RWANDA FDA
Rwanda Food and Drugs Authority

CLIENTS' SERVICE CHARTER FOR RWANDA FOOD AND DRUGS AUTHORITY

First Edition

MARCH 2021

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ABBREVIATIONS & ACCRONYMS

ADR	Adverse Drug Reaction
CSC	Clients' Service Charter
EAC	East African Community
GMP	Good Manufacturing Practices
ISO	International Organization for Standardization
QMS	Quality Management System
SOPs	Standard Operating Procedures
RWANDA FDA	Rwanda Food and Drugs Authority
WHO	World Health Organization

FOREWORD

The National Industrialization Economic Agenda compels both public and private institutions to create conducive and enabling business environment in Rwanda. In this regard, 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 Rwanda has 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) and these needs to be reviewed from time to time to exceed customer needs and expectations.

Rwanda Food and Drugs Authority (Rwanda FDA) is serving different types of customers to embrace those who are dealing with manufacturing, distribution and selling of products it regulates. In order to improve its quality of service delivery, the Authority has developed this document.

Our esteemed customers are requested to read this Client Charter and notify us in case we do not meet the timelines highlighted in this document. Rwanda FDA promises to utilize all of its available resources including human, financial and materials, to offer services that would meet and exceed the customer requirements. Any comments or suggestions that would improve this document are also welcomed and the same may be submitted by email, letter or any means of communication. Rwanda FDA always strives to improve its documents including this one, to comply with the quality management system requirements of ISO 9001:2015 standard.

Dr. Charles KARANGWA
Ag. Director General

INTRODUCTION

The Rwanda Food and Drugs Authority (Rwanda FDA) is committed to implement the Quality Management System (QMS) ISO 9001:2015 standard. The QMS observes among others, two principles namely effective quality service delivery and customer satisfaction. To cope with this, the Authority is also committed to conduct on regular basis; systematic customer satisfaction surveys and the results will be guiding the review of this document.

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

This Charter applies to external clients and stakeholders who utilize Rwanda FDA 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.

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 Rwanda FDA. They also include government and private institutions as well as consumers and the general public.

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

Regulated products
Means medicines, food, and any other product stated in article 3 of the Law Nº 003/2018 of 09/02/2018 Establishing Rwanda Food And Drugs Authority and determining its mission, organization and functioning;

Stakeholder
Means an individual, institution or organization which in one way or another is related to or

affected by Rwanda FDA services and/or functions.

RWANDA FDA PROFILE

Rwanda FDA is an autonomous regulatory body which is responsible for protecting and promoting public health by ensuring quality, safety and effectiveness of medicines, food products and all other regulated products.

VISION

A world class regulatory Authority effectively protecting and promoting public health

MISSION

To regulate medical products, processed foods, household products, and tobacco and tobacco products to ensure their quality and safety so as to protect the population of Rwanda from defective, falsified and substandard products.

CORE VALUES

Rwanda FDA always embraces and institutionalizes values that guarantee customer satisfaction. All Rwanda FDA employees are expected to be committed to upholding the following values to define their character and personal attributes:

Professionalism	Serving with **professionalism** for excellent service delivery
Integrity	Continuously working with **integrity**
Accountability	Promoting **accountability** for actions and outcomes
Teamwork	Nurturing **teamwork** to achieve common objectives
Innovation	**Striving for innovation** to create value for our stakeholder and other interested parties

QUALITY POLICY STATEMENT

Rwanda Food and Drugs Authority (Rwanda FDA) is committed to providing the highest standard of regulatory services to all customers by implementation of a quality management system that complies with ISO 9001:2015.

Timely and reliable service, compliance to all applicable statutory and regulatory requirements, continual improvement of the processes, systems and procedures; and meeting customer

requirements underlie all our efforts in ensuring quality, safety, efficacy, and wholesomeness of all regulated products used in Rwanda.

This is achieved through assessment and registration; inspection and licensing; control of imports and exports; pharmacovigilance; post-marketing surveillance; clinical and field trials; control of publications and advertisements; laboratory testing; and enforcement.

