

# RWANDA FOOD AND DRUGS CUSTOMER SATISFACTION SURVEY FY 2021-2022

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#### FOREWORD



The Rwanda Food and Drugs Authority (Rwanda FDA or the Authority) was established by law N°. 003/2018 of 09/02/2018 determining its mission, organization, and functioning. The mandate of the Authority is to assure the safety, quality, and efficacy of human and veterinary medicines, food, biological products, cosmetics, medical devices, household chemical substances, clinical trials, and the control and use of tobacco products, through the enforcement of relevant national and international standards to protect public health.

As part of our quest to improve services rendered to our customers and stakeholders, Rwanda FDA conducted a periodic customer satisfaction

survey (CSS) for the fiscal year 2021-2022 to provide guidance on the key areas for improvement in service delivery, for increased customer satisfaction and public awareness with a focus on protecting and promoting public health.

For Rwanda FDA to become a World-Class Regulatory Authority and effectively promote and protect public health, the authority should have a strong mechanism in place to evaluate the satisfaction of internal and external customers and other interested parties for system improvement.

It is in this context that Rwanda FDA conducted the customer satisfaction surveys (CSS) for the fiscal year 2021-2022. The findings from this CSS will guide Rwanda FDA on the key areas for improvement in service delivery, for increased customer satisfaction and public awareness with a focus to protect and promote public health. The findings will also help to know areas that need to be improved to align with the Authority's service delivery commitment and its QMS principles as well asWHO global benchmarking revision VI and ISO 90001: 2015 requirements.

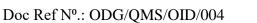
This Rwanda FDA Customer Satisfaction Survey would not have been possible without the teamwork and dedication of Rwanda FDA staff, several institutions, and individuals who contributed with invaluable, ideas, and a wealth of experience. Enumerators who administered survey tools to all groups of stakeholders in 14 Districts, and supervisors who were indebted.

Also, we wish to extend our profound gratitude to all the respondents for their commitment, time, and willingness to participate in the CSS. We are thankful to key Informants who took part in the indepth interviews. We remain grateful for the time, energy, and insights they provided to inform this valuable CSS. We are thankful to the decentralized entities (Districts and Sectors) authorities in the 14 Districts sampled for their cooperation and permission to allow this survey to be conducted.

Also, we wish to extend our thoughtful gratitude to all who responded to the survey tools such as organizations from both the public and private sectors, including wholesalers, retail pharmacies, hospitals, health centers, compounding facilities, Pharmacy processing plants, food outlets, food industry, and cosmetics companies amongst others for their commitment, availability, and willingness to participate in this Rwanda FDA first Customer Satisfaction Survey, FY 2021-2022.

Finally, our sincere gratitude goes to the US Agency for International Development (USAID)-Global Health Supply Chain and Procurement Supply Management (GHSC-PSM) Program for the financial support and technical expertise they provided throughout the survey.

Prof. Emile BIENVENU Director General



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# ACRONYMS AND ABBREVIATIONS

CFO	Chief Finance Officer
CPD	Continuing professional development
CRC	Citizen Report Card
CSS	Customer Satisfaction Survey
DFAR	Department of Food and Drugs Assessment and Registration
DG	Director General
FDA	Food and Drug Administration
FDISM	Department of Food and Drugs Inspection and Safety Monitoring
FY	Financial year
GBT	Global Benchmarking Tool
GDP	Good Distribution Practice
GHSC	Global Health Supply Chain Program Procurement and Supply Management
GLP	Good Laboratory Practice
GoR	Government of Rwanda
GSP	Good Storage Practices
GWP	Good Weighing Practice
ISO	International Standards Organization
ML3	Maturity Level 3
NGOs	Non-Government Organizations
NISR	National Institute of Statistics of Rwanda
NST1	National Strategy for Transformation1
PBF	Performance Based Financing
QCL	Quality Control Lab
QMS	Quality Management System
RGS	Rwanda Governance Score Cards
SDPs	Service Delivery Points

# Rwanda FDA Customer Satisfaction Survey FY 2021-2022

SERVQUAL	Service quality
USAID	U.S Agency for International Development
Vs	Versus
WHO	World Health Organization

#### **EXECUTIVE SUMMARY**

The Rwanda Food and Drugs (Rwanda FDA) mandate is to assure the safety, quality, and efficacy of human and veterinary medicines, food, biological products, cosmetics, medical devices, household chemical substances, clinical trials, and the control and use of tobacco products, through the enforcement of relevant national and international standards to protect public health. To fulfil this mandate, the Authority has set the goal of maintaining a high level of customer and other stakeholders' satisfaction through excellence in service delivery.

To achieve this goal, customer and stakeholders' feedback is important as it informs the Authority on how its service delivery is perceived by stakeholders. The Customer satisfaction survey is one of the ways in which an organization can capture customers' and other stakeholders' feedback. It is in this line that Rwanda FDA is committed to conducting periodic Customer Satisfaction Surveys. The 2021-2022 CSS is the first customer satisfaction survey conducted by the Authority in collaboration with US Agency for International Development (USAID)-Global Health Supply Chain and Procurement Supply Management (GHSC-PSM) Program.

The overall objective of this survey is to examine the level of satisfaction of staff, customers, and stakeholders about the services offered by Rwanda FDA towards the continuous Quality Management System improvement and customer satisfaction. Specifically, the survey was meant to provide information on areas where Rwanda FDA is doing well in service delivery and highlight gaps in service delivery that need to be addressed as to improve the level of customer satisfaction. All four provinces namely Kigali City, Northern Province, Southern, Eastern, and Western participated in the survey.

Different districts were selected from each region making a total of 14 districts that participated in the survey. Data was collected from Rwanda FDA employees, households, regulated customers/ clients, suppliers, and other stakeholders in 14 districts. Structured questionnaires, focus group discussions and in-depth interviews were used to gather information from respondents.

# **KEY FINDINGS**

Overall, stakeholders and the public who know Rwanda FDA appreciate the role of Rwanda FDA in the country and the Authority is on track in terms of fulfilling its mission in society. It has managed to reduce counterfeit products in the market through regulation, frequent inspections, and post-market surveillance activities.

Rwanda FDA has been rated as the preferred employer, with a level of standards with reasonable salaries and incentives in place and an effective regulator with good working conditions. Steadily the quality of services rendered by Rwanda FDA to its stakeholders continues to increase. About 94% of respondents agreed to work with Rwanda FDA over the next 3-5 years due to employment security satisfaction and commitment of the organization to become an internationally recognized institution by achieving ML3, ISO certification, and establishing vaccine regulatory functions. Furthermore, 94% of employees are motivated to work for Rwanda FDA and 76 % of the staff reveal that they have the materials and equipment they need to perform efficiently. Another positive feedback was that 79% of staff reported that there was a fair policy for promoting the employees at Rwanda FDA due to the strong QMS system in place aiming to provide service at the international standards with reasonable salaries and incentives in place.

Effective collaboration and cooperation with the development partners is part of Rwanda FDA core values to work together to achieve a common objective and create value for all stakeholders and other interested parties. Most of the partners working with Rwanda FDA believe that the mission and vision of Rwanda FDA is convincing at 66.7% and very convincing at 33.3%. Half of the sample appreciated that the timeline set by Rwanda FDA is met and are satisfied by Rwanda FDA services.

Rwanda FDA customers mentioned numerous challenges experienced in their working relationships with the Authority. Most of the companies (77.2%) revealed that there were delayed responses from Rwanda FDA, the extended registration timelines due to the lack of guidance regarding regulatory procedures as well as the lack of transparency of regulatory decisions. In relation to Rwanda FDA service fees, about 54% of the Rwanda FDA customers rated the Authority's service fees as reasonable whereas almost an equal proportion of 43% revealed that the service fees were highly costly, and fines were unreasonably high. Customers also highlighted that some missing services including but not limited to close, to non-existent customer care services and lack of services supporting small to medium enterprises.

When assessing the knowledge and source of information about Rwanda FDA at the household level, only 42% of the total 385 individuals interviewed have heard about Rwanda FDA. Radio and television were the main sources of information on Rwanda FDA in the community (35.8%). Other sources of information such as social media (7.3%), and public events (6.3%) constituted of smaller percentages due to their difficulty in accessibility.

Rwanda FDA receives different services across a range of supplier fields categorized in the form of consultancy, provision of services, supply medical-related goods and other activities. The feedback from these suppliers highlighted strengths in the availability of information on procurement, clear terms of reference and conditions, time granted for bid preparation and submission, procurement transparency and finally the receiving and handover process of good, works and services.

However, there is a room for improvement in terms of providing feedback/comment about rejection/defects of the work done or good supplied, time between award notification and contract signing, compliance with terms and conditions in purchase orders or contracts.

At the Service Delivery Points, 41.67% of hospitals were very satisfied with the services rendered by Rwanda FDA. On the other hand, the same percentage (41.67%) revealed that health centres were unsatisfied with the service rendered by Rwanda FDA. As a general observation, health centres showed less satisfaction in comparison to hospitals, with only 20.83% showing a high satisfaction of the services rendered by Rwanda FDA.

### **High-level Recommendations**

Based on the findings the survey recommends Rwanda FDA to:

- a) Improve staff retention strategies such as work transportation, salary review, on-time promotion, communal activities, comfortable workspace, mentoring and tailored trainings.
- b) Improve Awareness of Rwanda FDA services in both urban and rural areas to reach the wider community. This would also enhance close interaction between customers and Rwanda FDA employees as well as building Rwanda FDA brand.
- c) Improve the internal data management information system in place to integrate regulatory functions; online application forms; customer feedback; clients database.
- d) Improve and train Rwanda FDA staff on effective communication with external customers which would improve the service delivery & customer care.
- e) Improve the GMP inspection process and allow for more flexibility by increasing the frequency and sites to be visited and training staff when inspecting premises.
- f) Improve the categorization, communication, and management of regulated industries (from start-ups to well-established industries) both in urban and rural settings.
- g) Decentralisation of Rwanda FDA services to district and provincial level (including inspection officers).
- h) Improve the investigation, management, and reporting of substandard/counterfeit products on the Rwandan market by adequately training Rwanda FDA staff and stakeholders
- i) Revise the cost of all the Rwanda FDA services and fines considering the financial consequences of COVID-19.
- j) Fast-track and improve the registration process, visa importation, dossier assessment and archiving processes for both local and international industries to ensure client satisfaction.
- k) Develop/ strengthen the framework of collaboration between Rwanda FDA and DTCs, RMS and other International regulatory bodies.

# I. INTRODUCTION

Rwanda Food and Drugs Authority (Rwanda FDA) was established by Law N° 003/2018 of 09/02/2018. The mandate of Rwanda FDA is to protect public health by regulating the use of human and veterinary medicines, vaccines, medical devices, biological products, processed foods, household chemicals, poisons, medicated cosmetics, tobacco, and tobacco products. Rwanda FDA is also in charge of regulating clinical trials.

Some of the core values of Rwanda Foods and Drugs Authority are to serve with professionalism for excellent service delivery and striving for innovation to create value for stakeholders and other interested parties. To achieve these goals, customer and stakeholders' feedback is important as it informs the Rwanda FDA on how it is performing in service delivery and the gaps in service delivery as perceived by stakeholders.

The Customer Satisfaction Survey is one of the ways an organization can capture its customers and other stakeholders'feedback necessary to plan for system improvement. It is from this fact that Rwanda FDA is committed to conduct periodic customer satisfaction surveys.

