CONTENTS

ABBREVIATIONS

ADR	-	Adverse Drug Reaction
AIDS	-	Acquired Immune-Deficiency Syndrome
Cap	-	Chapter
CHAI	-	Clinton Health Access Initiative
CRS	-	Catholic Relief Services
CSC	-	Clients' Service Charter
CSSC	-	Christian Social Services Commission
EAC	-	East African Community
GMP	-	Good Manufacturing Practices
HIV	-	Human Immunodeficiency Virus
IEC	-	Information, Education and Communication
ISO	-	International Organization for Standardization
MAB	-	Ministerial Advisory Board
NCDs	-	Non Communicable Diseases

PO-PSMGG	-	President's Office - Public Service Management and Good Governance
QMS	-	Quality Management System
SADC	-	Southern Africa Development Community
SOPs	-	Standard Operating Procedures
TBS	-	Tanzania Bureau of Standards
TFDA	-	Tanzania Food and Drugs Authority
TMDA	-	Tanzania Medicines and Medical Devices Authority
WHO	-	World Health Organization
WLA	-	WHO Listed Authorities

ACKNOWLEDGEMENTS

This fourth edition of the Clients Service Charter has been compiled by a team of staff from the Communication and Public Education unit in collaboration with staff from other sections and units within the TMDA

I would like to sincerely thank Ms. Gaudensia Simwanza, Mr. Damas Matiku, Dr. Henry Irunde, Mrs. Agnes Mneney, Mrs. Roberta Feruzi, Mr. James Ndege, Mr. Sigfrid Mtey, Mrs. Njuu Kapwera and Mr. Rutta Kahamba for their tireless efforts in reviewing the previous versions of the Clients Service Charter including incorporating various views of TMDA stakeholders during the preparation and finalization of this Charter.

Similarly, I wish to congratulate Mr. John Mwingira, Mrs. Deborah Wami, Mrs. Prisca Matagi, Mr. Hussein Makame, Mr. Martin Malima, Mr. Suleiman Kichawele, Dr. Elirehema Mfinanga, Mr. Daniel Francis Msilamgunda, Mrs. Marcelina Mtalo, Mrs. Martha Malle, Mrs. Dorosella Kahwa and Mrs. Mariam Mirambo who also participated in various stages of the preparation of this Charter.

I would also like to thank all TMDA Managers who met from 23rd to 27th March, 2020 for a

comprehensive review of the draft Charter and agreed on appropriate service delivery standards based on the current resources of the Authority and the use of systems in service delivery.

Special gratitude is owed to the Catholic Relief Services (CRS) with its affiliated institutions namely Clinton Health Access Initiative (CHAI) and Christian Social Services Commission (CSSC) working in Tanzania under the project 'FASTER' for their financial assistance to support convening of drafting meetings, validation workshops and stakeholder consultations.

In addition, various stakeholders, who submitted their comments through the TMDA website and a series of meetings organized, are likewise acknowledged as their inputs have greatly bolstered this Charter including adjusting the timelines outlined.

Lastly, I would like to thank the Management and the Ministerial Advisory Board (MAB) of the Ministry of Health, Community Development, Gender, Elderly and Children for TMDA for the guidance, comments and the final endorsement of the Charter.

Chrispin Mesiaki Severe
DIRECTOR OF BUSINESS SUPPORT

FOREWORD

The National Industrialization Economic Agenda compels both public and private institutions to create a conducive and enabling business environment in Tanzania. In tandem with this, public institutions are required to set standards of service to customers to meet their needs and expectations. Importantly and in line with the principles of good governance, such standards should be mutually agreed with clients and stakeholders to be served.

The Government of Tanzania through the President's Office, Public Service Management and Good Governance (PO PSMGG) adopted the concept of setting service standards through mutual agreement between service providers and customers. Since then this has been fundamental in laying down principles and guidelines for development and implementation of Clients Service Charters (CSCs). The same needs to be reviewed from time to time to exceed customer needs and expectations.

The current TMDA's CSC which supersedes the 2016 edition has been drafted in line with the agreement of African Public Service Ministers who signed an African Public Service Charter in Windhoek, Namibia in 2001. The signing of the Pan-African charter has shifted the paradigm

of public institutions on the way they observe, handle and serve customers in most public institutions.

