ASSESSING THE CAPACITY OF RWANDA FDA IN ENSURING THE QUALITY OF MEDICINES IN RWANDA.

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"A Dissertation *submitted in partial fulfilment* of the Requirements for the Award of the Degree of *Master of Health Supply Chain Management in the School of Public Health of the University of Rwanda"*

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DECLARATION

I declare that this dissertation is my original work and has not been submitted for a degree at any other University. It has been verified and passed via the anti-plagiarism system and it is compliant. It contains my work, except where it is specifically acknowledged.

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ABSTRACT

Background- Several studies have shown that measures put in place to ensure the quality of medicines in the health supply chains of the low and middle-income countries (LMICs) are not sufficient. National Medicines Regulatory Authorities (NMRAs) in LMICs have limited capacity to prevent and detect the supply of poor-quality medicines. Therefore, this study was designed to assess the capacity of Rwanda FDA to ensure the quality of medicines in Rwanda.

The objective- This study aimed to assess the capacity of Rwanda FDA, (the national medicine regulatory authority in Rwanda) to identify gaps and existing opportunities for improving regulatory capacity and ensuring the quality of medicines in Rwanda.

Methods-The study design and approach used is descriptive and cross-sectional. Both quantitative and qualitative approaches were used. The Quantitative research used a selfadministered questionnaire while the qualitative research approach covered a desk review of key regulatory documents including policies, laws, regulations, guidelines, procedures, reports and lists of registered products, a list of published licensed premises. The data collection tool was developed based on the World Health Organization (WHO) Global Benchmarking Tool (GBT) for "Evaluation of National Regulatory System of Medical Products Revision VI".

Results-The findings of this study showed that among 251 sub-indicators assessed; 179 subindicators (71%) were scored as implemented, 17 sub-indicators (7%) were scored as partially implemented, 9 sub-indicators (4%) were scored as ongoing implementation while 46 sub-indicators (18%) were scored as not implemented. The findings of the present study also showed the overall sub-indicators implementation percentage of 71% (179/251).
26 (96%) out of 27 sub-indicators implemented were at maturity level 1; 27 (93%) out of 29 sub-indicators implemented were at maturity level 2; 121 (86%) out of 141 sub-indicators implemented were at maturity level 3 and 5 (9%) out of 54 sub-indicators implemented were at maturity level 4. The findings of the study showed that the estimated maturity level at which Rwanda FDA operates is maturity level 2.

Conclusions-The results showed that all key regulatory functions which are Registration and Marketing Authorization, Vigilance, Market Surveillance and Control, Licensing Establishments, Regulatory Inspection, Laboratory Testing and Clinical Trials Oversight were addressed. The legal framework was in place to enable effective and efficient implementation of the key regulatory functions. The legal framework provides adequate powers to the Rwanda FDA to ensure the quality, safety and efficacy of medicines on the market. The scope of products to be regulated is well defined. However, the implementation of key regulatory functions faced challenges that need to be addressed. Therefore, recommendations implementation to address challenges are needed by each department/division/unit of the Rwanda FDA.

Keywords: poor-quality medicines, falsified medicines, substandard medicines, medicines regulatory practices, health supply chain, Rwanda FDA.

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LIST OF ABBREVIATIONS AND ACRONYMS

GBT: Global Benchmarking Tool

GMP: Good Manufacturing Practices

GoR: Government of Rwanda **LI:**

Licensing Establishments

LMICs: Low and Middle-Income Countries

MA: Marketing authorization

MC: Market Surveillance and Control

NMRA: National Medicine Regulatory Authority

PV: Pharmacovigilance

SF: Substandard and Falsified

QC Laboratory: Quality Control Laboratory

QMS: Quality Management Systems

RI: Regulatory Inspection

RS: Regulatory System

SOP: Standard Operating Procedure

VL: Vigilance

Rwanda FDA: Rwanda Food and Drugs Authority

WHO: World Health Organization

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CHAPTER ONE: INTRODUCTION

I.1 Background to the study

Nowadays, the fast-paced health supply chain management is facing the challenge of predominant poor-quality medicines namely substandard and falsified (SF) medicines in the legal supply chain, especially in poor-resource countries (1).

Weak capacity of medicines regulatory authorities to perform key regulatory functions and lack of political will to support medicines regulatory functions by governments have been associated with factors enhancing the infiltration of SF medicines in the legal health supply chain in the low and middle-income (LMICs) countries; SF medicines can also be found in developed countries even though their percentage is very low and they mainly enter the healthcare supply chain, especially through online pharmacy practices (2).

Most research related to the quality of medicines focused more on the prevalence and socialeconomic impacts of SF medicines in the healthcare supply chain of low and middle-income countries. For instance, Ozawa et al., (2018) systematically reviewed 265 studies containing 400, 647 medicine samples and conducted a meta-analysis of ninety-six (96) studies having 67 839 medicine samples. Ozawa and colleagues found the overall prevalence of SF medicines of 13.6% with a regional prevalence of 18.7% and 13.7% medicines in Africa and Asia respectively. They concluded that the SF medicines were the under-researched problem with huge economic impact and the existing literature are not evenly distributed in terms of quality (3).

Very few studies conducted an assessment of the performance of National Medicines Regulatory Authorities (NMRAs). For example, Ndomondo-Sigonda, M., et al. (2017) carried out the study to inform the current status, future actions and recommendations for medicines regulatory framework in Africa. Ndomondo-Sigonda and colleagues found that all countries in Africa have an established NMRA with an exception of one country, the Sahrawi Republic. The findings of the study revealed that no NMRA can perform the full range of key regulatory functions. The observed weaknesses in almost all countries were associated with not only limited resources to ensure the quality of medicines in their healthcare supply chain but also with a limited capacity of

the national medicine regulatory authority in terms of human resources, financial support and weak technical capacity and tools. They concluded that the harmonization program of NMRAs in East Africa is an opportunity to cope with the high prevalence of SF medicines in Africa (4).

The presence of SF medicines was reported in almost all East African Countries. The study conducted by Mawien Arik et al. (2020) found that almost all countries in East African Community reported to World Health Organization (WHO) the incidence of SF medicines in their supply chain. They also concluded that the harmonization of NMRAs is an opportunity to cope with the high prevalence of SF medicines in the region (5).

In this study, we will review the practices of seven core regulatory functions that include medicines registration, establishments licensing, import and export control, regulatory inspections, laboratory testing for medicine quality control, market surveillance and clinical trials oversight to assess the capacity of Rwanda FDA to ensure the quality of medicines in Rwanda. In addition to this, the regulatory framework of Rwanda FDA was assessed.

I.1.1 Medicines registration and marketing authorization (MA)

The registration of medicines is one of the key functions played by any NMRA to ensure that medicines with quality assured, safe and efficacious is on the market. These practices required an NMRA to have transparent legal provisions, regulations, guidelines, standard operating procedures adequate funding, political will and sufficient competent personnel. Failure to have in place all the requirements to perform medicines evaluation and assessment process results in the supply chain filled with SF medicines (6).

I.1.2 Licensing establishments

Licensing of private and public manufacturers, wholesalers, retailer sellers, importers and exporters require a technical and financial capacity of any NMRA to ensure that medicines conform with the quality standards until they reach the end-users. The licensing shall be

accompanied by inspections and market surveillance to enforce compliance and cope with poor-quality medicines in the legal health supply chain (6).

I.1.3 Import and export control

The practices of import and export control of medicines shall imply that each import/export act be subjected to an import/export license issued by NMRA based on the registration status to ensure that only medicines of quality-assured, safe and efficacious are imported/exported. The Import and export control practices shall be strengthened through physical inspection and other SF medicines screening technologies for all imported products at each port of entry to protect public health from SF medicines (6).

I.1.4 Regulatory inspections

Regulatory inspection is a key regulatory function in any NMRA because it reveals deficiencies and potential errors in the manufacturing process, quality control, storage and distribution of medicines. Therefore, an inspection is a key regulatory function to ensure the quality, safety and efficacy of medicines throughout the healthcare supply chain. To be effective and efficient, qualified inspectors are needed and inspection need to be well coordinated among all key stakeholders (6).

I.1.5 Laboratory testing for medicine quality control

To ensure that the medicines comply with the specifications provided in the product dossier submitted during the registration; the quality control (QC) laboratory shall have sufficient qualified personnel, required equipment and materials shall be in place as well as quality management system. This will help the QC laboratory to identify SF medicines before they reach the end-users (6).

QC Laboratory plays an important role to ensure the quality of medicines in the supply chain by performing quality control tests of sampled medicines based on quality risk-based approaches

during the post-marketing surveillance activities. Laboratory test results guide the NMRA to take regulatory actions against the identified SF medicines (6).

I.1.6 Market surveillance

SF medicines may circulate on the market if good manufacturing practices, good storage and distribution practices are not complied with. To cope with this challenge, there shall be in place a well-established system of inspection that consider a risk-based approach. All parties involved shall be obliged to report medicines quality issues to NMRA. An effective mechanism to remove the poor quality products from the market shall be established. This will require good coordination among all key stakeholders (6).

I.1.7 Oversight of clinical trials

Clinical trial oversight is a key regulatory function to ensure that trials comply with ethical principles. Good Laboratory Practices (GLP) and Good Clinical Practices (GCP) shall be enforced according to quality standards to ensure that quality medicines reach the patient
(6).

I.1.8 Legal framework and financing of Rwanda FDA

NMRAs can fully perform their mandate to ensure the quality-assured medicines in their market if they are administratively, technically and financially autonomous bodies, which makes it easier for them to strengthen the regulatory system (6).

I.1.9 The situation of SF medicines in Rwanda from 2018 to 2021

To prevent and combat SF medicines in the Rwandan health supply chain; the Government of Rwanda (GoR) in 2018 established Rwanda Food and Drugs Authority “Rwanda FDA” as a medicine regulatory authority with the following main scope of regulatory functions: Premises licensing and inspection, medicines evaluation and registration, import and export control, good

manufacturing practices (GMP) inspection of manufacturers of regulated products, vigilance and safety monitoring and clinical trials oversight (7).

The establishment of the Rwanda FDA has revealed the existence of poor-quality medicines on the market. For instance, from 2018 to October 2021, a number of 98 batches of medicines were reported over quality issues and they have been incriminated and recalled for disposal (8).
The challenge of the presence of poor-quality medicines in the Rwandan health supply chain includes deciding how Rwanda FDA shall enforce the regulatory functions to cope with key barriers to quality medicines since almost all medicines used in Rwanda are imported (8).

The establishment of any NMRA is effective only if accompanied by knowledgeable and skilled personnel, clear laws and practices, guidelines and policies, effective technical, financing support and well-functioning quality control (2).

Knowing that there exists limited literature on the practices of national medicines authority of poor countries, it was important to assess the capacity of Rwanda FDA to perform the core regulatory functions. This study aimed to fill this knowledge gap and identify important challenges and opportunities a country has to face to ensure equal access, availability, affordability of quality medical products.

I.2 Problem Statement

Poor-quality medicines are a major concern and threat to public health. The prevalence of poor-quality medicines was reported to be high in the developing world compared to the developed world. For instance, according to the report of the World Health Organization (WHO) of 2017 on global monitoring of medicines quality in the health supply chain; one out of ten medicines in developing countries were of poor quality either substandard or falsified (2).

A study by Mackey, (2018) found that the reported rate of 1 in 10 of medicines in LMICs to be SF medicines cannot be relied upon because it has notable limitations such as low reporting rate, inconsistency in sampling methods, and variability in the type and quality of product testing. The

study recommended further research on medicines quality in different countries and an appeal to the global community to invest in SF medicines research, as this area is understudied (9).

The presence of SF medicines in the legal health supply chain leads to antimicrobial resistance which disturbs the standard treatment guidelines and treatment protocols set by different governments, reduces the public trust in health systems, regulatory bodies, and healthcare providers (2).

The use of poor-quality medicines by the public increases costs for both clients and health systems; this leads to the waste of limited resources, a decrease in economic growth due to prolonged illness and death of people, reduced sales and taxes, and an increase in costs associated with interventions and initiatives in place to cope with consequences caused by poor-quality medicines (2).

A study conducted by Ndomondo-Sigonda, M., et al. (2017) to assess the regulatory capacity of twenty-six African countries found that all countries assessed lacked the capacity to ensure the quality of medicines in their supply chain. Ndomondo-Sigonda, M. and colleagues highlighted the areas that need improvement which include training of personnel, financial management and other technical capacities to ensure the quality of medicines (4).

A study conducted by Roth L, Biggs KB, Bempong DK, (2019) identified weakness of NMRA, lack of screening technologies for SF medicines, weak technical capacity, poor medicine governance, and poor health supply chain management as the main causes leading to the penetration of SF medicines in the legal health supply chain in low-income countries
(10).

A study conducted by Khurelbat and Colleagues, (2020) in Mongolia found the prevalence of SF medicines of 5.9% and 4.17 % for locally produced and imported medicines respectively. This same study concluded that remarkable efforts are needed to strengthen the technical and financial capacity of NMRAs, to ensure the control of importers and exporters, to conduct inspections of good manufacturing practices of manufacturing facilities to increase the quality of medicines (1).

In line with the goals and objectives of its fourth Health Sector Strategic Plan 2018 -2024 (HSSP4) (11), the GoR through its Ministry of Health has recently established a semiautonomous Medicines Regulatory Authority (Rwanda FDA) with the mandate to protect public health from defective and SF medicines through transparent regulation of medicines and vaccines entering the supply chain (7).

However, we have limited information and evidence about the capacities of Rwanda FDA to exercise its mandate and functions. Therefore, this study aimed to assess the capacities and challenges faced by the Rwanda FDA in ensuring the quality of medicines in the Rwandan healthcare supply chain. Specifically, this study aimed to shed light on the regulatory capacity of the Rwanda FDA and propose priority actions to further strengthen its regulatory capacities.

The above-stated concerns and challenges constituted the motivation for us to conduct a study aiming at assessing the capacity of Rwanda FDA in ensuring the quality of medicines in Rwanda.

I.3 Research Objectives

I.3. 1 General Objective

This study aimed to assess the capacity and challenges of Rwanda FDA in ensuring the quality of medicines in Rwanda.

I.3.2 Specific Objectives

The present study was guided by the specific objectives below:

- To assess the regulatory framework supporting the functioning of Rwanda FDA
- To assess the practices of medicines registration and marketing authorization (MA) in Rwanda FDA
- To assess the practices of vigilance system in Rwanda FDA
- To assess the practice of Market Surveillance and Control

- To assess the practices of licensing establishments in Rwanda FDA.
- To assess the practices of regulatory inspections in Rwanda FDA.
- To assess the practices of laboratory testing for medicine quality control in Rwanda FDA - To assess the practices of oversight of clinical trials in Rwanda FDA

I.4 Research questions

To achieve the aim of this study the following research questions were answered:

- How effective and efficient is the regulatory framework supporting the functioning of the Rwanda FDA?
- How effective/efficient are Rwanda FDA practices regarding registration and marketing authorization?
- How effective/efficient are Rwanda FDA practices regarding the vigilance system?
- How effective/efficient are Rwanda FDA practices regarding Market Surveillance and Control?
- How effective and efficient are Rwanda FDA practices regarding the licensing of regulated establishments?
- How effective and efficient are Rwanda FDA practices regarding the regulatory inspections?
- How effective and efficient are Rwanda FDA practices regarding the quality control laboratory?
- How effective and efficient are Rwanda FDA practices of oversight of clinical trials?

I.5 Significance and anticipated output

This study was significant because it is the population's right to access quality health services and quality-assured medicines with approved safety and efficacy at an affordable price to both health systems and clients (2). To our knowledge, no prior research was conducted to assess the capacities and challenges of the FDA in Rwanda to which the researcher will refer.

The results of this study will improve the functioning and capacity of Rwanda FDA because it will equip the regulatory authority with materials and guidance to effectively perform its daily regulatory functions and it will be instructive to medicines regulatory agencies of the developing world because once gaps and weaknesses are identified, appropriate actions and recommendations will be proposed to ensure the availability of quality medicines to the population.

The results of this study are expected to contribute to the literature by identifying key gaps and challenges faced by NMRAs in ensuring the quality of medicines, which will help policy decision-makers to focus on the priorities areas and gaps in planning future regulatory functions.

Upon completion of the present study, the Rwandan population will benefit from it later on by accessing medicines quality medicines after the implementation of proposed actions and recommendations. The findings will also be useful for further research projects in the scope of quality of medicines.

I.6 Limitations of the study

To our knowledge, there are no prior research studies related to the capacity of medicine regulatory authority in Rwanda to which the researcher referred to.

In addition to this, the study provided the general overview of the capacity of Rwanda FDA and did not go into deep for each regulatory function.

CHAPTER TWO: LITERATURE REVIEW

2.0 Introduction

This chapter focused on the review of the existing literature, both published and grey literature, including textbooks and documents related to the prevalence of poor-quality medicines in the healthcare supply chain system. This chapter comprises an overview of the topic, empirical literature review, a summary of the literature review, conceptual framework and rating scale of the World Health Organization to assess the capacity of NMRAs.

2.1 Overview of the topic and definitions of keywords

Poor-quality medicines namely substandard and falsified medicines are a global public health concern and pose a serious problem in many countries and especially in developing countries. This is because poor countries do not possess the technical and financial capacities to regulate and control medicines entering their national health supply chain (12).

Poor-quality medicines refer to medicines that fail to meet established standards of the national medicines regulatory authority (2).

Substandard medicines also called "out of specification"; refer to authorized medicines that fail to meet specifications stated in recognized compendia or the manufacturer's approved product dossier submitted for registration (2).

Falsified medicines refer to unauthorized medicines that deliberately/fraudulently misrepresent their identity, composition or source (2).

Medicines Regulatory Authority refers to an essential component of any resilient health system and a critical enabler toward achieving quality medicines in the legal health supply chain and preventing supply chain vulnerability (6).

Health Supply Chain refers to the system that plans, implements and controls the forward and reverse flows of medicines and health commodities as well as their storage and taking into consideration all information related to the manufacture, import and export, finance and information technology from the point of origin to the consumption point to meet client's requirements (13).

Registered medicines: Registered medicines are medicines that were evaluated for quality, safety and efficacy by NMRA during the medicines registration process (6).

Authorized medicines: These are medicines authorized to be imported into Rwanda. The list was drawn up based on existing medicines on the market during the establishment of the Rwandan FDA to cope with the shortage of medicines that could occur if the Authority banned the importation of all unregistered drugs (14).

2.2 Empirical literature review

Poor-quality medicines are a big challenge in the global public health supply chain of both developed and developing countries (2).

The presence of poor-quality medicines especially SF medicines in low and middle-income countries had been associated with factors such as inadequate funding, lack of qualified personnel, inefficient regulatory systems and frameworks (2).

A weak national medicines regulatory authority has a direct impact on the healthcare system and patient's outcomes. This is because weak medicines regulatory authority contributes to the increase in the prevalence of SF medicines in the health supply chain (3).

Substandard and falsified medicines endanger health, compromise standard treatment protocols of infectious and chronic diseases which are increasing in poor countries, prolong illness, lead to death, promote antimicrobial resistance, and reduce confidence in health professionals and health systems (1).

A study conducted by Ozawa et al., (2018) found the overall prevalence for SF medicines of 13.6% with a regional prevalence of 18.7% and 13.7% in Africa and Asia respectively. This research revealed the reasons for the presence of poor-quality medicines in LMICs to be the weak regulatory capacity to perform its regulatory functions such as licensing manufacturers to ensure good manufacturing practices and quality control systems. This research concluded that poor-quality medicines are still an unstudied problem (3).

Several published literature on the quality of medicines showed low and middle-income countries to have a high rate of SF medicines due to the weak medicines regulatory authority and lack of technical and financial capacities. For instance, the study conducted by Orubu et al. (2018) found that poor-quality medicines are highly prevalent in countries having limited access to essential quality medicines, low priority for SF medicines and weak regulatory capacity. This study recommended LMICs prioritize the quality assurance of medicines and health technologies by equipping regulatory bodies in terms of technical and financial capacity, and increasing technologies for detecting poor-quality medicines (15).

Comparable results to the findings of the study of Orubu et al. were reported by the study conducted by Mackey, (2018) on the prevalence of poor-quality medicines in LMICs revealing a high rate of SF medicines in Africa and Asia where medicines regulatory capacities are limited (9).

Research conducted by Kniazkov and Dube, (2020) on prevention, detection and response to the incidence of SF medicines in Southern African countries found an increased availability of poor-quality medicines in those countries due to deficiencies in terms of medicines registration policies and weak regulatory capacity (16).

Similar results to the study of Kniazkov and Dube were reported by the study conducted by Rasheed et al., (2019) on the regulatory framework in Pakistan that revealed the presence of poor-quality medicines in the legal health supply chain despite the presence of medicines regulatory authority in place. The study of Rasheed et al., (2019) suggested the need for wellfunctioning and stable medicines regulatory authority in LMICs to ensure quality medicines in the health supply chain by strengthening regulatory functions such as good manufacturing practices of manufacturing facilities, import and export control, medicines registration, quality control laboratories as well as training and expertise of staffs performing those regulatory functions (17).

2.3 Summary of literature review

Published literature and reports showed that measures to ensure the quality of medicines in the health supply chains of the low and middle-income countries are weak and LMICs have limited capacity to prevent and detect the supply of poor-quality medicines.

Therefore; stable and well-functioning national medicines regulatory authority is needed to ensure that the practices of Medicines evaluation and registration, licensing of activities and premises, import and export control of medicines, regulatory inspections, laboratory testing, market surveillance, and oversight of clinical trials are implemented countrywide to prevent the harm and consequences that can be caused by poor-quality medicines on both supply and demand sides.

2.4 Conceptual framework

Effective implementation of key medicine regulatory functions is needed to ensure the availability and affordability of quality, safe and efficacious medicines in the legal health supply chain. For instance, the study of Rasheed et al., (2019) found that a well-functioning and stable NMRA shall be in place to ensure quality medicines in the health supply chain by strengthening regulatory functions such as good manufacturing practices of manufacturing facilities, import and export control, medicines registration, quality control laboratories as well as training and expertise of staffs performing those regulatory functions (17).

The quality of medicines relies on the effective and efficient implementation of key regulatory functions of any NMRA. According to WHO, quality of medicines cannot be achieved without a well-functioning NMRA in place to perform key regulatory functions, also factors like the autonomy of the agency, competent human resources, finance, quality management system (QMS) and political will link the implementation of key regulatory functions and availability of quality medicines throughout the supply chain (2).

Therefore, the conceptual framework in this study has been developed based on a literature review of existing studies and theories about the topic. It is formulated as follows: key regulatory functions of a medicines regulatory authority are independent variables whereas the presence of

quality medicines in the health supply chain are dependent variables because it is known from the literature that the effective implementation of medicines regulatory functions is needed to ensure availability and affordability of quality, safe and efficacious medicines in the legal health supply chain. Variables that link independent and dependent variables are called intervening variables or mediating variables for this research they include autonomous of the Rwanda FDA, human resources, finance, quality management system (QMS) and political will.

