



RWANDA FDA CODE OF CONDUCT

RWANDA FDA
Rwanda Food and Drugs Authority

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a public institution established by the law No 003/2018 of 09/02/2018 with clear mandate to protect public health by regulating the use of human and veterinary medicines, vaccines and others biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco, tobacco products and regulate clinical trials. This requires a well-equipped skilled staff for regulatory compliance.

Maintaining high ethical standards within Rwanda FDA, its customers, suppliers, and the general public is vital to our continuous success wherever we operate. In order to ensure access to quality safety and efficacious regulated products, Rwanda FDA needs to:

- a) assure the highest personal standards of integrity, honesty and independence;
- b) foster the spirit of loyalty and commitment of staff members to the goals of the Authority;
- c) assure impartiality and discretion to applicants and;
- d) develop public confidence in the transparency of or the Authority's processes.

To be effective towards this target, the work of Rwanda FDA must be perceived to be objective and independent and performed by irreproachable personnel who observe principles of high level of integrity, objectivity, transparency and respect of others.

From that background, Rwanda FDA has developed this Code of Conduct that sets the principles to be applied to all Rwanda FDA staff everywhere and in any circumstance. It is important that its content is well known and understood by every specific Rwanda FDA staff member and partners. It highlights responsibility, as a group and as individuals, to implement and protect the core values and ethical standards in the way we operate in Rwanda FDA.

Dr. Emile BIENVENU
Director General

F. Coly
28/01/2022



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ABBREVIATIONS AND DEFINITIONS

Abbreviations

MAN	Manual
ISO	International organization for standardization
Rwanda FDA	Rwanda Food and Drugs Authority
SOP	Standard Operating Procedure
QMS	Quality Management Systems

Definitions

“**Code**”: A course or principle of actions adopted or proposed by an organization. Policies and rules, principles, guidelines of frameworks that are adopted or designed by the Authority to achieve set goals.

“**Conduct**”: a behavior, attitude and/or character exhibited by any personnel within and outside the working environment. The standards of conduct generally required for any personnel of the Authority in terms of excellence, selflessness, competence, integrity, impartiality, fairness, and honesty in matters affecting work and status in society.

“**Misconduct**”: any act or omission by any personnel of the Authority without reasonable cause which:

- amounts to a failure to perform in a proper manner any duty imposed on him/her or; contravenes any enactment relating to the Rwanda FDA and its services generally; is otherwise prejudicial to the efficient conduct of functions of Rwanda FDA; and,
- tends to bring Rwanda FDA and its services as a whole into disrepute, for example conviction, fraud, dishonesty or moral turpitude.

“**Advantage**”: includes gift, loan, reward, commission, employment or contract, service or favour and exercise of right or power.

“**Confidential Information**” is all information or material that has or could have commercial value or other utility in the business in which Disclosing Party (Herein referred to as Authority’s clients or suppliers) is engaged.

“**Classified Information**”: includes information marked or determined as “top secret”, “secret”, “confidential” unauthorized person may cause harm to the nation or institution.

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“Conflict of Interest”: refers to a situation in which the Authority personal benefit or interest conflicts with or is likely to conflict with the functions under his/her official capacity.

“Confidentiality” refers to a set of rules or a promise that limits access or places restrictions on certain types of information.

“Gift”: something of value given without the expectation of receiving something in return.

“Non-Public Information”: information that the Authority personnel gains by reason of the Rwanda FDA employment and which the Rwanda FDA personnel knows or reasonably ought to know has not been made available to the general public nor has been authorized to be made available to the public on request.

“Private Interest”: is a financial or other interest of the Authority personnel and those of:

- family members, relatives;
- personal friends;
- clubs and associations; and,
- Persons to whom the personnel of the Authority owe a favor or is obligated.

“Professionalism”: high standard (performance) expected from a person well trained in a particular job.

“Unethical Conduct”: Any serious act, omission or intention which is contrary to Rwanda FDA’s policies, operating procedures, or the code is illegal, unethical, and immoral with serious or negative implications for the public interest and the integrity of Rwanda FDA.

“Personnel”: For the purpose of this code, personnel mean any staff, board member, expert committee member, contractor, consultant, or any other person who is engaged with Rwanda FDA in order to execute the Authority mandate

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1. INTRODUCTION

1.1. Rwanda FDA Mandate, Vision, Mission and Core values

1.1.1. Mandate

Rwanda FDA hereafter designated as the “Authority”, was established by law N° 003/2018 of 09/02/2018 determining its mission, organization and functioning. The mandate of the Authority is to protect public health through regulation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products.

1.1.2. Vision

A world class regulatory Authority effectively protecting and promoting public health.

