

# MAMLAKA YA CHAKULA NA DAWA



Tanzania Food & Drugs Authority

## TEN YEARS OF REGULATING FOOD, MEDICINES, COSMETICS AND MEDICAL DEVICES: MILESTONES ATTAINED



2003-2013





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## ABBREVIATIONS

AAS	- Atomic Absorption Spectrophotometer
ACT	- Anti Malaria Combination Therapy
ADDO	- Accredited Drug Dispensing Outlet
APHFTA	- Association of Private Health Facilities in Tanzania
ADRI	- Animal Diseases Research Institute
AGORA	- Access to Global Online Research in Agriculture
ALAT	- Association of Local Authorities of Tanzania
ALu	- Artemether + Lumefantrine
CEM	- Cohort Event Monitoring
CSC	- Clients Service Charter
CSR	- Corporate Social Responsibility
EAC	- East African Community
FTIR	- Fourier Transformed Infra Red
GCL	- Government Chemist Laboratory
GCLA	- Government Chemist Laboratory Agency
GCP	- Good Clinical Practices
GDP	- Good Dispensing Practices
GHP	- Good Hygienic Practices
GLP	- Good Laboratory Practices
GMP	- Good Manufacturing Practices
GSP	- Good Storage Practices
HACCP	- Hazard Analysis Critical Control Point
HINARI	- Health Inter Network Access to Research Initiatives
HIV	- Human Immunodeficiency Syndrome
HPLC	- High Performance Liquid Chromatography
HPTLC	- High Performance Thin Layer Chromatography
ICT	- Information and Communication Technology
IEC	- International Electrochemical Commission/Information Education and Communication
IV	- Intravenous
IMCI	- Integrated Management of Childhood Illnesses
ISO	- International Organization for Standardization
KCMC	- Kilimanjaro Christian Medical Centre
MAB	- Ministerial Advisory Board
MIS	- Management Information System
MUHAS	- Muhimbili University of Health and Allied Science
MSD	- Medical Stores Department
MSH	- Management Sciences for Health
NEMC	- National Environmental Management Council

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NGOs	- Non-Governmental Organisations
NHL-QATC	- National Health Laboratory – Quality Assurance and Training Centre
NIMR	- National Institute for Medical Research
NIT	- National Institute of Transport
NRA	- National Regulatory Authority
NFCC	- National Food Control Commission
OARE	- Online Access to Research in the Environment
OPRAS	- Open Performance Review and Appraisal System
OSHA	- Occupational Safety and Health Authority
OTC	- Over-The-Counter
PCCB	- Prevention and Combating of Corruption Bureau
PHLB	- Private Health Laboratories Board
POM	- Prescription Only Medicines
PSRP	- Public Service Reform Programme
PST	- Pharmaceutical Society of Tanzania
QMS	- Quality Management System
RDT	- Rapid Diagnostic Test
RUCO	- Ruaha University College
SADCAS	- Southern African Development Community Accreditation Services
SADC	- Southern African Development Community
SOPs	- Standard Operating Procedures
TAFOPA	- Tanzania Food Processors Association
TASA	- TFDA Annual Staff Appraisal
TFDA	- Tanzania Food and Drugs Authority
TFNC	- Tanzania Food and Nutrition Centre
TNF	- Tanzania National Formulary
TSJ	- Times School of Journalism
TUGHE	- Tanzania Union of Government and Health Employees
UNICEF	- United Nations Children’s Fund
WHO	- World Health Organization
ZOLGAC	- Zone Offices and Local Government Authorities Coordinator

2003

2013

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# HATUA KWA HATUA

## MISINGI YA KAZI

Kufanya kazi  
kwa ushirikiano

Uaminifu

Kuzingatia  
mahitaji ya  
wateja

Ubora

Uwajibikaji

Udhibiti wa;

Chakula

Dawa

Vipodozi

Vifaa Tiba

### DHIMA

Kulinda afya ya jamii  
kwa kuzuia athari  
zinazoweza kujitokeza  
kutokana na matumizi  
ya chakula, dawa,  
vipodozi na vifaa tiba.

### DIRA

Kuwa Mamlaka  
inayoongoza barani  
Afrika katika kudhibiti  
usalama, ubora na  
ufanisi wa chakula,  
dawa, vipodozi na vifaa  
tiba kwa wote.

### FALSAFA

Kutoa huduma bora za  
udhibiti katika kulinda  
afya ya jamii na  
mazingira kwa kutumia  
wafanyakazi wenye  
ujuzi na ari ya kazi.



2003-2013

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“Nawapongeza sana kwa mafanikio hayo mliyoyapata, ikiwa ni pamoja na Maabara ya TFDA kuwa ya kwanza barani Afrika miongoni mwa maabara za Serikali za udhibiti wa bidhaa kutambuliwa na Shirika la Afya Duniani... Mnaipeperusha vyema bendera ya nchi yetu na mmetuletea heshima kubwa, hongereni sana.”

Mhe. Dkt. Jakaya Mrisho Kikwete, Rais wa Jamhuri ya Muungano wa Tanzania, wakati akizindua maabara ya TFDA tarehe 18 Machi, 2013

## LETTER OF TRANSMITTAL



Honourable Dr. Hussein A. Mwinyi, (MP)  
Ministry of Health and Social Welfare  
P.O. Box 9083  
Dar es Salaam



Ms. Regina L. Kikuli,  
Acting Permanent Secretary,  
Ministry of Health and Social Welfare  
P.O. Box 9083  
Dar es Salaam

Hon. Minister,

I am greatly honoured to present to you the TFDA 10 Anniversary Book. The Book entails historical background of product regulation in the country before TFDA came into operation in 2003 and milestones reached in control food, drugs, cosmetics, and medical devices between July 2003 and June 2013.

The Book also outlines challenges which TFDA faced in control of regulated products within the stated period of 10 years of operation.

I submit,

A handwritten signature in black ink.

Regina L. Kikuli  
ACTING PERMANENT SECRETARY

## MESSAGE FROM THE CHAIRMAN – MINISTERIAL ADVISORY BOARD

I am delighted to witness the 10th Tanzania Food and Drugs Authority (TFDA) Anniversary in regulating food, medicines, cosmetics and medical devices in the country by deploying national policies, regulation and guidelines. Let me take this opportunity to congratulate the Management and staff of TFDA for registering considerable successes as provided for in this Book.

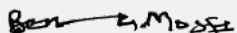
The Ministry of Health and Social Welfare (MoHSW) is indebted for strategic directions which have enabled TFDA to attain these success milestones for the period of 10 years. I would also like to thank members of the Ministerial Advisory Board (MAB) at different occasions for their contribution towards improving TFDA services to its stakeholders.

I acknowledge the advisory, financial and material support that has been received from various TFDA stakeholders including Development Partners, which have contributed greatly in building the capacity of TFDA. TFDA's great success is a result of contribution and collaboration from its important stakeholders. It is my expectation that the existing engagement and cooperation with stakeholders will be strengthened in order to attain the TFDA's mission and vision of ensuring the public of quality, safety and effectiveness of food, medicine, cosmetics and medical devices.

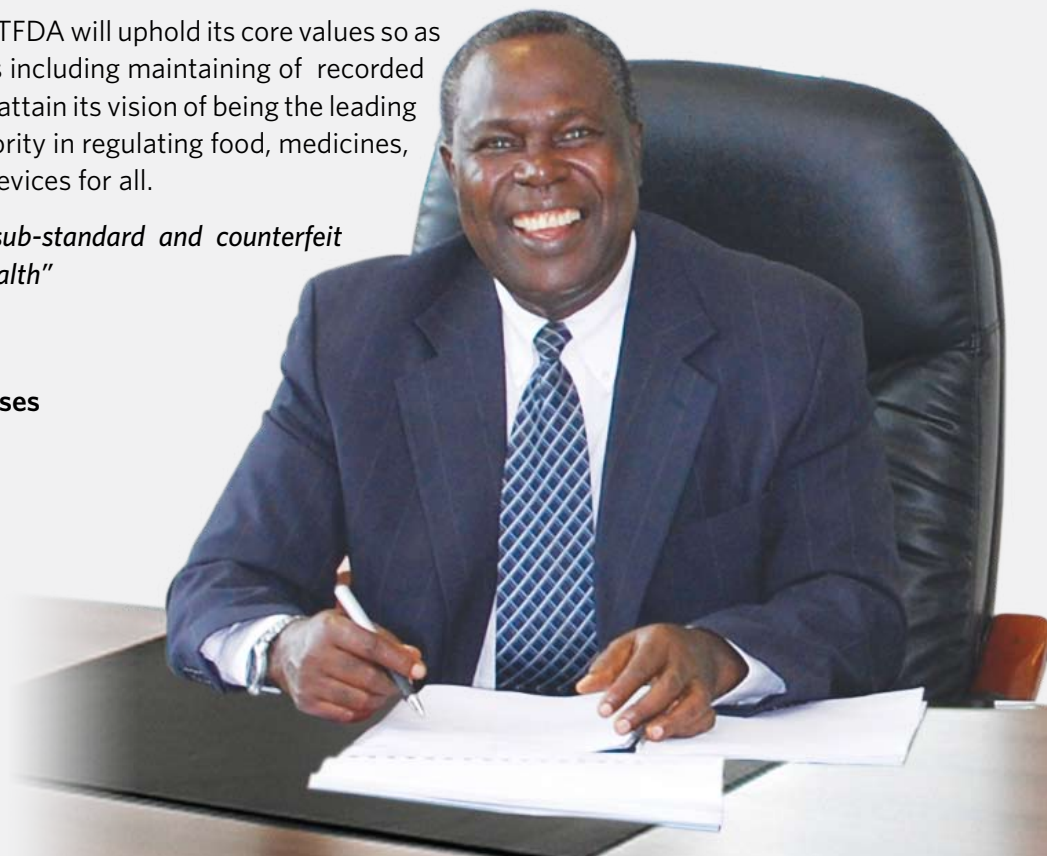
Special gratitude is bestowed to the TFDA Director General, Mr. Hiiti B. Sillo and the entire TFDA Management team for proper leadership and direction as well as TFDA staff for their dedication in attainment of the TFDA milestones outlined in this Book.

It is my expectation that, TFDA will uphold its core values so as to strengthen its services including maintaining of recorded achievements in order to attain its vision of being the leading African Regulatory Authority in regulating food, medicines, cosmetics and medical devices for all.

*"Together, let's combat sub-standard and counterfeit products to protect our health"*



**Ambassador Dr. Ben Moses**  
**CHAIRMAN (MAB)**



## PREFACE

The regulation of food and medicines began prior to the establishment of TFDA in July 2003. During that period, food and medicinal products were regulated through different laws enforced by departments and divisions under different Ministries. The regulation of such products was later done under Professional Boards.

Due to rapid growth and advancements in science and technology as well as free market forces, the Government through The President's Office - Public Service Management (PO-PSM), decided to establish executive agencies. This move was geared towards improving public services to meet customer needs and expectations. In this respect, a number of executive agencies were established including TFDA in accordance with the Executive Agencies Act, Cap 345 of 1997 and its amendments of 2009.

TFDA was mandated to regulate the quality, safety and efficacy of food, medicines, cosmetics and medical devices. Such functions are also provided under the Tanzania Food, Drugs and Cosmetics Act, Cap 219. TFDA began its operations on 1st July 2003.

In the period of 10 years since its inception, TFDA has attained notable achievements in regulating the quality, safety and efficacy of food, medicines, cosmetics and medical devices. Amongst its achievements, TFDA has developed robust systems and put in place guidelines for registration of products, inspection and surveillance as well as laboratory analysis of product samples prior to market authorization.

TFDA has also set up systems for pharmacovigilance and food borne diseases surveillance as well as a clinical trials control system for medicines and medical devices. The main objective is to protect the health of consumers by ensuring that only products that meet quality, safety and efficacious specifications circulate in Tanzania market.

Furthermore, TFDA has managed to develop and implement Quality Management System (QMS) in order to deliver quality and consistent services to its customers. In view of implementing QMS, TFDA attained ISO 9001: 2008 certified since 2008/09 in areas of food, medicines, cosmetics and medical devices regulatory systems. The certification was done by ACM Limited of UK.

In 2006, TFDA developed and implementing a Client's Service Charter which was reviewed in 2012 in consultation of stakeholders with the aim of improving efficiency and effectiveness in service delivery and meeting customer needs and expectations without compromising quality, safety and efficacy of regulated products.

In addition, TFDA has also managed to construct a new building at its headquarters in Dar es Salaam along Mandela Road, Mabibo External. Five Zone Offices have also been opened up in Arusha, Mwanza, Mbeya, Dar es Salaam and Dodoma regions in order to bring TFDA services in close proximity to customers.



Conversely, TFDA has also managed to expand its laboratory building including procurement of state of the art analytical equipment and instruments. Above all, much needed training had been conducted to all laboratory staff. Such improvement as enabled the laboratory to be prequalified by the World Health Organization (WHO) in January, 2011. The Microbiology and Food laboratories have been accredited by the Southern African Development Cooperation Accreditation System (SADCAS) to ISO/IEC 17025:2005 standards. This implies that analytical results obtained from the TFDA laboratory are internationally recognized and accepted.

The Authority has created a robust financial management system which has facilitated effective collection of fees and charges and as a result, internal and external revenue collections have increased tremendously over the past ten years to reach 727%. Furthermore, during the period of July 2003 and June, 2012 TFDA's financial statements and accounts had been audited by the Controller and Auditor General (CAG) and obtained a clean audit report for 9 consecutive years.

Despite the successes attained, TFDA is still facing challenges in executing its functions ranging from inadequate staffing levels and existence of substandard and counterfeit products in the market which pilferage through unauthorized borders. Other challenges include lack of harmonized regulatory systems in the East African Community (EAC) and Southern Africa Development Community (SADC) regions.

Nevertheless, TFDA is responsible for improving inspection activities and public education to all stakeholders in order to achieve its mission and vision of becoming a leading African regulatory authority in ensuring the safety and quality of food, medicines, cosmetics and medical devices for all.

I would like to take this opportunity to thank Mr. Adam Mitangu Fimbo - Director of Medicines and Cosmetics and other members; Mr. Brycesson Kibasa, Ms. Siya Augustine, Mr. Didas K. Mutabingwa, Mr. Jason J. Kyaruzi, Mr. Francis Mapunda, Mr. Sunday Kisoma, Mr. Yonah Hebron, Mr. David Matle and Ms. Joyce Komba for overseeing and coordinating the preparation of this Book.

The valuable contribution of Dr. Sikubwabo S. Ngendabanka - Director of Business Support, Mr. Chrispin Severe - Marketing Manager, Ms. Gaudensia Simwanza - Public Relations Officer, Mr. James Ndege, Dr. Nditonda B. Chukilizo and Mr. Octavius Soli in designing and editing this important Book is also greatly acknowledged.

It is my expectation that in the coming 10 years, we will significantly strengthen regulatory systems by addressing the available challenges and envisaged ones in order to meet the mission of TFDA of protecting and promoting public health against hazards associated with the use of unsafe food, medicines, cosmetics and medical devices.

*'Let's join hands to combat counterfeit food, medicines, cosmetics and medical devices to protect our health'*



**Hiiti B. Sillo**

**DIRECTOR GENERAL**



## Mission

To protect and promote public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices.

## Vision

To be the leading African Regulatory Authority in ensuring safe, quality and effective food, medicines, cosmetics and medical devices for all.

## Philosophy

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

## Core Values

TFDA core values are pivotal for our character identity. They include;

- Honesty,
- Customer focus
- Quality
- Teamwork and Accountability

## CHAPTER ONE

## 1

## REGULATION OF PRODUCTS BEFORE ESTABLISHMENT OF TFDA

**1.1 Introduction**

The regulation of food and medicines began in 1930s under different laws administered by the colonial rule. The laws have been changing from time to time in order to improve the regulation of these products.

However, all the laws that were in place before the TFDA establishment could not cope with the pace of economic and technological developments that were taking place in the country. These rapid changes resulted in massive increase in trade of regulated products which made their control to be a challenging task. There was no specific institution mandated to enforce these laws before 1978, instead regulatory functions were performed by different ministerial departments or sections.

The mentioned laws, roles of different institutions which were in place before the establishment of TFDA and responsible personnel's in regulatory functions have been outlined in this chapter.

**1.2 Regulation of Medicines**

The regulation of medicines before the establishment of TFDA was administered through various laws as follows:

- The Food and Drug Ordinance Cap 93, 1937;
- The Pharmacy and Poison Ordinance Cap 416, 1937; and
- The Dangerous Drugs Ordinance, 1937.
- Pharmaceuticals and Poisons Act 1978

The then Ministry of Health through its Pharmaceutical Unit was responsible for enforcement of these laws up to 1978. The said Unit has been headed by the Registrar whose names at various periods between 1937 - 1977 are indicated in Table No. 1 below.

**Table No.1: Heads of Pharmaceutical Units 1937 - 1977**

S/N	Name	Duration (Year)
1.	Mr. H. M. W. Nicholson	1937 - 1955
2.	Mr. P. J. Mackenzie	1956 - 1961
3.	Mr. D. Moors	1962
4.	Mrs. P. M. Shiel	1963
5.	Mr. J. Karey	1964 - 1968
6.	Mr. C. Mshiu	1969 - 1977

In 1978, all laws related to regulation of pharmaceuticals were repealed and replaced by the Pharmaceuticals and Poisons Act, 1978 under which the Pharmacy Board was established to oversee its enforcement.

**1.2.1 Establishment of the Pharmacy Board**

The Pharmacy Board was established in 1978 in order to regulate the quality, safety and efficacy of medicines and the pharmacy profession in the country. This Board did put in place systems and procedures for regulation of medicines and was headed by a Registrar who was the chief executive and responsible for all day to day operations of the institution. The names of Registrars who served the Board between 1979 and 2003 are shown in Table No.2 hereunder;

**Table No.2: Names of Registrars of Pharmacy Board 1978 - 2003**

S/N	Name of the Registrar	Duration (Year)
1.	Mr. C. Mshiu	1978 - 1979
2.	Mr. J. E. Chiliko	1979 - 1992
3.	Mr. L. R. Mhangwa	1993 - 1996
4.	Mrs. M. Kimaro	1997 - 1998
5.	Mrs. M. Ndomondo-Sigonda	1998 - 2003

## 1.2.2 Organization Structure of the Pharmacy Board

The Pharmacy Board was made up of four Sections as follows:

- i. Medicines Registration
- ii. Inspection
- iii. Laboratory Services
- iv. Drug Information.

The Heads of Sections were responsible to the Registrar who was reporting to the Executive Board appointed by the Minister for Health.

## 1.2.3 Medicines Regulatory Systems

The Pharmacy Board did put in place basic systems for regulation of medicines which included among others: registration of medicines, registration and licensing of premises, inspection and enforcement, import and export control, post marketing surveillance, control of advertisements and promotional materials, laboratory analysis and public education.

The Board was also responsible for registration of Pharmacists before being authorized to practice the pharmacy profession in Tanzania and thereafter the professional conduct.

A number of regulations were made under the Pharmaceuticals and Poisons Act, No. 9 of 1978 in order to facilitate the regulation of medicines. The following is a list of regulations made under the law;

- i. The Poisons List (Declaration) Order, 1979;
- ii. The Pharmaceuticals and Poisons Regulations, 1980;
- iii. The Pharmaceuticals and Poisons Regulations, 1990;
- iv. The Registration of Drug Premises Regulations, 1992;
- v. The Guidelines for Good Manufacturing Practices Order, 1999;
- vi. The List of Human Notified Drugs Order, 1999 and 2001;

vii. The List of Veterinary Notified Drugs Order, 1999 and 2001;

viii. The Code of Conduct for Drug Promoters Order, 1999.

Through these regulations and guidelines, the Board was able to effectively control medicines in the country.

### 1.2.3.1 Registration of Premises

The procedure of registering premises for the conduct of pharmaceutical businesses, was set up way back in 1937s even before establishment of the then Pharmacy Board in order to identify and regulate areas where medicines are being manufactured, stored and dispensed to patients. This process assisted in the control of counterfeit and sub standard medicines in the Tanzanian market.

Premises that were being registered include; wholesale and retail pharmacies, warehouses, pharmaceutical industries, medical stores and conveyances used to transport medicines.

Regulations and Guidelines were prepared to facilitate the registration of premises including provision of adequate information to be followed by applicants when submitting their applications.

### 1.2.3.2 Inspection of Premises

The procedure for carrying out inspection of pharmaceutical premises started in 1992 after regulations for premises registration were made. Various Guidelines for inspection and enforcement were prepared in order to ensure compliance with the laws and regulations.

Premises inspected include; foreign and domestic pharmaceutical manufacturers, hospitals, health centers, dispensaries, warehouses, wholesale and retail pharmacies and medical stores. The main objective was to ensure compliance with Good Manufacturing Practices (GMP), Good Storage Practices (GSP) and Good Distribution Practices (GDP).



Through these inspections counterfeit and substandard medicines were detected and measures taken to withdraw them from the market with subsequent destruction of the unfit products.

### 1.2.3.3 Registration of Medicines

The mandatory requirement for registration of medicines was introduced by the Pharmacy Board in 1998 so as to ensure that before medicines were sold in the market, they meet quality, safety and efficacy standards.

The processes involved evaluation of medicines scientific information on their quality, safety and efficacy, GMP inspection and laboratory analysis of registration samples.

Guidelines for registration were made, training conducted in and outside the country so as to build staff capacity in assessment of medicines techniques.

***A medicinal product by the name of Artemam (Artemether injection) that was manufactured by Dragon Pharmaceuticals Limited UK was the first to be registered by the Pharmacy Board in March, 1999***

### 1.2.3.4 Laboratory Analysis

The Drug Quality Control Laboratory was built by the Pharmacy Board between 1994-1998 and was officially inaugurated in the year 2000 by the then Minister of Health, the late Dr. Aaron Chiduo. It was established for carrying out analysis of quality and safety of medicines so to enable the Board make evidence based regulatory decisions.

Laboratory equipment and instruments were procured and installed, chemicals procured and analysts recruited and trained so as to carry out the analysis efficiently. Analysis was done against internationally recognized standards such as British Pharmacopoeia, International Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia and Japanese Pharmacopoeia in order to get credible

results. Laboratory results enabled the Board to identify counterfeit and substandard medicines and thus take appropriate regulatory measures such as litigation and withdrawal of products from the market.