The overall objective of this survey is to examine the level of satisfaction of staff, customers, and stakeholders in relation to the services offered by Rwanda FDA towards the continuous Quality Management System improvement and customer satisfaction.

### 1.1. Rationale

The National Strategy for Transformation (NST1) of the Government of Rwanda under the leadership of H.E President Paul KAGAME emphasizes strengthening capacity, service delivery, and accountability of public Institutions by enshrining a culture of accountability and dedicated service to citizens of Rwanda for fast and effective service delivery, (PRIMATURE, 2017).n line with the NST1 goals, Rwanda FDA is committed to continuously keep on improving the quality of services offered to its staff, customers, and different stakeholders.

Rwanda FDA deals with a wide range of customers and stakeholders such as product manufacturers, distributors (retailers and wholesalers); law enforcement institutions; practitioners; health care providers; Government Institutions; International institutions; NGOs; the general public as well as the media. Their opinions(whether positives or negatives) have a direct impact on Rwanda FDA's credibility, popularity, and attraction to acquire new customers.

The expectations of these different stakeholders are diverse, and their interests may at times be conflicting. Rwanda FDA is also devoted to improving the working environment for its internal customers (e.g. employees and advisory board members) but also strengthening the relationship with other collaborators including, but not limited to local Government entities.

The Authority envisages developing a roadmap that outlines the quality improvement milestones that will fast-track the realization of its vision. To this end Rwanda FDA intendto to engage all customers, to have a view on areas of improvement, efficiency, and effectiveness of service delivery.

Continuous improvement in the quality of services requires amongst others, capturing the voices of stakeholders and customers but also getting feedback on the Authority's performance based on the various customers' and stakeholders' preferences.

Therefore, there is a need for Rwanda FDA to conduct periodic customer satisfaction surveys (CSS), The findings from CSS will guide Rwanda FDA on the key areas for improvement in service delivery, for increased customer satisfaction and public awareness with a focus to protect and promote public health. The findings will also help to know areas that need to be improved in order to align with the Authority's service delivery commitment and its QMS principles and also with WHO global benchmarking revision VI and ISO 90001: 2015 requirements.

# 1.1.1. Quality Management system (QMS): ISO 9001: 2015

ISO 9001:2015 specifies requirements for a quality management system (QMS) when an organization:

- a) Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
- c) All the requirements of ISO 9001:2015 are generic and are intended to apply to any organization, regardless of its type or size, or the products and services it provides.

In reference to conformance with ISO 9001\_2015 requirements, performance evaluation (Clause 9.1.2), An organization with an effective management system should monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled, (9001, 2015).

# 1.1.2. WHO Global Benchmarking Tool (GBT) Maturity level 3

Efficiency and transparency in the operations of regulatory bodies are essential characteristics of a well-functioning and integrated regulatory system in assuring the quality, safety, and efficacy of medical products. The use of the WHO global benchmarking tool (GBT) is the primary means by which the WHO assesses regulatory systems to identify areas of strength, and areas that need to be improved.

The GBT assesses the overall maturity of the regulatory system on a scale (level) of 1 (existence of some elements of the regulatory system) to 4 (operating at an advanced level of performance and continuous improvement) (Maturity Levels from 1 to 4). Level 3 indicates that the system is well functioning and integrates all previous maturity levels required to guarantee its stable performance. Being cognizant of Rwanda FDA journey towards attaining World Health Organization Maturity Level 3 ('WHO ML3') and the vision of becoming a World-Class Regulatory Authority effectively promoting and protecting public health, Rwanda FDA should have a mechanism in place to evaluate the satisfaction of internal and external customers and other interested parties for system improvement, (WHO, Global Benchmarking Tool, Revision VI, RS05.10., 2020).

To reach WHO ML3, Rwanda FDA should have documented evidence that monitoring of customer satisfaction measurements using surveys, complaints analysis, and claims analysis is made and that actions are taken to deal with unsatisfied customers. Mapping or identifying the customers and other stakeholders is essential for the proper implementation of this required ML3 indicator.

# 1.2. Rwanda FDA Mission, Vision, and Core values

Rwanda Food and Drugs Authority (Rwanda FDA) was established by Law N° 003/2018 of 09/02/2018. The mandate of Rwanda FDA is to protect public health by regulating the use of human and veterinary medicines, vaccines, medical devices, biological products, processed foods, household chemicals, poisons, medicated cosmetics, tobacco, and tobacco products. Rwanda FDA is also in charge of regulating clinical trials, (FDA, 2018).

Rwanda FDA aims to be classified as a world class regulatory Authority effectively protecting and promoting public health led by the following five core values:

- a) Serving with Professionalism for excellent service delivery
- b) Continuously work with Integrity
- c) Promoting Accountability at all times
- d) Nurturing Teamwork to achieve common objectives
- e) Striving for Innovation to create value for our stakeholders and other interested parties

In line with the above, Rwanda FDA is conducting a periodic customer satisfaction survey (CSS) for the fiscal year 2021-2022 to provide guidance on the key areas for improvement in service delivery, for increased customer satisfaction and public awareness with a focus to protect and promote public health.

# **1.3.** Objectives of the survey

The overall objective of this Customer Satisfaction Survey (CSS) is to examine the level of stakeholders' satisfaction with services offered by the Rwanda Food and Drugs Authority. The outcome of this CSS is aimed at identifying the areas that Rwanda FDA needs to improve on, especially by enhancing quality service delivery to its customers and stakeholders.

The findings of this survey will also serve as input to:

- a) Generate evidence for the WHO GBT (sub-indicator RS05.10) and ISO 9001\_2015 requirements
- b) Inform pricing of Rwanda FDA services fees/ tariffs and fines restructuring
- c) Developing the new Rwanda FDA strategic plan and operational plans
- d) Establishing a strong and sustainable Quality Management System

The customer satisfaction survey will also support and get insight into the authority's performance across all its services including product registration and processes in the country aiming to ensure safety and quality availability and accessibility of health commodities.

### II. LITERATURE REVIEW

In this Customer satisfaction survey, a review of the literature related to the survey was also conducted. This included variables such as customer satisfaction, service quality, and its determinants. Also, the review involved organizational support, the relationship between organizational support and customer service as well as the Rwanda FDA client service charter.

#### 2.1 Satisfaction

Satisfaction describes the pleasant feeling that people have when they get something to their needs and wants. Satisfaction refers to the fulfilment of customers 'wishes, (Tao, 2014). Satisfaction with government service quality is also known as citizen satisfaction with public service delivery (Sulieman Ibraheem Shelash Al-Hawary & Saleh Mohammad Al-Menhaly, 2016). Citizen satisfaction reflects citizens' perception of the quality of the goods and services that are provided by the government, (Salim, Xiaobao, Almaktary, & Saleem, 2017).

Citizen perception of government services affects their decisions to continue to use public services and to trust the government. Public service quality, service value, and citizen satisfaction are interdependent, and their interaction motivates the continuous use of government service. Citizen satisfaction reflects the citizen's views about government programs and services. A survey on citizen satisfaction is one of the effective methods to accurately evaluate government performance and citizen perceptions of the quality of government services corresponding to actual service quality, (Chingos, Michael, & Martin, 2012).

Citizen satisfaction with government services is not only about the service quality but also the public information and improving the provision of more public services, (Jeremy, John, Lise, & Zahir, 2015). Government services represent public value and citizen satisfaction.

This value is highly dependent on the level of quality of the service delivered by the government, (Chingos, Michael, & Martin, 2012).

Citizens are expecting the superior performance of government services in turn to the regulated services they paid for. The government investments in public services and goods should be aligned with the citizens' satisfaction and benefits, (Alireza & Fereydoon, 2013). The level of satisfaction reflects a certain mood and a clear evaluation of the quality of a specific service and when and how this happens depending on the survey context.

In most countries, public sector organizations, departments, and agencies regularly monitor citizen satisfaction with public services to evaluate the impact of reforms and identify the services that need to improve, (OECD, 2017). Although many citizens complain about public services and civil servants, this is not often reflected in the satisfaction surveys or the number of complaints about the services provided by organizations, (Geert & Steven, 2003). The reason why customer satisfaction surveys must be of good quality and their results be disseminated to improve service delivery and the performance of the institution.

In Rwanda, Over the last 20 years, the Government of Rwanda (GoR) has put in place several policies with a view to continuously improve the quality of service delivery, people-centred governance, and a world-class service-driven economy as well as positioning the country as a dynamic global hub for business, investment, and innovation (MIFOTRA, 2021).

The National Strategy for Transformation (NST1) aspires among others, to strengthen the capacity, service delivery, and accountability of public institutions and strengthen citizen participation in national development processes.

By 2024, GoR has committed to attaining 90% of citizen satisfaction with services and ensuring 100% of government services are delivered online<sup>10</sup>. Furthermore, the 13<sup>th</sup>, 14<sup>th</sup>, 15<sup>th</sup>, and 17<sup>th</sup> National Leadership Retreat resolutions held in Combat Training Centre-GABIRO in 2016, 2017, 2018, and 2020 respectively emphasized improving and fast-tracking service delivery in public institutions, which has also been a subject during various National Strategic Fora.

Nonetheless, the current data indicates more to be done on the quality-of-service delivery. The Rwanda Governance Score Cards (RGS) score service delivery at varying levels. In 2020 it rated at 78.31 % from 70.5% in 2019 and in 74.25% in 2018 while the Citizen Report Card (CRC) rated at 70.4% up from 69.3%. Considering the above performance and recognizing the critical role of quality service delivery in national transformation, there is a need to establish a service excellence framework at a national level to provide an orientation of the required service quality standard.

# 2.2 Service quality

There are many definitions of service quality but the most used delineates service quality as the extent to which a service meets customers' needs or expectations, (Wisniewski & & Donnelly, 1996). In other words, service quality is the difference between the services expected by customers and the perceived services. This implies that when customers' expectations are greater than performance, perceived quality will be less than satisfactory hence customer dissatisfaction, (Parasuraman, 1985).

Service quality is considered a key tool for an organization or firm's struggle to distinguish itself from its competitors, (Parasuraman, 1985). Service quality offers a competitive advantage to organizations that attempt to improve it and hence bring customer satisfaction. Studies have shown that service quality is closely linked to customer satisfaction, (Sureshchandar & Rajendran, 2002). It is therefore vital for organizations to know how to measure these constructs from the customers' perspective to better understand their needs and hence satisfy them. In any organization, service quality is crucial because it leads to higher customer satisfaction, profitability, reduced cost, customer

loyalty, and retention, (Chingang & Lukong, 2010).

While efforts have been made to measure service quality, there has been no consensus on the measurement of the concept. Nonetheless, most of the work to date has attempted to use the SERVQUAL methodology proposed by, (Parasuraman, 1985).

He proposed that ten dimensions determine service quality: reliability, responsiveness, competence, access, courtesy, communication, credibility, security, understanding, knowing the customers, and tangibles, (Parasuraman, 1985).