1.1.3. 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.

1.1.4. Core Values

The conduct and performance of the Authority is underpinned by the following five core values:

Serving with **Professionalism** for excellent service delivery,

Continuously work with **Integrity**,

Promoting **Accountability** at all times,

Nurturing **Teamwork** to achieve common objectives,

Striving for **Innovation** to create value for our stakeholder and other interested parties.

1.2. Quality policy

The Authority is committed to providing the highest standard of quality regulatory services that meet customer requirements by implementation of a quality management system that complies with the requirements of ISO 9001:2015 standards.

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This is achieved through assessment and registration, inspection and licensing, control of imports and exports, pharmacovigilance, post marketing surveillance, clinical trial, control of promotional materials and advertisements, laboratory testing and enforcement.

The Authority therefore, commits for adequate financial, human, physical and technological resources for implementing, maintaining and continually improving the quality management system to achieve set quality objectives; and maintain an adequate workforce that is trained, motivated, facilitated and empowered to achieve intended results.

1.3. Purpose

The purpose of this Code of Conduct describes ethical principles of the personnel of the Authority in providing services and guidance in decision-making. All employees are expected to become familiar and in compliance with the Authority's Code of Conducts in their daily work.

1.4. Scope

This code applies to all employees and contractors of the Authority. Contractors include any consultants, suppliers and vendors who have access to Rwanda FDA's confidential and proprietary information in order to perform their duties.

1.5. Responsibilities

Every personnel of the Authority has overall responsibility for implementation of this Code in order to avoid misconduct, assuring ethical behavior within the Authority and ensure a suitable and friendly working environment.

Heads of Departments, Division Managers and Directors in collaboration with the Director of Administration and Human Resources are responsible to guide and remind the personnel to comply with this Code to avoid any misconduct in services delivery.

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2. CODE OF CONDUCT PROCEDURES

2.1. Identification of Potential professional ethics

The personnel of the Authority must protect and preserve the rights of the clients and obligate themselves to maintain moral principles for intercultural interaction at all locations of the Authority.

The personnel must consider the diversity and the various cultural backgrounds that the employees contribute to Rwanda FDA, because they promote innovative power, creativity, tolerance and community within Rwanda FDA, and last but not least an understanding of the requirements and concerns of our international and national customers.

The personnel must therefore not tolerate any kind of discrimination in the institution. The Authority expects that all employees in all locations of the Authority interact in a respectful manner. We comply with applicable laws and regulations on working conditions.

2.2. Responsibilities to report unethical conducts

Everybody at Rwanda FDA is required to report any known or suspected unethical conduct, which includes any violation of this Code by other employees or anyone in any way associated with the organization. The Authority is committed to protect all employees who report unethical conduct from reprisal as well as offering any necessary support to individuals who make reports. When an employee makes a report of unethical conduct he/she should do so in good faith and with evidence.

2.3. Guidance on Confidentiality

In the course of discharging regulatory functions, staff members, experts, contractors and other concerned persons will gain access to certain information, which is proprietary to the Authority or its collaborating entities, including the regulated industry. They undertake to treat such information (hereinafter referred to as “Confidential Information”) as confidential and proprietary to Rwanda FDA or its aforesaid collaborating parties.

The access to information within the stakeholders, shall be balanced by the rules of professional secrecy for Rwanda FDA personnel and other concerned persons with respect to laws on the protection of commercially confidential data received and stored for regulatory purpose.

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Members of the Board of Directors, members of advisory committees, experts and Rwanda FDA staff members must treat information on the Rwanda FDA related work with the utmost discretion and confidentiality.

Therefore, they shall be required to complete and submit the confidentiality agreement form No QMS/FOM/003 and shall be bound by this confidentiality undertaking throughout his/her service period in order to:

- a) protect personal data and respect confidential information.
- b) exercise care when answering questions so as not to supply information to third parties regarding specific products where this information is not public;

2.4. Disclosure to the media

If a personnel of the Authority is delegated to speak on behalf of the institution, he/she will be briefed prior to being interviewed and will review what is, and what is not public information. He/she is required to seek information on the topic he/she will talk about and be informed. She or he is also expected to uphold the reputation of the Authority and avoid derogating from his or her delegations.

2.5. Conduct when representing Rwanda FDA

Rwanda FDA personnel shall behave professionally with personal integrity within or outside the workplace by reflecting institution's values. They shall communicate and negotiate with honesty with other employees, customers, development partners, stakeholders, suppliers, associates and other members of the public.