Rwanda FDA shall therefore, commit adequate financial, human, physical and technological resources for implementing, maintaining and continually improving the quality management systems to achieve set objectives; and maintain an adequate workforce that is trained, motivated, facilitated and empowered to achieve results.

Quality objectives, processes, systems and procedures that support this quality policy are established and reviewed periodically for continuing suitability.

ROLES AND FUNCTIONS OF RWANDA FDA

Pursuant to the Law N^{o} 003/2018 of 09/02/2018, missions of Rwanda FDA are the following:

1) regulate pharmaceutical products, vaccines, human and veterinary processed foods and other biological products used in clinical as drugs food supplements, food fortificants fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products, management of unfit pharmaceutical and food products and clinical trials on pharmaceutical products for human and veterinary use;
2) regulate compliance with quality standards relating to the manufacture, storage, sale, distribution, use, import and export, labels, packages and raw materials used in the manufacture of products regulated under this Law;
3) regulate laboratory and cleaning chemicals and pesticides as well as premises involved in the manufacture of products regulated under this Law;
4) establish, approve and publish the list of human and veterinary food and pharmaceutical products as well as other products regulated under this Law for which marketing authorization has been granted;
5) establish and publish the list of prohibited cosmetics;
6) establish the quality assurance and quality control of products regulated under this Law through designated quality control laboratories when necessary; to regulate and inspect clinical trials;
7) ensure that processed food, food supplements and fortified food meet the prescribed quality standards before they are placed on the market;
8) conduct pharmacovigilance and post marketing surveillance for safety and quality of products regulated under this Law;

9) follow up and analyze information on the use of pharmaceutical products that are subject to global drugs safety monitoring;
10) regulate and analyze information used in the promotion, advertising and marketing of products regulated under this Law;
11) regulate the use of unregistered products regulated under this Law for clinical trial purposes or compassionate use;
12) disseminate information on quality and safety of products regulated under this Law to health professionals and to other concerned persons;
13) conduct research and studies on food and pharmaceutical products and publish the findings in order to promote investment;
14) build cooperation and partnership for harmonization of practices with regional and international bodies with similar missions;
15) to advise the Government on matters regarding the products regulated under this Law;

PURPOSE OF THE CLIENTS' SERVICE CHARTER

This Charter intends to underscore the accountability of Rwanda FDA to comply with pre-determined standards of service delivery to its clients. Moreover, it aims to strengthen relationships between the Authority and its clients by sharing information on Rwanda FDA 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.

BENEFITS OF THE CLIENT'S SERVICE CHARTER

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

Benefits to Clients

i. To understand the types of services offered by Rwanda FDA;
ii. To measure the level of satisfaction after service delivery by Rwanda FDA;
iii. To evaluate the quality of services offered by Rwanda FDA and provide feedback for the purpose of improving the services;
iv. To realize customer contribution in provision of services offered by Rwanda FDA;
v. To realize value for money of the rendered services;
vi. To determine the time it would take for Rwanda FDA to offer services; and

vii. To plan in advance and allocate appropriate resources depending on services to be delivered.

Benefits to Rwanda FDA

i. To realize its vision and mission;
ii. To improve transparency on service delivery to clients;
iii. To improve commitment on timelines and responsibility to customer needs;
iv. To strengthen relationship and communication between Rwanda FDA and its clients;
v. To maintain good reputation and image of the Authority to clients and other stakeholders; and;
vi. To evaluate the level of service delivery and make efforts for improve where necessary.

SERVICE GUIDELINES AND COMMITMENT

In order to ensure that Rwanda FDA is providing high quality services to its clients, the following service values and commitments will be adhered to:

a. Engaging competent and dedicated staff in service delivery;
b. Being fair;
c. Being respectful and value remarks of clients and stakeholders;
d. Showing integrity;
e. Demonstrating openness and transparency;
f. Being flexible in facing challenges;
g. Avoiding conflicts of interest; and
h. Considering ethics and codes of conduct.