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Thus, they proposed that the difference between perceived performance and expected performance of these ten dimensions determines overall perceived quality. As a result of the empirical test, Parasuraman modified the ten determinants of service quality and came up with five key dimensions commonly used: tangibles, reliability, responsiveness, assurance, and empathy, (Parasuraman, 1985). The five dimensions are defined as follows:

- a) Tangibles: The appearance of physical facilities, personnel, tools, or equipment, the technology used to provide the service, and communication material.
- b) Reliability: Ability to perform the promised service dependably and accurately.
- c) Responsiveness: The willingness to help the customer and to provide prompt service,
- d) Assurance: Knowledge and courtesy of employees and their ability to convey trust and confidence.
- e) Empathy: Caring, individualized attention the institution provides to its customers.

In this study, the quality of service provided by the Rwanda FDA is determined based on the level of regulated entities' satisfaction in terms of the five key dimensions (reliability, responsiveness, empathy, assurance, and tangibles) as well as other specific services.

### 2.3 Relationship between service quality and customer satisfaction

(Parasuraman, 1985), contend that there is a positive correlation between service quality and customer satisfaction. They argue that high perceived service quality leads to an increase in customer satisfaction. This is in consonant with, (Saravanan & Rao, 2007) and (Haksik, Yongki, & Dongkeun, 2000) who acknowledge that customer satisfaction is based on the level of service quality provided by service providers. (Rakshit, 2009), affirms that the idea of associating service quality with customer satisfaction has been in existence for a long time.

In (Rakshit, 2009) on the relevance of customer-perceived service quality in determining customer overall satisfaction in the context of mobile services, it was found that reliability is a fundamental factor in assessing overall service quality but also tangibles, empathy and assurance should not be ignored when evaluating perceived service quality and customer satisfaction. Similarly, Fen & Lian, (2005) found that service quality and customer satisfaction are interrelated and play an important role regarding the success and survival of any business in the competitive market. In a study conducted by Su et al., (2002) to examine the link between service quality and customer satisfaction, it was revealed that both constructs are interdependent in the sense that an increase in one is likely to lead to an increase in another.

However, service quality is more abstract than customer satisfaction because customer satisfaction reflects the customer's feelings about encounters and experiences with services provided by an organization while service quality may be affected by perceptions of value (benefit relative to cost) or by the experiences of other customers that may not be necessarily good.

Furthermore, a study conducted by (Chingang & Lukong, 2010), on perceived service quality and customer satisfaction in a store performance framework equally revealed a positive relationship between perceived service quality and customer satisfaction. It was found that customer satisfaction derives from high perceived service quality, and this makes the customer loyal. However, it should be noted that a satisfied customer may not necessarily be loyal.

# 2.4 Quality regulatory services

For any regulatory authority to adhere to the principles, it is imperative to have quality regulatory services. Regulatory entities denote services and information, which the organization provides to regulated entities so as fulfil their obligations. An organization is supposed to provide to regulated entities with clear guidelines on the services it offers. The services offered should not only address the expressed needs of the regulated entities but also include assistance in areas in which the regulated entities might be aware that compliance could be facilitated through regulated services and information, (Alireza & Fereydoon, 2013).

Quality service is meant to ensure that there is timely handling of clients' complaints and that the Regulatory officials have empathy and are competent. The staff of the regulatory Agency must be located in a convenient area where it is easily accessible, and the staff has to effectively communicate with the regulated entities and endeavour to cater to further special needs of the regulated entities. The physical appearance of equipment, facilities, and layout should facilitate regulated entities' services, (Geert & Steven, 2003).

# **2.5 Organizational support**

Perceived organizational support refers to the extent to which employees perceive that the organization recognizes their contribution, cares about their well- being and facilitates their work (Matthew, Michael, & Martin R.). Individuals form beliefs concerning the extent to which the organization values their contribution and cares about their welfare; (Chingang & Lukong, 2010).

Through the process of ascription about the way the organization functions, employees arrive at an evaluation of the degree to which they believe that the organization supports them, values their contribution, and is concerned with their wellbeing (Polly,2002). Therefore, perceived Organizational Support represents an employee's belief about the degree of the organization's effective commitment towards that employee and this has a direct effect on the quality of the employee's input to their work, (Haksik, Yongki, & Dongkeun, 2000).

Ideally, a supportive organization values employees' general contributions and facilitates and cares for their well-being. Such an organization is more likely to have employees who strive to promote its values and achieve the intended goals. In other words, high levels of support will build organizational commitment among employees, (Sureshchandar & Rajendran, 2002).

This implies that employees who perceive their employer to be highly supportive are more likely to interpret organizational gains and losses, adopt values and norms and demonstrate a greater level of commitment to the firm than those who do not perceive the same level of support from the organization.

A disappointing scenario is a situation where employees motivated to behave in the best interests of the organization are prohibited from doing so by existing policies and practices; (Jeremy, John, Lise, & Zahir, 2015). So, organizational support may not yield good results from employees if the existing policies and practices are not fair.

According to the internal marketing perspective, if the service organization wants its employees to do a great job with its customers, it must be prepared to do a great job with its employees, (Rakshit, 2009). Organizational support has been viewed as a strategic weapon for achieving high-quality service, (Alireza & Fereydoon, 2013).

### 2.6 Organizational support and customer service

According to social exchange theory (Tao, 2014), employees who get support from their organization value their organization at a greater scale and tend to actively collaborate to achieve the organization's goals, (Chingang & Lukong, 2010). The internal marketing perspective also suggests that service employees are internal customers. Therefore, the support of employees is required prior to the achievement of high service quality for external customers. (Saravanan & Rao, 2007) emphasizes that customers report quality services when employees indicate that they work in a positive climate for service.

Furthermore, studies show that perceived organizational support is positively correlated to customer service and thus, the way an organization treats its employees is directly reflected in the way employees treat their customers, (Wisniewski & & Donnelly, 1996). It is not possible to achieve high-quality customer service simply by establishing policies and practices that affect the virtues of service to customers unless there is sufficient prior organizational support.

Based on the internal marketing perspective, it is only after internal exchanges have occurred that successful external exchanges between employees and customers can take place, (Wisniewski & & Donnelly, 1996). The personal interaction between the customers and the employee is the heart of most service experiences.

More specifically, contact service employees are seen as the organization as far as customers are concerned, (Alireza & Fereydoon, 2013). Service employee behaviours have the potential of positively or negatively impacting on the customer's perception of service quality (Wisniewski & & Donnelly, 1996).

# III. METHODOLOGY

# **3.1.Data collection**

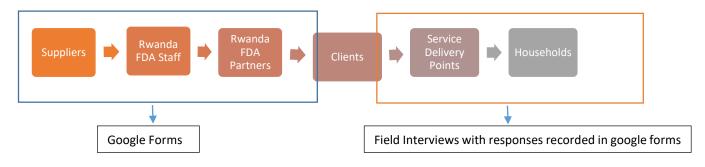
A descriptive cross-sectional study was used to conduct this survey. The data to measure customer satisfaction was collected from direct observations at the individual customer/stakeholders level. During data collection, the survey was made up of double data collection methods: a) Sending a survey using Google forms and b) Conducting a field visit with interviews.

# 3.1.1. Google form

A Google form was accessed directly from a hyperlink sent to the participants. One advantage of responding to the survey through Google forms is that it allowed for quick analysis and minimal Human resource capacity. Another advantage is that answers from this survey tool were aggregated automatically.

The data was automatically downloaded in a ".csv" file which was sorted in a downloadable spreadsheet file. Secondly, the google forms were easily designed and free to use.

The forms were used in assessing Rwanda FDA Suppliers, Rwanda FDA staff, Rwanda FDA partners, Rwanda FDA customers, Healthcare facilities and Households. In total, 6 forms were designed.



# Figure 1: Sample categories for the CSS FY 21/22

The design of each questionaire was based on the objectives set for each categories. Refer to **Appendix 1**, for the detailed objectives.

# 3.1.2. Rwanda FDA suppliers

Rwanda FDA has been working with suppliers since its inception. Those suppliers can supply goods, services, and other work activities. Due to the small population size of the suppliers, the survey strategy will be to send the survey tools to all whose contact addresses are available.

# 3.1.3. Rwanda FDA staff

Rwanda FDA has a total number of 183 out of 194 employees on the organizational structure (as per March statistics). The survey tool was distributed to all staff (100%) to collect the maximum information from the Director General, SOffice, CFO Office and other technical departments. All staff will complete the survey through the Google form link.

# 3.1.4. Rwanda FDA partners

Effective collaboration and cooperation with the development partners is part of Rwanda FDA core values to work together to achieve a common objective and create value for all stakeholders and other interested parties. Focal points from development partners agencies actively working with Rwanda FDA were contacted and provided a google form hyperlink to provide their insight on their working collaboration with Rwanda FDA.

### 3.1.5. Rwanda FDA Customers

As previously mentioned, Rwanda FDA deals with a wide range of customers and stakeholders. For this specific survey, the targeted customers were: Veterinary wholesale pharmacies; Veterinary retail pharmacies; Small compounding facilities, Pharmacy processing plants, Orthopedic shops, Optical shops, Online pharmacies, Human wholesale pharmacies, Human retail pharmacies, Food outlets, Food industry, and cosmetics.

When grouped, these different categories fell into a common cluster namely:

- a) Pharmaceutical products containing Human medicines, veterinary products, medical devices, and consumables.
- b) Food and beverage products containing: Food and Beverages.
- c) Cosmetics & Household chemicals containing: Medicated cosmetics, non-medicated cosmetics, and Household chemicals. For each cluster, questions were aimed at all categories i.e., manufacturers, wholesalers, and retailers. **See Annex 2** for the detailed categorization.

To get the exact sample that was used to disseminate the google forms, a proportional stratified sampling strategy was (where each regulated industry will represent strata). Each regulated industry was represented by a given number of representations (see details in **Table 1**).

The Rwanda FDA customer dataset was used with the goal of achieving a representative cross-section of the regulated industry. The sample universe for this survey included all concerned entities from Rwanda FDA customer data base. A representative sample was designed from the estimated universea of total number of entities. Probability sampling was respected to ensure that every regulated industry had an equal chance of selection.

The Raosoft sample size calculator tool<sup>1</sup> was used to get the sample size with the formula below:

where:

$$n = (N (zs/e)^2)/(N-1) + (zs/e)^2)$$

z = 1.96 for 95% confidence level s = p (1-p) p = estimated proportion or p = to 50%

e = desired margin of error

N = study population

<sup>&</sup>lt;sup>1</sup> <u>http://www.raosoft.com/samplesize.html</u>

Basing on a confidence level of 95%, a margin of error of 5%, and using Raosoft sample size calculator tool, this survey targeted a sample size of 329<sup>2</sup>. Therefore, with a given universe of population, the proportional strata was determined from of every selected District. Refer to the below table (table 3) for the calculated sample size.

Entities	Total	Ratio	Sample size	Round up/down
Veterinary wholesale pharmacies	24	0.011701609	3.791321307	4
Veterinary retail pharmacies	93	0.045343735	14.69137006	15
Smallcompoundingg facilities	14	0.006825939	2.211604096	2
Pharmacy processingplantn	6	0.002925402	0.947830327	1
Orthopedic shops	2	0.000975134	0.315943442	2
Optical shop	14	0.006825939	2.211604096	2
Online pharmacies	3	0.001462701	0.473915163	3
Human wholesale pharmacies	157	0.076548025	24.80156021	25
Human retails pharmacies	603	0.294002925	95.25694783	95
Food outlet	333	0.162359824	52.60458313	53
Food industry	738	0.359824476	116.5831302	117
Cosmetics	64	0.031204291	10.11019015	10
Total	2051	1	324	329

Table 1: Proportional strata of every selected regulated entity

For the total number of entities that were less than 5, whole numbers were considered for the sample size and the overall total sample increased from 324 to 329. Refer to **Appendix 3** to view the response rate obtained from respondents per regulated entity. For a response rate over 100%, only the original sample size was considered using a randomized sampling methodology.

