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RWANDA FDA
Rwanda Food and Drugs Authority

ANNUAL REPORT

2019/2020

August 2020

RWANDA FDA PERFORMANCE HIGHLIGHTS

Issued 10,473 import licences/permits and 102 export licenses for different regulated products including medicines, food products and other regulated products.

1,524 applications for regulated products including food, cosmetics, drugs and health technologies were received.

1,586 establishments were inspected for premise licensing, Good manufacturing practice, Post marketing surveillance, Good distribution practice, Good clinical practice for regulated products

908 applications of regulated products were assessed. 17 in cosmetics, 162 in food, 729 in medicine and health technologies

6 clinical trial applications were reviewed and 4 were approved within the predefined timeline.

184 applications of regulated products were registered. 43 in drugs and health technologies, 140 in food and 1 in cosmetics.

3 clinical trials amendments were reviewed and approved within the predefined timeline

425 samples were tested and reported for evidence based regulatory decision making

16 workshops/meetings with industry and other stakeholders to ensure compliance to Rwanda FDA requirements

35 pharmaceutical and 9 food products were recalled from the market due to poor quality issues.

850 adverse drug reaction (ADR) reports received and reviewed, 8 ADR reports were submitted to WHO and 12 New Medicine safety communication were issued

19 guidelines and 7 regulations were developed to help in the enforcement of Rwanda FDA mandate

JOINT FOREWORD FROM CHAIRMAN AND DIRECTOR GENERAL

The operations of Rwanda FDA are continuously evolving as we embark on our journey to become a world-class regulatory Authority effectively protecting and promoting the public health of all Rwandans. As a new entity, Rwanda FDA aims to be a transparent and effective regulator, sensitive to the context in which it operates whilst being independent of public, commercial and political pressures. Rwanda economy continues to develop, we are responding to the rapid pace of innovation, the tighter integration of global supply chains, and the increasing demands of our citizens for safe and healthy products. The general public has become increasingly aware of the importance of a regulatory Authority and has collaborated with the Authority through reporting of suspected or substandard products found on the market.

This is indeed a huge step in promoting public health. Our stakeholders have also adapted to the requirements of the Authority as witnessed by the number of manufacturers registering their products, applying for inspection of their premises among others.

We also attribute part of our success to our partners that have contributed to the implementation of our strategies to strengthen management systems and processes for access to safe, quality, and efficacy of regulated products on a timely basis through appropriate regulations. Their continued support and cooperation have fostered institutional development and achieving of the Rwanda FDA's strategies, targets, and milestones so far.

In order to triumph, Rwanda FDA has adopted strategies towards achieving of our mandate. Several technical documents that guide the implementation of Rwanda FDA operations have been developed as one of the ways to exercise the mandate. This report summarizes the 2019-2020 achievements of the Authority. Rwanda FDA has not only made positive achievements for our external stakeholders but also our staff through capacity building because this strengthens and motivates employees to perform effectively at their roles.

Rwanda FDA has a key role to play in achieving universal health coverage and in the planning for National Health Insurance by ensuring equitable access to safe, effective and quality medicines and health products is an essential pillar to a revamped and reinvigorated health system.

The authority has employed 132 staff and in its final stage of recruiting additional 23 new staff at all levels and in all departments of the organisation. Product registration, pharmacovigilance and clinical trial control are receiving renewed attention, while new portfolios including Radiation Control and medical devices are receiving priority attention to address identified shortcomings. Radiation Control, a service that is essential both for public health and for heath security, will see major changes and improvements in the coming year aimed at streamlining its mandate and addressing backlogs. Registration of medical devices will continue to be aligned with global best practices and its staff contingent will be bolstered to implement new strategies. The new vision for pharmacovigilance, which is key to ensuring the safety of all health

products, includes proactive multistakeholder communication. A new communication strategy is being introduced that places at its core the wellbeing of individuals and communities. The next year will see redesigning of the website, and the use of all forms of media to proactively and interactively communicate with the public, professionals and industry.

The critical priority for Rwanda FDA since its establishment in February 2018 has been the clearance of the medical products backlog for registration. Using the current strategies, it would take 1 years to clear the backlog, it is impossible to achieve Rwanda FDA vision of establishing a world class regulatory authority while this burden of the backlog continues to weigh us down. To address this immense challenge, Rwanda FDA trained pool of assessors (40) with the support of WHO and experts from EAC regulatory Authorities and these assessors seats every quarter to work on over 100 dossiers.

