity of its assets which were made available to the contractor in the course of execution of the contract and ensuring that they not damaged;

(d) ensuring that all the documentation like maps, blueprints, diagrams, specifications, plans, statistical data, calculations, operational and maintenance manuals and any other documents relevant during the implementation of the contract have been submitted to the procuring entity;

(e) ensuring completion certificate or acceptance certificate for goods supplied is issued;

(f) ensuring that a performance report of the service provider is prepared;

(g) ensuring that all issues which arise during the contract execution have been addressed and that there are no outstanding claims;

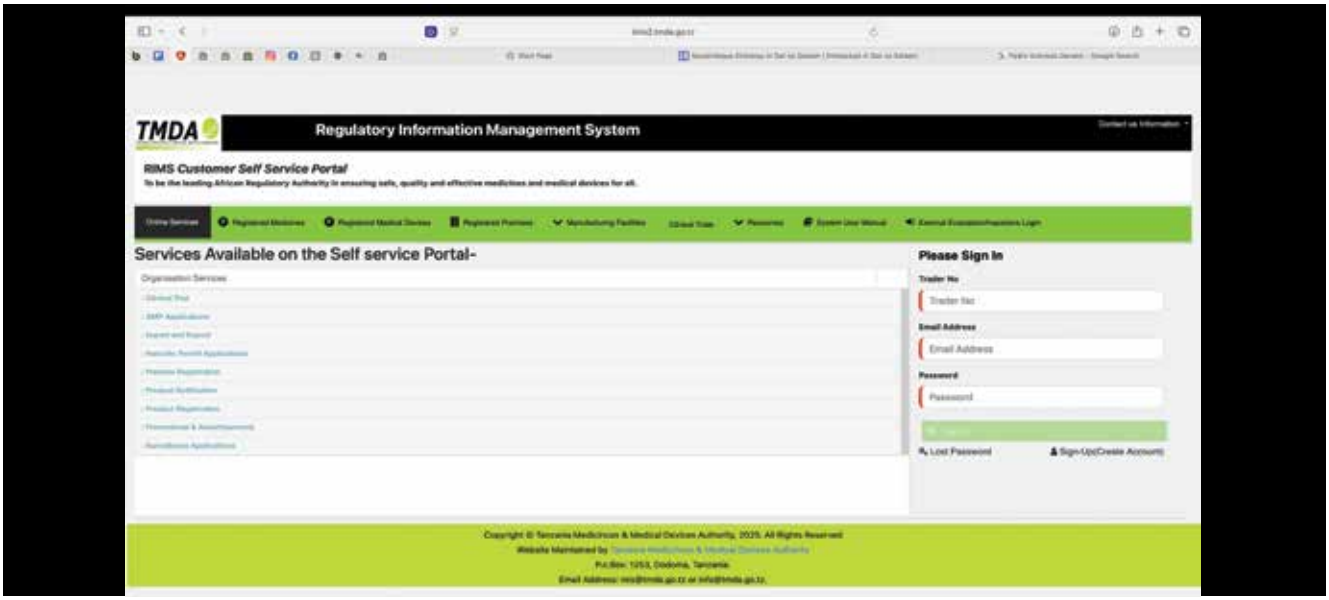
(h) ensuring that all payments have been effected and the performance guarantee has been returned to the supplier, contractor or service provider; and

(i) ensuring that a final project and financial report is prepared.

The contract manager shall submit the final project and financial report to the Director General after contract closure.

CHAPTER - 10

Information and Commutation Technology Services



10.1 Introduction

This chapter examines the role of Information and Communication Technology (ICT) Services in enhancing TMDA's operational efficiency, service delivery, and digital transformation efforts.

The ICT and Statistics Unit was established with the aim of assisting the Authority to realize optimal use of ICT services and resources to support the Authority's business processes.

Between 2003 and 2023n the section was led by a succession of managers whose names and respective tenures are detailed in Table 59 below.

Table 59: Information, Communication & Technology Section Manager's 2003 -2023

Section Name	Manager's Name	Period
Information, Communication & Technology	Mtumwa Simba	2004 - 2011
Information, Communication & Technology	Fausta Nguzo	2011 - 2013
Information, Communication & Technology and Statistics	Ambele Mwafula	2013 – Todate

The ICT and Statistics Unit is responsible for the following functions:-

- To develop and implement ICT policy and strategy that is sensitive to emerging technologies and responsive to changing needs and practices
- To guarantee the security of ICT resources and the safety of people working in ICT environments
- To enhance skills to develop, implement, support and exploit ICT resources effectively and efficiently
- To provide quality network infrastructure and improve staff access to ICT services in line with Authority priorities
- To ensure that business systems accommodate and facilitate changes in business practice that reflect changing Authority needs

The ICT and Statistics Unit is led by the Manager of Information and Communication Technology and is staffed with thirteen (13) ICT professionals comprising of One (1) Principal ICT Officer, three (3) Senior ICT Officers, two (2) ICT Officers I, five (5) ICT Officers II and two (2) ICT Technicians.

10.2 ICT Steering Committee

TMDA has an Institutional ICT Steering committee comprising of members of the Management team. The Director General is the Chairman and the Manager of Information and Communication Technology serve as Secretary. The following are terms of reference of the ICT Steering Committee.

a) Review and approve ICT policy and strategy of the institution;

b) Review and provide advice on ICT investment portfolio and priorities;

c) Ensure alignment of ICT with the TMDA's business needs;

d) Ensure that the e-Government guidelines and standards are implemented by the institution;

e) Ensure continuous monitoring and evaluation of institutional ICT projects;

f) Review and approve institutional disaster recovery plan and ensure its effective implementation;

g) Approve any other institutional e-Government sub-committee as may, from time to time, be constituted and address specific ICT related matters;

h) Prepare and submit quarterly TMDA e-Government progress report to the eGA

10.3 ICT Systems and Software

The institution has undertaken a range of initiatives to use ICT system in carrying out regulatory functions. The initiatives started way back in 2009 when, then Tanzania Food and Drugs Authority (TFDA), started using a Management Information System (MIS) which was not web-based and had few options for processing regulatory functions.

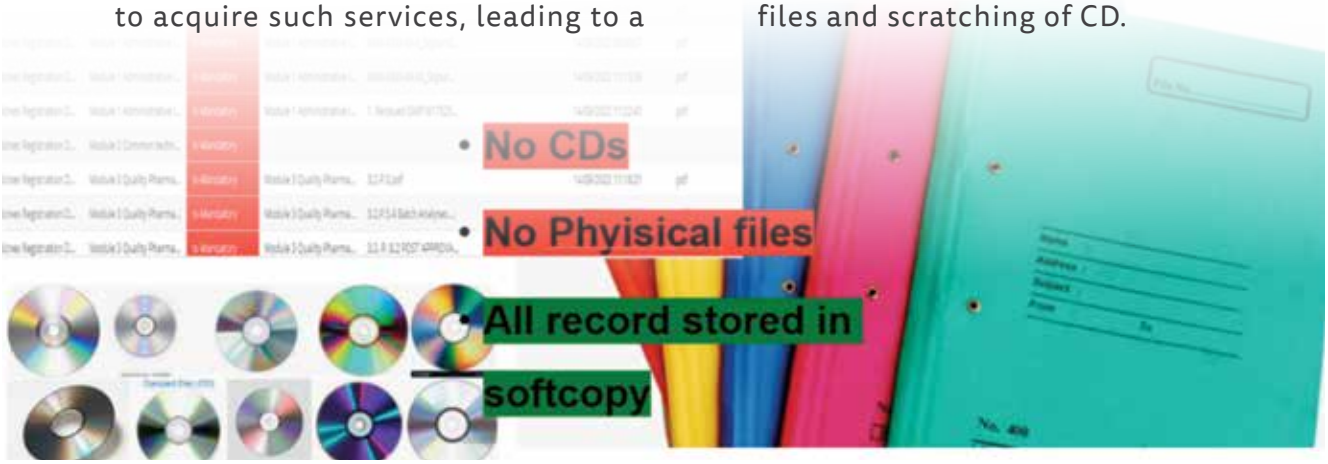
In 2014, TFDA upgraded the MIS by making it web-based and therefore enabling online submission of import and export applications. The system eliminated the need for customers to physically walk into TFDA offices to acquire such services, leading to a time reduction for processing some applications for approximately 50% from 48 hours to 24 hours.

However, the Authority was not able to fully optimize the use of online technologies because customers had to physically fill in application forms for most of the services, with the exception of import and export services. To address the shortcomings of MIS an improved new system the Regulatory Information Management System (RIMS) was developed in 2021.

The following are the advantages of the Regulatory Information Management System (RIMS):-

(a) Online submission of dossiers and other regulatory documents

The RIMS has enhanced the receipt of an electronic dossiers online. Before, the dossiers were received in CD and Physical files formats (Fig. 4) which created challenges of the storage space. The introduction of online dossier submission has addressed the challenges of the physical storage of files and scratching of CD.



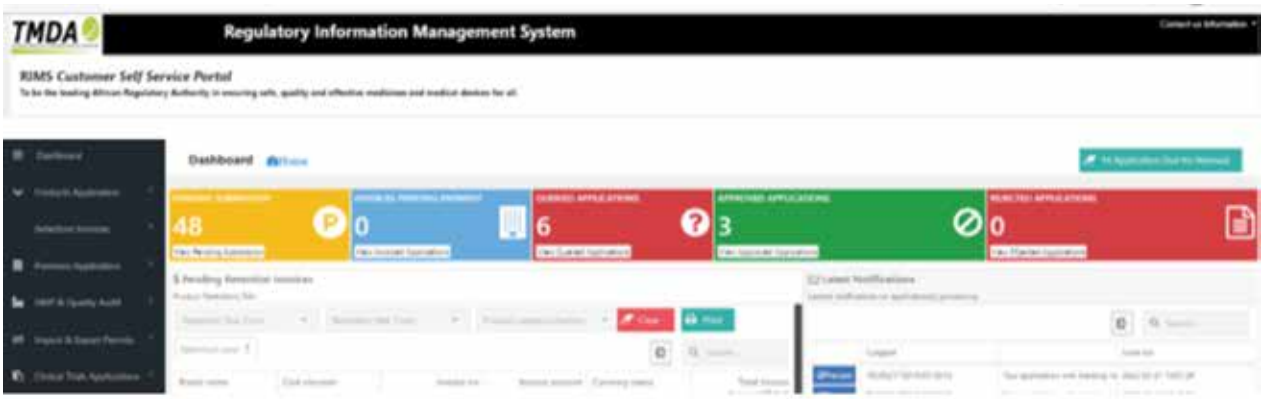


Figure 4: Files and CD

(b) Tracking of the submitted applications

The RIMS is enhanced with a module for tracking the applications alongside with the number of days taken in respective stages.

(c) Control of the application life cycle (Renewal, Variations, Withdraw)

The WHO Global Benchmarking Tools (GBT), among other things, require National Medicines Regulatory Authority to establish an electronic system that enables control of the life cycle of applications. This has been achieved as the RIMS has enabled the control of applications life cycles.

(d) Timelines tracking in the system

RIMS has timelines tracking and notifications functionality that helps Directors, Managers and other staff to be alerted on the overdue applications. The alerting and notification functionality facilitates adherence to application timelines stipulated in the Client Service Charter.

(e) Improved interaction between customers and TMDA staff through the online self-service portal

The Self-Service portal for customers was established in order to strengthen communication with external customers. Using RIMS, customers can obtain the status of their applications, receive invoices, receive receipts, print certificates and respond to any raised queries. The diagram below shows the customer interface

From 2019 to 2022 a total of 5,068 customers have been registered in the TMDA portal and they interact with TMDA for various regulatory services.

(f) Maintenance of the register for all registered products, licensed premises and manufacturing facilities and clinical trials

The RIMS is capable of storing the information and records for all registered products, registered premises, GMP inspected and complied facilities and approved clinical trials. The register is available online in real-time and it is updated automatically on daily basis. All registers are available in the TMDA website (www.tmda.go.tz).

(g) Control of import and export of products

The system facilitates control of importation and exportation of the products. The system allows customers to submit applications via online platform, online receiving of invoice, online payment and print permit online.

(h) Improved the revenue collection

The system has a billing module that is configured to enforce the collection of revenues in line with TMDA fees and charges regulations. The system is connected with all banks and mobile payments through the government payment gateway (GePG).

(i) Recommended Model to be used in Africa National Regulatory Agencies

The introduction and establishment of the RIMS, has inspired its adoption by several regulatory authorities from neighbouring countries and other countries from the and African continent at large. Medicines Regulatory Agencies from Rwanda, Burundi, Botswana, Zambia, Uganda and Ghana have visited TMDA to learn how the existing RIMS works.

The following is a list of other Information management systems used at TMDA:-

a) Laboratory Information Management System (LIMS);

b) Financial Management System known as Epicor 10 at Headquarters and zone offices;

c) Financial Management System known as Mfumo wa Uhasibu Serikalini (MUSE);

d) Human Resource Management System and Payroll known as ARUTI;

e) Implementation of E-Office System;

f) Implementation of PLANREP System;

g) Implementation of Tanzania Electronic Single Window System (TeSWS)

h) Nest

CHAPTER - 11

Financial Management

11.1 Introduction

This chapter outlines the financial management practices and strategic initiatives implemented by TMDA to ensure operational efficiency and financial stability throughout the reporting period. The Authority successfully maintained a strong financial position through sound fiscal policies and consistent oversight.

The Finance and Accounts Unit played a central role in this process, overseeing key financial activities such as budgeting, forecasting, investment planning, and resources management to align with TMDA's strategic goals highlighted below. The Unit has evolved under several leaders since its inception as described in Table No. 60 below;

Table No. 60 Finance and Accounts Managers between 2003 -2023

No.	Name	Duration
1.	Moses Malipula	2003 - 2004
2.	Shaban Mhando	2004 - 2005
3.	CPA. Sadi Kajuna	2005 - 2018
4.	CPA. Paschal Makoye	2018 - 2020
5.	CPA. Setta Masunga	2021 – 2023

11.2.1 Budgeting

Preparation of annual budgets that align with strategic objectives and monitoring by regularly tracking budget performance to manage variances.