# 3.2. Conducting field visits with interviews

For the field visits, the Rwanda FDA team went to collect information at the household level and selected healthcare facilities.

# 3.2.1. Households

Households were selected to represent the general public. The field visits were carried out in fourteen (14) districts which constituted almost half of the total districts of the country. The selection of the interviewed households was carried out using a proportional stratified sampling (where each district represents a strata), and probability sampling was also respected (See details in **Table 2**).

The population dataset on selected districts was drawn from the fourth population and housing census done in 2012 of the NISR<sup>3</sup> to achieve a representative cross-section of selected districts per population. The sample universe for this survey included all concerned people from the selected districts aged 18 years and above. The Raosoft sample size calculator tool was also used in to get the exact sample size at 95% confidence level 5% of the margin of error.

<sup>&</sup>lt;sup>2</sup> The exact sample size was calculated using Raosoft sample size calculator and the figure to be used was drawn from updated Rwanda FDA client database

<sup>&</sup>lt;sup>3</sup> <u>https://microdata.statistics.gov.rw/index.php/catalog/65</u>

Districts	Total Pop. / District	Ratio	Sample size	Round up/down
Burera	336,582	0.064516772	24.83895726	25
Musanze	368,267	0.070590222	27.17723548	27
Rubavu	403,662	0.077374813	29.78930295	30
Ngoma	336928	0.064583094	24.86449124	25
Kirehe	340,368	0.065242481	25.11835512	25
Rwamagana	313,461	0.060084888	23.13268202	24
Kayonza	334,157	0.064051943	24.65999798	25
Gatsibo	433,020	0.083002218	31.95585406	32
Nyagatare	465,655	0.089257766	34.36424004	33
Nyamagabe	341,491	0.06545774	25.20122987	25
Huye	328,398	0.062948045	24.23499737	24
Rusizi	400,858	0.076837336	29.58237436	30
Gasabo	529,561	0.101507408	39.08035202	39
Nyarugenge	284,561	0.054545273	20.99993023	21
Igiteranyo	5,216,969	1	385	385

#### Table 2: Proportional strata of every selected District

### **3.2.2.** Service delivery points

In each district, three service delivery points (one hospital and two healthcares centres) were visited, making a total of 36 Service delivery points (SDPs). **Refer to appendix 5** for the list of visited Service delivery points.

A total of six data collectors were selected across three departments of Rwanda FDA to conduct the data collection exercise. The data collection took nine working days in fourteen districts of the country.

**Refer to Appendix 4** for the detailed activity timeline of the entire activity.

#### 3.2.3.Data Cleaning, analysis, and report writing

Data collected from google forms was firstly cleaned then coded and populated into STATA and SPSS softwares for analysis. Qualitative data were transcribed and key themes identified and charted using a framework tool for the analysis.

The data analysis process and report writing took five working days. In addition to the six data collectors from Rwanda FDA, two GHSC-PSM staff members joined the team to support in the data cleaning, analysis and report writing exercise.

# **IV. SURVEY FINDINGS**

This section is highlighting findings obtained from Rwanda FDA suppliers; Rwanda FDA staff; Rwanda FDA partners; Rwanda FDA customers; Service delivery points and Households.

### 4.1.Rwanda FDA Staff

The mandate of Rwanda FDA cannot be achieved without the support of committed staff and the of the Authority is based on its core values mentioned here below:

- a) Serving with Professionalism for excellent service delivery
- b) Continuously work with Integrity
- c) Always promoting accountability
- d) Nurturing Teamwork to achieve common objectives
- e) Striving for Innovation to create value for our stakeholder and other interested parties

In this study, the survey tool was sent to all available staff to collect the maximum information from the DG office, CFO Office and other technical departments. 86% of the staff completed the survey through Google form link.

			Gender			Age Group		
					Greater or	Less		
					Equal to 35	than 35		
		Female	Male	Total	years	Years	Total	
	Analyst	4%	12%	16%	12%	4%	16%	
	Director	1%	1%	2%	1%	1%	2%	
	Division Manager	2%	3%	5%	5%	0%	5%	
Staffing Level	Managerial	0%	1%	1%	1%	0%	1%	
	Officer	5%	9%	14%	4%	10%	14%	
	Specialist	24%	33%	56%	18%	39%	56%	
	Technician/Supporting staff	2%	3%	6%	2%	3%	6%	
Total		37%	63%	100%	44%	56%	100%	

#### Table 3: Staffing level, gender, and age group

Rwanda FDA's staffing levels include managerial staff (1%), division managers (5%), analysts (16%), directors (2%), specialists (56%), officers (14%), technicians (6%), and supporting staff (6%) with a total of 63% males in comparison to 37% females. When looking at the age group in the Authority, there are 56% of staff aged less than 35 years old. The remaining 44% are greater or equal to 35 years old.

		Understand the Mission and vision of Rwanda FDA				
		Agree	Strongly agree	Strongly Disagree	Total	
	CFO Office	3.1%	8.0%	0.0%	11.1%	
	DFAR Department	0.0%	24.5%	0.6%	25.1%	
Doportmont	DG Office	0.6%	5.5%	0.0%	6.1%	
Department	FDISM Department	2.5%	38.0%	0.0%	40.5%	
	FINANCE UNIT	0.6%	0.0%	0.0%	0.6%	
	QCL Division	3.1%	13.5%	0.0%	16.6%	
Total	9.9%	89.5%	0.6%	100%		

 Table 4: Understanding the mission and vision of Rwanda FDA by department

When looking at the mission and vision of Rwanda FDA, 89.5% of respondents have a good understanding of the mission and vision of the Rwanda FDA. Only 0.6% of the Rwanda FDA staff strongly disagree with the mission and vision of Rwanda FDA.

 Table 5: Link between staff work, mission and vision, the goal of Rwanda FDA, team performance and executive Organ

	I see a clear lin my work and t and the goal o FDA	he mission of Rwanda	Inspired by th FDA team performing	n while	The Executive Organ contributes to positive work culture	
	Frequency Percent		Frequency	Percent	Frequency	Percent
Agree	27	16.6%	55	33.8%	70	43%
Disagree	1	0.6%	3	1.8%	1	0.60%
Neutral	0	0%	10	6.1%	11	6.7%
Strongly agree	135	82.8%	95	58.3%	81	49.7%
Total         163         100%		163	100%	163	100%	

As highlighted above, almost 83% of the respondent strongly agree that there was a clear link between their work and the mission & goal of Rwanda FDA, 58.3% were inspired with Rwanda FDA Team while performing their work and only 49.7% said that Executive Organ contributes to positive work culture.

# 4.1.1. Staff capacity building in Rwanda FDA services area

Rwanda Food and Drugs Authority promotes personal career development and growth because: Survey results revealed that all the 163 Rwanda FDA staff that participated in the Staff Satisfaction Survey have undertaken at least one or more training regarding Authority functions.

Many of these respondents revealed to have undertaken capacity building in the following service areas which include but not limited to; Audit, Clinical Trial, Import and Export control, Pharmacovigilance, Statistic and Research, Finance and Accounting, Regulatory Inspections, Supply chain, IT Function, Quality Control Laboratory, Statistic and Research, Quality Management System,

Licensing, Resource Management, Procurement and Logistic, Pharmaceutical pricing and Safety Monitoring.

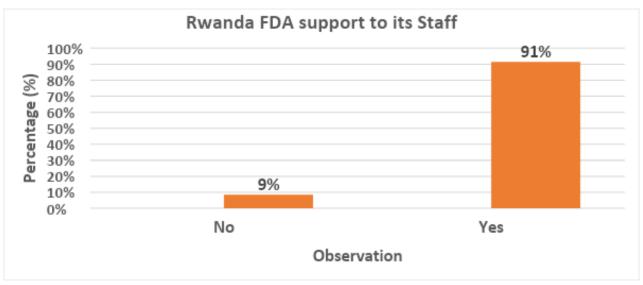


Figure 2: Rwanda FDA support staff in professional development

As per the above figure, the majority of Rwanda FDA staff (91%) shared that they received support in their professional development which include but not limited to the following: Staff promotion, online trainings in different services fields, Conducive work environment and work experience. s

Table 6: Opportunity for individual car	eer growth and development within	n Rwanda FDA
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	Opportunity for individual career growth and development within Rwanda FDA				
Response	Frequency Percent				
No	14	9%			
Yes	149	91%			
Total	163	100%			

The survey indicated that 91% of participants agreed with the opportunity for career growth and development within Rwanda FDA.

#### 4.1.2. Staff challenges versus Staff Motivation and possession of materials/equipment

		Are you motivated to work for Rwanda FDA?			Do you have the materials and equipment you need to perform		
		No	Yes	Total	No	Yes	Total
Q. How challenged are	Less	1%	31%	32%	6%	25%	31%
you when performing your daily duty?	Moderate	4%	53%	57%	13%	44%	57%
your daily duty:	More	1%	10%	11%	5%	7%	12%
Total		6%	94%	100%	24%	76%	100%

The challenges, motivation, and equipment ownership of the Rwanda FDA employee were shown in Figure 2 above According to the survey, 94% of employees are motivated and 76% of the staff reveal that they have the materials and equipment they need to perform efficiently.

Among the motivated personnel, 53% claimed that their daily duties were challenging, and another 10% said the challenges were very difficult. Among the non-motivated workers (6%), 1% of the respondents found their daily duties to be not challenging and another 1% said they were quite challenging. In addition, the poll revealed that 44% of the personnel who had access to the necessary materials were moderately challenged while 7% faced greater challenges as they perform their daily duties.

# Table 8: Application of a job outside of Rwanda FDA

Response	Have you ever applied for a job outside of Rwanda FL				
	Frequency	Percent			
No	143	88%			
Yes	20	12%			
Total	163	100%			

Table 8 highlighted that 88% of respondents had never applied for a job while employed at Rwanda FDA whereas 12% admitted they were actively seeking for jobs. The working environment was mentioned to be good however, some staff expressed the wish to have more support from their colleagues.

It was also mentioned that the high level of bureaucracy made the working atmosphere hostile. Furthermore, hhaving short-term contracts was also mentioned as a factor to apply for position outside of the Authority.

Table 9:Job security satisfaction and commitment to work with Rwanda FDA for the next 3-5years

		Working with Rw next 3-5		
Response		No	Yes	Total
	Agree	2%	39%	40%
	Disagree	1%	7%	9%
Job security satisfaction	Neutral	2%	24%	26%
satisfaction	Strongly agree	0%	19%	19%
	Strongly disagree	1%	5%	6%
Total		6%	94%	100%

As per the table 9 above, 94% of respondents agreed to work with Rwanda FDA over the next 3-5 years due to employment security satisfaction and commitment. Some observations made were the following: the working environment at Rwanda FDA is favourable and salary scale is appreciable based on the educational background of the staff.

The 94% respondents wanting to work with Rwanda FDA over the next 3-5 years also expressed their willingness to work for an authority that is aiming to progress to internationally recognized institutions by achieving ML3, ISO certification, and establishing vaccine regulatory functions.