Rwanda FDA would like to thank all members of industry who patiently supported this process and for their willingness to embrace the many changes that have taken place. We have put a roadmap in place to clear the backlog using totally re-engineered approaches for medicines registration. This includes digitalisation, reliance procedures that allow FDA to exchange information

with recognised regional and international regulatory authorities, and standardisation of evaluation processes allowing applicants and regulators alike to know what's excepted of them and how long it should take. This means that these new processes will increase access to affordable medicines and to medicines of public health importance, while simultaneously supporting the growth of a thriving local pharmaceutical industry.

Our aim in the next year is to strengthen the executive and senior management team and their supporting departments, and to continue on the steady path already started. The current progress has required many inputs including political support and vision, an effective Board that understands good governance, and extraordinary staff with skill, commitment and dedication. I would like to sincerely thank the Ministers of Health for the support they have offered Rwanda FDA during this journey.

My immense appreciation goes to the Board members who have gone way beyond the call of duty to ensure that FDA has proper oversight as it pursues its mission, and finally, my enormous gratitude goes to the FDA Executive, Management and staff members for their outstanding resilience and dedication throughout the year. This determination has sustained the collective vision that Rwanda FDA is destined to become a world-class regulatory authority

Ag. Director General

Chairman Rwanda FDA

EXECUTIVE SUMMARY

Rwanda Food and Drugs Authority is established by the law Nº 003/2018 of 09/02/2018 determining its mission, organization and functioning to assure the safety, quality and efficacy of human and veterinary medicines, food, biological products, cosmetics, medical devices, household chemical substances and clinical trials, and the control and use of tobacco products, through the enforcement of relevant national and international standards to protect public health. This report gives account of Rwanda Food and Drugs Authority performance in the execution of its core mandate for the period July 2019 – June 2020.

Product Registration

Rwanda FDA received a total of one thousand five hundred and twenty four (1,524) dossiers for food, cosmetics, drugs and health technologies. Seven hundred and seventy two (772) for drugs and health technologies. Twenty one (21) for cosmetics and three hundred seventy three (373) for processed food requesting for marketing Authorization.

Forty three (43) products from drugs and health tech nologies were approved and registered. Seven hundred and twenty nine (729) applications were fully assessed (first and second assessment) with feed back to the applicants for additional data. Twenty (20) cosmetics applications were screened and assessed and query responses sent to applicants.

In Food applications, the Authority has assessed three hundred and two (302) Applications, where two hundred and thirty three (233) were screened and feedback sent to applicants for Additional data and one hundred and forty (140) processed food were assessed and approved and registered
Premise licensing

Rwanda FDA has inspected 636 Food manufacturing facilities, 50 food establishment facilities for food safety, 450 premises for Human pharmaceutical prod ucts, 344 premises of veterinary medicines, and recall audit was conducted in 48 premises.

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Import and export control

The Authority issued ten thousand four hundred and seventy three(10,473) import licenses, one hundred and two (102) export licenses and six hundred nine hundred and twenty seven (6,927) VISA for different regulated products including medicines, food products and other regulated products.

Clinical trial

Received a total of six (6) new clinical trial applications, three (3) amendment and four (4) Ad-Doc applications for consideration; six (6) fresh and three (3) amendment applications were approved. Twelve (12) Suspected Unexpected serious adverse events (SUSARs) reports were received and analyzed. Two (2) GCP inspections were conducted over the period under review.

Adverse Drug Reaction

Rwanda FDA received eight hundred and fifty (850) adverse drug reaction (ADR) reports and seven hundred and twenty (720) ADR reports were reviewed and (8) ADR reports were submitted to WHO

Post market surveillance

A total of fifty four (54) market surveillance operations were carried out across the country.
Rwanda FDA has sampled and tested Ninety Eight (98) products for Post Marketing Surveillance and recalled Thirty Five (35) Pharmaceutical Products and Nine (9) Food Products from the Market recall audit was conducted in forty eight (48) premises.

Product testing

The laboratory received and tested four hundred and twenty five (425) samples of in different categories that include medicines, hand sanitizers, rice, alcoholic drinks and maize flour and other food samples.

Finance

The FDA through its Fees, Charges and Administrative Fines collected a total of two Billion two hundred twenty-three million four hundred thirty three thousand six hundred sixty nine Rwandan Francs (2,223,433,669 RWF); an increase of approximately 56% compared to 2018/2019 and, one million four hundred and two thousand and forty three United State Dollar (1,402,043.17 USD); an increase of approximately 71.5% compared to 2018/2019.