2.6. Legal and social responsibility

Rwanda FDA personnel shall ensure that their actions comply with all applicable laws and regulations especially laws on Leadership code of conduct as the Presidential Order governing the public servants and, are free from suspicion, criticism and have no unfavorable effects on society.

2.7. Corporate Information

The disclosure of information about the Authority to non-authorized persons within or outside the institution is not allowed unless in accordance with the approval of Competent Authority. The Authority personnel is not allowed to discuss or disclose confidential customer's information outside or inside the workplace.

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2.8. Registered Information

Every employee of the Authority shall ensure that information contained in the public registries of the institution is used according to the appropriate policies and laws. All information shall not be used for purposes other than conducting Rwanda FDA mission.

2.9. Computer systems and software

Computer systems and software form the backbone of registry services and operations infrastructure. Every effort should be made to protect the Authority 's computer systems and associated software from various threats to their security such as accidental or deliberate destruction of data or equipment, interruption of service, disclosure of confidential information, theft or corruption of data. Any security concerns with respect to the systems or software, or any virus or data network attack, weakness or unexplained system change should immediately be reported to the Authority.

2.10. Corporate property

Corporate property includes, but is not limited to: premises, equipment, supplies, furnishings, accounts, funds, reports, records, vehicles, customers' information, computer software, hardware and networks, internet accounts and intangible items such as the details of application systems. Rwanda FDA's physical property and revenues shall be protected.

Corporate property under Rwanda FDA control shall be used in accordance with Rwanda FDA's acceptable uses and procedures, and protected from unauthorized persons. Employees are responsible for ensuring that Rwanda FDA's assets are properly used and not utilized for personal purposes, unless otherwise authorized.

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3. WORK ENVIRONMENT

3.1. Employee Professionalism

All employees should commit to support a safe, healthy and positive workplace for everyone. Rwanda FDA will not tolerate any behavior that interferes with employees' ability to perform their duties. The use or effects of alcohol or illegal drugs are not acceptable in a working environment.

3.2. Equity

Rwanda FDA personnel shall respect the rights, culture and dignity of all individuals and adhere to the principles of equity and non-discrimination when dealing with employees, customers, suppliers and others. Rwanda FDA will not tolerate any form of discrimination or harassment, in accordance with applicable laws and regulations of Rwanda.

3.3. Employee privacy

All employees are committed to protect the privacy of employees' personal information. Employees' personal information will not be collected, used or disclosed other than as authorized or as required for Rwanda FDA's service reasons.



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4. CONFLICT OF INTEREST

4.1. Introduction

Rwanda FDA personnel is required to conduct regulatory activities in a manner that will assure independence from outside influence and interest, which would otherwise compromise his/her ability to render a fair and impartial opinion regarding any regulatory activity conducted.

They are prohibited to get involved in circumstances or activities (social, professional or financial etc.) that can influence them to make a decision because of the potential to gain power, prestige, or money, or to favor any other person.

Every employee must not engage in any activities which could give rise to, or could be perceived to give rise to conflict of interest. As employees, managers, executives and members of the Board of Directors, the business loyalty remains in place of Rwanda FDA's interests, including those of its customers and stakeholders before the personal interests.

A “conflict of interest” arises in a situation where personal activities, interests or dealings may actually, potentially or be perceived to:

- impair her/his ability to perform her/his duties;
- have a negative impact on Rwanda FDA’s reputation; or
- result in a personal gain or advantage due to her/his position in Rwanda FDA.

Employees must not use their positions to influence or bypass Rwanda FDA procedures neither for personal gain nor for the interests of a family member, friend, colleague or anyone else.

4.2. Avoidance of conflicts of interests

If a personnel becomes aware or in doubt of accuracy of a conflict of interest might exist, he/she seeks clarification and guidance from Rwanda FDA leadership through immediate supervisor before proceeding or, if the activity has commenced, immediately cease the activity and disclose it by completing the occasional declaration of interest form as stated in SOP on Managing of Conflict of Interests and Impartiality QMS/SOP/035.

4.3. Outside activities, employment and business involvement

An employee may take outside employment, directorships or volunteer positions or engage in outside business or other activities unless such activities:

- create a real, potential or perceived conflict with Rwanda FDA’s interests;

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- interfere with the performance of his/her duties or which adversely affects his/her performance at work;
- intrude on the time, attention and energies normally applied to Rwanda FDA; or
- are forbidden by law or involve any unethical or immoral conduct.

An employee may **not** receive a financial benefit from an individual or organization doing business with Rwanda FDA when he/she is in a position to influence Rwanda FDA's decisions pertaining to that individual or organization. None is allowed to provide preferential treatment on any Rwanda FDA activities or transactions to family members, friends or any organizations which may be perceived to have a conflictual relationship with him/her.