# 4.1.3. Rwanda FDA policies for promoting employees

	Fair policies for promoting the e	Fair policies for promoting the employees at Rwanda FDA			
Response	Frequency	Percent			
No	35	21%			
Yes	128	79%			
Total	163	100%			

### Table 10: Rwanda FDA policies for promoting employees

As per the above **figure**, 79% of staff shared that there was a fair policy for promoting the employees at Rwanda FDA due to the strong QMS system in place aiming to provide service at the international level of standards with reasonable salaries and incentives in place.

79% of the staff also shared that the job profiles were equivalent to qualification and profiles hired and the laws, rules, and regulations governing the promotion of employees for public servants are applied. For the remaining disagreed with the statement, the main arguments were around the lack of awareness of such policies and the lack of transparency in the promotion process.

# 4.1.4. Supervisor understanding a healthy balance between work and personal life

T-11. (	
Table 11: Supervisor understanding a health	ly balance between work and personal life

		-	inderstands a healt work and personal	hy balance between life
		No	Yes	Total
Fairness of rewards e.g. PBF	No	3%	13%	16%
Mission allowances etc	Yes	7%	77%	84%
Total	·	10%	90%	100%

The survey showed that 90% of the respondents agreed that the supervisors understood the importance of a healthy balance between work and their personal life. Furthermore, 84% of the participants agree that there is the fairness of rewards (PBF and Mission allowances etc.) based on work activities.

# 4.2.Rwanda FDA Clients

Rwanda FDA clients who were included in the study were divided in three categories: a) The food and beverages products represented 50% of the total sample size, b) pharmaceutical products which represented 46% of the total sample size and c) cosmetics and household chemicals products which represented 4% of the total sample. As presented in figure 3 these categories were further classified into manufacturers, retailers, and wholesalers.

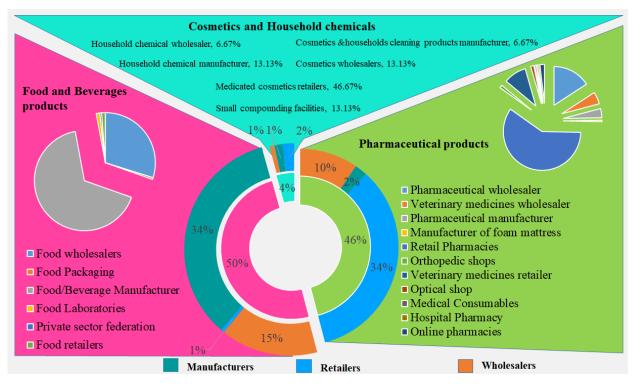


Figure 3: Categories of Rwanda FDA Clients

# 4.2.1. Company location and working relationship with Rwanda FDA

		How long have you been in the business working with Rwanda FDA					Under norma use th		stances ho s of Rwan		do you
		1-5 years	6-10 years	Over 10 years	Under One year	Total	Annually	Daily	Monthly	Not sure	Total
Location of	Rural	34%	5%	1%	2%	42%	33%	2%	6%	1%	42%
Company	Urban	39%	10%	7%	2%	58%	28%	10%	18%	2%	58%
Total		73%	15%	8%	4%	100%	61%	12%	24%	3%	100%

Table 12: Company location and working relationship with Rwanda FDA

As indicated in the **table 12** above, 58% of the companies working with Rwanda FDA are located in urban areas in comparison to 42% in rural areas. The results also revealed that the majority of the companies that participated in the survey (73%) have been in business with Rwanda FDA for a period between 1-5 years, these companies are mostly based in urban areas (39%) and 34% are based in rural areas.

When looking at the frequency of service use with Rwanda FDA, 58% of the companies based in urban settings revealed that they use the service of Rwanda FDA annually (28% and), monthly (18%), daily (10%) while 2% were not sure of their frequency of use of services rendered to Rwanda FDA. For 42% of the companies in rural settings, they also consented to use Rwanda FDA services on an annual, monthly, and daily basis.

### 4.2.2. Services requested by clients at Rwanda FDA

Below are the key services requested by clients at Rwanda FDA:

- a) GMP Inspection
- b) Registration & Licensing
- c) Regulatory Inspections (GMP, GDP, GLP)
- d) Licensing, Pharmacovigilance
- e) Quality control
- f) Import and Export
- g) Advertisement and promotion
- h) Case report/PMS.

### 4.2.3. Challenges experienced when dealing with Rwanda FDA

Challenges experienced while dealing with Rwanda FDA					
	Frequency	Percent			
Delayed Response from Rwanda FDA	266	77.2%			
Extended registration timelines	16	4.7%			
Lack of guidance on documentation for regulatory procedures	13	3.8%			
Rwanda FDA website not -up- to date	1	0.3%			
Others	30	9.0%			
No challenges	18	5.0%			
Total	344	100.0%			

 Table 13: Table: Challenges encountered while dealing with Rwanda FDA

As per the table 13 above, clients working with Rwanda FDA mentioned numerous challenges experienced in their working relationships with the Authority. Most of the companies (77.2%) revealed that there were delayed responses from Rwanda FDA on some requests and services leading to extensive back and forth communication over a single-issue.

Another challenge that was mentioned by 4.7% of companies was the extended registration timelines differing from the Authority's guidelines directly affecting companies' performances. This was also explained by 3.8% of companies who revealed that the delay resulted from a lack of guidance on documentation regarding regulatory procedures, and the lack of transparency of regulatory decisions. More challenges were mentioned in the "other" category which includes but not limited to poor GMP Inspection practices, unprofessional or inconsistent advice from inspectors, poor communication and difficulty in contacting Rwanda FDA customer care and inspectors, and inadequate handling of some

complaints or issues raised. However, 5% of the companies that participated in the survey revealed that they had not encountered any challenges while dealing with Rwanda FDA.

# 4.2.4. Rating Rwanda FDA Service fees and/ or fines

Tuble 111 Running Remainder 1 Dir Ber vice rees und, or miles						
Response	Frequency	Percent				
Reasonable	185	54%				
Highly costly	148	43%				
No idea	11	3%				
Total	344	100%				

### Table 14: Rating Rwanda FDA Service fees and/ or fines

The table 14 above reveals that 54% of the Rwanda FDA customers rated the Authority's service fees as reasonable whereas almost an equal proportion of 43% revealed that the service fees were highly costly, and fines were unreasonably high. In addition, 3% of the Rwanda FDA clients did not have any idea regarding Rwanda FDA fees and/or fines.

# 4.2.5. Product Recall and Compensation

# Table 15: Product Recall and Compensation

In Case of products recall how are you compensated								
ResponseFrequencyPercent								
Compensated	30	9%						
Not compensated	164	48%						
No Product Recall	47	14%						
No Idea	103	30%						
Total	344	70%						

In reference to the table above, from a total of 344 Rwanda FDA customers contacted during the assessment, majority (**48%**) revealed that they have never been compensated for any product recall by the institution with only **9%** consenting to the fact that they had been compensated under the above-mentioned circumstances.

Additionally, it is also important to note that **30%** of the customers contacted revealed not to have any idea with regards to product recall by Rwanda FDA meaning that they have faced with such a scenario in their working relations with Rwanda FDA. **14%** have not faced with any product recall by Rwanda FDA.

Launched complaint/feedback to Rwanda FDA					
Response Frequency Percent					
No	257	75%			
Yes	87	25%			
Total	344	100%			

Table 16: Launching a Complaint or /feedback to Rwanda FDA

Findings regarding the launch of complaints or providing feedback to Rwanda FDA revealed that only **25%** of the customers contacted during the assessment have either launched a complaint or provided feedback to the Institution in one of the other while the majority **75%** revealed not to have neither launched a complaint not provided feedback to the institution.

# 4.2.6. Missing services within Rwanda FDA

Various services were mentioned as missing or not available by companies dealing with Rwanda FDA. These services mentioned include but not limited to the following: close to non-existent customer care services, lack of services supporting small to medium enterprises.

# 4.3.Households

Further to visiting fourteen districts, a total of 385 individuals from across the country were consulted to share their perceptions and expectations of Rwanda FDA. Below are the findings obtained for this specific category.

Occupation	Gender			Heard about Rwanda FDA		
	Female	ale Male Total		No	Yes	Total
Employed	8%	18%	25%	9%	16%	25%
Farmer	7%	7%	14%	11%	3%	14%
Retired	1%	2%	3%	1%	3%	4%
Self-employed	26%	27%	53%	36%	17%	53%
Student	2%	2%	4%	1%	3%	4%
Total	44%	56%	100%	58%	42%	100%

### Table 17: Gender, occupation

The above table 16 shows that the population for this survey consisted of 44% females and 56% males. Out of this sample, only 42% knew of the institution and the remaining had never heard of Rwanda FDA prior to this interview.

In terms of occupation, 53% of the population assessed were self-employed and 25% employed. The remaining of the population were farmers, retired, and students.

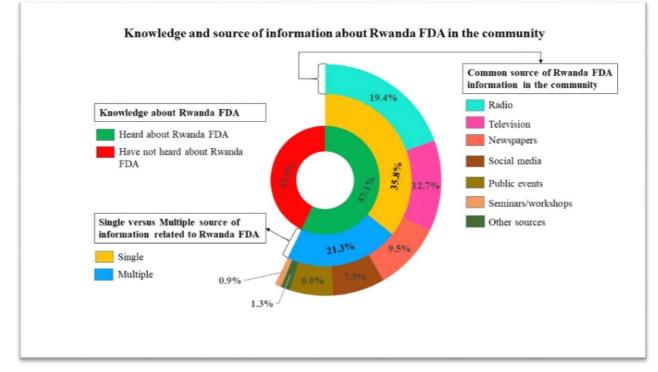


Figure 4: Knowledge and Source Information about Rwanda FDA

When assessing the knowledge and source of information about Rwanda FDA (**see fig...**), Radio and ttelevision were the main sources of information on Rwanda FDA in the community (35.8%). Other sources of information such as social media (7.3%), public events (6.3%) constituted of smaller percentages due to their difficulty in accessibility.

# 4.3.1. Service Rating of Rwanda FDA

		Rwanda FDA Service Rating						
		Very			Not			
		Important	Important	Neutral	important	Worse	Total	
Heard about	No	0	0	0	0	0	220	
Rwanda FDA	Yes	77	45	13	8	7	165	
	Total	77	45	13	8	7	385	

Table 18: Service Rating of Rwanda FDA

**Table** showed that out of 385 interviewees, 220 did not hear about Rwanda FDA and did not rate institutional services. Out of 165 respondents who knew of Rwanda FDA, 77 shared that they believed Rwanda FDA's services were extremely important and along the same line 45 confirmed services provided were important while 7 respondents shared that the services provided were of very poor quality and 13 respondents expressed no opinion regarding the Authority's services.

### **4.3.2.** Counterfeit products in Rwanda

		Frequency	Percent
	No Response	133	35%
	Beverage	21	5%
	Beverage - Food	9	2%
Due de st	Food	10	3%
Product	Herbal medicines	100	26%
	Human Medicines	94	24%
	Veterinary medicines	18	5%
	Total	385	100%
Awareness of R	wanda FDA actions on coun	terfeited Yes	115
products		No	220
		Total	385

Table 19: Counterfeit products in Rwanda

As shown in the table above, out of the total 385 interviewees, **26%** stated that herbal medicines were the most counterfeited products. With almost the same percentage (**24%**) human medicines were positioned second following food and Beverages (**10%**) and veterinary medicines (**5%**). A high percentage of neutral responses were recorded (**35%**).