### 1.2.3.5 Drug Information

The Pharmacy Board, established a program namely; Tanzania Drugs and Toxicology Information System (TADATIS) within the Pharmacy Department of the then Muhimbili Medical Centre in 1993 so as to collect and disseminate information on adverse drug reactions to the public and health care providers. Various publications including leaflets, brochures, booklets, newsletters, journals and posters were prepared and distributed to the public. The objective was to disseminate information on the quality, safety, and efficacy of medicines to the general public and health care professionals.

### 1.2.3.6 Registration of Pharmacists

The Pharmacy Board was responsible for registering pharmacists. They were registered upon graduation from any recognized University and completion of one year internship program. The Board was also responsible for enforcing the Code of Ethics and Conduct for pharmacists and was able to take disciplinary actions for any breach of the code.

The responsibility of registering pharmacists was transferred to the Pharmacy Council of Tanzania following the enactment of the Pharmacy Act 2002, which was then repealed by the Pharmacy Act, 2011.

## 1.3 Regulation of Cosmetics and Medical devices

Under the Pharmaceuticals and Poisons Act No. 9 of 1978 the Pharmacy Board was not mandated to regulate cosmetics and medical devices. These products including their storage and selling premises were neither registered by the Board nor regulated by any entity.



## 1.4 Regulation of Food

The regulation of food before the establishment of TFDA was carried out under various laws such as:

- The Food and Drug Ordinance Cap 93, 1937 (under the Ministry of Health) ;
- The Meat Hygiene Ordinance, 1961 (under the Ministry of Agriculture) ;
- Dairy Industries Act, 1966, (under the Ministry of Agriculture and Livestock);
- The Fisheries Act, 1970, (under the Ministry of Natural Resources and Tourism); and
- The Standards Act, 1975, (under the Ministry of Industry and Commerce).

The Ministry of Health was responsible for enforcement of the Food and Drug Ordinance Cap 93, 1937 whereas the Ministry of Agriculture and Livestock Development was responsible for enforcement of the Meat Hygiene Ordinance, 1961.

The above laws were repealed and replaced by the Food (Control of Quality) Act, No. 10 of 1978 which also established the National Food Control Commission (NFCC).

### 1.4.1 Establishment of the National Food Control Commission (NFCC)

The National Food Control Commission (NFCC) was established in 1978 to control the safety and quality of food in the country. The Commission did put in place food quality and safety control systems. NFCC was headed by a Registrar who was the Chief Executive and responsible for daily operations of the commission.

The names of NFCC's Registrars who served between 1978 and 2003 are shown in Table No.3 hereunder;

**Table No. 3: Names of Registrars of National Food Control Commission 1978-2003**

S/N	Name	Duration (Year)
1.	Mr. W. Mnyone	1978 - 1988
2.	Mr. E. D. Kadete	1988 - 1989
3.	Mr. F. A. Shirima	1989 - 1996
4.	Mr. F. Magoma	1996 - 2000
5.	Mr. O. M. Soli	2000 - 2003

### 1.4.2 Organization Structure of NFCC

The National Food Control Commission had four (4) Sections namely:

- i. Registration of Premises
- ii. Inspection
- iii. Administration
- iv. Food Import and Export control.

The heads of the above Sections reported to the Registrar who in turn was answerable to the Permanent Secretary of Ministry of Health.

### 1.4.3 Food Control Systems

NFCC did put in place systems of food control which include; issuance of permits for food imports and exports, registration of business premises, inspection, and surveillances on safety and quality of food in the market. Food samples were tested by the laboratory of the former Chief Government Chemist now the Government Chemist Laboratory Agency (GCLA).

Several regulations were made under the Food (Control of Quality) Act, No. 10 of 1978 to facilitate control of food quality. The regulations include;

- i. Food Additive Regulations, 1994
- ii. Marketing of Breast Milk Substitutes and Designated Products Regulations, 1994
- iii. Slaughter houses, Slaughtering and Inspection of Meat Regulations, 1994
- iv. Palm Oil Regulations, 1994
- v. Food Hygiene Regulations, 1982

The Commission in collaboration with Local Government Authorities used the above regulations with corresponding Guidelines to execute food control functions countrywide.

#### 1.4.3.1 Registration of Food Premises

The NFCC used to register manufacturing, storage and selling premises of food products in order to ensure that they meet prescribed standards.

Food premises that were registered include; wholesale and retail food outlets, hotels, restaurants, warehouses, factories and meat transporting

vehicles. To facilitate registration processes, various Regulations and Guidelines were prepared and made available for use by applicants.

### **1.4.3.2 Food Inspection**

The NFCC in collaboration with Local Government Authorities carried out inspection on food related products so as to ensure compliance with the laws and regulations.

The food inspection was done during its processing, storage and at their selling premises and conveyances. The selling premises included; wholesale and retail outlets, hotels and restaurants. The objective of food premises inspection was to ensure compliance with Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP).

Through inspection processes, substandard and unfit food products were identified, condemned and disposed off in accordance with existing laws.

### **1.4.3.3 Food Registration**

The NFCC used to register food products by issuing manufacturing permits and import permits after food samples were analyzed to certify their conformity to safety and quality standards.

### **1.4.3.4 Laboratory Food Testing**

The Commission collected food samples from the port of entry and market and submit them to the then Chief Government Chemist Laboratory for testing their quality and safety specifications. The analytical results enabled NFCC to make regulatory decisions on food products.

## **1.5 The Repeal of the Pharmacy Board and the NFCC**

The Public Service Reform Program (PSRP) that was being implemented in 1990's envisaged the streamlining of Government departments to improve the provision of services to the public. Among strategies was to establish Government Agencies that will serve customers and general public in a business oriented manner. As a result of these reforms, the Government enacted the Executive Agencies Act, 1997, as amended in 2009, which enabled some Government departments and institutions to be transformed into Executive Agencies. The Pharmacy Board and NFCC were among institutions which were merged to form TFDA.

The process of establishing TFDA started way back in year 2000 by repealing the Pharmaceuticals and Poisons Act No. 9 of 1978 and The Food (Control of Quality) Act, No. 10 of 1978 and replacing them with the Tanzania Food, Drugs and Cosmetics Act, 2003, Cap 219.

## THE ESTABLISHMENT OF TANZANIA FOOD AND DRUGS AUTHORITY (TFDA)

### 2.1 Introduction

As stated in Section 1.5, the formation of the Tanzania Food and Drugs Authority was part of the government initiative (under the Public Service Reform Programme -PSRP) to improve its service provision to the general public. The process of establishing TFDA started in 1996 whereby a select team was constituted to review systems and working policies of institutions and departments of the then Ministry of Health. The select team recommended merger of the Pharmacy Board and the National Food Control Commission (NCC) to form one organization because they had similar working systems and functions.

Following the above recommendation, a team was constituted in 2000 to coordinate the establishment TFDA. Members of the team were as shown below:

- i. Sikubwabo S. Ngendabanka (Dr.) -Team Leader
- ii. Raymond Wigenge - Member
- iii. Martin Kimanya - Member
- iv. Ndengerio J. Ndossi - Member
- v. Rosemary Aaron - Member
- vi. William S. Kitundu - Member
- vii. Emmanuel D. Kadete - Member
- viii. Mariam Mirambo - Member

The team was responsible for development the relevant documents for establishing the agency including Strategic plan, Business plan, Business Analysis report, Framework Document, Cabinet Paper for Establishment of the Tanzania Food, Drugs and Cosmetics Act.

### 2.2 Establishment of TFDA

Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and

Cosmetics Act; CAP 219. This law repealed the Pharmaceuticals and Poisons Act No. 9 of 1978 and The Food (Control of Quality) Act, No. 10 of 1978. The government had also enacted the Executive Agencies Act No.30 of 1997 which paved the way for the formation of government agencies. The Authority was established to regulate safety, quality and efficacy of food products, medicines, cosmetics and Medical devices.

Before TFDA was established, cosmetics and Medical devices were not controlled. The former Pharmacy Board and the then National Food Control Commission were only involved in controlling the safety and quality of food and medicines.

Other reasons that lead to the repeal of the Pharmaceuticals and Poisons Act No. 9 of 1978 and The Food Control of Quality Act, No. 10 of 1978 and establishment of TFDA were;

- (a) The emergence in the market of food supplements whose controls required skills of both food and pharmaceutical sciences,
- (b) Pooling of available meager resources so as to improve efficiency in regulating food and medicines,
- (c) To improve effectiveness of regulating food and medicines, by broadening the scope of the Act.

Moreover, the economical, social and technological changes, and the Government's implementation of free market policies were impacting upon the business environment and therefore added impetus to the urgent need to bring the product control functions under one institution to meet the challenges of free market.

## 2.3 Mission, Vision and Philosophy

The Mission, Vision and the Philosophy of an institution are the corner stone's upon which the foundation of the institution is built and they portrays an institution's desired outlook or image in its effort to fulfill its corporate responsibility and goals.

**TFDA Mission** is to protect and promote public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices.

The first **Vision** statement formulated after the establishment of the TFDA in 2003 states that: To be the leading African Regulatory Authority in ensuring safe, quality and effective food, medicines, cosmetics and medical devices by the year 2015

However, soon after the review of the TFDA Strategic Plan in year 2011/12, the Authority came up with revised vision statement. The new vision goes thus: To become the leading African Regulatory Authority in ensuring safe, quality and effective food, medicines, cosmetics and medical devices for all.

**TFDA Philosophy** is to offer quality regulatory services in pursuit of protecting public health and environment by using competent and dedicated staff.

In addition to the establishment of the corporate Mission, Vision and the Philosophy, TFDA has also its core values as an integral part of the TFDA's code of conduct to be observed by all staff namely;

■ <b>Honesty</b>	To carry out works openly and honestly,
■ <b>Customer Focus</b>	To attend customers timely and with care,
■ <b>Quality</b>	To provide skilful and quality service,
■ <b>Team work</b>	To work together as a team and respect others opinions,
■ <b>Accountability</b>	To be accountable for all actions at work.

In order to provide quality services to the customers, TFDA has put in place an Internal Quality Policy which states that:

"TFDA is well prepared in delivering quality services in order to satisfy its customers and meet customer expectation. The Authority is directing its efforts towards meeting its customer expectation while ensuring the maintenance of quality, safety and efficiency of food, medicines, cosmetics and Medical devices. We have resolved to follow and implement the requirements of the international standards on delivering the best quality services as specified by the ISO 9001:2008 and also continue to improve our services through the adoption of Quality Management Systems. We shall ensure and oversee that appropriate required resources are available in the process of improving customer care in order to satisfy and meet their expectations."

## 2.4 TFDA Roles and Responsibilities

The TFDA functions and responsibilities are as provided under Section 5 of the Tanzania Food, Drugs and Cosmetics Act, Cap 219. These include:

- To control of production, importation, distribution, and sale of food, medicines, cosmetics and medical devices;
- To prescribe standards of quality and safety of food, medicines, cosmetics and medical devices;
- To inspect product manufacturing facilities and outlets in order to ensure compliance to the set standards;
- To evaluate and register food, medicines, cosmetics and medical devices and ensure that prescribed standards are met before authorized into the Tanzanian market;

- (e) To issue licences and various permits for food products, medicines, cosmetics and medical devices including import and export Licences for regulated product;
- (f) To carry out laboratory analysis in order to determine the safety and quality of the regulated products.
- (g) To monitor the adverse reactions arising from the use of regulated products;
- (h) To promote rational use of medicines, cosmetics and medical devices; and
- (i) To educate and provide correct information to the stakeholders and the general public about the regulated products.

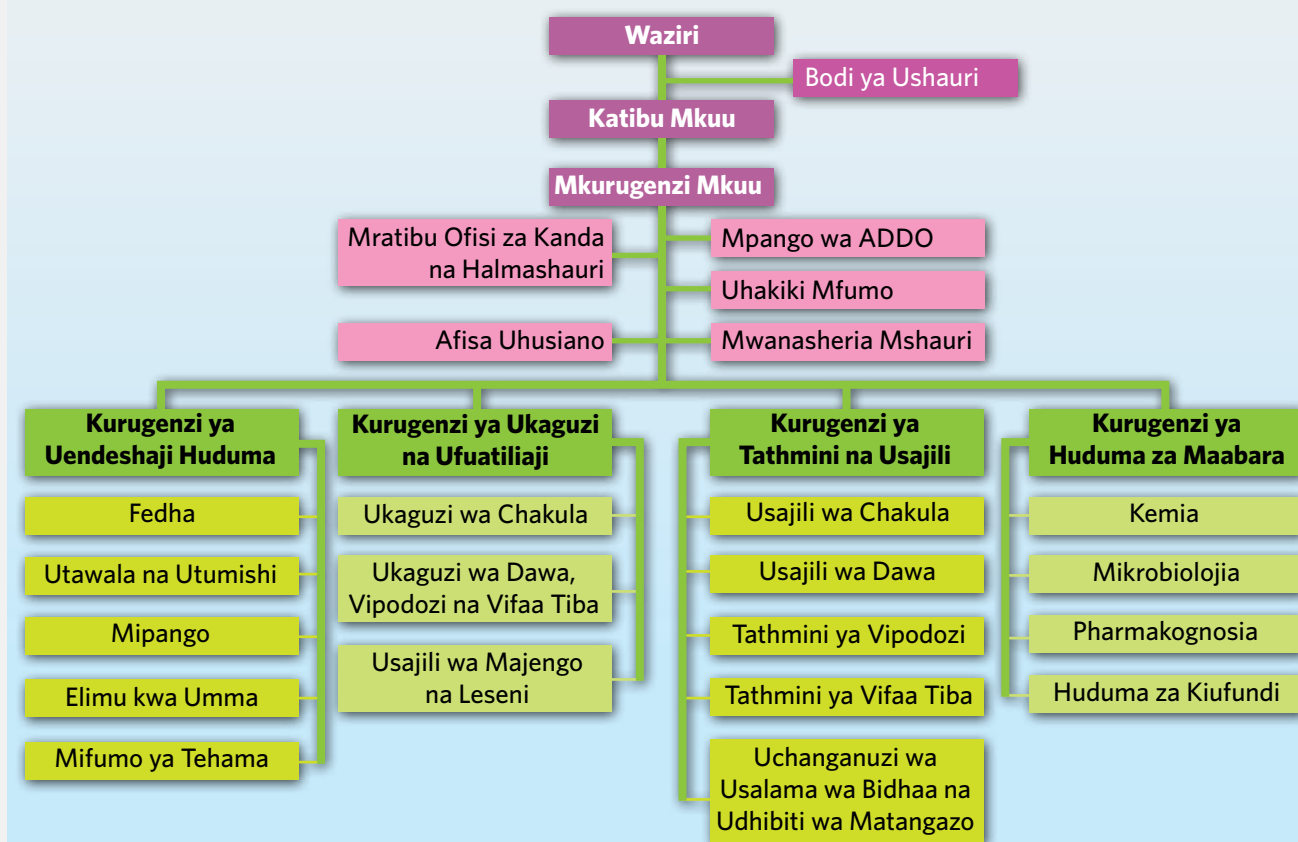
## 2.5 Structure of TFDA

### 2.5.1 The First TFDA Structure

The first TFDA Structure that was used immediately after it became operational in July 2003 consisted of four directorates namely Product Evaluation and Registration; Inspection and Surveillance; Laboratory Services and Business Support. This structure lasted until February 2008.

Under the above structure, the Director General was the Chief Executive responsible for the TFDA's daily operations. The Director General reported directly to the Permanent Secretary, Ministry of Health and Social Welfare who was also the Chairman of the Ministerial Advisory Board (MAB) to TFDA.

**Diagram No. 1: The First TFDA Organization Structure (2003-2008)**



Under the Director General there were five units and four directorates as described below:

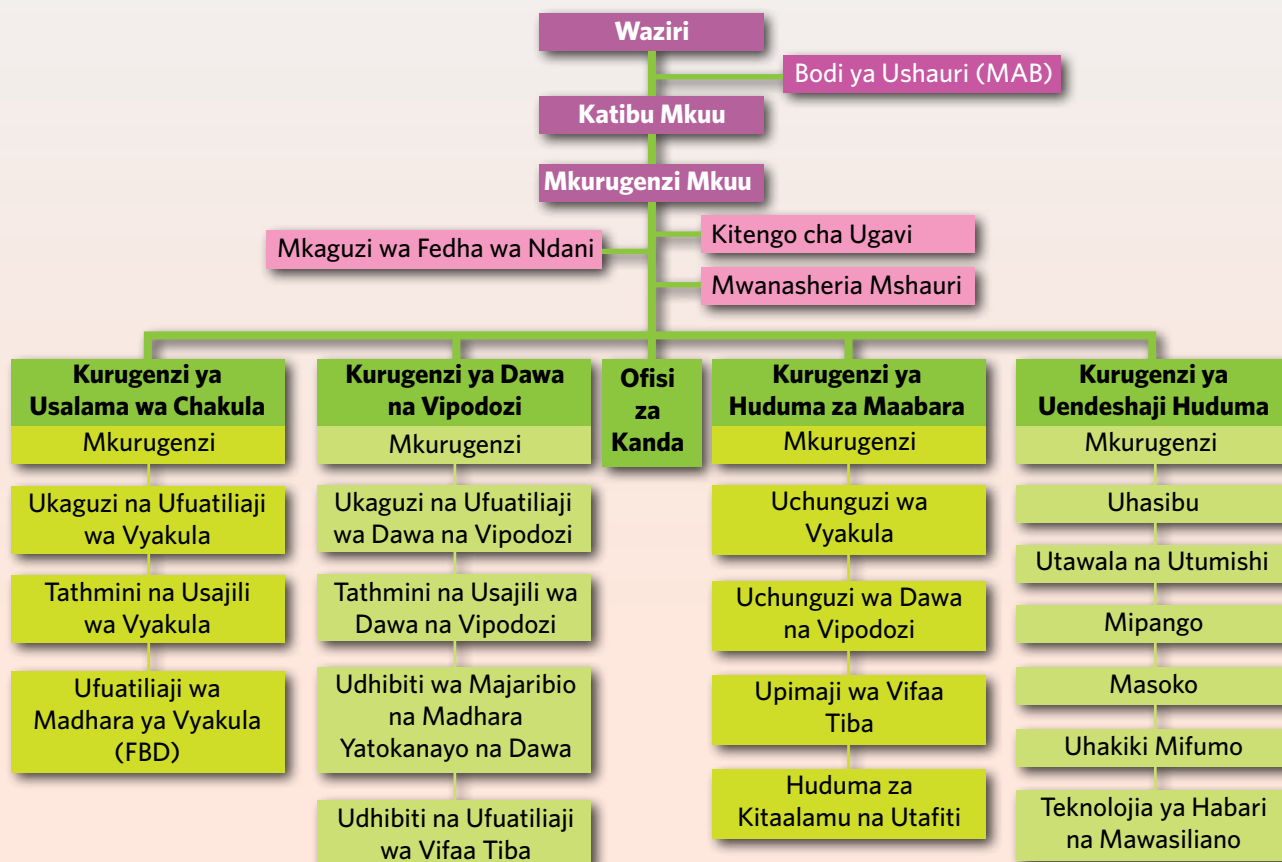
- (i) **Directorate of Product Evaluation and Registration** - was responsible for ensuring quality, safety and efficacy of food products, medicines, cosmetics and medical devices by doing assessment of product dossiers and product registration, evaluating promotional materials and monitoring of adverse effects of food, medicines and medical devices in the market;
- (ii) **Directorate of Inspection and Surveillance** - was responsible for conducting inspection for manufacturing and business premises, carrying out post marketing surveillance of food, medicines, cosmetics and medical devices in the

market, issuing licences for business premises and import and export permits for regulated product;

- (iii) **Directorate of Laboratory Services** - was responsible for conducting laboratory analysis of food, medicines, cosmetics and medical devices to enable the Authority make science decisions on matters related to regulation of products;
- (iv) **Directorate of Business Support** - was responsible for administration and human resources management, finance, planning, public education and management information system.

The first TFDA organization structure has been shown here under as Diagram No.1.

**Chart No.2: The Second Organization Structure of TFDA (2008-2013)**



## 2.5.2 The Second TFDA Organization Structure

TFDA second organization structure was implemented in March, 2008 following a review of the first structure. The review was intended identify shortcomings and take remedial measures to rectify them together with rationalisation of activities and accommodate new needs to improve enforcement of the TFDC Cap 219.

Shortcomings which were revealed by the review of the first structure included:

- (a) The structure hinged on functions rather than products leading to imbalances;
- (b) Absence of zone offices ;

- (c) The Procurement Unit being under the Directorate of Business Support contrary to the requirement of the Procurement Act of 2004 which requires the unit to be under the Chief Executive;
- (d) The structure did not include the office of the Internal Auditor as required by the Finance Act, 2004..

### 2.5.2.1 Ministerial Advisory Board (MAB)

The Ministerial Advisory Board (MAB) is responsible to advise the Minister for Health and Social Welfare on matters pertaining to TFDA's strategic issues.

The Board was established pursuant to the Tanzania Food, Drugs and Cosmetics Act 2003, Cap 219, read together with the Executive Agencies Act, Cap 345 as amended in 2009.