Tanzania Medicines and Medical Devices Authority (TMDA) is serving different types of customers to embrace those who are dealing with manufacturing, distribution and selling of medicines, medical devices and diagnostics, different Ministries, public entities, private and non-governmental organizations, media and the general public. Review for the CSC 2016 has been conducted with the aim of improving customer service delivery in line with various technological, systemic and legislative changes. These include the implementation of the Management Information System (MIS), the available resources as well as the adoption of the Finance Act No. 8 of 2019 which made changes to the functions of the then Tanzania Food and Drugs Authority (TFDA) whereby the control of food and cosmetics was transferred to the Tanzania Bureau of Standards (TBS).

I would like to call on all customers and stakeholders to read this Charter and notify us in case we do not meet the timelines highlighted in this document. On behalf of the Management and staff of TMDA, I would like to promise to allocate sufficient resources to include human, financial and materials, to offer services that would meet and exceed the anticipations of our customers.

Any comments or suggestions that would improve this document are also welcomed and the same may be submitted by email, letter or any other means of communication through the

TMDA Headquarters and / or Zone Offices located in Mwanza, Arusha, Dar es Salaam, Mbeya, Dodoma, Tabora, Mtwara and Simiyu Regions. In addition, the TMDA will always strive to ensure that its documents including this Charter, comply with the Quality Mnagement System (QMS) in accordance with the International standard ISO 9001: 2015.

Adam Mitangu Fimbo
ACTING DIRECTOR GENERAL

1.0 INTRODUCTION

The Tanzania Medicines and Medical Devices Authority (TMDA) had been implementing the Quality Management System (QMS) and accredited to ISO 9001:2015 standard since 2011. The QMS observes two principles namely effective quality service delivery and customer satisfaction. As part of this system, the TMDA first approved the CSC in 2006 and later on reviewed the superseded editions in 2012 and 2016 respectively. This is the fourth edition of the CSC to be revised by TMDA.

The TMDA had also conducted systematic customer satisfaction surveys between 2004 and 2014. According to the surveys done, in 2004, the external customer satisfaction index was 42% and 72% for internal customers. In 2008, the external customer satisfaction index was 66% and 63% for internal customers. While in 2014, the comparison was 67.6% and 74.4% for external and internal customers respectively.

Assessment of the indices observed delineates that there was an upward trend in satisfaction for external customers between 2004 and 2014. This is a good sign and signals out that the trend needs to be maintained by TMDA. The current CSC has considered the outcomes of the survey and the TMDA commits to offer services that will exceedingly surpass the needs and

expectations of our customers.

This revised edition highlights amongst others, the TMDA profile, vision, mission, core values, quality policy statement, roles and functions of TMDA. Other items articulated include the purpose of this CSC, its benefits, service standards, promises to our clients, customer feedback and complaints handling as well as monitoring and evaluation of set standards. The rights and responsibilities of our clients have also been articulated.

This 2020 edition has also taken into account the below listed TMDA's strategic objectives which have also been underlined in the revised Strategic Plan:

- HIV/AIDS infections and Non Communicable Diseases (NCDs) reduced and Services improved;
- National Anti-Corruption Strategy effectively implemented and sustained;
- Gender and environmental issues improved;
- Quality, effectiveness and Safety of medicines, medical devices and diagnostics assured;
- Laboratory services improved;
- Public education strengthened and customer services improved; and
- Institutional capacity to deliver regulatory services strengthened.

This Charter will serve as an important tool in enhancing and monitoring these strategic objectives.

2.0 APPLICATION

This Charter applies to external clients and stakeholders who utilize TMDA services. The Charter provides for standards of service delivery expected by clients and what the Authority anticipates from its clients including what can be done if the specified standards are not met.

3.0 DEFINITION OF TERMS

In accordance with this Charter, the following terms and phrases are defined as follows:

Client(s)

Means product manufacturers, healthcare providers, researchers, distributors, processors, wholesalers, retailers, a group or any individual interested or affected by services offered by TMDA. They also include government and private institutions as well as consumers and the general public;

Days

Means days from Monday to Friday except public holidays. The days highlighted in the delivery of services do not mean calendar days but working days;

Regulated products

Means medicines (includes human and veterinary medicines), medical devices, diagnostics, laboratory equipment, blood and blood products, biocidals, radiopharmaceuticals, medical gases and herbal medicines, regulated and as defined under the Tanzania Medicines and Medical Devices Act Cap, 219;

Stakeholder

Means an individual, institution or organization which in one way or another is related to or affected by TMDA services and/or functions.