11.2.2 Funding Sources

Providing government subvention and understanding the impact of government budgets on operations for funding staff salaries. Nevertheless grants and donations for funding different regulatory functions coming from different international organizations like Global Fund were also executed.

11.2.3 Financial Reporting

Was done in ensuring that public funds are allocated effectively by providing clear and accurate financial reports to stakeholders and adhering to national and international financial reporting standards (IPSAS).

11.2.4 Internal Controls

Risk management practices were introduced in implementing internal controls to mitigate financial risks and having regular internal and external audits to ensure accountability.

11.2.5 Procurement Management

To achieve cost-effectiveness by ensuring that procurement processes are cost-effective and transparent and assessing suppliers to ensure quality and reliability.

11.2.6 Revenue Generation

Fees and Charges in establishing a transparent fee structure for services rendered and collaborating with private sectors for resource mobilization.

11.2.7 Capacity Building

Investing in training of staff on financial management practices and the use of technology in utilizing financial management software to improve efficiency i.e. MUSE, RIMS and GePG.

11.2.8 Regulatory Compliance

Adherence to laws by following national laws and regulations governing financial practices and International Standards by complying with global best practices in financial management

The Finance and Accounts unit ty under the Director General is responsible for those controls and advice the management on financial matters. The unit performs its duties basing on established Laws and Regulations.

11.3 Sources of Revenue

The Authority derives its Revenue from the following sources:

i. Drugs Import/Export Permit Applications
ii. Medical Devices Import/Export Permit Applications
iii. Disposal Fee on Drug Products
iv. GMP Inspection fee on Drug Products
v. Drugs Annual Business Permits
vi. Medical Devices Annual Business Permits
vii. Medical Devices Registration
viii. Drug products Registration
ix. Retention fees on Medical Devices
x. Retention fees on Drug Products
xi. Clinical trials Registration Fee
xii. Rent Income - Lake Zone
xiii. Laboratory Analysis Services
xiv. GMP Inspection fee on Medical Devices
xv. Disposal Fee on Medical Devices
xvi. Registration of Antiseptics and Disinfectants
xvii. Products Promotional Materials on Medical Devices
xviii. Inspection of Drug Consignments at owners' premises
xix. Inspection of Medical Devices Consignments at owners' premises
xx. Products Promotional Materials on Drug

11.4 Management of Expenditure

The management of expenditure is crucial for ensuring the effective regulation and oversight of medicines and medical devices in the country. The following aspects have been managed in the management of expenditure within the Authority between 2003 and 2023.

11.4.1 Budget Allocation

Developing an annual budget that outlines expected revenues and expenditures through the use of PLANREP. This includes funding for personnel, operational costs, training, and development.

11.4.2 Financial Planning

Establishing a financial plan that aligns with strategic goals, ensuring that resources are allocated efficiently to support regulatory activities and public health initiatives.

11.4.3 Monitoring and Evaluation

Implementing systems to monitor spending against the budget, evaluating the effectiveness of expenditures, and making adjustments as necessary.

11.4.4 Resources Mobilization

Identifying additional funding sources, such as partnerships, grants, or collaborations with international organizations to supplement Authority operations.

11.4.5 Procurement Practices

Through the use of TANePS ensuring transparent and efficient procurement processes, which significantly enhances expenditure management.

11.4.6 Capacity Building

TMDA invests in training and development of staff to improveefficiency and effectiveness in regulatory processes, which ultimately helped in cost management.

11.4.7 Financial Reporting

To ensure accountability and effective use of public funds, TMDA consistently prepares and submits accurate financial reports in line with both national and international financial reporting standards, particularly the International Public Sector Accounting Standards (IPSAS).

As a result of its strong financial governance and adherence and compliance to requirements, the Authority has received unqualified (clean) audit opinions from the Controller and Auditor General (CAG) for 20 consecutive years, underscoring TMDA's commitment to financial integrity and transparency.

11.4.8 Compliance and Risk Management

TMDA ensures compliance with financial regulations and manages risks associated with expenditure, such as fraud or misallocation of resources.

11.4.9 Stakeholder Engagement

TMDA collaborates with various stakeholders, including government ministries, healthcare providers, and the private sector, to align expenditure with national health priorities.

11.5 Financial Systems and Software

To enhance transparency, accountability, and efficiency, TMDA has progressively automated its financial systems. Initially, the Authority implemented Epicor 7.0, which was later upgraded to Epicor 9.0. These systems facilitated comprehensive financial management across the organization.

Additionally, the integration of Regulatory Information Management System (RIMS) and Government Electronic Payment Gateway (GePG) significantly streamlined revenue collection and enabled real-time transaction reporting.

In July 2021, TMDA transitioned to the MUSE (Mfumo wa Uhasibu Serikalini) system—a web-based accounting software developed by the Government of Tanzania under the Ministry of Finance. MUSE supports full-cycle government financial operations and was seamlessly integrated with other platforms, including RIMS, GePG, and TANCIS, to support unified operations in both revenue and expenditure management.

During the period under review, TMDA experienced substantial growth in revenue collection. This was driven by enhanced enforcement of fee and charges regulations, as well as improved oversight and automation in the collection process.

Revenues were primarily generated from the following services:

- Import/Export permit applications for medicines
- Import/Export permit applications for medical devices
- Disposal fees for pharmaceutical products
- GMP inspection and quality audit fees
- Licensing of premises handling medicines and medical devices

11.6 Financial sustainability

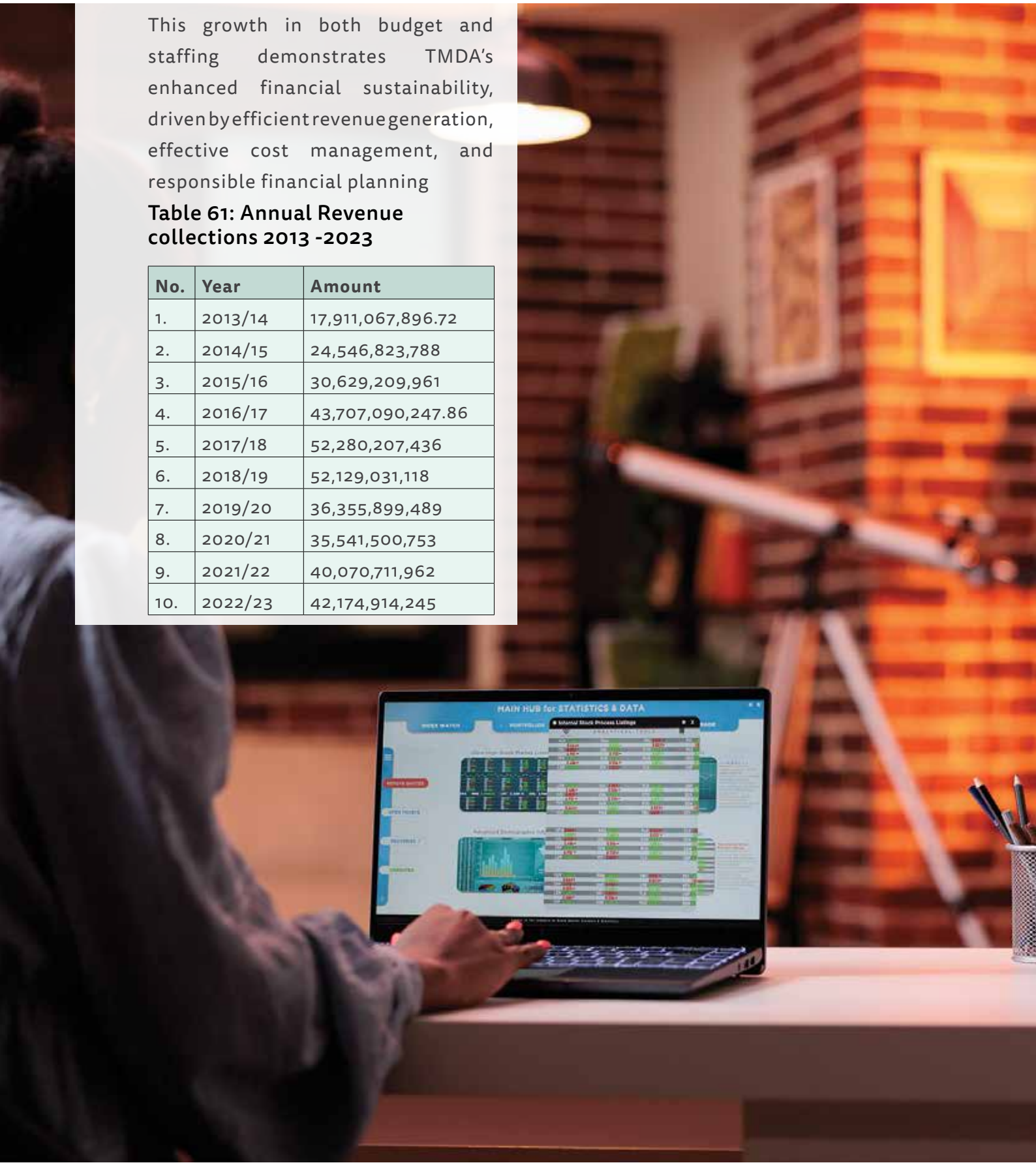
Financial sustainability is critical for TMDA's long-term operations. In 2003, the authority's budget was TZS 138 million, managed by just three staff members (Chief Accountant, Cashier, and one Accountant). Over time, the budget and the staffing capacity have expanded significantly.

- Current Budget: For the 2022/2023 financial year, the budget from internal sources alone is TZS 39.3 billion; and
- Staff Growth: The number of accountants has increased to 25, working across TMDA's Head Office and Zonal Offices.

This growth in both budget and staffing demonstrates TMDA's enhanced financial sustainability, driven by efficient revenue generation, effective cost management, and responsible financial planning

Table 61: Annual Revenue collections 2013 -2023

No.	Year	Amount
1.	2013/14	17,911,067,896.72
2.	2014/15	24,546,823,788
3.	2015/16	30,629,209,961
4.	2016/17	43,707,090,247.86
5.	2017/18	52,280,207,436
6.	2018/19	52,129,031,118
7.	2019/20	36,355,899,489
8.	2020/21	35,541,500,753
9.	2021/22	40,070,711,962
10.	2022/23	42,174,914,245



CHAPTER - 12

Human Resources Management

12.1 Introduction

This chapter explores Human Resources Management at TMDA, focusing on staff recruitment, development, retention, and the policies and practices that support it.

The Section has been under the leadership of various managers from 2003 to 2023 as outlined in Table 62

Table 62: HR Section Managers

No.	Name	Duration
1.	Pius Usingizimali Matagi	2004 - 2017
2.	Gloria Kaaya	2017 - 2018
3.	Moses Magoma	2018 – To date

12.2 Recruitment

Over the past 20 years the Authority has recruited qualified staff for available vacant positions at different periods of time. When the Authority was established in 2003,

it started with 62 employees who were inherited from the then Pharmacy Board and National Food Control Commission. Since then, the number of staff has increased to 356. In spite of the positive achievement in terms of recruitment procedures and implementation of TMDA Human Resources Plan, the current number of staff is still below the current requirements of 488 staff projected in the three years Human Resources Plan (2020/21 – 2022/23).

TMDA has established zone offices to provide services closer to customers across regions and hence enabling quicker responses to regional needs and expectations. Moreover, this strategy has improved human resource utilization that can be allocated based on regional demands, ensuring that expertise and resources are utilized where they are needed most. Currently, TMDA operates its functions at Dodoma Capital City (Head Quarters), sub office in Dar es Salam and in eight (8) zone offices, namely Central Zone, Eastern Zone, Lake Zone - East, Lake Zone - West, Northern Zone, Southern Highlands Zone, Southern Zone and Western Zone as indicated in Table No. 63.

Table No. 63: Distribution of staff by geographical location

Position/ Designation	Workstation										Total
	HQ	Central Zone	Eastern Zone	Lake Zone - East	Lake Zone - West	Northern Zone	Southern Highlands	Southern Zone	Sub - office	Western Zone	
Director General	1	0	0	0	0	0	0	0	0	0	1
Directors	4	0	0	0	0	0	0	0	0	0	4
Head of Units	3	0	0	0	0	0	0	0	0	0	3
Zonal Managers	0	1	1	1	1	0	1	1	0	1	7
Managers	3	0	0	0	0	0	0	0	1	0	4
Officers	62	5	22	9	4	6	4	1	17	3	133
Principal Officers	10	1	2	0	0	0	0	0	2	0	15
Senior Officers	25	1	2	4	1	6	1	2	1	0	43
Assistants	23	5	29	8	4	7	4	4	10	4	98
Supporting Staff	8	2	6	3	2	3	3	2	5	2	36
Total	**139**	**15**	**62**	**22**	**12**	**22**	**13**	**10**	**36**	**10**	**344**

12.3 Training and Development

Through its third edition of the Training and Development Guidelines, TMDA employees can undergo long term and short-term training within and outside the country so as to enhance and improve their performance. Training Needs Assessment (TNA), is another important exercise conducted regularly to identify employees' gaps in knowledge, skills and understanding and its outcome have been taken into consideration during planning and implementation of training programmes. In addition, the Authority has been implementing three (3) years training programme since 2005. In these two decades the Authority trained over 470 employees (including staff transferred to TBS) on either long term or short-term courses within the country or abroad.

Currently TMDA have 38 employees undergoing training at different levels including; PhD, Master's Degree and Diploma levels, 26 of them are undergoing training within the country and 12 abroad. The Authority has also been providing in-house training in the field of Good Clinical Practice (GCP), PMS and PIR, GMP, Audit and Risk Management, Adverse Drug Reactions, Adverse Events of Medical Devices and diagnostics, QMS, Assessment of MD's and IVD's, Quality Audit, Advanced Driving, customer care, post-retirement, talent management, records management, corruption and ethics, HIV/AIDS, gender mainstreaming, mental health and NCD's.