## Wajumbe wa MAB (2003 - 2006)



**Bi. Mariam J. Mwaffisi**  
Mwenyekiti



**Bi. Margareth**  
Ndomondo-Sigonda  
Mjumbe



**Dkt. W. C. Mleche;**  
Mjumbe



**Bw. Mick Kiliba;**  
Mjumbe



**Bw. G. Nanyaro;**  
Mjumbe



**Bw. Abraham Nyanda,**  
Mjumbe



**Bw. Charles Ekelege;**  
Mjumbe



**Bi. Christine Kilindu;**  
Mjumbe



**Bi. Sia B. Mrema;**  
Mjumbe



**Bw. S. Nyimbi;**  
Mjumbe



**Dkt. Deo Mtasiwa;**  
Mjumbe



**Dkt. D. G. Ndossi;**  
Mjumbe



**Bi. Tabu Chando;**  
Katibu



**Bw. John Mngondo;**  
Mjumbe



**Dkt. Malik A. Juma;**  
Mjumbe

## Wajumbe wa MAB (2006 - 2010)



**Bi. Hilda A. Gondwe**  
Mwenyekiti - 2006-2007



**Wilson C. Mukama**  
Mwenyekiti - 2007-2008



**Bi. Blandina S. J. Nyoni**  
Mwenyekiti - 2008-2010



**Bi. Margareth**  
Ndomondo-Sigonda  
*Mjumbe*



**Dkt. W. C. Mleche;**  
*Mjumbe*



**Bw. Mick Kiliba;**  
*Mjumbe*



**Bw. G. Nanyaro;**  
*Mjumbe*



**Bw. Abraham Nyanda,**  
*Mjumbe*



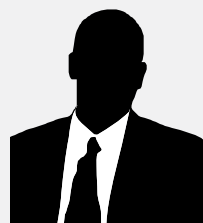
**Bw. Charles Ekelege;**  
*Mjumbe*



**Bi. Christine Kilindu;**  
*Mjumbe*



**Bi. Sia B. Mrema;**  
*Mjumbe*



**Bw. S. Nyimbi;**  
*Mjumbe*



**Dkt. Deo Mtasiwa;**  
*Mjumbe*



**Dkt. D. G. Ndossi;**  
*Mjumbe*



**Bi. Tabu Chando;**  
*Katibu*



**Bw. John Mngondo;**  
*Mjumbe*

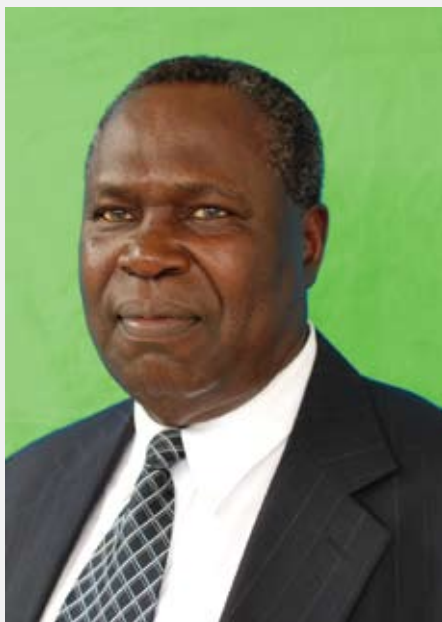


**Dkt. Malik A. Juma;**  
*Mjumbe*

## Wajumbe wa MAB (Juni 2010 - Juni 2013)



Dkt. Subilaga Kazimoto  
*Mjumbe*



Balози Dkt. Ben Moses  
**Mwenyekiti**



Prof. Bendantunguka  
Tiisekwa  
*Mjumbe*



Bw. John Mponela  
*Mjumbe*



Bw. Hiiti B. Sillo  
*Katibu*



Dkt. Joseph Mhando  
*Mjumbe*



Prof. Olipa Ngassapa  
*Mjumbe*

## Wakurugenzi wa TFDA 2013



**Bw. Hiiti B. Sillo**  
**Mkurugenzi Mkuu**



**Bw. Raymond Wigenge**  
*Mkurugenzi, Usalama wa  
Chakula*



**Bi. Charys N. Ugullum**  
*Mkurugenzi, Huduma za  
Maabara*



**Bw. Adam M. Fimbo**  
*Mkurugenzi, Dawa na Vipodozi*



**Dkt. Sikubwabo S.  
Ngendabanka**  
*Mkurugenzi, Uendeshaji Huduma*

### 2.5.2.2 Director General

In the second TFDA's organization structure, the Director General (DG) is the chief executive officer and is in charge of all TFDA day to day operations. The DG is answerable to the Permanent Secretary, Ministry of Health and Social Welfare.

Under the Director General's office, there are four Directorates and Zone offices which are responsible for providing TFDA services in the respective zones.

### 2.5.2.3 Directorates

The four Directorates and respective functions are as follows;

- i. **Directorate of Medicines and Cosmetics;** is responsible for ensuring quality, safety and efficacy of medicines, cosmetics and medical devices by conducting product evaluation and registration, inspection, monitoring of the quality and safety of products in the market, registration of business premises, control of promotional materials, control of clinical trials and monitoring and evaluation of adverse drug reactions.

- ii. **Directorate of Food Safety;** is responsible for ensuring safety and quality of food by carrying out registration of food products, inspection and surveillance of food in the market. Other functions include control of advertisements of food, registration of food premises including manufacturing and selling outlets, follow up of food borne diseases, food export and import certification, and food risk analysis.

- iii. **Directorate of Laboratory Services;** is responsible for conducting laboratory analysis of food, medicines and cosmetics and testing of medical devices for enhancing decision-making within the Authority.

- iv. **Director of Business Support;** is established to provide and enhance good management of TFDA's resources and to give support to all technical operations of the Authority. It is also involved with development and implementation of public education programmes and management information systems.

Table No. 4 shows Management Team Members of TFDA between 2003 and 2013.

**Table No.4: Management Team of TFDA (2003-2013)**

FIRST ORGANIZATION STRUCTURE					
Duration	Director General	Heads of Departments			
		Evaluation and Registration	Inspection and Surveillance	Laboratory Services	Business Support
Jul 2003 - Jan 2005	Margareth Ndomondo - Sigonda	Legu R. Mhangwa	Octavius M. Soli	Bi. Ollympia Kowero	Sikubwabo S. Ngendabanka (Dr.)
Feb 2005 - Feb 2008	Margareth Ndomondo - Sigonda	Legu R. Mhangwa	Bi. Ollympia Kowero	Bi. Charys Ugillum	Sikubwabo S. Ngendabanka (Dr.)
SECOND ORGANIZATION STRUCTURE					
Kipindi	Director General	Heads of Departments			
		Food Safety	Medicines and Cosmetics	Laboratory Services	Business Support
March 2008 - April 2010	Margareth Ndomondo - Sigonda	Raymond Wigenge	Hiiti B. Sillo	Charys N. Ugillum	Sikubwabo S. Ngendabanka (Dr.)
May 2010-June 2011	Hiiti B. Sillo	Raymond Wigenge	Adam M. Fimbo	Charys N. Ugillum	Sikubwabo S. Ngendabanka (Dr.)
June 2011 - June 2013					

In order for TFDA to execute its functions successfully, it had initiated and put in place various control systems as detailed in the following chapters:

## CHAPTER THREE

## 3

## FOOD CONTROL

**3.1 Introduction**

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 has put in place food control systems in the country as detailed in this chapter.

**3.2 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 below;

**Table No. 5: Food classification**

No.	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

No.	Food Types
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 includes the following;

- Evaluation of scientific information on safety and quality of food ingredients, additives and used packaging materials;
- Laboratory food analysis;
- Evaluation of information on food labels; and
- Inspection of manufacturing systems at the premises where food is being processed in accordance with good processing practices such as; GMP, GHP, HACCP.

TFDA has managed to register 5,918 foods since its inception 10 years ago. Table No.6 shows breakdown of food registered between July 2003 and June 2013. It should also be noted that there has been an increase in the number of applications for the registration of products over years.

**Table No.6: Food Registration (2003-2013)**

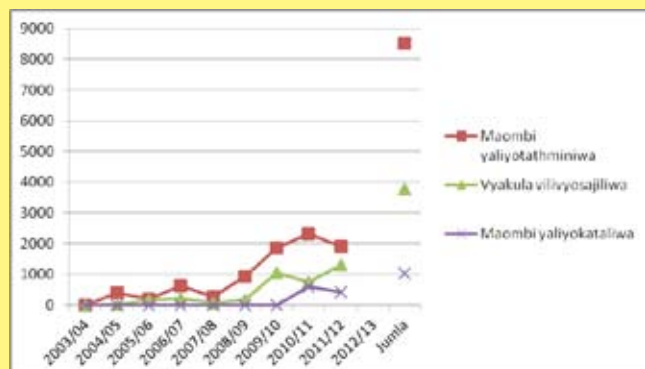
Year	Received Applications	Evaluated Applications	Registered Foods	Rejected Applications <sup>a</sup>
2003/04	162	2	0	0
2004/05	612	406	26	0
2005/06	272	187	179	0
2006/07	583	625	219	0
2007/08	253	263	64	0
2008/09	1,533	933	176	0
2009/10	1,446	1,869	1,054	0
2010/11	2,585	2,321	746	597
2011/12	2,109	1,923	1,308	429
2012/13	2,134	2,728	2,146	639
<b>Total</b>	<b>11,689</b>	<b>11,257</b>	<b>5,918</b>	<b>1,665</b>

**Note:**

*Some products were evaluated but were neither registered nor rejected, because TFDA was still waiting for applicant's responses on the queries raised by the evaluators. It should also be noted that products that were not evaluated during the year were carried forward to the next year. During the financial year 2003/04, very few applications were processed because of inadequate number of evaluators. Similarly, during the same year, no food was registered because all evaluated applications had queries pending for response.*

*After realising that applicants were taking longer time to respond to queries that caused backlog, from 2010/2011, the Authority changed the time set for receiving responses from 6 months to 4 months and improved its record keeping systems. From that time decisions for not registering un-responded queries within the allowable time started to be effected.*

**Graph No. 3: Evaluated Applications for food registration, Registered Products and Rejected Applications (2003/04 - 2012/13)**



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

### 3.3 Premises Registration

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

The registration of food premises includes the following procedures;

- To receive applications for premises registration;
- To evaluate received applications;
- To conduct inspection of respective premises; and
- To register premises.

During the past 10 years of TFDA existence, it has been able to register 7,373 food premises and the number has been increasing over years.

The system of premises registration has assisted TFDA in identifying premises that are used for food processing, storage, distribution and sale. This new system has become a great help to TFDA in ensuring that all food premises comply with quality specifications in accordance with the existing laws, regulations and procedures.

### 3.4 Food Inspection

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

Inspections activities are carried out any time in order to evaluate the condition of the premises, production systems, environment, distribution, storage, sale and quality of the food. Inspectors are 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.

Over the past 10 years, a total of 14,394 premises were inspected by TFDA. Various measures were taken against violators including; educating them, issuing warning letters, restricting their products from reaching the market, refusing to issue business permits, suspending their businesses and/or prosecuting them.

Within 10 years of TFDA existence, the inspection functions have been strengthened 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.

### 3.5 Control of Food at Ports of Entry

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

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



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

No.	Name of Ports of Entry	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 includes the following steps;

- To receive applications for registration of importers and food to be imported/ Exported;
- To evaluate applications;
- To carry out laboratory analysis of respective food samples; and
- To issue Import Permits or Health Certificates for exports where desired.

A total of 19,925 import permits were issued between July, 2005 and June, 2013. At the same time 2,115 export permits were also issued. Breakdown of the issued permits is shown in Table No. 8 below;

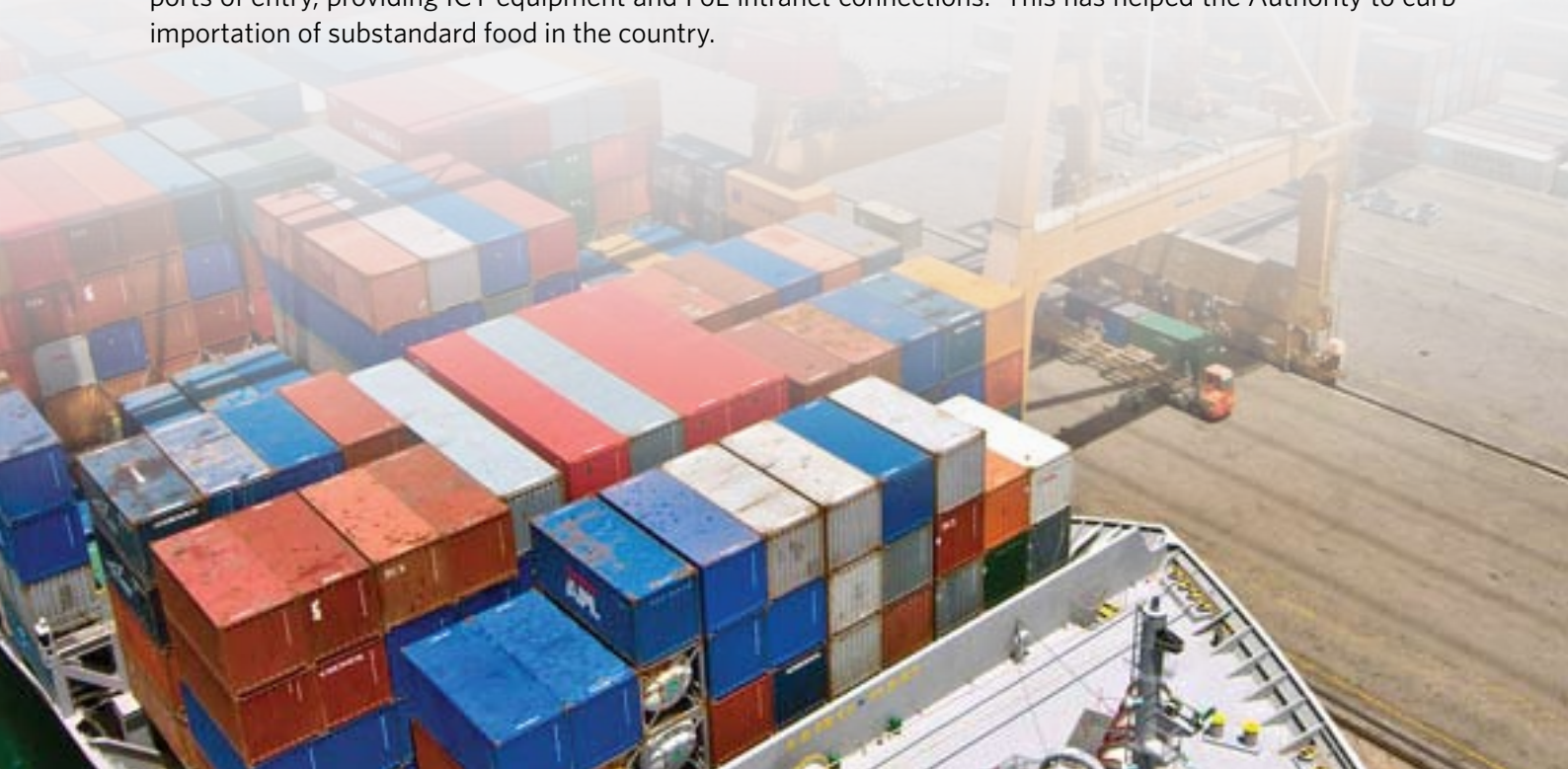
**Table No. 8: Import and Export Permits (July 2005 - June 2013).**

Year	Food Imports Applications		Food Exports Applications	
	Approved	Not Approved	Approved	Not Approved
2005/06	1718	5	-	-
2006/07	1630	43	21	-
2007/08	2148	0	44	1
2008/09	3283	30	126	4
2009/10	2665	236	-	-
2010/11	3008	444	659	6
2011/12	3649	386	673	10
2012/13	1824	177	592	0
<b>Total</b>	<b>19,925</b>	<b>1,321</b>	<b>2,115</b>	<b>21</b>

**Note:**

*The procedure of keeping records for number of issued permits started in the year 2005/06. Before that time, only quantities of food consignments that were permitted or rejected to enter into the country were recorded.*

The control systems of food imports and exports been improved by increasing the number of inspectors at ports of entry, providing ICT equipment and PoE intranet connections. This has helped the Authority to curb importation of substandard food in the country.



### 3.6 Control of Food Advertisements

Sections 95-98 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap. 219 prohibits 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 is to protect the public from misleading information about the regulated product. Dealers are required to submit applications to TFDA for evaluation of promotional materials before permit is granted. Advertisements authorised for public consumption are only those approved and issued with a TFDA permit. These permits are normally given within the same duration of the food permit to circulate in the market.

For the last 10 years, TFDA issued 180 permits for food adverts. During the same period; control of advertisements has been strengthened whereby a number of approved adverts has been increasing and misleading ones have been removed from the market.

### 3.7 Post Marketing Surveillance

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

The PMS in food products started in 2006/07. Since then to June 2013, 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 are as shown in Table No. 9 below;

**Table No. 9: Food Post Marketing Surveillance (2006/07 -2012/13)**

Year	(Food Type)	Number of Samples			
		Zilizochukuliwa	Zilizopimwa	Zilizokidhi	Zisizokidhi
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	The results are not yet out because the surveillance process is still ongoing.	
	Fish	74	74		
	Eggs	72	72		
	Milk	83	83		
	Poultry Meat	48	48		

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

The PMS has generally enabled TFDA to know the situation of food safety and quality in the market that would have compromised with the health of consumers. Likewise, this system has enabled TFDA to ensure that foods in the market continue to maintain safety and quality standards. Strategies have been developed to ensure that substandard food products are removed from the Tanzanian market so that consumers are protected against potential risks which may be associated with their use.

### 3.8 Risk Assessment and Food Borne Disease Surveillance

TFDA has put in place a system that monitors and analyzes potential risks that may arise due to consumption of unfit food. This system has been developed so as to assist TFDA understand the potential health hazards to human beings that may be caused by consuming food that has been contaminated by microorganisms, pesticides, natural toxins, anti bacterial residues and heavy metals.

This system includes the following steps;

- To distribute forms that are used for providing feedback on food borne diseases;
- To receive reports on hazards associated with unsafe food;
- To evaluate received reports;
- To take steps that include; 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 have been received, evaluated and alert notice issued at different times between July, 2003 and June, 2013. Reported health hazards include; diarrhoea, vomiting, typhoid, dysentery and allergy. TFDA also received death reports caused by consumption of contaminated and unsafe food

### 3.9 Disposal of Food products

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

- To receive requests for disposal of food;
- To inspect the quantity and type of food to be disposed;



- To conduct valuation of the food consignment to be disposed;
- To dispose condemned food at the expense of the owner; and
- To issue disposal certificate.

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

Between July 2003 and June 2013, TFDA managed to oversee the disposal of condemned food stuffs worth approximately TZS. 11.88 billion as shown in Table No.10 hereunder;

**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
<b>Total</b>	<b>11,877,894,261</b>

Njia za uteketezaji (Disposal Methods) zinategemea na aina ya chakula kinachokusudiwa kuteketezwa. Utaratibu wa kuteketeza vyakula visivyofaa umesaidia kuzuia vyakula hivyo visiwapikie walaji. Ushirikishaji wa NEMC umewezesha kupata ushauri wa kitaalamu wa kuteketeza bila kuharibu mazingira.

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

### **3.10 Harmonising Food Control Systems**

TFDA has been participating in discussions on harmonization of food control systems within the East African Community (EAC) and the Southern African Developing Countries (SADC). The systems aim at having harmonized procedures for registration, transportation across borders and sale of food among member countries.

Among issues that have been harmonised include; Sanitary and Phytosanitary Protocol, EAC- Food Standards Law and some food standards. The procedures for harmonizing food safety measures are ongoing.

### **3.11 Setting of Food Standards**

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

### **3.12 Researches**

Various researches on food safety and quality have been conducted by TFDA during the last 10 years. Some of them include;

- Pesticide residues in food (2003 – 2006);
- The identification and assesment of food processing industries in the country (2005-2006);
- The evaluation of extent of poisonous fungus (aflatoxin) in the grains and children's food
- The effects of poisonous fungus on human beings (2011- to date)
- Post harvest reduction of poisonous fungus in grains (2012 – to date)
- Assessment of pesticide residues in tomatoes (2012).

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

### **3.13 Preparation of Guidelines**

In order to improve the Authority's performance; transparency in service delivery procedures and various guidelines have been prepared/developed. The following are some of the prepared guidelines;

- Food Registration Guidelines 2004 (Reviewed 2006, 2009 and 2011);
- Food Premises Registration Guidelines 2011;
- Food Import and Export Guidelines 2011;
- Food Risk Assessment and Control of Food Hazards Guidelines 2011;
- Food Fortification Guidelines 2011; and
- Good Manufacturing Practice (GMP) Inspection Guidelines 2013 (Draft).

## CHAPTER FOUR

## 4

## CONTROL OF MEDICINES

**4.1 Introduction**

The Food, Drugs and Cosmetics Act 2003, Cap 219 defines a medicine or drug as 'any substance or mixture of substances prepared or sold for the purpose of:

- Diagnosis, treatment or prevention of any disease, disability or any symptoms of diseases in humans and animals ;
- Restoring, correcting or beneficial modification of mental functions in man or animal; and
- Sterilization of the premises or equipments to kill parasites where food and medicines are being produced including hospitals and animal stables.

Medicines may be categorised into different groups such as human, veterinary, traditional, herbal medicines, vaccines and biologicals. Medicines are generally used for treatment or prevention of diseases that affect various body systems and organs such as digestive system, kidneys, liver, backbone, brain, chest, skin, legs, body tissues, eyes, ears, mouth, reproductive system and diseases that affect children.

TFDA has put in place systems for the control of medicines as outlined hereunder:

**4.2 Registration of Medicines**

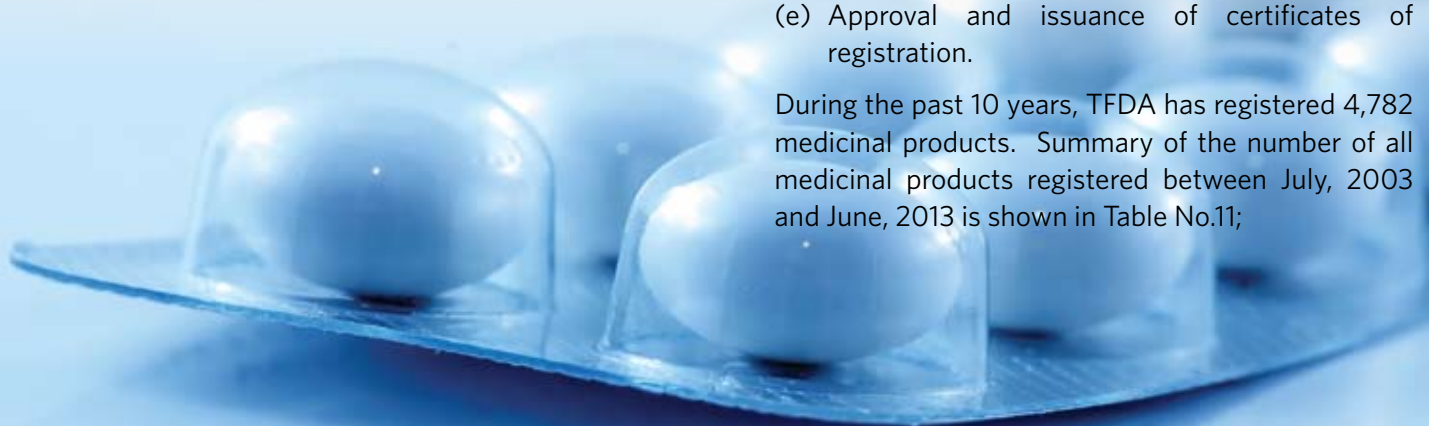
Section 51 of the Tanzania Food, Drugs and Cosmetics Act 2003; Cap 219 mandates TFDA to register all medicines before they are allowed to circulate in Tanzania market. Prior to medicines registration, the following conditions must be met;

- (a) The respective manufacturing facilities and operations must comply with Good Manufacturing Practices (GMP) standards;
- (b) The medicines should be of proven safety, efficacy and required quality;
- (c) Its availability must be of public interest.