4.0 TMDA PROFILE

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

TMDA formerly Tanzania Food and Drugs Authority (TFDA) became operational on 1st of July, 2003. However the name TFDA was staturily changed into TMDA on the 1st of July 2019 after the amendment of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 by the Finance No. 8 of 2019 whose effect was to separate the regulation of medicinal products from food products.

4.1 VISION

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

4.2 MISSION

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

4.3 PHILOSOPHY

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

4.4 CORE VALUES

We always embrace and institutionalize values that guarantee customer satisfaction. We are expected to be committed to upholding the following values to define our character and personal attributes:

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

4.5 QUALITY POLICY STATEMENT

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

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

4.6 ROLES AND FUNCTIONS OF TMDA

Pursuant to the *Tanzania Medicines and Medical Devices Act, Cap 219*, TMDA discharges the following functions:-

a. Regulating the manufacturing, importation, distribution and selling of medicines, medical devices and diagnostics;
b. Inspecting manufacturing industries and business premises dealing with regulated products and make sure the standards required are attained;
c. Evaluating and registering medicines, medical devices and diagnostics so as to reach the required standards before marketing authorization;

d. Issuance of business permits for premises dealing with regulated products;
e. Assessing the quality, safety and efficacy of controlled drugs;
f. Conducting laboratory investigations for regulated products to ascertain their quality specifications;
g. Conducting pharmacovigilance of medical products and vigilance of medical devices and diagnostics circulating on the market;
h. Promoting rational use of medicines, medical devices and diagnostics; and
i. Educating and sharing accurate and reliable information to stakeholders and the general public on regulatory matters.

5.0 PURPOSE OF THE CLIENTS' SERVICE CHARTER

This Charter intends to imperatively underscore the accountability of TMDA to comply with pre-determined standards of service delivery to its clients. Moreover, the Charter aims to strengthen relationships between the Authority and its clients by sharing information on TMDA services in the following areas:

(a) What it does;
(b) Standards of service clients can expect;
(c) Client's rights and responsibilities;

(d) How to communicate; and

(e) How to submit complaints, comments, remarks and suggestions regarding service delivery.

6.0 BENEFITS OF THE CLIENT'S SERVICE CHARTER

The benefits of this CSC to TMDA and its clients are as follows:

6.1 Benefits to Clients

- To understand the types of services offered by TMDA;
- To measure the level of satisfaction after service delivery by TMDA;
- To evaluate the quality of services offered by TMDA and provide feedback for the purpose of improving the services;
- To realize customer contribution in provision of services offered by TMDA;
- To compare services offered by TMDA with other government institutions and give suggestions on how to improve where necessary;
- To realize value for money of the rendered services;
- To determine the time it would take for TMDA to offer services; and
- To plan in advance and allocate appropriate resources depending on services to be delivered.

6.2 Benefits to TMDA

- To realize its vision and mission;
- To improve transparency on service delivery to clients;
- To improve work discipline and responsibility to customers;
- To strengthen relationship and communication between TMDA and its clients;
- To maintain good reputation and image of the Authority to clients and other stakeholders; and
- To evaluate the level of service delivery and make efforts to improve where necessary.

7.0 SERVICE GUIDELINES AND COMMITMENT

In TMDA's desire to provide high quality services to our clients, the following service values and commitments will be adhered to:

- Engaging competent and dedicated staff in service delivery;
- Being honest to clients and institution;
- Being fair;
- Being respectful and value remarks of clients and stakeholders;

- Showing integrity;
- Demonstrating openness and transparency;
- Being flexible in facing challenges;
- Avoiding conflicts of interest; and
- Considering ethics and codes of conduct.

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:

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
1.	**1.1 Registration of Premises and Issuance of Business Permits (Domestic)**	
	i. Inspection of new premises for manufacturing of medicines, medical devices, diagnostics and other regulated products	Within 5 days
	ii. Sending of inspection report after GMP inspection	Within 5 days
	iii. Inspection of new premises for storage and distribution of medicines, medical devices diagnostics and other regulated products	Within 7 days
	iv. Issuance of premises registration certificate and business permits	Within 3 days
	v. Issuance of GMP compliance certificate	Within 3 days
	vi. Renewal of business permits for manufacturing, storage and distribution of medicines, medical devices, diagnostics and other regulated products	Within 3 days