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ACRONYMS

ADR	Adverse Drug Reaction
ADE	Adverse Drug Events
AEFI	Adverse Event Following Immunisation
AMQF	African Medicines Quality Forum
APIs	Active Pharmaceutical Ingredients
BoDs	Board of Directors
CIP	Coalition of Interested Partners
CROs	Contracted Research Organisations
DP	District Pharmacies
DTC	Drugs and Therapeutics Committee
DG	Director General
EAC	East African Community
EDPRS	Economic Development and Poverty Reduction Strategy
FDAR	Food and Drugs Assessment and Registration
FDISM	Food and Drugs Inspection and Safety Monitoring
FPPs	Finished Pharmaceutical Products
GMP	Good Manufacturing Practice
GDP	Good Distribution Practices
GDP	Growth Domestic Product
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GOR	Government of Rwanda
GPCL	Good practices for pharmaceutical quality control laboratories
HC	Health Centres
HPLCs	High Performance Liquid Chromatography
ICT	Information Communication Technology
IEC	International Electrotechnical Commission
IDP	Institutional Development Plan
ILC	Inter Laboratory Comparisons
ISO	International Standards Organisation
PIATI	Professionalism, Integrity, Accountability, Teamwork and Innovation
PRIMS	Pharmaceutical Regulatory Information Management System
QC	Quality Control
QMS	Quality Management System
PV	Pharmacovigilance
RDB	Rwanda Development Board
Rwanda FDA	Rwanda Food and Drug Authority
SOPs	Standard Operating Procedures
STM	Standards Test Methods
UR	University of Rwanda
WHO	World health Organization
WHO-CRP	World Health Organization Collaborative Registration Procedure

1.0 BACKGROUND INFORMATION

Rwanda Food and Drugs Authority hereafter designated as the "Authority", was established by the law Nº 003/2018 of 09/02/2018 determining its mission, organization and functioning.

The mandate of the Authority is to protect public health through regulation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products.

The documents of the Vision 2020 and the Economic Development and Poverty Reduction Strategy [EDPRS II] 2013-2018 set the target to achieve income status by 2020 with an annual growth rate of 11.5% and the GDP per capita of USD 1,200 by 2020. In line with its policy of economic development and good governance, the Government of Rwanda (GoR) has established the Rwanda Food and Drugs Authority so that it contributes to the achievement of its socio-economic goals.

Rwanda FDA is a regulatory entity that regulates Human and Veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco & tobacco products and conduct of clinical trials.

The Authority reports to the Board of Directors (BoDs) and it coordinates with line ministry responsible for Health. In addition to the law creating Rwanda FDA, there is a number of other legal and regulatory instruments which help Rwanda FDA to discharge its responsibilities in each specific sector to be regulated. The Board of Directors of Rwanda FDA is the supreme management and decision making organ. It has full powers to make decisions regarding administration, human resources and property of Rwanda FDA in order to fulfil its mission.

Rwanda FDA has comprehensive law approved and gazetted in the official gazette of the Republic of Rwanda and that is being implemented thereby presenting a clear opportunity to build a system properly from the base up, most legal provisions, regulations, guidelines, SOPs, and forms for regulatory oversight have been developed and approved
The authority has the vision to become a world class regulatory Authority effectively protecting and promoting public health. Rwanda FDA is committed to providing the highest standard of regulatory services to all customers by implementation of a quality management system that will continue to improve the processes, systems and procedures; and meeting customer requirements underlie all efforts in ensuring quality, safety, efficacy, and wholesomeness of all regulated products used in Rwanda that will be achieved through assessment and registration; inspection and licensing; control of imports and exports; pharmacovigilance; post-marketing surveillance; clinical and field trials; control of publications and advertisements; laboratory testing; and enforcement.

The authority has the vision to become a world class regulatory Authority effectively protecting and promoting public health. Rwanda FDA is committed

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

Rwanda FDA has core responsibility to ensure Safety, Efficacy and Quality of drugs, Food, Cosmetics and regulate the products from tobacco and household chemicals in an effective and efficient manner. Therefore, the Authority intends to focus on building confidence in the population pertaining; the regulatory framework that will increase the investment opportunities and improve the regulatory and health outcomes whilst meeting the stakeholders' expectations.

It is indeed a key responsibility of the Authority to serve the people of Rwanda, harness the stakeholders' expectations through enhancing the service coverage, communication and publication of the regulatory framework, applying the regulatory decisions in a fair, transparent and accountable manner, timely responding to the customer needs. Constructive collaborations and partnerships with the National, Regional, International agencies and institutions that contribute to core responsibilities of Rwanda FDA.