The medicines registration process as set by TFDA is as follows;

- (a) Receiving of applications;
- (b) Evaluating scientific data obtained during pharmaceutical development and clinical trials done to demonstrate quality, safety and efficacy of the medicine;
- (c) Conducting quality control tests of medicine samples submitted;
- (d) Conducting inspection of respective manufacturing facilities to verify compliance to GMP; and
- (e) Approval and issuance of certificates of registration.

During the past 10 years, TFDA has registered 4,782 medicinal products. Summary of the number of all medicinal products registered between July, 2003 and June, 2013 is shown in Table No.11;

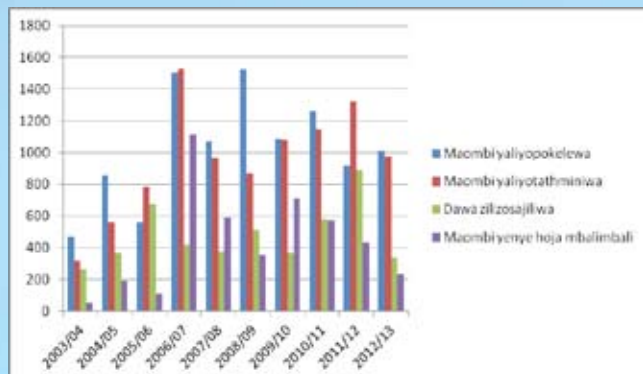


**Table No.11: Registered Medicines (2003-2013)**

Mwaka	Applications Received	Applications Evaluated	Medicines Registered	Applications Queried
2003/04	471	321	265	56
2004/05	857	557	368	189
2005/06	557	783	673	110
2006/07	1,504	1,531	417	1,114
2007/08	1,074	964	374	590
2008/09	1,525	865	512	353
2009/10	1,088	1,082	369	713
2010/11	1,264	1,148	576	572
2011/12	920	1,322	891	431
2012/13	1,011	975	337	235
Total	10,271	9,548	4,782	4,363

Ever since TFDA became operational in July, 2003 on average there have been an upward increase in the number of applications for registrations of medicines, number of evaluated and registered medicinal products as illustrated by Graph No.2 below;

**Graph No.2: Evaluation and Registration of Medicines (2003-2013)**



### 4.3 Registration of Premises

TFDA had been responsible for registering all premises dealing in medicinal products such as manufacturing facilities, wholesale and retail pharmacy, warehouses for storage of pharmaceuticals and vehicles used for their transporting medicines from July 2003 to July 2011. This was done pursuant to Section 21 of the Tanzania Food, Drugs and Cosmetics Act, Cap 219.

Following the enactment of the Pharmacy Act, Cap 311, the responsibility of registering wholesale and retail pharmacies for sale of human medicines were shifted to the Pharmacy Council.

TFDA has remained with the power to regulate pharmaceutical manufacturing industries and importers of all kinds of medicines and veterinary medicine business.

The process for registration of premises is as follows;

- Receiving applications for registration of premises;
- Verification of applications;
- Inspection of premises;
- Approval and issuance of certificates of registration of premises, and;
- Issuance of business permits.

In the 10 years of TFDA existence, it has registered 17,013 various pharmaceutical premises as detailed in Table No.12 below:

**Table No.12: Registered Premises (2003 - 2013)**

Year	Premises					
	Overseas and Local Pharmaceutical Manufacturing Industries	Pharmacy	Warehouses	ADDOS	Part II shops	Total
2003/04 -2007/08	250	677	-	820	9,274	11,021
2008/09	26	619	35	-	1058	1,738
2009/10	12	455	27	1,096	0*	1,590
2010/11	31	314	12	1,419	0*	1,776
2011/12	23	286	0	537	0*	846
2012/13	25	46	31	0	0*	102
Total	367	2,397	105	3,872	10,332	17,073

The number of registered Part II shops has been decreasing yearly because of implementation of the Accredited Drug Dispensing Outlets Programme (ADDO). Moreover, after enactment of the Pharmacy Act, Cap 311 the mandate of Licencing, pharmacies and ADDO were shifted to the Pharmacy Council.

Processes for registration of premises facilitates TFDA to identify and ensure that those involved in the production, distribution, storage and sale of medicines comply with the requirements of the laws, regulations and guidelines.

#### 4.4 Inspection of Medicines

Pursuant to Section 5(1) (I) and 106 of the Tanzania Food, Drugs and Cosmetics Act 2003 Cap 219 TFDA is mandated to inspect all premises involved in the business of medicines. Premises that are subject to inspection include; manufacturing facilities, wholesale and retail shops, vehicles transporting medicines, warehouses, hospitals, health centres, dispensaries, veterinary centres, open markets and trade fairs.

Inspections are conducted to ascertain that medicines circulating in the markets are registered and comply with prescribed storage conditions or the production operations and sales outlets meet the set standards. Inspectors are appointed by the Director General and gazetted in Government Gazette as required by section 105 of Tanzania Food, Drugs and Cosmetics Act 2003; Cap 219.

In the past 10 years, TFDA has registered 17,073 premises. These include; wholesale and retail pharmacies for human and veterinary medicines, ADDOs and Part II shops; warehouses for storage

of medicine and areas that dispense medicines in hospitals. During this period regulatory functions were strengthened by increasing the number of inspectors. This has contributed towards better control of the quality of medicines in the country.

Upon conclusion of inspections a number of regulatory actions have always been taken against the violators such as reminders, issuance of warning letters, seizing medicines, rejection of applications for permit, closure of businesses or arraigning the suspects in court.

#### 4.5 Control of Medicines at Ports of Entry

Consignments of medicines including raw materials or imported through customs at different ports of entry. Section 73 of the Food, Drugs and Cosmetics Act 2003; Cap 219 gives authority to TFDA to control all medicine imports into the country.

There are 10 official ports of entry for medicines as shown in Table No.13 below;

### Jedwali Na. 13: Vituo vya forodha vinavyoruhusiwa kupitisha dawa

No.	Ports of Entry	No.	Ports of Entry
1.	Namanga	6.	Kasumulu
2.	Sirari	7.	Uwanja wa Ndege wa Dar es Salaam
3.	Tunduma	8.	Uwanja wa Ndege wa Kilimanjaro
4.	Holili	9.	Bandari ya Dar es Salaam
5.	Horohoro	10.	Bandari ya Tanga

The process of import and export certification is as follows;

- Receiving applications for importation of medicines;
- Determine respective registration status;
- Conducting laboratory tests; and
- Issuing Import or Export Certificate.

During the last 10 years 20,233 import permits and 539 export certificates were issued as shown in Table No.14 below;

**Table No.14: Import and Export Permits of Medicines Issued 2003-2013**

Mwaka	Applications for Importation		Application for Exportation	
	Approved	Rejected	Approved	Rejected
<b>2003/04 -2007/08</b>	6,523	447	122	0
2008/09	1,808	0	37	0
2009/10	2,538	94	41	0
2010/11	4,457	132	190	0
2011/12	2,911	177	87	0
2012/13	1,996	111	62	0
Total	20,233	961	539	0

Inspection of consignments at ports of entry has been strengthened thereby enabling TFDA to curb importation of substandard and counterfeit medicines.

## 4.6 Control of medicines Promotional Materials

Sections 95-98 of the Tanzania Food, Drugs and Cosmetics Act 2003; Cap 219 prohibits promotion of medicines without a written permit issued by the Authority. The promotional materials include; photographs, films, bill boards, leaflets, publications; and radio and TV clips.

Promotional materials are controlled so as to ensure that their contents are true and provide correct information about medicines to avoid misleading

the public. Applicants are required to submit their applications so as to be evaluated before TFDA issues respective permits.

In the past 10 years, TFDA approved 859 promotional materials. The number of applications for approval of promotional materials of medicines received, evaluated and approved or rejected is as shown in Table No.15 below;

**Table No. 15: Promotional Materials Applications 2003-2013**

Year	Received	Evaluated	Approved	Rejected
<b>2003/04 - 2007/08</b>	387	386	345	41
<b>2008/09</b>	92	86	86	0
<b>2009/10</b>	196	190	175	15
<b>2010/11</b>	116	91	79	12
<b>2011/12</b>	100	118	118	0
<b>2012/13</b>	62	62	56	6
<b>Total</b>	<b>953</b>	<b>933</b>	<b>859</b>	<b>74</b>

During the 10 years period, regulation of promotional materials has improved considerably. Moreover, the number of promotional materials received and evaluated has been varying and those complying were approved whereas those deemed to contain misleading information were rejected and removed from the market.

## 4.7 Post Market Surveillance of Medicines

TFDA has set up Post Market Surveillance (PMS) system to systematically monitor the quality of medicines in the Tanzanian market. Samples of the targeted medicines are collected and analysed; results compiled and appropriate regulatory actions taken accordingly for respective products. The actions include; removing the product found to be substandard or counterfeit from the market, issuing warnings letters to the concerned parties banning the product and educating them where appropriate.

The PMS was introduced in 2009 and up to 2013, 423 samples had been collected from the market and subjected to quality control tests. Results of quality control tests are as shown in the Table No.16 below shows;

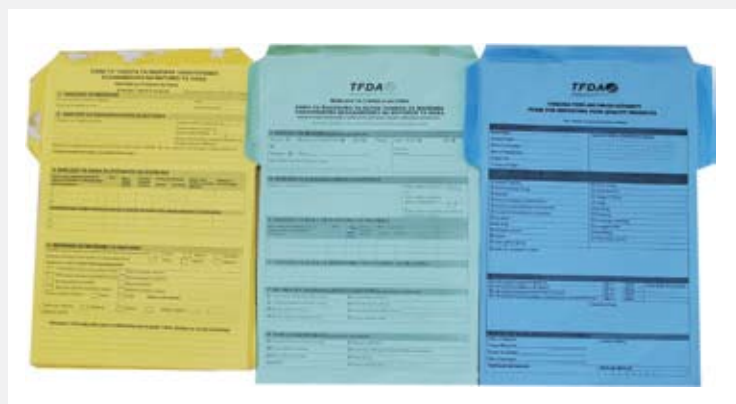
**Table No.16: PMS Samples Collected and Analysed (2009-2013)**

Year	Medicine Type	Number of Samples			
		Collected	Tested	Passed	Failed
2009/10	Cloxacillin	138	60	30 (50%)	30 (50%)
	Quinine	143	70	70 (100%)	0 (0%)
2010/11	Artemether + Lumefantrine	59	9	9 (100%)	0 (0%)
2011/12	Stavudine + Lamivudine + Nevirapine	58	22	20 (90.9%)	2 (9.1%)
2012/13	Zidovudine + Lamivudine + Nevirapine	25	12	12 (100%)	0 (0%)
Total		423	173	141 (81%)	32 (18%)

Samples were collected from the Medical Stores Department (MSD), healthcare facilities and pharmacies in Morogoro, Dodoma, Mbeya, Lindi, Mtwara, Ruvuma, Iringa, Shinyanga, Kagera, Singida and Rukwa regions.

The PMS has enabled TFDA to unearth sub-standard medicines such as cloxacillins produced by some manufacturers which were found to have less concentration of active ingredient than normal and therefore removed from the market.

On the other hand medicines such as quinine, Artemether + Lumefantrine a fixed dose combination antimalarial (popularly known as Alu), fixed dose combinations antiretroviral medicinal products such as Zidovudine + Lamivudine + Nevirapine and Stavudine + Lamivudine + Nevirapine met quality specifications and were therefore allowed to continue being on the Tanzanian market.



## 4.8 Monitoring of Adverse Drug Reactions

The system for monitoring Adverse Drug Reactions (ADR) started in 1993. This system which is known as "spontaneous pharmacovigilance system" involves the use of ADR Reporting Forms commonly known as (Yellow Forms) for voluntary reporting adverse drug reactions by healthcare workers. The forms have been widely distributed to hospitals, health centers, dispensaries and pharmacies country wide.

Patients are requested to give report to healthcare workers whenever they experience any adverse effects after using a medicine(s) who are then supposed to fill in the Yellow Forms with the details of the suspected adverse reaction and submit them to TFDA. The cost of sending the Yellow Forms by post has been pre-paid by TFDA.

The ADR reports collected from different areas of the country are evaluated by TFDA and the results are disseminated through leaflets, public notices or special report.

In order to facilitate collection of adverse drug reactions, pharmacovigilance centers were established in 2001 in the following areas; Mwanza (Bugando Hospital), Dar-es-Salaam (Muhimbili National Hospital), Mbeya (Referral Hospital) and Kilimanjaro (KCMC Hospital). Additional ADR centres were inaugurated in the 2011, in Dodoma (Regional Hospital), Mtwara (Ligula Hospital) and Kigoma (Regional Hospital).

Between 2002/03 - 2012/13, TFDA collected 7,212 ADR reports through the use of this system. The number of reports received by TFDA has been increasing annually as shown in Graph No.5 below;

**Graph No.5: Adverse Drug Reaction Reports Collected 2003-2013**



According to the WHO guidelines, at least a minimum of 200 reports are required to be collected for every 1,000,000 people annually in order to obtain scientific evidence of the reaction being attributed to the medicine. For a country like Tanzania whose population is estimated at around 40 Million people, a minimum 8,000 reports would be required to be collected annually.

Graph No. 5 shows that reports that were received by TFDA through the use of this system fell short of the target recommended by the WHO. Therefore, reports that were received by TFDA, which were only 2.5% of the annual recommended target cannot be used conclusively to determine the safety of the medicine being reported. Nevertheless, TFDA is still continuing with its determination to obtain the reports using this passive system and using pro-active approaches.

Another system that is being used for collecting ADR drug reactions reports is professionally known as "Cohort Event Monitoring (CEM)". This system was adopted by TFDA in 2009 in order to collect more ADR reports. This system involves a close follow up

(Active surveillance) of specified medicines used at health centres.

Medicines used in treating illnesses that affect many people (diseases of public health importance) such as malaria, tuberculosis, and HIV AIDS are subjected to a CEM approach. Through CEM, 8040 reports of Antimalarial namely as Artemether + Lumefantrine (ALu) have been collected and evaluated.

Also through the use of CEM, another antimalarial drugs known as Dihydroartemisinin + Piperaquine (Duo-cotecxin) and some Antiretroviral (ARV) medicines have been subjected under surveillance and results are expected to be out in 2014.

## 4.9 Control of Clinical Trials of Medicines

Sections 61-67 of The Food, Drugs and Cosmetics Act 2003, Cap 219 empower TFDA to control medicines clinical trials in the country.

Clinical trials are research conducted in humans to ascertain safety and efficacy specifications of medicines. The trials are normally done after completing the initial steps of assessing the potency of the medicines in small animals such as rats and rabbits. Any researcher who wants to conduct clinical trials of any medicine is required to apply and obtain a clinical trials permit from TFDA before embarking on the trial.

Once the permit is granted by TFDA, an inspection is conducted to verify if proper procedures for conducting clinical trials are adhered to, including compliance to Good Clinical Practice - (GCP) standards. Up to June 2013, TFDA has approved 83 clinical trials of medicines in the country. This system has enabled TFDA to identify the number and types of clinical trials that are being conducted in the country and also has helped in protecting human rights and well being of those involved in trials.

In carrying out this function, TFDA collaborates with other institutions such as National Institute for Medical Research (NIMR) who are responsible for enforcing ethical conduct of clinical trials in human beings. The Animal Diseases Research Institute (ADRI) is responsible for conducting clinical trials in

animals, in particular when veterinary medicines are the subject of study.

## 4.10 Palliative Care

Sections 78 (1-3) of The Food, Drugs and Cosmetics Act 2003; Cap 219 mandates TFDA to regulate medicines that are used for palliative care. These are medicines which are addictive, includes; "narcotics" and "psychotropic substances", that are used in hospitals particularly for reduction of the severe pain caused by diseases such as cancer.

TFDA has put in place strict control mechanisms because these products which are addictive have high potential of causing severe adverse health effects on human being if not used properly. Furthermore, such drugs are prior to diversion into illegal use. In regulating these medicinal products, the authority recognizes the existence of the Drugs and Prevention of Illicit Traffic in Drugs Act, 1995.

Importation of these medicinal products is restricted to Medical Stores Department (MSD) which then distribute them to government and private hospitals that have been approved by TFDA. All hospitals that use these products are required to submit to TFDA quarterly reports for the purpose of monitoring there use and approving quantities required for replenishment. TFDA compile national reports and submits it to Narcotics Control Board based in Vienna - Austria. As of June, 2013 a total of 890 permits for the import of these drugs were issued by TFDA.

## 4.11 Disposal of Medicines

Section 99 of the Food, Drugs and Cosmetics Act 2003, Cap 219 empowers TFDA to prevent and seize, forfeit, condemn and destroy unfit medicines. The procedures for disposal of unfit medicines are the same as those applicable to food (See Part 3.9 Chapter Three)

TFDA has up to June 2013 supervised disposal of unfit medicines worth around TZS 4,941,259,131 as indicated in Table No.17 hereunder;

**Table No.17: Value of Disposed Drugs and Medicines**

Year	Value in TZS
July 2003 - June 2008	786,148,786
July 2008 - June 2009	1,265,620
July 2009 - June 2010	1,915,495,744
July 2010 - June 2011	844,302,796
July 2011 - June 2012	1,353,186,185
July 2012 - June 2013	40,860,000
<b>Total</b>	<b>4,941,259,131</b>

## 4.12 Accredited Drugs Dispensing Outlets (ADDO) Programme

TFDA in collaboration with a non government international organization known as “Management Sciences for Health (MSH)” and Local Government Authorities initiated a programme of Accredited Drugs Dispensing Outlets (ADDO) which aimed at improving the availability of safe, quality and efficacious medicines in the rural and peri-urban areas.

This followed an assessment that was made on the level of service provision by Part II Poison shops (DLDB) that were established under the repealed Pharmaceuticals and Poisons Act, 1978. The results of the assessment indicated a great need of improving pharmaceutical services particularly in rural and peri-urban areas.

The implementation of ADDO started as a pilot in Ruvuma Region between 2002-2005. The guidelines for rolling out this programme to other areas of the country were prepared and implemented after successful evaluation of programme in 2005. Among improvements that were noted after ADDO piloting in Ruvuma region were as follows:

- (a) The quality of medicines outlets greatly improved
- (b) Improvement in medicine storage;
- (c) Drug dispensers acquired adequate knowledge of medicines management and Good Dispensing Practices;

- (d) Involvement of the councils in the approval processes of business permits at all levels from the ward to the regional level;
- (e) Expansion scope of inspectors thus enabling Wards to be aware of medicine outlets in their wards;
- (f) To have in place a good system of control of medicines, including newly approved outlets in a given locality;
- (g) Using ADDO as a platform for providing avenue for other public health interventions such as health insurance, Integrated Management of Childhood Illness (IMCI) and distribution of subsidized first line drugs such as Anti malarials Artemesin Combination Therapy (ACT).



The implementation of the programme involves the following steps;

- (a) To sensitize government leaders at the Regional and District levels;
- (b) To map DLDBs
- (c) To conduct preliminary inspections of DLDBs;
- (d) To train staff working in DLDBs, owners and ward inspectors;
- (e) To conduct final inspection on DLDBs that have undergone renovation;
- (f) To hold meetings with Food and Drugs Committees under the district councils; and
- (g) To promote and accredit DLDB to ADDO

Due to success of ADDO pilot in Ruvuma region, the government decided to roll out the programme throughout the country.

In order to regulate effectively the ADDOs, Regulations for Accredited Drug Dispensing Outlets (2004) were prepared and reviewed in 2006. They provide for requirements for establishing ADDOs, operation and types of medicines that are allowed to be sold in outlets. These are over the counter (OTC) medicines and some prescription medicines which are in Essential Drug List as indicated in Table No. 18 hereunder.