The conceptual framework of the study was developed based on the existing literature related to the medicine regulatory framework. (2, 17) (See figure 1)

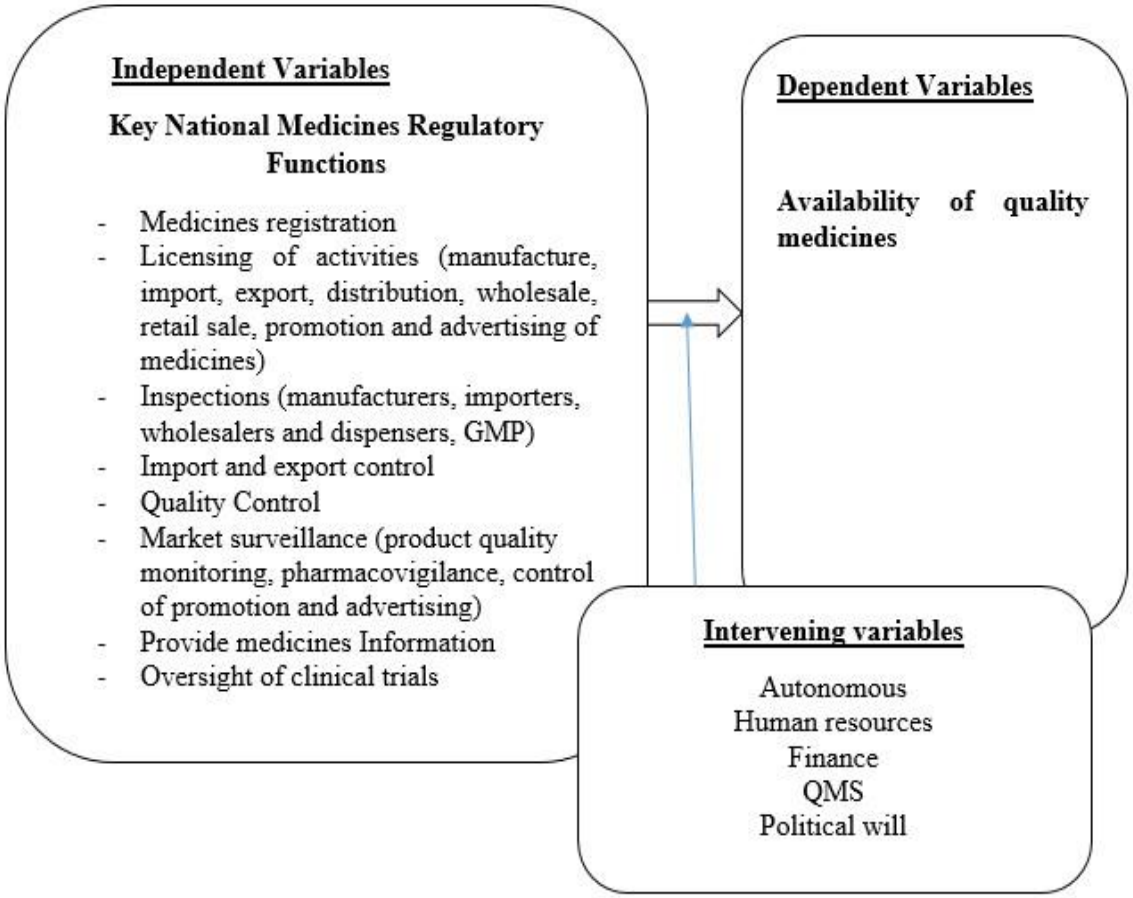

Figure 1: Conceptual framework of the study

2.5 Rating scale of World Health Organization (WHO) to assess the capacity of NMRAs.

To assess the capacity of any NMRA; the WHO uses the Global Benchmarking Tool (GBT) to evaluate the National Regulatory System of Medical Products (6).

The GBT also incorporates the concept of 'maturity level' or ML (adapted from International Organization for Standardization: ISO 9004:2018-Guidance to achieve sustained success) allowing the World Health Organization to assess the overall 'maturity' of the NMRA.
NMRAs can be at different maturity levels (ML): ML1, ML2, ML3 or ML4 (6).

Table 1: WHO-GBT Maturity Level Meaning

Approach/Maturity Level	ISO 9004:2018 Meaning (Approach)	WHO-GBT Meaning (Maturity Level: ML)
1	No formal approach	**ML1**: There is the existence of some elements of the regulatory system.
2	Reactive approach	**ML2**: Evolving National Regulatory System that partially essential regulatory functions.
3	Stable formal system approach	**ML3**: Stable, Well-functioning and integrated regulatory system.
4	Continual improvement emphasized	**ML4**: NMRA is operating at the advanced level of performance and continuous Improvement.

Rating Scale

In assessing the capacity of a national medicines regulatory authority (NMRA), the following rating scale was used (6):

NOT IMPLEMENTED: This means that there is no evidence of the regulatory document/process required.

ONGOING IMPLEMENTATION: This means that the NMRA drafted the regulatory document required or put in place the process required but not yet followed in the implementation

PARTIALLY IMPLEMENTED: This means that the NMRA has the required document/process that has been implemented for less than two years.

IMPLEMENTED: This means that the NMRA has the required document/process in place used for at least two years and it can show the track record of applying it.

WHO Global Benchmarking Tool (GBT) Outline

The tool used to evaluate the capacity of any NMRA has the following features (6)**:**

Table 2: WHO-GBT Outline

Functions	**9 GBT functions** 1. National Regulatory System (RS) 2. Registration and Marketing Authorization (MA 3. Vigilance (VL) 4. Market Surveillance and Control (MC) 5. Licensing Establishments (LI) 6. Regulatory Inspection (RI) 7. Laboratory Testing (LT) 8. Clinical Trials Oversight (CT) 9. NRA Lot Release (LR)
Indicators	**9 indicator categories** 1. Legal provisions, regulations and guidelines 2. Organization and governance 3. Policy and strategic planning 4. Leadership and crisis management 5. Quality and risk management system 6. Resources (Human Resources, Financial Resources, infrastructure and equipment) 7. Regulatory process 8. Transparency, accountability and communication 9. Monitoring progress and assessing outcomes & impact
Sub-indicators	**268 sub-indicators:** That shall be assessed to determine the system maturity level **NB: In this study, only 251 sub-indicators were assessed because Rwanda is not a vaccine-producing country, therefore 17 subindicators of NRA Lot Release (LR) function was not assessed.**

CHAPTER THREE: METHODS

This chapter of the study focused on a brief description of the study area from the research concept perspective, research design and research approach, population and sample design, method of data collection and analysis.

3.1 Research design and Research approach

The study design and approach will be descriptive and cross-sectional, the study used a mixed approach and both quantitative and qualitative combining qualitative and quantitative research components.

The quantitative research used a self-administered questionnaire while the qualitative research approach consisted of a desk review of key regulatory documents including policies, laws, regulations, guidelines, procedures, reports and lists of registered products. The data collection tool was developed from the World Health Organization (WHO) Global Benchmarking Tool (GBT) for "Evaluation of National Regulatory System of Medical Products Revision VI".

3.2 Location of the Study

The research project was conducted in Rwanda Food and Drugs Authority (Rwanda FDA) premises located in Nyarutarama Plaza, KG 9 Avenue, Gasabo District, Kigali City and its quality control laboratory located in Kicukiro District, Kigali City near the building of Rwanda Standard Board at the road KK 15 Rd.

This study location was chosen because Rwanda FDA is the right and competent authority to provide relevant information on quality issues related to medicines and from the findings, appropriate interventions will be taken to prevent the infiltration of poor-quality medicines in Rwanda.

3.3 Study Population

The population in this research was employees of Rwanda FDA who have expertise in medicine regulatory practices based on their roles in ensuring the quality of medicines.

3.3.1 Inclusion criteria

Rwanda FDA staffs from technical departments (registration, inspections and quality control laboratory) engaged in practice aiming to ensure the quality of human medicines, having an experience of more than one year in Rwanda FDA and having a willingness to participate in this study.

3.3.2 Exclusion criteria

Rwanda FDA staffs from technical departments (registration, inspections and quality control laboratory) who were not engaged in practices aiming to ensure the quality of medicines, having an experience of less than one year in Rwanda FDA and without a willingness to participate in this study.

3.4 Sample size

In this research project, the Researcher used a sample size from the target population and it was determined by applying **Yamane's formula**:

$$n = \frac{N}{1 + N * (e)^2}$$

Where **n** is the sample size, **N** is the total target population and **e is the margin of error**. By using the formula above when **e= 0.05 and N=58.**

$$n = \left(\frac{58}{1 + 58 \acute{} 0.05}\right)^2 = 51$$

The sample size of this study was **51 Rwanda FDA staffs** selected purposively from technical departments (registration, inspections, quality control laboratory and administration) engaged in practices aimed at ensuring the quality of human medicines, having an experience of more than one year in Rwanda FDA and have a willingness to participate in this study.

Table 3 below indicates the distribution of study participants in the aforementioned division/unit.

Table 3: Study population and sample size

s/n	**Name of targeted Division/Unit**	**Population Size**	**Sample Ratio (51/58)**	**Sample Size**	**Relative share in the sample size (%)**
1	Human Medicine and Devices Assessment & Registration Division	15	0.87	13	25
2	Food and Drugs Import & Export Control Division	20	0.87	18	35
3	Food and Drugs Inspection & Compliance Division	8	0.87	7	14
4	Pharmacovigilance & Food Safety Monitoring Division	6	0.87	5	10
5	Quality Control Laboratory Division/ Medicines and Cosmetics Testing Unit	6	0.87	5	10
6	Administration	3	0.87	3	6
Total		58		51	100

Source: Prime Minister's Order N° **162/03 of 21/12/2020** determining organizational structure of Rwanda Food and Drugs Authority (18).

3.5 Sampling technique

This study used a non-probability sampling technique known as purposive sampling. Participants will be selected depending on their position in the selected targeted divisions or units, year of experience based on the inclusion criteria and capacity to provide the richest information regarding the research objective and research questions.

3.6 Data Collection

To answer the objectives of the study, a mixed approach was used. Data collection tools included a self-administered questionnaire. A desk review focused on key regulatory documents including policies, laws, regulations, guidelines, procedures, reports and lists of registered products, list of licensed establishments and the number of GMP inspections conducted. The self-administered questionnaire was organized according to the research topic and division/unit of the participant to ensure the research questions and objectives are covered. Written informed consent was obtained from each participant before completing the questionnaire.

3.7 Data Analysis

After collecting data with target respondents, the data entry was done using MS Excel. These data were exported into SPSS 16.0 version for further analysis. Data were cleaned before being analyzed. The analysis plan included descriptive analysis and univariate analysis.

3.7.1 Univariate Analysis

For both categorical and numerical data, summary statistics were produced to describe the collected data and provide general information about the study variables. Results in form of frequencies and percentages were produced and presented into tables and graphs.

3.7 Ethical Considerations

In this study, ethical considerations were involved to ensure that the research carried out did not cause any harm to anybody. The confidentiality will be kept for the participants involved in the study. All data have been collected with consent. Analysis of the data is presented in a way that excludes the possibility of the identification of individuals. The approval clearance was given by the university; the Institutional Review Board of the College of Medicines and Health Sciences.

The researcher obtained permission to collect data from the Director General of Rwanda FDA. The respondents were informed about the general nature of the study. Study participants were assured of the safety of the data, preserving confidentiality, objectivity, and truthfulness before

giving their informed consent to participate in the research. There was no remuneration for study participants.

CHAPTER FOUR: RESULTS

4.0 Socio-demographic characteristics of respondents

This section describes the socio-demographic characteristics of the study participants as displayed in table 4 below. Most of the study respondents were aged between 25- 34 years (51%) and the majority of the respondents were male (71%). The majority of the respondents was Bachelor's Degree (A0) holders (90%). Regarding the working experience of the respondents, the majority was in the range of 1-5 years (59%). All respondents received basic training related to the responsibilities of the position occupied.

Table 4: Characteristics of Respondents

Characteristics	**Frequency**	**Percentage (%)**
Age		
Below 25 years	1	2
Between 25- 34 years	26	51
Between 35- 45 years	24	47
Total	51	100
Gender		
Male	36	71
Female	15	29
Total	51	100
Level of education		
Bachelor's Degree (A0)	46	90
Masters' Degree	4	8
PhD	1	2
Total	51	100
Working experience		
Between 1-5 years	30	59
Between 5-10 years	19	37
Above 10 years	2	4
Total	51	100
Basic training related to the responsibility of the position received		

YES	51	100
NO	0	0
Total	51	100

4.1 Rwanda FDA Regulatory System (RS)

NMRAs can fully perform their mandate to ensure the quality-assured medicines in their market if they are administratively, technically and financially autonomous bodies, which makes it easier for them to strengthen the regulatory system (6).

4.1.2 RS sub-indicators implementation level

The overall sub-indicators implementation level in RS function showed that 37 (62%) subindicators out of 60 were scored as IMPLEMENTED; 4 sub-indicators (7%) were scored as PARTIAL IMPLEMENTED and 19 sub-indicators (32%) were scored as NOT IMPLEMENTED. All sub-indicators scored as NOT IMPLEMENTED are at the maturity level 4 (ML4).

Table 5: Overall RS sub-indicators implementation

Implementation Level	**NI**	**OI**	**PI**	**I**	**Total**
# Sub-indicator	19	0	4	37	60
Percentage (%)	32	0	6	62	100

Caption:
NI: Not Implemented, **OI**: Ongoing Implementation, **PI**: Partially Implemented, **I**: Implemented

Details on the level of implementation of the sub-indicators in RS function considering their maturity levels are shown in tables 6, 7, 8 and 9.

Table 6: Implementation of RS sub-indicators at maturity level 1

				Implementation Level	Response	
s/n	Indicator Category	Sub-indicator	Maturity Level of Sub-indicator	(NI, OI, PI or I)	N	Per cent (%)
1	1	RS01.01	**1**	I	3	100
2	1	RS01.02	**1**	I	3	100
3	1	RS01.05	**1**	I	3	100
4	1	RS01.07	**1**	I	3	100

Caption:

RS01.01: Legal provision and regulations define the medical products that should be regulated.

RS01.02: Legal provision and regulations define the institutions that are involved as part of the regulatory system, as well as their mandates, functions, roles, responsibilities and enforcement powers.

RS01.05: Legal provisions and relevant regulations to take actions on recall, suspension, withdrawal and/or destruction of substandard and falsified (SF) medical products.

RS01.07: Development of the regulations involves Rwanda FDA responsible for their implementation and enforcement.

Table 6 above shows that all sub-indicators at maturity level 1 in RS function were rated as implemented by respondents.

Table 7: Implementation of RS sub-indicators at maturity level 2

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	RS01.03	**2**	I	3	100
2	1	RS01.06	**2**	I	3	100
3	2	RS02.04	**2**	I	3	100
4	3	RS03.04	**2**	I	3	100
5	4	RS04.02	**2**	I	3	100
6	5	RS05.07	**2**	I	3	100
7	6	RS08.01	**2**	I	3	100

Caption:

RS01.03: When more than one institution or authority is involved in regulatory oversight, the regulations should define administrative arrangements and the channels of communication and coordination.

RS01.06: Legal provisions and regulations define requirements of transparency and dissemination of information to the public and relevant stakeholders.

RS02.04: Independence of Rwanda FDA from researchers, manufacturers, distributors and wholesalers, as well as from the procurement system.

RS03.04: Documented policies, procedures and mechanisms, including written criteria, are established for recognition and reliance on decisions of other National Regulatory Authorities

RS04.02: A rapid alert system to for managing the threats by SF medical products and for recalling these products from the market. RS05.07: Requirements for documentation management as well as traceability of regulatory activities are established. RS08.01: The workspace and work environment provided for performing the regulatory activities are adequate.

Table 7 above shows that all sub-indicators at maturity level 2 in RS function were rated as implemented by respondents.

Table 8: Implementation of RS sub-indicators at maturity level 3

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	RS01.04	**3**	I	3	100
2	1	RS01.08	**3**	I	3	100
3	2	RS02.01	**3**	I	3	100
4	2	RS02.02	**3**	I	3	100
5	2	RS02.03	**3**	I	3	100
6	3	RS03.02	**3**	I	3	100
7	3	RS03.03	**3**	I	3	100
8	4	RS04.03	**3**	I	3	100
9	4	RS04.04	**3**	I	3	100
10	5	RS05.01	**3**	I	3	100
11	5	RS05.02	**3**	I	3	100
12	5	RS05.03	**3**	I	3	100
13	5	RS05.09	**3**	I	3	100
14	5	RS05.11	**3**	I	3	100
15	6	RS06.03	**3**	I	3	100
16	6	RS06.04	**3**	I	3	100
17	6	RS07.01	**3**	I	3	100
18	6	RS07.02	**3**	I	3	100
19	6	RS08.02	**3**	I	3	100
20	8	RS09.02	**3**	I	3	100
21	8	RS09.04	**3**	I	3	100
22	8	RS09.06	**3**	I	3	100
23	8	RS09.09	**3**	I	3	100
24	1	RS01.09	**3**	PI	3	100
25	4	RS04.05	**3**	PI	3	100
26	5	RS05.04	**3**	PI	3	100

27	8	RS09.07	**3**	PI	3	100

Caption:

RS01.04: All regulatory entities (central and decentralized ones) follow non- contradictory regulations, standards, guidelines and procedures.
RS01.08: Rwanda FDA consults or involves specific sectors of the civil society (such as non-governmental organizations (NGOs) representing health professionals, industry, consumers and patients) during the development or adoption of regulations and guideline. RS02.01: The structure and line of authority among, and within, all institutions that participate in the regulatory system is defined, documented and implemented.
RS02.02: Channels of communication and decision-making are clearly established among the structures, institutions, and departments forming the NRA.
RS02.03: Scientific and advisory committees exist to advise Rwanda FDA on topics of scientific and regulatory interest and on future objectives and strategies.
RS03.02: Rwanda FDA has established and declared its vision, mission and strategic priorities.
RS03.03: A plan for achieving strategic objectives is developed, implemented and regularly updated.
RS04.03: A rapid alert and recall system based on documented communication to the appropriate level of the distribution channel and with a feedback mechanism.
RS04.04: Recall system based on documented confirmation that appropriate, batch-traceable action and/or destruction has been undertaken when necessary.
RS05.01: Top management demonstrates commitment and leadership to develop and implement quality management system (QMS).
RS05.02: Quality policy, objectives, scope and action plans for establishment of the QMS are in place and communicated to all levels.
RS05.03: Organizational chart, with roles and responsibilities to establish the QMS are defined and in place.
RS05.09: The externally provided products and services relevant to regulatory activities are controlled through established mechanisms.
RS05.11: Internal and external audits of the QMS are established and conducted at planned intervals.
RS06.03: A documented policy or procedure for the appointment and recruitment of external experts is available.
RS06.04: Documented mechanism to handle potential conflicts of interest for internal and external experts and committee members, to gather declarations of interest and to guarantee the update of these declarations for all regulatory functions.
RS07.01: Sources of funding are established for the NRA and affiliated institutions to carry out all regulatory functions.
RS07.02: The amounts collected for fees, taxes, tariffs or dues payable for the services provided are defined and publicly available.
RS08.02: The workspace and work environment provided for performing the regulatory activities includes essential requirements.
RS09.02: The information on laws, regulations guidelines and procedures is publicly available and is kept duly updated.
RS09.04: Information on marketed medical products, authorized companies and licensed facilities is publicly available.
RS09.06: Appropriate mechanisms exist for management of confidential information.
RS09.09: The NRA has its own web page with timely information that gives public access to related legal provisions, guidelines and decisions.
RS01.09: A guideline on complaints and appeals against regulatory decisions is available to the public.
RS04.05: Written criteria to cover circumstances in which the routine regulatory processes may not have to be followed in relation to crises and emergencies linked to a risk management plan.
RS05.04: Enough competent staff is assigned to develop, implement and maintain the QMS.
RS09.07: A code of conduct, which includes management of conflicts of interest, is published and enforced for internal and external staff, including members of the advisory committees.

Table 8 above shows that 23 sub-indicators out of 27 at maturity level 3 in RS function were rated as implemented by respondents whereas 4 sub-indicators out of 27 were rated as partially implemented.

Table 9: Implementation of RS sub-indicators at maturity level 4

	Implementation Level	Response

s/n	Indicator Category	Sub-indicator	Maturity Level of Sub-indicator	(NI, OI, PI or I)	N	Per cent (%)
1	6	RS07.03	4	I	3	100
2	6	RS07.04	4	I	3	100
3	6	RS07.05	4	I	3	100
4	3	RS03.01	4	NI	3	100
5	3	RS03.05	4	NI	3	100
6	4	RS04.01	4	NI	3	100
7	5	RS05.05	4	NI	3	100
8	5	RS05.06	4	NI	3	100
9	5	RS05.08	4	NI	3	100
10	5	RS05.10	4	NI	3	100
11	5	RS05.12	4	NI	3	100
12	5	RS05.13	4	NI	3	100
13	5	RS05.14	4	NI	3	100
14	6	RS06.01	4	NI	3	100
15	6	RS06.02	4	NI	3	100
16	6	RS08.03	4	NI	3	100
17	8	RS09.01	4	NI	3	100
18	8	RS09.03	4	NI	3	100
19	8	RS09.05	4	NI	3	100
20	8	RS09.08	4	NI	3	100
21	9	RS10.01	4	NI	3	100
22	9	RS10.02	4	NI	3	100

Caption:

RS07.03: There are provisions relating to reduction or exemption of dues, taxes, tariffs or fees in defined situations for public health interest.
RS07.04: Rwanda FDA has authority to manage the funds allocated and/or generated internally.
RS07.05: Rwanda FDA periodically publicizes its budget.
RS03.01: A national drug policy, aligned with health policy, exists and is implemented.
RS03.05: Rwanda FDA is promoting good regulatory practices (GRPs).
RS04.01: Leadership ensures that the strategic priorities and objectives are well known and communicated throughout the NRA.
RS05.05: Rwanda FDA establishes mechanisms to continually improve the QMS.
RS05.06: Rwanda FDA has identified its regulatory processes, determined their interactions and defined the methods needed to control these processes.
RS05.08: External and internal issues including relevant potential risks are defined and assessed periodically for proper risk mitigation. RS05.10: A mechanism to evaluate the satisfaction of internal and external customers and other interested parties is in place for system improvement.
RS05.12: Corrections, corrective actions, and other actions for risk mitigation and overall improvement, are implemented and documented and their effectiveness is verified
RS05.13: Top management reviews and documents the organization's QMS at planned intervals (i.e., management review).
RS05.14: A mechanism is established to evaluate and demonstrate the effectiveness of training activities.
RS06.01: The NRA has the power to select and recruit its own staff following documented procedures based on its own written criteria (i.e., education, training, skills and experience).
RS06.02: A periodic staff appraisal system is established to review performance and competencies, to identify training needs, and to agree on performance targets.

RS08.03: The equipment provided for performing the regulatory activities is adequate.
RS09.01: The NRA participates in regional and/or global networks to promote convergence and harmonization efforts and expand its collaboration in the regulatory field.
RS09.03: Information on decisions related to regulatory activities is available to the public.
RS09.06: Appropriate mechanisms exist for management of confidential information.
RS09.08: Rwanda FDA uses computerized systems to process information, manage records, and analyze data.
RS10.01: Requirements established to monitor, supervise and review the performance of the NRA and affiliated institutions using key performance indicators (KPIs).
RS10.02: Reports on the regulatory activities and on the progression and status of resources are available at regular intervals.

Table 9 above shows that only 3 sub-indicators out of 22 at maturity level 4 in RS function were rated as implemented by respondents whereas 19 sub-indicators out of 22 were rated as not implemented.

4.1.3 Challenges revealed by respondents in RS function

Poor implementation of Quality Management Systems (QMS) was the main challenge highlighted by respondents in RS function. Table 10 below provides the detail of the challenge faced in RS function.

Table 10: Challenges highlighted by respondents in RS function

Challenge	**Total number of respondents (N)**	**Responses**			
		YES		NO	
		N	**%**	**N**	**%**
Quality management systems not fully implemented	3	3	100	0	0

4.1.4 Summary of RS findings

4.1.4.1 Legal provisions, regulations and guidelines

The findings of the present study showed that Rwanda FDA has legal provisions. Law N^{o} 003/2018 establishing Rwanda FDA especially in its article 9; following powers are given to Rwanda FDA: formulate regulations and guidelines; granting, suspending or withdrawing authorization; seize or confiscate products not conforming to the provisions of the laws, establish a tariff for services rendered by Rwanda FDA; impose administrative sanctions arising from breach of the provisions of this Law (7).

The available legal provisions define Rwanda FDA scope including products to be regulated on the article 3 of the Law N° 003/2018: human and veterinary medicines, vaccines and other biological products, processed foods, poisons, herbal medicines, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products (7).

4.1.4.2 Organization, human resources and governance in Rwanda FDA

Rwanda FDA is a semi-autonomous NMRA affiliated to the Ministry of Health (7) and it has a well-defined structure. 173 staff were recruited out of the 194 positions on the organizational structure (18). The Authority has established the human resource development plan based on the training needs assessment.

4.1.4.3 Finance

Rwanda FDA main sources of finance are state budget allocation, donor funding, income from services rendered (product registration fees, annual product retention fees, premises licensing, import and export licenses, GMP inspection fees). Rwanda FDA has the power to prepare its annual budget to be approved by the competent authority (7).

The finance unit has the following tasks: management of revenue, collection of revenue, management of expenditure, report of finance financial statement, on monthly basis and consolidate report at the end of each financial year.