When assessing the knowledge of the public on Rwanda FDA's actions to destroy counterfeit products, 220 out of the 385 respondent (57.2%) were not aware of actions taken by Rwanda FDA. For the respondents who knew of the actions taken by Rwanda FDA to combat counterfeit products, 72,7% rated these actions as important.

# 4.4.Suppliers

In this survey, a total of 15 suppliers working with Rwanda FDA were contacted to provide their perception on Rwanda FDA performance and below are the tabulated findings:

		Duration in business with				Total estimated value of business in		
		Rwanda FDA			Rwanda Frw			
		Less						
		than 1	2-3	Over 5		Below 50	Between 50 to 200	
		year	years	years	Total	million	million	Total
	Consultancy	6.7%	6.7%	0.0%	13.3%	6.7%	6.7%	13.3%
Business activities	Provision of services	60.0%	13.3%	0.0%	73.3%	73.3%	0.0%	73.3%
provided to Rwanda FDA	Supply of Medical related goods	0.0%	0.0%	6.7%	6.7%	0.0%	6.7%	6.7%
	Other activities	6.7%	0.0%	0.0%	6.7%	6.7%	0.0%	6.7%
Total		73.3%	20%	6.7%	100%	87%	13%	100%

Table 20: Services to Rwanda FDA Vs Duration in business and Estimated business budget

As highlighted above, Rwanda FDA receives different services across a range of supplier fields categorized in the form of consultancy, provision of services, supply medical-related goods and other activities. Among the suppliers, 73.3% are involved in the provision of services to Rwanda FDA.

Also, to note is the fact that most of Rwanda FDA suppliers (73.3%) have worked with the institution for a period less than one year and only 7% have worked with Rwanda FDA for a period above 5 years. It was also revealed that majority of the suppliers (87%) have an estimated value of business below 50 million and 13% have a budget ranging between 50 to 200 million.

			ng availabi tion of pro plans	ility of ocurement		-	evel of com Rwanda FD.	-		-	erms of reference ns included in documents			Rating Rwanda FDA specifications and Terms of reference			
		Good	Not sure	Very good	Total	High	Normal	Very High	Total	Neutral	Realistic	Very realistic	Total	Neutral	Realistic	Very realistic	Total
	Consultancy	0.0%	6.7%	6.7%	13.4%	0.0%	6.7%	6.7%	13.4%	6.7%	0.0%	6.7%	13.4%	0.0%	0.0%	13.4%	13.4%
Business activities	Provision of services	6.7%	6.7%	60.0%	73.4%	0.0%	6.7%	66.7%	73.4%	6.7%	0.0%	66.7%	73.4%	6.7%	0.0%	66.7%	73.4%
provided to Rwanda FDA	Supply of Medical related goods	6.5%	0.0%	0.0%	6.5%	6.5%	0.0%	0.0%	6.5%	0.0%	6.5%	0.0%	6.5%	0.0%	6.5%	0.0%	6.5%
	Other activities	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	6.7%
Total		13%	13%	73%	100%	7%	13%	80%	100%	13%	7%	80%	100%	6.7%	6.7%	86.7%	100%

Table 21 : Services to Rwanda FDA Versus Availability of Information/level of competition/Terms and Conditions/Specifications and ToR

Table above revealed that when rating availability of information on procurement plans, Most suppliers (73%) Rated the availability as very good. With regards to the level of competition in Rwanda FDA, 80% of the suppliers rated the competition as very high. For the terms of reference and conditions included in bidding documents, 80% of the suppliers stated there were very realistic. Finally, Rwanda FDA specifications and terms of reference were rated as very realistic by 86.7% of the suppliers.

		bidders t	e granted to o prepare mit offers		Rating transparency of Rwanda FDA in procurement activities			Rating receiving & handover process at Rwanda FDA			Rating re-	ceiving fee	edback about reje	ections ar	nd defects	
		Sufficient	Very Sufficientt	Total	Highly recommendable	Recommendable	Total	Good	Very good	Total	No idea	Poor	Very poor	Well	Very well	Total
	Consultancy	6.7%	6.7%	13.3%	6.7%	6.7%	13.3%	6.7%	6.7%	13.3%	6.7%	0.0%	0.0%	6.7%	0.0%	13.3%
Business activities	Provision of services	0.0%	73.3%	73.3%	73.3%	0.0%	73.3%	0.0%	73.3%	73.3%	6.7%	0.0%	0.0%	0.0%	66.7%	73.3%
provided to Rwanda FDA	Supply of Medical related goods	6.7%	0.0%	6.7%	6.7%	0.0%	6.7%	6.7%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%
	Other activities	0.0%	6.7%	6.7%	6.7%	0.0%	6.7%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%
Total		13%	87%	100%	93%	7%	100%	13%	87%	100%	13.3%	6.7%	6.7%	6.7%	67%	100%

Table 22 : Services to Rwanda FDA Vs Time granted to bidders/ Rwanda FDA Transparency/ Receiving and Handover processes/ Feedback on rejections

Table 3 above, reveals that the rating time granted to bidders to prepare and submit their offers was very sufficient rated at 87%. Majority of the suppliers of services to the Authority also rated the transparency of Rwanda FDA in its own procurement activities as highly recommendable (93%).

For rating, receiving & handover process at Rwanda FDA for goods, works and services respectively was also rated the different service suppliers as very good with 87% rating. However, there was a drop in the rating for 'receiving feedback/comments about rejections and defects' of the work done or goods supplied as only 67% rated this as very well, 13% did not have an idea on this aspect and 6.7% revealed that feedback on rejections was very poor.

Business	Rwai	nda FDA	communic	ate its sup	pliers		Rating reason by Rwanda FDA on delayed payments				Rwanda FDA Internal stakeholders' involvement during implementation of service contracts				Rating information provided duri the implementation for consultanc			0			
provided to Rwanda FDA	Bad	No idea	Very bad	Very good	Good	Total	Good	Neutral	Very bad	Very good	Total	Good	Neutral	Very bad	Very good	Total	Good	Neutral	Very bad	Very good	Total
Consultancy	0.0%	6.7%	0.0%	0.0%	6.7%	13.3%	6.7%	6.7%	0.0%	0.0%	13.3%	6.7%	0.0%	0.0%	6.7%	13.3%	6.7%	6.7%	0.0%	0.0%	13.3%
Provision of services	0.0%	0.0%	13.3%	60.0%	0.0%	73.3%	0.0%	0.0%	13.3%	60.0%	73.3%	0.0%	6.7%	13.3%	53.3%	73.3%	6.7%	0.0%	13.3%	53.3%	73.3%
Supply of Medical related goods	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	6.7%
Other activities	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%
Total	7%	7%	20%	60%	7%	100%	13.3%	6.7%	20.0%	60.0%	100%	13.3%	6.7%	20.0%	60.0%	100%	13.3%	6.7%	20.0%	60.0%	100%

 Table 23 : Services to Rwanda FDA Vs Rwanda FDA Communication with suppliers on delayed payments/Internal stakeholder involvement and implementation of consultancies

Table above, revealed that 60% of the suppliers rated the Rwanda FDA communication to its suppliers/providers when faced with delays in payment was very good however, it is important to note that another 20% of the suppliers also revealed that this communication from Rwanda FDA was very bad.

Additionally, it was also revealed that 60% were content with the reasons provided by Rwanda FDA on delayed payments though 20% did not agree with reasons provided by the Authority. The performance of Rwanda FDA in adequate involvement and availability of Internal stakeholders during implementation of service contracts or consultancies was rated by more than half of the suppliers (60%) as very good same as information/data provided during the implementation for consultancies.

Business activities	Rating c	urrent mecl probl		resolving			on between a on to contrac			Drat	fting Rwanda	FDA contra	acts	Rwanda FDA comply with te conditions in purchase orders o					
provided to Rwanda FDA			Very	Very			Very	very					Very				Very	Very	
Kwalida FDA	Good	Neutral	bad	good	Total	Good	bad	good	Total	Excellent	Good	Neutral	poor	Total	Good	Neutral	bad	good	Total
Consultancy	13.3%	0.0%	0.0%	0.0%	13.3%	13.3%	0.0%	0.0%	13.3%	0.0%	13.3%	0.0%	0.0%	13.3%	13.3%	0.0%	0.0%	0.0%	13.3%
Provision of services	0.0%	0.0%	13.3%	60.0%	73.3%	6.7%	53.3%	13.3%	73.3%	53.3%	0.0%	6.7%	13.3%	73.3%	0.0%	0.0%	60.0%	13.3%	73.3%
Supply of Medical related goods	0.0%	6.7%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%
Other activities	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	6.7%
Total	13%	7%	20%	60%	100%	26.7%	53.3%	20.0%	100%	53.3%	20.0%	13.3%	13.3%	100%	13.3%	6.7%	66.7%	13.3%	100%

Table 24: Services to Rwanda FDA Vs Time granted to bidders/ Rwanda FDA Transparency/ Receiving and Handover processes/ Feedback on rejections

Table above, revealed that 60% of the suppliers rated Rwanda FDA current mechanism of resolving problems once they arise during implementation of a contract as very good though another 20% of suppliers rated that mechanism as very bad. The duration it takes from award notification to contract signing or submission of offer to receipt of a purchase order was noted by the majority of suppliers (53.3%) as very bad and the performance of Rwanda FDA in the drafting contracts was rated as excellent by 53.3% of suppliers.

However, another 13.3% of suppliers revealed that the Authority was very poor in this aspect and rated it as very poor. Rwanda FDA compliance with other terms and conditions stipulated in the purchase orders or contracts was rated by more than half of the suppliers (66.7%) as very bad with only 13.3% of the suppliers indicating that the Authority was doing very good in this aspect.

Business activities provided to	Relationshi its supp	p between liers and so				Willingness	Willingness and deliberate efforts of Rwanda FDA to foster a good relationship				FDA staff c	ommunicat	d clarity of l ion and colla & service p	aboration		within	FDA staff k the limits on tract terms	of the		
Rwanda FDA				Very						Very					Very			Very		
Kwallua FDA	Excellent	Good	Poor	poor	Total	Excellent	Good	Neutral	Poor	poor	Total	Excellent	Good	Neutral	poor	Total	Excellent	Good	Good	Total
Consultancy	0.0%	6.7%	6.7%	0.0%	13.3%	0.0%	6.7%	0.0%	6.7%	0.0%	13.3%	0.0%	6.7%	0.0%	6.7%	13.3%	0.0%	6.7%	6.7%	13.3%
Provision of services	60.0%	0.0%	0.0%	13.3%	73.3%	60.0%	0.0%	0.0%	0.0%	13.3%	73.3%	60.0%	0.0%	0.0%	13.3%	73.3%	13.3%	40.0%	20.0%	73.3%
Supply of Medical related goods	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	6.7%
Other activities	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	6.7%	6.7%
Total	66.7%	6.7%	6.7%	20%	100%	60.0%	13.3%	6.7%	6.7%	13.3%	100%	60.0%	13.3%	6.7%	20.0%	100%	13.3%	53.3%	33.3%	100%

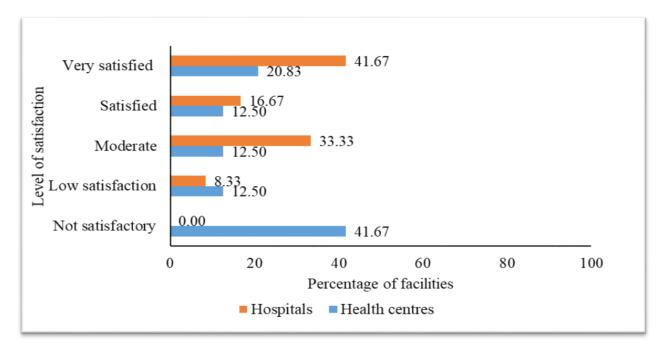
Table 25: Services to Rwanda FDA Vs Relationship between Rwanda FDA and Suppliers/ Staff communication and Limits

Table above, indicates from the findings that the relationship between Rwanda FDA and its suppliers and service providers was excellent as rated by 66.7% of the suppliers though also to note is the fact that 20% rated this aspect as very poor. The willingness and deliberate efforts of Rwanda FDA to foster a good relationship with its suppliers or in creating a friendly environment to work with its suppliers was rated by more than half of the suppliers (60%) as excellent though 13.3% rated this as very poor.