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
	vii. Follow up inspection for new premises upon notification by applicant	Within 5 days
	1.2 GMP Inspection reports and certificates (Overseas)	
	i. Sending of inspection report after GMP inspection for imported products	Within 45 days
	ii. Issuance of GMP compliance certificate	Within 45 days
2.	**Product Marketing Authorization**	
	2.1 Registration of medicinal products including vaccines from domestic manufacturers	
	i. Evaluation of medicinal products including vaccines upon receipt of completed application	Within 60 days
	ii. Evaluation of query responses	Within 30 days

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
	2.2 Registration of imported medicinal products including vaccines	
	i. Evaluation of medicinal products including vaccines upon receipt of completed application from foreign manufacturers	Within 180 days
	ii. Evaluation of query responses	Within 80 days
	2.3 Registration of medicines under priority procedures	
	i. Products under WHO collaborative procedure	Within 90 days
	ii. Orphan medicines	Within 90 days
	iii. Medicines approved by WLA countries	Within 90 days
	iv. Products from EAC and SADC	Within 90 days
	2.4 Registration of antiseptics and disinfectants	
	i. Registration of domestic manufactured antiseptics and disinfectants	Within 30 days

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
	ii. Registration of imported antiseptics and disinfectants	Within 60 days
	2.5 Registration of Herbal Medicines	
	i. Registration of domestic manufactured herbal medicines	Within 90 days
	ii. Registration of imported herbal medicines	Within 180 days
	2.6 Registration of Medical Devices and Diagnostics	
	i. Notification of class A medical devices	Within 5 days
	ii. Registration of domestic manufactured Class A & B medical devices.	Within 20 days
	iii. Registration of imported Class A & B medical devices	Within 45 days
	iv. Registration of domestic Class C & D medical devices and diagnostics	Within 45 days

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
	v. Registration of imported Class C & D medical devices and diagnostics	Within 90 days
3.	**Renewal of Product Marketing Authorization**	
	i. Medicinal products (including Vaccines) from domestic manufacturers	Within 20 days
	ii. Imported medicinal products	Within 30 days
	iii. Domestic manufactured herbal medicines, antiseptics and disinfectants	Within 20 days
	iv. Imported herbal medicines, antiseptics and disinfectants	Within 30 days
	v. Medical devices and diagnostics	Within 20 days

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
4.	**Issuance of Clinical Trial Certificates**	
	i. Issuance of clinical trial certificates for a new application	*Within 30 days
	ii. Issuance of clinical trial certificates under emergency situation	*Within 14 days
5.	**Approval of Alterations and Variations**	
	i. Major variation of a registered medicine	45 days
	ii. Minor variation of a registered medicine	Within 30 days
	iii. Variation of registered medical devices and diagnostics	10 days
	iv. Major amendment for approved clinical trial	30 days
	v. Minor amendment for approved clinical trial	10 days

*** Timeliness have been changed please refer Annex 1**

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
6.	**Issuance of Import/Export Permits**	
	i. Import and export permits of registered medicines, medical devices, diagnostics, antiseptics, disinfectants and other regulated products	Within 1 day
	ii. Special import and export permit of medicines, medical devices , diagnostics, antiseptics, disinfectants and other regulated products	Within 7 days
	iii. Issuance of certificate for importation of controlled drugs	Within 5 days
	iv. Issuance of permits for procurement and use of narcotic drugs	Within 3 days
7.	**Evaluation and Approval of Promotional Materials**	
	Evaluation and approval of promotional materials for medicines, herbal medicines, medical device, diagnostics, antiseptics and disinfectants	Within 10 days

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
8.	**Disposal of products**	
	Issuance of Disposal Certificate for unfit medicines, herbal medicines, medical devices, antiseptics, disinfectants and other health related products.	Within 3 days after disposal
9.	**Issuance of Laboratory Results for Samples of TMDA regulated products**	
	i. Issuance of laboratory results for medicines, antiseptics, disinfectants and other regulated product samples	Within 20 days
	ii. Issuance of laboratory results for medical devices and diagnostic samples	Within 30 days

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
10.	**Feedback to Customers and whistleblowers**	
	i. Acknowledgement after receiving customer complaints/ comments/suggestions or inquiries	Within 3 days
	ii. Providing feedback after receiving customer/ complaints/ comments/suggestions or inquiries	Within 30 days
	iii. Acknowledgement after receiving emails sent through info@tmda.go.tz	Within 2 days
	iv. Providing feedback after receiving emails	Within 5 days
	v. Acknowledgement after receiving information from whistleblowers	Within 3 days
	vi. Providing feedback after receiving information from whistleblowers	Within 20 days