Revenues and expenses are managed using software called Smart-IFMIS (Integrated Financial Management Information System).

Smart-IFMIS is a technology used to help financial managers make decisions based on budget execution and planned activities. It also helps track cash flow, debt and liabilities in financial management (20).

Smart IFMIS enhances public accountability and transparency and improve public services quality in terms of costs. The system promotes fairness and transparency in public procurement of

different services and works: It contributes to increasing transparency and accountability and is the tool that can be used to prevent corruption and fraud (20).

The findings of this study are similar to the study conducted by Harelimana (2017) to assess the impact of IFMIS on the Performance of Public Institutions in Rwanda that found that IFMIS was widely used in the financial institutions to monitor and guard against the irregular expenditure of state funds (21).

The results of this study showed that Rwanda FDA's budget increased from FRW 0.64 billion in the fiscal year 2018/2019 to FRW 6.2 billion in the fiscal year 2021/2022. Table 11 below shows the budget used by the Rwanda FDA from Fiscal Year 2018/2019 to the fiscal year 2021/2022.

Table 11: Budget used by the Rwanda FDA from FY 2018/2019 to FY 2021/2022

s/n	Fiscal Year	Estimated Budget per year in billions (FRW)
1	2018/2019	0.64
2	2019/2020	4.5
3	2020/2021	5.5
4	2021/2022	6.2

Source: QMS Audit Report of Rwanda FDA by SSALI Mukasa Peter**,** under consultancy agreement *# SPM_A584_0621, 2021.*

4.1.4.4 Quality Management System (QMS)

The quality management system shall be established and implemented by any NMRA to ensure that each operation/activity is carried out to a defined and uniform standard. The QMS shall ensure that each step of the regulatory process is identified, documented and monitored
(4).

In Rwanda FDA, there is no QMS structure but QMS focal persons have been appointed by the management in each division/unit. Most of the QMS focal persons received general training on QMS.

Rwanda FDA is not ISO 9001:2015 certified but the top management is committed to implementing a comprehensive QMS that integrate risk management principles. The quality policy statement has been established and posted on each entrance of every floor of the building (22).

The findings of the present study showed that Rwanda FDA is not implementing the comprehensive QMS and there was no adequate human resource and specific training for staff to perform regulatory activities.

4. 2 Medicines registration and marketing authorization (MA)

Medicines registration is one of the key functions of any NMRA to ensure that qualityassured, safe and efficacious medicines are on the market. Authorization of medicines for sale in the country must be based on scientific evaluation of their quality, safety and efficacy (23).

4.2.1 MA sub-indicators implementation level

The overall sub-indicators implementation level in MA function showed that twenty-nine of 35 sub-indicators (83%) were scored by respondents as IMPLEMENTED, four of 35 subindicators (11%) were scored by respondents as PARTIALLY IMPLEMENTED and two of 35 sub-indicators (6%) were scored by respondents as NOT IMPLEMENTED. (See table 12 below)

Table 12: Overall MA sub-indicators implementation

Implementation Level	NI	OI	PI	I	Total
# Sub-indicator	2	0	4	29	35
Percentage (%)	6	0	11	83	100

Details on the level of implementation of the sub-indicators in MA function considering their maturity levels are shown in tables 13, 14, 15 and 16.

Table 13: Implementation of MA sub-indicators at maturity level 1

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	MA01.01	1	I	13	100
2	1	MA01.02	1	I	13	100
3	1	MA01.03	1	I	13	100
4	1	MA01.06	1	I	13	100
5	1	MA01.07	1	I	13	100
6	1	MA01.08	1	I	13	100

Caption:

MA01.01: There are legal provisions that require the receipt of a registration or marketing authorization (MA) before placing the product on the market.
MA01.02: There are legal provisions that require the NRA to withhold, suspend, withdraw or cancel an MA if there are concerns regarding quality, safety or efficacy issues.
MA01.03: There are legal provisions that require demonstration of the product quality, safety and efficacy prior to registration or MA. MA01.06: There are legal provisions to cover circumstances under which the routine MA procedures may not be followed (e.g., for public health interest).
MA01.07: There are legal provisions or regulations that define regulatory requirements to approve donation of medical products. MA01.08: Legal provisions or regulations allow the NRA to recognize and/or rely on MA-relevant decisions, reports or information from other NRAs or regional and international bodies.

Table 13 above shows that all sub-indicators at maturity level 1 in MA function were rated as implemented by respondents.

Table 14: Implementation of MA sub-indicators at maturity level 2

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
4	1	MA01.04	2	I	13	100
14	2	MA02.01	2	I	12	92

Caption:

MA01.04: There are legal provisions or regulations limiting the duration of the validity of the MA and requiring periodic reviews of MAs (i.e. renewals).

MA02.01: There is a defined structure with clear responsibilities to conduct registration or MA activities.

Table 14 shows that two sub-indicators of maturity level 2 in the MA function were rated as implemented by respondents.

Table 15: Implementation of MA sub-indicators at maturity level 3

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	MA01.05	3	I	13	100
2	1	MA01.09	3	I	13	100
3	1	MA01.10	3	I	13	100
4	1	MA01.11	3	I	13	100
5	1	MA01.12	3	I	13	100
6	1	MA01.13	3	I	13	100
7	2	MA02.02	3	I	13	100
8	6	MA03.01	3	I	13	100
9	6	MA03.02	3	I	12	92
10	6	MA03.03	3	PI	12	92
11	6	MA03.04	3	I	12	92
12	7	MA04.01	3	I	13	100
13	7	MA04.02	3	PI	11	85
14	7	MA04.03	3	I	13	100
15	7	MA04.04	3	I	13	100
16	7	MA04.06	3	I	13	100

17	7	MA04.07	3	I	13	100
18	7	MA04.08	3	I	13	100
19	7	MA04.09	3	PI	13	100
20	7	MA04.10	3	I	13	100
21	8	MA05.01	3	I	12	92
22	8	MA05.02	3	I	13	100
23	9	MA06.01	3	I	13	100

Caption:

MA01.05: There are regulations or guidelines for the definitions, types and the scope of variations along with the required documentation for these variations.

MA01.09: Specific guidelines on the quality, nonclinical and clinical aspects are established and implemented.

MA01.10: There are guidelines on the format and content for submission of MA applications that are consistent with the WHO or other internationally accepted standards.

MA01.11: There are guidelines for MA holders that define the types and scope of variations, the format and content to be used for documenting the variations, and the identification of those variations that require prior approval or notification.

MA01.12: There are established guidelines that cover circumstances under which the routine MA procedures may not be followed (e.g., for public-health interest).

MA01.13: There are guidelines on the content of product information leaflets, SPC-like information, and product packaging and labelling. MA02.02: Documented and implemented procedures exist to ensure involvement and communication with all relevant regulatory entities as necessary.

MA03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform MA or registration activities. MA03.02: Duties, functions, and responsibilities of the staff in charge of MA or registration activities are established and updated in the respective job descriptions.

MA03.03: Training plan developed, implemented and updated at least once a year for staff in charge of MA or registration activities.

MA03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.

MA04.01: Documented procedures and tools are implemented for the assessment of the different parts of the application (i.e., quality, and efficacy) and for the assessment of specific requirements applicable to specific classes of medical products.

MA04.02: Documented procedures have been implemented to renew and/or to periodically review the MAs granted.

MA04.03: Documented procedures are implemented for assessing applications for variations of MAs.

MA04.04: The same criteria apply for assessing applications regardless of the origin of or destination for the medical products (e.g., domestic, foreign, public sector, or private sector).

MA04.06: Timelines for the assessment of the applications are defined and an internal tracking system has been established to monitor adherence to the targeted time frames.

MA04.07: There are documented mechanisms to handle non-routine registration or MA requirements in special situations (e.g., publichealth interest).

MA04.08: SPC-like, labelling and packaging information are approved by the Rwanda FDA as part of the MA procedure.

MA04.09: GMP inspection report and/or certification is considered as part of the MA process.

MA04.10: The regulations and guidelines for good review practices (GRevPs) are developed or recognized and implemented.

MA05.01: Web site or other official publication with SPC-like information is available and regularly updated.

MA05.02: Updated list of all medical products granted MA is regularly published and publicly available.

MA06.01: There is a database of all product applications received, approved, rejected, suspended or withdrawn along with their supporting documentation.

Table 15 above shows that twenty sub-indicators of 23 at maturity level 3 in MA function were rated as implemented by respondents whereas three sub-indicators of 23 were rated as partially implemented.

Table 16: Implementation of MA sub-indicators at maturity level 4

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	7	MA04.05	4	I	12	92
2	8	MA05.03	4	NI	13	100
3	8	MA05.04	4	NI	13	100
4	9	MA06.02	4	PI	12	92

Caption:

MA04.05: An advisory or scientific committee, including external experts is involved in the review of MA applications (as needed). MA05.03: A summary technical evaluation report for approved registration MA applications is published and available to the public. MA05.04: A summary technical evaluation report for deferred or rejected registration or MA applications is published and available to the public. MA06.02: Performance indicators for registration and MA activities are established and implemented.

Table 16 above shows that two sub-indicators out of four at maturity level 4 in MA function were rated as not implemented by respondents whereas the other two sub-indicators were rated as partially implemented and not implemented by respondents respectively.

4.2.2 Challenges in Medicines registration and marketing authorization (MA)

The findings of this study have revealed challenges faced by Rwanda FDA in the implementation of Medicines registration and marketing authorization (MA) activities.

The main challenges identified were insufficient training in the assessment of key parts of the Common Technical Document (Bioequivalence, API, Clinical review data etc.) and lack of software for managing and handling the product dossier applications with the percentage of YES answers of 92% of respondents (12/13) for each challenge; submitted dossiers, not in the standardized format of submission was rated 85% (11/13) as challenges faced in MA function.

Availability of GMP report/certificate, huge backlogs of product dossiers to assess, the timeline for product registration not respected were also other challenges rated at 54% (7/13) each, while

the lack of sufficient staff for product dossier assessment and applicants who do not meet set deadlines to provide additional data requested were the least rated challenges with a rate of 46% (6/13) each. Table 17 below provides the detail of the challenge faced in RS function.

Table 17: Challenges in Medicines registration and marketing authorization (MA)

Challenge	**Total number of respondents (N)**	**Responses**			
		YES		NO	
		N	**%**	**N**	**%**
Insufficient training on the assessment in key parts of the Dossier (Bioequivalence, API, Clinical review data etc.)	13	12	92	1	8
Lack of A Software for Managing and Handling the Product Dossier Applications	13	12	92	1	8
Product dossier applications not in the standardized format (CTD)	13	11	85	2	15
Availability of GMP Inspection report/certificate before MA is issued	13	7	54	6	46
Huge backlogs of product dossiers to assess	13	7	54	6	46
Timeline for product registration not respected	13	7	54	6	46
Lack of sufficient staff for product dossier assessment	13	6	46	7	54
Applicants do not meet set deadlines to respond to additional data requested	13	6	46	7	54

4.2.3 Summary of MA findings

4.2.3.1 Legal provisions, regulations, guidelines and standard operating procedures

The findings of the practices of the MA function revealed that Rwanda FDA has the legal provisions that give the power to grant; re-grant (renew), suspend or withdraw the marketing authorization (7).

Legal provisions for regulatory reliance and recognition of scientific assessments and inspections reports of resourced NMRAs were in place to cope with the challenge of lack of expert assessors and scientific expertise.

Rwanda FDA is a member of the WHO Collaborative Registration Procedure (CRP) and this means that it can use the results of the WHO prequalification to issue the registration of WHO-prequalified products (24).

The guidelines to guide the applicants during the submission of the product dossiers were available and published on the website. Those guidelines indicate the conditions, content, format, required tools (forms etc.) used in the application, duration of the marketing authorization, registration fee and other technical requirements that are the basis for products dossiers assessment and evaluation for marketing authorization.

Standard operating procedures (SOPs) were in place to help personnel to perform daily activities related to the product dossiers assessment and evaluation for quality, safety and efficacy.

4.2.3.2 Registered products and timeframe for registration

The registry of registered products was published on the website. During the time of the study, only 148 products equal to 7% of all submitted applications were registered among 2182 dossier applications submitted for registration from May 2018-January 2022. The registered products (148) rate compared to the authorized list of medical products (4758) of December 2021 to be

imported is 3%. This means that only 3% of medicines imported in Rwanda are registered. Table 18 provides more detail on the status of MA application dossiers submitted for registration (from May/2018-January/2022)

18: Status of MA application dossiers submitted for registration from May 2018 to January 2022

Item	**Number**
Application Received	2182
Applications Assessed	1294
Applications not Assessed	716
Applications pending for registration due to the lack of GMP inspection report	11
# Registered Products	148
# Products at Authorized List	4758
Applications Withdrawn	12
% of Products Registered compared to the number of total applications received	7
% of medicines allowed to be imported (authorized medicines list) compared to the registered products	3

Source: Database of Cumulative Medicinal Products Applications from May 2018 to January 2022 of Human Medicine and Devices Assessment & Registration Division, Consulted on 31/01/2022.

The defined registration timeline to register the product was stated to be nine (9) months in the guidelines but the finding of the present study showed the timeframe for product registration can go beyond the required timeframe due to different challenges highlighted by respondents.

4.2.3.3 Expert assessors, staff and electronic systems

The findings of this study revealed that Rwanda FDA lacks expert assessors for the key parts of the dossier, lacks adequate staff to perform medicines registration activities and does not have

Electronic Regulatory Management Information Systems for managing and handling the dossier applications effectively and efficiently.

4.2.3.4 Logistics (infrastructure and equipment)

The findings of the present study showed that Rwanda FDA had enough and secured space for storing confidential data and archiving applicants' property (product dossiers, samples, etc.) Assessors had access to the current technology and other technical information needed for assessing the dossiers submitted.

4.3 VIGILANCE (VL)

4.3.1 VL Sub-indicators implementation level

The overall sub-indicators implementation level in VL function showed that twenty of 26 sub-indicators (77%) were scored by respondents as IMPLEMENTED, two of 26 subindicators (8%) were scored by respondents as PARTIALLY IMPLEMENTED and four of 26 sub-indicators (15%) were scored by respondents as NOT IMPLEMENTED. All subindicators scored as NOT IMPLEMENTED are at maturity level 4 (ML4). (See table 19 below)

Table 19: Overall VL sub-indicators implementation

Implementation Level	**NI**	**OI**	**PI**	**I**	**Total**
# Sub-indicator	4	0	2	20	26
Percentage (%)	15	0	8	77	100

Details on the level of implementation of the sub-indicators in VL function considering their maturity levels are shown in table 20.

20: Implementation of VL sub-indicators at maturity level 1, maturity level 2, maturity level 3 and maturity level 4

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	VL01.01	1	I	3	100
2	1	VL01.02	1	I	3	100
3	1	VL01.03	1	I	3	100
4	1	VL01.07	1	I	3	100
5	7	VL04.05	1	I	3	100
6	1	VL01.04	2	I	3	100
7	2	VL02.01	2	I	3	100
8	8	VL06.01	2	I	3	100
9	1	VL01.05	3	I	3	100
10	1	VL01.06	3	I	3	100
11	6	VL03.01	3	I	3	100
12	6	VL03.02	3	I	3	100
13	6	VL03.04	3	I	3	100
14	7	VL04.01	3	I	3	100
15	7	VL04.02	3	I	3	100
16	7	VL04.04	3	I	3	100
17	7	VL04.06	3	I	3	100
18	9	VL05.01	3	I	3	100
19	8	VL06.02	3	I	3	100
20	8	VL06.03	3	I	3	100
21	2	VL02.02	3	PI	3	100
22	6	VL03.03	3	PI	3	100
23	7	VL04.03	4	NI	3	100
24	7	VL04.07	4	NI	3	100
25	7	VL04.08	4	NI	3	100
26	9	VL05.02	4	NI	3	100

Caption:

VL01.01: Legal provisions for a national vigilance system exist.

VL01.02: Legal provisions and regulations require the manufacturers and/or MAHs to set up a vigilance system of their medical products and periodically report vigilance data to Rwanda FDA

VL01.03: Guidelines ensure that distributors, importers, exporters, healthcare institutions, consumers and other stakeholders are encouraged to report adverse drug reactions (ADRs) and AEs to the MAH and/or NRA.
VL01.04: Legal provisions and regulations allow NRA to require manufacturers and/or MAHs to conduct specific studies on safety and effectiveness under specific conditions.
VL01.05: Legal provisions, regulations and guidelines require manufacturers and/or MAHs to designate an individual person to be in charge of vigilance system
VL01.06: There are guidelines for planning, conducting, monitoring, and reporting of vigilance activities.
VL01.07: Legal provisions and regulations allow recognition and/or reliance on vigilance-related decisions, reports or information from other countries or regional or international bodies.
VL02.01: There is a defined organizational structure with clear responsibilities to conduct vigilance activities.
VL02.02: Documented procedures and mechanisms are implemented to ensure the involvement, coordination and communication among all stakeholders relevant to vigilance activities
VL03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform vigilance activities
VL03.02: Duties, functions, and responsibilities of the staff in charge of vigilance activities are established and updated in the respective job descriptions.
VL03.03: Training plan developed, implemented and updated at least once a year for staff in charge of vigilance activities.
VL03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.
VL04.01: Vigilance procedures and tools are in place and implemented for collection and assessment of ADRs and AEs.
VL04.02: Vigilance procedures and tools are in place for investigation, interpretation of and response to ADRs and AEs.
VL04.03: Standard procedures exist and are implemented for enforcement of the national vigilance system.
VL04.04: Risk approach is considered throughout different vigilance activities, including timely response to detected signals for risks or benefits.
VL04.05: Staff access to information resources relevant to vigilance processes (e.g., safety information sources and reference materials) is ensured.
VL04.06: Rwanda FDA has access to expert committees for review of serious emergent safety concerns, when needed.
VL04.07: With respect to vigilance data, assessment of the risk-benefit balance of medical products is regularly conducted.
VL04.08: Active vigilance activities, as well as proactive monitoring programs (when needed) have been developed and implemented. VL05.01: Vigilance information is used in timely manner to amend existing regulatory decisions or to issue new regulatory decisions or actions.
VL05.02: Performance indicators for vigilance activities are established and implemented.
VL06.01: Vigilance activities and relevant feedback are appropriately communicated to the public.
VL06.02: Mechanism for regular feedback to all stakeholders on vigilance events exists and is complemented with a risk communication plan.
VL06.03: Vigilance data and findings are shared with relevant regional and international partners.

Table 20 above shows that all five sub-indicators at maturity level 1 in VL function were rated as implemented by respondents, all three sub-indicators at maturity level 2 were rated as implemented by respondents. Among 14 sub-indicators at maturity level 3, twelve subindicators were rated as implemented by respondents and two sub-indicators were rated as partially implemented by respondents. All four sub-indicators at maturity level 4 were rated as not implemented.

4.3.2 Challenges revealed by respondents in VL function

Under-reporting of ADRs/AEFI, understaffing and lack of awareness of PV activities among key stakeholders were the main challenges highlighted by respondents in the VL function.
Table 21 provides the detail of the challenges identified.

21: Challenges reported by respondents in VL function

Challenge		**Respons s**

	Total number of respondents (N)	YES		NO	
		N	%	N	%
Under-reporting of ADRs/AEFI	3	3	100	0	0
Understaffing	3	3	100	0	0
Lack of awareness of PV activities among key stakeholders	3	3	100	0	0

4.3.3 Summary of VL findings

Rwanda FDA put in place a PV system that can perform the minimum functions of the national PV system:

- Rwanda FDA has **dedicated staff for PV activities** (3 working full-time staff: WHO recommended at least one full-time staff) (18).
- **The national spontaneous reporting system** is in place with a national individual case safety report (ICSR) form. ADR/AEFI reporting forms and poor quality drug reporting forms were developed and distributed in the health facilities. Rwanda is member number 113 in Uppsala Monitoring Centre (UMC) which is a WHO Collaborating Centre for International Drug Monitoring hosting Global Database of Adverse Drug Reaction reports.
- **National databases for ADRs and AEFI** are available. It was found that from JuneDecember 2021; 512 ADR/AEFI cases were received. Among the 512 ADR/AEFI cases received; 155 (30%) were reviewed whereas 128 (83%) of the reviewed cases were reported to Uppsala Monitoring Centre. It was found that 13 serious cases were investigated.

22: ADRs/AEFI reported from June-December 2021

Item	Number
# ADR/AEFI Cases received	512

# ADR/AEFI Cases Reviewed	155
# ADR/AEFI Cases reported to Uppsala	128
# Serious cases investigated	13
Percentage (%) of # ADR/AEFI cases reviewed	30
Percentage (%) of # ADR/AEFI reported to Uppsala	83

Source: Database of ADR/AEFI of PV-SM Division of Rwanda FDA, 2021

- A national **pharmacovigilance advisory committee whose mandate is to provide** the technical assistance on causality assessment, risk assessment, risk management case investigation, and where necessary crisis management including crisis communication was established and members were appointed. This PV advisory committee is composed of 13 members from different disciplines (Dermatologist, Internist, Division Manager of Pharmacovigilance & Safety Monitoring in Rwanda FDA, Clinical Pharmacist, Pharmacist, Toxicologist, Surgeon, Cardiologist, Oncologist, Pediatrician, Pharmacologist, Veterinary and Gynecologist).
- **Communication strategy** for routine communication and crises communication. This includes medicines safety bulletins, alerts, and medicines safety information.

The findings of this study showed that Rwanda FDA has a working national PV system that can perform its functions even if the system is challenged with the under-reporting of ADRs/AEFI, understaffing, and lack of awareness of PV activities.

4.4 Market Surveillance and Control (MC)

The market surveillance and control activities are important to ensure that products in circulation on the market complied with pre-set specifications for quality, safety and efficacy before they are put on the market during the registration (6).

This function focused on control of import and export, prevention and detection as well as response to SF products, post-market surveillance and control of promotional, marketing and advertising activities.

4.4.1 MC Sub-indicators implementation level

The overall sub-indicators implementation level in MC function showed that twenty out of 27 sub-indicators (74%) were scored by respondents as IMPLEMENTED, two of 27 subindicators (7%) were scored by respondents as PARTIALLY IMPLEMENTED and five of 27 sub-indicators (19%) were scored by respondents as NOT IMPLEMENTED. All subindicators scored as NOT IMPLEMENTED are at maturity level 4 (ML4). (See table 23 below)

Table 23: Overall MC sub-indicators implementation

Implementation Level	**NI**	**OI**	**PI**	**I**	**Total**
# Sub-indicator	5	0	2	20	27
Percentage (%)	19	0	7	74	100

Details on the level of implementation of the sub-indicators in MC function considering their maturity levels are shown in table 23.

24: Implementation of MC sub-indicators at maturity level 1, maturity level 2, maturity level 3 and maturity level 4

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	MC01.01	1	I	18	100
2	1	MC01.02	1	I	18	100
3	1	MC01.03	1	I	18	100
4	1	MC01.04	2	I	18	100
5	1	MC01.06	2	I	18	100
6	1	MC01.07	2	I	18	100
7	2	MC02.01	2	I	18	100
8	6	MC03.01	3	I	18	100
9	6	MC03.02	3	I	18	100

10	6	MC03.04	3	I	18	100
11	7	MC04.01	3	I	18	100
12	7	MC04.02	3	I	18	100
13	7	MC04.04	3	I	18	100
14	7	MC04.05	3	I	18	100
15	7	MC04.06	3	I	18	100
16	7	MC04.07	3	I	18	100
17	7	MC04.08	3	I	18	100
18	8	MC06.01	3	I	18	100
19	8	MC06.02	3	I	18	100
20	8	MC06.03	3	I	18	100
21	2	MC02.02	3	PI	18	100
22	6	MC03.03	3	PI	18	100
23	1	MC01.05	4	NI	18	100
24	7	MC04.03	4	NI	18	100
25	9	MC05.01	4	NI	18	100
26	9	MC05.02	4	NI	18	100
27	9	MC05.03	4	NI	18	100

Caption:

MC01.01: Legal provisions and regulations are in place with respect to import activities including permanent regulatory intervention at designated entry and exit ports where medical products are being moved.

MC01.02: Legal provisions and regulations authorize market surveillance and control activities which include product sampling from different points of the supply chain.