Table 64: Educational Profile of the TMDA Staff

S/N	Position/ Designation	Academic Qualifications															
		Below Secondary		Certificate		Diploma		Advanced Diploma		Degree		Postgraduate Diploma		Masters		PhD	
		M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
1	Director General	0	0	0		0		0	0	0		0	0	1		1	0
2	Directors	0	0	0		0		0	0	0		0	0	2	1	2	1
3	Head of Unit	0	0	0	0	0	0	0	0	0	0	0	0	2	1	0	0
4	Zonal Managers	0	0	0	0	0	0	0	0	0	0	0	0	5	2	0	0
5	Manager	0	0	0	0	0	0	0	0	0	0	0	0	3	0	1	0
6	Principal Officers	0	0	0	0	0	0	0	0	0	1	0	0	8	6	0	0
7	Senior Officers	0	0	0	0	0	0	4	0	7	2	0	0	22	7	0	0
8	Officers	0	0	0	0	1	0	3	0	63	26	1	0	27	10	0	0
9	Assistant	0	0	0	4	58	37	1	0	0	0	0	0	1	0	0	0
10	Support Staff	1	0	30	4	1	0	0	0	0	0	0	0	0	0	0	0
Gender Total		**1**	**0**	**30**	**8**	**60**	**37**	**8**	**0**	**70**	**29**	**1**	**0**	**71**	**27**	**3**	**0**
Total		**1**		**38**		**97**		**8**		**99**		**1**		**97**		**5**	

12.4 Performance Assessment

Since its establishment, The Authority implements staff performance appraisal system in accordance with the government directives. Formerly, the Authority customized the popular Open Performance Review and Appraisal System (OPRAS) the then government performance appraisal system to suit its performance objectives. The Authority amended the said system and formed a customized Staff Appraisal known as TASA (TFDA Annual Staff Appraisal).

The system was pre-tested and rolled out to all employees and turned out to be very successful. In recent years, the Government through the President's Office, Public Service Management and Good Governance introduced new performance management systems, namely the Public Employees Performance Management Information System (PEPMIS) and Public Institutions Performance Management Information System (PIPMIS). These new systems replace the old systems of OPRAS and IPCS. All TMDA employees have registered in the new electronic Performance Appraisal since December, 2023.

12.5 Employee Retention Strategies

Over the past 20 years, the Authority has introduced a number of employee retention strategies with the purpose of reducing turnover costs, enhancing stability, improving morale and productivity, increasing customer satisfaction, supporting growth and innovation, boosting the institution reputation, and ensuring better resource allocation. By prioritizing this, TMDA has maintained a motivated employees, engaged workforce that contributes to long-term success and sustainability in protecting public health. TMDA has put in place well-developed retention strategies by doing the following:

i) Providing food and refreshment at work place to avoid unnecessary movement during working hours;

ii) Providing internal loan scheme to employees to cater for building houses, purchase motor vehicle, furnishing houses and repair of houses;

iii) Improving health insurance to supplementary package scheme through NHIF;

iv) Improved employee's incentive scheme;

v) Having gender mainstreaming and wellness programme;

vi) Implementable succession plan; and

vii) Having a well-structured scheme of service and salary structure.

12.6 Occupational Safety and Health

The Authority implements the statutory Occupational Safety and Health Agency (OSHA) provisions, in order to protect the safety and health of staff at their workplace. Over the years, TMDA complied with National Occupational Safety Policy of 2003 and Occupational Health and Safety Act of 2003 for ensuring a safe and healthy working environment which involves implementing, maintaining, and continually improving various safety and health practices at work places. In addition, TMDA works closely with OSHA to inspect TMDA offices in all aspects related to occupational safety and health as per requirements. The respective guidelines for protecting the health and safety of all staff including those who are working in high risk areas have also been developed.

12.7 HIV/AIDS and Non-Communicable Diseases (NCD's)

As advocated in the National HIV and AIDS Policy of 2001, the fight against HIV and AIDS is a corporate responsibility for both public and private institutions. Since its establishment TMDA ensures that all staff living with HIV/AIDS receive staff rights without any discrimination and avails all the necessary information in relation to HIV/AIDS including counseling, treatment and care. Moreover, recruitment, training and career development are provided equitably to all staff without discrimination on grounds of health status. TMDA management always strives to maintain positive attitude towards staff living with HIV/AIDS and provide facilities for HIV prevention measures, care and treatment including encouraging staff to do voluntary counselling and testing.

Moreover, non communicabe diseases (NCDs) pose a great threat to health and lives in the community. NCDs are diseases that are not infectious and cannot be transferred to others. The main types of NCDs include cardiovascular diseases, cancer, chronic respiratory diseases and diabetes. In Tanzania like many developing countries the burden of NCDs has been increasing steadily. WHO estimates of 2010 showed that NCDs account for 27% of all deaths in Tanzania.

For the past 20 years, the Authority has taken the following strategic initiatives to curb the the increase of the health challenges:

- Appointing an HIV/AIDS and NCD's Coordinator;
- Conducting staff training on HIV/AIDS and Non-Communicable Diseases;
- Distribution of condoms to staff and customers through TMDA washrooms;
- Providing special diet to HIV / AIDS and Non-Communicable Diseases affected employees;
- Preparing and planning of HIV/ AIDS informative flyers on the entrances of staff washrooms;
- Providing awareness training and voluntary counselling and testing for HIV and AIDS; and
- Providing medical insurance Supplementary package under National Health Insurance Fund (NHIF).

Management and implementation of these policies and strategies are in accordance with the Guidelines on Prevention of HIV and AIDS in Public Service issued in November 2011, and the Public Service Circular No. 2 of 2006, regarding provision of services to employees living with HIV or AIDS.

12.8 Anti-Corruption strategies

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

Since its establishment TMDA has been at the forefront in supporting national policies and laws that are intended to prevent corruption in the country. To fight against corruption the government enacted a law, the Prevention and Combating Corruption Act, as amended in 2022 which also established the Prevention and Combating of Corruption Bureau (PCCB).

To combat corruption TMDA has undertaken the following initiatives:

(a) Complied with National Anti-Corruption Strategy and Action Plan Phase Four (NACSAP IV) 2023/2030,

(b) Including anti-corruption measures as one of the strategic objective B in the TMDA Strategic Plan of 2021/22 – 2025/26;

(c) Providing training to staff on corruption practices including emphasizing on code of conduct and ethics in public service;

(d) Supervising procurement processes and ensuring that they are done in accordance with the Public Procurement Act;

(e) Every employee to provide Integrity pledge;

(f) Vetting of new employees and ensure they take oath;

(g) Creating good working environment by increasing staff salaries and providing working tools to minimize corruption practices; and

(h) Conducting research on corruption practices including collecting data showing signs of corruption tendencies at TMDA.

12.9 Gender issues

The Gender Development Policy of 2000 elaborates the need for the society to acknowledge that there are biological differences between male and female which naturally assign different but interdependent responsibilities between them. In view of this, TMDA as a Public entity has developed Gender Strategy aimed at reducing disparities between female and male employees. The strategy sets out clear and enforceable approaches and mechanisms for overcoming gender constraints that limit the capabilities and welfare of male and female employees at the work place. The Strategy also aim to discourage gender discrimination and guide TMDA in recruitment, operational planning and decision-making processes. Since its establishment, there has been a significant improvement. In 2003 the Authority had 62 employees of whom only 10% were female. By the year 2023/24, the Authority had a total of 314 employees comprising 120 women (38%) and 194 men (62%). This reflects a significant and positive shift in gender representation over the past 20 years as illustrated in the Table 65:

Table No. 65: Distribution of employees by Age and Gender June 2023?

S/N	Position/ Designation	Age groups												Gender per Position		Head count per Position as per due Date
		20 - 30		31- 40		41 - 50		51-53		54 -56		57 - 59				
		M	F	M	F	M	F	M	F	M	F	M	F	M	F	
1	Director General	0		0		1		0		0	0	0	0	1	0	1
2	Directors	0		0		2		1		1	0	0	0	4	0	4
3	Head of Units	0	0	0	0	2	1	0	0	0	0	0	0	2	1	3
4	Zonal Managers	0	0	0	0	3	0	2	2	0	0	0	0	5	2	7
5	Managers	0	0	0	0	2	0	1	0	0	0	1	0	4	0	4
6	Principal Officers	0	0	0	0	2	5	4	0	2	2	0	0	8	7	15
7	Senior Officers	0	0	5	4	21	5	4	0	1	0	2	0	33	9	42
8	Officers	2	4	66	21	25	11	1	0	0	0	1	0	95	36	131
9	Assistant	6	6	47	19	4	8	1	4	1	3	1	1	60	41	101
10	Support Staff	2	0	7	1	12	2	3	1	5	0	3	0	32	4	36
Age group/Gender Total		**10**	**10**	**102**	**38**	**74**	**32**	**17**	**7**	**10**	**5**	**8**	**1**	**244**	**100**	**344**
Age group Total		**20**		**140**		**106**		**24**		**15**		**9**		**344**		

Moreover, the Gender policy recognizes various gender roles and the importance of working together in the society so as to achieve development. The fact remains that, nature has assigned various responsibilities between different sexes which are interdependent and all important in the development of the family, community and Nation at large. TMDA started implementing this Gender Policy in 2007. Among the issues that have already been implanted include the following: -

(a) Embracing aspects related to women development in the TMDA's Strategic Plan of 2021/22– 2025/26;

(b) Development and implementation of Gender mainstreaming strategy;

(c) Establishment of the TUGHE Women Council;

(d) Encouraged more women to fill up senior positions within TMDA. Currently there are 12 women out of 31 Managerial posts equivalent to 39%; and

(e) Setting up policies that encourage more women to attend higher education training so as to equip them with required skills and competencies.

12.10 Sports and Games

Sports and games are physical activities important for building human bodies and bringing societies together. The National Sports Development Policy of 1995 highlights the important issues in terms of sports and recreation. TMDA has set up a sports programme for its staff and in the past 20 years of its operation, TMDA has done the following:

(a) Identified gym areas for employees to exercise;

(b) Coordinated and participted in various sports activities and competitions with other institutions in football, netball, handball and athletics;

(c) Organised teams for Football, Netball, Volleyball and internal sporting activities

(d) Participated in sports competitions;

(e) Staging up inter departmental competitions in various sports activities;

(f) Hired a coach to train TMDA staff on physical exercises;

(g) Provided sports gear and equipment to staff;

(h) Encouraged staff to participate in sport activities; and

(i) Provided sporting areas close to TMDA HQ offices.

12.11 Notable changes

Over the past 20 years, Human Resources Management (HRM) has undergone significant changes, driven by government directives, technological advances, shifting workplace dynamics, and evolving business needs. Here are some notable changes in HRM:

i) Change of schemes of services in the year 2019 and in the year 2023;

ii) Approved functions and organizational structure of TMDA in 2022;

iii) Transfer of food cadre employees to TBS as per The Finance Act, 2019 following the transfer of regulatory functions of food and cosmetics from the then TFDA to TBS; and

iv) Relocation of office and employees from TMDA head quarters in Dar es salaam to the Capital City Dodoma.

CHAPTER - 13

Communication and Public Education

13.1 Introduction

This chapter discusses TMDA's approaches to communication, customer care services, and public education, highlighting efforts to enhance stakeholder engagement, service delivery, and public awareness on regulatory matters.

Between 2003 and 2023, the Unit underwent several name changes and was headed by different managers, reflecting its evolving role and structure within the institution. Their names and respective tenures are as indicated in Table 66 below.

Table 66: Communication and Public Education Unit Managers between 2003 - 2023

Unit/ Section Name	Manager's Name	Duration
Public Education Section	1. Henry Irunde	2003 - 2004
	2. Rehema Shemhina	2004 - 2008
Public Relation Unit	Gaudensia Simwanza	2006 - 2008
Marketing	Chrispin Severe	2008 - 2013
Public Education and Customer Care	1. Chrispin Severe	2013 - 2016
	2. James Ndege	2016 - 2017
Communication and Public Relations	Gaudensia Simwanza	2012 - 2017
Cummunication and Public Education	Gaudensia Simwanza	2017 – To date

Section No. 5(1)(k) of the Tanzania Medicines and Medical Devices Act of 2019, requires TMDA to issue timely and accurate information to the public regarding the quality, safety and efficacy of regulated products. Such information includes: public education on the rational use of medicines and medical devices; procedures to follow when opening up business of regulated products, risks that may be associated with the use of sub-standard and counterfeit products and the responsibility of consumers and other stakeholders on products safety. Also, it highlights the requirements of public education activities in enhancing the public on voluntary compliance to the laws and regulations.

This chapter illustrates TMDA's strategies, regulations and public education programmes over the past 20 years.

13.2 Public Education Programs and Publicity

In order to enhance stakeholders' awareness on TMDA's activities, the Authority conducts various educational and publicity programmes to the public as outlined below.

13.3 Participation in Exhibitions

Over the past two decades, TMDA has consistently pursued a strategy aimed at bolstering public education and enhancing customer service in the realm of public health. Since 2003, TMDA has actively engaged in various initiatives to educate the public about various regulatory functions including the rational use of medicines and medical devices. A significant element of this initiative has been their consistent participation into both local and international exhibitions., TMDA has consistently showcased its presence in key events such as Sabasaba trade fair show, Nanenane show, Tanga trade fair, Juakali- Nguvu kazi show, East Africa Trade Fair, International Drug Abuse show, Public Service Week, Pharmacy week, and various national and international business forums and exhibitions including International Business and Medical Expos. Between July 2003 to June 2023 TMDA participated in 440 events.

During these exhibitions, TMDA showcased and distributed a range of public education, publicity and promotional materials to pavilion visitors. In addition books, guidelines, regulations and other regulatory publications were offered for sale to interested members of the public. Furthermore, TMDA staff particing in these exhibitions use the opportunity to identify dealers of regulated products for future follow up and engagement.

These exhibitions have provided TMDA with crucial platforms to interact directly with the public, healthcare professionals, and stakeholders worldwide. Through these engagements, TMDA has not only showcased its regulatory role but also disseminated vital information on the safe use of medicines and medical devices. By leveraging these events, TMDA has contributed significantly to raising public awareness about regulatory standards, substandard and falsified medicines, and the importance of quality assurance in healthcare products.

Through these initiatives, TMDA reaffirms its commitment to advancing public education and customer service, thereby ensuring that Tanzanians continue to access safe and effective medicines and medical devices. Looking ahead, TMDA remains dedicated to expanding its outreach efforts, harnessing the power of exhibitions and other educational initiatives to further strengthen the healthcare landscape in Tanzania.