Additionally, the promptness and clarity of Rwanda FDA staff communication and collaboration with its own suppliers & service providers was also rated by more than half of the suppliers (60%) as excellent, however another 20% of the suppliers rated this as very poor. Rwanda FDA staff keeping within the limits of the contract terms or scope to the benefit of the Authority rather than for their own personal benefit was rated 'very good' by approximately half (53.3%) of the suppliers and 33.3% of the suppliers rated this same aspect as 'good'.

## **4.5.Service Delivery Points**

To assess the customer care in service delivery points, 36 Service delivery points (SDPs) were visited by the data collectors. The following graph, shows the level of Rwanda FDA services satisfaction in public service delivery points.



## 4.5.1. Rwanda FDA services satisfaction level in public health facilities

Figure 5: Rwanda FDA services satisfaction level in public health facilities

As per the graph above, 41.67% of hospitals were very satisfied by the services rendered by Rwanda FDA. On the other hand, the same percentage (41.67%) revealed that health centres were unsatisfied by the service rendered by Rwanda FDA. As a general observation, health centres showed less satisfaction in comparison to hospitals, with only 20.83% showing a high satisfaction of the services rendered by Rwanda FDA.

## 4.5.2. Rwanda FDA services in public service delivery points

Variables (n)	Responses	Frequency	%
Do you think our service rates are	Yes	30	76.92
reasonable?	No	6	15.38
	Very easy	6	42.86
How every is it to file a claim with we?	Easy	1	7.14
How easy is it to file a claim with us?	Difficult	4	28.57
	Very difficult	3	21.43
	Very satisfied	3	21.43
How satisfied are you with the outcome of	Satisfied	3	21.43
your claims?	Less satisfied	4	28.57
	Not satisfied	4	28.57
Customer service representatives are	Yes	8	57.14
knowledgeable and helpful?	No	6	42.86
How likely is it that you would recommend	Very likely	24	61.54
Rwanda FDA to other Health Care	Likely	6	15.38
providers?	Less likely	6	15.38

 Table 26 : Rwanda FDA services in public service delivery points

As seen in the table 25 above, 76% of public service delivery points shared that the rate of services of Rwanda FDA were reasonable. When looking at the claiming process, approximately half of the public service delivery points found it difficult or very difficult to deal with the claims and the other half felt it was manageable.

When looking at the outcomes of claims made to Rwanda FDA, almost 60% of the public service delivery points were not satisfied about the outcomes of the claims they made to Rwanda FDA. When looking at the knowledge and the help provided by Rwanda FDA customer representatives to public SDPs, more than half of them (57.4%) felt that Rwanda FDA customer representatives were helpful.

Finally, when asked whether these facilities would recommend Rwanda FDA to other healthcare providers, 61.54% said there were very likely to recommend Rwanda FDA services to other healthcare providers.

## 4.6.Development Partners

During this survey, the focal points from six developments partners agencies actively working with Rwanda FDA were consulted and the below findings were gathered.

Figure 6 highlights the cooperation and satisfaction of the development partners working with Rwanda FDA. Most of the partners working with Rwanda FDA believe that the mission and vision of Rwanda FDA is convincing at 66.7% and very convincing at 33.3%. Half of the sample appreciated that the timeline set by Rwanda FDA is met while the other half believe that Rwanda FDA is neither late nor closely meeting the set timeline.

Very closely 50%			Coopera 33.3%	tive	Satisfied 50%					
			cooperat 33.3%	ion	Neither	Very	Convincing 66.7%			
Neither closely nor Late 50%	Very likely 100%	Very likely 100%	Very coopera tive 16.7%	Less coopera tive 16.7%	satisfied nor unsatisfied 33.3%	satisf ied 16.7 %	Very convincing 33.3%			
Legend:	Are you will Would you re How would you How are you	Image: Second Control (Second Contro) (Second Control (Second Control (Second C								

Figure 6: Perception on Rwanda FDA Services

Rwanda FDA was rated 3 and 4 by 33.3% of partners while it was rated 2 and 5 by 16.7% when asked to compare Rwanda FDA cooperation compared with other institutions. When asked about the satisfaction of Rwanda FDA services, Half of the partners were satisfied with the services provided; 16.7% of the partners were very satisfied while 33.3% are neither satisfied nor unsatisfied. Finally, all partners shared that they were willing to continue to work with the Authority and could recommend it to other partners.

## V. CONCLUSION

In order to meet customers' expectations, improvement in the quality of services is imperative. Accordingly, the following recommendations were suggested per categories:

## 5.1.1. Staff

Below are the compiled recommendations made by Rwanda FDA staff:

#### Capacity building plan

- a) Effectively implement the annual capacity-building plan to promote efficient individual career growth and development.
- b) Improved guidance from supervisors on daily tasks
- c) Implement tailored training and workshops with knowledge- transfer from advanced regulatory authorities (ex: GxP (GDP, GLP, GSP, GWP) practices)
- d) Promote long term capacity building plan (Masters and Ph.D.)
- e) Increase awareness of fair policies for promoting the employees and clear and transparent promotion system to incentivise capacity building

#### Work Environment

- a) To increase the number of staff to handle the issues related to workload faced by some divisions.
- b) Improve staff retention strategies such as work transportation, salary review, on-time promotion, PBF, communal activities, comfortable workspace, and other incentives

#### **Tools and Equipment**

- a) Improve availability and maintenance of equipment such as laptops; protective (for Occupational safety health) and testing equipment; inspection uniforms and materials, release stamps and cameras
- b) Improve the data management information system in place: an automated system that integrates all the regulatory functions that can allow M&E tracking of the progress

## 5.1.2. Rwanda FDA clients

#### Awareness

Improve Awareness of Rwanda FDA services in both urban and rural areas to customers but also members of the public

## Training

- a) Training of clients to improve their service
- b) Training of Rwanda FDA staff especially on inspection services and the food and beverages industry (eg. Reviewing the checklist for high-risk and low-risk foods)
- c) Establishing a council for official certifications of manufacturers (including ISO certifications)

#### **Rwanda FDA Operations**

- a) Clear differentiation of services with other public authorities such as RICA, RSSB
- b) Improve Rwanda FDA customer services with 24/7 hotline service with polite service providers; ensuring there are staff in duties over the weekend for services such as import/visa licensing, dossier assessment etc.
- c) Improve communication with external customers (for ex: Decrease time to respond to emails and allow for physical meetings with customers, prompt notification on any procedural changes to facilitate clients internal planning process)
- d) Improve and allow for more flexibility in the GMP inspection process by increasing the frequency and sites to be visited and reviewing staff attitudes when inspecting premises
- e) Improve the categorisation, communication, and management of regulated industries (from start-ups to well established industries) both in urban and rural settings and terminate the use of "authorized lists" to encourage more manufacturers to apply for registration
- f) Review industries' trade names before registration that can 'mimick' established brands affecting their reputation and bringing confusion
- g) Decentralisation of Rwanda FDA services to district and provincial level (including inspection officers)
- h) Reducing the cost of all the Rwanda FDA services and fines considering the financial consequences of COVID-19.
- i) Fast-track and improve the registration process, visa importation, and dossier assessment processes for both local and international industries to ensure client satisfaction.
- j) Improve the archiving process and accessibility of documents to avoid loss of documents such as CTD dossier

- k) Improve the management of substandard/counterfeit products on the Rwandan market
- 1) Increase the license for operating a wholesale or retail pharmacy (should be at least one year or up to three years)
- m) Encourage collaboration and knowledge-sharing with neighbouring regulatory authorities
- n) Organize periodic meetings for discussion with stakeholders
- o) Improve internal quality management systems (especially PRIMS and IT related challenges)
- p) Improve the website online application forms (Refer to RICA's system)
- q) Invest in bar code or lot numbers for certificate of analysis or other documents
- r) Improve the compensation of recalled products

#### Households

- a) Decentralization of Rwanda FDA activities through enhanced collaboration and communication with local government officers in charge of health at district and lower levels for more effective visibility on cross-border district trade and implementations of regulations and herbal medicines.
- b) Increase investigation procedures on existing counterfeit/substandard products on the market (eg., Contraceptives) as well as inspection in the communities to avoid the use of expired beverages, food stuff, cosmetics, and all other counterfeit products at the different rural outlets.
- c) Appointment of a Rwanda FDA inspection focal person (speaking Kinyarwanda) at the district level to for inspection, sensitization, product label interpretation and capacity building of the different stakeholders involved with Rwanda FDA.
- d) Increase public education campaigns on Rwanda FDA services as well as food and drugs safety on media platforms but also at ground level through the dissemination of information using printable booklets, and theatre plays.
- e) Easily accessible platform in place (toll-free, mobile phone numbers and forms) to report counterfeit products in the communities.
- f) Implementation of a standard pricing policy in the country making sure that product sellers do not exploit citizens by hiking prices, especially on medicines and imported food.

## **Suppliers**

- a) Improve communication with suppliers: bid award notification
- b) Review efficient field work processes
- c) Clear boundaries set between Rwanda FDA and their suppliers management authority
- d) Improve customer care especially in the finance department: fast-track payments, inform suppliers if payment details
- e) Methods of transporting refrigerated adopted by the manufacturers should be accepted by Rwanda FDA

## Service delivery points

## Trainings

- a) Health workers on basic skills regarding the quality and safety of the regulated products at all levels of service delivery points (e.g: Online CPD-oriented training).
- b) Pharmacists on how to identify and report substandard & counterfeit products.

## **Rwanda FDA operations**

Strengthen Rwanda FDA operations such as:

- a) Encourage rapid feedback by the Rwanda FDA on reported cases for effective product recall.
- b) Thorough check of all medicines and medical devices before they are released onto the market.
- c) Improve the channel of communication between healthcare workers and Rwanda FDA (e.g online platform, WhatsApp number).
- d) Reviewing incineration practices, especially in health centres
- e) Providing pharmacovigilance systems in centres and health post level and improving the investigation of substandard & counterfeit products through for ex: tracing falsified/ counterfeit products or adverse source ingredients.
- f) Encourage inspection of wholesalers and district pharmacies to ensure compliance and reduce the recall of products.
- g) Establishing and maintaining the pricing policy for all drugs especially non-refundable drugs.

