TANZANIA FOOD AND DRUGS AUTHORITY

TFDA
Tanzania Food & Drugs Authority

CLIENTS' SERVICE CHARTER

2016

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FOREWORD

For the past 10 years, the Tanzania Food and Drugs Authority (TFDA) has been consistently providing quality regulatory services to its esteemed customers inline with service standards depicted in its Clients Service Charter (CSC) 2006 as amended in 2012. The objective of this charter is to make transparency commitment to clients, listen and serve them to the possible highest standards aiming to satisfy them in the service delivery. The implementation of Quality Management Systems (QMS), use of Integrated Management Information System (IMIS) and adherence to Laws, Regulations and Guidelines in providing services has made it possible for TFDA to meet our customers' needs and expectations to satisfactory levels.

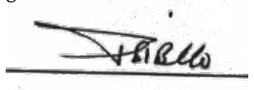
The Authority's achievement in service provision is derived from the unmeasured and timely support and cooperation from many key players particularly our esteemed customers, stakeholders and the general public including their feedback and suggestions on the services.

The attainment and retention of accreditation certificates for our Food and Microbiology Testing Laboratories inline with ISO/IEC 17025:2005 International Standard issued by SADCAS/SANAS Accreditation Board as well as World Health Organization (WHO) Prequalification Certificate for the Medicines Testing Laboratory since January 2011 to date have further increased customer trust in our services.

However, various changes including technological advancements, socio - economic changes pose challenges to the operating procedures, processes, practices and services provided by TFDA. These scenarios call upon the need for regular review of the TFDA Client's Service Charter in order to accommodate the emerging challenges. The reviewed

2016 CSC has taken into consideration these changes in cognizance of available resources. In this case therefore, and considering stakeholders involvement and discussion on the Charter, I have no doubt that they will be effectively and efficiently adhered to during services provision to clients.

TFDA will strive to ensure that all our esteemed customers are best served in accordance with the laws, regulations, guidelines and the CSC, 2016 standards.



Hiiti B. Sillo
Director General

1.0 INTRODUCTION

In this era of observing good governance as well as good regulations practices, it is important that the standards for services provided by Government Institutions to be reached in consultation and agreement with stakeholders. Following the African Public Service Charter signed by African Public Service Ministers in Windhoek Namibia in 2001, the Government of Tanzania and its institutions including TFDA positively responded by introducing respective Client's Service Charters.

As for TFDA, the charter was established and officiated in 2006 and then reviewed in 2012. In order to strengthen service delivery culture inline with technological growth and advancement, TFDA reviewed the charter and came up with the current 2016 version.

The new client's service charter 2016 hinges on the six TFDA's strategic objectives as mentioned in the TFDA's five years Strategic Plan, 2012/13- 2016/17. These strategic objectives are as follows;

- Regulation of safety, quality and effectiveness of food, medicines, cosmetics and medical devices improved;
- Public education and marketing of TFDA services strengthened;
- Resources management improved;
- Services to people with HIV/AIDS improved and new infections reduced;
- National Anti-Corruption Strategy enhanced, sustained and effectively implemented and
- Gender and environmental issues improved;

Therefore, this Charter is among the tools to enhance effective implementation of the TFDA Strategic and Business Plans.

2.0 APPLICATION

This charter is basically for external customers who use TFDA services. The Charter provides for standards of services expected by the clients from TFDA and what TFDA expect from them including the explanation of what can be done if the specified standards are not met.

3.0 DEFINITION OF TERMS

The following are the definitions of terms and phrases used in this Clients' Service Charter:

Regulated products

These are products regulated by Tanzania Food and Drugs Authority (TFDA) which are food, food supplement, human and veterinary medicines including vaccines and biologicals, herbal medicines, cosmetics, disinfectant and medical devices.

Client

Client consists of a product manufacturer, marketing health care provider, doctor/researcher, processor, distributor, wholesaler and retailer, industry, a business group or any individual who is interested in services provided by TFDA together with those who come to give us information pertaining safety and quality of regulated products.