The Authority will continuously invest in research and development and provide a platform for innovative solutions that will foster continued process re-engineering for service delivery excellence. Continue to invest in training its work force, offer appropriate staff welfare and provide the right psychological infrastructure to enable the effective regulation in service delivery.

The Authority will strive to achieve the highest standards of corporate governance and put in place the right infrastructure, this strategy should be well documented in the Rwanda FDA strategic plan supported with clear a robust monitoring and evaluation program.

2.0 STRATEGIC OVERVIEW

2.1 Vision of Rwanda FDA

Rwanda FDA Mission is to become a world class regulatory Authority effectively protecting and promoting public health

2.2 Mission of Rwanda FDA

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

2.3 Core values

The conduct and performance of the Authority is underpinned by the following five core values (abbreviated as PIATI):

1. Serving with professionalism for excellent service delivery
2. continuously working with integrity
3. Promoting accountability at all times
4. Nurturing teamwork to achieve common objectives
5. Striving for innovation to create value for our stakeholder and other interested parties.

Table 1: values and principles governing Rwanda FDA

No	Value	Description
1	**Professionalism**	Valuing good work ethics and striving towards service excellence and sociability. This represents being committed to working with stakeholders and building good relationships with them by understanding their needs, responding quickly to their needs and providing appropriate solutions that are underpinned by the core mission and values of the Authority.
2	**Integrity**	Commitment to moral conduct by promoting and protecting the health of all Rwandans and of its animals through relevant, scientifically sound and ethical regulatory practices.
3	**Accountability**	Ensuring efficiency in the best use of public resources. Creating a work environment underpinned by a culture of fairness, impartiality, independence, accountability and transparency.
4	**Teamwork**	Achieving collaboration through pooling of resources, work-sharing and effective communication, as teamwork and cohesion are key. Fostering professionalism, trust and honesty in interactions with colleagues and stakeholders.
5	**Innovation**	Promoting the sharing of ideas and supporting innovation, research and development in the public's interest. Identifying needs and challenges present in society. Creating an enabling environment for sound, ethical research and backing new ideas by bringing them to the market. Pursuing cost-effective solutions in operations, research and training. Monitoring and evaluating the impact of interventions on the challenges faced. Applying new ways of doing things at all levels of the Authority.

2.4 Quality Policy Statement

The Authority is committed to providing the highest standard of regulatory service to all customers by implementation of a quality management system that complies with ISO 9001:2015.
Timely and reliable service, compliance to all applicable statutory and regulatory requirements, continual improvement of the processes, systems and procedures; and meeting customer requirements underlie all our efforts in ensuring quality, safety, efficacy, and wholesomeness of all regulated products used in Rwanda. This is achieved through assessment and registration; inspection and licensing; control of imports and exports; pharmacovigilance; post-marketing surveillance; clinical and field trials; control of publications and advertisements; laboratory testing; and enforcement.

3. 0 INSTITUTIONAL OVERVIEW

Rwanda FDA is managed by the Director General who reports to the Board of Directors, the supervising authority of Rwanda FDA is the Ministry of Health. The management organs of Rwanda FDA are Board of Directors and Executive organ, The Board of Directors of Rwanda FDA is the supreme management and decision making organ, it has full powers to make and oversee the functioning of the Executive Organ and provides strategic guidance to be followed in the fulfilment of its mission.

3.1 RWANDA FDA BOARD OF DIRECTORS

Rwanda FDA board of Directors is composed of seven (7) members of which includes chairman, vice chairperson and other five (5) members. The table below shows the names and positions of Board of Directors:

Table 2 Rwanda FDA Board of Directors

Number	Name of the board member	Position
1	***Dr. Karita Etienne***	***Chairman***
2	***Dr. Mukantwali Christine***	***Vice Chairperson***
3	***Prof. Eleni Aklillu***	***Member***
4	***Prof. Chabner Bruce***	***Member***
5	***Dr. Kayihura Didas***	***Member***
6	***Dr. Ruhara Murindabigwi Charles***	***Member***
7	***Ms. Umurungi Providence***	***Member***

The Executive Organ of Rwanda FDA is composed of the Director General appointed by a Presidential Order and other staff members recruited in accordance with relevant laws. A Presidential Order may also appoint Deputy Director General and determine his/her powers and duties.