MC01.03: Legal provisions and regulations address the role of NRA in dealing with substandard or falsified (SF) medical products. MC01.04: Legal provisions and regulations exist for the control of promotion, marketing and advertising of medical products to avoid communication of false or misleading information.

MC01.05: Legal provisions and regulations exist for placement of a product's unique identification number on its outer packaging. MC01.06: Guidelines exist for importers that specify the format and content of the relevant applications and procedures to receive the necessary authorizations or permissions.

MC01.07: Guidelines exist on the recall, storage and disposal of SF medical products.

MC02.01: There is a defined structure, with clear responsibilities, to conduct market surveillance and control activities.

MC02.02: Documented procedures or mechanisms are implemented to ensure the involvement and communication among all stakeholders relevant to market surveillance and control activities.

MC03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform market surveillance and control activities.

MC03.02: Duties, functions, and responsibilities of the staff in charge of market surveillance and control activities are established and updated in the respective job descriptions

MC03.03: Training plan developed, implemented and updated at least once a year for staff in charge of market surveillance and control activities.

MC03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.

MC04.01: Documented and implemented procedures exist to grant the necessary authorizations or permissions for import activities.

MC04.02: Documented and implemented procedures exist for regulation of promotion and advertisement of medical products

MC04.03: Documented and implemented procedures for active monitoring of the promotion and advertisement of medical products MC04.04: Documented and implemented procedures exist for risk-based sampling of medical products from different points of the supply chain.

MC04.05: Documented and implemented procedures exist to enable the public to report suspected SF medical products.

MC04.06: Documented and implemented procedures exist in the NRA to review any complaints or market reports received.

MC04.07: Documented and implemented procedures and mechanisms exist to prevent, detect and respond to SF medical products.

MC04.08: Documented and implemented procedures exist to ensure safe storage and disposal of detected SF medical products.

MC05.01: Database exists of approved and refused promotional and advertising materials along with the supporting documentation. MC05.02: Database for product batches that have undergone surveillance along with their relevant testing results and regulatory actions is established and periodically reviewed.

MC05.03: Performance indicators for market surveillance and control activities are established and implemented MC06.01: Market surveillance and control activities are appropriately communicated within Rwanda FDA.
MC06.02: Findings and regulatory decisions of market surveillance and control activities are appropriately communicated to all national stakeholders including the general public.
MC06.03: Findings and regulatory decisions of market surveillance and control activities of common interest are appropriately communicated and shared with other countries and regional and international organizations.

Table 24 above shows that all three sub-indicators at maturity level 1 in MC function were rated as implemented by respondents, all four sub-indicators at maturity level 2 were rated as implemented by respondents. Among 15 sub-indicators at maturity level 3, thirteen subindicators were rated as implemented by respondents and two sub-indicators were rated as partially implemented by respondents. All five sub-indicators at maturity level 4 were rated as not implemented.

4.4.2 Challenges reported by respondents in MC function

Lack of screening tools/technologies at the port of entry (minilab, etc.) was the main challenge identified at the rate of 100% (18/18) followed by the lack of an adequate budget dedicated to PMS activities 67% (12/18) and lack of stakeholder's involvement in PMS activities 50% (9/18). Lack of laboratory capacity to test all sampled medicines and lack of staff training were also identified and were rated as challenges by respondents at 33% (6/18) and 28% (5/18) respectively. (See table 25 below)

25: Challenges reported by respondents in MC function

Challenge	**Total number of respondents (N)**	**Responses**			
		YES		NO	
		N	**%**	**N**	**%**
Lack of screening tools/technologies at the port of entry (minilab, etc.)	18	18	100	0	0
Lack of budget dedicated to PMS activities	18	12	67	6	33
Lack of stakeholders involvement in PMS activities	18	9	50	9	50

Lack of laboratory capacity to test all sampled medicines	18	6	33	12	67
Lack of training for staff	18	5	28	13	72

4.4.3 Summary of MC findings

The findings of this study showed that legal provisions and regulations were in place even to enforce post-marketing surveillance (PMS) activities, control of import and export, prevention, detection and response to SF medical products as well as control of promotional, marketing and advertising activities even if the practice was hindered by certain challenges listed above.

4.4.3.1 Post Marketing Surveillance (PMS)

The findings of this study showed that Rwanda FDA developed an annual PMS Plan; from the PMS plan, sampling and testing of medicines were performed. Recall of several batches of medicines was done as a regulatory action following the quality issue. See tables 26, 27 and 28 below:

26: Sampled and Tested Medicines in PMS from 2019 to 2021

Year	# Sample tested	# Compliant Samples	# Non-Compliant Sample
2019	38	34	4
2020	49	45	4
2021	377	359	18
Total	464	438	26

Source: Database of Pharmaceutical Products Tested for Post Marketing Surveillance Purpose, PV-SM Division. Doc Ref Nº: QMS Nº: DIS/FMT/104, 2021.

Table 26 above shows that in the last three years, 464 samples were analyzed for PMS purposes, the majority of them 377 were performed in 2021.

Particularly, in the PMS activity of 2021; 618 medicine batches were sampled in all 30 districts of the country and the source of the sampled medicines was the public institutions only (Central Medical Store RMS Branches, Former District Pharmacies). This means that the sampling of medicines for PMS are not done following the risk-based sampling approach.

Table 27: Number of medicines batches sampled for PMS activity in 2021

Province	**# Batch of medicines Sampled**
South	145
North	154
East	105
West	149
Kigali City	65
Total batches sampled	**618**

Source: Report of Countrywide Sampling Activity for Post Marketing Surveillance purpose for both Pharmaceutical Products and Food Products conducted from 18th to 29th January 2021; Rwanda FDA.

Lack of budget to purchase samples in private sectors and lack of awareness of the sampling activity in local governments and the private sector were among the challenges listed by inspectors in the report on sampling activity for PMS in 2021.

28: Number of medicines batches recalled by Rwanda FDA from 2018 to 2021

Year	# batches recalled	(%) of batches recalled per year
2018	1	1
2019	19	19
2020	42	43
2021	36	37
Total	98	100

Source: Databases of Recalled Pharmaceutical Products; PV-SM Division, 2021.

Table 28 above shows that a total of 98 medicine batches were incriminated and recalled for proper management; the majority of them 42 (43%) were recalled in 2020.

4.4.3.2 Control of import and export

It has been found that only licensed establishments can import or export medicines after meeting the import/export requirements.

Requirements to import or export medicines must be met by licensed importers/exporters including the central medical store, private distributors/wholesalers, public and private hospitals. Donated medicines also need an import/export license.

Import and export of medicines are based on the authorized medicines list and not on the list of registered medicines. There are specific legal provisions on the import and export of narcotics. At the port of entry, a visual inspection of each shipment is performed. Table 29 below shows consignments inspected, VISA and license issued from July-September 2021.

Table 29: Summary of import and export activities from July-September 2021

Consignment Inspected		**VISA Issued**	**Import License Issued**	**Export License Issued**
Port of Entry	**Released Under Seal**			
4,161	823	3,394	2,278	189

Source: Rwanda FDA Quarter I Report (2021-2022: July-September 2021)

4.4.3.3 Prevention, detection and response to SF medicines

The method used to prevent and detect SF medicines at the port of entry is not adequate, as only visual inspection is performed to verify label requirements and package integrity, storage conditions, dosage units and documentation according to import or export requirements.

To ensure that only medicines of assured quality, safety and efficacy enter the legal supply chain; it is recommended to adopt the use of screening technologies for SF medicines at specific ports of entry. SF medicines screening technologies/tools are necessary for any NMRA to use in the field to prevent and detect SF drugs before they enter the market (27).

4.4.3.4 Control of promotional, marketing and advertising activities

Legal provisions and guidelines governing promotion advertisement and marketing of regulated products are in place as well as the database of all received, vetted and approved promotional materials. SOP for receiving, recording and approving promotions and SOP for vetting promotional materials of medical products are available.

Rwanda FDA received 42 applications related to medicines promotion, advertisement and marketing. Thirty of 42 applications were approved whereas nine applications are still pending due to missing documents required not being submitted. (See table 30 below)

Table 30: Medicines promotion, advertisement and marketing applications from 2019 to 2021

Year	Applications Received	Applications approved	Pending Applications
2019	4	1	3
2020	11	10	1
2021	27	22	5
Total	**42**	**33**	**9**

Source: Database of the promotion, advertisement and Marketing Application, PV-SM Division. Doc Ref Nº: QMS Nº: DIS/FMT/130, 2021.

4.5 LICENSING ESTABLISHMENTS (LI) AND REGULATORY INSPECTION (RI).

Establishments licensing and regulatory inspection are important regulatory functions to ensure the quality, safety and efficacy of medicines across the supply chain (6).

4.5.1 LI and RI Sub-indicators implementation level

The overall sub-indicators implementation level in LI and RI functions are shown in tables 31 and 32 respectively.

Table 31: Overall LI sub-indicators implementation

Implementation Level	NI	OI	PI	I	Total
# Sub-indicator	3	1	0	15	19

Percentage (%)	16	5	0	79	100

Table 31 above shows the findings of implementation level of sub-indicators of LI function where 15 sub-indicators out of 19 (79%) were scored as IMPLEMENTED; one sub-indicator (5%) was scored as ONGOING IMPLEMENTATION and 3 sub-indicators (16%) were scored as NOT IMPLEMENTED. All sub-indicators scored as NOT IMPLEMENTED are at maturity level 4 (ML4).

Table 32: Overall RI sub-indicators implementation

Implementation Level	**NI**	**OI**	**PI**	**I**	**Total**
# Sub-indicator	9	1	0	16	26
Percentage (%)	34	4	0	62	100

Table 32 above shows the level of implementation of sub-indicators in the Regulatory Inspection (RI). The findings of implementation level of sub-indicators of RI function showed that 16 sub-indicators out of 26 (62%) were scored as IMPLEMENTED; one subindicator (4%) was scored as ONGOING IMPLEMENTATION and 9 sub-indicators (34%) were scored as NOT IMPLEMENTED. All sub-indicators scored as NOT IMPLEMENTED are at maturity level 4 (ML4) except one sub-indicator of maturity level 3.

Details on the level of implementation of the sub-indicators in LI and RI functions considering their maturity levels are shown in tables 33 for LI and 34 & 35 for RI.

Table 33: Implementation of LI sub-indicators at maturity level 1, maturity level 2, maturity level 3 and maturity level 4

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	LI01.01	1	I	7	100
2	1	LI01.02	1	I	7	100
3	2	LI02.01	2	I	7	100
4	1	LI01.03	3	I	7	100
5	1	LI01.04	3	I	7	100
6	1	LI01.05	3	I	7	100
7	2	LI02.02	3	I	7	100
8	6	LI03.02	3	I	7	100
9	6	LI03.03	3	I	7	100
10	6	LI03.04	3	I	7	100
11	7	LI04.01	3	I	7	100
12	7	LI04.02	3	I	7	100
13	7	LI04.03	3	I	7	100
14	7	LI04.04	3	I	7	100
15	9	LI06.01	3	I	7	100
16	6	LI03.01	3	OI	7	100
17	8	LI05.01	4	NI	7	100
18	8	LI05.02	4	NI	7	100
19	9	LI06.02	4	NI	7	100

Caption:

LI01.01: There are legal provisions for licensing of facilities throughout the supply chain and based on Good Practices (GXPs) compliance.

LI01.02: There are legal provisions to empower the NRA to issue, suspend or revoke licenses for establishments.

LI01.03: There are legal provisions that require that the NRA to be informed, for the purpose of notification or approval, in case postlicensure changes or variations are made.

LI01.04: There are guidelines on the procedures to apply for a license and on content and format of the license application.

LI01.05: There are legal provisions that require manufacturers to inform the NRA about the appointed qualified and authorized person for the purpose of acknowledgment or approval.

LI02.01: There is a defined structure with clear responsibilities to conduct establishments licensing activities.

LI02.02: Documented procedures and mechanisms are implemented to ensure the involvement and communication between all stakeholders relevant to establishments licensing activities.

LI03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform licensing activities

LI03.02: Duties, functions, and responsibilities of the staff in charge of licensing activities are established and updated in the respective job descriptions.

LI03.03: Training plan developed, implemented and updated at least once a year for staff in charge of licensing activities.

LI03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.

LI04.01: Procedures for assessment of applications for licensing activities, including license issuance, renewal, modification or revocation, are established and documented.

LI04.02: Inspection is required for granting or re-granting a license or approval of a substantial modification.

LI04.03: There are clearly defined timelines for the assessment of applications.

LI04.04: The same criteria are used for the licensing of domestic, public and private establishments regardless of ownership.
LI05.01: A database is established and regularly updated that includes all licensing applications received, approved, refused, suspended or withdrawn, along with the essential documentation for each application.
LI05.02: Performance indicators for licensing activities are established and implemented

LI06.01: An updated list or database of all licensing applications, along with the regulatory decision for each, is regularly published and publicly available.
LI06.02: Inspection reports or summaries (or excerpts) relevant to licensing activities are published and publicly available.

Table 33 above shows that all two sub-indicators at maturity level 1 in LI function were rated as implemented by respondents, one sub-indicator at maturity level 2 was rated as implemented by respondents. Among 13 sub-indicators at maturity level 3, twelve subindicators were rated as implemented by respondents and one sub-indicator was rated as ongoing implementation by respondents. All three sub-indicators at maturity level 4 were rated as not implemented.

Table 34: Implementation of RI sub-indicators at maturity level 1, maturity level 2 and maturity level 3

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	RI01.01	1	I	7	100
2	1	RI01.02	1	I	7	100
5	1	RI01.05	1	I	7	100
3	1	RI01.03	2	I	7	100
6	2	RI02.01	2	I	7	100
4	1	RI01.04	3	I	7	100
7	2	RI02.02	3	I	7	100
8	6	RI03.02	3	I	7	100
9	6	RI03.03	3	I	7	100
10	6	RI03.04	3	I	7	100
11	7	RI04.01	3	I	7	100
12	7	RI04.02	3	I	7	100
13	7	RI04.04	3	I	7	100
14	7	RI04.05	3	I	7	100
15	7	RI04.06	3	I	7	100
16	9	RI05.02	3	I	7	100

17	6	RI03.01	3	OI	7	100
18	7	RI04.03	3	NI	7	100

Caption:

RI01.01: Legal provisions authorize the inspectorate to inspect and enforce Good Practices (GXPs) throughout the supply chain.
RI01.02: Legal provisions allow inspectors to enter facilities throughout the supply chain at any reasonable time and in any place.
RI01.03: Legal provisions allow inspectors to collect relevant evidence, including samples, during GXP inspections.
RI01.04: Updated national GXP regulations, norms or guidelines are mandatory.
RI01.05: Legal provisions and regulations allow the recognition of and/or reliance on foreign NRA inspections and enforcement actions based on well- defined criteria.

RI02.01: There is a defined organizational structure with clear responsibilities to conduct regulatory inspection activities.
RI02.02: Documented procedures and mechanisms are implemented to ensure the involvement and communication among all stakeholders relevant to regulatory inspection activities.
RI03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform regulatory inspection activities
RI03.02: Duties, functions, and responsibilities of the staff in charge of regulatory inspection activities are established and updated in the respective job descriptions
RI03.03: Training plan developed, implemented and updated at least once a year for staff in charge of regulatory inspection activities.
RI03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.
RI04.01: The different inspection activities, including inspection preparation, conduct and reporting, are documented for GXP inspections.
RI04.02: Regulatory inspection follow-up, decision-making (including certification) and enforcement activities are documented.
RI04.03: Inspection planning is based on quality risk management (QRM).
RI04.04: Multi-disciplinary teams are used to ensure proper expertise for inspection of specific medical products.
RI04.05: Inspection findings and observations are categorized according to QRM.
RI04.06: The same criteria are used for the inspection of domestic, foreign, public and private facilities regardless of the ownership. RI05.02: Inspection reports are well-archived and easily retrieved.

Table 34 above shows that all three sub-indicators at maturity level 1 in RI function were rated as implemented by respondents, all two sub-indicators at maturity level 2 were rated as implemented by respondents. Among 13 sub-indicators at maturity level 3, eleven subindicators were rated as implemented by respondents, one sub-indicator was rated as ongoing implementation by respondents and one sub-indicator was rated as not implemented by respondents.

Table 35: Implementation of RI sub-indicators at maturity level 4

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	9	RI05.01	4	NI	7	100
2	9	RI05.03	4	NI	7	100
3	9	RI05.04	4	NI	7	100
4	9	RI05.05	4	NI	7	100
5	8	RI06.01	4	NI	7	100
6	8	RI06.02	4	NI	7	100

7	8	RI06.03	4	NI	7	100
8	8	RI06.04	4	NI	7	100

Caption:

RI05.01: A database is established and regularly updated of all establishments which may be subject to inspection, along with their relevant regulatory decisions (certifications and/or enforcement activities).

RI05.03: Inspection reports are subjected to a regular and robust review by experts other than the designated inspection team.

RI05.04: Inspection data and outcomes are systematically evaluated or interpreted.

RI05.05: Performance indicators for regulatory inspection activities are established and implemented

RI06.01: The list of inspectors is publicly available and the identity of the designated team for each inspection is communicated to the relevant institutions subject to inspections.

RI06.02: The updated list or database of all inspected facilities along their regulatory decisions, actions and enforcement activities, is regularly published and publicly available.

RI06.03: Inspection metrics are regularly published and publicly available.

RI06.04: Information on inspections conducted is regularly published and publicly available in accordance with national confidentiality requirements.

Table 35 above shows that all eight sub-indicators at maturity level 4 in RI function were rated as not implemented by respondents.

4.5.2 Challenges reported by respondents in LI&RI functions

Lack of sufficient staff to perform licensing and inspections activities, lack of inspection tools (Camera for inspectors, uniform and measuring devices: tapes) and lack of an automated system for licensing establishments and regulatory inspection were the major challenges reported by all respondents (100%).

Insufficient training related to the regulatory inspections and Inspection planning which are not done based on quality risk management (QRM) were also reported as challenges faced by staff in the licensing and inspection division rated at 86% (6/7) and 71% (5/7) respectively.

Table 36 below provides the detail on the challenges reported by respondents in LI and RI functions.

Table 36: Challenges reported by respondents in LI&RI functions

Challenge	**Total number of respondents (N)**	**Responses**			
		YES		O	
		N	**%**	**N**	**%**
Understaffing to perform licensing and inspections	7	7	100	0	0
Lack of inspection tools (Camera, uniform, measuring devices: Tapes)	7	7	100	0	0
Lack of automated system for licensing establishments and Regulatory Inspection	7	7	100	0	0
Insufficient training related to the regulatory inspections and licensing	7	6	86	1	14
Inspection planning is not done based on quality risk management (QRM).	7	5	71	2	29

4.5.3 Summary of LI&RI findings

The findings of this study showed that public and private manufacturers, distributors, wholesalers, importers/exporters as well as retailers shall possess an operational license issued by Rwanda FDA.

An inspection for confirmation of compliance with good practices is required in order to grant or re-grant a license or approval of a substantial modification.

Licensing establishments and Regulatory inspections are supported by legal provisions, regulations and guidelines.

The practices of licensing establishments and regulatory inspection are backed by laws and regulations. An updated list of licensed premises was published and can be accessed on the Rwanda FDA website.

Table 37: Licensed premises till September 2021

s/n	Premise Type	# Licensed Premise
1	Human Retail Pharmacy	612
2	Human Wholesale Pharmacy	137
3	Manufacture of Medical Products (medicines, consumables, etc.)	7
4	Optical Shops	15
5	Orthopedic Shop	2
6	Online Pharmacy	3
7	Small Scale Manufacturing Facility	14
8	Veterinary Retail Pharmacy	13
9	Veterinary Wholesale Pharmacy	23
10	Wholesale of Medical Device and Equipment	17
Total		**843**

Source: Rwanda FDA Website assessed on 29 Jan 2022; Licensed Premises available on: https://www.rwandafda.gov.rw/publications

About the 2018-2021 Good Manufacturing Practice (GMP) applications for pharmaceutical establishments; it was found that only 145 GMP inspection applications were received out of 345 expected applications (58%). Of the 145 GMP inspection applications received, five (3%) were physically or virtually inspected, and only six (4%) applicants received the GMP certificate. Thirteen GMP desk reviews were performed, 45 complete dossiers were waiting for further actions, incomplete dossiers were 62 (43%) and 14 applications were pending for screening. See figures 2 and 3 below (**Source:** Minutes of the meeting N°: 17/01/FDA/2022 for Food and Drugs Inspection and Safety Monitoring Department held via WebEx Platform on 17/01/2022**)**

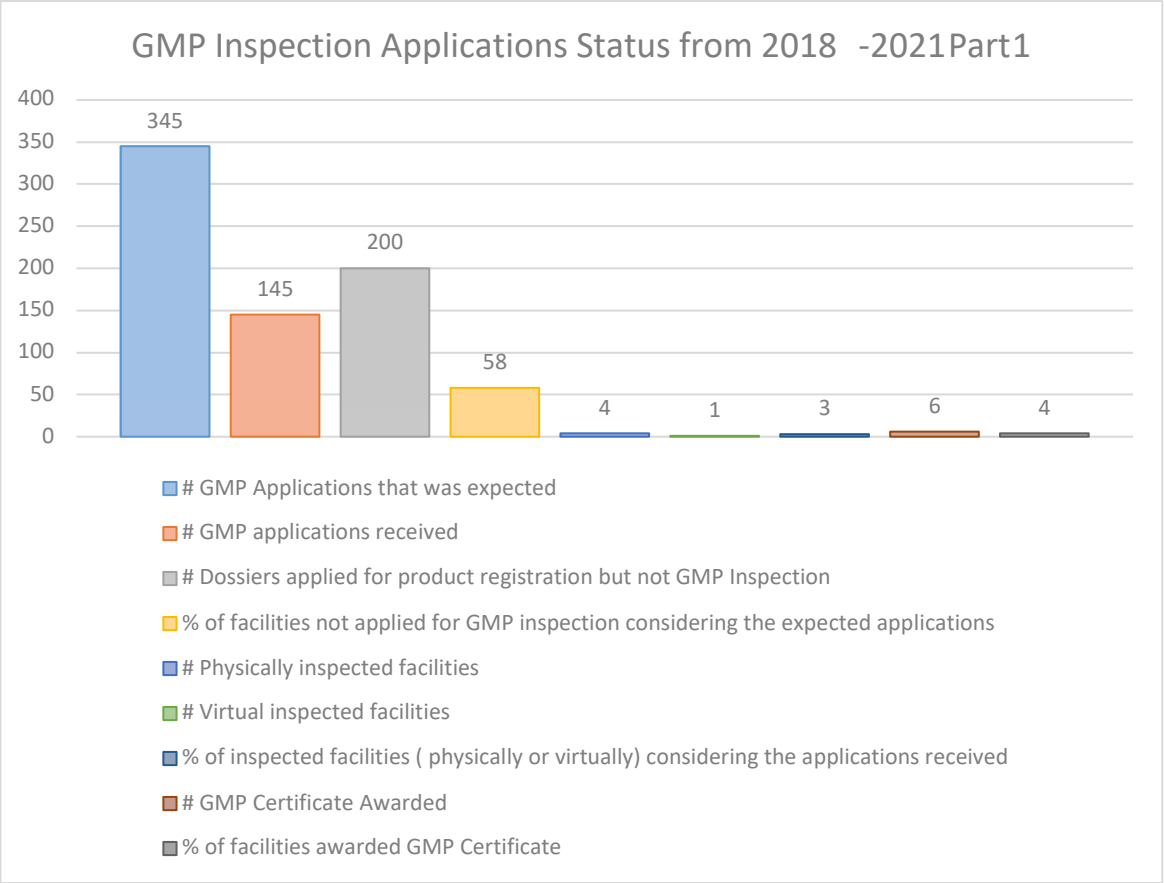

Figure 2: Status of GMP inspection applications received from 2018 to 2021 Part1

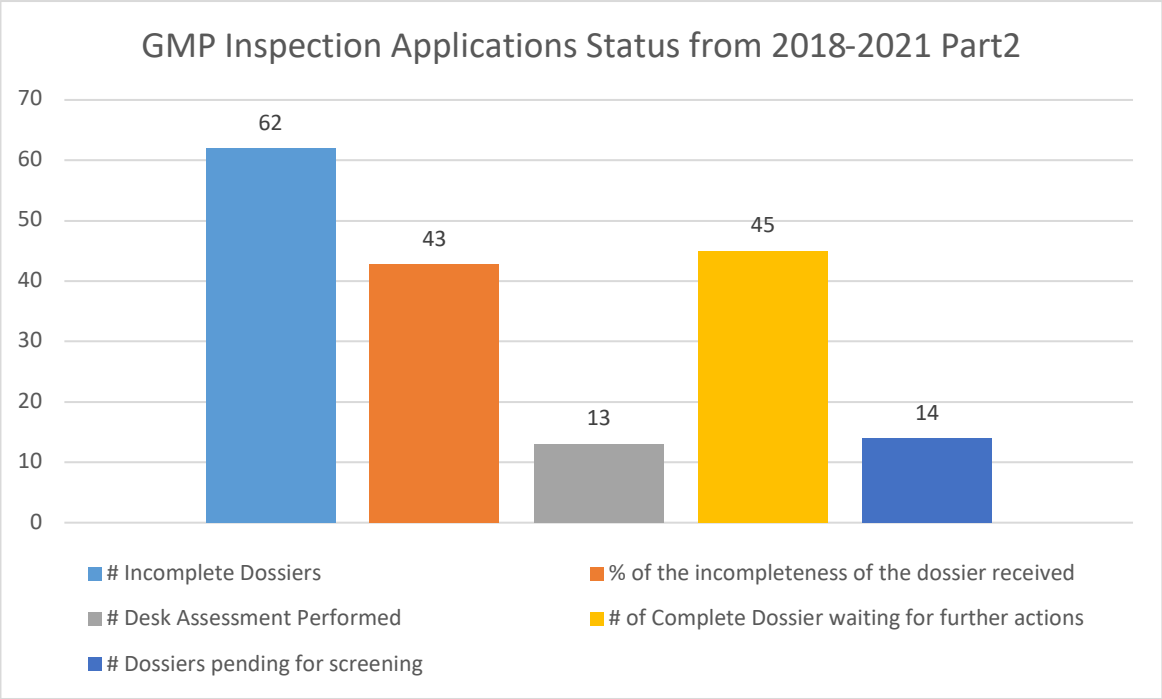

Figure 3: Status of GMP inspection applications received from 2018 to 2021 Part2

The above findings on GMP applications showed that Rwanda FDA lacks sufficient staff to perform licensing and regulatory inspections activities.