Working days

Days from Monday to Friday, except public holidays. According to this charter, the days highlighted in the delivery of services do not mean the calendar days but working days.

Stakeholder

An individual or instruction/organization which in one way or another is related to or affected by TFDA services and/or functions.

4.0 TFDA PROFILE

TFDA is an acronym of Tanzania Food and Drugs Authority which is a regulatory body of the government, under the Ministry of Health, Community Development, Gender, Elderly and Children (MHCDGEC) responsible for controlling the quality, safety and effectiveness of food, medicines, cosmetics and medical devices in the country for the purpose of protecting public health. TFDA is established under section 4(1) of the Tanzania Food, Drugs and Cosmetics Act Cap 219, and became operational on 1st July, 2003.

TFDA headquarter offices are located at Mabibo External, off Mandela road, Dar es Salaam. TFDA also operates in seven zone offices in Mwanza, Arusha, Mbeya, Dar es Salaam, Dodoma, Mtwara and Tabora.

In implementation of Tanzania Food, Drugs and Cosmetics Act Cap 219, TFDA works collaboratively with Municipals and Local Government Authorities.

4.1 VISION

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

4.2 MISSION

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

4.3 PHILOSOPHY

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

4.4 CORE VALUES

TFDA core values are pivotal for our character identity. They include Honest, Customer focus, Quality, Teamwork and Accountability.

4.5 QUALITY POLICY STATEMENT

TFDA is committed to provide quality services to meet customer needs and expectation by ensuring quality, safety, and effectiveness of food, medicines, cosmetics and medical devices in accordance to ISO 9001:2015

4.6 ROLES AND FUNCTIONS OF TFDA

i. To regulate manufacturing, importation, distribution and selling of food, medicines, cosmetics and medical devices;
ii. To prescribe standards of quality, safety and effectiveness for food, medicines, cosmetics and medical devices;
iii. To inspect manufacturing industries and business premises of regulated products and make sure the standards required are reached;
iv. To evaluate and register food, medicines, cosmetics and medical devices so as to reach the required standards before market authorization;
v. To issue licence and permits of products controlled by the Authority;

vi. To assess the quality and safety of controlled products and laboratory investigations;
vii. To monitor side effects and use of products in the market controlled by the Authority;
viii. To emphasize the correct uses of medicines, cosmetics and medical devices; and
ix. To educate and give appropriate information to stakeholders and public at large about the regulated products.

5.0 PURPOSE OF THE CLIENTS' SERVICE CHARTER

The purpose of this Charter is to openly show the responsibilities of TFDA to comply with the required quality standards in provision of services to clients. This is inline with the National Development Vision 2025, the National Strategy for Economic Growth and Poverty Reduction, 2015 and the National Trade Policy, 2003 on promotion of the private sector as the engine of the economy as well as being flexible to address the new changes.

Moreover, the Charter aims at providing information to clients about TFDA services and strengthens the relationship between the Authority and its clients in the following areas:

i. What TFDA does;
ii. The standard of service clients can expect from TFDA;
iii. Client's basic rights;
iv. Client's responsibilities;
v. How to communicate with TFDA; and
vi. How to present comments together with the complaints, reports, remarks and different suggestions about TFDA activities.

6.0 BENEFITS OF THE CLIENT'S SERVICE CHARTER

The Client's Service Charter is beneficial to the clients and to TFDA as follows:

(a) Benefits to the clients

(i) To know the types of services provided by TFDA;
(ii) To know specifically the quality of service to receive from TFDA;
(iii) To be sure with quality of services from TFDA;
(iv) To be able to evaluate the perfomance of services rendered by TFDA and give feedback for the purpose of improving the services;
(v) To realize his/her contribution in the quality services provided by TFDA; and
(v) To be able to compare services provided by TFDA and other government institutions and give suggestions on how to improve where necessary.

(b) Benefits to TFDA

(i) To define its Vision, Mission, Philosophy and core values together with culture, norms and codes of conducts;
(ii) To measure and evaluate the services delivered to clients and make improvement efforts where necessarly;
(iii) To improve work discipline and responsibility to services delivery; and
(iv) The tool for transparency and responsibilities will be performed through this charter so as to make TFDA clients sure of the quality and safety of regulated products circulating in the market.