13.4 Articles on print Media

In the past two decades, TMDA has embarked on a robust strategy aimed at enhancing public education and elevating customer service standards to safeguard and advance public health. Central to this initiative has been the widespread dissemination of about 160,680 informative articles across various print media platforms. These articles, precisely crafted and disseminated through newspapers, magazines, brochures, posters, and flyers, have served as pivotal tools in communicating TMDA's vision and mission. They have not only educated the public on the rational use of medicines and medical devices but also fostered a deeper understanding of regulatory processes and their responsibility in protecting public health.

Moreover, TMDA has prepared and published three (3) landmark editions documenting its milestones, underscoring its commitment to transparency and accountability. In addition to these publications, the authority has consistently released informative resources including 12 editions of the TMDA Newsletter and six (6) editions of the Drug Safety Bulletin. These publications have played a pivotal role in keeping stakeholders informed of regulatory updates, emerging health risks, and advancements in pharmaceutical safety. Through these initiatives, TMDA continues to empower the general public with knowledge fostering informed decision-making and reinforcing its pivotal role in protecting and promoting public health.

13.5 Radio and Television Programmes

Over the past two decades, TMDA has steadfastly pursued its mission to enhance public education and elevate customer service standards in safeguarding public health. Through an array of strategic initiatives, TMDA has effectively utilized radio and television platforms to disseminate crucial information. Broadcasting a total of 1,026 radio programs across commercial and community channels, TMDA has consistently educated the public on the rational use of medicines and medical devices, as well as highlighted its pivotal role in protecting and promoting public health. These initiatives have not only fostered awareness but also empowered communities with essential knowledge to make informed health decisions.

Simultaneously, TMDA expanded its outreach dissemination through 802 television programs broadcasted on prominent channels to include ITV, TBC One, Azam Media, Clouds TV, and Tumaini TV. Among these, the widely acclaimed "TMDA na Jamii Program" has emerged as a cornerstone in strengthening public education initiatives. It has served as a beacon of information, enlightening viewers about the regulatory functions of TMDA and reinforcing the significance of adhering to regulatory regulations and requirements for the collective well-being of society. Through these comprehensive media campaigns, TMDA continues to set new standards in public health communication, ensuring that every Tanzanian is equipped with the knowledge necessary to optimize health outcomes and contribute to a healthier nation.

13.6 Seminars and Trainings

From 2003 to 2023, TMDA has pursued a steadfast strategy aimed at enhancing public education and optimizing customer service for the protection and advancement of public health. Central to this strategy has been the coordination of 800 seminars and training sessions though out the country, strategically conducted through extensive outreach campaigns. These initiatives have been pivotal in equipping the public with essential knowledge on the rational use of medicines and medical devices. By imparting the knowledge and raising awareness and understanding, TMDA has empowered individuals to make informed decisions regarding their health, thereby contributing significantly to the overall well-being of the Tanzanian population.

Furthermore, these efforts have not only focused on education but also on fostering a deeper appreciation of the role and functions of the authority itself. Through comprehensive sensitization outreach campaigns, TMDA has effectively communicated its mandate and responsibilities to the public. This transparency has bolstered trust and confidence in the Authority, ensuring greater compliance with regulations and guidelines governing medicines and medical devices.

As Tanzania continues to progress in its healthcare initiatives, TMDA remains committed to furthering these educational endeavors, setting a strong regional benchmark for public health authorities across the region.

13.7 Promotional Materials

During the past two decades, TMDA has diligently pursued its mission to enhance public education and elevate customer service standards in the realm of public health. From 2003 to 2023, TMDA spearheaded the creation and dissemination of 152 distinct types of promotional materials, producing a total of 10,520,000 items. These materials have played a pivotal role in raising awareness, educating the populace, disseminating crucial information, and sensitizing communities about TMDA's vital role and the rational use of medical products.

Through these efforts, TMDA has not only bolstered its visibility but has also empowered individuals across Tanzania to make informed decisions regarding their health and well-being. By prioritizing comprehensive public education and improving service delivery, TMDA continues to uphold its commitment to safeguarding public health and ensuring that medical products are utilized effectively and responsibly throughout the nation.

13.8 Website and social media

In the period in question, TMDA has pursued strategic initiatives aimed at enhancing public education and improving customer services to safeguard and promote public health. Since 2003, TMDA has diligently maintained its official website and successfully launched social media accounts on platforms including Facebook, Twitter, Instagram, and YouTube. These efforts have not only facilitated direct engagement with the public but also enabled the dissemination of crucial regulatory information. With an impressive follower of 120,000 on each social media platform, TMDA has effectively utilized these channels to educate and inform the public on various regulatory issues pertaining to medicines and medical devices. Moreover, TMDA has ensured that its website remains a robust resource hub by consistently updating it with approximately 1500 pieces of current information. This proactive approach has empowered the public with timely and relevant updates, reinforcing TMDA's commitment to transparency and accessibility in healthcare regulation.

As TMDA looks ahead, its strategy continues to evolve with unwavering focus on expanding educational outreach and enhancing customer service delivery. By leveraging digital platforms, TMDA has not only expanded its reach but also fostered a community where stakeholders stay informed and engaged.

The strategic use of social media has played a pivotal role in bridging communication gaps and fostering public trust . Moving forward, TMDA remains dedicated to advancing its mission of protecting public health through proactive regulatory measures and educational initiatives. With a decade of impactful digital engagement behind it, TMDA is well positioned innovating and evovling , ensuring Tanzanian citizens remain well-informed and empowered in matters of healthcare regulation and safety.

13.9 School Clubs

Over the past two decades, TMDA has pursued a robust strategy aimed at fortifying public education and enhancing customer service to safeguard and advance public health. A cornerstone of this initiative has been the establishment of school clubs across the nation since 2003. These clubs serve as dynamic platforms dedicated to continually educating and raising awareness among students throughout Tanzania. As of now, approximately 50 school clubs have been established across 10 regions, each playing a pivotal role in disseminating crucial information on medical products . Coordinators of these clubs receive comprehensive training and are equipped with a variety of Information, Education, and Communication (IEC) materials, ensuring they can

effectively engage their peers and communities. Moreover , since the establishment of these clubs in 2013 annual performance evaluations have consistently monitored and enhanced their impact, reinforcing their vital role in the national healthcare education landscape.

Through these concerted efforts, TMDA fostered a culture of proactive health education among the youth while significantly improved community-level awareness on medical products . The sustained commitment to these school clubs highlights TMDA's dedication to equipping future generations with essential public health knowledge. As Tanzania progresses into the next phase of healthcare advancement, these initiatives are poised to continue making a lasting impact, ensuring that informed and empowered citizens contribute to the nation's health and well-being effectively.

13.10 Media Engagement

In the past 20 years, TMDA has pursued a comprehensive strategy aimed at enhancing public education and optimizing customer service to safeguard and enhance public health. Since 2003, TMDA has actively involved the media and journalists in numerous initiatives designed to familiarize them with regulatory functions, enabling them to effectively educate the public. From July 2003 to June 2023, TMDA successfully organized

84 working sessions and meetings across the country, strategically engaging with media professionals to encourage unbiased reporting on regulated products. This initiative was enhanced with 102 press releases and 96 press conferences. Furthermore, TMDA has honoured journalistic excellence by awarding nine (9) deserving journalists who have shown dedication in reporting on critical regulatory issues, thereby

Through these concerted efforts, TMDA has not only strengthened its regulatory framework but has also significantly bolstered its relationship with the media as a vital partner in promoting public health. By equipping journalists with the knowledge and tools necessary to effectively communicate regulatory matters, TMDA has helped ensure that accurate and impartial information reaches the public domain.

This proactive engagement underscores TMDA's commitment to transparency, accountability, and public service excellence, setting a benchmark for regulatory bodies seeking to enhance public understanding and engagement on issues related to regulation of health products . As TMDA charts its way foward, its continued collaboration with the media remains vital to its mission of safeguarding the well-being of Tanzanian citizens through informed decision-making and community participation in health matters.

13.11 Public Relations, Customer Services

TMDA has maintained good relations with its customers so as to enhance the implementation of regulatory activities. In 2006, the Authority established the Public Relations and Customer Care Unit in order to coordinate all customer related issues and serve as a link between TMDA and its stakeholders.

13.12 Collaborations and Engagement of Stakeholders

In the last 20 years, TMDA has pursued a multifaceted strategy aimed at bolstering public education and enhancing customer service in the area of public health protection. From 2003 to 2023, TMDA has forged robust partnerships with law enforcement agencies and engaged extensively with both internal external stakeholders. In close collaboration with the Ministry of Health, government Agencies, medical product manufacturers, importers, exporters, distributors, and wholesalers- TMDA has consistently regulated the market to ensure adherence to quality standards and safety protocols.

Central to TMDA's approach is proactive communication and stakeholder engagement. Through approximately 400 meetings held during this period, TMDA has kept stakeholders informed about regulatory changes and sought their feedback on newly introduced guidelines and regulations.

Moreover, recognizing the pivotal role of public awareness and education , the authority during this conducted extensive educational campaigns to enlighten and sensitize manufacturers and the public on good manufacturing practices and proper storage protocols to promote voluntary compliance with prescribed standards. In this way , TMDA strives to ensure that all regulated products circulating within the Tanzanian market are of high quality, safe, and efficacious, thereby safeguarding and promoting public health across the nation.

13.13 Customer Satisfactions Survey and Operational researches

In pursuit of enhancing public education and elevating customer service standards for the protection and promotion of public health, TMDA from 2003 to 2023 implemented a number of strategic plans. During this period, TMDA undertook four (4) comprehensive Service Delivery Surveys aimed at assessing institutional performance and gauging the satisfaction levels of both internal and external stakeholders. Notably, these surveys have demonstrated a significant improvement in satisfaction rates, rising from 64% to 80% among external stakeholders by 2008 and 2020, and maintaining a steady increase for internal stakeholders as well.

These operational researches were conducted by the Authority in collaboration with other stakeholders and external consultants. Some of the researches conducted include; customer satisfaction surveys that were conducted by M/s Excel Media (2004), M/s Prime Consult (T) Ltd (2008) and The University of Dar es Salaam (2021). TMDA also conducted internal survey on customer satisfaction in 2005. The Findings obtained were used to improve services. Also, the findings assisted the Authority to identify gaps in public education and take necessary measures to address the gaps.

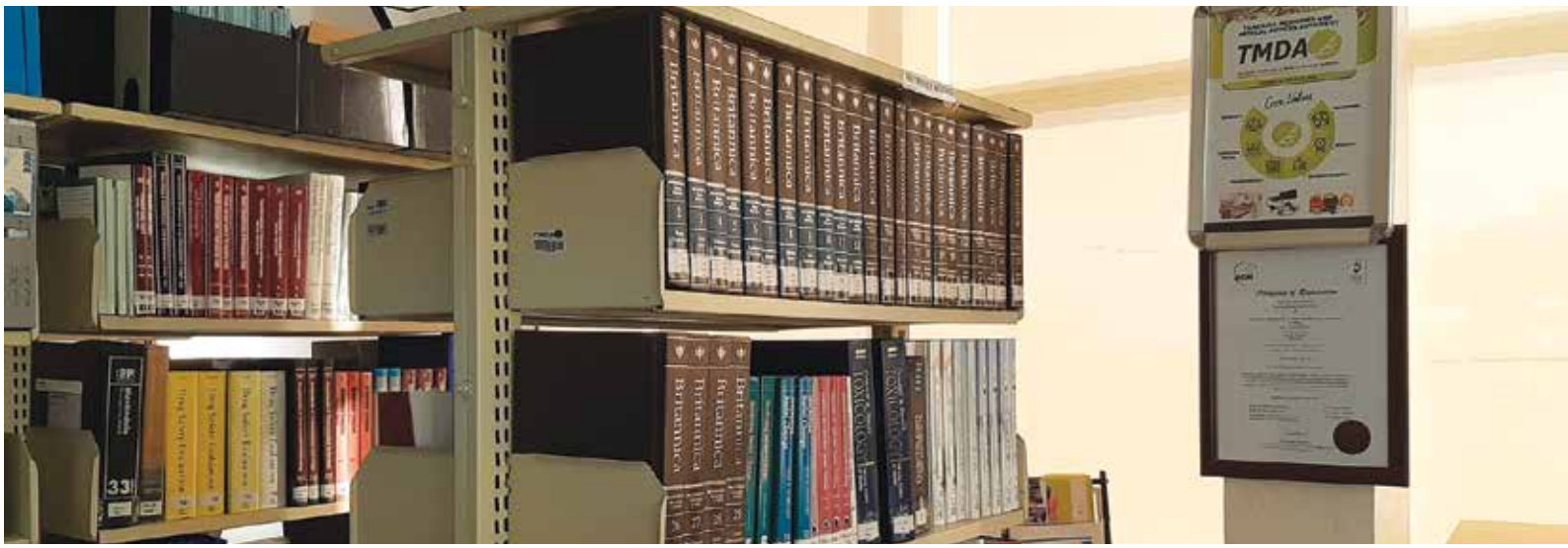
The Authority also introduced different plans such as combined strategies for marketing and public education. Another research was conducted by TMDA in collaboration with TFNC about awareness of public

on the importance of using iodated salt. This research was conducted in 2008 under the support of UNICEF. The findings obtained from this research contributed to development of information, education and communication materials which were distributed to several regions particularly those which had critical iodine deficiency.

Pursuant to its commitment to transparency and accountability, TMDA introduced a Client Service Charter in 2006, with subsequent revisions in 2012 and 2020 to incorporate stakeholders' feedback and align with evolving technological standards a pivotal initiative designed to communicate service standards and organizational commitments to all stakeholders. This proactive approach has fostered stronger relationships with the public, instilling confidence in the agency's dedication to delivering high-quality services. As TMDA continues to refine its strategies, these efforts reflect its deep commitment and dedication to advancing public health objectives through effective governance and responsive service delivery mechanisms.

13.14 Library services

In 2000, TMDA took a proactive step strengthen the professional expertise by establishing a dedicated resource library. This initiative was pivotal in ensuring that TMDA experts have access to the latest scientific knowledge essential for their roles. Over the years, this library has grown into a comprehensive resource centre, meticulously curated with reference books, journals, and other pertinent publications. In 2003, the appointment of a dedicated Librarian further fortified the library's role, ensuring efficient coordination in identifying and



making available up-to-date scientific information. Through partnerships with international platforms like HINARI, AGORA, and OARE, the TMDA library got access to a wealth of scientific publications, empowering its experts to stay informed and capable of providing science based recommendations to TMDA Management thereby enaling evidence based decisions.