The Executive Organ of Rwanda FDA has the responsibilities to monitor and coordinate daily duties and activities; to perform any other duty as may be assigned by the Board of Directors falling within the mission of Rwanda FDA.

The Director General of Rwanda FDA has the power of decision in the administrative and financial management of Rwanda FDA in accordance with relevant laws. He coordinates and directs the activities of Rwanda FDA. The senior management team of Rwanda FDA is made of Director General, Head of Departments and Division managers

3.2 RWANDA FDA SENIOR MANAGEMENT TEAM

The authority's executive team is detailed in the following table 3:

Table 3 Rwanda FDA senior management team

Number	Executive Member	Position	Area
1	*Dr. KARANGWA Charles*	***Ag. Director general***	***Rwanda FDA***
2	*GISAGARA Alex*	***Head of Department***	***Food and Drugs Inspection and Safety Monitoring***
3	*KABATENDE Joseph*	***Head of Department***	***Food and Drugs Assessment and Registration***
4	*BERWA Francoise*	***Chief Finance Officer***	***Finance office***
5	*MUKUNZI Antoine*	***Division Manager***	***Quality Control Laboratory***
6	*IRASABWA Clarisse*	***Division Manager***	***Health Technologies Assessment and Registration***
7	*MUSANGWA Desire*	***Division Manager***	***Food Assessment and Registration***
8	*MUNYANGAJU Jose Edouard*	***Division Manager***	***Drugs, Food Inspections and Compliance***
9	*NTIRENGANYA Lazare*	***Division Manager***	***Pharmacovigilance and Food Safety Monitoring***

Rwanda FDA functions are executed through three departments namely Food & Drugs Assessment and Registration department, Food and Drugs Inspection and Safety Monitoring Department and Office of the Chief Finance.

The three departments are supported by five divisions namely Drug & Health Technologies Assessment and Registration, Food Assessment and Registration, Pharmacovigilance & Food Safety Monitoring, Drug and Food Inspection & Compliance and Quality Control Laboratory, Rwanda FDA staff is also made by Directors of units, Specialists, Officers and Technicians.

The Department of Food and Drugs Inspection and Safety Monitoring (FDISM) is one of the technical departments that make Rwanda FDA. It ensures that all food and medicines manufactured locally and imported into the country are of good quality and are properly handled. It also ensures that food and drugs are inspected at all major ports of entry to stop the entry of substandard and counterfeit drugs into Rwanda.

The Department of Food and Drugs Assessment and Registration (FDAR) is one of the technical departments and contributes to the overall mission of the Authority by conducting Assessment and evaluations of application dossiers for processed foods/ drinks, food additives, food supplements, both human and veterinary medicines, vaccines and other biologics, medicated cosmetics, medical devices, chemicals and pesticides and tobacco and tobacco products.

The Division of Food Assessment and Registration offers the service of assessing and registering processed food/ drinks, food supplements, food additives and tobacco products. The process takes between 1 and half to 2 months. It is also worth noting that after a product is registered, there is an annual retention, while registration renewal is made after 5 years.

The Division of Drugs and Health Technologies Assessment and Registration offers the service of assessing and registering human and veterinary medicines, human and veterinary biologicals and vaccines, human and veterinary medical devices, herbal medicines, medicated cosmetics and laboratory and cleaning chemicals. When all required documents and samples have been submitted, it takes between 6-9 months to get registration.

The division of Drug and Food Inspection & Compliance conducts inspections for facilities requesting for registration and licenses of premises dealing with regulated products including but not limited to Food manufacturing facilities, pharmaceutical manufacturing facilities, premises for human pharmaceutical products, premises for veterinary medicines, optical shops, orthopaedic shops, chemical shops, and medicated cosmetics shops.

It also conducts Good Manufacturing Practice (GMP) inspections, Good Distribution Practices (GDP) inspections, Good Clinical Practices (GCP) inspections in various establishments/manufacturing facilities dealing with regulated products

The Law No 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority, especially in its article 8, paragraph 9, the Authority is mandated to conduct pharmacovigilance and post marketing surveillance for safety and quality of regulated products among other regulatory functions.

Rwanda FDA's Pharmacovigilance and safety monitoring system is established to detect, assess, understand and prevent adverse events or any other possible medicine-related problems. Rwanda FDA has developed guidelines on safety and vigilance of medical products and health technologies, which includes ADE/AEFI reporting form, Suspected poor quality reporting form, medical device reporting form, Patient reporting form among others.