**Table No. 18: ADDO Prescription Medicines**

No.	Drug / Medicine Type	Potency
<b>Asthma Drugs</b>		
	Aminophylline injection (ampoules)	25mg/mL in 10mL
<b>Antibiotics</b>		
	Amoxycillin trihydrate capsules	250mg, 500mg
	Amoxycillin trihydrate oral suspension	125mg/5ml, 250mg/ml
	Benzyl Penicillin powder for injection	3gm (500,000 IU) in vial
	Co-trimoxazole suspension	240mg/5ml in 100 mL Bottle
	Co-trimoxazole tablets	480mg
	Doxycycline capsules/tablets	100mg
	Erythromycin oral suspension	125mg/5ml, 250mg/5ml.
	Erythromycin tablets	250mg, 500mg
	Metronidazole tablets	200mg, 250mg, 400mg,
	Metronidazole suspension	200mg/5ml in 100mL
	Metronidazole injection	200mg/100ml
	Nitrofurantoin tablets	50mg, 100mg
	Oxytetracycline Hydrochloride eye ointment	5% (w/v), 10% (w/v)
	Phenoxymethyl Penicillin suspension	125mg/5ml, 250mg/5ml in 100mL
	Phenoxymethyl Penicillin tablets	250mg
	Procaine Penicillin Fortified	4g (400,000IU) - 4MU
	Silver sulfadiazine cream	10mg
	Chloramphenicol eye drops/ointment	5mg/ml in 10ml
<b>Anti-Inflammatory/Analgesics</b>		
	Diclofenac sod. Tablets	25mg, 50mg
	Indomethacin capsules	25mg
	Hydrocortisone ointment/cream	1%, 0.5%
	Annusol suppositories	Bismuth Oxide Anhydrous - 24 mg Zinc Oxide - 296 mg Balsam Peru - 46 mg Bismuth Subgallate - 59 mg
<b>Anaesthetics, local</b>		
	Lignocaine injection	1% in 10ml vial, 2% in 30ml vial
<b>Anti-Fungal</b>		
	Nystatin oral suspension	100,000IU/ml in 30mL Bottle
	Nystatin pessaries	100,000IU
	Nystatin skin Ointment	100,000IU/gm
	Nystatin tablets	500,000IU
	Ketoconazole tablets	200mg
<b>Anti Malarials</b>		
	Quinine tablets (sulphate or bisulphate)	300mg
	Quinine injection (as dihydrochloride)	300mg/ml in 2mL

No.	Drug / Medicine Type	Potency
	Artemether + Lumefantrine tablets/ACT	Artemether 20 mg Lumefantrine 120 mg
<b>Cardiovascular (Anti-arrhythmic drugs)</b>		
	Propranolol tablets (Hydrochloride)	10mg, 40mg, 80mg
<b>Diuretics</b>		
	Bendrofluazide tablets	5mg
<b>Oxytocics</b>		
	Ergometrine Injection (maleate)	0.2mg/mL in 1mL ampoule, 0.5mg/mL in 2mL ampoule
<b>Laxative</b>		
	Bisacodyl tablets	5 mg
<b>Antihistamines</b>		
	Cetirizine hydrochloride tablets	10 mg
	Cetirizine hydrochloride oral solution	5mg/5ml
<b>Antispasmodics</b>		
	Hyoscine butylobromide tablets	10 mg
	Hyoscine butylobromide injection	20mg/ml
<b>Oral Contraceptives</b>		
	EthinylestRediol (0.03mg) + Novethisterone (0.3mg)	0.03mg + 0.30mg
	EthinylestRediol (0.03mg)+ Levonorgestrel (0.15mg)	0.03mg + 0.15mg
<b>Minerals/vitamins</b>		
	Neurobion Forte	Thiamine Mononitrate - 10 mg Ribo flavine - 10 mg Pyridoxide HCL - 3 mg Cynocobalamine - 15 mg Nicotinamide - 45 mg Calcium Pantothenate - 50 mg
	Zinc sulfate tablets	20mg
<b>Anti Emetic</b>		
	Promethazine Hydrochloride Injection	25mg/ml in 2mL ampoule
<b>Fluids and Electrolytes</b>		
	Dextrose	5%
	Normal Saline Injection	0.9%
	Water for Injection	N/A
<b>Anti-Epileptic</b>		
	Phenytoin tablets/capsules (Sodium salt)	50mg, 100mg

By June 2013, the ADDO programme had been implemented in all regions of Tanzania. A total of 13,643 drugs dispensers were trained on dispensing drugs and 3,873 ADDOs were registered.

After enacting the Pharmacy Act Cap 311, in 2011, the responsibility for control of ADDOs was shifted to the Pharmacy Council while TFDA continued with the power to regulate the quality, safety and efficacy of medicines.

### 4.13 Harmonization of Regulatory Systems

Tanzania is a member of the East African Community (EAC) and the Southern African Development Community (SADC). These countries have been discussing and setting strategies for harmonizing medicines regulation processes. The aim is to have streamlined systems in the control of medicines in the regions.

In order to implement these strategies, institutions from partner states have started a process of harmonizing medicines regulatory systems including procedures for registration of medicines, GMP inspection, ICT systems and QMS.

This programme was officially inaugurated in Arusha by the Chairperson of East African Cabinet in March, 2012. The programme involves National Regulatory Authorities (NRAs) within the partner states and shall be implemented within a period of four years (2012-2016).

Within the SADC region, the guidelines for control of clinical trials, guidelines for conducting bioequivalence and bioavailability studies, and guidelines on pooled procurement have been harmonized in year 2005 whereby member countries have agreement for the use.

Other areas that are still in process of harmonisation since 2005 include; guidelines on research for HIV vaccines, guidelines for registration of vaccines, guidelines for registration of traditional and alternative medicines, guidelines for monitoring safety and quality of medicines in the market, guidelines for registration of food supplements and guidelines for registration of premises and control of advertisements.

### 4.14 Technical Committees

Section 13 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap 219 empowers the Director General of TFDA to establish Technical Committees to advise him on matters pertaining to control of foods, medicines, cosmetics and medical devices. The following Committees have been established:

- (a) Human Medicines Registration Technical Committee;
- (b) Veterinary Medicines Registration Technical Committee;
- (c) Pharmacovigilance Technical Committee; and
- (d) Clinical Trials Technical Committee.

#### 4.14.1 Human Medicines Registration Technical Committee

The Human Medicines Registration Technical Committee was established in 2008 and it is made up of members from outside while the Director of Medicine and Cosmetics serve as the secretary to the committee. Members include medical doctors, pharmacists, microbiologists, vaccinologists, pharmacologists and pharmacognosists. Appointment of members is based on their profession, experience and competence in their field of expertise. This Committee amongst other things provides advice on registration matters for human medicines. Up to June 2013, the committee had met 13 times.

The list of members who served in this Committee is shown in Table No.19 (check 4.14.4)

#### 4.14.2 Veterinary Medicines Registration Technical Committee

The Veterinary Medicines Registration Technical Committee was established in 2008. Professionals in this Committee include veterinary doctors, pharmacists, microbiologists, vaccinologists and pharmacologists. The Director of Medicine serve as the secretary to the committee. This committee provides advice on matters related to the registration of veterinary medicines.

So far the committee has met 5 times since its inception. Its members are shown in Table No. 19 (check 4.14.4)



#### 4.14.3 Pharmacovigilance Technical Committee

The Pharmacovigilance Technical Committee was established in 2008 and it includes experts from within and outside TFDA. These experts embrace pharmacists, pharmacologists, medical doctors and microbiologists.

The Committee amongst other things provides advice on matters related to detection, evaluation and prevention of adverse drug reactions. The Committee is supposed to meet quarterly and it has conducted three meetings since its establishment. Members of this Committee are listed in Table 19 below.

#### 4.14.4 Clinical Trials Technical Committee

The Clinical Trials Technical Committee was established in 2008 and members of this Committee include professionals with a medical, research, ethics, pharmacy, microbiology and pharmacology background. The Committee provides advice on matters related to control of critical trials. The Committee has already met 6 times since its inception. The past and present members of this Committee are as shown in Table No. 19 below;

**Table No. 19: Technical Committee Members 2008 -2013**

Duration	Technical Committees			
	Registration of Human Medicines	Registration of Veterinary Medicines	Pharmacovigilance	Clinical Trials
Jul 2008 – Jun 2011	Prof. M. Moshi (Chairman) Mr. H. B Sillo/Bw. A. M. Fimbo (Secretary) Prof. O. Ngassapa Prof. P. Rugarabamu Prof. S. Aboud Dr. E. Kaale Dr. R. Kaushik Dr. M. Shimwela Dr. S. Kubhoja Mr. Y. Hebron Mr. L. Mhangwa	Prof. L. Kinabo (Chairman) Bw. H. B. Sillo/Bw. A. M. Fimbo (Secretary) Dr. B. Jullu Dr. S. Luwongo Dr. P. Risha	Mr. G. Y. Mlavwasi (Chairman) Mr. H. B. Sillo/ Mr. A. M. Fimbo (Secretary) Dr. Venance Maro Dr. O. Minzi Mr. J. Pemba	Dr. R Kingamkono (Chairman) Mr. H. B. Sillo/ Mr. A. M. Fimbo (Secretary) Bi. J. Ikingura Dr. D. Mloka Prof. A. KamuhaMra Dr. G. Massenga Dr. Vicky Manyanga

Duration	Technical Committees			
	Registration of Human Medicines	Registration of Veterinary Medicines	Pharmacovigilance	Clinical Trials
Jul 2011 – todate	Prof. S. Aboud (Chairman) Mr. A.M Fimbo (Secretary) Prof. M. Moshi Dr. E. Kaale Dr M. Shimwela Dr. S. Kubhoja Dr. E. Ngaimisi Dr. E. Kija Dr. S. Maregesi Dr. G. Shoo	Prof. L. Kinabo (Chairman) Mr. A. M Fimbo (Secretary) Dr. B. Jullu Dr. S. Luwongo Dr. P. Risha	Mr. G. Y. Mlavwasi (Chairman) Mr. A. M Fimbo (Secretary) Dr. Venance Maro Dr. O. Minzi Mr. J. Pemba	Dr. R. Kingamkono (Chairman) Mr. A. M Fimbo (Secretary) Bi. J. Ikingura Dr. D. Mloka Prof. A. KamuhaMra Dr. G. Massenga

#### 4.15 Guidelines development

A number of guidelines for regulation of medicines have been developed between 2003 and 2013. They provide for guidance for applicants to follow when submitting their applications to TFDA and staff in evaluating the applications. The developed guidelines and manuals are listed below:

- (a) Guidelines for Registration of Human Medicines (2004 revised in 2008 and 2012);
- (b) Guidelines for Registration of Veterinary Medicines (2003);
- (c) Guidelines for Registration of Biological products (2004);
- (d) Guidelines for Registration of Herbal Medicines (2004);
- (e) National Guidelines for Medicines Safety (2006, revised 2010);
- (f) Guidelines for Registration of Business Premises (2008);
- (g) Guidelines for Variations of Human Medicines (2008);
- (h) Guidelines for Good Manufacturing Practices for Pharmaceuticals (2008);
- (i) Training Manual for ADDO Dispensers (2008);
- (j) Training of Trainers Manual for ADDO programme (2008);
- (k) Training Guide for ADDO Owners (2008);
- (l) Training Manual for Inspectors (2008);
- (m) Guidelines for Establishment of ADDOs (2008);
- (n) Guidelines for Disposal of Medicines (2009);
- (o) Guidelines for Importation and Exportation of Medicines (2000; revised 2011);
- (p) Guidelines for Control of Narcotics and Psychotropic Substances (2008);
- (q) Guidelines for Control of Clinical Trials of Medicines (2009);
- (r) Guidelines for Good Distribution Practices for Medicines (2009);
- (s) Post Marketing Surveillance Guidelines (2010);
- (t) Training Manual of Healthcare Providers on Safety of Medicines (2010);
- (u) Guidelines on Insurance for Participants in Clinical Trials (2010);
- (v) Guidelines for Registration of Paediatric Medicines (2011); and
- (w) Guidelines for Safety Reporting in Clinical Trials (2011).

**CONTROL OF COSMETICS****5.1 Introduction**

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. Nevertheless, cosmetics are manufactured using different ingredients.

Some ingredients used in manufacturing cosmetics are safe and others are not safe to users. It is therefore, TFDA's responsibility to ensure that cosmetics manufactured with harmful ingredients which have been prohibited are not used in the country. Prohibited ingredients are listed below in Table No. 20;

**Table No.20: 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 are prohibited for use under Section 87 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap. 219.

## 5.2 Health Risks of Harmful Ingredients

When harmful ingredients are used in manufacturing of cosmetics, may lead to various health risks to the users. Among health and economic effects due to use of harmful cosmetics includes;

- Skin allergy;



- Skin diseases and skin irritation when exposed to the sun;
- Skin becomes softer and prone to infections such as fungus and bacterial diseases;



- Harmful effects to babies in the mother's womb when expectant mothers use cosmetics that have mercury;
- Skin and lung cancer due to the use of cosmetics with Vinyl Chloride and Zirconium;
- Skin irritation and pigment orientations that cause dark and light spots on the skin due to the use of Hydroquinone; and



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

### 5.3 Local Cosmetics (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 out of the farm produce and its allied products, are safe as they have no health risks to the users. Nevertheless, other local cosmetics are made out of a mixture of various products including chemicals and medicines. These local cosmetics that are popularly known as “Mikorogo” are available in different names as shown in Table No. 21 below;

**Table No. 21: Various Types of harmful/unwanted Local Cosmetics**

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

### 5.4 Misuse of Medicines as Cosmetics

Among the prohibited ingredients used in cosmetics is a 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, Gentrison, etc.

These products are dispensed as “prescription only medicines” and are only given to the skin patients subject to the doctor’s prescription and the pharmacist advice. They are not allowed to be used as cosmetics despite of misuse by some people due to skin bleaching effects.

Other medicines that have been prohibited for use as cosmetics are those for hip, penis and breast enhancement. These drugs are believed to have harmful effects that may trigger cancer (cancer enhancers) to users.

Due to health and economic risks caused by use of unsafe cosmetics, TFDA has put in place control systems in order to ensure that cosmetics that are available in the country



are safe and of good quality to the users. This is to ensure that all cosmetics circulating in Tanzanian market have no prohibited ingredients that can cause harm to users.

## 5.5 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 may cause harm to users. The law requires that all those who are engaged in the distribution and selling of cosmetics in the country to register their cosmetic products.

The process for registration of cosmetics includes;

- Receiving and evaluating information on the presence of ingredients in cosmetics;

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

- Conducting laboratory analysis of cosmetic samples, and
- Evaluating product information including labels.

Before the registration procedure was introduced, a system for notification of cosmetics was in place between July 2003 and February 2008. Over the past ten years, TFDA has been able to notify and register a total of 3,968 cosmetics as highlighted in Table No.22 hereunder;

**Table No. 22: Notified and Registered Cosmetics by TFDA (2003-2013)**

Year	Received Applications	Evaluated Applications	Approved Cosmetics
2003/04	0	0	0
2004/05	805	798	787
2005/06	402	340	161
2006/07	1,142	1,279	308
2007/08	512	512	444
2008/09	481	301	34
2009/10	1,119	1,024	505
2010/11	886	886	501
2011/12	1066	786	422
2012/13	1095	850	806
<b>Jumla</b>	<b>7,508</b>	<b>6,776</b>	<b>3,968</b>

The system for registration of cosmetics has been improving annually and the number of cosmetics registered has 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 reach users.

## 5.6 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 that are not registered by TFDA. Registered premises include manufacturing facilities, warehouses, wholesale and retail cosmetic outlets.

Procedures for premises registration involve the following steps;

- Receiving applications;
- Verifying the received applications;

- Inspecting premises;
- Issuing registration certificates; and
- Issuing business permits.

Within the last 10 years, TFDA has been able to register a total 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.

## 5.7 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 2013, TFDA has been able to inspect 4,164 business premises as shown in Table No. 23 hereunder;

**Table No. 23: 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
<b>Total</b>	<b>709</b>	<b>144</b>	<b>908</b>	<b>1,052</b>	<b>874</b>	<b>477</b>	<b>4,164</b>

Meanwhile, regulatory actions have been taken against violators of cosmetics regulations which include issuing warning letters, prohibiting their products from reaching the market, denying business permits, closing down of their businesses, educating and or instituting legal actions.

## 5.8 Import and export control of cosmetics

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

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

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

- Reviewing the applications, and
- Issuing import or export permits.

During the last 10 years, TFDA has 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 has assisted the Authority to prevent the importation of harmful cosmetics into the country and thereby protecting the general public health.



## 5.9 Disposal of cosmetics

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

Receiving applications for disposal of cosmetics;

- Conducting inspect of the quantity and type of cosmetics to be disposed off;
- Estimating the value of cosmetics to be disposed off;
- Disposing cosmetics at the expense of the applicant; and
- Issuing Disposal Certificates.

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

## 5.10 Regulations and Guidelines

In order to improve the Authority's efficiency and transparency specific regulations for registration of cosmetics were developed in 2010 as required by the Tanzania Food, Drugs and Cosmetics Act, Cap 219. Guidelines for control of cosmetics were also developed including one for Registration of Cosmetics of 2008.

## CONTROL OF MEDICAL DEVICES

### 6.1 Introduction

Medical devices are instruments used in the medical diagnosis, treatment, bone fixation or for prevention of diseases in human beings or animals. This definition has been provided for in Section 3 of the Tanzania Food, Drugs and Cosmetics Act 2003, Cap 219. Medical devices are divided into four main classes according to their potential risks as follows:

- (a) Low risk medical devices such as gauze, bandages, tongue depressors and surgical retractors;
- (b) Low - moderate risk medical devices such as hypodermic needles and suction equipment;
- (c) Moderate - high risk medical devices such as lung ventilators and bone fixation plates; and
- (d) High risk medical devices such as prosthetic heart valves and implantable defibrillators.

Regulation of these products depends on their respective class. Regulatory systems for control of medical devices are outlined in succeeding Section:

### 6.2 Usajili wa Vifaa Tiba

Kifungu cha 51 cha Sheria ya Chakula, Dawa na Vipodozi, Sura 219 kinaipa uwezo TFDA kusajili vifaa tiba kabla ya kuruhusiwa kutumika Tanzania. Utaratibu wa kusajili vifaa tiba unahusisha:

### 6.2 Registration of Medical Devices

Section 51 of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 mandates TFDA to register medical devices before being allowed to circulate in Tanzania market. The process of registration of medical devices includes the following steps;

- (a) Receiving applications for registration of a medical device;

- (b) Conducting initial screening in order to classify the device according to the associated risks and subsequently payment of required fees;
- (c) Evaluating their quality, safety and efficacy standards; and
- (d) Issuance of the registration certificates.

**“Vifaa tiba  
vimegawanyika  
katika makundi  
manne  
kulingana na  
madhara yake  
(risk)”**

The processes for registration began in 2008, after the establishment of the Medical Devices Assessment and Enforcement Department under Directorates of Medicines and Cosmetics. It was decided that medical devices ought to first be notified before full fledged registration. 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. As at June 2013, the following types of devices have already been registered - "syringes, surgical sutures, examination and surgical gloves, scalp vein sets, intravenous cannulae, catheters and tubes, condoms, needles and administration sets (blood giving and taking sets, blood lancets and I.V giving sets)". Others are "blood collection bags, surgical dressings, internal prosthetic replacements, orthopaedic implants, bone cements, drug eluting stents and intraocular lenses".

A total of 96 medical devices were registered between 2010 and 2013

### 6.3 Registration of Premises

Registration process for medical devices premises have been done by TFDA since 2003 to 2011. Premises registered include manufacturing facilities, retail and wholesale shops and warehouses. Premises registration is done in accordance with the requirements of Section 21 of the Tanzania Food, Drugs and Cosmetics Act, Cap 219.

These requirements to register medical devices premises changed in 2011 after the enactment of the Pharmacy Act, Cap 311. The new legislation empowered the Pharmacy Council to register all non imported wholesale and retail shops that are engaged in the sale of medical devices.

As of June, 2013 TFDA had been able to register six (6) premises that are involved in the sale of medical devices. One (1) premise was registered in 2008/09 and the remaining five (5) were registered in 2009/10.

### 6.4 Inspection of Medical Devices

According to Sections 5 (1) (h) and 106 of the, Tanzania Food, Drugs and Cosmetics Act, Cap 219, TFDA is required to inspect all premises that are involved in the business of medical devices. As of June 2013, a total of 28 business premises that are involved in medical devices dealings had been inspected by TFDA. The inspected premises include manufacturing facilities, warehouses, wholesale and retail shops.

### 6.5 Import and Export Control

According to Section 73 of the Tanzania Food, Drugs and Cosmetics Act, Cap 219; all importers and exporters of medical devices are required to obtain a permit for importation or exportation of medical devices from TFDA.

Over the last 10 years, a total of 4,967 and 34 import and export permits respectively were issued as shown in Table No.24 hereunder;

**Table No. 24: Issuance of Permits (2003-2013)**

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
<b>Jumla</b>	<b>4,967</b>	<b>1,969</b>	<b>34</b>	<b>0</b>

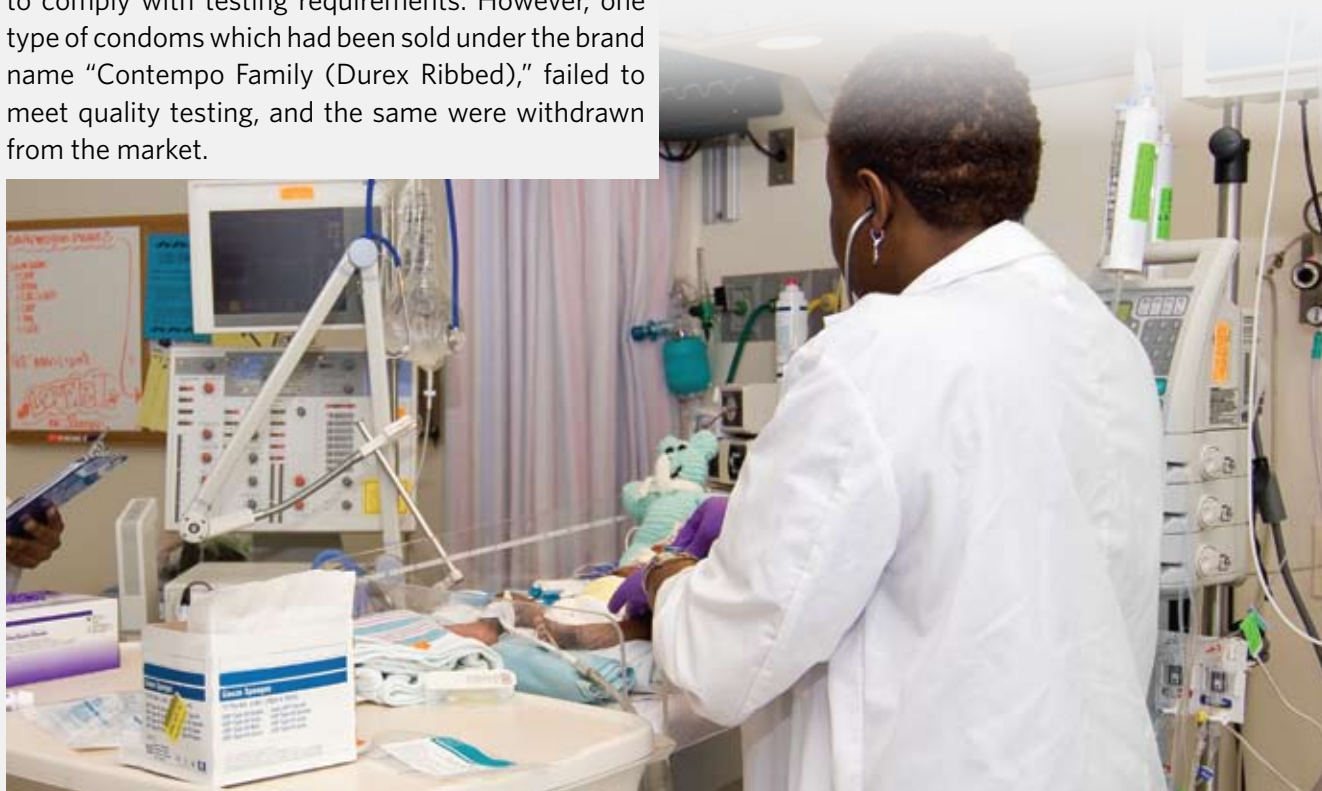
*Note: The regulation of Medical devices started in 2008/09*

## 6.6 Post marketing surveillance

Medical devices are products that might cause harm to human beings if do not conform to prescribed standards or misused. Monitoring of Medical devices is mandatory to ascertain their quality, safety and efficacy standards post registration. The surveillance system involves sample collection, analysis, evaluation of results and taking regulatory actions.

