2018 Quality Control LAB attained WHO ML4

The Quality Control Laboratory complies with the WHO Good Practices for Pharmaceutical Quality Control Laboratories. It was the first Quality Control Laboratory to attain WHO ML4 for testing pharmaceutical products in Africa.

2018 Created a Clinical Trials Registry for recording and monitoring clinical trials conducted in the country

The Authority is regulating clinical trials and monitoring the quality, safety and effectiveness of medicines and biological in the manner that is acceptable for safety monitoring

2019 Change of name from the then TFDA to TMDA

The Authority has experienced massive changes as from 1st July 2019 in its regulatory functions whereby the control of cosmetics and food products has been shifted to the Tanzania Bureau of Standards (TBS) following the Finance Act, 2019 which in turn led to the transformation of name from the then Tanzania Food and Drugs Authority (TFDA) to Tanzania Medicines and Medical Devices Authority (TMDA).

2020 Completion of TMDA zone office and laboratory building in Dodoma

The construction of the Central Zone office and Laboratory together with the procuring of state of art modern analytical equipment and instruments, expanded the scope of laboratory services provided by the Authority and hence boosting its capacity to analyze samples of products.

2021 TMDA assigned to regulate tobacco products

Pursuant to Section 18 of the Tobacco Products (Regulations) Act, Cap 121, the Minister of Health designated the Tanzania Medicines and Medical Devices Authority (TMDA) as the regulator of tobacco products.

2022 Established mobile and patient reporting systems for safety monitoring of medicines

The authority continuously monitors quality, safety and effectiveness through vigilance and post-marketing surveillance activities whereby vigilance centers have been established and effectively used throughout the entire country. In the event of Adverse event or Incident, quick detection is made and reported through the established Safety and Quality Reporting Tool (SQRT) for prompt remedial regulatory action.

2023 20 Years of successful operations

TMDA mark its 20th Anniversary of successful regulations of quality and safety of medicines, medical devices and diagnostics since its establishment as the regulatory Authority on 1st July, 2003.

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TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

A JOURNEY OF MILESTONES

TMDA 20th
2003–2023

A JOURNEY OF MILESTONES 2003-2023.

2003 Establishment of Regulatory Authority

TMDA which was formerly known as Tanzania Food and Drugs Authority (TFDA) was established in 2003 after enactment of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 by the Parliament.

From 2003 Obtainment of clean Audit Certificates

In the last 20 years, the Authority has constantly qualified for a clean audit certificate on yearly consecutively audited by the office of the CAG in financial and institutional management

2004 Expansion of TMDA laboratory in Dar es Salaam

The then TFDA managed to expand its Quality Control laboratory building and equip with a state of art modern analytical equipment and instruments.

2005 Innovated and successfuly implemented the ADDO program

In the protection of public health, the Authority innovated regulatory system to mitigate mushrooming of informal market on sale outlets for medical products, a lesson that have been learnt by other NRAs in Africa.

2006 Launched and operationalization of Zone office in Mwanza

Mwanza Zone office has been fully established with the overall aim of bringing regulatory services closer to the public and serve them better. With this necessity, since 2006, eight Zone offices have been established to carry on among other functions effective and prompt enforcement roles on daily bases.

2007 Completion of the then TFDA Headquarters office building in Dar es Salaam

The construction of the Headquarters building in Dar es Salaam increased the productivity of the then TFDA's activities and other operational functions.

2008 The then TFDA Headquarters office building in Dar es Salaam launched

The Construction of the Head office building of the then TFDA provided sufficient space for the Authority to perform its mandated regulatory functions.

2009 Setting up a Quality Management System (QMS) that has attained ISO 9001:2015 certification

Since 2009, the Authority has demonstrated its ability to consistently provide quality services that meet customer and regulatory requirements through the implementation of Quality Management System principles stipulated in the ISO 9001:2015 Quality management systems - Requirements.

2010 Awarded best Managed Institution in Tanzania

The Authority has proven to be among the best managed Institutions in Tanzania and it was recognised amongst Ministries, Departments and Agencies category for years 2010 and 2011 respectively.

2011 Established and implemented a laboratory QMS for medicines that has attained WHO prequalification in 2011

Being the WHO prequalified Laboratory, the Quality control laboratory provide a reliable analytical testing services to Government and private companies dealing with medical products. Test results generated enable the Authority to make evidence-based regulatory decisions and be reliable internationally.

2012 Designated as the Center of Excellence for Registration of Medicines in Africa

The Authority designated as the Center of Excellence for Registration of Medicines in Africa as part of the African Medicines Regulatory Harmonization (AMRH) initiative. While embracing a broad spectrum of expertise and specialities, TMDA is in a unique position to address some of the most challenging and pressing issues in the regulatory framework in Africa.

2013 Established center of laboratory training to other NRAs in Africa

TMDA has been constantly providing scientific and analytical on job training to other NRAs in Africa. TMDA strives to be a valued partner that forges strategic linkages with international agencies that share its commitment to public health protection.

2014 Establishment of an Integrated Management Information System – IMIS

The Integrated Management Information System was developed with technology that allows to be accessed online.

2015 Automation of regulatory services

The Authority established an IT infrastructure which is very effective including offering online services to customers such as an online import application system and electronic submission system for product dossiers that has been used to provide lessons to partner NRAs within Africa to improve their e-commerce in regulatory services

2015 Financial Stability

The financial position of the Authority has been improved yearly due to collection arised from the fees and charges obtained through services rendered hence contributing 15% of its gross income and 70% of excess capital as required by the office of the Treasurer Registrar.

2016 Completion of Lake zone office and laboratory building in Mwanza

The construction of the Lake Zone offices and Laboratory together with the procurement of state of art modern analytical equipment and instruments, expanded the scope of laboratory services provided by the Authority, thereby boosting its capacity to analyze samples.

2017 Created a condusive and enabled business environment in Tanzania

The Authority reviewed its Fees and Charges Regulations, 2017 purposely to reduce the burden of charges and remove the inspection fee for premises and fee for importation of raw materials in order to support the government Industrialization Agenda.

2018 Attained WHO Maturity Level 3; the first of its kind in Africa

The Authority was the first National Regulatory Authority (NRA) in Africa to attain Maturity Level (ML) 3 for setting up a robust medicines regulatory system in 2018. This status made Tanzania become the first World Health Organization (WHO) member state in Africa to reach its advanced medicines regulatory system.