The impact of the library extends beyond its physical walls, benefiting not only the authority's staff but also stakeholders and the general public. By facilitating access to cutting-edge research based publications and knowledge, the library plays a crucial role in enhancing evidence based decision-making within the TMDA. This initiative underscores TMDA's commitment.

This initiative reflects TMDA's commitment to regulatory excellence and its dedication to cultivating a knowledge-driven environment. As the repository of current scientific literature, the TMDA library stands as a testament to the authority's proactive commitment to elevating healthcare standards and regulatory efficacy in Tanzania.

13.15 Corporate Social Responsibility

Over the past two decadesTMDA has consistenly implanted a comprehensive strategy aimed at enhancing public education and elevating customer service standards to safeguard and promote public health. Central to this strategy has been the implementation of a robust communication plan integrating

Corporate Social Responsibility (CSR) initiatives. 2003 to 2023, TMDA dedicated TZS 1,086,000,000 towards several CSR activities across the country. These initiatives encompassed diverse undertakings, including support for hospital visitations, assistance to orphanage centers, and aid for victims of natural disasters.

Additionally, TMDA has contributed significantly to national education by providing desks to primary schools and honouring outstanding achievements in pharmacy practice at Muhimbili University of Health and Allied Sciences (MUHAS). The authority also facilitated sizable number of crucial gatherings by supporting institutions in organizing and attending meetings, seminars, and workshops, while extending aid to vulnerable groups such as patients and the disabled. Notably, TMDA's CSR efforts have extended to promoting menstrual health among secondary students and disabled girls through the provision of sanitary pads, underscoring its commitment to holistic community support and public welfare.

Through its enduring dedication to CSR, TMDA has not only fulfilled its regulatory role but has also fostered meaningful societal impact across Tanzania. By prioritizing initiatives that resonate with local needs and challenges, TMDA has set a commendable precedent in corporate citizenship within the healthcare sector. This sustained commitment underscores the authority's proactive approach to public health, ensuring that its efforts extend beyond regulatory mandates to encompass broader societal welfare. As TMDA continues to evolve, its steadfast integration of CSR into its operational framework serves as a testament to the transformative power of public-private partnerships in advancing healthcare accessibility, education, and community resilience across the nation.

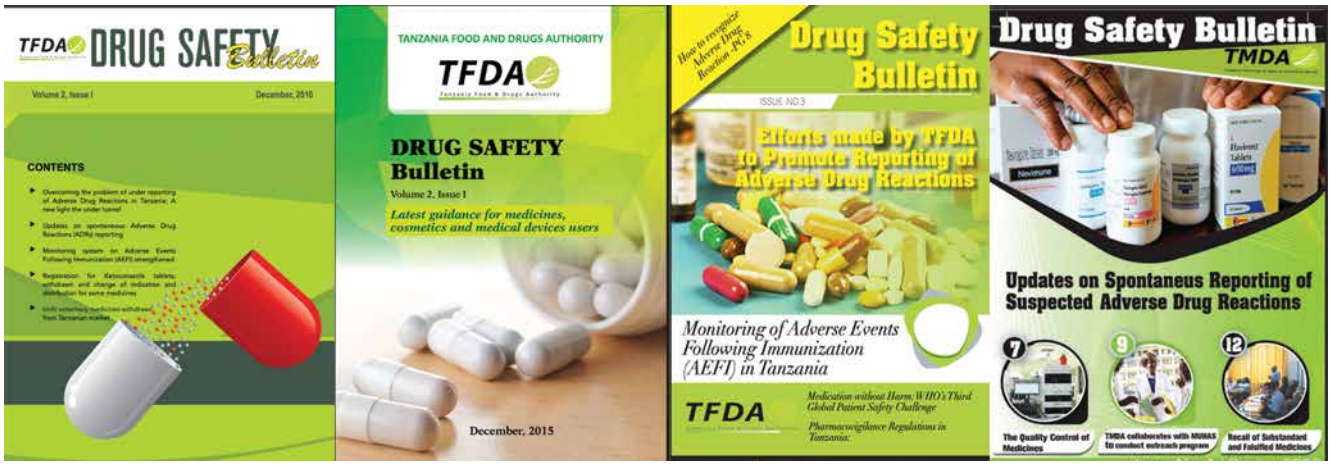
13.16 Publications

For the past two decades, TMDA has implemented a comprehensive strategy aimed at enhancing public education and advancing customer service to safeguard and promote public health. Central to this initiative the Authority crafted publications to inform and engage stakeholders effectively. These included newsletters, drug safety bulletins, and scientific publications, each designed to disseminate critical information on health products as follows;.

13.16.1 TMDA Newsletter

In its ongoing commitment to strengthening public education and enhancing customer service to safeguard and promote public health, the Authority has strategically -utilized the TMDA Newsletter since 2003. Over the course of two decades leading up to 2023, this publication has evolved into a leading tool of communication, disseminating crucial regulatory updates and insightful articles to over 1,200,000 stakeholders. These include government ministries, agencies, educational institutions, and the broader public, ensuring comprehensive awareness on regulatory matters, educational initiatives, events, sports, and staff welfare. Through its 12 editions the Newsletter, has served as a platform through the Authority has effectively fostered informed engagement and collaboration, thereby reinforcing its role as a pivotal entity in Tanzania's public health landscape.

The TMDA Newsletter stands as a testament to the Authority's Communication and Customer Services Strategy, serving as more than a mere informational conduit. It embodies dedicated efforts to bridge the gap between regulatory requirements and public understanding, empowering stakeholders with the knowledge necessary for informed decision-making and compliance. Beyond regulatory updates, the newsletter has embraced a holistic approach, featuring educational content and highlighting community activities. By nurturing this platform, the TMDA not only enhances transparency and



accountability but also cultivates a culture of proactive communication that is indispensable in safeguarding public health priorities.

13.16.2 Drug Safety Bulletin

From 2003 to 2023, the Authority has implemented a comprehensive strategy aimed at bolstering public education and enhancing customer service to safeguard and promote public health. Central to this strategy has been the innovative use of the Drug Safety Bulletin as a pivotal tool for engaging stakeholders. This platform has played a pivotal role in raising public awareness on critical issues related to the quality and safety of medicines. Through more than six meticulously curated editions, the Authority has effectively disseminated vital information, including safety monitoring during mass drug administration, reports of suspected adverse drug reactions, and mandatory periodic safety updates required of market authorization holders. Moreover, the Bulletins have served as a a foundational platform for advancing good regulatory practices of medicines, medical devices and diagnostics.

The Drug Safety Bulletin stands as a testament to TMDA's commitment to transparency and proactive communication with stakeholders. By cultivating a culture of shared knowledge and accountability, TMDA has empowered both healthcare providers and consumers while simulataneously o strengthening regulatory practices throught Tanzania. As a vital conduit for information exchange, the Bulletin has bridged gaps between regulatory updates and public understanding, ensuring that the public is well informed and equipped to make informed decisions regarding their health. Looking ahead, TMDA remains dedicated to further advancing these initiatives, aiming to continuously protect and promote the well-being of all Tanzanians through informed and responsive regulatory practices.

13.16.3 Scientific Publications

TMDA has played a pivotal role in advancing public health through rigorous research and effective regulatory practices. Over the past two decades, TMDA has spearheaded numerous publications aimed at strengthening public education and enhancing customer services in the realm of healthcare. These efforts were geared towards the protection and promotion of public health, leveraging scientific information derived scientific research. From 2003 to 2013 alone, TMDA in collaboration with experts from the medical and pharmacy fields in Tanzania, conducted a number of researches and published 67 papers in peer reviewed journals. These publications serve as a testament to the Authority's commitment to sharing evidence-based insights that are crucial for informed decision-making and policy formulation in public health.

One notable publication, ***"Pharmacovigilance of Mass Drug Administration as Preventive Chemotherapy to Control and Eliminate Lymphatic Filariasis in Tanzania,"*** exemplifies TMDA's proactive approach in combating endemic diseases through robust regulatory frameworks. Furthermore, studies such as "Post Marketing Surveillance on Malaria and Antibiotic Utilisation Patterns in Tanzania," highlight TMDA's responsiveness in tracking healthcare trends and adapting regulatory strategies to emerging challenges, including t hose posed by the COVID-19 pandemic.

By leveraging longitudinal data collected before and after a pandemic, TMDA provides invaluable insights into shifts in antibiotic utilization patterns, informing targeted interventions to optimize healthcare delivery. These publications not only enrich the scientific community but also equip stakeholders with evidence essential for sustaining improvements in public health outcomes across Tanzania

CHAPTER - 14

Internal and External Auditing

14.1 Introduction

This chapter outlines the internal and external auditing functions at TMDA, emphasizing their roles in promoting transparency, accountability, and effective governance through regular financial and operational assessments.

The establishment of internal audit is set out in regulation 28 of the Public Finance Regulations, 2001. 'In order to discharge its responsibilities under these regulations an Accounting Officer shall establish an effective internal audit service unit'.

Internal audit function aligns to the requirements of the International Professional Practices Framework (IPPF) issued by the Institute of Internal Auditors to regulate the work of internal audit service.

TMDA's Internal Audit Unit was established in September 2007 to provide assurance and advisory services, and has been led by CPA Cyriacus Katunzi (2007–2018) followed by CPA Godian Ngamesha (2018– To date).

14.2 Internal Audit Charter

A formal document that includes the internal audit function's mandate, organizational position, reporting relationships, scope of work, types of services and other specifications.

14.3 Audit and Risk Management Committee

Audit and Risk Management Committee has been established in accordance with Circular No. CEA.111/732/01 issued by Treasury Registrar on 15th August, 2016.

The purpose of the Audit and Risk Management Committee of the MAB is to assist the Board in its oversight of governance, risk management and control processes of the Authority.

The Committee does not replace or replicate established management responsibilities and delegates, the responsibility of other executive management groups within organization or the reporting lines and responsibilities of either internal audit or external audit functions.

The Audit and Risk Management Committee shall consist of a minimum of three and a maximum of five members of the Ministerial Advisory Board.

The Committee shall be composed of mixture of skills and where such skills are not available, the Committee shall co-opt some experts after the approval of the Board.

At least one member of the Committee must have accounting or related financial management expertise.

Members of the Committee shall be appointed by the Board and may be replaced or removed by the Board with reason.

The term of appointment shall be three years and can be extended for further term subject to the extension of tenure of the Board or re-appointment of Members.

The Committee shall undertake an annual self-assessment of its performance for the previous twelve months at their first meeting of each financial year.

The Committee shall provide a report of the annual assessment outcomes to MAB.

At least once in its tenure, the Committee shall arrange for an external peer review of its operations and activities. The results of this review will be submitted directly to the Chairperson of Ministerial Advisory Board.

The Chairperson shall provide each individual member with feedback on member's contribution to the Committee's activities annually. This feedback shall include any training needs of the member.

14.4 Internal Auditing

Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control and governance processes.

14.5 Vision and Mission of the Internal Audit Unit

14.5.1 Vision of the Internal Audit Unit

To be a professional internal audit service provider performing audit activities that meet international audit standards to strengthen good governance, risk management and control processes towards the achievement of the Authority's objectives.

14.5.2 Mission of the Internal Audit Unit

To enhance and protect organizational value by providing risk-based and objective assurance, advice and insight.

14.6 Responsibilities of the Internal Audit Unit

The Internal Audit Unit is dedicated to evaluating and advising on governance, risk management and control processes within the Authority. Its primary objective is to provide reasonable assurance and advisory/consulting services aimed at enhancing the value of the Authority's operations.

As an independent appraisal unit within the Authority, the Unit offers objective assurance to Management and the Board regarding the effectiveness of risk management plans. The unit ensures:

a) Identification and mitigation of risks to the Authority;

b) Effective and efficient utilization of resources;

c) Achievement of organizational objectives;

d) Adherence to corporate governance principles;

e) Compliance with external regulations, laws, and internal policies; and

f) Accuracy and reliability of financial and operational information.

In fulfilling these responsibilities, the unit conducts internal audit activities by identifying risks that could hinder the Authority's objectives, assessing controls, evaluating governance structures, and providing recommendations to enhance operational efficiency.

The focus is on reviewing and evaluating the adequacy and effectiveness of internal controls to identify potential loopholes that could expose the Authority to financial and reputational risks, ensuring they are appropriately managed and controlled.

14.7 External Auditing

Pursuant to Article 143 (5) of the Constitution of the United Republic of Tanzania as amplified in Sections 5, 9, 12 and 32 of the Public Audit Act No. 11 of 2008, the Controller and Auditor General is a statutory Auditor of all Public Organisations. However, according to Section 33 of the same Act, the Controller and Auditor General has the mandate to authorize any eligible Auditor to carry out the audit of these public entities on his behalf. However, the Controller and Auditor General reserves the right to terminate the appointment any time during the three years tenure.

Since its establishment TMDA has received Unqualified Opinion for external audits conducted by the Controller and Auditor General.

CHAPTER - 15

Zone offices and Local Government Authorities Coordination

15.1 Introduction

This chapter highlights the role of TMDA's zone offices and the delegation of regulatory functions to Local Government Authorities, emphasizing their contribution to enhancing service delivery and accessibility across the country.

From their establishment in 2006, Zone offices have been instrumental and quite useful in assisting TMDA in delivering services to its customers particularly those who reside in remote areas. In addition, pursuant to the mandate provided under section 121 of the Tanzania Food, Drugs and Cosmetics Act, Cap 219, the then

Minister responsible for health delegated some functions and powers of the Authority to Local Government Authorities through Government Notice No. 476 of 2015.