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
11.	**Response to ADR Reports**	
	i. Acknowledgement after receiving Adverse Drug Reaction (ADR) reports	Within 3 days
	ii. Acknowledgement after receiving SAE reports	Within 3 days
	iii. Providing feedback after evaluation of ADR reports	Within 90 days

8.2 PROMISES TO CLIENTS

The Authority promises the following to its clients in accordance with this Charter, existing quality policy statement and staff code of conduct:

(i) Equality when dealing with clients

TMDA will treat all clients fairly and professionally. Any sort of discrimination based on place of origin, race, gender, religion, ethnicity, philosophical or political views or personal considerations will not be allowed and entertained.

(ii) Staff conduct

TMDA staff will identify themselves to clients by wearing identity cards and name tags during working hours and introduce themselves by their names whenever necessary. Staff will always be polite, courteous, friendly, empathic, considerate, helpful, cooperative and caring to clients all the time.

(iii) Responsiveness

TMDA commits to adhere to the set service standards and provide correct and timely information to our clients and the public at large on regulated products.

(iv) Appropriateness

TMDA will work to ensure that the quality of service delivery meet s and exceeds our customer needs and expectations in line with existing laws, regulations, guidelines and standard operating procedures (SOPs) while at the same time preserving the environment.

(v) Confidentiality

TMDA will treat information accessed from clients with the highest and utmost level of confidentiality and use the same only for the intended purpose and as required by existing laws

or regulations and not otherwise.

(vi) Decision- making process

TMDA aims at a fair balance between speed of decision making and assessment of the matter at stake and will give reasons for decisions that will be made.

(vii) Accessibility

TMDA services will be accessible physically at its Headquarter and Zone offices by phone, fax, mobile phone and email address between Mondays to Fridays, from 8:00.am to 5:00pm excluding public holidays. The toll free number 0800110084 will also be available during working hours to respond to customer enquiries. Moreover, TMDA services at ports of entry and online portal services will be accessible 24 hours for seven days a week (24/7). Additionally, all information about TMDA regulatory activities and guidelines will be directly accessible through the website www.tmda.go.tz at all times.

(viii) Dissemination of information

TMDA will disseminate information to its clients through website, mass media, Information, Education and Communication (IEC) materials such as brochures, pamphlets, billboards, stickers and fliers. Other promotional materials namely caps, 'T-shirts' and wheel covers will

also be used. Furthermore, information about TMDA and its functions will also be disseminated through public education programmes to include radio, TV, print media and exhibitions.

9.0 CLIENT'S RIGHTS AND RESPONSIBILITIES

9.1 CLIENTS RIGHTS

In connection to the services TMDA offers and in accordance with the set standards, our clients have a right to expect high quality services from TMDA. These expectations may differ depending on categories of clients as delineated below:-

(a) Product manufacturers, processors, distributors and retailers

These categories of clients have the following rights:

- To understand the standards of services offered by TMDA;
- To receive timely feedback from TMDA on the outcome of their applications for approval;
- To access information and receive education on regulated products;
- To participate in the development and amendment of laws, regulations and guidelines pertaining to TMDA services;
- To receive assurance on privacy and confidentiality of information related to their products, premises and any other submitted information in the course of securing TMDA services;

- To be treated equally, fairly and without any bias;
- To be given quality services, with courteousness, professionalism, value and respect from TMDA staff;
- To appeal against any decision made by TMDA on services delivered once aggrieved; and
- To lodge complaints, concerns, compliments, remarks or suggestions regarding TMDA services.

(b) Consumers and general public

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

(ii) Timely getting of information on falsified and substandard products, adverse health effects and other unfit products;

(iii) Continuous education on TMDA regulated products, requirements of the Tanzania Medicines and Medical Devices Act, Cap 219 and their rights to take part in enforcing the existing laws;

(iv) Timely response to comments, complaints and enquiries regarding TMDA services;

(c) Health Care Professionals and Researchers

The rights of these clients include;

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

9.2 CLIENT'S RESPONSIBILITIES

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

i. Voluntary compliance to Tanzania Medicines and Medical Devices Act, Cap 219;
ii. Be honest to TMDA and general public;
iii. Respect TMDA staff and not using abusive language when doing business with TMDA;
iv. To adhere to institutional procedures pertaining to services provision;
v. To read and understand this charter and governed laws, regulations, guidelines and other relevant documents related to services provided by TMDA;
vi. Timely and accurately respond to TMDA requests regarding regulated products; and;

vii. Timely payments of fees and charges for regulatory services provided by TMDA.