Unless otherwise authorized, employees must not:

- either directly, or indirectly, through immediate families, have a financial or other interest in any concern doing business with Rwanda FDA or otherwise derive any benefit from a business transaction (other than employment or use of the registry services as a customer) with Rwanda FDA;
- participate in any outside activity which competes directly or indirectly with Rwanda FDA;
- act in the capacity of a director, officer, partner, consultant, employee or agent for any supplier, contractor, subcontractor, customer or competitor of Rwanda FDA;
- enter into business relationships on behalf of Rwanda FDA with relatives, close friends or any company controlled by such persons;
- convey to others or use for her/his benefit, non-public information acquired during her/his employment; and
- sell anything to Rwanda FDA.

4.4. Involvement in political activity

Employees may participate in the political processes at any level of government providing that their involvement does not interfere with their work or the effectiveness of their position. Rwanda FDA personnel members shall ensure that any political activity does not place them in a conflict of interest situation with Rwanda FDA.

4.5. Gift Acceptance

Gifts or benefits of any kind must not be given or received by an employee or his/her immediate family, when it might be perceived that an obligation is created or a favor is expected. The giving and receiving of gifts and promotional items of modest value is acceptable as reasonable entertainment within the limits of generally accepted business practices.

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4.6. Payments to Agents, Consultants, Government Officials and Others

Payments of any nature, which would be in violation of any law, are prohibited. All payments of commissions and fees shall be in accordance with sound services practices.

Payments, gifts or favors must not be made to any person with intent to induce him/her to violate his/her duties or to obtain favorable treatment for employee or Rwanda FDA.

4.7. Reporting and investigations

With reference to the Presidential Order N° 021/01 of 24/02/2021 determining professional ethics for public servants, the internal disciplinary committee of Rwanda FDA is responsible for jointly leading all internal investigations into real or suspected unethical conduct or violation of the code of conduct at Rwanda FDA except those involving the Director General and members of Board of Directors.

Upon completion of the investigation, the internal disciplinary committee will provide a report of the findings to the Office of Director General with a proposed appropriate decision in compliance with the Presidential Order N° 021/01 of 24/02/2021. When making a report, the committee should try to include or be able to provide the following information:

- the details of the situation, the person(s) involved, how frequent the unethical conduct or violation of code has occurred or is still occurring,
- any other avenues taken to prevent and correct the concern.

4.8. Protection from Retaliation/Revenge

Rwanda FDA employees who report unethical conduct or violation of this Code are protected from reprisal/revenge. Any reprisal or attempted reprisal against an employee who makes a report in accordance with the Code is considered to be in breach of the Code.

Rwanda FDA employees who feel that they have been discriminated as a result of reporting unethical conduct or violation of the code should report the discriminatory actions directly to the Director General of Rwanda FDA or to the Board of Directors.

4.9. Adherence to guiding principles of public life

The personnel of Rwanda FDA shall adhere to the following principles:

- **Selflessness:** A personnel of Rwanda FDA shall take decisions exclusively in the interest of the public and not to gain financial or other material benefits for him/herself, family or friends.

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- **Integrity:** A personnel of Rwanda FDA shall not place him/herself under any financial or other obligation to any individual or organizations that might influence him/her in the performance of his/her official duties.
- **Justice and Fairness:** In carrying out official services, including making appointments, promotions, awarding contracts, or recommending individuals for rewards and benefits etc., Rwanda FDA personnel shall make choices based solely on merit.
- **Accountability:** A personnel of Rwanda FDA shall be responsible to Rwanda FDA, the country and the public in general for his/her decisions, actions and inactions, and shall submit him/herself to scrutiny, where appropriate.
- **Transparency:** A personnel of Rwanda FDA shall be as open as possible about all the decision-making processes and actions thereon. He/she shall restrict access to information unless appropriate approval is obtained.
- **Excellence:** A personnel of Rwanda FDA shall strive to excel in his/her endeavors, be an example to others and encourage others to follow his/her footsteps



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5. REFERENCES

- Presidential Order No 021/01 of 24/02/2021 determining professional ethics for public servant and Law No 66/2018 of 30/08/2018 regulating labor in Rwanda;
- Presidential Order N°45/01 Of 30/06/2015 Establishing The Code of Professional Ethics for Public Servants;
- Law No 62/2018 of 25/08/2018 Governing Public Procurement;
- Law No 003/2018 of 09/02/202018 Establishing Rwanda Food and Drugs Authority and determining its Mission, Organization and Function.
- Law No 54/2018 of 13/08/2018 on Fighting Against Corruption
- Rwanda FDA Quality Manual No QMS/MAN/002

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