This system started in the year 2012 whereby samples of medical devices that are being used in the market (including bandages, syringes, condoms and gloves) were collected. Such products were tested and found to comply with testing requirements. However, one type of condoms which had been sold under the brand name "Contempo Family (Durex Ribbed)," failed to meet quality testing, and the same were withdrawn from the market.

In carrying out its PMS function, TFDA has also been working in collaboration with other institutions such as Medical Stores Departments (MSD), Private Health Laboratory Board (PHLB) and National Health Laboratory – Quality Assurance and Training Center (NHL-QATC). Through this collaboration, 40 samples of diagnostics namely HIV Test Kits were collected from the market and tested in the NHL-QATC laboratory. Amongst them, 22 were Allere determine and 18 Unigold. Results showed that, all samples complied with test specifications. This program is being financed by WHO and the support shall be for 2 years (2012/13 – 2013/14).



## 6.7 Guidelines development

Various guidelines for the control of medical devices have been developed between 2003 and 2013. These guidelines outline requirements to be followed up by customers who intend to submit their applications to TFDA, and they include the following:

- (a) Guidelines for Registration of medical devices of 2009;
- (b) Guidelines for Registration of medical devices premises of 2011; and
- (c) Guidelines for Good Distribution Practices for medical devices of 2011.

## CHAPTER SEVEN

## 7

## LABORATORY SERVICES

**7.1 Introduction**

TFDA has built a Quality Control (QC) laboratory for the purposes of analysing food, medicines, cosmetics and medical devices. This laboratory was established inline with the provisions of Section 14(1) of Tanzania Food, Drugs and Cosmetics Act, Cap 219. The laboratory began operating in 2000 under the auspices of the then Pharmacy Board. In 2009, the TFDA QC laboratory was expanded to cope with the advancements in science and technology and accreditation as per requirements of international standards.

**7.2 Laboratory Organization Structure**

The TFDA laboratory is made up of 4 departments as follows:

- Medicines and Cosmetics Laboratory;
- Food laboratory;
- Microbiology laboratory; and
- Technical support and Research.

The structure has taken into account the types of regulated products to be analyzed and international standards.





### 7.3 Testing of Samples

The QC laboratory perform analysis of food, medicines, cosmetics, and medical devices samples to ascertain their quality aspects. The analysis is conducted in line with national and international standards, using modern equipment available in TFDA Laboratory. Some of the equipments are listed in Table No. 25 below.

**Table No. 25: Analysis of Equipment**

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

Analytical test parameters for medicines include dissolution, disintegration, identification, assay, bioassay, related substances (impurities profiles), friability, pH, melting point and microbiology analysis.

For cosmetics, parameters analysed include presence of prohibited ingredients such as mercury and hydroquinone, steroids and microorganisms.

Analysis of food supplements, pre-packaged and non-packaged foods focuses on disintegration, dissolution rate, presence of minerals, pH, conductivity, refractive index, proximate analysis, sweeteners, food colours,

preservatives, heavy metals, antibiotics residues, mycotoxins, veterinary pesticides and residues and microbiological analysis.

For medical devices, analysis focuses on microbiological testing, pyrogens and sterility.

As at 30th June 2013, a total of 5,652 samples of food products, medicines, cosmetics and medical devices had been analysed, of which 4,835 samples, equivalent to 85.5% passed laboratory testing. Table No. 26 below summarizes results of analysed samples for the period between July 2003 and June 2013.

**Jedwali Na. 26: Uchunguzi wa Sampuli (2003 - 2013)**

Year	Food			Medicine			Cosmetics			Medical Devices		
	Tested	Pass	Fail	Tested	Pass	Fail	Tested	Pass	Fail	Tested	Pass	Fail
2003/04	318	279	39	429	398	31	2	2	0	0	0	0
2004/05	587	512	75	921	850	71	121	15	106	0	0	0
2005/06	494	421	73	1341	1302	39	61	48	13	0	0	0
2006/07	629	589	40	452	439	13	20	3	17	0	0	0
2007/08	127	92	35	240	227	13	78	45	33	0	0	0
2008/09	412	367	45	482	436	46	20	20	0	0	0	0
2009/10	426	377	49	700	658	42	0	0	0	0	0	0
2010/11	544	414	130	301	297	4	0	0	0	8	7	1
2011/12	665	577	88	626	590	36	2	2	0	19	19	0
2012/13	1,450	1,207	243	1,322	1,281	41	3	3	0	15	14	1
<b>Total</b>	<b>5,652</b>	<b>4,835</b>	<b>817</b>	<b>6,814</b>	<b>6,478</b>	<b>336</b>	<b>307</b>	<b>138</b>	<b>169</b>	<b>42</b>	<b>40</b>	<b>2</b>

\*Most of the cosmetics are failing due to presence of prohibited ingredients. Due to the fact that use of cosmetics is more of psychological, efforts are made to educate the public in rational use of cosmetics.

## 7.4 Researches

The TFDA laboratory has managed to conduct a number of research and published results in various local and international scientific journals such as: Journal of Chromatography, Journal of Pharmaceutical and Biomedical Analysis, Journal of Chromatographic Sciences, Journal of Food Science and Biotechnology, Journal of Food Control, Journal of Food Science of Animal Resources and Journal of Radiation Physics and Chemistry.

The laboratory collaborates with stakeholders within and outside the country in conducting researches. As of now the laboratory is conducting research in collaboration with the Muhimbili University of Health and Allied Sciences (Tanzania), the National University of Gyeosang (Korea), Universities of Brussels and Ghent (Brussels) and the Leeds University (UK).

## 7.5 Training

The TFDA laboratory conducts training on analysis of food, medicines, cosmetics and medical devices to various national and international institutions. During these 10 years of TFDA existence, training has been conducted in the following areas:

- Development of analytical and validation methods;
- Good Laboratory Practices (GLP) according to ISO/IEC 17025:2005;
- Good Clinical and Laboratory practices (GCLP) in clinical trial sites;
- Good Laboratory Practices (GLP) in analysis of samples in hospitals according to ISO 15189 standards.

# CHAPTER EIGHT

8

## PUBLIC EDUCATION

### 8.1 Introduction

Section No. 5.(1)(k) of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 calls for TFDA to issue timely and accurate information to the public regarding the quality, safety and efficacy of regulated products. Such information include: public education on the rational use of food, medicines, cosmetics, and medical devices; procedures to follow opening up business of regulated products, risks that may associated with the use of sub-standard and counterfeit products and 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 TFDA's strategies, regulations and public education programmes for the last 10 years.

### 8.2 Public Education and Publicity

In order to enhance stakeholders' awareness on TFDA's activities, the Authority conducted various educational and publicity programmes to the public as follows:

#### 8.2.1 Seminars and Trainings

Awareness seminars and trainings are conducted for the purposes of informing the public and other stakeholders on the requirements of the Tanzania

Food, Drugs and Cosmetics Act 2003, Cap 219 as well as TFDA functions at large.

In its 10 years of existence, TFDA had been able to conduct seminars and trainings to various groups of stakeholders throughout the country. Participants included manufacturers, importers, distributors, wholesalers and retailers of food, medicines, cosmetics, and medical devices. Seminars and trainings have also been conducted to law enforcers, representatives from Government and private institutions, journalists and editors from media houses, secondary schools and university students, special groups and the public at large.

With regards to trainings conducted to college students, the institutions that participated include Muhimbili University of Health and Allied Sciences (MUHAS), Ruaha University College (RUCO), National Institute for Tourism (NCT), National Institute of Transport (NIT), Times School of Journalism (TSJ) and Daystar College (Dar es salaam). Schools which participated in the trainings are Kibaha Secondary School (Coast Region), Kifungilo (Iringa region), Makamba, Bunju and Loyola (Dar Es Salaam Region). Training was also conducted to members of cultural groups for the deafs namely KISUVITA on various occasions between 2010 and 2012.



### 8.2.2 Radio and Television Programmes

The Authority also used radio and television programmes as an important media for transmitting public awareness information. During the past 10 years of its existence, TFDA produced and aired various educational programmes including 157 and 41 radio and TV programmes respectively and 105 radio spots on the themes indicated below:

**Table No. 27: Themes used for Education Programmes**

Na.	TOPIC
1.	Requirements of the Tanzania Food, Drugs and Cosmetics Act Cap 219
2.	TFDA Structure, Functions and Responsibilities
3.	Processes for obtaining permits and licences for food, medicines, cosmetics and medical devices businesses
4.	Consumers responsibility in ensuring product safety, especially food products
5.	Control of cosmetics and medical devices in the country
6.	Import and export control
7.	Product promotion controls on food, medicines, cosmetics and medical devices
8.	Rational use of medicines especially use of ARVs, anti -malarial and antibiotics
9.	Registration of food, medicines, cosmetics and medical devices
10.	Control of salt iodation
11.	Control of cosmetics and side effects of using cosmetics with prohibited ingredients
12.	Adverse Drug Reactions
13.	Important information to look for on food labels
14.	Infant food controls
15.	TFDA laboratory services
16.	Challenges in control of products at borders and how TFDA is addressing such challenges

Radio stations that were mostly used to air TFDA programmes include; BBC, Radio Tanzania (now renamed TBC Taifa), Radio One, Radio Free Africa (RFA), Radio Clouds, Radio Uhuru, Radio Upendo, Radio Tumaini, Radio Maria, Radio Pambazuko, Radio Kweizera - Ngara and Best FM - Iringa. Television Stations that were also used to air TFDA programmes include: ITV, DTV-Channel 10, Star-TV, TBC-1 and Mlimani TV.

### 8.2.3 Articles on print Media

Articles regarding quality, safety and efficacy of regulated products had been prepared, published and aired through various print media such as newspapers, journals and magazines. These publications have contributed immensely in promoting TFDA and educating the public.

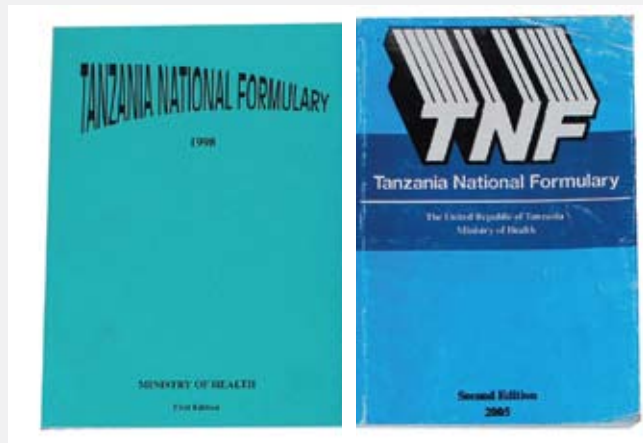
In the past 10 years, TFDA made various publications on topics regarding safety and quality of food, medicines, cosmetics and medical devices. A total of 103 articles were published through various newspapers namely; The Guardian, Daily News, The Express, The Citizen, The East African, Nipashe, Mwananchi, Mtanzania, Uhuru, Majira and Raia Mwema. Public information had also been issued through public address system at the Ubungu Bus Stand, various social media and TFDA website.

Furthermore, TFDA adverts have been published in different magazines to include; Health Focus (2006 - 2008), Tanzania Medical Directory (2009 - 2013), SADC Directory (2008 - 2009), Yellow Pages (2003 - 2013) and East African Manufacturer's Directory (2009).

### 8.2.4 Tanzania National Formulary (TNF)

Section 5 (1) (j) of the Tanzania Food, Drugs and Cosmetics Act, Cap 219, requires TFDA to develop and publish a drug information booklet namely Tanzania National Formulary (TNF). The first edition of TNF issued in 1998 was reviewed and republished in 2005 with 1,500 copies that were distributed to health providers countrywide.

The publication of TNF have since then been transferred to the Pharmacy Council following the enactment of the Pharmacy Act of 2011, Cap 311.



### 8.2.5 Participation in Exhibitions

Participating in exhibitions is a direct way of reaching the general public whereby apart from educating and informing the public on TFDA's activities, the public also have the opportunity to get on the spot clarifications on questions from stakeholders on quality and safety of regulated products.

In a period of 10 years, the Authority has been able to participate in various exhibitions as follows:

- Public Service Week exhibitions;
- Dares Salaam International Trade Fair commonly known as Sabasaba;
- Farmers Trade Fair known as Nanenane;
- Food Safety Week;
- Milk Consumption Promotion week;
- 50 Years of Tanganyika Independence;
- Small Business Entrepreneurs (SIDO); and
- Annual General Conferences organised by NIMR, ALAT, PST, TAFOPA, APHFTA and Regional Medical Officers.

During such exhibitions, various publicity and promotional materials were distributed to individuals who visited TFDA pavilion. Moreover, books, guidelines and regulations are also sold to the interested members of the public.

Furthermore, the TFDA staffs participating in such exhibitions takes such as opportunity to identify dealers of regulated products for future follow up purposes.



## 8.2.6 Promotional Materials

Publication aiming at informing, educating and communicating to stakeholders on regulatory activities and rational use of food, medicines, cosmetics and medical devices have been issued and distributed to the public. These included; brochures, leaflets, fliers, banners, journals, annual progress reports and other promotional materials such as calendars, diaries, T-shirts and wheel covers.

During the past 10 years, a total of 196,924 promotional materials were issued for public information, education and communication purposes as outlined in Table No.28 below;

**Table No. 28: Promotional Materials Issued (2003-2013)**

No.	Type of Promotional material	Year						Jumla
		2003-2008	2008-2009	2009-2010	2010-2011	2011-2012	2012- 2013	
1.	Brochures	72,300	16,500	18,500	18,000	18,000	20,000	163,300
2.	Banners	26	15	4	9	6	19	79
3.	Diaries	800	200	200	300	300	450	2250
4.	Calendars	5000	1500	1500	1500	2500	2500	14,500
5.	Wheel covers	200	200	0	50	150	200	800
6.	Bags	200	150	0	0	150	300	800
7.	T-shirts	700	1000	300	320	300	725	3,345
8.	Caps	400	1000	0	100	0	350	1,850
9.	Annual Progress Reports	5000	1000	1000	1000	1000	1000*	10,000
	<b>Grand Total</b>	<b>84,626</b>	<b>21,565</b>	<b>21,504</b>	<b>21,279</b>	<b>22,406</b>	<b>24,544</b>	<b>196,924</b>

The promotional materials had been distributed to TFDA stakeholders on various occasions including exhibitions, professional conferences organized locally and internationally and to different groups of stakeholders who visit TFDA Headquarters and Zone offices. Some publications had also been distributed to the public through local government offices and different Libraries.

## 8.2.7 The Website

The Authority's Website ([www.tfda.or.tz](http://www.tfda.or.tz)) has been used among other means, to inform, educate and communicate with the public on TFDA activities.

Included in the website are information on quality, safety and efficacy of regulated products; lists of registered products; guidelines, regulations, publications and procedures for dealing with regulated products.

Statistics show that more than 305,982 users have visited TFDA Website between 2004 when it was launched and June 2013. Moreover, by use of TFDA internet, the Authority has been able to receive queries, recommendations and complaints from stakeholders on various TFDA services. These issues had been handled within the agreed timeframes as indicated in the Clients Service Charter 2012.



## 8.3 Public Relations and Customer Care Services

TFDA 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 Offices in order to coordinate all customer related issues and serve as a link between TFDA and its stakeholders.



### 8.3.1 Public Relations

TFDA have established a good working relations with various stakeholders including; public institutions, Policeforce, Local Government Authorities, Ministries, Departments, Government Agencies, International organizations, NGOs, dealers of regulated products, media, consumers and the general public.

In order to improve its relation with customers, TFDA had established different forums to interact with its stakeholders such as; stakeholders' meetings, awareness seminars and trainings.

### 8.3.2 Customer care services

TFDA had improved services to its customers through establishment of one stop customer care centre where stakeholders' applications, information, recommendations, complaints and queries are received, recorded and handled. Up to June 2013, a total of 127 complaints were received and registered, of which 114 were attended and completed and 13 are yet to be concluded.

### 8.3.3 Information and Communication Technology

Information and Communication Technology (ICT) has been an important tool in improving efficiency by rendering services electronically. Through ICT, TFDA created a database for accounts, inspection, registered products, laboratory services, and import and export services. In 2008, TFDA innovated and implemented a prototype Management Information System (MIS) so as to improve service delivery through ICT. More improvements are being made so that most of the applications can be processed electronically.

Furthermore, TFDA introduced an Internal ICT policy which provides guidelines for the use of this system. TFDA staff have been provided with training on how to use MIS effectively.

### 8.3.4 Clients Service Charter

In its desire to improve TFDA services, commitments and execution of its functions transparently, TFDA developed a Clients Service Charter in 2006 whose implementation aims at sustaining the existing customer service culture within the Authority. The Charter describes responsibilities, commitment and accountability of TFDA staff to its clients and sets out quality service standards to meet stakeholders' expectations. The Clients Service Charter was reviewed in 2012 having incorporated stakeholders' inputs on the desired services standards that can match with advancements in technological changes.



### 8.4 Library Services



In order to ensure that TFDA experts receive current and up-to-date scientific information, in year 2000, the Authority established a library that has been improved by furnished with reference books. Inline with that, in 2003 TFDA employed a Librarian who coordinates identification and availability of reference books, journals and other publications containing current information as needed by staff, stakeholders and general public. The TFDA library is registered, thus it has access to scientific publication from several international websites that publish journals such as HINARI, AGORA and OARE.

The obtained scientific information facilitate TFDA experts to execute their duties effectively and make scientific recommendations to TFDA Management based on Current Scientific Information.

### 8.5 Operational researches

In order to come up with specific strategy for public education and service delivery improvement, the Authority conducted various operational researches in collaboration with other stakeholders and external consultants.

Some of the researches conducted include; customer satisfaction surveys that were carried out by M/s Excel Media (2004) and M/s Prime Consult (T) Ltd (2008). TFDA also conducted internal survey on customer satisfaction in 2005. Findings obtained from the mentioned researches, as detailed in

Chapter 10, (Section 10.2.2), inspired TFDA to set specific strategies in pursuing its responsibilities and fulfilling customer needs and expectations without compromising the quality and safety of regulated products. Also, the findings assisted TFDA to identify gaps in public education; as a result it set aside sufficient funds as well as introducing different plans such as combined strategies for marketing and public education.

Another research that was conducted by TFDA in collaboration with TFNC was 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 in developing the appropriate information, education and communication materials which were distributed to various regions particularly those with critical iodine deficiency namely; Kigoma, Katavi, Iringa, Kilimanjaro (Same), Singida and Lindi.

Moreover, the findings of these researches have been an input in developing TFDA Marketing Communication Plan (2008- 2013) which was reviewed in 2013. Currently, TFDA is in its final stages of launching another customer satisfaction survey which is expected to be completed before the end of year 2014.



## CHAPTER NINE

## 9

## ZONE OFFICES AND LOCAL GOVERNMENT AUTHORITIES COORDINATION

### 9.1 Introduction

TFDA has established five (5) zone offices in different regions in order to provide timely services to customers. The Authority also works in close collaboration with the local government authorities (LGAs) in implementing its regulatory functions and it had taken steps to build their capacity to efficiently enforce the Tanzania Food, Drugs and Cosmetics Act, Cap 219 of 2003.

### 9.2 Establishment of Zone Offices

Zone offices were established with the overall aim of bringing TFDA services closer to the public and serve them better. With this necessity, since 2006 TFDA Zone offices have been established in the Northern Zone, Lake Zone, Southern Highlands Zone, Eastern Zone and Central Zone.

As of June 2013, five zone offices have been established as highlighted in Table No. 29 below

**Table No. 29: Zone Offices**

S/N	Zone	Regions served
1.	Northern Zone	Arusha, Manyara, Kilimanjaro and Tanga
2.	Lake Zone	Mwanza, Mara, Kagera, Shinyanga, Geita and Simiyu
3.	Southern Highlands Zone	Mbeya, Iringa, Rukwa, Njombe, Ruvuma and Katavi
4.	Eastern Zone	Dar es Salaam, Morogoro and Coast Region
5.	Central zone	Dodoma and Singida.

The remaining four regions where zone offices are not available are being administratively served by the Eastern Zone (covering Mtwara and Lindi regions) and Central Zone (which covers Tabora and Kigoma regions). The current state of affair will prevail until the official zone offices in the missing areas have been established.

### 9.3 Delegation of Powers to Local Government Authorities

The Authority has delegated some of its functions to the local government authorities in line with the Delegation of Powers order through Government Notice No. 162 of 2006 given by the Prime Minister's Office-Regional Administration and Local Government (PMO-RALG). The main purpose of this move was to strengthen administration and enforcement of existing regulatory laws and regulations and minimizing running costs for the Authority. However, the Director General of TFDA is responsible for the delegated functions.

In the past 10 years, the Authority has managed to build capacity of LGAs in law enforcement through training of staff and distribution of working tools such as Regulations, Guidelines and SOPs.

## 9.4 Coordination of Zone Offices and LGAs

In order to effectively coordinate functions delegated to LGAs, the Authority established a unit within the DG's office. The unit among other things coordinates various TFDA activities to ensure that working tools are available as well as routine monitoring and management of the zone offices.

## 9.5 Services provided

### 9.5.1 Zone Offices

Zone Offices are providing services that are essentially offered at TFDA Headquarters.

The main services offered by zone offices include the following:-

- i. Inspection of regulated products, respective premises and ports of entry;
- ii. Issuing import and export permits;
- iii. Renewing business permits;
- iv. Revenues collection;
- v. Post marketing surveillance;
- vi. Product promotion and advertisements control;
- vii. Coordination and supervision of implementation the delegated functions by LGAS;
- viii. Mini lab centres used to screen medicines and iodated salt;
- ix. Public education on the responsibilities and duties of the Authority; and
- x. Taking necessary regulatory actions to ensure quality, safety and efficacy of food, medicines, cosmetics and medical devices in order to protect and promote public health.