The Quality Control Division is established under the article 8 of the law establishing the Rwanda FDA that mandates the Authority to establish the quality assurance and quality control of regulated products. The Authority is also mandated to analyse different categories food and food products, medicines, medical devices and Public health products, and samples are obtained from pre market, post shipment and Post Market Surveillance.

The purpose of the testing is also to ensure that the assessment, registration and inspection are conducted based on scientific data; the laboratory data also support the pharmacovigilance and clinical trial processes. The generated quality control results are also important in ensuring that the Authority makes evidence-based regulatory decisions during marketing authorization and enforcement of other requirements of the Rwanda Food and Drugs Authority Law.

FUNCTIONS OF RWANDA FDA

Functions of Rwanda FDA are reflected by the respective technical department, divisions and units within the organization. the daily activities of all operations of Rwanda FDA find their place within the following functions.

1 Regulate pharmaceutical products, vaccines, human and veterinary processed foods and other biological products used in clinical as drugs food supplements, food fortificants, fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products, management of unfit pharmaceutical and food products and clinical trials on pharmaceutical products for human and veterinary use

2 Regulate compliance with quality standards relating to the manufacture, storage, sale, distribution, use, import and export, labels, packages and raw materials used in the manufacture of products regulated.

3 Regulate laboratory and cleaning chemicals and pesticides as well as premises involved in the manufacture of products regulated

4 Establish, approve and publish the list of human and veterinary food and pharmaceutical products as well as other products regulated for which marketing authorization has been granted;

5 Establish and publish the list of prohibited cosmetics;

6 Regulate and inspect clinical trials

7 Ensure that processed food, food supplements and fortified food meet the prescribed quality standards before they are placed on the market;

8 Conduct pharmacovigilance and post marketing surveillance for safety and quality of products regulated

9 Follow up and analyse information on the use of pharmaceutical products that are subject to global drugs safety monitoring;

10 Regulate and analyse information used in the promotion, advertising and marketing of products

11 Regulate the use of unregistered products regulated for clinical trial purposes or compassionate use

12 Disseminate information on quality and safety of products regulated to health professionals and other concerned persons;

13 Conduct research and studies on food and pharmaceutical products and publish the findings in order to promote investment;

14 Build cooperation and partnership for harmonization of practices with regional and international bodies with similar missions;

15 To advise the Government on matters regarding the products regulated

16 To advise the Government on matters regarding the products regulated

4.1 2019-2020
INSTITUTIONAL GOALS

4.1.1 Food and Drugs Inspection and Safety Monitoring (FDISM)

The Department of Food and Drugs Inspection and Safety Monitoring (FDISM) is one of the technical department that makes Rwanda FDA. The department ensures that all food and medicines manufactured locally and imported into the country are of good quality and are properly handled.

It also ensures that food and drugs are inspected at all major ports of entry to stop the entry of substandard and counterfeit drugs into Rwanda. It also does the inspection and licensing of all foods and drugs handling facilities, monitoring of illegal operators of foods and drugs outlet, substandard and counterfeit regulated products through regular supervision and post marketing surveillance. It ensures stakeholders; service providers and the general public receive the right information on the regulated products.

It ensures that the food and drug promotion materials are vetted, approved and monitored to ensure that misleading, biased and inaccurate information on regulated products is not disseminated. It is also responsible for pharmacovigilance programs adverse drug reactions reporting and hosting the national pharmacovigilance centre.

The department of Food and Drugs Inspection and Safety Monitoring has the following objectives in meeting Rwanda FDA's Mission to become a world class regulatory Authority effectively shielding and promoting public health.

•Prepare and conduct Stakeholders consultation meetings on current procedures

•Conduct inspection of facilities and food products

•inspection of imports and exports at ports of entry

•Conduct Inspections facilities and other premises dealing with regulated medical products

•Conduct GMP inspection of local and foreign pharmaceutical facilities(FPPs/CROs/APIs/Biologicals/Herbals,)

•Conduct good distribution practice (GDP) among public pharmacies in Hospitals, DPs & HC

•Conduct good clinical trial practices (GCP) inspection

•Capacity building of GMP, GCP, GLP and GDP Inspectors

•Conduct desk review of facilities located in countries with stringent (listed) regulatory authorities

•Destruction of impounded drugs

•Conduct price surveys to inform price and mark ups

•Develop and integrate the pharmacovigilance module into PRIMS

•Capacity building on the use of the PV module

•Capacity building on pharmacovigilance for DTC in health facilities (public and private)