7.0 OUR SERVICE GUIDELINES AND COMMITMENT

In our desire to provide high quality sevices to our clients, the following service values and commitment will be adhered to by:

i. Involving competent and dedicated staff in service delivery
ii. Being honest to clients and institution;
iii. Being fair;
iv. Being respectful and value the remarks of clients and stakeholders;
v. Showing intergrity;
vi. Demonstrating openness;
vii. Being flexible in facing the TFDA challenges;
viii. Avoiding conflicts of interest; and
ix. Considering ethical conducts.

8.0 SERVICE STANDARDS AND PROMISES TO CLIENTS

8.1 SERVICE STANDARDS

The Authority aims at providing quality services to our clients. We will fulfill this by meeting the service standards as shown in the table below:

No.	Type of services	Standards of service delivery
1.	**Registration of Premises and Issuance of Business Permit**	
	i. Inspection of premises for manufacturing, storage and distribution of food, medicines, cosmetics, medical devices	10 days
	ii. Inspection of new premises	5 days
	iii. Issuance of premises registration certificate and business permit	5 days
	iv. Renewal of business permits for manufacturing, storage and distribution of food, medicines, cosmetics and medical devices	3 days
2.	**Product Market Authorization**	
	i. Registration of low risk food products.	40 days
	ii. Registration of high risk food products.	50 days
	iii. Registration of medicinal products from domestic manufacturers.	120 days
	iv. Registration of imported medicinal products.	240 days
	v. Registration of priority medicines.	120 days
	vi. Registration of complementary medicines	200 days
	vii. Registration of cosmetics	50 days
	viii. Registration of Class A medical devices.	100 days
	ix. Registration of Class B, C and D medical devices	200 days

No.	Type of services	Standards of service delivery
3.	**Renewal of product Market Authorization**	
	i. Low risk food products.	25 days
	ii. High risk food products	40 days
	iii. Medicinal products from domestic manufacturers.	30 days
	iv. Imported medicinal products.	30 days
	v. Complementary medicines (herbal medicines, antiseptics and disinfectants).	30 days
	vi. Cosmetics	20 days
	vii. Medical devices	30 days
4.	**Issuance of clinical trial permits**	60 days
5.	**Approval of Alterations/Variations for Registered Products**	
	i. Alterations in a registered food product	14 days
	ii. Variation of a registered medicine, cosmetics and medical devices	45 days
6.	**Issuance of Import/Export Permits**	
	i. Import and export permits of registered food, medicines, cosmetics and medical devices	1 day
	ii. Import and export permits of non-registrable products after receiving pre-shipment sample.	25 days

No.	Type of services	Standards of service delivery
7.	**Evaluation and Approval of promotional materials**	
	i. Evaluation and approval of medicines and complimentary products promotional materials	10 days
	ii. Evaluation and approval of food promotional materials.	3 days
8.	Issuance of Disposal certificate for unfit food products, medicines, cosmetics and medical devices.	3 days
9.	Issuance of Laboratory results for samples of TFDA regulated products	20 days
10.	Providing feedback after receiving customer/ complaints/comments/ suggestions.	5 days
11.	Follow up and investigation of Adverse Drugs Reactions (ADR)	20 days

Note: These standards will be implemented after receipt of a complete application from the client

8.2 PROMISES TO CLIENTS

The Authority also provides the following promises to its clients in accordance with the quality policy statement and staff code of conducts;

(i) Equality when dealing with clients

We will treat all TFDA clients fairly and professionally. Any discrimination based on the places of origin, race, gender, religion, ethnic group, philosophical or political views, or personal considerations are prohibited;

(ii) Staff conduct

Our staff will identify themselves to you by wearing identity cards and/ or name tags during working hours and identify by names where necessary. They will be polite, courteous, friendly, considerate and caring to clients, helpful and cooperative all the time;

(iii) Responsiveness

We are committed to provide correct and timely information to our clients and the public at large about regulated products;