### 9.5.2 Local Government Authorities

LGAs are responsible to undertake the following delegated functions:

- i. Inspection of regulated products, premises and ports of entry;
- ii. Issuing and renewing business permits for food premises except manufacturing premises and tourist hotels;
- iii. Collecting fees and charges and remitting them to TFDA;
- iv. Post Market Surveillance and submission of product samples to TFDA laboratory for testing;
- v. Conducting Council Food and Drugs (CFDCs) meetings;
- vi. Taking necessary regulatory actions to ensure quality, safety and efficacy of food, medicines, cosmetics and medical devices in order to protect and promote public health.

# CHAPTE TEN

10

## QUALITY MANAGEMENT SYSTEMS

### 10.1 Introduction

Quality Management Systems (QMS) are processes and procedures aimed at providing quality services to clients. TFDA had developed and implements QMS in line with the requirements of ISO 9001:2008 for the entire organization and ISO/IEC:17025:2005 for TFDA laboratory. In addition, the TFDA laboratory has been prequalified by the World Health Organization (WHO) since January 2011.

### 10.2 Implementation of ISO 9001:2008

The introduction of QMS at TFDA was the result of self assessment of the performance of TFDA in 2005 which was done under the guidance of the then Quality Assurance Officer, Mr. Hiiti B. Sillo. The system was done sequentially as follows:

- Conducting training to all staff on QMS and its implementations;
- 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 of which 16 have been trained so far; and
- Establishing systems for conducting internal audits to identify gaps and rectify non conformances.

In order to improve efficiency in implementing QMS, review of the TFDA organization structure was done in 2008 to create QMS department. In the period of 10 years, a total of 30 processes and 105 SOPs were developed.



#### 10.2.1 Service Delivery Survey

Through QMS, Service Delivery Survey was conducted in 2008. Results showed that external customers satisfaction level for services offered by TFDA was 67% compared to 42% in 2004. The satisfaction level for internal customers was 63% as compared to 72% in 2004.

The observations of the survey were considered for improvement through QMS and included in the TFDA's 5 Year Strategic Plan: 2008/09 - 2012/13.

#### 10.2.2 ISO 9001:2008 Award

After successful implementation of QMS, in 2007 TFDA applied to ACM Limited(UK) for accreditation. After the audits, TFDA 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, TFDA's quality systems were re-audited in May 2012 and the Authority retained the ISO certificate for three more years until May 2015.

## 10.3 Laboratory QMS (ISO/IEC 17025:2005)

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

The outcome of the two assessments resulted into robust measures being introduced to enable the laboratory offer reliable services to TFDA clients. Among strategies taken include implementation of ISO/IEC 17025:2005. In implementing these QMS standards, the following steps were taken:

- 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.

During implementation of ISO/IEC 17025:2005, the laboratory managed to develop 22 SOPs.

### 10.3.1 Accreditation by SADCAS

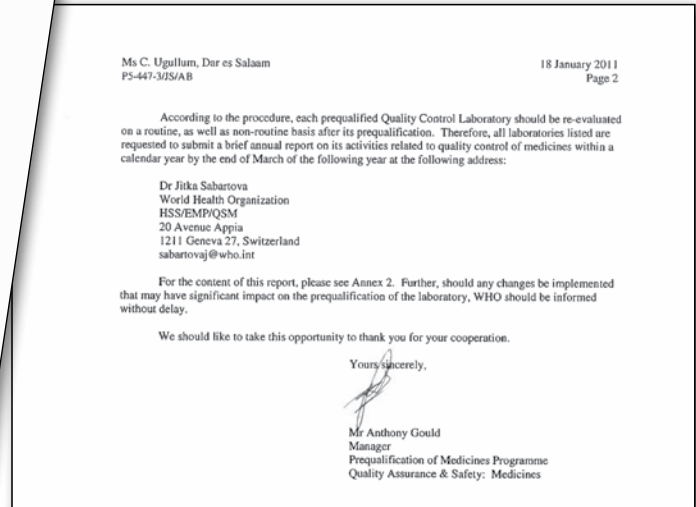
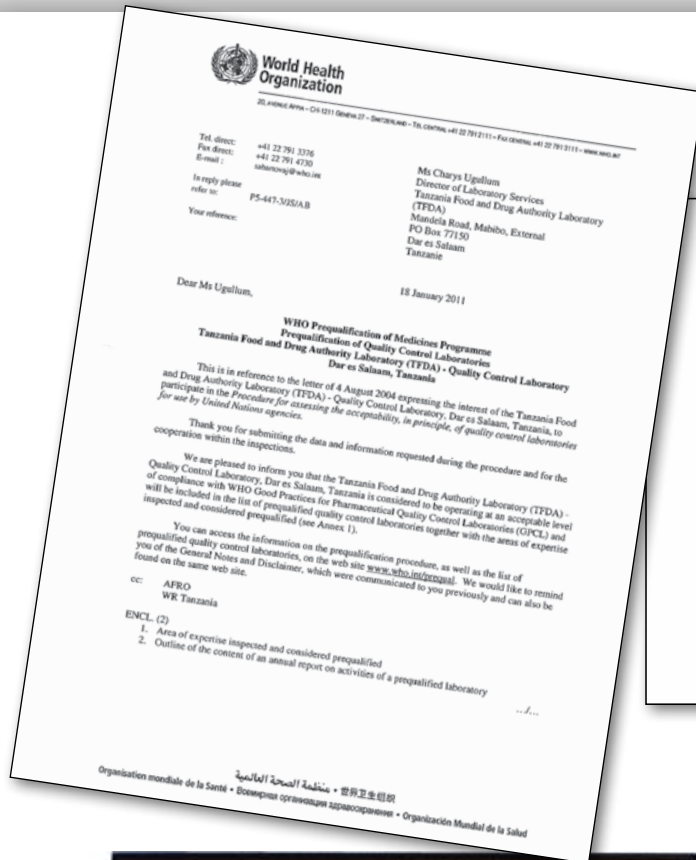
In 2011 auditors from Southern African Development Community Accreditation Services (SADCAS) conducted an audit to TFDA's laboratory to ascertain the compliance to ISO/IEC 17025:2005. Following this audit, TFDA laboratory was awarded an accreditation certificate in accordance with ISO/IEC 17025:2005 standard on 18th September, 2012.

### 10.3.2 WHO prequalification of TFDA laboratory

The World Health Organization (WHO) has set a global programme to prequalify laboratories that have quality systems for testing medicines. During the year 2004 and 2011 laboratory was inspected by the WHO. A number of observed non-conformances by WHO auditors were addressed and rectified by TFDA.

Some of the identified non conformances include inadequate space, testing equipment, reagents and reference standards, improper maintenance of equipment and absence of SOPs for some analytical methods. It took five (5) years to address the identified non-conformances. After the re-inspection of Lab in 2010, it was prequalified by WHO on 18th January 2011. In this respect, analytical results obtained from this laboratory are internationally recognized.





## CHAPTER ELEVEN

11

### LEGISLATION AND RESOURCES MANAGEMENT

#### 11.1 Introduction

The TFDA 10 years successes have been possible due to dedication and commitment of staff, good enforcement systems and appropriate management of resources including revenues and equipment. Through understanding the importance of staff in achieving the organisational goals, the Authority ensured qualified personnel are recruited and provided with working tools and the suitable working environment to perform their work diligently.

This chapter illustrates TFDA's legislation and resources management over the last 10 years of its existence.

#### 11.2 Law enforcement

When TFDA was established in 2003, there was no Legal Unit that caused challenges in implementing regulatory activities. Areas that required legal services included translation and interpretation of the existing laws, development of guidelines and regulations, litigation and other legal advices which were not served on time.

In year 2005, the Legal Unit was established and headed by the Legal Counsel. In order to implement

effectively regulatory activities under the Tanzania Food and Drugs Authority Act, Cap 219, regulations and guidelines were developed to ensure quality, safety and efficacy of food, medicines, cosmetics and medical devices. Since then, a total of 231 cases were filed at different courts of which five (5) were civil cases and 226 were criminal cases. All filed cases ended by offenders to either pay a fine between TZS 50,000 – TZS 1,000,000 or jailed for less than two (2) years.

#### 11.3 Human resources

##### 11.3.1 Recruitment

The Authority has been recruiting qualified staff as per 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. More employees were recruited over years and as of June 2013, the number of staff reached 181. Regardless of the positive achievement in terms recruitment procedures and implementation TFDA Human Resources Plan, the current number is still below the current requirements of 266 staff projected in the five years Human Resources Plan (2010/11 – 2014/15) as indicated in table No.30.



**Table No. 30: TFDA staff disposition (July 2003 -June 2013)**

Sn.	Position	Existing Staff in 2003/04	No. of Employees as at 31st June 2013
1.	Senior Pharmacist	29	42
2.	Food Technologist/ Chemist	5	48
3.	Health Officer	4	9
4.	Veterinary Doctors.	2	10
5.	Microbiologist	1	2
6.	Laboratory Technicians	1	8
7.	Assistant Laboratory Technicians	2	2
8.	Laboratory Assistants	1	1
9.	ICT Experts	-	4
10.	Accountants	-	3
11.	Assistant Accountant	-	6
12.	Accounts Clerk	1	2
13.	Economists	-	0
14.	Administrative Officers	-	1
15.	Legal Counsel	-	4
16.	Internal Auditor	-	2
17.	Supplies Officer	1	2
18.	Public Relations, education and information Officers	-	3
19.	Librarian	1	3
20.	Personal Secretary	4	1
21.	Registry Officer	1	8
22.	Receptionist	1	3
23.	Drivers	3	1
24.	Office Attendants	2	12
25.	Security Guards	3	3
<b>Total</b>		<b>62</b>	<b>182</b>

### 11.3.2 Training

Through an internal training policy that was set up by the Authority in 2005, TFDA employees can undergo long term and short term training so as to enhance and improve their performance. In addition to that, the Authority has been implementing three (3) years training plan since 2005.

In the period of 10 years the Authority existence, 177 staff have been trained on either long term or short term courses within the country or abroad as indicated in Table No. 31 below:

**Table No. 31: Staff Training (2003-2013)**

No.	Type of Training	local	Abroad	Total
1.	Doctor of philosophy (PhD)	1	3	4
2.	Masters Degree/ Higher Diplomas	17	8	25
3.	Bachelor's Degrees/ Advanced Diplomas	2	-	2
4.	Ordinary Diploma	4	-	4
5.	Short Term and Certificate	58	84	142
	<b>Total</b>	<b>82</b>	<b>95</b>	<b>177</b>

Furthermore, 14 staff who are currently undergoing training at different levels including; PhD, Masters Degree and Diploma levels, 11 of them are undergoing training within the country and three (3) abroad.

The Authority has also been providing in-house training in the field of entrepreneurship, customer care, post-retirement, records management, QMS, corruption and ethics, HIV and AIDS as well as training on evaluation and inspection of regulated products.

### 11.3.3 Performance Assessment (TASA)

The Authority implements staff performance appraisal system in accordance with the directives of the government. The OPRAS system which was introduced by the government in 2005 was customised by the Authority to suit its performance objectives. The amendments have resulted into the formation of TFDA Annual Staff Appraisal (TASA) system which was pre-tested in 2008-2009. Respective Guidelines were developed in 2009-2010 which aimed at assessing individual performances in accordance with objectives and goals set by the Authority. After pre-testing of TASA for three (3) years, it turned out to be successful and was forwarded to the President's Office - Public Service Management for approval.

### 11.3.4 Safety at Workplace

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. 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.

## 11.4 Resources Management

### 11.4.1 Procurement

The Authority has been managing procurement processes in accordance with the Public Procurement Act of 2004. Acquisition of working tools such as laboratory equipment, vehicles, office furniture and other utility services such as electricity, water, telecommunications, security services, equipment repairs and property maintenance were done according to the Annual Procurement Plan which is approved by the Authority through its Tender Board. All assets were acquired, recorded in the special register and stored before distribution.

In the period of 10 years, the Authority has been able to procure various materials and equipment as needed, ensuring equipment maintenance and construction of the New Headquarters building and extension of the laboratory building.

### 11.4.2 Supplies

Distribution of equipment and consumables within the Authority has been done in accordance with the guidelines and provisions of the Public Procurement Act 2004 and its regulations. The Authority also conducted asset verification and services offered.

By 30th June 2013, the Authority has been issued with nine (9) Clean Audit Certificates from the Controller and Auditor General (CAG) for proper Management of resources inline with implementation of the Public Procurement Act 2004, and its regulations of 2005.

## 11.5 Financial Resources

### 11.5.1 Revenues

The Authority has continuously increased its annual revenue and expenditure budget since its inception. This has been possible due to its ability to collect fees and charges through authorised sources.

For TFDA to increase its annual revenues, different strategies were engineered including identification of various new sources of fees and charges. TFDA's main sources of revenues include fees and charges as provided for in the respective regulations, government subventions and donor funds.

The Authority has been empowered under Section 7 of the Tanzania Food, Drugs and Cosmetics Control Act, Cap 219 to charge and collect fees for the services it provides. In 2005 the Authority developed the Fees and Charges Regulations which were later amended in 2011 outlining various services that TFDA's clients are required to pay for, that includes:-

- Registration of products;
- Importation of product;
- Selling of published materials and guidelines;
- Laboratory sample testing;
- Inspection;
- Premises registration;
- Product promotion;
- Penalty fees for late payment of permits and licences;



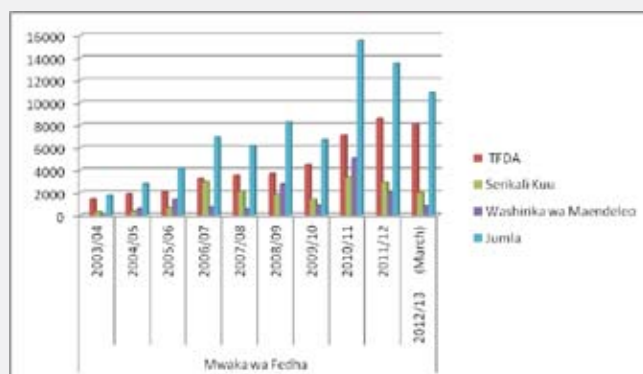
- Registration of Medical Representatives; and
- Permits and licences.

The implementation of these regulations started in 2006 whereby some of TFDA responsibilities including collection of fees were delegated to Local Government Authorities; in order to make TFDA services more accessible to all citizens. Nevertheless, the final accountability on matters related to revenue collections and expenditures rests with the TFDA Director General.

During the last 10 years, the revenues collected from all sources had increased by 727% as shown in Graph No. 4. The increase in revenues has been attributed by the increase on the internal collection through fees and charges. The internal revenues collection increased from TZS 1.443 bilion in 2003/04 to TZS 10.848 bilion in 2012/13 which is equivalent to 460.2% increase..

**Graph No.4: Revenue Collection for 2003/04-2012/13 (In Millions of TZS)**

(Amount x 000,000 TZS)



## 11.5.2 Expenditure

Expenditure budget of TFDA has been increasing annually due to expansion of regulatory services. Expenditure of the TFDA financial resources has been managed in accordance with the Finance Act of 2001 and its regulations as revised in 2004. However, to achieve proper revenue expenditure the Authority created internal staff and financial regulations of 2004 which were approved by the President's Office - Public Services Management and reviewed in the year 2011 so as to improve financial expenditure of the Authority.

In the last 10 years, the Authority has constantly received a clean audit certificate for nine consecutive years i.e. 2003/04 - 2011/12 issued by CAG in financial management after audits conducted by CAG annually.

The signed CAG report of 30th June 2012 is attached with this Book.

## CHAPTER TWELVE

## 12

### CROSS CUTTING ISSUES

#### 12.1 Introduction

TFDA like other governmental and non-governmental organizations has been forefront in implementing national policies and plans on the fight against HIV and AIDS, corruption, gender, environment protection, sports and other social matters.

This chapter highlights involvement of TFDA in these cross cutting issues apart from its normal regulatory activities:

#### 12.2 Fight against HIV and AIDS

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. TFDA, in implementing this national policy, has put in place a system aimed at combating HIV and AIDS in its workplace. The initiatives which have been taken for the past 10 years are as follows:

- Appointing an HIV/AIDS Coordinator;
- Conducting staff training on HIV and AIDS and on protective measures;
- Distribution of condoms to staff and customers through TFDA washrooms;
- Providing special diet to HIV and AIDS infected staff;
- Preparing and planning of HIV/AIDS informative flyers on the entrances of staff washrooms;
- Encouraging staff to do voluntary counselling and testing for HIV and AIDS; and
- Providing medical insurance through 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.

#### 12.3 Fight against corruption

Corruption is a menace in public service and the society at large and it impedes social justice. TFDA has been forefront in supporting national policies and laws that are intended to prevent corruption in the country. The laws which had been enacted to fight against corruption include the Preventing and Combating Corruption Act, No. 11 of 2007 which also established the Prevention and Combating of Corruption Bureau (PCCB).

TFDA has put measures in the fight against corruption by doing the following:

- (a) Including anti-corruption measures as one of the strategic objective in the TFDA Strategic Plan of 2013/14 - 2017/18;
- (b) Providing training to staff on corruption practices including emphasizing on code of conduct and ethics in public service;
- (c) Supervising procurement processes and ensuring that they are done in accordance with the Public Procurement Act of 2004;
- (d) Vetting of new employees and ensure they take oath;
- (e) Creating good working environment by increasing staff salaries and providing working tools to minimize corruption practices; and
- (f) Conducting research on corruption issues including collecting data showing signs of corruption practices at TFDA.

## 12.4 Gender issues

The Gender Development Policy of 2000 elaborates the need for the society to acknowledge that there are biological differences between men and women which naturally assign different but interdependent responsibilities between them. The 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.

TFDA started implementing this Gender Policy from 2007. Among the issues that have already been done include the following:-

- (a) To embrace aspects related to women development in the TFDA's Strategic Plan of 2012/13 - 2016/17;
- (b) To consider gender when recruiting staff as stipulated in the Employment and Labour Relations Act No. 8 of 2004. TFDA has already recruited 67 women which accounts for 37% of the total number of staff;
- (c) To establish the TUGHE Women Council;
- (d) To encourage more women to fill up senior positions within TFDA. Currently there are

6 women out of 32 senior officials which is equivalent to 19%; and

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

## 12.5. Corporate Social Responsibility

It is a statutory obligation for public and private institutions to assume social responsibilities within their community. In the course of implementing this duty, TFDA has developed a programme for charity and fund raising. As part of corporate social responsibility, donations have been made to various charitable groups depending on the needs and the financial capacity of the Authority.

TFDA provides support in the following manner:

- (a) By conducting hospital visitation and consoling the sick and wishing them quick recovery;
- (b) Visiting orphanages and providing basic assistance such as food, soft drinks, clothes, shoes, soaps and toothpastes;
- (c) Visiting victims of natural calamities such as the bomb victims, flood victims and those who lost properties through fire accidents;





## 12.6 Environmental protection

Protecting the environment is important for survival of all living things. It is through the protected environment that countries get their basic social and economic needs. The National Environmental Policy of 1997 recognizes the importance of protecting the environment. The policy aims at:

- (a) Ensuring sustainability, safety and appropriate use of natural resources for current and future generation without degrading the environment or risking public health and safety;
- (b) Controlling and preventing soil degradation, crop, water and air pollution which are the main sources of life;

- (d) Developing Guidelines programme for assistance in good times and in times of peril.
- (e) To provide staff support by visiting employees who are blessed with new born or undergoing bereavement or any other social festivities.

In implementing corporate social responsibility, TFDA has distributed food and clothing to various orphanages such as The Guardian Angel – Kimara, Furaha Village – Mbweni and another group based in Kigogo. The Authority through staff contributions has also been able to provide for 100 desks to Makuburi and Mabibo Primary Schools located in External Makuburi area in Dar es Salaam.

In addition, TFDA has been awarding each year's best student(s) in Pharmacy Practice from MUHAS. It also sets aside in its annual budgets a substantial amount of funds for assisting various individuals and institutions for meetings, seminars, workshops and individual /personal who are in need of assistance such as patients.

- (c) Restoring degraded areas for crop production, residences in the rural and urban areas so as to ensure that all Tanzanians live in safe areas free from public health hazards and encourages growth and production of goods in a safe environment.

TFDA has been among the leading advocates for environmental protection, and in the past 10 years the Authority has done following:

- (a) Developing programme for disposal of products that goes inline with protection of the environment. Decisions on disposal methods are made in accordance with the type of product being disposed off. Disposal engages different law enforcing agencies such as TFDA itself, Tanzania Police Force, District and City Councils and the National Environment Management Council (NEMC);
- (b) Developing disposal guidelines;
- (c) Issuing Disposal Certificates after safe destruction of products;
- (d) Ensuring that the environment surrounding the offices are properly maintained at all times;

- (e) Planting trees and grass lawns so as to create a clean environment surrounding the offices;
  - (f) Instituting an appropriate paper management system;
  - (g) Developing a chemical disposal system that is environmental friendly;
  - (h) Outsourcing cleaning and disposal services to a qualified institution that maintains a clean office environment;
  - (i) Providing for a separate area for staff during lunch time (Staff Cafeteria); and
  - (j) Incorporating environmental issues in the Strategic Plan 2012/13 – 2016/17.
- (a) Coordinating and participating in various sports activities and competitions with other institutions in football, netball, handball and athletics;
  - (b) Staging up inter departmental competitions in various sports activities;
  - (c) Hiring a coach to train TFDA staff on physical exercises;
  - (d) Providing for sports equipment to staff;
  - (e) Encouraging staff to participate in sport activities; and
  - (f) Providing for sporting areas nearby HQ offices.

## 12.7 Sports and entertainment

Sports and entertainment activities are important ways of building human bodies and bringing societies together. The National Sports Development Policy of 1995 highlights the important issues in terms of sports and recreation.

TFDA has set up a sports programme for its staff and in the past 10 years of its operation, TFDA has done the following:



## CHAPTER THIRTEEN

## 13

## SUSTAINABLE GAINS AND CHALLENGES

**13.1 Introduction**

For a period of 10 years since its inception, TFDA has experienced a number of sustainable gains while executing its functions. Nevertheless, despite the gains, the Authority had also faced various challenges as outlined below in this chapter below.