15.2 Establishment of Zone Offices

To bring TMDA services closer to the public and enhance service delivery, zone offices were established to facilitate smooth implementation of TMDA functions as stipulated under section 5(1) of the Act. TMDA established its first zone office in 2006 in Lake Zone with its headquarters in Mwanza city. The next zone office was established in Arusha city to serve the northern regions of the country in 2007 and then followed by the rest which were established between 2007 and 2016. Since then, TMDA has established 8 zone offices that serve the following regions in Tanzania mainland: -

Table No. 67: Eight zones and regions covered

S/N	NAME OF ZONE	REGIONS COVERED	OFFICE LOCATION
1	Eastern Lake Zone	Mwanza, Simiyu and Mara	Mwanza City
2	Western Lake Zone	Geita, Shinyanga and Kagera	Geita TC
3	Western Zone	Tabora, Kigoma and Katavi	Tabora Municipality
4	Central Zone	Dodoma, Singida, Iringa and Morogoro	Morogoro City
5	Northern Zone	Arusha, Manyara and Kilimanjaro	Arusha City
6	Southern Highland Zone	Mbeya, Songwe, Njombe and Rukwa	Mbeya City
7	Southern Zone	Mtwara, Lindi and Ruvuma	Songea Municipality
8	Eastern Zone	Dar es Salaam, Tanga and Coast	Dar es salaam City

15.3 Zone Managers

Since the establishment of the first zone office in 2006. Zone offices have had different Managers as shown in a Table 68 below:-

Table No. 68: List of zone managers between 2003 - 2023

S/N	Name of Zone	Name of the Manager (Period)
1	Eastern Lake Zone (Formerly Lake Zone)	Mr. Justin Makisi (Jan., 2005- March 2008), Mr. Seth Kisenge (April, 2008-Dec. 2012), Mr. Moses Mbambe (Jan., 2013-March, 2019) and Ms. Sophia Mziray (April, 2019- June 2023)
2	Western Lake Zone	Mrs. Nuru Mwasulama (March-Oct. 2019), Dr. Edgar Mahundi (2022- To Date)
3	Western Zone	Dr. Edgar Mahundi (2016-2022) and Mr. Christopher Migoha (2022- To date)
4	Central Zone	Mr. Florent Kyombo (2011-Jul, 2016), Dr. Engelbert Bilashoboka (2016- Jan, 2020) and Mrs. Sonia Mkumbwa (2020-To date)
5	Northern Zone	Mr. Damas Matiko (2005-2015), Mr. Didas Mutabingwa (2015-2018), Mr. Francis Mapunda (2018-Oct. 2019) and Mr. Proches Kimario (2019- To date)
6	Southern Highlands Zone	Mr. Lazaro Mwambole (2009-March, 2015), Mr. Rodney Alananga (2015- Oct., 2019), Mrs. Anitha Mshighati (2019- To date)
7	Southern Zone	Mr. Juma Bukuku (2015-Oct. 2019), Dr. Engelbert Bilashoboka (2019-To Date)
8	Eastern Zone	Mrs. Agnes Kijo (2007-Jan, 2014), Mr. Emmanuel Alphonce (2014- March, 2019), and Mr. Adonis Bitegeko (April, 2019- June 2023)

15.4 Functions of Zone Offices

Zone offices carry out responsibilities through three dedicated desks namely Medicines Control; Medical Devices and Diagnostics Control and support services. The following are functions performed under each desk; -

15.4.1 Medicines Control Desk

i. Registration and issuance of permits for premises dealing with medicinal products;

ii. Inspection of medicinal products and premises;

iii. Control of importation and exportation of medicines;

iv. Maintenance and updating of register of medicines premises;

v. Issuance of import permits and controlling the consumption of narcotics and psychotropic substances;

vi. Conducting post marketing surveillance (PMS) and pharmacovigilance activities;

vii. Supervising quality assurance centers;

viii. Monitoring advertisement and product promotional activities;

ix. Participating in GCP inspection of trials conducted in the zone;

x. Participating in GMP inspection of facilities in the zone; and

xi. Handling of recall and disposal of unfit medicinal products.

15.4.2. Medical Devices and Diagnostics Control Desk

i. Registration and issuance of permits for premises dealing with medical devices and diagnostics;

ii. Inspection of medical devices and diagnostics and premises;

iii. Control of importation and exportation of medical devices and diagnostics;

iv. Maintenance and updating of register of medical devices and diagnostics premises;

v. Conducting post marketing surveillance (PMS) and vigilance activities;

vi. Monitoring advertisement and product promotional activities;

vii. Participating in GCP inspection of medical device and diagnostic trials conducted in the zone;

viii. Participating in quality audit of facilities in the zone; and

ix. Handling of recall and disposal of unfit medical devices and diagnostics;

15.4.3 Support Services Desk

i. Managing office facilities, buildings, security services and station upkeep;

ii. Managing human and financial resources;

iii. Monitoring and coordinating inspections conducted by LGAs;

iv. Creating awareness to the public and market TMDA services;

v. Fostering cooperation and collaboration with LGAs and other stakeholders; and

vi. Participating in operational researches, programmes and projects;

15.5 Delegation of Powers and Gazetting of Inspectors and Analysts

Pursuant to section 105 of the Tanzania Medicines and Medical Devices Act, Cap.219 which empowers the Authority (Director General) to appoint, authorize and recognize inspectors to perform functions and powers of inspectors under the Act, the Director General has appointed and published in the government gazette 917 inspectors of which 146 are TMDA employees and 771 are from Local Government Authorities between 2003 and 2023.

CHAPTER - 16

Planning, Monitoring and Evaluation

This chapter presents TMDA's approach to planning, monitoring, and evaluation, focusing on the development and implementation of five year strategic plans that guided the Authority's efforts to fulfill its public health mission.

Since its establishment in 2003 the Authority has prepared and implemented 5 different Strategic Plans which highlights a number of strategies and targets that are pivotal in attaining TMDA's mission of promoting and protecting public health by ensuring safety, quality and effectiveness of Medicines, Medical Devices, Diagnostics and other health related products. From 2004 the Authority has had five Strategic Plans each covering a period of five (5) years as highlighted in the table below: -

Table No. 69: List of five strategic plans implemented between 2003 - 2023

No.	Period	Status
First	2004/2005-2009/2010	Implemented
Second	2009/2010-2013/2014	Implemented
Third	2013/2014-2017/2018	Implemented
Fourth	2017/2018-2021/2022	Implemented
Fifth	2021/2022-2025/2026	On going

Through Planning, Monitoring and Evaluation for the past 20 years the Authority has been able to execute successfully 20 approved budgets and attained and at times surpassed its revenue targets. Prudent management of the collected revenue has consistently enabled the Authority to get unqualified opinion from the Controller and Auditor General over the years.

The Authority has embeded a strong culture of Monitoring and Evaluation within its strategic plans and programmes fostering efficiency and effectiveness in achieving of organisational goals. For example , during the review the Authority undertook the following evaluations;

a) Mid-term Evaluation of TMDA Strategic Plans

b) End-term Evaluation of TMDA Strategic plans

c) Institutional self-assessment and

d) Routine Monitoring and Evaluation of TMDA Operations.

TMDA has consistently been able to properly implement the approved Work plans and Budgets through careful planning and proper resources allocation.

CHAPTER - 17

Milestones attained and challenges

This chapter outlines the key milestones achieved by TMDA over the years, along with the major challenges encountered in the course of fulfilling its regulatory mandate.

TFDA
Tanzania Food & Drugs Authority

2003: Establishment of TFDA

TFDA was established after the enactment by Parliament of the Tanzania Food, Drugs and Cosmetics Act (Chapter 219).

2004: Expansion of TFDA Laboratory in Dar Es Salaam

The TFDA expanded its Quality Control Laboratory building in Dar es Salaam and equipped it with state-of-the-art analytical instruments, machines and equipment.

2005: Innovation and Successful implementation of Accredited Drug Dispensing Outlets (ADDO) Programme

In its efforts to safeguard public health, the Authority developed innovative a regulatory system to curb the proliferation of unlicensed drug outlets in the market.v This led to the approval and establishment of accredited drug dispensing outlets for the sale of medical products a model that has since been adopted as best practice by other National Drug Regulatory Agencies (NRAs) in Africa.

2006: Launching and Operationalisation of Zone Office in Mwanza

The first Zone Office was established in Mwanza with the overall aim of bringing regulatory services closer to the public . in response to this need, eight (8) zone offices have been established since 2006 to carry out among other functions effective inspection and enforcement roles.

2007: Completion of the TFDA Headquarters' Office building in Dar Es Salaam

The construction of the headquarters building in Dar es Salaam was completed and ready to be commissioned to commence operations.

2007: TMDA SACCOS

TMDA SACCOS was established.

2008: The TFDA Headquarters' Office building in Dar es Salaam was officially commissioned

The TFDA headquarters building was officially commissioned by His Excellency Amani Abeid Karume, President of Zanzibar and Chairman of the Revolutionary Council.

2009: Attaining ISO certification

The Authority attained ISO 9001: 2008 certification for setting up an effective QMS that responds to customer satisfaction. The standard was later on updated to ISO:9001: 2015 in 2015.

2010: Awarded Best Managed Institution in Tanzania

The Authority was ranked to be the best-managed institution in Tanzania amongst Ministries, Departments and Agencies for the years 2010 and 2011 consecutively.

World Health Organization

2011: Attainment of WHO Prequalification for the TFDA Laboratory

The TFDA medicines laboratory attained WHO prequalification following a successful inspection conducted by WHO. Since becoming WHO-prequalified, the laboratory had continued to provide reliable analytical testing services to domestic and international clients dealing with medical products. The test results generated enable the Authority to make evidence-based regulatory decisions.

2012: Designated as Africa's Centre of Excellence for Registration of Medicines

The Authority was designated as Africa's Centre of Excellence for Registration of Medicines as part of the African Medicines Regulatory Harmonisation (AMRH) initiative. With its wide array of expertise and specializations , TMDA is in a unique position to tackle some of the most complex and pressing regulatory challenges across Africa.

2013: Establishment as Centre of Excellence for Laboratory Training serving NRAs in Africa

TFDA has consistently provided scientific and analytical on job training to other NRAs across Africa. It remains committed to forging strategic linkages with international agencies that share its dedication to safeguarding public health.

2014: Commissioning of an Integrated Management Information System (IMIS)

IMIS was commissioned to commence provision of of online services.

2015: Automation of Regulatory Services

The Authority established a robust and efficient IT infrastructure enabling provision of online services such as an online import application gateway and electronic submission system for product dossiers. The system has drawn interest from other African NRAs who have visited to learn on how to strengthen their digital in regulatory services.

2016: Completion of Lake Zone Office and Laboratory in Mwanza

The construction of the Lake Zone office and Laboratory was completed including procurement of modern analytical equipment and instruments. This expanded the scope of laboratory services provided by the Authority, thereby boosting its capacity to analyse samples.

2018: Attainment of WHO Maturity Level 3; the first of its kind in Africa

The Authority was the first NRA in Africa to attain Maturity Level (ML) 3 for setting up a robust medicines regulatory system in 2018. This status made Tanzania to become the first WHO member state in Africa to reach this advanced stage in medicines regulation.

2018: Quality Control Laboratory Attains WHO Maturity Level 4 (ML4)

The Dar es Salaam Quality Control Laboratory attained Maturity Level 4 (ML4) after a successful WHO inspection. It was the first Quality Control Laboratory in Africa to attain WHO ML4 for testing pharmaceutical products.

TMDA
Tanzania Medicines & Medical Devices Authority

2019: Change of name from TFDA to TMDA

The name of Tanzania Food and Drugs Authority (TFDA) was changed to Tanzania Medicines and Medical Devices Authority (TMDA) after amendment of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 and the Standards Act, Cap 130. Following the amendments, the regulation of food products and cosmetics was transferred from TFDA to the Tanzania Bureau of Standards (TBS). The amendment was done through the Finance Act of 2019.

2020: Completion of TMDA Zone Office and Laboratory in Dodoma

The construction of the Central Zone Office and Laboratory was completed including procuring modern analytical equipment and instruments and commenced laboratory services.

2021: TMDA Assigned to Regulate Tobacco Products

Under Section 18 of the Tobacco Products (Regulations) Act (Chapter 121), the Minister for Health designated TMDA as the Regulator of tobacco products.

2022: TMDA Establishes Mobile and Patient Reporting Systems for Safety Monitoring of Medicines

The Authority launched the patient safety reporting system to enhance the monitoring of safety of medicines circulating on the market.

2023: Ratification of AMA Treaty

The treaty for establishment of the African Medicines Agency was ratified by the Parliament of the United Republic of Tanzania.

2023: Construction of Incinerator

The construction of incinerator for disposal of unfit products started.

2003 - 2023: Obtaining Clean Audit Certificates

The Authority consistently received Clean Audit Certificates from the Controller and Auditor General (CAG) in recognition for its prudent management of resources.

2003 - 2023: Registration of Products

The number of registered medicines grew by over 50% rising from 591 in 2013 to 891 in 2023 and in the same period the number registered medical devices and diagnostics increased by more than 10 fold from 265 in 2013 to 2,804 in 2023.

2003 - 2023: Import and Export Permits Issued

The number of import permits issued per-annum increased by more than 60% from 3,952 in 2013 to 10,257 in 2023 and the number of export permits issued per-annum increased by more than 10 fold from 82 in 2013 to 824 in 2023

2003 - 2023: Registration of Premises

The number of registered pharmaceutical premises increased by more than 23 fold from189 in 2013 to 4,428 in 2023 and the number of registered medical device premises increased astronomically from 0 in 2013 to 2,443 in 2023

2003 - 2023: Authorization of Clinical Trials

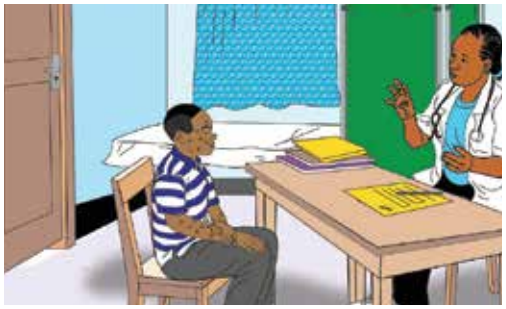
The number of authorized clinical trials increased by more than three fold from 63 in 2013 to 208 in 2023

2003 - 2023: GMP Inspection and Quality Audit

The number of pharmaceutical manufacturing facilities inspected for GMP compliance increased from 72 in 2013 to 116 in 2023 and the number of medical devices and diagnostics manufacturing facilities audited increased from 0 in 2013 to 65 in 2023

2003 - 2023: GCP Inspection

The number of clinical trials inspected for GCP compliance rose from 72 in 2003 to 116 in 2023



2003 - 2023: ADR and AEFI Reporting

The number of ADRs reported increased by than five fold from 2,263 in 2013 to 10,921 in 2023 and the number of AEFIs reported increased by more tha 8 fold from 2004 in 2013 to 16,963 in 2023

2003 - 2023: Laboratory Analysis

The number of samples analyzed in the QMS laboratory per-annum rose from 1,305 in 2013 to 1,553 in 2023

2003 - 2023: Human Resources Capacity

The number of permanent and pensionable employees increased by more than five fold from 62 in 2003 to 349 in 2023

2003 - 2023: Customer Satisfaction Level

The external customer satisfaction level rose from 74 in 2014 to 75 in 2020 and Internal customer satisfaction level rose from 68 in 2014 to 80 in 2020

2003 - 2023: Communication Platforms

- TMDA Website launched
- Social media accounts (facebook, twitter (now X) and instagram) launched
- TMDA TV online launched
- TMDA Toll free number launched
- TMDA na Jamii Programme launched

2003 - 2023: Financial Stability

The Authority's financial position has consistently improved each year driven by revenue from fees and charges collected for services rendered. These collections contribute 15% of its gross income and 70% of excess capital as required by the office of the Treasury Registrar.