SERVICE STANDARDS AND PROMISES TO CLIENTS

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.	**Registration of Premises and Issuance of premise licenses (Domestic)**	
	a. Inspection of new premises for manufacturing of Food, medicines, medical devices, diagnostics and other regulated products after receiving the application	Within five (5) days in Kigali City and ten (10) days in provinces
	b. Conduction of GMP inspection for foreign manufacturing facilities of regulated products	Within 120 days after receiving a complete application
	c. Conduction of GMP inspection for domestic manufacturing facilities of regulated products	Within thirty (30) days after receiving a complete application
	d. Sending of inspection report after GMP inspection	Within ten (10) days
	e. Inspection of new premises for storage and distribution of medicines, Food products, medical devices diagnostics and other regulated products after receiving application	Within five (5) days in Kigali and ten (10) days in provinces
	f. Issuance of premises registration certificate and business permits or feedback	Within ten (10) days
	g. Issuance of GMP compliance certificate after sending inspection report	Within ten (10) days
	h. Renewal of licenses for manufacturing, storage and distribution of Food, Drugs, medical devices, diagnostics and other regulated products	Within five (5) days
	i. Re-inspection for premises upon notification by applicant	Within five (5) days in Kigali City and ten (10) days in other provinces
2.	**Product Marketing Authorization**	
	2.1 Registration of medicines and food products from domestic manufacturers	
	a. Evaluation of medicines upon receipt of completed application from domestic manufacturers	Within 90 days
	c. Evaluation of medicines query responses	Within 30 days

d. Evaluation of food products with low risk upon receipt of complete application	Within 45 days
e. Evaluation of food products with high risk upon receipt of complete application	Within 60 days
f. Evaluation of food products query responses	Within 14 days
2.2 Registration of imported food products and medicines	
a. Evaluation of medicines upon receipt of completed application from foreign applicants	Within 9 months
b. Evaluation of query responses	Within 60 days
2.3 Registration of medicines under priority procedures	
a. Products under WHO collaborative procedure	Within 90 days
b. Orphan medicines	Within 90 days
c. Medicines approved by WLA countries	9 months
d. Products from EAC partner states	Within 90 days
2.4 Registration of antiseptics and disinfectants	
a. Registration of domestic manufactured antiseptics and disinfectants	Within 60 days
b. Registration of imported antiseptics and disinfectants	Within 120 days
2.5 Registration of Herbal Medicines	
a. Registration of domestic manufactured herbal medicines	Within 90 days
b. Registration of imported herbal medicines	Within 180 days
2.6 Registration of Medical device	
a. Registration of domestic manufactured medical devices and in vitro diagnostics	Within 120 days
b. Evaluation of additional queries for domestic Medical devices and in vitro diagnostics	Within 30 days
c. Registration of imported medical devices and in vitro diagnostics	9 months

	d. Evaluation of additional queries for imported medical devices and in vitro diagnostics	Within 60 days
3.	**Renewal of Product Marketing Authorization**	
	a. Medicinal products from domestic manufacturers	Within 60 days
	b. Imported medicinal products	Within 90 days
	c. Domestic manufactured herbal medicines, antiseptics and disinfectants	Within 60 days
	d. Imported herbal medicines, antiseptics and disinfectants	Within 90 days
	e. Medical devices and in vitro diagnostics	Within 60 days
4.	**Issuance of Clinical Trial Certificates**	
	a. Issuance of clinical trial certificates for a new application	Within 2 months
	b. Issuance of clinical trial certificates under emergency situation	Within 1 month
5.	**Approval of Variations**	
	a. Major variation of a registered medicine	60 days
	b. Minor variation of a registered medicine	Within 30 days
	c. Variation of registered medical devices and in vitro diagnostics	30 days
	d. Major amendment for approved clinical trial	15 days
	e. Minor amendment for approved clinical trial	10 days
6.	**Issuance of Import/Export Permits**	
	a. Import and export permits of registered food, medicines, medical devices, diagnostics, antiseptics, disinfectants and other regulated products if all requirements are met	Within one (1) day
	b. Issuance of certificate for importation of controlled drugs if all requirements are met	Within three (3) days
7.	**Evaluation and Approval of Promotional Materials**	
	a. Evaluation and approval of promotional materials for regulated products	Within 5 days