•Conduct assessment on rational drug use

•Dissemination and communication of information on safety, efficacy and quality of regulated products

•Initiate the revision of essential medicine lists (child and adult)

•Conduct active monitoring of drugs safety

•Conduct supervision and mentoring to improve the PV reporting system on ADRs, Safety and vigilance of vaccines (AEFIs) from public and private facilities

•Conduct Food safety monitoring inspections

•Conduct audit recall

•Conduct Post marketing surveillance for products

•Establish systems for clinical trial oversight and evaluation through development of their management database

•Regulate clinical and field trial approvals to maximise safety of the regulated products by conducting Clinical

•Trial Site inspections

•Capacity building on clinical trials

4.1.2 Food and Drugs Assessment and Registration (FDAR)

The Department of Food and Drugs Assessment and Registration (FDAR) is one of the technical departments and contributes to the overall mission of the Authority by conducting Assessment and evaluations of application dossiers for processed foods/ drinks, food additives, food supplements, both human and veterinary medicines, vaccines and other biologics, medicated cosmetics, medical devices, chemicals and pesticides and tobacco and tobacco products.

The department through its technical divisions offers the services of assessing and registering processed food/ drinks, food supplements, food additives and tobacco products. When all required documents and samples have been submitted, it takes between 1 and half to 2 months to get registration.

It also offers services of assessing and registering human and veterinary medicines, human and veterinary biologicals and vaccines, human and veterinary medical devices, herbal medicines, medicated cosmetics and laboratory and cleaning chemicals and pesticides. When all required documents and samples have been submitted, it takes between 6-9 months to get registration.

The department to carry out its responsibility the following plan of activities are set in an effort to register products for market authorization and protect public health. The fiscal year objectives include the following:

- Capacity building of assessors in dossier assessment and evaluation for market authorisation
- Stakeholders consultation & Dissemination workshops for technical regulation for regulatory compliance
- Dossier assessment of regulated products
- Participate in the EAC joint dossier assessment for medicines registration
- Review of dossiers and validation
- Assessment of herbal and complementary medicines
- Listing of health technologies
- Establishment of Authorized list of Regulated products
- Harnessment of Registered products
- Intercede an electronic web application of regulated products register
- Dossier assessment of food products and food supplements
- Capacity building on processed food, fortified food and food supplements assessment and registration
- Reception of all incoming files at the Department and the responses of the outgoing correspondences
- Development of documents related to food fortification

4.1.3 Quality Control Laboratory (QCL)

Rwanda Food and Drugs Authority is also mandated to analyse different categories of food and food products, medicines, medical devices and Public health products, and samples are obtained from pre market, post shipment and Post Market Surveillance.

Test results generated are important in ensuring products comply with the set standards and enable the Authority to make evidence-based regulatory decisions.

The Quality Control Laboratory Division is established under article 8 of the law establishing Rwanda FDA that mandates the Authority to establish the quality assurance and quality control of regulated products, the Authority through this Division set the following major goals:

•Conducting quality testing of food and drugs samples and provide accurate and precise results

•Carry out laboratory process and activities in accordance with World Health Organization (WHO) Good practices for pharmaceutical quality control laboratories (GPCL) and ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

•Meet the objectives of the Rwanda Food and Drugs Authority

•Ensure customer satisfaction

The purpose of the testing is also to ensure that the assessment, registration and inspection are conducted based on scientific data; the laboratory data also support the pharmacovigilance and clinical trial processes.

The generated quality control results are also important in ensuring that the Authority makes evidence-based regulatory decisions during marketing authorization and enforcement of other requirements of the Rwanda Food and Drugs Authority Law.

5.0 RWANDA FDA ACHIEVEMENTS / PERFORMANCE ASSESSMENT

The Authority through its department of Food and Drugs Inspection and Safety Monitoring registered the following achievements during the 2019/2020 fiscal year operationalization:

5.1 License and visa issued

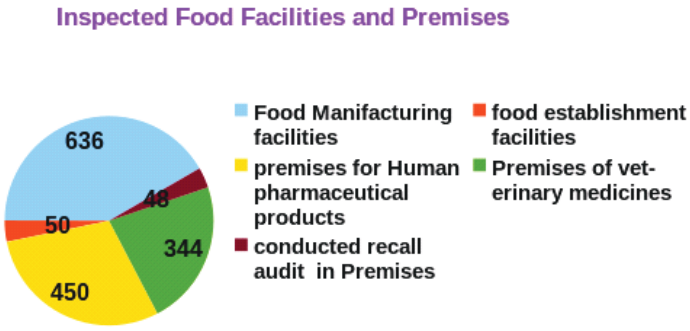
The Authority has issued 10,473 import licenses, 102 export licenses and 6,927 VISA for different regulated products including medicines, food products and other regulated products.