The findings of the study showed that 148 products were registered (see table 18). Reference made to the *Regulations Governing Registration of Medicinal Products* Doc. Ref. No.: CBD/TRG/010 Rev_2 and guidelines DHT/GDL/001 governing submission of documentation for registration of human medicinal products; *paragraph 1.10* related to the compliance with GMP during the product registration; which states that a GMP Certificate is one of the requirements to be granted the marketing authorization, 148 GMP certificates instead of 6 GMP Certificates would have been issued to respect set requirements.

This study also showed that Rwanda FDA lacks inspection tools for inspectors to perform an inspection. The tools listed include cameras, uniform and measuring devices (measuring tapes)

Respondents also highlighted the lack of an automated system for licensing establishments and Regulatory Inspection as a handicap for daily activities.

Insufficient training related to the regulatory inspections and licensing and Inspection planning which is not done based on quality risk management (QRM) were highlighted as challenges.

4.6 LABORATORY TESTING (LT)

4.6.1 LT Sub-indicators implementation level

The overall sub-indicators implementation level in LT function showed that 23 out 28 subindicators (82%) in the LT function (when we consider the percentage of response which is above eighty per cent) were scored by respondents as IMPLEMENTED, two (7%) were scored as ONGOING IMPLEMENTATION, while three (11%) were scored by respondents as NOT IMPLEMENTED. (See table 38 below)

Table 38: Overall LT sub-indicators implementation

Implementation Level	**NI**	**OI**	**PI**	**I**	**Total**
# Sub-indicator	3	2	0	23	28
Percentage (%)	11	7	0	82	100

Details on the level of implementation of the sub-indicators in LT function considering their maturity levels are shown in tables 39 and 40.

Table 39: Implementation of LT sub-indicators at maturity level 1, maturity level 2, and maturity level 4

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	LT01.01	1	I	5	100
2	1	LT01.02	1	I	5	100
3	2	LT02.01	2	I	5	100
4	3	LT03.04	2	I	5	100
5	8	LT07.01	4	NI	5	100
6	9	LT08.01	4	NI	4	80
7	9	LT08.03	4	NI	4	80
8	9	LT08.04	4	NI	4	80
9	3	LT09.02	4	I	5	100
10	3	LT09.03	4	I	4	80

Caption:

LT01.01: There are legal provisions to establish a national quality control laboratory (NCL) to perform quality control (QC) testing, and/or to authorize the National Regulatory Authority (NRA) to sub-contract the required testing services.
LT01.02: Legal provisions and regulations allow the NRA to recognize and use laboratory testing-related decisions, reports or information from other NRAs or regional and international bodies.
LT02.01: There is a defined organizational structure with clear responsibilities to conduct laboratory testing activities.
LT03.04: Documented and implemented procedures exist for handling atypical or out-of-specification (OOS) results, including a retest policy.
LT07.01: Laboratory testing activities are appropriately communicated to the public community.
LT08.01: There is an updated database of all medical products batches that have undergone quality testing.
LT08.03: Regular participation in proficiency schemes, collaborative studies and inter-laboratory comparisons.
LT08.04: Performance indicators for laboratory testing activities are established and implemented.
LT09.02: A laboratory safety program exists and a designated person is responsible for its management. LT09.03: Staff immunization requirements are defined, implemented and monitored.

Table 39 shows that the two sub-indicators of maturity level 1 and the two sub-indicators of maturity level 2 of the LT function were rated as implemented by the respondents.

Among six sub-indicators at maturity level 4, four sub-indicators were rated as not implemented by respondents whereas two sub-indicators were rated as implemented by the respondents.

Table 40: Implementation of LT sub-indicators at maturity level 3

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	2	LT02.02	3	I	5	100
2	3	LT03.01	3	I	5	100
3	3	LT03.02	3	I	4	80
4	3	LT03.03	3	I	5	100
5	6	LT04.01	3	I	4	80
6	6	LT04.02	3	I	5	100
7	6	LT04.03	3	I	4	80
8	6	LT04.04	3	I	5	100
9	6	LT05.01	3	OI	4	80
10	6	LT05.02	3	I	5	100
11	7	LT06.01	3	I	5	100
12	7	LT06.02	3	I	5	100
13	7	LT06.03	3	I	5	100
14	7	LT06.04	3	I	5	100
15	7	LT06.05	3	I	5	100
16	9	LT08.02	3	I	4	80
17	3	LT09.01	3	I	4	80
18	7	LT10.01	3	I	5	100

Caption:

LT02.02: Documented procedures are implemented to ensure the involvement and contributions of the NCL to support regulatory oversight.
LT03.01: Documented and implemented policy for testing exists that is based on the product's risk.
LT03.02: Documented and implemented policy exists on the validation, verification and transfer of analytical procedures.
LT03.03: A policy is in place to establish or qualify all reference standards used in laboratory testing activities.
LT04.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform laboratory testing activities.
LT04.02: Duties, functions, and responsibilities of the staff in charge of laboratory testing activities are established and updated in the respective job descriptions.
LT04.03: Training plan developed, implemented and updated at least once a year for staff in charge of laboratory testing activities.
LT04.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification LT05.01: Laboratory facilities are adequate to perform quality testing activities.
LT05.02: Equipment calibration, qualification and maintenance plans have been defined and implemented and records have been maintained.
LT06.01: There are procedures for receipt, handling, storage and retention of samples.
LT06.02: There are documented procedures for performing tests in accordance with MA documentation.
LT06.03: A documented procedure is implemented for notification of test results and for ensuring that test results are issued following a standardized format.
LT06.04: There are appropriate procedures for obtaining and handling of all materials required for testing.
LT06.05: Staff has access to reference documents, including pharmacopoeias, textbooks and operational manuals.
LT08.02: Monitoring and trend analyses are carried out for laboratory testing results data of reference materials and medical products.
LT09.01: A laboratory hazardous substances list exists and documented procedures for storage, handling and disposal of these substances are implemented.
LT10.01: Documented procedures are implemented for managing outsourced QC activities.

Table 40 above shows that among 18 sub-indicators at maturity level 3 in LT function, seventeen sub-indicators were rated as implemented by respondents and one sub-indicator was rated as ongoing implementation by respondents.

4.6.2 Challenges reported by respondents in LT function

Lack of sufficient and adequate equipment was the main challenge reported at a rate of 80% (4/5) followed by the Lack of training for staff 60% (3/5). See table 41 below for more details.

Table 41: Challenges reported by respondents in LT function

Challenge	**Total number of respondents (N)**	**Responses**			
		YES		NO	
		N	**%**	**N**	**%**
Lack of sufficient and adequate equipment	5	4	80	1	20
Lack of training for staff	5	3	60	2	40
Insufficient Staff	5	2	40	3	60

4.6.3 Summary of LT findings

The findings of this study showed that Rwanda FDA possesses a Quality Control Laboratory which is operating according to the established standards and organizational frameworks but the laboratory lacked adequate equipment to ensure the quality of medical products in the Rwandan supply chain.

The laboratory does not have ISO 17025 Quality Management System (QMS) accreditation and is not the WHO Guidance for Good Laboratory Practice Prequalified, which are the global reference tools for measuring the performance standards of quality control laboratories to ensure the quality of medicines throughout the supply chain (29).

The findings of this study showed a strong political will and commitment from the leadership to ensure that the laboratory reaches the required level (30).

For example, the following are some of the achievements recorded during the last four years (2018-2021):

- QC Laboratory received two High-Performance Liquid Chromatography (HPLCs) with Diode Array Detectors (DAD) and Fluorescent detector (FLD). Those two HPLCs were an addition to the existing HPLC machine, disintegration machine, friability, atomic Absorption Spectrophotometer (AAS) and dissolution system.
- From 2018 to 2020, the Quality Control Laboratory Division tested and reported 158 samples of medicines from pre-market whereas in 2021 tested and reported 377 samples of medicines from pre-market, post-shipment and Post Market Surveillance where 18 of them failed to comply with the standard requirements.
- The laboratory developed a quality manual and Regulations for analysis of products regulated by the Rwanda FDA
- 30 Standards testing Procedures (STPs) as per World Health Organization (WHO) Good practices for pharmaceutical quality control laboratories (GPCL) and ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories, 30 Protocols for methods validation and method verification and 11 validation reports and 19 verification reports were elaborated.
- Quality Control Laboratory Division registered and successfully participated in the interlaboratory comparisons (ILC) for the following parameters:

    - Qualitative analysis of Atazanavir related substances: From USP Ghana
    - The disintegration of paracetamol: From USP Ghana
    - Assay and Dissolution of ciprofloxacin: From Muhimbili University of Health and Allied Sciences (MUHAS)

4.7 CLINICAL TRIALS OVERSIGHT (CT)

4.7.1 CT Sub-indicators implementation level

The overall sub-indicators implementation level in CT function showed that 19 out 30 subindicators (63%) in the CT function were rated by respondents as IMPLEMENTED, 3 subindicators (10%) were scored as PARTIAL IMPLEMENTED; 5 sub-indicators (17%) were scored as ONGOING IMPLEMENTATION and 3 sub-indicators (10%) were scored as NOT IMPLEMENTED. All sub-indicators scored as NOT IMPLEMENTED are at maturity level 4 (ML4). (See table 42 below)

Table 42: Overall CT sub-indicators implementation

Implementation Level	**NI**	**OI**	**PI**	**I**	**Total**
# Sub-indicator	3	5	3	19	30
Percentage (%)	10	17	10	63	100

Details on the level of implementation of the sub-indicators in LT function considering their maturity levels are shown in tables 43 and 44.

Table 43: Implementation of CT sub-indicators at maturity level 1, maturity level 2, and maturity level 4

				Implementation Level	Response	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	CT01.01	1	I	2	100
2	1	CT01.11	1	OI	2	100
3	1	CT01.02	2	I	2	100
4	1	CT01.03	2	I	2	100
5	1	CT01.05	2	I	2	100
6	1	CT01.08	2	I	2	100

7	1	CT01.09	2	I	2	100
8	1	CT01.10	2	I	2	100
9	2	CT02.01	2	I	2	100
10	1	CT01.07	2	OI	2	100
11	7	CT04.01	4	NI	2	100
12	8	CT05.02	4	NI	2	100
13	9	CT06.02	4	NI	2	100

Caption:

CT01.01: Legal provisions and regulations for clinical trials (CTs) oversight exist.

CT01.11: Legal provisions or regulations allow the NRA to recognize and use relevant CT decisions, reports or information from other NRAs or from regional and international bodies.

CT01.02: Legal provisions and regulations that stipulates that notification to Rwanda FDA and authorization from Rwanda FDA is required for any changes or variations (i.e., amendments) in the original protocol or in any relevant documents of the CT.

CT01.03: Legal provisions and regulations requiring research centers, researchers, sponsors, clinical research organizations (CROs) and all relevant institutions in the CT to comply with GCP

CT01.05: There are legal provisions or regulations covering circumstances in which the routine CT evaluation procedures may not be followed (e.g. for public-health interests).

CT01.08: Legal provisions, regulations and guidelines that require authorization for the import or destruction of IMPs.

CT01.09: There are requirements for monitoring and reporting of adverse events and reactions during conduct of CT.

CT01.10: There are guidelines on the format and content of CT applications.

CT02.01: There is a defined structure with clear responsibilities to conduct CT oversight activities.

CT01.07: There are legal provisions or regulations that require the establishment of an Independent ethics committee (IEC).

CT04.01: Rwanda FDA has access to an advisory committee for review of CT applications and post-approval safety and compliance issues.

CT05.02: The list of the CTs (approved and rejected applications), including summarized evaluation reports by the NRA, are publicly available or recorded in a domestic or international database.

CT06.02: Performance indicators for CT oversight activities are established and implemented.

Table 43 above shows that two sub-indicators at maturity level 1 of CT function were rated as implemented and ongoing implementation respectively. And among eight sub-indicators at maturity level 2, seven were rated as implemented while one sub-indicator was rated as ongoing implementation. All three sub-indicators at maturity level 4 were rated as not implemented.

Table 44: Implementation of CT sub-indicators at maturity level 3

				Implementation Level	Re ponse	
s/n	**Indicator Category**	**Sub-indicator**	**Maturity Level of Sub-indicator**	**(NI, OI, PI or I)**	**N**	**Per cent (%)**
1	1	CT01.04	3	I	2	100
2	1	CT01.06	3	I	2	100
3	6	CT03.02	3	I	2	100
4	6	CT03.04	3	I	2	100
5	7	CT04.03	3	I	2	100
6	7	CT04.04	3	I	2	100
7	7	CT04.05	3	I	2	100
8	7	CT04.06	3	I	2	100
9	8	CT05.01	3	I	2	100
10	9	CT06.01	3	I	2	100
11	9	CT06.04	3	I	2	100
12	2	CT02.02	3	PI	2	100
13	7	CT04.07	3	PI	2	100
14	9	CT06.03	3	PI	2	100
15	6	CT03.01	3	OI	2	100
16	6	CT03.03	3	OI	2	100
17	7	CT04.02	3	OI	2	100

Caption:

CT01.04: Legal provisions, regulations and guidelines requiring that investigational medical products (IMPs) comply with good manufacturing practices (GMP) for IMPs.

CT01.06: Legal provisions, regulations or guidelines exist for NRA to inspect, suspend or stop CTs.

CT02.02: Documented procedures are implemented to ensure the involvement and communication among all stakeholders relevant to CTs.

CT03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform CT oversight activities.

CT03.02: Duties, functions, and responsibilities of the staff in charge of CT oversight activities are established and updated in the respective job descriptions.

CT03.03: Training plan developed, implemented and updated at least once a year for staff in charge of CT oversight activities.

CT03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.

CT04.02: The existence of the Ethics Committees with clearly defined composition.

CT04.03: Nonclinical data is considered within CT application review.

CT04.04: There are defined roles for ECs at all levels (e.g., national, sub-national, or institutional).

CT04.05: Documented and implemented procedures exist to review CT applications.

CT04.06: There are procedures for EC responsibility for clearance and follow up until completion of the CT.

CT04.07: The same policies are used for the evaluation of CT applications regardless of the applicant (e.g., domestic, foreign, public sector, or private sector).

CT05.01: There is clarity about the funding of the EC and its members

CT06.01: There is an internal list or database of all approved and rejected CTs, and the NRA maintains a record of each approved and rejected CT.

CT06.03: Progress reports from sponsors or CROs during and after CTs sent to and shared among NRAs and ECs.

CT06.04: There are timelines for the assessment of CT applications and an internal tracking system to follow the targeted time frames.

Table 44 above shows that among 17 sub-indicators at maturity level 3 in CT function, eleven sub-indicators were rated as implemented by respondents, three sub-indicators were rated as partially implemented and three sub-indicators were rated as ongoing implementation by respondents.

4.7.2 Challenges revealed by respondents in CT function

Lack of equipped CT sites, Long Approval Process and Lack of specific training of staff were the main challenges identified in CT function. (See table 45 below)

Table 45: Challenges reported by respondents in CT function

Challenge	**Total number of respondents (N)**	**Responses**			
		YES		NO	
		N	**%**	**N**	**%**
Lack of equipped CT sites	2	2	100	0	0
Long Approval Process	2	2	100	0	0
Lack of specific training of staff	2	2	100	0	0

4.7.3 Summary of CT findings and discussion

The results of this study showed that the Rwanda FDA monitored the clinical trials in collaboration with external entities which are the Rwanda National Ethics Committee (RNEC) and the Rwanda Biomedical Center (RBC) to ensure the safety of the research subjects and the scientific integrity of the clinical data.

The regulations require the principal investigator or sponsor to monitor, record and report the outcome of the clinical trial, including any serious adverse events. The regulations also require that investigational drugs conform to good manufacturing practices.

Oversight of clinical trials at the Rwanda FDA was found to be supported by clear laws and regulations. This will help the Authority to overcome the challenges faced in drug research and development. Good clinical practice (GCP) guidelines were established and implemented. The following table 46 shows the summary of all activities performed by the Rwanda FDA regarding the clinical trial oversight from 2019 to 2021.

Table 46: Status of CT applications from 2019 to 2021

Name of activity performed	**Number**	**Percentage (%)**
Total clinical trial applications received	23	
Total clinical trial applications assessed	16	70
Clinical trial pending applications	7	30
Clinical trial amendment applications	10	43
Clinical trial amendment approved	9	39
GCP site inspections performed	21	91

Source: Databases of Clinical Trials Oversight; PV-SM Division, 2021.

The findings of this research showed that Rwanda FDA conducted 21 good clinical practice site inspections to ensure that clinical trials are conducted in compliance with laws, regulations and guidelines. This guarantees the quality, safety and efficacy of the investigational products as well as the protection of the research subjects.

Lack of trained principal investigators and lack of equipped CT sites were among the challenges hindering the practice of clinical trial oversight in Rwanda FDA revealed by respondents.

4.8 Overall implementation level of sub-indicators

The findings of this study showed that in Rwanda FDA; the implementation level of the monitored sub-indicators provided the following results: In 251 sub-indicators assessed; 179 sub-indicators (71%) were scored as implemented, 17 sub-indicators (7%) were scored as partially implemented, 9 sub-indicators (4%) were scored as ongoing implementation while 46 sub-indicators (18%) were scored as not implemented. Figure 4 below provides more details.

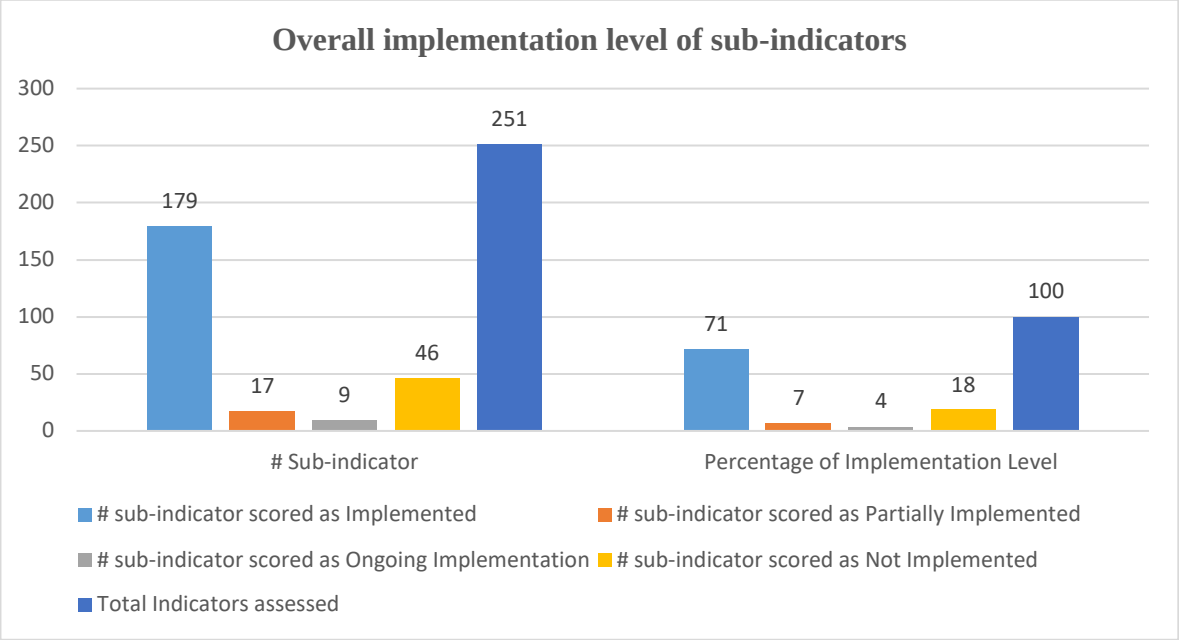

Figure 4: Overall implementation level of sub-indicators

A total of 26 out of 27 sub-indicators (96%) were implemented at maturity level 1; 27 out of 29 sub-indicators (93%) were implemented at maturity level 2; 121 out of 141 sub-indicators (86%) were implemented at maturity level 3 and 5 out of 54 sub-indicators (9%) were implemented at maturity level 4 (See figure 5 below).

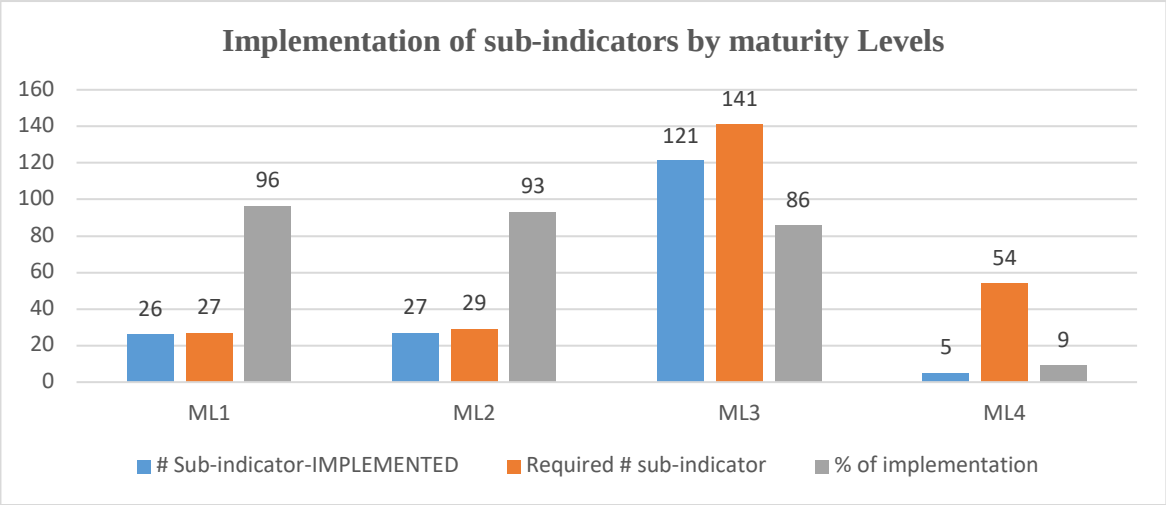

Figure 5: Implementation of sub-indicators by maturity Levels

The results of this study showed that the most implemented functions were MA and LT, implemented at the rate of 83% and 82 respectively while RS and RI were the least implemented functions rated at 62% each. (See figure 6 below).