10.0 STAKEHOLDER RIGHTS

In the context of this charter stakeholders include Government Institutions, Development Partners, law enforcers, Civil Society Organizations (CSOs), Media and Libraries and service providers. Their rights are indicated as follows;

(a) Government Institutions and other Law enforcers

- Positive cooperation and collaboration in enforcing the Tanzania Medicines and Medical Devices Act, Cap 219;
- Timely provision of technical inputs and tools required in dealing with matters related to law enforcement of the Tanzania Medicines and Medical Devices Act, Cap 219;
- Timely and accurate information and education on any progress made in executing activities related to regulated products;
- Being involved in the review of Law, regulations and guidelines of regulated products where applicable;

(b) Development Partners

- To getting information from TMDA regarding regulated products, services and Implementation status of funded projects; and

- To make follow up and advice according to implementation of contracts offered by

(c) Civil Society Organizations (CSOs)

i) Positive cooperation and support in executing projects and businesses related to regulated products
ii) Timely and accurate information and education on the quality and safety of products

(d) Media and Libraries

- Timely dissemination of information and education materials regarding regulated products and other services offered by TMDA using appropriate channels and within the internal Quality policy, laws and procedures of the Authority;
- To be involved in various stakeholders` meetings regarding operational activities including reviewing of regulations and different guidelines under the Tanzania Medicines and Medical Devices Act, Cap 219.

(e) Service providers

- Given fair opportunity in the processes of obtaining services providers;
- Timely payments for services offered to TMDA; and
- Timely information on the status of applications to become a service provider when

participating in pre-qualification

- To participate in the bidding process of getting a contract for provision of goods/services in accordance with the existing laws.

11.0 MONITORING, EVALUATION AND REPORTING PERFORMANCE AGAINST STANDARDS

11.1 MONITORING AND EVALUATION

TMDA shall conduct periodic monitoring and annual performance evaluation of the set standards in this Charter. We will promptly implement measures to improve our services when opportunities to improve are identified.
M&E of these Charter will be done directly by using the following mechanism:

(a) Inspection of Operating systems

Inspection of TMDA 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 TMDA 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 client's complaints

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

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

(i) Using specific forms for the submission of various customer complaints and comments available at the customer service desk and on the Authority's website (www.tmda.go.tz).

(ii) Using the TMDA email interface directly via info@tmda.go.tz.

(iii) Using customer suggestion boxes at all TMDA offices.

(iv) Using mobile services that are open daily during working days together with Toll Free number 0800110084.

(v) Conduct surveys on customer satisfaction levels and services provided by TMDA.

(vi) Conducting direct or direct discussions with clients.

(vii) Receiving information from whistleblowers as part of the implementation of the whistleblowing Policy.

(viii) Obtaining information through a specific customer feedback questionnaire on the availability of TMDA services (Exit Interview Questionaire Form)

(ix) Using a specific questionnaire to obtain information from the public if various TMDA information is accessed through various means of communication.

11.2 REPORTING PERFORMANCE AGAINST STANDARDS

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

The reporting mechanism will be as follows:

(i) 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;

(ii) Discuss the charters' implementation with staff during staff meeting which are scheduled twice a year; and

(iii) Provide charter performance information annually to the Ministerial Advisory Board (MAB).

12.0 REVIEW AND MAINTENANCE OF THE CHARTER

This Charter is a living document and goes in tandem with changes that might occur in society and that may affect our service delivery. Review of this Charter is pivotal to ensure that it is up-to-date. Review will be done by engaging with clients and other stakeholders after every three years or as the need arises. The review will take into consideration the following:-

a. Monitoring and evaluation of this Chatter;
b. Feedback from clients and stakeholders;
c. Changes in the organizational structure;
d. Changes in client's profile, needs and priorities; and
e. Changes in service delivery systems.

13.0 BUSINESS HOURS

TMDA offices will be open for our clients and stakeholders from 08:30am - 05:00pm, Monday to Friday except weekends and public holidays.