(iv) Appropriateness

We will work to ensure that the quality of service delivery meet our client's expectations inline with existing laws, regulations and guidelines and while preserving the environment;

(v) Confidentiality

We will keep any confidential information given to us and use it only for the purpose of which it was intended as per requirement of law and not otherwise;

(vi) Decision making process

We aim for a fair balance between speed of decision making and assessment of the matter at stake and give reasons for decisions that we make;

(vii) Accessibility

We will be accessible physically in our Headquarters and zone offices by phone, fax and email between Mondays to Fridays, from 8.30am to 2.30pm excluding public holidays. However, the TFDA website www.tfda.go.tz which is open all the time and whereby all information about TFDA, regulatory activities and guidelines are directly accessible.

(viii) Dissemination of information

We will disseminate information to our clients through letters, media, website, IEC materials such as brochures, pamphlets, billboard, stickers, fliers also through promotional materials like caps and 'T-shirts'.

Information about TFDA and its activities will also be disseminated through public educating programs in different mass media, participate in debates and direct discussions with the public, educating our clients from different places as well as special groups like disabled people and participating in different exhibitions to illustrate important issues about TFDA services to the public.

Note:

i. Where services delivery is outsourced, we will work to ensure that the service provider complies with our standards and we shall finally be responsible for the service provided; and

ii. Incase the prescribed service standards are not met, our clients will be pre-informed early and the reasons led to such state of affairs inline with the ways to rectify the situation.

9.0 CLIENTS RIGHTS AND RESPONSIBILITIES

9.1 CLIENTS RIGHTS

In view of the service we provide to our clients in accordance with the prescribed service standards, our clients have the right to expect certain levels of quality services from the Authority. These expectations may be different depending on categories of clients as follows;-

(a) Consumers and general public

(i) Assurance on quality, safety and effectiveness of TFDA regulated products;

(ii) Timely getting of information on the regulated counterfeit products adverse health effects and other unfit products. Also getting information on the healthy risk of the products and withdrawn products from the market due failure to meet quality and safety standards;

(iii) Continuous education on TFDA regulated products, requirement of the Tanzania Food Drugs and Cosmetics Act, Cap 219 and their rights to take part in enforcing the existing laws;

(iv) Timely response of comments and complaints regarding TFDA activities;

(v) To participate in bidding process of getting contract for provision of goods/services to in accordance to the existing laws.

(b) Products manufacturers, processors, distributors and retailers:

The clients have the following rights;

i. To know the timely processing of applications for products registration, timely licensing for new business premises, export and import permit for the regulated products;

ii. Timely feedback on the outcome of applications for services from TFDA and clear reasons of decision making;

iii. Timely receiving of information and education on regulated products;

iv. Consultation on the proposed development and amendments of laws, regulations and guidelines pertaining to the services we provide;

v. The rights to privacy and confidentiality of scientific information relating to their products and other submitted information in the course of securing TFDA services;

vi. Equal, fair, and unbiased treatment;

vii. Given quality services, with courteousness, and professionalism, value and respect from TFDA staff;

viii. The right to appeal against the decision made by TFDA on submitted applications when

unsatisfied;

ix. The right to lodge any comment as well as special applications, complaints, remarks, suggestions and reports on how to improve regulatory activities.

(c) Law enforcers

Law enforcers have the following rights;

i. Positive cooperation in dealing with matters related to regulated products;
ii. Timely provision of technical inputs and tools required in dealing with matters related to law enforcement of the Tanzania Food, Drugs, and Cosmetics Act, Cap 219;
iii. Timely and accurate information and education on any progress made in executing activities related to regulated products;
iv. Being involved in all processes related to review the Law, regulations and guidelines on the services delivery.

(d) Health Staff and Researchers

The rights of these clients is as follows

i. Assurance of quality and safety of products regulated by TFDA;
ii. Timely information regarding registered and withdrawn products from the market when needed;
iii. The highest positive cooperation in administering research to determine efficacy of human and veterinary medicines, herbal and local medicines as well as medical devices;
iv. Timely approval of applications of clinical trials and medical devices; and
v. Timely and accurate information regarding the achievements made regulatory activities and on rational use of regulated products.