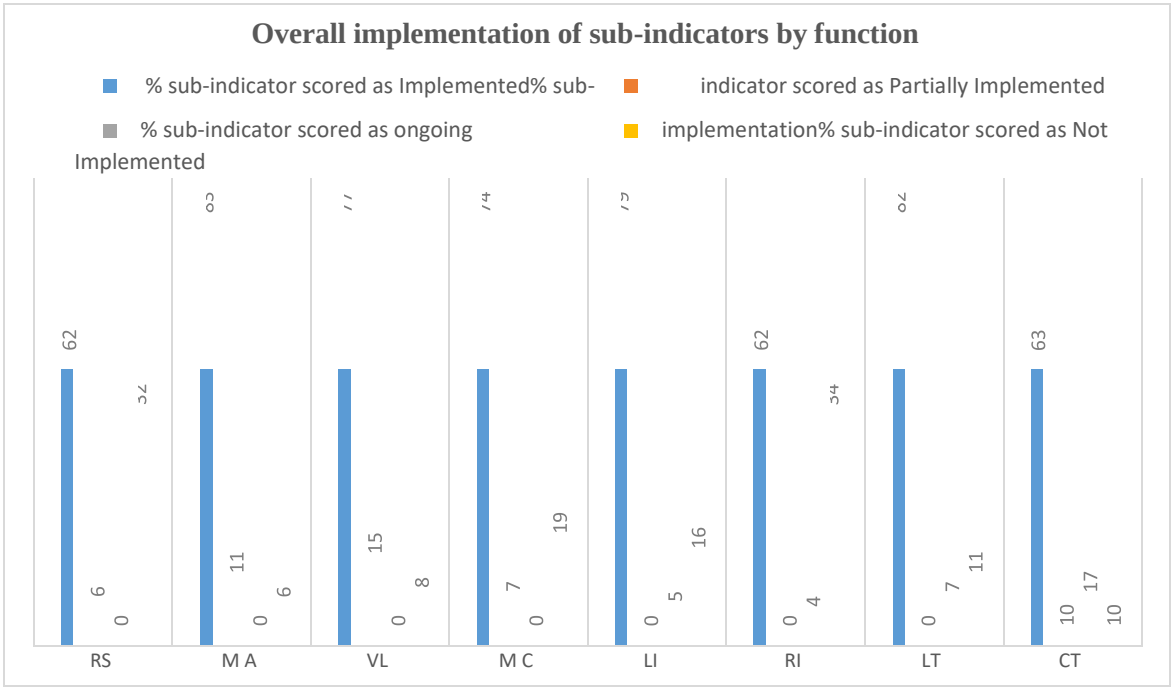

Figure 6: Overall implementation of sub-indicators by function

Considering the category of indicators, the results of this study showed that the subindicators related to the first indicator category which is **legal provisions, regulations and guidelines**

were the most implemented because 55 of the 59 sub-indicators (93%) were rated as implemented; sub-indicators related to the second indicator category which is **organization and governance** were rated as implemented at 83% (15 sub-indicators out of 18); sub-indicators related to the third indicator category which is **policy and strategic planning** were rated as implemented at 75% (9 sub-indicators out of 12); sub-indicators related to the fourth indicator category which is **leadership and crisis management** were rated as implemented at 60% (3 sub-indicators out of 5); sub-indicators related to the fifth indicator category which is **quality and risk management system** were rated as implemented at 43% (6 sub-indicators out of 14); sub-indicators related to the sixth indicator category which is **Resources** were rated as implemented at 76% (32 sub-indicators out of 42); sub-indicators related to the seventh indicator category which is **regulatory process** were rated as implemented at 80% (39 sub-indicators out of 49); sub-indicators related to the eighth indicator category which is **transparency, accountability and communication** were rated as implemented at 46% (13 sub-indicators out of 28) while the sub-indicators related to the ninth indicator category which is **monitoring progress and assessing outcomes & impact** were rated as implemented at 29% (7 sub-indicators out of 24). (See figure 7 below)

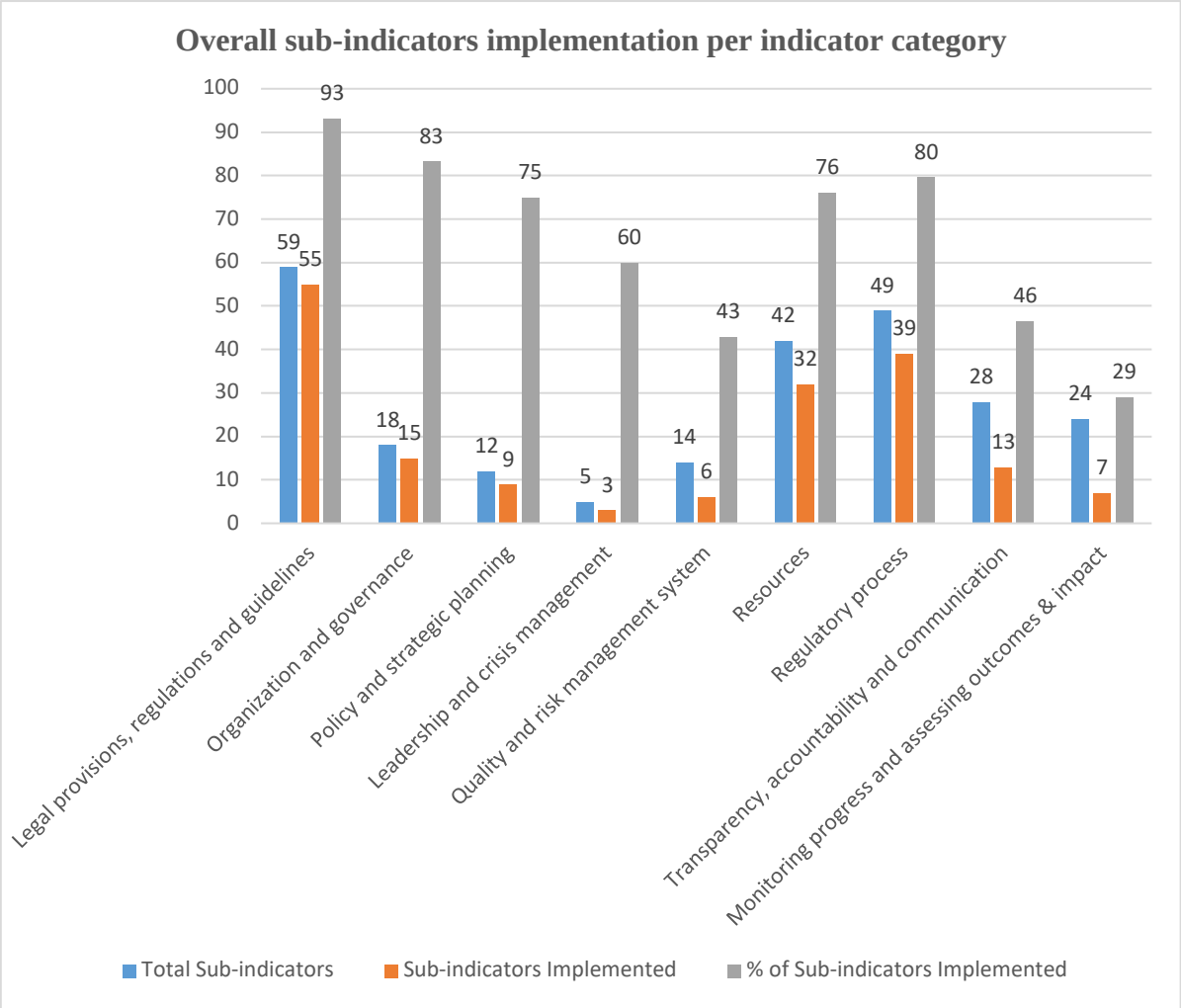

Figure 7: Overall implementation of sub-indicators by indicator category

4. 9 Estimated maturity level of Rwanda FDA

According to the World Health Organization, NMRAs can reach different levels of maturity and a regulatory function cannot be scored less than maturity level 1 (ML1). In addition, upon reaching maturity level 2 (ML2) up to maturity level 4 (ML4), it is mandatory that all sub-indicators linked to the lower maturity levels are fully implemented (31).

Table 47 below provides more details on how to calculate the estimated maturity levels based on the number of sub-indicator implementations.

Table 47: WHO maturity level algorithm

Maturity Level	% of implementation for sub-indicators			
	% I sub-indicators	% PI subindicators	% OI subindicators	% NI subindicators
1	Up to 100% of ML1	Up to 100% of ML1		Up to 100% of ML1
2	95% of ML1+ML2	5% of ML1+ML2		0
3	100% of ML1+ML2 and 90% of ML3	10% of ML3		0
4	100% of ML1+ML2+ML3 and 80% of ML4	20% of ML4		0

Table 48:Sub-indicator per regulatory component

Function	RS	MA	VL	MC	LI	RI	LT	CT	Total
# sub-indicator	60	35	26	27	19	26	28	30	251
# sub-indicator measuring Maturity Level 1	4	6	5	3	2	3	2	2	27
# sub-indicator measuring Maturity Level 2	7	2	3	4	1	2	2	8	29
# sub-indicator measuring Maturity Level 3	27	23	14	15	13	13	18	18	141
# sub-indicator measuring Maturity Level 4	22	4	4	5	3	8	5	3	54

Table 48 above shows sub-indicator per regulatory component whereas the interpretation of the study results based on WHO maturity level algorithm is provided in table 49.

Table 49: WHO maturity level Algorithm-Study Results

Maturity Level	**% of implementation for sub-indicators**						
	% I subindicators	**Study results**	**% PI subindicators**	**% OI subindicators**	**Study results**	**% NI subindicators**	**Study results**
1	Up to 100% of ML1=**27 subindicators**	**26 subindicators**	Up to 100% of ML1= **0 subindicator**		**One indicator**	Up to 100% of ML1	
2	95% of ML1+ML2= 95% (27+29 subindicators)= **53 sub-indicators**	**53 subindicators**	5% of ML1+ML2= **3 sub-indicators**		**3 subindicators**	0	
3	100% of ML1+ML2 and 90% of ML3=(27+29)+12 7=**183 subindicators**	**174 subindicators**	10% of ML3=**14 subindicators**		**23 subindicators**	0	
4	100% of ML1+ML2+ML3 and 80% of ML4= **197+43= 240 subindicators**	**179 subindicators**	20% of ML4= 11 **subindicators**		0	0	**49 subindicators**

Considering the maturity level algorithm as defined by World Health Organization, the findings of this study showed that at maturity level 1, a total of 26 out of 27 sub-indicators were rated as implemented whereas one sub-indicator was scored ongoing implementation. At maturity level 2, all fifty-three required sub-indicators were scored as implemented and all three sub-indicators were scored either as partially implemented or ongoing implementation.

At maturity level 3, one hundred and seventy-four out of the 183 required sub-indicators were rated as implemented, while twenty-three sub-indicators, instead of fourteen, were rated as partially implemented or ongoing implementation. **Therefore, the estimated maturity level at which Rwanda FDA operates is maturity level 2,** if we apply the WHO maturity level algorithm rule, which states that the overall maturity of the regulatory system is equal to the lowest maturity level of any function subject to benchmarking. (See table 50 below).

Table 50: Estimated maturity level of Rwanda FDA

Maturity Level	# required subindicators fully implemented	Study results	# required sub-indicators PI or OI	Study results	# required sub-indicators NI	Study results
1	27	26	0	1	0	0
2	**53**	**53**	**3**	**3**	**0**	**0**
3	183	174	14	23	0	0
4	240	179	11	0	0	49

CHAPTER FIVE: DISCUSSION AND CONCLUSION

5.1 DISCUSSION

The main sources of funding for the Rwandan FDA have been found to be the State budget allocation, donor funding and income for services rendered. The results of the present study are similar to the results of the study conducted by Ndomondo-Sigonda, M., et al. (2020) to assess NMRAs financial sustainability in the East African Community that revealed that most of NMRAs in the East African Community rely on states budget allocation, internally generated revenues and donor funding to perform the regulatory functions. The same study also showed that adequate and sustainable funding capacity is needed to ensure the quality, safety and efficacy of medical products circulating on the market of any country (19).

It was found that Rwanda FDA has no QMS structure to implement implementing a comprehensive QMS that integrate risk management principles. Similar results were also found in the assessment conducted by the World Health Organization (2010) in the NMRAs of sub-Saharan African countries, where four of the 26 NMRAs (15%) were found to have some elements of QMS (23).

Medicines registration and marketing authorization was found to be supported by legal provisions. The results of the present study are similar to the results of the study conducted by Ndomondo-Sigonda, M., et al. (2017) to assess the regulatory capacity of twenty-six African countries which revealed that all countries assessed had in place legal provisions, regulations, guidelines and standard operating procedures for marketing authorization of medicines and vaccines (4).

The defined registration timeline to register the medicines was stated to be nine months in the guidelines but the finding of the present study showed the timeframe for product registration can go beyond the required timeframe due to different challenges highlighted by respondents. Similar results were found in the study conducted by Ndomondo-Sigonda, M., et al. (2017) to assess the regulatory capacity of twenty-six African countries which revealed

that long registration time by NMRA in Africa is one of the reasons why manufacturing facilities refuse to supply medical products in some African countries (4).

The findings of this study revealed that Rwanda FDA lacks expert assessors for the key parts of the dossier, lacks adequate staff to perform medicines registration activities and does not have Electronic Regulatory Management Information Systems for managing and handling the dossier applications effectively and efficiently. Similar results were found in the study conducted by Ndomondo-Sigonda, M., et al. (2017) to assess the regulatory capacity of twenty-six African countries which revealed that all assessed countries lacked expert assessors/inspectors, lacked sufficient human resources and other technical capacity. Ndomondo-Sigonda, M. and colleagues highlighted the areas that need improvement which include training of personnel and other technical capacities to ensure the quality of medicines (4).

The findings of the present study showed that Rwanda FDA has established a pharmacovigilance system that is supported and enforced by legal provisions, regulations and guidelines. Similar results were found in the study conducted by Barry A, Olsson S, Minzi O, Bienvenu E, Makonnen E, Kamuhabwa A, et al. (2020) in comparative assessment of PV systems in East Africa (25). Similar results were also found in the study conducted by Ampadu HH, Hoekman J, de Bruin ML, Pal SN, Olsson S, Sartori D, et al. (2016) on ADR reporting in Africa that found that the reporting rate of Individual Case Safety Report (ICSR) was low in Africa compared to the rest of the world. The same study found that the PV system in Africa lacked sufficient human resources and training of staff implementing the PV system (26).

The results of this study showed that a remarkable step forward has been achieved in Post Marketing Surveillance since the creation of Rwanda FDA. Similar results were found in the study conducted by Ndomondo-Sigonda, M., et al. (2017) to assess the regulatory capacity of twenty-six African countries which revealed that there was a good improvement in the regulatory capacity of assessed NMRAs, especially in PMS, quality control laboratory, pharmacovigilance and clinical trial oversight (4).

The findings of this study showed that Rwanda FDA uses the PMS and vigilance activities to detect and respond to the problem of SF medicines that may arise but there are porous borders that can be used to smuggle medicines into the country. Similar findings were revealed in the study conducted by Roth L, Biggs KB, Bempong DK, (2019) on SF medicines screening technologies which found that the use of screening technologies are not widely implemented in LMICs to combat SF medicines (10).

The study showed that the method used to prevent and detect SF medicines at the port of entry is not adequate, as only visual inspection is performed to verify label requirements and package integrity, storage conditions, dosage units and documentation according to import or export requirements. Similar findings were revealed in the study conducted by Roth L, Biggs KB, Bempong DK, (2019) on SF medicines screening technologies that SF medicines screening technologies/tools should be used for any NMRA in the field to prevent and detect SF medicines before they enter the market. However, the study of Roth L, Biggs KB, Bempong DK, found that the use of screening technologies are not widely implemented in LMICs to combat SF medicines (10).

It was found that there was insufficient staff to conduct regulatory inspection, especially onsite GMP inspection, virtual GMP inspection or GMP desk review assessment. This may hinder the registration process and affect the availability of quality assured, safe and efficacious medicines in the Rwandan market. Similar findings were revealed in the study conducted by Thumm Mellisa, Goredema Wonder, Gaparayi Patrick TD to assess the medicine regulatory system in Angola that showed that the Inspection Department was understaffed and the lack of staff in the inspection department hampered the registration department to perform its daily tasks (28).

It was found that the laboratory does not have ISO 17025 Quality Management System (QMS) accreditation and is not the WHO Guidance for Good Laboratory Practice Prequalified. Similar results were found in the assessment conducted by the World Health Organization (2010) to access the capacity of 26 NMRAs in sub-Saharan African countries,

which showed that most of the countries assessed lacked a QMS and adequate equipment for quality control laboratories (23).

Lack of equipped clinical trial sites was reported as one of the challenges hindering the practice of clinical trial monitoring in Rwanda FDA. Similar findings were revealed in the study conducted by Maïga D, Akanmori BD, Chocarro L (2009) to evaluate the progress of the regulatory oversight of clinical trials in Africa that found that NMRAs in Africa lacked the adequate infrastructure to conduct clinical trials as well as qualified personnel to host clinical trials conduct (31).

5.2 CONCLUSION

Similar to the existing literature related to the capacity of NMRA to ensure the quality of medicines throughout the supply chain; the results of this study showed there is a progressive improvement in the regulatory capacity of the Rwanda FDA since its inception.

The results showed that all key regulatory functions which are Registration and Marketing Authorization, Vigilance, Market Surveillance and Control, Licensing Establishments, Regulatory Inspection, Laboratory Testing and Clinical Trials Oversight were addressed. The legal framework is in place to enable effective and efficient implementation of the key regulatory functions. The legal framework provides adequate powers to the Rwanda FDA to ensure the quality, safety and efficacy of medicines on the market. The scope of products to be regulated is well defined.

However, respondents reported internal and external challenges that might hinder the successful implementation of those key regulatory functions to ensure the quality of medicines including understaffing, lack of capacity building for staff, lack of automation system, poor implementation of the quality management system, under-reporting of ADRs/AEFI, lack or poor stakeholders involvement, lack of awareness of some regulatory activities, lack of screening technologies for SF medicines, low capacity of the quality control laboratory to test all sampled medicines, lack of a budget dedicated to some activities especially post-marketing surveillance, lack of regulatory inspections tools/equipment,

regulatory inspection not planned based on quality risk management (QRM) and applicants that do not comply with laws and regulations and delay to respond to queries addressed to them by the Rwanda FDA.

This suggests a need for adequate interventions targeting all key stakeholders of Rwanda FDA both public and private for awareness of regulatory activities, avail sufficient staff to perform key regulatory functions, avail screening technologies for SF medicines at the main ports of entry, equip the quality control laboratory with adequate equipment and plan regulatory inspection based on quality risk management (QRM) approach for effective use of available resources.

5.3 RECOMMENDATIONS

Based on the findings of this research, recommendations have been proposed for Rwanda FDA so that the Authority can attain the World Health Organization (WHO) Maturity Level 3, which indicates that the system is well-functioning and integrates all required elements to guarantee its stable performance and to be qualified to host vaccine manufacturing plants. This will ensure that the Authority can fully perform its mandate to ensure the qualityassured medicines in the market.

- Rwanda FDA needs to avail sufficient personnel to carry out regulatory activities related to the evaluation and assessment of dossiers submitted for marking authorization, establishment licensing and regulatory inspections, pharmacovigilance, post-marketing surveillance as well as clinical trial oversight. A sustainable solution to overcome the understaffing challenge would be to increase the staff number. This will require revising the current structure of the Rwanda FDA, hiring contract staff or maximizing internal staff work arrangement.

- The automation system to manage all key regulatory functions which can improve the performance of Rwanda FDA is an area of improvement that needs to be considered to ensure transparency, accountability and effective communication with all stakeholders.

- Rwanda FDA will need to implement a comprehensive quality management system (QMS) that integrate risk management principles to ensure compliance with established standards and the satisfaction of customer needs. To this end, the Authority should aim to obtain ISO 9001:2015 certification. The implementation of a comprehensive QMS will ensure that each step of the regulatory process is identified and documented.

- Rwanda FDA needs to design and implement interventions targeting all key stakeholders both public and private involved in ensuring the quality of medicines throughout the supply chain to improve awareness of the mandate of the Authority to protect and promote public health. The awareness company shall include the importance of ADRs/AEFI reporting, post-market surveillance as well as the published laws, regulations and guidelines.

- Rwanda FDA needs to invest in SF screening technologies such as minilabs, etc. at the main ports of entry of imported medicines as well as medicines already on the market. Investing in SF screening technologies will help to identify poor quality medicines before they reach the market and facilitate the withdrawal of these poor-quality drugs from the market.

- Rwanda FDA will need to equip the quality control laboratory according to international standards. To do so, the Rwanda FDA should have a quality control laboratory with ISO 17025 Quality Management System (QMS) certification or a laboratory prequalified according to the WHO Guide to Good Laboratory Practice. These are the global reference tools for measuring the performance standards of quality control laboratories to ensure the quality of medicines throughout the supply chain.

- Rwanda FDA needs to avail appropriate regulatory inspections tools/equipment for inspectors to ensure the safety of inspectors as well as the quality of inspections reports performed.

- Rwanda FDA needs to plan regulatory inspection based on quality risk management (QRM) principles to ensure effective and efficient use of available resources. To this end, Rwanda FDA should develop and implement a standard operating procedure for planning regulatory inspections based on the QRM approach.

- Rwanda FDA needs to build the capacity of staff in all regulatory functions to ensure that staff are of the required level to carry out regulatory activities to acceptable standards.

5.4 RECOMMENDATION FOR FUTURE RESEARCH

The study provided the general overview of the capacity of Rwanda FDA and did not go into deep for each regulatory function. Therefore, authors recommend future research to address limitations of the study by conducting deep analysis of each functionality, to assess issues and how they can be addressed.

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ANNEX 1: INFORMED CONSENT FORM

Title: Assessing the Capacity of the National Medicine Regulatory Authority in Ensuring the Quality of Medicines in Rwanda.

PART I: Information Sheet Introduction

My names are BIRIKUNZIRA SHABANI JEAN BAPTISTE, a student at the University of Rwanda, EAC Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management. I am conducting a study to assess the capacity of the national medicine regulatory authority in ensuring the quality of medicines in Rwanda.

Purpose of the research

The study will assess the capacity of the Rwanda FDA in ensuring the quality of medicines in Rwanda and come up with the findings and recommendations that will help the decisionmakers and stakeholders to focus on the priorities areas and gaps in planning future regulatory functions to combat the poor quality medicines.

Type of Research Intervention

N/A

The research will use a semi-structured questionnaire, a review of key regulatory documents and an interview with the key informants.

Selection of participants

The population in this research are employees of the Rwanda FDA who have expertise in medicine regulatory practices based on their roles in ensuring the quality of medicines.

This study will use a non-probability sampling technique known as purposive sampling. Participants will be selected depending on their position in the selected targeted divisions or units, year of experience based on the inclusion criteria and capacity to provide the richest information regarding the research objective and research questions.

Voluntary Participation

Your participation in this study is voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your professional standing or your everyday life. You may change your mind later and stop participating even if you agreed earlier.

Procedures

The study will include completing the semi-structured questionnaire and review of key regulatory documents. An interview with the key informant to validate the information obtained from the documented evidence if necessary can be conducted.

Duration

The fill the questionnaire will each take approximately thirty minutes' maximum of your time.

Risks and Discomforts

E.g. The risks to you as a participant in this study are minimal. During the group discussion, you may decide to share information. But, again, you may decline to answer any questions that you do not wish to answer or stop the interview at any time, without giving any reasons.

Benefits

There will be no direct benefit to you, but with your participation, we hope to improve the availability of quality medicines in the Rwandan health supply chain.

Reimbursements/ Incentives

You will not receive any payment or any other benefit to take part in this study, but your participation in this research is essential. Only will refund the transportation fees if any.

Confidentiality

We will not share information about you and your institution/company with anyone outside of the team undertaking this activity. The information that we collect will be kept private. All collected data will be stored in a database accessible only by the principal investigator. Any information about you and your institution will be identified by a number on it instead of your name/your institution.

