

Introduction

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

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

Vision:

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

Mission:

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

Philosophy:

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

Core values:

- Integrity
- Customer focus
- Quality
- Teamwork
- Accountability
- Transparency

Quality policy statement

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

TMDA is committed to comply with the requirements of ISO 9001:2015 Standard and continually improve effectiveness of Quality Management System. It shall manage and provide resources for continuous improvement of our services to ensure customers' satisfaction."

Organization Structure and functions of TMDA

TMDA is headed by the Director General who is the accounting officer and takes executive responsibility for strategy, operational management and service delivery of the Authority. He is accountable to the Permanent Secretary, Ministry of Health, Community Development, Gender Elderly and Children. The office of the Director General is supported by the following units: Legal services, Procurement Management, Communication and Public Education, Quality and Risk Management Unit and Internal Audit. Under the Director General there are four directorates and zone offices as follows:

Directorate of Medical Product Control

- Registration and issuance of permits for manufacturing and selling premises of medicines, medical devices and diagnostics.
- Inspection of medicines, medical devices and diagnostics manufacturing facilities and selling outlets
- Inspection of medicines, medical devices and diagnostics consignments at ports of entry
- Issuance of importation and exportation permits of medicines, medical devices and diagnostics
- Evaluation and registration of medicines, medical devices and diagnostics before market authorization
- Control of clinical trials and monitoring of adverse drug reactions (ADRs)
- Control of medicines, medical devices and diagnostics promotional activities



Directorate of Laboratory Services

It conducts laboratory analysis of medicines and testing of medical devices and diagnostics to enhance regulatory decision making within the Authority.

Directorate of Business Development

It provides and enhances good management of TMDA resources. The directorate supports all technical operations to ensure smooth running of the Authority. It is responsible for administration, planning, finance and information technology management.

Zone Offices

Currently there are seven (7) zone offices in Mwanza, Arusha, Mbeya, Dodoma, Mtwara, Dar es Salaam and Tabora regions to perform TMDA functions at zone levels. These offices cater for the following regions;

Zone	Regions
Northern Zone	Arusha , Manyara and Kilimanjaro
Lake Zone	Mwanza, Shinyanga, Mara, Kagera, Simiyu and Geita regions
Eastern Zone	Dar es salaam, Coast Region and Tanga
Central Zone	Dodoma, Morogoro and Singida regions
Southern Zone	Mtwara, Ruvuma and Lindi regions
Western Zone	Tabora, Katavi and Kigoma

TMDA also collaborates with the regional administration and local government authorities in enforcing the Tanzania Medicines and Medical Devices Act, 2019

TMDA 's stakeholders

Product manufacturers ,distributors,wholesalers and retailers

- Law enforcers
- Practitioners/researchers
- Health care providers
- Government institutions
- Non government organization(NGO's)
- Media and information centres
- Consumers and general public

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY



Tanzania Medicines & Medical Devices Authority

Director General,

Tanzania Medicines and Medical Devices Authority (TMDA)

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