#### Framework of collaboration between:

- a) Rwanda FDA and Drug Therapeutic Committees (DTCs) to ensure adequate reporting of adverse drug reactions in hospitals;
- b) Rwanda FDA and Rwanda Medical Supply (RMS Ltd) to ensure uninterrupted availability of good quality medicines in hospitals and health centres;
- c) Other regulatory bodies for harmonization of regulations and requirements for the products sold in the Rwandan market.

#### Awareness activities on:

- a) Rwanda FDA mission and services to the community, healthcare providers and health service delivery points to encourage effective collaboration (e.g. design of Rwanda FDA booklets), emphasizing the role of healthcare services in implementing Rwanda FDA mandate
- b) Reporting mechanisms for adverse drug reactions and adverse events (e.g. toll-free numbers) by patients but also by healthcare workers in the private sector and all service delivery points (health centres, health posts, Community healthcare workers facilities); through the use of small cards that can be distributed to healthcare workers and patients to enforce reporting AER/ADR
- c) Need for competent and enough supply chain workers (pharmacists, store managers) in health facilities for good practices, and management of good quality medicines.

#### **5.1.3 Development partners**

- a) Decentralization of power to ensure middle level managers to perform technical duties and achieve more and in a short period
- b) Improve engagement and communication with stakeholders to ensure there is no delay in planned activities implementation and support is provided appropriately
- c) Adopting a bottom-up approach for technical work and a top-to-bottom approach for policy and governance-related matters
- d) Increase awareness among the implementers (private sector and FBOs)
- e) Words of encouragement were shared by the partners on Rwanda FDA's current work and future work

# VI. LIMITATIONS

**Financial Resources**: Limited budget hindered a wider coverage of the survey however, with the available financial resources and support from partners, the assessment was able to cover all the different stakeholder categories with a reasonable and representative sample size to have general observation with regards to the survey objectives.

**Literature review**: There was a need to consider more literature review from the different stakeholders considered during the assessment in addition to the interviews that were conducted. However, some of these documents were not accessible from the stakeholder perspective. Nevertheless, other sources were utilized during the assessment including but not limited to published papers, interview questionnaires developed for each stakeholder category as well as field observations during data collection to meet the assessment objectives.

**Time constraint**: considering the time and delivery of this assessment report, the team had very limited time for the whole assessment process The team worked with fixed timelines right from the concept paper, assessment tools development, data collector trainings, field data collection, untimely online responses from some of the stakeholders, data analysis and interpretation to report writing. Nevertheless, within all the limitation the team was able to deliver on this aspect in appreciation for the support from partners.

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# ENDORSEMENT OF THE DOCUMENT

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# ANNEXES

# Annex 1: Objectives of each questionnaire

Categories	Objectives – to get an insight on:
1. Rwanda FDA Suppliers	1. To know whether the suppliers are working efficiently with
	Rwanda FDA to supply goods/ equipment
	2. Assessing the communication channels between the
	suppliers and Rwanda FDA
	3. Accessibility of source of information
	4. Respect of contract clauses and payment delays
	5. Feedback processes
2. Rwanda FDA staff	1. Identification of demographics and staff diversity
	2. Asses the understanding of the Organization's mission and
	vision
	3. Assess the understanding on the role and contribution to
	Rwanda FDA
	4. Internal understanding on the means allowing the staff to
	perform efficiently
	5. Motivational factors that can contribute to effective service
	delivery
	6. Challenges leading to poor service delivery
	7. Experience with suppliers
	8. Communication channel with customers
	9. Dealing with Complaints
	10. Recommendations
3. Rwanda FDA partners	1. Ranking Rwanda FDA mission and vision
	2. Respect of activity timeline
	3. Cooperation relationship
	4. Recommendation to other organizations
	5. Satisfaction with Rwanda FDA services
4. Rwanda FDA customers	1. Category of the business
	2. Time working with Rwanda FDA
	3. Services required at Rwanda FDA
	4. Challenges when dealing with Rwanda FDA
	5. Insight on fees and fines charged
	6. Complaint & feedback procedures
	7. Missing services
5. Service delivery points	1. Service rates
	2. Claims modalities
	3. Customer service representatives
	4. product recall
	5. Recommendation to other healthcare facilities

6. Households	1. To assess the awareness of the public of Rwanda FDA as a
	national institution
	2. To understand what communication channel works well in
	disseminating Rwanda FDA work
	3. To rate the services provided by Rwanda FDA
	4. To assess the public knowledge on counterfeit products
	5. To assess whether the public knows what benefits Rwanda
	FDA can provide them.

-	Pharmaceutical	Food and beverages	cosmetics and household
	products	products	chemicals
Wholesalers	<ol> <li>Pharmaceutical wholesaler</li> <li>Veterinary medicines wholesaler</li> </ol>	1. Food wholesalers	<ol> <li>Household chemical wholesaler</li> <li>cosmetics</li> </ol>
Manufacturer	<ol> <li>Pharmaceutical manufacturer</li> <li>Manufacturer of foam mattress</li> </ol>	<ol> <li>Food Packaging</li> <li>Food/Beverage Manufacturer</li> <li>Food Laboratories</li> <li>Private sector federation</li> </ol>	<ol> <li>Household chemical manufacturer</li> <li>Cosmetics &amp;Households Cleaning Products Manufacturer</li> <li>small compounding facilities</li> </ol>
Retailer	<ol> <li>Retail Pharmacies</li> <li>Orthopedic shops</li> <li>Veterinary medicines retailer</li> <li>Optical shop</li> <li>Medical Consumables</li> <li>Hospital Pharmacy</li> <li>Online pharmacies</li> </ol>	1. Food retailers	1. Medicated cosmetics company

Annex 2: Categories of customers assessed

# Annex 3: Response rate and additional variables

Category of the		Expected	Response	
company	Responses	Response	rate in %	Additional Variables
Pharmacy processing				Pharmaceutical Manufacturer; PSF
plant	9	6	150%	(private sector federation)
Small compounding				Household chemical manufacturers/
facilities				household cleaning product
lacinties	6	2	300%	manufacturer
Pharmaceutical				
wholesaler	26	25	104%	
Retail Pharmacies	95	95	100%	Hospitals
Food/Beverage				Food laboratory& food
Manufacturer				Packaging&Private sector
Wanufacturei	126	117	108%	federation
Food outlet	53	53	100%	Food retailer & food wholesaler
Veterinary medicines				
wholesaler	8	8	100%	
Veterinary retail				
pharmacy	17	15	113%	
				Cosmetics, household chemical
Cosmetics company				wholesaler; soap cosmetics,
	12	10	120%	packaged drinks exporter importers
Orthopedic shops	3	2	150%	Manufacturer of foam mattress
Optical shop	2	2	100%	
Online pharmacies	4	3	133%	
Rwanda FDA suppliers	15	16	94%	
Development partners	6	7	86%	
Members of the public	433	385	112%	
SDPs	39	36	108%	
Rwanda FDA staff	163	190	86%	
Others (consumables)	1	1	100%	

# Annex 4. Activity Timeline

#	Activity phases	Timeline
1	Draft Concept note, Methodology drafting, Desk review	June 2022
2	Feedback on materials (Data collection tools: questionnaire and question guide, sample size)	End of June 2022
3	Design of data collection tools& data collection process	July 2022
4	Review of data collection tools and processes	End of July 2022
5	Training/orientation of data collectors/team building	Begging of August 2022
7	Data collection field visits (logistics: Routing/cars/hotels)	15 <sup>th</sup> -26 <sup>th</sup> of August 2022
8	Data review and validation	15 <sup>th</sup> -26 <sup>th</sup> of August 2022
9	Data analysis and report writing	28 <sup>th</sup> of Aug- 2 <sup>nd</sup> of September 2022
10	Stakeholder workshop/meeting to validate survey findings	September
12	Dissemination of findings	End of September

# Annex 5. List of visited SDPs

Province				Health Facility	
Name	<b>District Name</b>	Sector	Cell	Name	Health Facility Type
	KAYONZA	Gahini	Urugarama	Gahini DH	District Hospital
	KAYONZA	Gahini	Urugarama	Gahini CS	Health Center
	KAYONZA	Kabare	Cyarubare	Mukarange CS	Health Center
	NGOMA	Kibungo	Karenge	Kibungo RH	Referral Hospital
	NGOMA	Kibungo	Cyasemakamba	Kibungo CS	Health Center
	NGOMA	Mutenderi	Mutenderi	Mutenderi CS	Health Center
	RWAMAGANA	Kigabiro	Nyagasenyi	Rwamagana PH	Provincial Hospital
	RWAMAGANA	Kigabiro	Nyagasenyi	Kigabiro CS	Health Center
	RWAMAGANA	Gishali	Bwinsanga	Gishali CS	health Center
	RWAMAGANA	Gishali	Ruhunda	Ruhunda CS	Health Center
East	KIREHE	Kirehe	Gahama	Kirehe DH	District Hospital
	KIREHE	Gahara	Nyagasenyi	Gahara CS	Health Center
	KIREHE	Kirehe	Gahama	Kirehe CS	Health Center
	KIREHE	Kigina	Rwanteru	Kigina CS	Health Center
	NYAGATARE	Nyagatare	Nyagatare	Nyagatare DH	District Hospital
	NYAGATARE	Gatunda	Nyarurema	Gatunda DH	District Hospital
	NYAGATARE	Nyagatare	Nyagatare	Nyagatare CS	Health Center
	NYAGATARE	Gatunda	Nyarurema	Gatunda CS	Health Center
	Gatsibo	Ngarama	Ngarama	Ngarama DH	District Hospital
	Gatsibo	Ngarama	Ngarama	Ngarama CS	Health Center
	Gatsibo	Nyagihanga	Murambi	Nyagihanga CS	Health Center
	MUSANZE	CYUVE	Bukinanyana	KARWASA CS	Health Center
	MUSANZE	MUHOZA	Kigombe	MUHOZA CS	Health Center
	MUSANZE	MUHOZA	Kigombe	RUHENGERI RH	Referral Hospital
North	BURERA	Butaro	Rusumo	Butaro DH	District Hospital
	BURERA	Butaro	Rusumo	Rusumo HC	Health Center
	HUYE	Ngoma	Butare	Kabutare DH	District Hospital
	HUYE	Ngoma	Matyazo	Matyazo CS	Health Center
~ 1	HUYE	Tumba	Rango B	Rango CS	Health Center
South	NYAMAGABE	Gasaka	Kigeme	Kigeme DH	District Hospital
	NYAMAGABE	Gasaka	Ngiryi	Gasaka CS	Health Center
	NYAMAGABE	Cyanika	Nyanza	Cyanika CS	Health Center
	RUBAVU	Gisenyi	Nengo	Gisenyi CS	Health Center
	RUBAVU	Gisenyi	Nengo	Gisenyi DH	District Hospital
	RUBAVU	Mataba	Nyundo	Nyundo CS	Health Center
West	RUBAVU	Rubavu	Murara	Murara CS	Health Center
	RUSIZI	Gihundwe	Gihundwe	Gihundwe DH	District Hospital
	RUSIZI	Nkombo	Bigoga	Nkombo CS	Health Center
	RUSIZI	Bweyeye	Kiyabo	Bweyeye CS	Health Center