2003 - 2023: Land Acquisitions

Plot located in Arusha
Plot located in Mbeya
Plot located in Mwanza
Plot located in Dodoma
Plot located in Pwani
Plot located in Tabora
Plot located Mtwara
Plot located in Geita
Plot located in Morogoro

2003 - 2023: Performance Appraisal Systems

The open performance appraisal system (OPRAS) was launched.

The TFDA/TMDA Annual Staff Appraisal (TASA) system was launched.

2003 - 2023: Promotion of Domestic Manufacturers

TMDA contributed to the increase in the number of domestic medical products manufacturers from 2013 to 2023 by creating an enabling business environment as illustrated below:

- Pharmaceutical manufacturers increased from 9 to 17
- Medical Device and Diagnostics manufacturers increased from 0 to 41

2003 - 2023: TMDA Staff Recruited in International Organizations

Owing to their proven competence, the number of TMDA staff recruited or seconded to international organizations has steadily increased:

Table No. 70: List of TMDA staff recruited in international organizations

S/N	Name	Organization
1	Dr. Margareth Ndomondo-Sigonda	NEPAD
2	Mr. Hiiti B. Sillo	WHO
3	Ms. Agnes S. Kijo	WHO
4	Mr. Akida Khea	WHO
5	Dr. Alex Nkayamba	WHO
6	Ms. Alambo Msussa	WHO
7	Mr. Sunday Kisoma	WHO
8	Mr. Alex Juma	NEPAD
9	Ms. Jeniva Jasson	WHO
10	Mr. Augustine Massawe	ECSA
11	Dr. Henry Irunde	EAC
12	Dr. Shani Maboko	Rwanda - FDA

17.1 Challenges Encountered

Regulating medical products is a complex and highly demanding task presenting persistent multifaceted challenges. In the 20 years of its operation the Authority has faced the following challenges;

i. Existence of sub -standard and falsified products ciculating on the market;

ii. Absence of TMDA offices throughout the country;

iii. Inadequate human resource capacity in relation to workload and volume of assigned activities including laboratory analysis, evaluation and inspection of products;

iv. Failure of the majority of domestic manufacturers of medical products to comply with minimum GMP and quality standards;

v. Limited public awareness and understanding of quality and safety issues for regulated products;

vi. Rapid changes in technology in manufacturing and regulation of products

vii. Proliferation of premises operating without business permits

viii. Pilferage of products intended for public supply chain to the private sector

ix. Irrational use of medicines that has contributed to the emergence of antimicrobial resistance

x. Existence of porous borders that has contributed to smuggling of unregistered and substandard and falsified products into the market

xi. Wide spread malpractices in ADDO shops

xii. Online selling of regulated products

xiii. Inadequate mechanism to reach out to the wider community to educate them on regulated products

xiv. Failure to comprehensively regulate promotional activities

xv. Limited revenue generation from TMDA's laboratory services.

xvi. Delays in delivery of goods or services from contracted suppliers

xvii. Regulation of food supplements and cosmeceuticals which falls in the borderline of control between TMDA and TBS

xviii. Lack of advanced knowledge and skills amongst TMDA staff on various fields of expertise such as intelligence gathering, ICT programming and cyber-security, analytical techniques, laboratory equipment maintenance, analysis method development and IT auditing

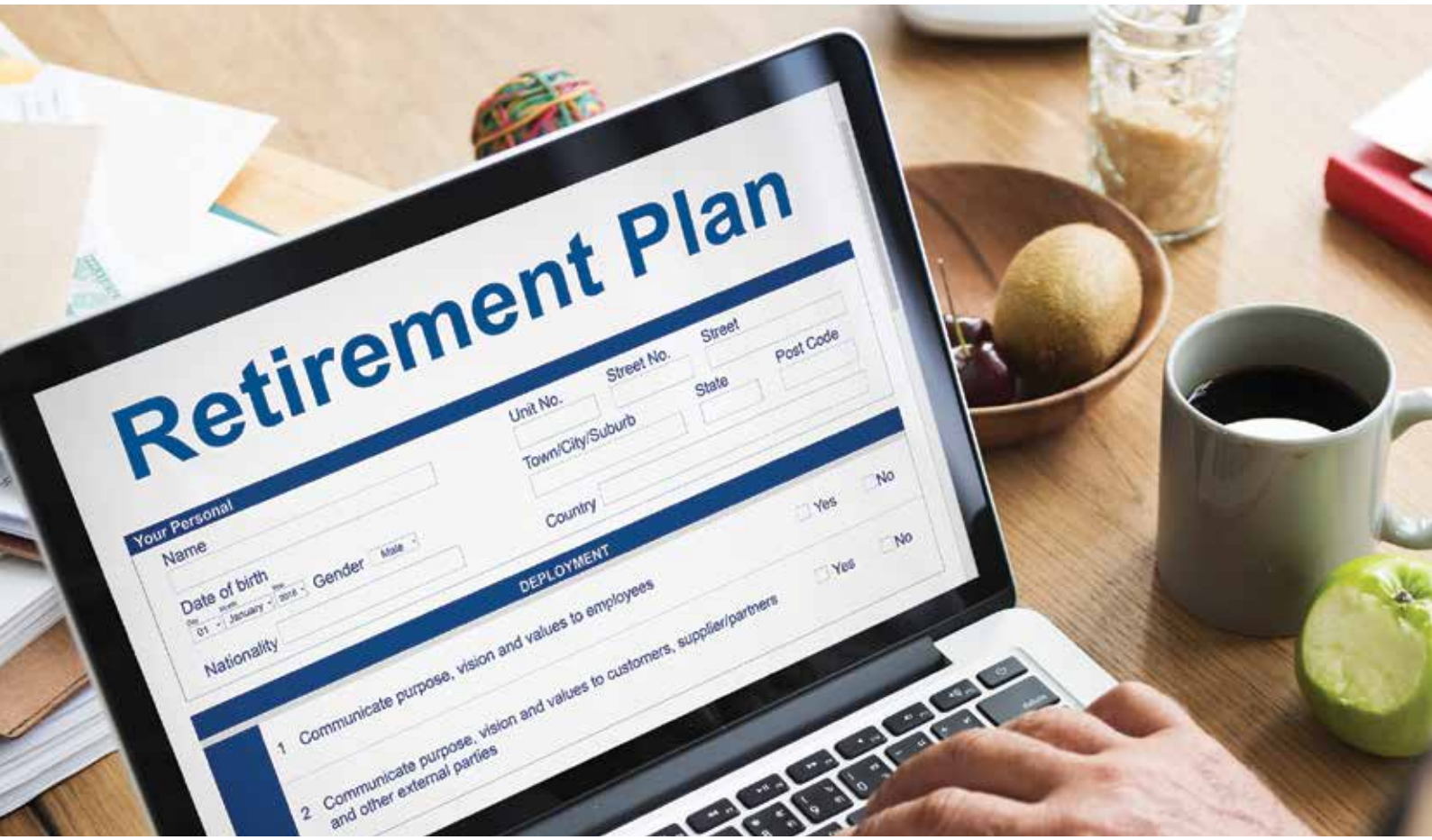
CHAPTER - 18

Retirees and Obituaries

18.1 Introduction

This chapter documents the service and legacy of the men and women who, through steadfast dedication, devoted their professional lives to the Authority. Their years of faithful service were marked by efforts to strengthen regulatory systems, enforce standards, and mentor the next generation of professionals. Through their stewardship, the Authority progressed from its formative years as the TFDA into the TMDA, a mature institution held in high regard nationally, regionally, and internationally.

It further records the memory of colleagues who passed on before the completion of their journey of service. Their commitment and contributions remain an integral part of the Authority's history and



continue to inspire those who follow in their footsteps. Over the past two decades, the defining strengths of both TFDA and TMDA has been its people. Behind every regulatory framework, inspection, policy, and innovation stood individuals whose professionalism and dedication gave practical effect to the mandate of protecting and promoting public health.

18.2 Our Retirees

Between 2003 and 2023, 29 staff employed with TMDA, have retired from public service. The retirees left an indelible mark on the Authority's governance and institutional development as TMDA relied heavily on their services in executing its regulatory functions. Moreover, they contributed much to the sustainability of the institution especially during the transition from TFDA to TMDA.

TMDA acknowledges the diverse roles and contributions of all retirees during their tenure. Their efforts, resilience, creativity, commitment and patriotism were pivotal to the Authority's achievements. Without their contributions and dedication the Authority would not have attained many of the milestones.

Albeit, it is not easy to outline every detail of all retirees, TMDA has taken note of special contribution from some of the retirees who held various managerial positions and as such their vision and leadership were instrumental in shaping the foundations upon which TMDA stands today. Among them were Dr. Sikubwabo Ngendabanka and Mr. Legu Mhangwa, who played a pivotal role in championing the transformation from the former Pharmacy Board to the establishment of the Tanzania Food and Drugs Authority (TFDA).

Ms. Charys Ugullum was at the forefront of establishing the Quality Control Laboratory, thereby ensuring the Authority's capacity to provide reliable and internationally recognized testing services. The advancement of the Quality Management System was spearheaded by Mr. Didas Mutabingwa, whose efforts laid the groundwork for operational excellence and accountability. In the area of food safety, Mr. Raymond Wigenge distinguished himself as a champion of regulatory oversight across the country, strengthening systems that continue to safeguard communities to this day.

Through their pioneering contributions, these leaders not only guided the Authority during

its formative years but also provided a model of governance, professionalism, and public service that continues to inspire future generations. These few examples represent only part of a larger group of retirees whose contributions collectively defined the growth and transformation of the institution. Each played a vital role in building TMDA into the respected regulatory body it is today.

Table No. 71: List of TMDA retirees between 2003 - 2023

NAME	TITLE	YEAR
Hamis Shengo	Principal Driver	2023
John Peter Makala	Security Guard	2023
Elizabeth Maleto	Procurement Officer	2022
Paul Makaranga	Laboratory Technician	2022
Didas Mutabingwa	Princilpal Quality Assurance Officer	2022
Agnes Mneney	Principal Quality Management Officer	2022
Dr. Gloria Omary	Principal Analyst	2022
Mwanaamani Mshana	Principal Office Assistant	2020
CPA Sadi Kajuna	Principal Accountant	2020
Rosemary Aaron	Principal Drug Registration Officer	2020
Justin Makisi	Manager, Food Inspection and Enforcement	2019
Raymond Wigenge	Director of Food Safety	2018
Ollympia Kowero	Principal Drug Inspector	2017
Dr. Sikubwako Ngendabanka	Director of Business Support	2017
Chriss E. Kahemele	Records Management	2017
Erasto Mosha	Principal Laboratory Investigator	2016
Zawadiel Senkoro	Laboratory Investigator	2015
Octavian Soli	Zonal Office and Local Government Authorities Coordinator	
Dr. Nditonda Chukilizo	Drugs and Cosmetics, Registration Manager	2014
Charlys Ugullum	Director of Laboratory Services	2014
Legu Mhangwa	Director of Drug Registration	2012
Idda Swai	Office Assistant	2012
Dr. Judicate Ndosi	Principal Health Food Inspector	2012
Rehema Shemhina	Principal Health Food Inspector	2012

Reflections on TMDA by retired Directors

Dr. Sikubwabo S. Ngendabanka
The first Director of Business Support of the then TFDA

I, Dr. Ngendabanka was appointed to position of Director of Business Support from 1st July, 2003 the date when the then Tanzania Food and Drugs Authority was inaugurated before being transformed into Tanzania Medicines and Medical Devices Authority (TMDA) on 1st July 2019.The Directorate of Business Support I headed was constituted of five sections namely; Human Resources and Administration, Finance, Planning, Information and Communication Technology and Marketing. My in-depth understanding of the Authority and therefore my suitability for the said post emanated from the fact that besides having the necessary qualifications I was the Team Leader for the establishment of TFDA. Our Team was responsible for drafting all the necessary documents for establishing the Authority including Tanzania Food and Drugs Act, 2003, Strategic Plan, Business Plan, Framework Document, Organization Structure, the first Work Plan and Budget and Human Resource Plan. Furthermore, our team played a pivotal role by liaising with key players in the formation of TFDA including; the President's Office, Public Service Management, Ministry responsible for Health, Registrars of Pharmacy Board and National Food Control Commission and other government departments such as Attorneys General's Chamber.

I am grateful for the steady growth and recognition of the Tanzania Food and Drugs Authority within the region, Africa and the rest of the world which is the result of good leadership and management of resources of which my Directorate had a big role to play. The Directorate of Business Support was one of the key arms of the Director General in ensuring that there are was smooth operations across the organization. As the Director responsible for human resources, I ensured that we have the right personnel in the right positions and led the teams in establishment of leadership and management systems by developing Human Resources Internal Polices, Regulations and Guidelines.

The Directorate of Business Support functioned as hub for our authority as the rest of the directorates including the Office of the Director General needed facilitation in terms of resources and systems including automation of service delivery processes, strategic planning, budget preparation, performance monitoring and evaluation, staff motivation, marketing, public education, revenue collection and expenditure management. I am happy to learn that for the period of 13 years I manned the directorate the Authority was assessed by the Controller and Auditor General to have clean Audit Reports.