**13.2 Notable achievements****13.2.1 Resources, Planning and Administration**

In the past 10 years, the Authority has managed to increase and improve its resources including the following:-

- i. Constructing the Headquarters' Office building;
- ii. Expanding and equipping the TFDA laboratory;
- iii. Increasing the human resources capacity from 62 in 2003/04 to 181 in June 2013;
- iv. Providing training to staff;
- v. Establishing five zone offices;
- vi. Developing and implementing Strategic Plans;
- vii. Increasing revenue collection of fees and charges by 460.2% between 2003/04 and 2012/13;
- viii. Good financial management which led to obtaining clean audit reports for nine (9) consecutive years;
- ix. Setting up and maintaining QMS that led to attaining ISO 9001:2005 certification, ISO/IEC 17025:2005 accreditation and WHO prequalification;
- x. Wining the Best Managed Institution award amongst Tanzania ministries, departments and agencies category for years 2010 and 2011; and
- xi. Innovating and successfully implementing the ADDO programme.



### 13.2.2 Regulation of products

TFDA for the past 10 years, has successfully enforced existing laws and regulations in the control of quality, safety and efficacy of regulated products as follows:

- i. Registration of food, medicines, cosmetics and medical devices according whereby the number of all registered products has increased annually from 265 in 2003 to 4,289 in 2013;
- ii. Registration of business premises whereby the number of registered premises has been increasing annually;
- iii. Improving Ports of Entry controls by deploying Inspectors and inspection tools.
- iv. Introducing alternative safety surveillance methods namely "Cohort Event Monitoring (CEM)" to actively monitor adverse reactions of medicines circulating in the market.
- v. Setting up a clinical trials control system for medicines and medical devices whereby researchers are required to obtain a permit before conducting trials in the country.
- vi. Conducting research on mycotoxins in cereals and using research findings to develop strategies on food safety control.
- vii. Setting up a Good Manufacturing Practices (GMP) inspection system whereby manufacturers (both locally and foreign) are required to comply before their products can be allowed to be registered in Tanzania.

- viii. Through public education, the awareness of the public in recognizing genuine and quality products in the market has improved significantly, and has made them make informed choices.

### 13.3 Challenges

In discharging its legislative duties the Authority has also experienced various challenges in its 10 years of operation including the following:-

- i. Absence of TFDA offices throughout the country;
- ii. Overlapping of TFDA responsibilities with other government institutions;
- iii. Inadequate Enforcement of Delegation of Powers Regulations order, 2006;
- iv. Inadequate human resources capacity in relation to workload /volume of activities assigned such as laboratory analysis, evaluation and inspection of products;
- v. Inability to recruit and retain staff;
- vi. Pilferage of sub-standard and counterfeit products through unauthorized Ports of Entry including existence of cosmetics with prohibited ingredients;
- vii. Majority of domestic manufacturers of food and medicines products failing to comply with minimum GMP; and
- viii. Low literacy levels in the general public on quality and safety issues for regulated products.



## TAARIFA YA HESABU ZILIZOKAGULIWA - 2011/2012

### 3.0 AUDIT REPORT ON THE FINANCIAL STATEMENTS

To: Ambassador Dr. Ben Moses,  
Chairperson Board of Directors,  
Tanzania Food and Drugs Authority,  
P. O. Box 77150,  
Dar es Salaam

#### Introduction

I have audited the accompanying financial statements of the Tanzania Food and Drugs Authority, which comprise the statement of financial position as at 30 June 2012, statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and a summary of significant accounting policies and other explanatory notes set out from pages 18 to 35 of this report.

#### Directors' Responsibility for the Financial Statements

The Board of Directors of the Tanzania Food and Drugs Authority is responsible for the preparation and fair presentation of these financial statements in accordance with International Public Sector Accounting Standard. This responsibility includes designing, implementing and maintaining internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error, selecting and applying appropriate accounting policies and making accounting estimates that are reasonable in the circumstances.

#### Responsibilities of the Controller and Auditor General

My responsibility as auditor is to express an independent opinion on the financial statements based on the audit. The audit was conducted in accordance with International Standards on Auditing (ISA) and such other audit procedures I considered necessary in the circumstances. These standards require that I comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers the internal control relevant to the Tanzania Food and Drugs Authority preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Tanzania Food and Drugs Authority internal control. An audit also includes evaluating the appropriateness of the accounting policies used and reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

In addition, Section 10 (2) of the PAA No. 11 of 2008 requires me to satisfy myself that the accounts have been prepared in accordance with appropriate accounting standards and that; reasonable precautions have been taken to safeguard the collection of revenue, receipt, custody, disposal, issue and proper use of public property, and that the law, directions and instructions applicable thereto have been duly observed and expenditures of public monies have been properly authorized.

Further, Section 44(2) of the Public Procurement Act No. 21 of 2004 and Regulation No. 31 of the Public Procurement (Goods, Works Non-consultant services and Disposal of Public Assets by Tender) Regulations of 2005 requires me to state in my annual audit report whether or not the auditee has complied with the provisions of the Law and its Regulations.

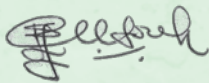
I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my audit opinion.

### Unqualified Opinion

In my opinion, the financial statements present fairly, in all material respects, (or give a true and fair view of) the financial position of Tanzania Food and Drugs Authority as at 30th June, 2012 and its financial performance and its cash flows for the year then ended in accordance with International Public Sector Accounting Standard and Tanzania Food, Drugs and Cosmetics Act No. 1 of 2003.

### Report on Other Legal and Regulatory Requirements Compliance with Public Procurement Act

In view of my responsibility on the procurement legislation, and taking into consideration the procurement transactions and processes I reviewed as part of this audit, I state that Tanzania Food and Drugs Authority has generally complied with the Public Procurement Act; 2004 and its related Regulations of 2005.



Ludovic S. L. Utouh  
**CONTROLLER AND AUDITOR GENERAL**



Office of the Controller and Auditor General,  
National Audit Office,  
**Dar es Salaam**

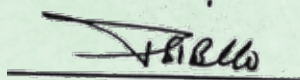
14th February, 2013

### **3.1 STATEMENT OF RESPONSIBILITY ON THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30TH JUNE, 2012**

These financial statements have been prepared by the Management of the Tanzania Food and Drugs Authority in accordance with the provisions of section 25(4) of the Public Finance Act No. 6 of 2001. The financial statements comply with generally accepted accounting practices as required by the said Act and are presented in a manner consistent with the International Public Sector Accounting Standard (IPSAS).

The Management of the Tanzania Food and Drugs Authority is responsible for establishing and maintaining a system of effective internal control designed to provide reasonable assurance that the transactions recorded in the accounts are within the statutory authority and that they contain the receipt and use of the Financial Statement for the 2011/2012 financial year.

I accept responsibility for the integrity of the financial statements, the information it contains, and its compliance with the Public Finance Act No. 6 of 2001 (revised 2004) and the instructions issued by the Treasury in respect of the year under review.



Signed by Director General

Date

12/02/2013

## 3.2 AUDITED FINANCIAL STATEMENTS

### TANZANIA FOOD AND DRUGS AUTHORITY

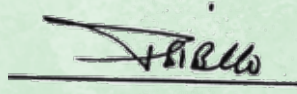
#### STATEMENT OF FINANCIAL POSITION AS AT 30TH JUNE, 2012

	Note	2012 Tshs.	2011 Tshs.
<b>Non Current Assets</b>			
Property, Plant and Equipment	2	3,007,399,112	2,742,785,367
<b>Current Assets</b>			
Accounts Receivable	4	1,054,617,568	582,325,034
Cash and Cash equivalent	5	6,287,850,704	3,817,823,190
Total Current Assets		7,342,468,272	4,400,148,224
<b>Total Assets</b>		<b>10,349,867,384</b>	<b>7,142,933,591</b>
<b>Equity and Liabilities</b>			
<b>Equity</b>			
Capital	6	1,139,932,800	1,139,932,800
Retained Surplus		8,313,840,430	5,649,422,399
		9,453,773,230	6,789,355,199
<b>Current Liabilities</b>			
Accounts Payable	7	896,094,154	353,578,392
<b>Total Equity and Liabilities</b>		<b>10,349,867,384</b>	<b>7,142,933,591</b>

Note 1 to 17 form part of the Accounts



Chairperson of the Board



Director General

Date 12/02/2013

Date 12/02/2013

**TANZANIA FOOD AND DRUGS AUTHORITY**  
**STATEMENT OF FINANCIAL PERFORMANCE**  
**FOR THE YEAR ENDED 30TH JUNE, 2012**

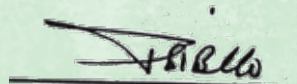
	<b>Note</b>	<b>2011/2012 Tsh</b>	<b>2010/2011 Tshs</b>
<b>Revenue</b>			
Fees and charges	8	8,528,640,917	7,087,847,287
Government Grants	9	2,908,295,455	3,370,939,882
Donors Grants	10	4,372,943,744	5,041,673,467
Revenue from exchange transactions	11	2,327,910	64,017,651
Other Revenue	12	94,974,726	37,656,901
<b>Total Revenue</b>		<b>15,907,182,752</b>	<b>15,602,135,188</b>
<b>Expenses</b>			
Salaries and employee benefits	13	6,048,759,822	5,248,714,404
Supplies and consumables used	14	2,790,500,974	2,677,943,971
Other expenses	15	3,752,326,958	3,694,805,098
Finance costs	16	62,266,880	28,092,527
Provision for doubtful debt		-	29,813,000
Depreciation and amortization	2	588,910,087	536,577,381
<b>Total Expenses</b>		<b>13,242,746,721</b>	<b>12,215,946,381</b>
<b>Surplus for the period</b>		<b>2,664,418,031</b>	<b>3,386,188,807</b>

Note 1 to 17 form part of the Accounts



Chairperson of the Board

Date 12/02/2013



Director General

Date 12/02/2013

## TANZANIA FOOD AND DRUGS AUTHORITY

## STATEMENT OF FINANCIAL POSITION AS AT 30TH JUNE, 2012

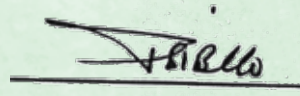
	Capital Fund Tshs	Accumulated Surplus (Deficit) Tshs.	Total Tshs.
Balance as at 01.07.2010	1,139,932,800	2,223,500,259	3,363,433,059
Restatement of error	-	39,733,333	39,733,333
Surplus for the year	-	3,386,188,807	3,386,188,807
<b>Balance as at 30.06.2011</b>	<b>1,139,932,800</b>	<b>5,649,422,399</b>	<b>6,789,355,199</b>
Balance as at 01.07.2011	1,139,932,800	5,649,422,399	6,789,355,199
Surplus for the year	-	2,664,418,031	2,664,418,031
<b>Balance as at 30.06.2012</b>	<b>1,139,932,800</b>	<b>8,313,840,430</b>	<b>9,453,773,230</b>

Note 1 to 7 form part of the Accounts



Chairperson of the board

Date 12/02/2013



Director General

Date 12/02/2013



# TANZANIA FOOD AND DRUGS AUTHORITY

## STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 30TH JUNE, 2012

	2011/2012 Tshs	2010/2011 Tshs
Surplus/(deficit)	2,6444,418,031	3,386,188,807
Add:Non Cash expenses		
Depreciation Expenses	588,910,087	536,577,381
Provision for doubtful debt	-	29,813,000
(Gain)/Loss on Disposal	-	-
	<b>3,253,328,118</b>	<b>3,952,579,188</b>
<b>Change in working capital</b>		
Increase/(decrease) in Receivables	472,292,534	320,710,354
Increase/ (decrease) in Accounts payable	542,515,762	112,273,144
<b>Net cash flow from operating activities</b>	<b>3,323,551,346</b>	<b>3,744,141,978</b>
<b>Investment activities</b>		
Proceeds from sale of assets		
Purchase of fixed assets	853,523,832	503,522,333
<b>Net cash used in investing activities</b>	<b>853,523,832</b>	<b>503,522,333</b>
<b>Net cash flow for the year</b>	<b>2,470,027,514</b>	<b>3,240,619,645</b>
Add: Cash the beginning of the year	3,817,823,190	577,2203,545
<b>Net cash and cash equivalent at the end of the year</b>	<b>6,287,850,704</b>	<b>3,817,823,190</b>

Note 1 to 17 form part of the Accounts

Chairperson of the Board

Director General

Date 12/02/2013

Date 12/02/2013

# MATUKIO KATIKA PICHA



Ugeni kutoka International Atomic Energy Agency



Tulianza Hapa



Maelekezo yako tutayazingatia



Baadhi ya Tuzo zetu



Ugeni kutoka NEPAD



Tuko tayari kukupokea mgeni wetu



Tuko tayari kukupokea mgeni wetu



Michezo huburudisha mwili n a akili



Hii inawezekana ukifanya mazoezi



Tunatambulika kitaifa



Hiki ndio moja ya kipodozi kisichofaa



Maelekezo yako tutayazingatia



Lengo letu ni moja



Wanawake wanaweza



Lengo letu ni moja katika masuala ya udhibiti



Kwa mtazamo wangu...



Michezo hutukutanisha pamoja



Tuko tayari kwa mechi



"Nawapongezeni"



Tunabadilishana mawazo



Tuko makini



Tuko tayari kukupokea mgeni wetu



Afiya ya mwili



Tumefurahi kwa kututembelea, Karibu tena



Uchunguzi hufanyika hivi



Kikosi cha mashambulizi



Tumekamilika



Uhuru, Julai 3, 2008



Nipashe, Agosti 27, 2010



Guardian, Aprili 1, 2009



Nipashe, Mei 27, 2011



The Express, Mei 9 - 15, 2013

# War against counterfeits: TFDA shows its commitment

By Martin Mafuma

As the rapid development in science and technology, counterfeiting shows up as a threat to the health. The situation is expected to be worse in developing countries. While most of these

pharmaceutical products. At least five countries visit Tanzania yearly for attachments and study tours. President Jakaya Kikwete recently visited TFDA and commended the authority for its immense contribution to promoting and protecting the public's health.

that TFDA's achievements have brought honour, respect and pride for to the country internationally. The competence of TFDA workers inspired President Kikwete. "You have been to school and utilize your knowledge to





Risasi, Machi 28 - 30, 2012

## TFDA yatoboa siri ya dawa feki

**Stori: Kulwa Mwaibale**

**M**AMLAKA ya Chakula na Dawa nchini (TFDA), imetoa siri ya dawa feki zinavyotengenezwa na wahalifu.

Siri hiyo iliwekwa wazi katika warsha iliyoandaliwa na mamlaka hiyo hivi karibuni mjini Morogoro iliyokuwa mahususi kwa wahariri na waandishi wa habari wa vyombo mbalimbali.

Akielezea namna dawa hizo zinavyotengenezwa na kuingizwa sokoni, Meneja wa Ukaguzi na Udhidhi wa Dawa na Vipodozi wa TFDA, Emmanuel Alphonse alisema zinatengenezwa kwa teknolojia ya hali ya juu hivyo kuwa vigumu mteja kugundua.

"Wanaojihusisha na utengenezaji wa dawa bandia ni watu makini na wanatumia teknolojia ya hali ya juu sana... hubadili herufi moja au mbili kwenye nembo ya dawa halisi na kuziweka kwenye makasha au makopo ambayo ni vigumu kuyatofautisha na ya dawa salama," alisema Alphonse.

Alitoa mfano wa dawa dawa halisi ya kutibu malaria litwayo Laefin ambayo kwenye makasha ya dawa bandia iliandikwa Laefin.

"Hebu angalieni hapa, hii ni dawa halisi imeandikwa Sulfametopyrazine 500& Pyrimethamine 25 mg na dawa feki imeandikwa Sulphamethoxazole 500 mg & Pyrimethamine 25 mg, je ukiwa na haraka unaweza kugundua tofauti hiyo?" alihoji Alphonse huku akiwaonesha waandishi majina ya dawa hizo.

Akifafanua zaidi meneja huyo alisema zipo dawa zinazotengenezwa chini ya kiwango ambapo baada ya kukaa muda fulani hubadilika rangi, mfano kama zilikuwa nyeupe zinakuwa nyeusi au njano jambo ambalo ni hatari kwa mtumiaji.

Mkurugenzi Mtendaji wa TFDA, Hiliti Sillo pamoja na mambo mengine, aliwaonya wote wanaojihusisha na biashara ya vyakula, dawa na vipodozi visivyofaa kuacha kwani ni makosa na wakibainika adhabu yake huwa ni kulipa faini au kifungo.

Ijumaa, Machi 30 - Aprili 5, 2012



• Home > Office of the Inspector General > Updates > Global Fund Signs Memorandum of Understanding with Tanzania's Food and Drugs Authority

### Global Fund Signs Memorandum of Understanding with Tanzania's Food and Drugs Authority

2013

The Office of the Inspector General of the Global Fund to Fight AIDS, Tuberculosis and Malaria has signed a Memorandum of Understanding with the Tanzania Food and Drugs Authority. The memorandum will facilitate the exchange of information concerning fraud and abuse in grant programs managed by the Global Fund, focusing on theft, diversion, or counterfeiting of pharmaceutical commodities.

Under the memorandum, both parties will cooperate by exchanging intelligence which may aid in investigations of people or networks suspected of engaging in manufacturing, distributing, transporting, or selling spurious, falsely-labelled, falsified, counterfeit medicines. Both parties will regularly exchange information and consult with one another to find new areas of cooperation and other potential joint activities falling within their respective mandates.

"Spurious, falsely-labelled, falsified, counterfeit drugs are silent murderers," said Hiliti Sillo, Director General of the Tanzania FDA. "Porous borders, wide price gaps, weak prosecution, lack of harmonized best practices, and lack of human resources facilitate this murder."

This Memorandum is the ninth such agreement signed by the Inspector General since 2010. For the Office of the Inspector General (OIG), partnerships with regulatory bodies and law enforcement agents are a critical success factor in the fight against fraud and corruption on the ground. Other recent examples of memoranda include agreements with the Malawi Police Service, the Nigerian Economic and Financial Crimes Commission and The Counter Fraud and Whistleblowing Unit of the UK Department for International Development.

The mission of the Tanzania Food and Drugs Authority (TFDA) is to protect and promote public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices. Its functions include Product Promotion Control, Laboratory Analysis for Quality, Safety and Effectiveness, Post Marketing Product Risk Analysis, Import and Export Control, and Premises Registration and Licensing.

"The MoU between the OIG and the TFDA represents the formal commencement of a long and fruitful relationship between the two bodies," said Norbert Hauser, interim Inspector General. "It is also another example of the OIG's commitment to engaging with key national law enforcement and drug regulatory authorities as part of the work of the Joint Inter-Agency Task Force (JIATF)."

The Office of the Inspector General was established by the Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria in July 2005. The Office of the Inspector General operates as an independent unit of the Global Fund, reporting directly to the Board through its Audit and Ethics Committee.

The mission of the Office of the Inspector General is to provide the Global Fund with independent and objective assurance over the design, quality and effectiveness of controls or processes to manage the key risks impacting the Global Fund's programs and operations.



Norbert Hauser, Interim Inspector General for the Global Fund (left) with Hiliti Sillo, Director General of the Tanzania Food and Drugs Authority.

## TFDA yaeleza wanawake 'wanavyojiua' kwa vipodozi

**NA KULWA MWAIBALE**

**MAMLAKA ya Chakula na Dawa nchini (TFDA), imeeleza jinsi wanawake wanavyoathiriwa na vipodozi vyenye viambato sumu ambavyo husababisha vifo.**

Hayo yalielezwa katika warsha iliyoandaliwa na mamlaka hiyo hivi karibuni mjini Morogoro iliyowahusisha wahariri na waandishi wa habari wa vyombo mbalimbali.

Kwa mujibu wa Meneja wa Udhidhi wa Dawa na Vipodozi wa TFDA, Emmanuel Alphonse, vina madhara makubwa kwa watumiaji ikiwa ni pamoja na kusababisha kansa ya ngozi, mapafu, muwasho wa ngozi, kuchubuka kwa ngozi, kupata mabaka meupe na meusi.

"Vipodozi vyenye viambato sumu vya hydroquinone kama Carolight cream, Rico cream, Princes cream, Mic cream, Tura, A3 lightening cream husababisha kansa ya mdomo," alisema Alphonse.

Meneja huyo alisema kuwa kuna vipodozi sumu vingi sana vimevunwa.

**Mkurugenzi wa TFDA, Hiliti Sillo**

Habari Leo, Aprili 24, 2013

## Maabara ya TFDA kujiendesha kibiashara

KABARA ya chakula na dawa ni bonbo muhimu katika udhibiti wa usalama, ubora na ufanisi wa chakula, dawa, vifaa kwa lugha nyingine, si rahisi hata hizi bila kupima katika

shua hili, serikali kupitia mshauri wa Chakula na Dawa kika wa kulinda afya za

wali katika maabara hiyo inaweli kuwa ubora, usalama na la, dawa, vipodozi na vifaa kwa njia ya kisayansi ambavyo maabara.

ya chakula, dawa, tibu kuanza kutumika vina- wa kimaabara ili kufahamu ufanisi wa bidhaa husika. Ilimwenguni kote kwa hakula na dawa, muhimu wa kudhibiti ikali imekuwa ikijitahidi binu ya maabara ya dawa inakuwa na vitendea a kutosha wa maabara tahili.

za kuboresha maabara ya dawa, kuwa barani Afrika na yenye i na maabara yoyote ile maabara ya TFDA ime- umakini na ufanisi ta kuonekana kuto- sahihi ya uchunguzi a kwenye maabara

ta maabara ya dawa 8 Januari 2011 ili- mataifa (WHO) kuwa moja ya maabara duni- vilitambuka kimataifa kwa



## Mahali Tulipo

### **Mamlaka ya Chakula na Dawa (TFDA)**

#### **Makao Makuu**

Barabara ya Mandela, External - Mabibo  
S. L. P. 77150, Dar es Salaam  
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+255 658 445222 / 685 701735 / 777 700002  
Nukushi: +255 22 2450793  
Barua pepe: info@tfda.or.tz  
Tovuti: www.tfda.or.tz

#### **Kanda ya Ziwa, Kanda ya Kati,**

Mtaa wa Nkurumah,	Jengo la Hospitali ya Rufaa ya Mkoa
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#### **Nyanda za Juu Kusini, Kanda ya Mashariki,**

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