Sharing of Research Findings

The research findings will be shared by Rwanda FDA, participants and other key stakeholders. We will in the future publish on the process and the results, but you and your feedback will remain anonymous.

Right to refuse or withdraw

To reiterate, you do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the group discussion(s) or interview at any time that you wish without your job being affected.

Whom to contact in case you have questions about your rights as a research participant

All research on human volunteers is reviewed by the College of Medicine and Health Sciences (CMHS) Institutional Review Board (IRB) which works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the CMHS/IRB through the:

Chairperson:
Prof Kato J NJUNWA
researchcenter@ur.ac.rw
Mobile phone: 0788 490 522

Secretary:
fsunday@khi.ac.rw
Mobile phone: **07885-63312** If you have any questions about this research, you may address your query to lead investigators:

Local Lead Investigator: BIRIKUNZIRA SHABANI Jean Baptiste, Tel: 0788540976 email: jbb.shabani@gmail.com

Supervisor: -Dr. INNOCENT HAHIRWA Tel: 0786006010
-Mr. MUNYANGAJU JOSE EDOUARD Tel: 0788857525

If you choose to be part of this research study, I will also give you a copy of this consent form to keep for yourself. Do you have any questions?

PART II: Certificate of Consent

I have been asked to participate in the study named "**Assessing the Capacity of the National Medicine Regulatory Authority in Ensuring the Quality of Medicines in Rwanda".**

I have read the information provided above. I have asked all the questions; I have at this time. I voluntarily agree to participate in this research study. I may withdraw my consent at any time and stop participation without penalty. By agreeing to be in this research, I have not given up any of my legal rights.

I consent voluntarily to be a participant in this study : Yes / No I agree to be recorded/…….. : Yes / No

Print name of participant:
Signature of participant:
Date (day/month/year):

Print name of Researcher:
Date (day/month/year):

If illiterate:
A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness:
Signature of witness:
Date (day/month/year):

Thumb print of participant:

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of Witness:

Signature of Witness:

Date (day/month/year):

Copy provided to the participant

ANNEX 2: QUESTIONNAIRE FOR THE STUDY

"ASSESSING THE CAPACITY OF THE NATIONAL MEDICINE REGULATORY AUTHORITY IN ENSURING THE QUALITY OF MEDICINES IN RWANDA".

Name and contact information of principal investigator/*IZINA N'IBIRANGA URIGUKORA UBUSHAKASHATSI*

BIRIKUNZIRA SHABANI JEAN BAPTISTE, STUDENT AT UNIVERSITY OF RWANDA, College of Medicine and Health Sciences.
Tel: +250788540976, Email: jbb.shabani@gmail.com

The following questionnaire will be completed with voluntary participation noted as consent.
IBIBAZO BIKURIKIRA BIRAZA GUSUBIZWA KUBUSHAKE

INSTRUCTIONS

1. This is the questionnaire to collect data on the capacity of Rwanda FDA in ensuring the quality of medicines in Rwanda; it is composed of two parts: Part I and Part II. **Ibi bibazo bigizwe n'ibice bibiri by'ingenzi**
2. The participant is requested to answer all questions/ **Murasabwa gusubiza ibibazo byose**
3. Answers have to be provided in appropriate, mentioned space/ **Murasabwa musubiriza mu mwanya wateganyijwe**
4. You are not allowed to mention your name on this questionnaire/ **Murasabwa kudashyiraho izina ryanyu**

Part I. Demographic data profile/Ibiranga usubiza

Please answer the following questions and give mark **(X)** On the parenthesis and fill in the blank area**. Murasabwa gushyira akamenyetso ko gukuba (X) mu mwanya wateganyijwe mu gihe musubiza**

1. Please indicate your age/Hitamo imyaka yawe:

a) Below 25 years/munsi y'imyaka 25: **(……)**
b) Between 25- 34 years/Hagati y'imyaka 25- 34: **(……)**
c) Between 35- 45 years/Hagati y'imyaka 35- 45: **(……)**
d) Above 45 years/Hejuru y'imyaka 45: **(……)**

2. Please indicate your Gender:

a) Male: **(……)**
b) Female: **(……)**

3. What is your level of education/ Hitamo amashuri wize?

a) Certificate (A2)/Ayisumbuye: **(……)**
b) Advance diploma (A1)/ Kaminuza ikicyiro cya mbere: **(……)**
c) Bachelor's Degree (A0)/ Kaminuza ikicyiro cya kabiri: **(……)**
d) Masters' Degree/ Kaminuza ikicyiro cya gatatu: **(……)**
e) PhD: **(……)**
f) Other (specify)/Ayandi mashuri muyavuge: **(……)**

4. What is your working experience/ *Mufite uburambe mukazi bungana gute*?
a) Less than one year/Munsi y'umwaka: **(……)**
b) Between 1-5 years/Hagati y'imyaka 1-5: **(……)**
c) Between 5-10 years/Hagati y'imyaka 5-10: **(……)**
d) Above 10 years/Hejuru y'imyaka 10: **(……)**

5. Have you ever taken any training related to your responsibilities of your position/Mwaba mwarahuguwe ku bijyanye nibyo mukora?

No: **(……), Yes: (……)**

If YES, Name the training you received/Niba mwarahuguwe, mwatubwira amahugurwa mwabonye:

Specific Objective One: To assess the regulatory framework supporting the functioning of Rwanda FDA

S/N	Indicators	Questions (Sub Indicator)	Please Respond by (Chose One): ***NI:*** *NOT IMPLEMENTED* ***OI:*** *ONGOING IMPLEMENTATION* ***PI:*** *PARTIALLY IMPLEMENTED* ***I:*** *IMPLEMENTED*
1	**RS01 Legal provisions, regulations and guidelines required to define regulatory framework of national regulatory system (RS)**	RS01.01: Legal provision and regulations define the medical products that should be regulated.	
		RS01.02: Legal provision and regulations define the institutions that are involved as part of the regulatory system, as well as their mandates, functions, roles, responsibilities and enforcement powers.	
		RS01.03: When more than one institution or authority is involved in regulatory oversight, the regulations should define administrative arrangements and the channels of communication and coordination.	

		RS01.04: All regulatory entities (central and decentralized ones) follow non- contradictory regulations, standards, guidelines and procedures.	
		RS01.05: Legal provisions and relevant regulations to take actions on recall, suspension, withdrawal and/or destruction of substandard and falsified (SF) medical products.	
		RS01.06: Legal provisions and regulations define requirements of transparency and dissemination of information to the public and relevant stakeholders.	

		RS01.07: Development of the regulations involves Rwanda FDA responsible for their implementation and enforcement.	
		RS01.08: Rwanda FDA consults or involves specific sectors of the civil society (such as nongovernmental organizations (NGOs) representing health professionals, industry, consumers and patients) during the development or adoption of regulations and guidelines.	
		RS01.09: A guideline on complaints and appeals against regulatory decisions is available to the public.	
2	**RS02 Arrangement for effective organization and good governance.**	RS02.01: The structure and line of authority among, and within, all institutions that participate in the regulatory system is defined, documented and implemented.	
		RS02.02: Channels of communication and decision-making are established among the structures, institutions, and departments forming the NRA.	
		RS02.03: Scientific and advisory committees exist to advise Rwanda FDA on topics of scientific and regulatory interest and future objectives and strategies.	
		RS02.04: Independence of Rwanda FDA from researchers, manufacturers, distributors and wholesalers, as well as from the procurement system.	
3	**RS03 Strategic plan with clarified objective in place.**	RS03.01: A national drug policy, aligned with health policy, exists and is implemented.	
		RS03.02: Rwanda FDA has established and declared its vision, mission and strategic priorities.	
		RS03.03: A plan for achieving strategic objectives is developed, implemented and regularly updated.	
		RS03.04: Documented policies, procedures and mechanisms, including written criteria, are established for recognition and reliance on decisions of other National Regulatory Authorities	

		RS03.05: Rwanda FDA is promoting good regulatory practices (GRPs).	
4	**RS04 Regulatory system is supported with leadership and crisis management plans.**	RS04.01: Leadership ensures that the strategic priorities and objectives are well known and communicated throughout the NRA.	
		RS04.02: A rapid alert system for managing the threats by SF medical products and for recalling these products from the market.	
		RS04.03: A rapid alert and recall system based on documented communication to the appropriate level of the distribution channel and with a feedback mechanism.	
		RS04.04: Recall system based on documented confirmation that appropriate, batch-traceable action and/or destruction has been undertaken when necessary.	
		RS04.05: Written criteria to cover circumstances in which the routine regulatory processes may not	

		have to be followed in relation to crises and emergencies linked to a risk management plan.	
5	**RS05 Quality management systems (QMS) including the risk management principles are applied and realized.**	RS05.01: Top management demonstrates commitment and leadership to develop and implement quality management system (QMS).	
		RS05.02: Quality policy, objectives, scope and action plans for establishment of the QMS are in place and communicated to all levels.	
		RS05.03: Organizational chart, with roles and responsibilities to establish the QMS are defined and in place.	
		RS05.04: Enough competent staff is assigned to develop, implement and maintain the QMS.	
		RS05.05: Rwanda FDA establishes mechanisms to continually improve the QMS.	
		RS05.06: Rwanda FDA has identified its regulatory processes, determined their interactions and defined the methods needed to control these processes.	
		RS05.07: Requirements for documentation management as well as traceability of regulatory activities are established.	
		RS05.08: External and internal issues including relevant potential risks are defined and assessed periodically for proper risk mitigation.	
		RS05.09: The externally provided products and services relevant to regulatory activities are controlled through established mechanisms.	

		RS05.10: A mechanism to evaluate the satisfaction of internal and external customers and other interested parties is in place for system improvement.	
		RS05.11: Internal and external audits of the QMS are established and conducted at planned intervals.	
		RS05.12: Corrections, corrective actions, and other actions for risk mitigation and overall improvement, are implemented and documented and their effectiveness is verified	
		RS05.13: Top management reviews and documents the organization's QMS at planned intervals (i.e., management review).	
		RS05.14: A mechanism is established to evaluate and demonstrate the effectiveness of training activities.	
6	**RS06 Human resources to perform regulatory activities.**	RS06.01: The NRA has the power to select and recruit its own staff following documented procedures based on its own written criteria (i.e., education, training, skills and experience).	
		RS06.02: A periodic staff appraisal system is established to review performance and competencies, to identify training needs, and to agree on performance targets.	
		RS06.03: A documented policy or procedure for the appointment and recruitment of external experts is available.	
		RS06.04: A documented mechanism to handle potential conflicts of interest for internal and	

		external experts and committee members, to gather declarations of interest and to guarantee the update of these declarations for all regulatory functions.	
7	**RS07 Financial resources to perform regulatory activities.**	RS07.01: Sources of funding are established for the NRA and affiliated institutions to carry out all regulatory functions.	
		RS07.02: The amounts collected for fees, taxes, tariffs or dues payable for the services provided are defined and publicly available.	
		RS07.03: There are provisions relating to reduction or exemption of dues, taxes, tariffs or fees in defined situations for public health interest.	
		RS07.04: Rwanda FDA has authority to manage the funds allocated and/or generated internally.	
		RS07.05: Rwanda FDA periodically publicizes its budget.	

8	**RS08 Infrastructure and equipment to perform regulatory activities.**	RS08.01: The workspace and work environment provided for performing the regulatory activities are adequate.	
		RS08.02: The workspace and work environment provided for performing the regulatory activities includes essential requirements.	
		RS08.03: The equipment provided for performing the regulatory activities is adequate.	
9	**RS09 Mechanisms exist to promote transparency, accountability and communication.**	RS09.01: The NRA participates in regional and/or global networks to promote convergence and harmonization efforts and expand its collaboration in the regulatory field.	
		RS09.02: The information on laws, regulations guidelines and procedures is publicly available and is kept duly updated.	
		RS09.03: Information on decisions related to regulatory activities is available to the public.	
		RS09.04: Information on marketed medical products, authorized companies and licensed facilities is publicly available.	
		RS09.05: All publicly available information is periodically reviewed and maintained.	
		RS09.06: Appropriate mechanisms exist for management of confidential information.	
		RS09.07: A code of conduct, which includes management of conflicts of interest, is published and enforced for internal and external staff, including members of the advisory committees.	
		RS09.08: Rwanda FDA uses computerized systems to process information, manage records, and analyze data.	
		RS09.09: The NRA has its own web page with timely information that gives public access to related legal provisions, guidelines and decisions.	
10		RS10.01: Requirements established to monitor, supervise and review the performance of the NRA	
	RS10 Mechanism in place to monitor regulatory performance and output.	and affiliated institutions using key performance indicators (KPIs).	
		RS10.02: Reports on the regulatory activities and on the progression and status of resources are available at regular intervals.	

What are challenges do you encounter in the regulatory framework supporting the functioning of Rwanda FDA (Rwanda FDA Regulatory System)

List of Challenges (if any):

……
……
……

Proposed ways to Prevent or Solve the challenges you listed above:
……
……
……

Specific Objective TWO: To assess the practices of medicines registration and marketing authorization (MA) in Rwanda FDA
NB: The following questions shall be completed by staffs of the Human Medicine and Devices Assessment & Registration Division.

S/N	Indicators	Questions (Sub Indicator)	Please Respond by (Chose One): ***NI:*** *NOT IMPLEMENTED* ***OI:*** *ONGOING IMPLEMENTATION* ***PI:*** *PARTIALLY IMPLEMENTED* ***I:*** *IMPLEMENTED*
1	**MA01 Legal provisions, regulations and guidelines required to define regulatory framework of registration and/or marketing authorization.**	MA01.01: There are legal provisions that require the receipt of a registration or marketing authorization (MA) before placing the product on the market.	
		MA01.02: There are legal provisions that require the NRA to withhold, suspend, withdraw or cancel an MA if there are concerns regarding quality, safety or efficacy issues.	
		MA01.03: There are legal provisions that require demonstration of the product quality, safety and efficacy prior to registration or MA.	
		MA01.04: There are legal provisions or regulations limiting the duration of the validity of the MA and requiring periodic reviews of MAs (i.e. renewals).	
		MA01.05: There are regulations or guidelines for the definitions, types and the scope of variations along with the required documentation for these variations.	

		MA01.06: There are legal provisions to cover circumstances under which the routine MA procedures may not be followed (e.g., for public health interest).	
		MA01.07: There are legal provisions or regulations that define regulatory requirements to approve donation of medical products.	
		MA01.08: Legal provisions or regulations allow the NRA to recognize and/or rely on MA-relevant decisions, reports or information from other NRAs or regional and international bodies.	
		MA01.09: Specific guidelines on the quality, nonclinical and clinical aspects are established and implemented.	
		MA01.10: There are guidelines on the format and content for submission of MA applications that are consistent with the WHO or other internationally accepted standards.	
		MA01.11: There are guidelines for MA holders that define the types and scope of variations, the format and content to be used for documenting the variations, and the identification of those variations that require prior approval or notification.	
		MA01.12: There are established guidelines that cover circumstances under which the routine MA procedures may not be followed (e.g., for public-health interest).	
		MA01.13: There are guidelines on the content of product information leaflets, SPC-like information, and product packaging and labelling.	
2	**MA02 Arrangement for effective organization and good governance.**	MA02.01: There is a defined structure with clear responsibilities to conduct registration or MA activities.	
		MA02.02: Documented and implemented procedures exist to ensure involvement and communication with all relevant regulatory entities as necessary.	
3	**MA03 Human resources to perform registration and**	MA03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform MA or registration activities.	

	marketing authorization activities.	MA03.02: Duties, functions, and responsibilities of the staff in charge of MA or registration activities are established and updated in the respective job descriptions.	
		MA03.03: Training plan developed, implemented and updated at least once a year for staff in charge of MA or registration activities.	
		MA03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.	
4		MA04.01: Documented procedures and tools are implemented for the assessment of the different	
	MA04 Procedures established and implemented to perform registration and/or marketing authorization.	parts of the application (i.e., quality, and efficacy) and for the assessment of specific requirements applicable to specific classes of medical products.	
		MA04.02: Documented procedures have been implemented to renew and/or to periodically review the MAs granted.	
		MA04.03: Documented procedures are implemented for assessing applications for variations of MAs.	
		MA04.04: The same criteria apply for assessing applications regardless of the origin of or destination for the medical products (e.g., domestic, foreign, public sector, or private sector).	
		MA04.05: An advisory or scientific committee, including external experts is involved in the review of MA applications (as needed).	
		MA04.06: Timelines for the assessment of the applications are defined and an internal tracking system has been established to monitor adherence to the targeted time frames.	
		MA04.07: There are documented mechanisms to handle non-routine registration or MA requirements in special situations (e.g., publichealth interest).	
		MA04.08: SPC-like, labelling and packaging information are approved by the Rwanda FDA as part of the MA procedure.	
		MA04.09: GMP inspection report and/or certification is considered as part of the MA process.	
		MA04.10: The regulations and guidelines for good review practices (GRevPs) are developed or recognized and implemented.	
5	**MA05 Mechanism exists to promote transparency,**	MA05.01: Web site or other official publication with SPC-like information is available and regularly updated.	

	accountability and communication.	MA05.02: Updated list of all medical products granted MA is regularly published and publicly available.	
		MA05.03: A summary technical evaluation report for approved registration MA applications is published and available to the public.	
		MA05.04: A summary technical evaluation report for deferred or rejected registration or MA applications is published and available to the public.	
6	**MA06 Mechanism in place to monitor regulatory performance and output.**	MA06.01: There is a database of all product applications received, approved, rejected, suspended or withdrawn along with their supporting documentation.	
		MA06.02: Performance indicators for registration and MA activities are established and implemented.	

What are challenges do you encounter in the process of medicines assessment and registration?

List of Challenges (if any):

……
……

Proposed ways to Prevent or Solve the challenges you listed above:
……
……

Specific Objective THREE: To assess the vigilance system in Rwanda FDA
NB: The following questions shall be completed by staffs of Pharmacovigilance & Food Safety Monitoring Division: STAFF DEALING WITH VIGILANCE (VL).

S/N	**Indicators**	**Questions (Sub Indicator)**	**Please Respond by (Chose One):** ***NI:*** *NOT IMPLEMENTED* ***OI:*** *ONGOING IMPLEMENTATION* ***PI:*** *PARTIALLY IMPLEMENTED* ***I:*** *IMPLEMENTED*
1	**VL01 Legal provisions, regulations and guidelines**	VL01.01: Legal provisions for a national vigilance system exist.	

	required to define regulatory framework of vigilance.	VL01.02: Legal provisions and regulations require the manufacturers and/or MAHs to set up a vigilance system of their medical products and periodically report vigilance data to Rwanda FDA	
		VL01.03: Guidelines ensure that distributors, importers, exporters, healthcare institutions, consumers and other stakeholders are encouraged to report adverse drug reactions (ADRs) and AEs to the MAH and/or NRA.	
		VL01.04: Legal provisions and regulations allow NRA to require manufacturers and/or MAHs to conduct specific studies on safety and effectiveness under specific conditions.	
		VL01.05: Legal provisions, regulations and guidelines require manufacturers and/or MAHs to designate an individual person to be in charge of the vigilance system	
		VL01.06: There are guidelines for planning, conducting, monitoring, and reporting of vigilance activities.	
		VL01.07: Legal provisions and regulations allow recognition and/or reliance on vigilance-related decisions, reports or information from other countries or regional or international bodies.	
2	**VL02 Arrangement for effective organization and good governance.**	VL02.01: There is a defined organizational structure with clear responsibilities to conduct vigilance activities.	
		VL02.02: Documented procedures and mechanisms are implemented to ensure the	
		involvement, coordination and communication among all stakeholders relevant to vigilance activities	
3	**VL03 Human resources to perform vigilance activities.**	VL03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform vigilance activities	
		VL03.02: Duties, functions, and responsibilities of the staff in charge of vigilance activities are established and updated in the respective job descriptions.	
		VL03.03: Training plan developed, implemented and updated at least once a year for staff in charge of vigilance activities.	
		VL03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.	
4	**VL04 Proceduresıd**	VL04.01: Vigilance procedures and tools are in place and implemented for collection and assessment of ADRs and AEs.	

	established nted to perfor e activities.	VL04.02: Vigilance procedures and tools are in place for investigation, interpretation of and response to ADRs and AEs.	
		VL04.03: Standard procedures exist and are implemented for enforcement of the national vigilance system.	
		VL04.04: Risk approach is considered throughout different vigilance activities, including timely response to detected signals for risks or benefits.	
		VL04.05: Staff access to information resources relevant to vigilance processes (e.g., safety information sources and reference materials) is ensured.	
		VL04.06: Rwanda FDA has access to expert committees for review of serious emergent safety concerns, when needed.	
		VL04.07: With respect to vigilance data, assessment of the risk-benefit balance of medical products is regularly conducted.	
		VL04.08: Active vigilance activities, as well as proactive monitoring programmes (when needed) have been developed and implemented.	
5	**VL05 Mechanism in to place a monitor outp tory performance**	VL05.01: Vigilance information is used in timely manner to amend existing regulatory decisions or to issue new regulatory decisions or actions.	
		VL05.02: Performance indicators for vigilance activities are established and implemented.	
6	**VL06 Mechanism exists to promote transparency, accountability and communication.**	VL06.01: Vigilance activities and relevant feedback are appropriately communicated to the public.	
		VL06.02: Mechanism for regular feedback to all stakeholders on vigilance events exists and is complemented with a risk communication plan.	
		VL06.03: Vigilance data and findings are shared with relevant regional and international partners.	

What are challenges do you encounter in the effective implementation of the vigilance system in Rwanda?

List of Challenges (if any):

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Proposed ways to Prevent or Solve the challenges you listed above:

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Specific Objective FOUR: To assess the practice of Market Surveillance and Control: ***Market surveillance program for monitoring the quality of medical products throughout the supply chain, and control of promotional, marketing and advertising activities.***

(NB: The following questions shall be completed by staffs from Food and Drugs Import & Export Control Division and staffs of Pharmacovigilance & Food Safety Monitoring Division DEALING WITH POST MARKET SURVEILLANCE)

S/N	Indicators	Questions (Sub Indicator)	Please Respond by (Chose One): ***NI:*** *NOT IMPLEMENTED* ***OI:*** *ONGOING IMPLEMENTATION* ***PI:*** *PARTIALLY IMPLEMENTED* ***I:*** *IMPLEMENTED*
1	**MC01 Legal provisions, regulations and guidelines required to define regulatory framework of market surveillance and control activities.**	MC01.01: Legal provisions and regulations are in place with respect to import activities including permanent regulatory intervention at designated entry and exit ports where medical products are being moved.	
		MC01.02: Legal provisions and regulations authorize market surveillance and control activities which include product sampling from different points of the supply chain.	
		MC01.03: Legal provisions and regulations address the role of NRA in dealing with substandard or falsified (SF) medical products.	
		MC01.04: Legal provisions and regulations exist for the control of promotion, marketing and advertising of medical products to avoid communication of false or misleading information.	
		MC01.05: Legal provisions and regulations exist for placement of a product's unique identification number on its outer packaging.	
		MC01.06: Guidelines exist for importers that specify the format and content of the relevant applications and procedures to receive the necessary authorizations or permissions.	
		MC01.07: Guidelines exist on the recall, storage and disposal of SF medical products.	

2	**MC02 Arrangement for effective organization and good governance.**	MC02.01: There is a defined structure, with clear responsibilities, to conduct market surveillance and control activities.	
		MC02.02: Documented procedures or mechanisms are implemented to ensure the involvement and communication among all stakeholders relevant to market surveillance and control activities.	
3	**MC03 Human resources to perform market surveillance and control activities.**	MC03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform market surveillance and control activities.	
		MC03.02: Duties, functions, and responsibilities of the staff in charge of market surveillance and control activities are established and updated in the respective job descriptions	
		MC03.03: Training plan developed, implemented and updated at least once a year for staff in charge of market surveillance and control activities.	
		MC03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.	
4	**MC04 Procedures established and implemented to perform market surveillance and control**	MC04.01: Documented and implemented procedures exist to grant the necessary authorizations or permissions for import activities.	
		MC04.02: Documented and implemented procedures exist for regulation of promotion and advertisement of medical products	
		MC04.03: Documented and implemented procedures for active monitoring of the promotion and advertisement of medical products	
		MC04.04: Documented and implemented procedures exist for risk-based sampling of medical products from different points of the supply chain.	
		MC04.05: Documented and implemented procedures exist to enable the public to report suspected SF medical products.	
		MC04.06: Documented and implemented procedures exist in the NRA to review any complaints or market reports received.	
		MC04.07: Documented and implemented procedures and mechanisms exist to prevent, detect and respond to SF medical products.	