14.0 CLIENT'S FEEDBACK AND COMPLAINTS HANDLING

TMDA is committed to improving the standards of service delivery from time to time. Feedback including complaints from our clients will foster and forge relationships and ensure that services

offered are of good quality, efficient, effective and up-to date.

We welcome feedback on this Charter including complaints, compliments and suggestions related to the services we offer. These can be given through postal addresses, emails, verbal conversations, letters, hotline number (toll free), telephones or faxes. Filling of the special complaint/compliment forms that are available on the website and Customer Care Desk will also be accepted and attended to. All complaints and suggestions will be taken seriously and dealt with as quickly as possible.

15.0 HOW TO CONTACT TMDA

All TMDA customers are entitled to the services that we offer. Clients are urged to submit their comments, opinions, suggestions, complaints, concerns or advice on the services we offer. By doing so, we as a government institution will be informed, take necessary actions needed and contribute towards protection of public health which is fundamentally the responsibility of both of us.

Clients can contact TMDA by letter, phone, fax or email through the following addresses:

Director General

Tanzania Medicines and Medical Devices Authority (TMDA),
Headquaters,
P. O. Box 1253 Dodoma

Sub-head office

P. O. Box 77150, Dar es Salaam
Phone: +255 22 2450512 /2450751 / 2452108
Fax: +255 22 2450793
Toll free: 0800110084
Email: info@tmda.go.tz, Website: www.tmda.go.tz

Lake Zone

Nyasaka Road, Nyakato Buzuruga,

P. O. Box 543, Ilemela-Mwanza

Tel: +255 28 2981224/5

Fax: +255 28 282981205

Email: info.mwanza@tmda.go.tz

Our Zone Offices can also be reached through the following addresses:

Northern Zone

Sakina Street,

P. O. Box 16609, Arusha

Tel: +255 27 2970333/73782442

Fax: +255 27 2547098

Email: info.arusha@tmda.go.tz

Southern Highlands Zone

NHIF Building 3rd floor,

P. O. Box 6171, Mbeya

Tel: +255 25 2504425

Fax: +255 25 2504425

Email: info.mbeya@tmda.go.tz

Eastern Zone

PSSF Building, Victoria

Ali Hassan Mwinyi Road,

P. O. Box 31356, Dar es Salaam

Tel: +255 737 226 328 / 788470312

Fax: +255 22 2450793

Email: info.easternzone@tmda.go.tz

Central Zone

PSSF Building,

P. O. Box 1253, Dodoma

Tel: +255 26 2320156

Fax: +255 26 2320156

Email: info.dodoma@tmda.go.tz

Southern Zone

PSSSF Building,

P. O. Box 1447, Mtwara

Tel: +255 23 2334655

Email: info.mtwara@tmda.go.tz

Western Zone

TUWASA Building,

P.O. Box 520, Tabora

Tel: +255 26 2600082/654817849

Cell: +255 654 817849

Fax: +255 26 2600081

Email: info.tabora@tmda.go.tz

TMDA	CUSTOMER COMPLAINT/COMPLEMENT FORM	*TMDA/DG/CPE/F/001* *Rev #:03*

Part I: Customer Particulars

Name: ..... Title: .....

Company:..... Address:.....

Phone No:..... E-mail:.....

Signature:..... Date:.....

Part II: Description of complaint/ complement

.....

.....

.....

.....

.....

.....

Received by: ..... Signature: ..... Date: .....

Part III: Review of complaint/complement by Manager, Communication and Public Education/Zone Manager and action taken.

.....

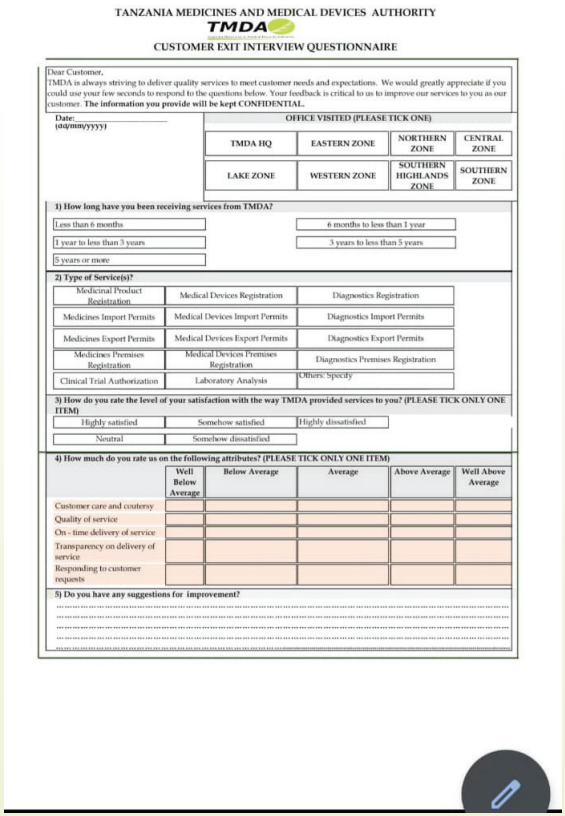
.....