(e) International Organisations and developmental institutions

i. The right for information from TFDA regarding regulated products;
ii. The right for information from TFDA regarding implementation status of funded projects; and
iii. To make follow up and advice according on implementation of contracts offered by international organizations to TFDA.

(f) Government institutions

i. Positive collaboration in enforcing the Tanzania Food, Drugs and Cosmetics Act, Cap 219;
ii. To be involved in meetings regarding operational activities including reviewing of regulations and different guidelines under the Tanzania Food, Drugs and Cosmetics Act, Cap 219; and
iii. To get different kinds of information when needed.

(g) Non Governmental Institutions (NGOs)

i. Positive cooperation and support in executing projects and businesses falling under the regulated products.
ii. Timely and accurate information and education on the quality and safety of products.

(h) Media and Libraries

i. Timely information and education regarding regulated products and other services offered by TFDA using appropriate channels and within the internal Quality policy, laws and procedures of the Authority;
ii. To be involved in various stakeholders meetings regarding operational activities including reviewing of regulations and different guidelines under the Tanzania Food, Drugs and Cosmetics Act, Cape 219.

(i) Service providers

i. Given equal priority and opportunity in the processes of obtaining services providers;
ii. Timely payments for services offered to TFDA; and
iii Timely information and education on products regulated by TFDA
iv Timely information on the status of applications to become a service provider when participating in pre-qualification

9.2 CLIENT RESPONSIBILITIES

TFDA expects close cooperation with the clients, thus our clients are obliged to:

i. Voluntary compliance to Tanzania Food, Drugs, Cosmetics Act, Cap 219;
ii. Be honest to TFDA and general public;
iii. Respect TFDA staff also avoiding using abusive language when doing business with TFDA;
iv. Timely attend the arranged meetings;
v. To read and understand this charter, laws, regulations, guidelines and other documents relevant to services to regulate quality and safety of food, medicines, cosmetics and medical device;.
vi. Timely and accurately respond to requests needed by TFDA for any important information about regulated products; and
vii. Timely payments of fees and charges for regulatory services provided by TFDA.

10.0 MONITORING, EVALUATION AND REPORTING PERFORMANCE AGAINST STANDARDS

We will monitor and evaluate (M&E) our services regarding to the standards we have set in this charter and report annually on how we have achieved according to the set standards.

M&E of these will be done directly by using the following mechanism:

(a) Inspection of Operating systems and staff

Inspection of TFDA Quality Management Systems will continuously be done according to approved schedules.

The inspection will gauge performance of services by studying performance reports from every directorate and department, Standard Operating Procedures (SOPs) and keeping of documents.

Auditing of TFDA resources including financial issues will be done by the internal Audit unit through financial and procurement processes which will be done according to procedures and the respective report submitted to the management for decision making.

(b) Efficient response of clients complaints

Clients' expectations change from time to time. In this regard, different channels will be used to facilitate clients express their opinions and comments on the levels of services standards delivered by TFDA.

The following approaches will be used in obtaining comments and feedback from our clients:

i. Special forms to be filled by clients in case of comments and complaints. The forms will be available at the Customer Care Desk;

ii. Complaints and comments online form obtained through TFDA website;
iii. Hotline service interface by writing emails to TFDA Directly through info@tfda.go.tz;
iv. Placement of suggestion box at TFDA offices;
v. Telephone services which are open daily in working days;
vi. Customer satisfaction survey on TFDA services;
vii Direct customer dialogue.

We will publicly account for our performance by publishing Annual Progress Reports whereby issues of compliance to TFDA service standards will be featured.

The reporting mechanism will be as follows:

(a) Ensure the Annual Progress Report includes the section for clients comments received in a year so as to make ease the follow up of this charter and ensure that staff and general public receive the reports accordingly;
(b) Discuss the charters' implementation with staff during staff meeting which are scheduled twice a year; and
(c) Provide charter performance information annually to the TFDA's management meetings.