	b. Issuance of Disposal Certificate for unfit medicines, herbal medicines, medical devices, antiseptics, disinfectants and other health related	Within three (3) days after disposal
8.	**Issuance of Laboratory Results for Samples of RWANDA FDA regulated products**	
	a. Issuance of laboratory results for food, medicines, antiseptics, disinfectants and other regulated product samples	Within fifteen (15) days except in case test methods state otherwise
9.	**Feedback to Customers**	
	a. Acknowledgement after receiving customer complaints/ comments/suggestions or inquiries	Within two (2) days
	b. Providing feedback after receiving customer/complaints/ comments/suggestions or inquiries	Within 30 days
	c. Acknowledgement after receiving emails sent through info@rwandafda.gov.rw and institutional social media accounts	Within one (1) days
	d. Providing feedback after receiving emails	Within two (2) days
10.	**Response to ADR Reports**	
	a. Acknowledgement after receiving Adverse Drug Reaction (ADR) or suspected poor quality reports	Within two (2) days
	b. Acknowledgement after receiving SAE reports	Within three (2) days
	c. Providing feedback after evaluation of ADR or the suspected poor quality reports	Within 30 days

NB: For all of these timelines, in case the Authority meets challenges for non-compliance (force majeur), the applicant shall be communicated through email, text message on the changes.

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:

Equality when dealing with clients

Rwanda FDA will treat all clients fairly and professionally. Any sort of discrimination based on

place of origin, race, gender, religion, ethnicity or political views or personal considerations will not be allowed.

Staff conduct

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

Responsiveness

Rwanda FDA commits to adhere to the set service standards and provides correct and timely information to its clients and the public at large on regulated products.

Appropriateness

Rwanda FDA will work to ensure that the quality of service delivery meets and exceeds its customer needs and expectations in line with existing laws, regulations, guidelines and standard operating procedures (SOPs)

Confidentiality

Rwanda FDA will treat information accessed from clients with highest level of confidentiality and use the same only for the intended purpose and as required by existing laws or regulations and not otherwise.

Decision making process

Rwanda FDA aims at fair balance between speed of decision making and assessment of raised matters and will give reasons for decisions that will be made.

Accessibility

Rwanda FDA will be accessible physically at its Headquarter from Mondays to Fridays; 7:00 am to 5:00pm excluding public holidays. However, the institutional social media accounts, mobile phone and email address can be used to reach the Authority any time to respond to customer enquiries. Additionally, Rwanda FDA services at ports of entry and online portal services will be accessible 24 hours for seven days a week (24/7). All information about Rwanda FDA regulatory activities and guidelines are directly accessible through website www.rwandafda.gov.rw at all times.

Dissemination of information

Rwanda FDA will disseminate information to its clients through website, social media, Information, Education and Communication (IEC) materials such as brochures, pamphlets, billboards, stickers and fliers. Other promotional materials namely cap, 'T- shirts' etc, will also be used. Furthermore, information about Rwanda FDA and its functions will also be disseminated through public education programs to include radio, TV, print media and exhibitions.

CLIENT'S RIGHTS AND RESPONSIBILITIES

CLIENTS RIGHTS

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

(a) Product manufacturers, processors, distributors and retailers

These categories of clients have the following rights:

i. To understand the standards of services offered by Rwanda FDA;
ii. To receive timely feedback from Rwanda FDA on the outcome of their applications for approval;
iii. To access information and receive education on regulated products;
iv. To participate in the development and amendment of laws, regulations and guidelines pertaining to Rwanda FDA services;
v. To receive assurance on privacy and confidentiality of information related to their products, premises and any other submitted information in the course of securing Rwanda FDA services;
vi. To be treated equally, fairly and without any bias;
vii. To be given quality services, with courteousness, professionalism, value and respect from Rwanda FDA staff;
viii. To appeal against any decision made by Rwanda FDA on services delivered once aggrieved; and
ix. To advance complaints, concerns, compliments, remarks or suggestions regarding Rwanda FDA services.