During the period under review TFDA managed to achieve to a great extent its mission and vision. The Authority managed to regulate the quality, effectiveness and safety of medicines and medical devices and the the quality and safety of food and cosmetics. It improved accessibility to medicines by facilitating establishment of regulated business by putting in place clear processes and procedures and more importantly establishment of zone offices an undertaking which was also facilitated by the Directorate of Business Support. In the course of improving access to safe, quality and efficacious medicines I was appointed and led the team that developed National Accredited Drug Dispensing Outlets programme in 2005 which had a significant impact on improved access to medicines.

The stability of TFDA until its transformation to TMDA is reflection of strong internal policies and working systems that led to good leadership. I am happy to have been one of the lead persons in establishing and implementing TFDA management systems until 2017 the time I took voluntary retirement when it has already attained Maturity Level 3 as per Word Health Organization benchmarking national medicines regulatory authorities.

Building on the rich resources, experiences and expertise inherited from TFDA and accumulated through its years of growth, it is my wish and conviction that TMDA is well positioned of emerging as a global leader in in the regulation of medical products. . I look forward to see services being improved at the grassroot levels, ports of entry, manufacturing sites, distribution and selling points. I would like commend the work done so far by retaining the ISO certification and WHO accreditation.

With globalization and increasing market competition consumers are at high risk thus the need for national investment in regulatory authorities. It is for this reason I urge the TMDA Management to invest in human resources development and technology to adequately protect innocent users of the regulated products.

Raymond Nicholaus Wigenge
The first Director of Food Safety of the then TFDA

Looking back on my journey, from the early days at the National Food Control Commission (NFCC) through to my final days at the Tanzania Food and Drugs Authority (TFDA), and now observing the continued progress of what is today the Tanzania Medicines and Medical Devices Authority (TMDA), I feel a deep sense of pride and fulfillment.

When I joined NFCC in 1990, food and medicine regulation in Tanzania was still in its formative stages. We worked with limited resources but carried a strong commitment to protect public health. It was during those years that I learned the importance of perseverance, teamwork, and visionary leadership in shaping effective institutions.

The transition from NFCC to TFDA in 2003 was a pivotal moment. Being part of the Agency Implementation Team that laid the groundwork for TFDA's establishment was a personal and professional milestone. We faced many challenges—developing regulatory frameworks, crafting policies, and building systems from the ground up. Yet, the determination of our team, and particularly the leadership of our first Chief Executive, Ms. Margareth Ndomondo-Sigonda, helped build a solid foundation for product regulation in Tanzania. Her visionary approach brought

structure, systems, and accountability into the authority, all of which were critical in earning both national and international recognition.

Throughout my tenure at TFDA, I served in several capacities—from Chief Food Inspector, to Coordinator of Zonal Offices and Local Government Authorities, and later, as Director of Food Safety. Each role presented unique challenges and opportunities. As Director of Food Safety, I had the responsibility and privilege of leading the development of a national food safety control system. We emphasized risk-based approaches, stakeholder engagement, and strengthening capacity at both central and local levels. Delegation of regulatory powers to Local Government Authorities proved especially crucial, given the limited number of inspectors and the growing volume of regulated products.

One of the greatest successes during my time at TFDA was the implementation of a quality management system that ensured consistency, transparency, and continuous improvement in regulatory services. Similarly, the annual staff appraisal system allowed open dialogue between supervisors and staff, aligning individual contributions with organizational goals. These systems fostered a culture of performance and accountability that I believe TMDA continues to benefit from today.

Regulation is a dynamic field—new products, technologies, and risks constantly emerge. Even after my retirement in 2018, I have observed with satisfaction how TMDA has remained resilient, efficient, and forward-looking. As regulatory workloads continue to rise with increasing trade volumes, I strongly support the continued implementation of a risk-based approach. This ensures that limited resources are focused where they are needed most, while also emphasizing education and voluntary compliance by stakeholders.

In conclusion, my time with NFCC, TFDA, and the broader public service has been deeply rewarding. I take great pride in having contributed to building an institution that protects public health and serves the nation with integrity. I trust that TMDA will continue to uphold these values and adapt to future challenges with innovation, professionalism, and commitment.

Charys Ugullum,
Former Director of Laboratory Services of the then TFDA

As the Tanzania Medicines and Medical Devices Authority (TMDA) commemorates 20 years of its existence, I take this moment to reflect with deep pride and appreciation on the remarkable journey of this institution one I was privileged to serve during its formative years. I joined the then Tanzania Food and Drugs Authority (TFDA) in March 2005, just two years after its establishment, and served as Director of Laboratory Services until my retirement in 2016. It was a time of great ambition, collective purpose, and unwavering commitment to public health.

During that period, TFDA was entrusted with the critical mandate of regulating food, medicines, medical devices, and cosmetics to ensure the safety, quality, and efficacy of these products for all Tanzanians. One of our major accomplishments, particularly in laboratory services, was attaining international accreditation. The TFDA laboratory received ISO/IEC 17025 accreditation, a globally recognized standard confirming the competence and reliability of testing services. This achievement elevated the credibility of the Authority not just nationally, but internationally, making it a model institution within the East African region and beyond.

Equally important was the attainment of ISO 9001 certification for the Authority's quality management systems. This milestone reflected our dedication to sound governance, efficiency, and continual improvement in our operations. Together, these certifications symbolized our pursuit of excellence and our firm commitment to science-led regulation.

These accomplishments were made possible by the dedication, expertise, and integrity of the staff who served during that era. I had the honour of working with a team of highly skilled professionals who believed in the mission of the Authority. We worked collaboratively, supported one another, and maintained high ethical standards in all our endeavours. It is this team spirit and professionalism that laid the solid foundation on which TMDA continues to build today.

Over the years, the Authority has undergone structural and administrative transformations, including the rebranding from TFDA to TMDA and the redistribution of some regulatory responsibilities. While change is inevitable in the evolution of institutions, I believe that the integrated model under TFDA offered a more comprehensive and efficient approach to protecting public health. The separation of food and cosmetics regulation to other entities poses challenges in ensuring a unified oversight system, particularly when public health implications remain at the core of all regulated products. I remain hopeful that decision-makers will, in the future, re-evaluate this structure and recognize the value of reintegrating these functions under TMDA for more cohesive regulation.

As I look back at the past 20 years, I am immensely proud of the contributions made by the Authority to national development and public safety. TMDA has continued to uphold the vision and values set forth in its early years, adapting to new challenges, embracing innovation, and maintaining a presence on the global stage. I commend the leadership and staff of TMDA for sustaining this legacy and driving the institution forward with purpose and dedication.

It has been an honour to be part of this journey. I remain a strong supporter of TMDA and its mission to safeguard the health of the people of Tanzania. As we celebrate this important milestone, I extend my heartfelt congratulations to all who have played a role in the Authority's growth and success. May the next decades be marked by continued excellence, innovation, and unwavering commitment to public health.

18.3 In Loving Memories (Obituaries)

Between 2003 and 2023, the Authority mourned the passing of fifteen dedicated staff members who departed while still in service. Each played an important role in advancing the growth and stability of the institution through their professionalism, integrity, and unwavering commitment to public health. Though their journeys ended too soon, their contributions remain deeply woven into the Authority's legacywhether by strengthening regulatory systems, advancing technical expertise, or supporting the daily operations that sustained institutional growth. Their memory endures as a source of inspiration, reminding us that TMDA's achievements rest not only on policies and systems, but also on the devotion, sacrifice, and humanity of its people.

Table No 72: Honouring Lives of Service 2003 – 2023.

S/N	NAME	TITLE	YEAR OF PASSING ON
1.	Ms. Zera Msuya	Drug Inspector	2007
2.	Mr. Abdallah Mangwasa	Security Guard	2008
3.	Mr. Satara Satara	Food Inspector	2008
4.	Mr. Festo John Nyagawa	Driver	2010
5.	Mr. Hamisi Lihoha	Driver	2010
6.	Mr. Aaron Elias	Assistant Drug Inspector	2011
7.	Ms. Maimuna Haji	Drug Inspector	2013
8.	Mr. Zuberi Ayoub	Driver	2016
9.	Mr. Said Kikome	Driver	2016
10.	Mr. Chris Edwin Kahemele	Record Assistant	2017
11.	Mr. Wenceslaus Henjewele	Record Assistant	2017
12.	Ms. Marry Mbwambo	Personal Secretary	2018
13.	Dr. Osidai Kivuyo	Drug Registrar	2020
14.	Mr. John Shallanda	Driver	2020
15.	Mr. Mtani Njegere	Drug Inspector	2022

CHAPTER - 19

Conclusion and Looking ahead in the Next Two Decades

This chapter presents the conclusion and a forward-looking perspective, outlining TMDA's vision, priorities, and strategic direction for the next two decades in strengthening regulatory systems and promoting public health.

The twenty-year journey of the Tanzania Medicines and Medical Devices Authority (TMDA), from its inception as the Tanzania Food and Drugs Authority (TFDA) in 2003 to its current mandate, is a story of transformation, resilience, and service to the nation. Established from the foundations of the former Pharmacy Board and the National Food Control Commission, the Authority emerged at a time when the country urgently needed a strong and credible institution to regulate medicines, food, cosmetics, medical devices, and diagnostics.

Over the years, TMDA has evolved into a mature, respected regulatory body recognized at national, regional and global levels. The Authority has built robust systems to ensure the quality, safety, and efficacy of health products, expanded its laboratory capacity, and extended its regulatory reach through zonal offices. Governance structures were strengthened, policies were aligned with international best practices, and innovations such as the adoption of electronic systems modernized service delivery.

The achieved progress would not have been possible without the people—the pioneers, staff, leaders, and stakeholders whose commitment turned vision into reality and policies into lasting impact. Retirees left behind a wealth of institutional memory, while colleagues who passed on in service left legacies of dedication and sacrifice. Together, they ensured that TMDA became a cornerstone in safeguarding public health and building public confidence in regulatory systems.

19.1 Lessons Learned Along the Way

From this two-decade history, several lessons emerge that continue to shape TMDA's identity and governance:

1. **Strong Institutions Depend on Strong People** – Policies and structures matter, but it is people who breathe life into them through professionalism, ethical conduct
2. **Adaptation** is Essential for sustenance of Relevance – TMDA's shift from manual systems to digital platforms, and its ability to align with global health standards, reflects a culture of adaptation which fuels institutional relevance.
3. **Partnerships Drive Impact –** Collaboration with government agencies, international organizations, industry players, and the public is vital in extending the reach and effectiveness of regulation.
4. **Public Trust is Earned, Not Given** – Every inspection, laboratory test, and regulatory decision reinforced public confidence in the Authority. Sustaining this trust remains a continuous responsibility.

19.2 Looking Ahead: The Next Two Decades

As TMDA steps into its third decade, the landscape of health regulation is rapidly changing. The future will bring both new opportunities and emerging challenges:

1. **Advancing Technology and Innovation:** New medical technologies, digital health tools, and advanced diagnostics will require agile regulatory frameworks to balance safety with innovation.

2. **Globalization of Supply Chains:** Increasing cross-border trade in health products will demand stronger collaboration with regional and international regulators.
3. **Public Health Emergencies:** Pandemics and other health crises will continue to test regulatory preparedness, highlighting the need for rapid response mechanisms.
4. **Sustainability and Inclusivity:** TMDA must ensure that regulatory systems are not only efficient but also inclusive, transparent, and responsive to the needs of all communities.

19.3 Commitment for the Future

Looking forward, TMDA's commitment rests on three pillars:

1. **Excellence in Regulation –** Building on international recognition, TMDA aspires to become a regional leader and model of regulatory excellence in Africa.
2. **Innovation in Service Delivery –** By deepening the use of digital systems, artificial intelligence, and data-driven decision-making, the Authority will improve efficiency, transparency, and stakeholder engagement.
3. **Investment in People –** The next generation of TMDA staff will be the custodians of this legacy. Investing in capacity building, continuous learning, and professional growth will ensure sustainability of the Authority's mission.

19.4 Closing Reflection

The history of TMDA is ultimately the history of Tanzania's commitment to protecting its people. From modest beginnings in 2003 to the present, the Authority has stood as a guardian of health, ensuring that medicines, devices, diagnostics and food products meet the highest standards of quality and safety.

As TMDA looks to the next 20 years, it does so with confidence—grounded in its legacy, guided by its lessons, and inspired by its people. The journey ahead will demand innovation, courage, and integrity, but with the same spirit that carried the Authority through its formative years, TMDA is prepared to meet the future.

The mandate remains clear; to protect and promote public health. This mission, carried forward with renewed vision and strengthened resolve, will continue to define TMDA's role for generations to come.

20 YEARS, MANY HEADLINES: A SHARED MEDIA PERSPECTIVE (2003 - 2023)


Guardian
TMDA all out to wage war against counterfeit drugs all over Tanzania
TMDA in drive to improve medicine quality, safety and ethical practices
TMDA warns advertisers of herbal drugs in social media
TMDA yajigamba urahisi uagizaji dawa, vifaa tiba
WIZI SERIKALINI
TMDA yamnasa anayeuza dawa za Serikali kimagendo
TMDA kufanya tathmini matumizi ya P2
TMDA ilivyojipanga kufanikisha chanjo dhidi ya corona
Lake zone TMDA's lab to bolster quality of disinfectants
TMDA kuziondoa bidhaa za tumbaku zenye kemikali
Chemicals in tobacco products bad - TMDA


Nipashe
HABARI KITAIFA
Kiwanda cha kutengeneza vifaa tiba chazinduliwa
16 Nipashe
HABARI MBEYA
TMDA yateketeza tani 10 dawa zilizopita muda
TMDA yaboresha huduma zake maeneo ya forodha
Government assures investors of health sector transformation
By Guardian Reporter
'Food safety not TBS regulation function'
TFDA kudhibiti bidhaa bandia mipakani
TFDA yaanza marekebisho ya sheria ya adhabu
TFDA yaburuta 21 mahakamani kwa dawa bandia
TFDA IMEZITHIBITISHA DAWA HIZI ZA KUONGEZA NGUVU ZA KIUME, ZISOME HAPA
VIAGRA

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