		MC04.08: Documented and implemented procedures exist to ensure safe storage and disposal of detected SF medical products.	
5	**MC05 Mechanism in place to monitor regulatory performance and output.**	MC05.01: Database exists of approved and refused promotional and advertising materials along with the supporting documentation.	
		MC05.02: Database for product batches that have undergone surveillance along with their	
		relevant testing results and regulatory actions is established and periodically reviewed.	
		MC05.03: Performance indicators for market surveillance and control activities are established and implemented	
6	**MC06 Mechanism exists to promote transparency, accountability and communication.**	MC06.01: Market surveillance and control activities are appropriately communicated within Rwanda FDA.	
		MC06.02: Findings and regulatory decisions of market surveillance and control activities are appropriately communicated to all national stakeholders including the general public.	
		MC06.03: Findings and regulatory decisions of market surveillance and control activities of common interest are appropriately communicated and shared with other countries and regional and international organizations.	

What are challenges do you encounter in the practice of Market Surveillance and Control?

List of Challenges (if any):

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Proposed ways to Prevent or Solve the challenges you listed above:
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Specific Objective FIVE: To assess the practices of licensing establishments in Rwanda FDA

(NB: The following questions shall be completed by staffs from Food and Drugs Inspection & Compliance Division)

S/N	Indicators	Questions (Sub Indicator)	Please Respond by (Chose One): ***NI:*** *NOT IMPLEMENTED* ***OI:*** *ONGOING IMPLEMENTATION* ***PI:*** *PARTIALLY IMPLEMENTED* ***I:*** *IMPLEMENTED*
1	**LI01 Legal provisions, regulations and guidelines required to define framework for licensing activities.**	LI01.01: There are legal provisions for licensing of facilities throughout the supply chain and based on Good Practices (GXPs) compliance.	
		LI01.02: There are legal provisions to empower the NRA to issue, suspend or revoke licenses for establishments.	
		LI01.03: There are legal provisions that require that the NRA to be informed, for the purpose of notification or approval, in case post-licensure changes or variations are made.	
		LI01.04: There are guidelines on the procedures to apply for a license and on content and format of the license application.	
		LI01.05: There are legal provisions that require manufacturers to inform the NRA about the appointed qualified and authorized person for the purpose of acknowledgment or approval.	
2	**LI02 Arrangement for effective organization and good governance.**	LI02.01: There is a defined structure with clear responsibilities to conduct establishments licensing activities.	
		LI02.02: Documented procedures and mechanisms are implemented to ensure the involvement and communication between all stakeholders relevant to establishments licensing activities.	
3	**LI03 Human resources to perform licensing activities.**	LI03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform licensing activities	
		LI03.02: Duties, functions, and responsibilities of the staff in charge of licensing activities are established and updated in the respective job descriptions.	
		LI03.03: Training plan developed, implemented and updated at least once a year for staff in charge of licensing activities.	

		LI03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.	
4	**LI04 Procedures established and implemented to perform licensing activities.**	LI04.01: Procedures for assessment of applications for licensing activities, including license issuance, renewal, modification or revocation, are established and documented.	
		LI04.02: Inspection is required for granting or re-granting a license or approval of a substantial modification.	
		LI04.03: There are clearly defined timelines for the assessment of applications.	
		LI04.04: The same criteria are used for the licensing of domestic, public and private establishments regardless of ownership.	
5	**LI05 Mechanism in place to monitor regulatory performance and output.**	LI05.01: A database is established and regularly updated that includes all licensing applications received, approved, refused, suspended or withdrawn, along with the essential documentation for each application.	
		LI05.02: Performance indicators for licensing activities are established and implemented	
6	**LI06 Mechanism exists to promote transparency,**	LI06.01: An updated list or database of all licensing applications, along with the regulatory decision for each, is regularly published and publicly available.	
	accountability and communication.	LI06.02: Inspection reports or summaries (or excerpts) relevant to licensing activities are published and publicly available.	

What are challenges do you encounter in the practice of in LICENSING ESTABLISHMENTS?

List of Challenges (if any):

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Proposed ways to Prevent or Solve the challenges you listed above:

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Specific Objective SIX: To assess the practices of regulatory inspections in Rwanda FDA

(NB: The following questions shall be completed by staffs from Food and Drugs Inspection & Compliance Division)

S/N	Indicators	Questions (Sub Indicator)	Please Respond by (Chose One): ***NI:*** *NOT IMPLEMENTED* ***OI:*** *ONGOING IMPLEMENTATION* ***PI:*** *PARTIALLY IMPLEMENTED* ***I:*** *IMPLEMENTED*
1	**RI01 Legal provisions, regulations and guidelines required to define regulatory framework of inspection and enforcement.**	RI01.01: Legal provisions authorize the inspectorate to inspect and enforce Good Practices (GXPs) throughout the supply chain.	
		RI01.02: Legal provisions allow inspectors to enter facilities throughout the supply chain at any reasonable time and in any place.	
		RI01.03: Legal provisions allow inspectors to collect relevant evidence, including samples, during GXP inspections.	
		RI01.04: Updated national GXP regulations, norms or guidelines are mandatory.	
		RI01.05: Legal provisions and regulations allow the recognition of and/or reliance on foreign NRA inspections and enforcement actions based on well- defined criteria.	
2	**RI02 Arrangement for effective organization and good governance.**	RI02.01: There is a defined organizational structure with clear responsibilities to conduct regulatory inspection activities.	
		RI02.02: Documented procedures and mechanisms are implemented to ensure the involvement and communication among all stakeholders relevant to regulatory inspection activities.	
3	**RI03 Human resources to perform regulatory inspection activities.**	RI03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform regulatory inspection activities	
		RI03.02: Duties, functions, and responsibilities of the staff in charge of regulatory inspection activities are established and updated in the respective job descriptions	
		RI03.03: Training plan developed, implemented and updated at least once a year for staff in charge of regulatory inspection activities.	
		RI03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.	

4	**RI04 Procedures established and implemented to perform inspection and enforcement.**	RI04.01: The different inspection activities, including inspection preparation, conduct and reporting, are documented for GXP inspections.	
		RI04.02: Regulatory inspection follow-up, decision-making (including certification) and enforcement activities are documented.	
		RI04.03: Inspection planning is based on quality risk management (QRM).	
		RI04.04: Multi-disciplinary teams are used to ensure proper expertise for inspection of specific medical products.	
		RI04.05: Inspection findings and observations are categorized according to QRM.	
		RI04.06: The same criteria are used for the inspection of domestic, foreign, public and private facilities regardless of the ownership.	
5	**RI05 Mechanism in place to monitor regulatory performance and output.**	RI05.01: A database is established and regularly updated of all establishments which may be subject to inspection, along with their relevant regulatory decisions (certifications and/or enforcement activities).	
		RI05.02: Inspection reports are well-archived and easily retrieved.	
		RI05.03: Inspection reports are subjected to a regular and robust review by experts other than the designated inspection team.	
		RI05.04: Inspection data and outcomes are systematically evaluated or interpreted.	
		RI05.05: Performance indicators for regulatory inspection activities are established and implemented	
6	**RI06 Mechanism exists to promote transparency, accountability and communication.**	RI06.01: The list of inspectors is publicly available and the identity of the designated team for each inspection is communicated to the relevant institutions subject to inspections.	
		RI06.02: The updated list or database of all inspected facilities along with their regulatory decisions, actions and enforcement activities, is regularly published and publicly available.	
		RI06.03: Inspection metrics are regularly published and publicly available.	
		RI06.04: Information on inspections conducted is regularly published and publicly available in	
		accordance with national confidentiality requirements.	

What are challenges do you encounter in **REGULATORY INSPECTIONS? List of Challenges (if any):**

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Proposed ways to Prevent or Solve the challenges you listed above:
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Specific Objective SEVEN: To assess the practices of laboratory testing for medicine quality control in Rwanda FDA

(NB: The following questions shall be completed by staffs from Quality Control Laboratory Division/ Medicines and Cosmetics Testing Unit)

S/N	Indicators	Questions (Sub Indicator)	Please Respond by (Chose One): ***NI:*** *NOT IMPLEMENTED* ***OI:*** *ONGOING IMPLEMENTATION* ***PI:*** *PARTIALLY IMPLEMENTED* ***I:*** *IMPLEMENTED*
1	**LT01 Legal provisions, regulations and guidelines required to define the regulatory framework of laboratory testing activities.**	LT01.01: There are legal provisions to establish a national quality control laboratory (NCL) to perform quality control (QC) testing, and/or to authorize the National Regulatory Authority (NRA) to sub-contract the required testing services.	
		LT01.02: Legal provisions and regulations allow the NRA to recognize and use laboratory testingrelated decisions, reports or information from other NRAs or regional and international bodies.	
2	**LT02 Arrangement for effective organization and good governance.**	LT02.01: There is a defined organizational structure with clear responsibilities to conduct laboratory testing activities.	
		LT02.02: Documented procedures are implemented to ensure the involvement and contributions of the NCL to support regulatory oversight.	
3	**LT03 Laboratory activities implemented as per well-established plans and policies according a Quality Management System (QMS).**	LT03.01: Documented and implemented policy for testing exists that is based on the product's risk.	
		LT03.02: Documented and implemented policy exists on the validation, verification and transfer of analytical procedures.	
		LT03.03: A policy is in place to establish or qualify all reference standards used in laboratory testing activities.	

		LT03.04: Documented and implemented procedures exist for handling atypical or out-of-	

		specification (OOS) results, including a retest policy.	
4	**LT04 Human resources to perform laboratory testing activities.**	LT04.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform laboratory testing activities.	
		LT04.02: Duties, functions, and responsibilities of the staff in charge of laboratory testing activities are established and updated in the respective job descriptions.	
		LT04.03: Training plan developed, implemented and updated at least once a year for staff in charge of laboratory testing activities.	
		LT04.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification	
5	**LT05 Well maintained and equipped infrastructures for laboratory activities.**	LT05.01: Laboratory facilities are adequate to perform quality testing activities.	
		LT05.02: Equipment calibration, qualification and maintenance plans have been defined and implemented and records have been maintained.	
6	**LT06 Procedures established and implemented to perform laboratory testing activities according to Quality Management System.**	LT06.01: There are procedures for receipt, handling, storage and retention of samples.	
		LT06.02: There are documented procedures for performing tests in accordance with MA documentation.	
		LT06.03: A documented procedure is implemented for notification of test results and for ensuring that test results are issued following a standardized format.	
		LT06.04: There are appropriate procedures for obtaining and handling of all materials required for testing.	
		LT06.05: Staff has access to reference documents, including pharmacopoeias, textbooks and operational manuals.	
7	**LT07 Mechanism exists to promote transparency, accountability and communication.**	LT07.01: Laboratory testing activities are appropriately communicated to the public community.	
8	**LT08 Mechanism in place to monitor**	LT08.01: There is an updated database of all medical products batches that have undergone quality testing.	

	regulatory performance and output.	LT08.02: Monitoring and trend analyses are carried out for laboratory testing results data of reference materials and medical products.	
		LT08.03: Regular participation in proficiency schemes, collaborative studies and interlaboratory comparisons.	
		LT08.04: Performance indicators for laboratory testing activities are established and implemented.	
9		LT09.01: A laboratory hazardous substances list exists and documented procedures for storage,	
	LT09 Measures for occupational health and safety.	handling and disposal of these substances are implemented.	
		LT09.02: A laboratory safety program exists and a designated person is responsible for its management.	
10	**LT10 Measures for good management of outsourced laboratory activities.**	LT10.01: Documented procedures are implemented for managing outsourced QC activities.	

What are challenges do you encounter in Quality Control Laboratory to ensure the quality of medicines?

List of Challenges (if any):

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Proposed ways to Prevent or Solve the challenges you listed above:
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Specific Objective EIGHT: To assess the practices of oversight of clinical trials in Rwanda FDA

S/N	**Indicators**	**Questions (Sub Indicator)**	**Please Respond by (Chose One):** ***NI:*** *NOT IMPLEMENTED* ***OI:*** *ONGOING IMPLEMENTATION* ***PI:*** *PARTIALLY IMPLEMENTED* ***I:*** *IMPLEMENTED*
1	**CT01 Legal provisions, regulations and guidelines required to define regulatory framework of clinical trials oversight.**	CT01.01: Legal provisions and regulations for clinical trials (CTs) oversight exist.	
		CT01.02: Legal provisions and regulations that stipulate that notification to Rwanda FDA and authorization from Rwanda FDA is required for any changes or variations (i.e., amendments) in the original protocol or in any relevant documents of the CT.	

		CT01.03: Legal provisions and regulations requiring research centers, researchers, sponsors, clinical research organizations (CROs) and all relevant institutions in the CT to comply with GCP	
		CT01.04: Legal provisions, regulations and guidelines requiring that investigational medical products (IMPs) comply with good manufacturing practices (GMP) for IMPs.	
		CT01.05: There are legal provisions or regulations covering circumstances in which the routine CT evaluation procedures may not be followed (e.g. for public-health interests).	
		CT01.06: Legal provisions, regulations or guidelines exist for NRA to inspect, suspend or stop CTs.	

		CT01.07: There are legal provisions or regulations that require the establishment of an Independent ethics committee (IEC).	
		CT01.08: Legal provisions, regulations and guidelines that require authorization for the import or destruction of IMPs.	
		CT01.09: There are requirements for monitoring and reporting of adverse events and reactions during conduct of CT.	
		CT01.10: There are guidelines on the format and content of CT applications.	
		CT01.11: Legal provisions or regulations allow the NRA to recognize and use relevant CT decisions, reports or information from other NRAs or from regional and international bodies.	
2	**CT02 Arrangement for effective organization and good governance.**	CT02.01: There is a defined structure with clear responsibilities to conduct CT oversight activities.	
		CT02.02: Documented procedures are implemented to ensure the involvement and communication among all stakeholders relevant to CTs.	
3	**CT03 Human resources to perform clinical trials oversight activities.**	CT03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform CT oversight activities.	
		CT03.02: Duties, functions, and responsibilities of the staff in charge of CT oversight activities are established and updated in the respective job descriptions.	
		CT03.03: Training plan developed, implemented and updated at least once a year for staff in charge of CT oversight activities.	
		CT03.04: Rwanda FDA generates and maintains records of staff training activities and training effectiveness verification.	

4	**CT04 Procedures established and implemented to perform clinical trials oversight**	CT04.01: Rwanda FDA has access to an advisory committee for review of CT applications and postapproval safety and compliance issues.	
		CT04.02: The existence of the Ethics Committees with clearly defined composition.	
		CT04.03: Nonclinical data is considered within CT application review.	
		CT04.04: There are defined roles for ECs at all levels (e.g., national, sub-national, or institutional).	
		CT04.05: Documented and implemented procedures exist to review CT applications.	
		CT04.06: There are procedures for EC responsibility for clearance and follow up until completion of the CT.	
		CT04.07: The same policies are used for the evaluation of CT applications regardless of the applicant (e.g., domestic, foreign, public sector, or private sector).	
5	**CT05 Mechanism exists to promote transparency, accountability and communication.**	CT05.01: There is clarity about the funding of the Ethics Committee and its members	
		CT05.02: The list of the CTs (approved and rejected applications), including summarized evaluation reports by the NRA, are publicly available or recorded in a domestic or international database.	
6	**CT06 Mechanism in place to monitor regulatory performance and output.**	CT06.01: There is an internal list or database of all approved and rejected CTs, and the NRA maintains a record of each approved and rejected CT.	
		CT06.02: Performance indicators for CT oversight activities are established and implemented.	
		CT06.03: Progress reports from sponsors or CROs during and after CTs sent to and shared among NRAs and ECs.	
		CT06.04: There are timelines for the assessment of CT applications and an internal tracking system to follow the targeted time frames.	

What are challenges do you encounter in CT activities to ensure the quality of medicines in Rwanda?

<u>List of Challenges (if any):</u>

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Proposed ways to Prevent or Solve the challenges you listed above:
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ANNEX 3: BUDGET IN RWANDAN FRANCS (FRW)

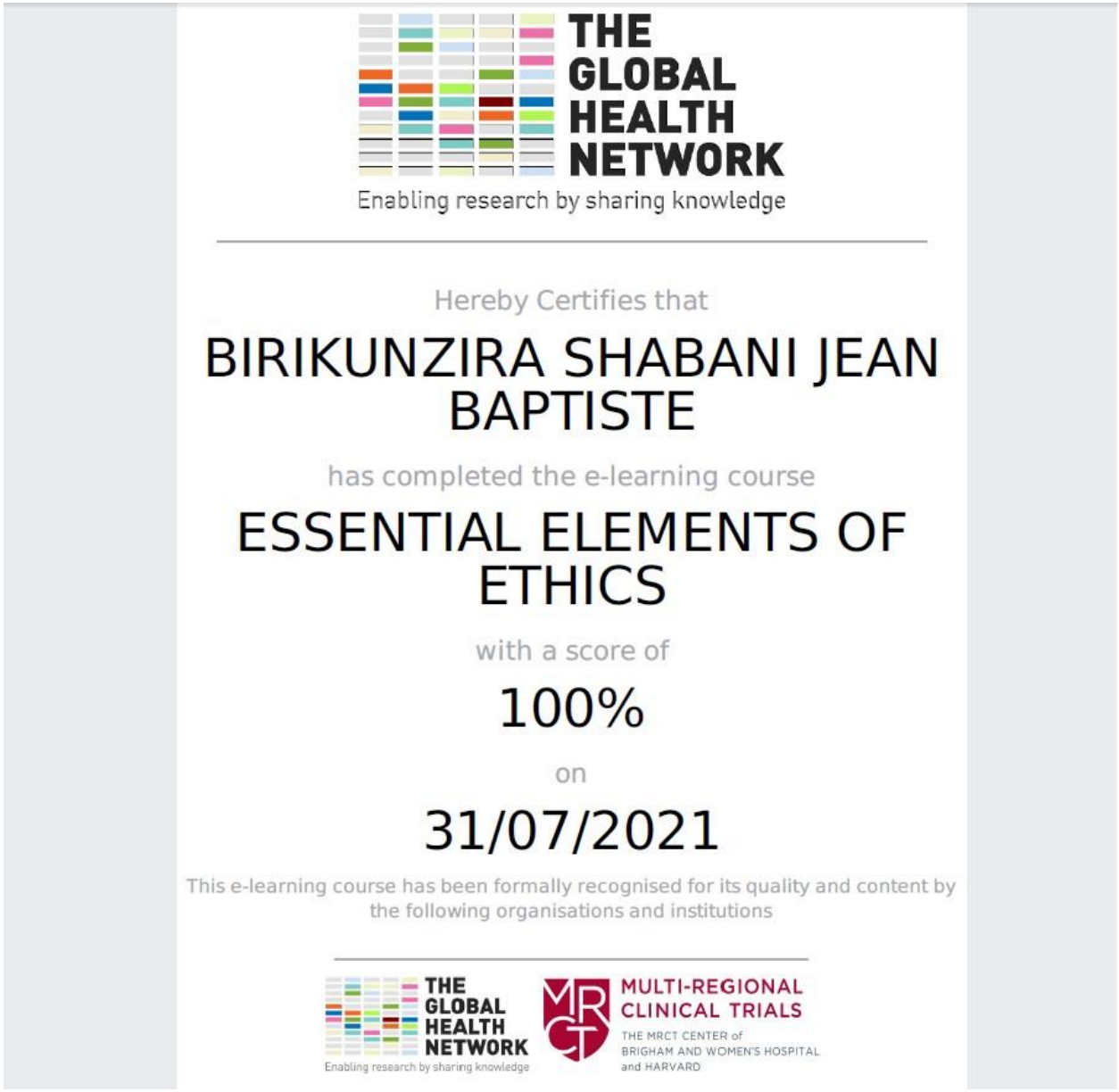
(Source of fund: Self-funding)

PARTICULARS	**UNITS**	**COST PER ITEM (FRW)**	**TOTAL AMOUNT (FRW)**
Pilot study	1	50,000	50,000
Transport	20	30000	600,000
Data Analysis	1	50,000	50,000
Printing	8	20000	160,000
Ream of papers	4	5000	20000
Pens	4	150	600
Pencils	4	50	200
Erasers	3	100	300
Photocopying	168	50	7400
Binding/ Lamination	4	5000	20000
TOTAL AMOUNT IN FRW			**908,500**

ANNEX 4: RESEARCH PLAN

PERIOD	ACTIVITIES PLANNED FOR THIS PERIOD
September-October 2021	○ RESEARCH PROPOSAL WRITING ○ REFINING THE DATA COLLECTION TOOLS
November 2021	○ ETHICAL CLEARANCE APPLICATION ○ FINETUNING THE DATA COLLECTION TOOLS
December 2021	○ DATA COLLECTION ○ DATA PROCESSING ○ DATA ANALYSIS
January 2022	○ FIRST DRAFT DISSERTATION WRITING ○ FIRST DRAFT DISSERTATION SUBMISSION
February 2022	○ ADDRESSING MANUSCRIPT REVIEWER COMMENTS ○ SECOND DRAFT DISSERTATION WRITING AND SUBMISSION ○ ADDRESSING MANUSCRIPT REVIEWER COMMENTS
March 2022 Week 1&Week2	○ DEFENSE OF DISSERTATION ○ FINAL SUBMISSION

ANNEX 5: A CERTIFICATE OF ATTENDANCE OF RESEARCH ETHICS TRAINING



ANNEX 6: APPROVAL FROM CMHS INSTITUTIONAL REVIEW BOARD (IRB)

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 20th /10/2021
Ref: CMHS/IRB/298/2021

BIRIKUNZIRA SHABANI Jean Baptiste
Master's in Health Supply Chain Management
CMHS, University of Rwanda

Dear BIRIKUNZIRA SHABANI Jean Baptiste

RE: ETHICAL CLEARANCE

Reference is made to your application for ethical clearance for the study entitled ***"Assessing the capacity of Rwanda FDA in ensuring the quality of medicines in Rwanda"***

Having reviewed your application and been satisfied with your protocol, your study is hereby granted ethical clearance. The ethical clearance is valid for one year starting from the date it is issued and shall be renewed on request. You will be required to submit the progress report and any major changes made in the proposal during the implementation stage. In addition, at the end, the IRB shall need to be given the final report of your study.

We wish you success in this important study.

Dr Stefan JANSEN
Ag Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal, College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate studies, UR

ANNEX 7: LETTER OF DATA ACCESS IN RWANDA FDA

Kigali on, 04/01/2022
Ref N°: ODG/ 004 /FDA/2022

RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 1948 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

To:
Jean Baptiste BIRIKUNZIRA SHABANI
Principal Investigator
Telephone: 0788540976
E-mail: jbb.shabani@gmail.com
KAMONYI

RE: Authorization to collect data in Rwanda FDA as part of the requirements for the award of a Master's Degree

Reference is made to your application letter dated 18th November 2021, requesting for a collaborative note and the permission to collect data in **Rwanda Food and Drugs Authority** for the purpose of your research entitled **"ASSESSING THE CAPACITY OF RWANDA FDA IN ENSURING THE QUALITY OF MEDICINES IN RWANDA"** as part of the requirements for the award of a Master's Degree;

Based on Institutional Review Board of College of Medicine and Health Sciences (CMHS/IRB) of the University of Rwanda with the Ref: CMHS/IRB/298/2021 granting ethical clearance to your research;

I am pleased to inform you that Rwanda Food and Drugs Authority (Rwanda FDA) has granted you authorization to collect data for your research in Rwanda FDA and you are requested to ensure that all information provided by targeted respondents is purely for academic purposes, and will be handled with the utmost confidentiality. In addition, at the end of the research, Rwanda FDA shall need to be given the final report of your study.

I look forward to your positive cooperation.

Sincerely,

Dr. Emile BIENVENU
Director General

Digitally signed by Rwanda FDA (Director General)
Date: 2022.01.04 07:20:49 +02'00'

Cc:
- **Heads of Department (All)**
- **Division Managers (All)**