11.0 CLIENTS FEEDBACK AND COMPLAINTS

We are keen and committed to ensure that our standards of service delivery to our clients are daily improved, so client's complaints in accomplishing the highlighted standards are important to the authority. Feedback form our clients will help to foster our relationship with them and to ensure that our services are of quality standards, effective and up-to date.

If you are not satisfied with the performance standards of TFDA services as highlighted in this charter, or if you have any feedback or any views about our services, please discuss with the staff member concerned, and if he/she cannot resolve a problem, ask to speak to his/her immediate supervisor/higher authority. The supervisor/higher authority will solve your complaint and if needs more investigations, you will be given the feedback and proposed day to come for the matter's progress according to the Charter.

If the client's feedback or comments identified a deficiency in our practices and maintaining procedures, then we will correct it for the benefits of all our clients and the organization and provide for preventive measures into the systems inline with Standards Operating Procedures (SOPs). If the feedback or complaints is about the law, we will keep the record and use it in giving advice to the government or concerned institute in control for public interest.

12.0 REVIEWING AND MAINTAINING THE CLIENT'S SERVICE CHARTER

This charter is a living document established by TFDA in collaboration with the clients and as such it will be reviewed in the light of feedback from the TFDA service users who are the clients. Reviewing of this third term Client's Services Charter is important in making sure it is relating with TFDA services. We will review this Charter in collaboration with our clients every three years or when need arises.

13.0 COMMUNICATION WITH TFDA

It is important for clients and general public to know their rights to communicate and give any information on how to improve regulatory activities on safety of food, medicines, cosmetics and medical devices in the country. Hence, clients can give comments on TFDA services, remarks, and suggestions on how to achieve TFDA mission of protecting and promoting public health as well as presenting complaints/or compliments on TFDA services and recommendations thereof to improve quality of services to clients.

The clients have the rights to directly submit comments and feedback of services to TFDA offices through letters, phone calls, sending fax or email to Tanzania Food and Drugs Authority (TFDA) through the following contacts;

Director General,
Tanzania Food and Drugs Authority (TFDA)
Head quarters
Mandela Road, External – Mabibo
P. O. Box 77150, Dar es Salaam – Tanzania
Phone: +255 22 2450512 /2450751 / 2452108
+255 658 445222 / 685 701735 / 777 700002
Fax: +255 22 2450793
Email: info@tfda.go.tz, Website: www.tfda.go.tz

TFDA Zone Offices

Lake Zone,
Nkurumah Street,
P. O. Box 543, Mwanza
Tel: +255 28 2500733
Fax: +255 28 2541484
Email: mwanza@tfda.go.tz

Central Zone,
Mwanza Avenue, Block T, Plot No.6
P. O. Box 1253, Dodoma
Tel: +255 26 2320156
Fax: +255 26 2320156
Email: dodoma@tfda.go.tz

Southern Highlands Zone,
Regional Veterinary Office Building,
P. O. Box 6171, Mbeya
Tel: +255 25 2504425
Fax: +255 25 2504425
Email: mbeya@tfda.go.tz

Eastern Zone,
GEPF Building,
Ali Hassan Mwinyi Road,
P. O. Box 77150, Dar es Salaam
Tel: +255 737 226 328 / 766 368 412
Fax: +255 22 2450793
Email: easternzone@tfda.go.tz

Northern Zone,
Sakina Street,
P. O. Box 16609, Arusha
Tel: +255 27 2547097
Fax: +255 27 2547098
Email: arusha@tfda.go.tz

Southern Zone,
The Clinical Officers Training College and Zonal Health Resource Centre (COTC/ZHRC) Building,
Ligula Road,
P. O. Box 1447, Mtwara
Tel: +255 23 2334655
Email: mtwara@tfda.go.tz

Western Zone,
Regional Referral Hospital (Kitete),
P.O. Box 520,
Tabora
Tel: +255 26 2600082
Cell: +255 654 817849
Fax: +255 26 2600081
Email: tabora@tfda.go.tz

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