(b) Consumers and general public

i. Assurance on quality, safety and effectiveness of Rwanda FDA regulated products;

ii. Timely be abreast of information on falsified and substandard products, adverse health effects and other unfit products;
iii. Continuous education on Rwanda FDA regulated products, and their rights to take part in enforcing the existing laws and regulations;
iv. Timely response to comments, complaints and enquiries regarding Rwanda FDA services;

(c) Health Care Professionals and Researchers

The rights of these clients include;

i. Assurance of quality and safety of products regulated by Rwanda FDA;
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, food products, herbal medicines, medical devices as well as other regulated products;
iv. Timely approval of applications of clinical trials of medicines and other regulated products
v. Timely and accurate information regarding the achievements made regulatory activities and on rational use of regulated products

CLIENT'S RESPONSIBILITIES

Rwanda FDA expects close cooperation with the clients and in this regard, our clients are obliged to:

i. voluntary comply to Rwanda FDA law and regulations;
ii. adhere to institutional procedures pertaining to services provision;
iii. read and understand this charter and governed laws, regulations, guidelines and other relevant documents related to services provided by Rwanda FDA;
iv. timely and accurately respond to Rwanda FDA requests regarding regulated products; and;
v. timely provision of necessary information relating to the regulated products to Rwanda FDA.

STAKEHOLDER RIGHTS

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

(a) Government Institutions and other Law enforcers

i. Positive cooperation and collaboration in enforcing the law Governing Rwanda FDA;

ii. Timely provision of technical inputs and tools required in dealing with matters related to law enforcement of the Rwanda FDA;
iii. Timely and accurate information and education on any progress made in executing activities related to regulated products;
iv. Being involved in the review of Law, regulations and guidelines of regulated products where applicable;

(b) Development Partners

i. Access information from Rwanda FDA regarding regulated products, services and implementation status of funded projects; and
ii. Make follow up and advice according to implementation of contracts offered by the Authority.

(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 regulated products

(d) Media

i) Timely dissemination of information and education materials regarding regulated products and other services offered by Rwanda FDA 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 Rwanda FDA law.

(e) Service providers

i) Given fair opportunity in the processes of obtaining services providers;
ii) Timely payments for services offered to Rwanda FDA; and
iii) Timely information on the status of applications to become a service provider.
iv) To participate in bidding process of getting contract for provision of goods/services in accordance to the existing laws.

MONITORING AND EVALUATION

RWANDA FDA shall conduct periodic monitoring and annual performance evaluation of the set

standards in this clients' Charter. The performance will be monitored through the use of internal systems including auditing, review of complaints and special M&E tools. We will promptly implement measures to improve our services when opportunities to improve are identified.

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 essential 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 need arise. The review will take into consideration the following:

a. Monitoring and evaluation of results;
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.

BUSINESS HOURS

Rwanda FDA offices will be open for our clients and stakeholders from 07:00 to 05:00pm, Monday to Friday except officially recognized public holidays.

CLIENT'S FEEDBACK AND COMPLAINTS HANDLING

Rwanda FDA is committed to improve 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 emails addresses, verbal conversations, letters, hotline number (toll free), telephones or social media platforms. Filling of the Customer/Client complaint form No: QMS/FOM/052 will also be accepted through our ways of communication and considered. All complaints and suggestions will be taken seriously and dealt with as quickly as possible.

HOW TO CONTACT RWANDA FDA

All Rwanda FDA customers are eligible to the services that we offer. Clients are advised to submit their comments, opinions, suggestions, complaints, concerns or advice on the services we offer. By doing this, The Authority will be informed, take necessary actions needed and

contribute towards protection of public health which is basically the responsibility of all of us. Clients can contact Rwanda FDA by letter, phone, email, social media, through the following addresses:

Director General
Rwanda Food and Drugs Authority (Rwanda FDA)
Physical address: Nyarutarama Plaza, KG 9 Ave
P. Box: 1948 Kigali
Tel: 0789193529
Twitter account: @RwandaFDA
Facebook account: Rwanda Food and Drugs Authority
Email: info@rwandafda.gov.rw, secretariat@rwandafda.gov.rw
Website: rwandafda.gov.rw

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