.....

.....

.....

Signature: ..... Date: .....



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA

CUSTOMER EXIT INTERVIEW QUESTIONNAIRE

Dear Customer,
TMDA is always striving to deliver quality services to meet customer needs and expectations. We would greatly appreciate if you could use your few seconds to respond to the questions below. Your feedback is critical to us to improve our services to you as our customer. **The information you provide will be kept CONFIDENTIAL.**

Date: _____
(dd/mm/yyyy)

OFFICE VISITED (PLEASE TICK ONE)			
TMDA HQ	EASTERN ZONE	NORTHERN ZONE	CENTRAL ZONE
LAKE ZONE	WESTERN ZONE	SOUTHERN HIGHLANDS ZONE	SOUTHERN ZONE

1) How long have you been receiving services from TMDA?

Less than 6 months	6 months to less than 1 year
1 year to less than 3 years	3 years to less than 5 years
5 years or more	

2) Type of Service(s)?

Medicinal Product Registration	Medical Devices Registration	Diagnostics Registration
Medicines Import Permits	Medical Devices Import Permits	Diagnostics Import Permits
Medicines Export Permits	Medical Devices Export Permits	Diagnostics Export Permits
Medicines Premises Registration	Medical Devices Premises Registration	Diagnostics Premises Registration
Clinical Trial Authorization	Laboratory Analysis	Others: Specify

3) How do you rate the level of your satisfaction with the way TMDA provided services to you? (PLEASE TICK ONLY ONE ITEM)

Highly satisfied	Somehow satisfied	Highly dissatisfied
Neutral	Somehow dissatisfied	

4) How much do you rate us on the following attributes? (PLEASE TICK ONLY ONE ITEM)

	Well Below Average	Below Average	Average	Above Average	Well Above Average
Customer care and coutersy					
Quality of service					
On - time delivery of service					
Transparency on delivery of service					
Responding to customer requests					

5) Do you have any suggestions for improvement?

.....
.....
.....
.....
.....

Annex 1

AMENDMENT OF THE TIMELINES FOR ISSUANCE OF CLINICAL TRIAL CERTIFICATES MAY 2023

1. Where the Tanzania Medicines and Medical Devices Authority (TMDA) have noted conflicting timelines for the issuance of Clinical Trial Certificates between the Client Service Charter,4th Edition and the Guidelines for Application to Conduct Clinical Trials in Tanzania, March 2020 Edition; and

2. Whereas the Client Service Charter has defined 14 and 45 working days for emergency and normal applications, respectively while the Guidelines indicate 30 and 60 working days which are in line with the technical committee meeting schedules; and

3. Whereas the Authority intends with effect from 1st June 2023, to use the timelines prescribed by the Guidelines for Application to Conduct Clinical Trials in Tanzania.

   Within 30 days, the Authority hereby provide amendment to clause 8.1 sub clause 4.i and 4.ii of the Client Service Charter 4th Edition hereby referred to the "principal Edition" as follows:

   THIS PART shall be read as one with the principal Edition of the Client Service Charter 4th Edition and therefore, esteemed customers are requested to take note of these amendments which will be enforced as one with the existing 4th Edition of Client Service Charter.

1. **Amendment of sub clause 4.i and 4.ii:**
   The timeline for issuance of clinical trial certificates for new applications and under emergence situation under sub clause 4.i and 4.ii of the principal Client Service Charter 4th Edition are hereby amended by deleting the timelines and replacing it with the following:

SN	TYPE OF SERVICE	STANDARD OF SERVICE DELIVERY
4.i	Issuance of clinical trial certificates for new applications	Within 60 days
4.ii	Issuance of clinical trial certificates under emergence situation	Within 30 days