Figure 1 licenses and visa issued

5.2 Inspection

A total of one thousand, five hundred and eighty-six (1586) inspections were conducted. Two (02) pharmaceutical manufacturing facilities were licensed, seven (7) small scale manufacturing plants (small compounding) were licensed, six hundred and thirty-six (636) Food manufacturing facilities were inspected and sixty- two (62) were licensed out of one hundred eighty- one (181) that applied for licensing, fifty (50) food outlets were inspected and one hundred and sixty five (165) food importers were licensed in Pharmaceutical Regulatory Information Management System and four (4) food supplement shops were given authorization, four hundred and fifty (450) premises for Human pharmaceutical pharmacies were inspected and seventy- two (72) (19 wholesale and 53 retail pharmacies) were licensed, three hundred and forty-four (344) premises of veterinary medicines were inspected and ten (10) were licensed, fifty four (54) Good Distribution Practices (GDP) inspections, recall audit was conducted in forty eight (48) premises, and two (2) Good Clinical Practices (GCP) inspection

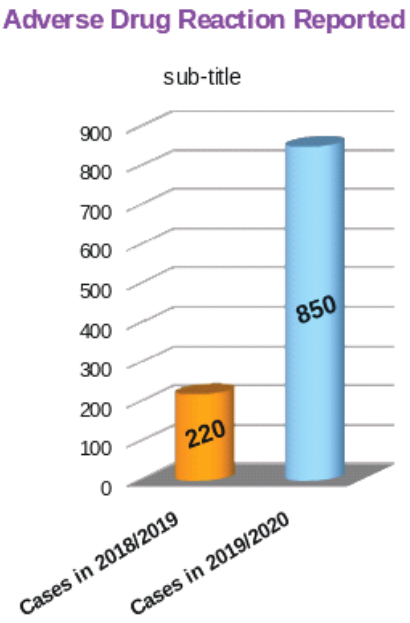
Figure 2 Inspected facilities and premises



5.3 Adverse Drug Reaction Monitoring

The Authority issued 12 medicines safety information, received and analysed 850 Adverse Drug Reactions/Adverse Events Following Immunisation (ADR/AEFI) reports which show an increase of 286% of the last year 2018/2019.

Figure 3 showing adverse drug reaction



5.4 Recalled products

Rwanda FDA has sampled and tested 98 products for Post Marketing Surveillance and recalled 35 pharmaceutical products and 9 food products from the market.

It has also conducted a baseline survey of pharmaceutical services in Rwanda in partnership with other stakeholders. A curriculum for pharmacovigilance was developed and it is being integrated in the University of Rwanda teaching schedules.

5.5 Mapping of Food Sector

Rwanda FDA conducted a food industry mapping exercise to identify their location, products manufactured, capacity and category of manufacturing capabilities. A total of 636 industries were mapped during the exercise and this will help Rwanda FDA to work with other government institutions in making a long-term plan for the industry development and regulation.

Figure 4 Recalled products

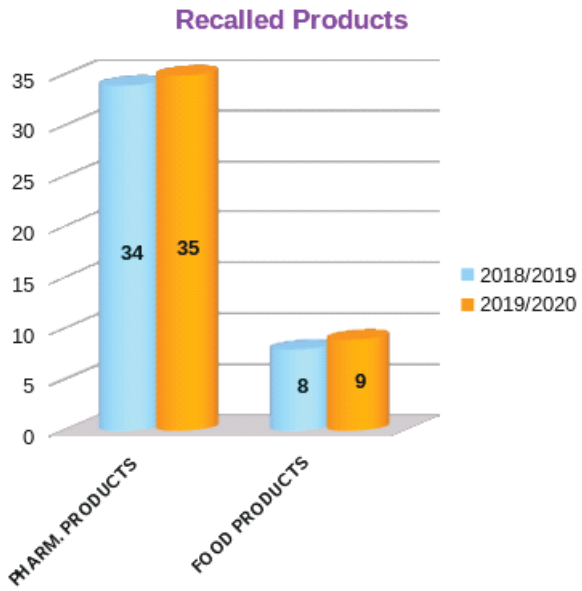


Figure 5 Geographical location of Food industries

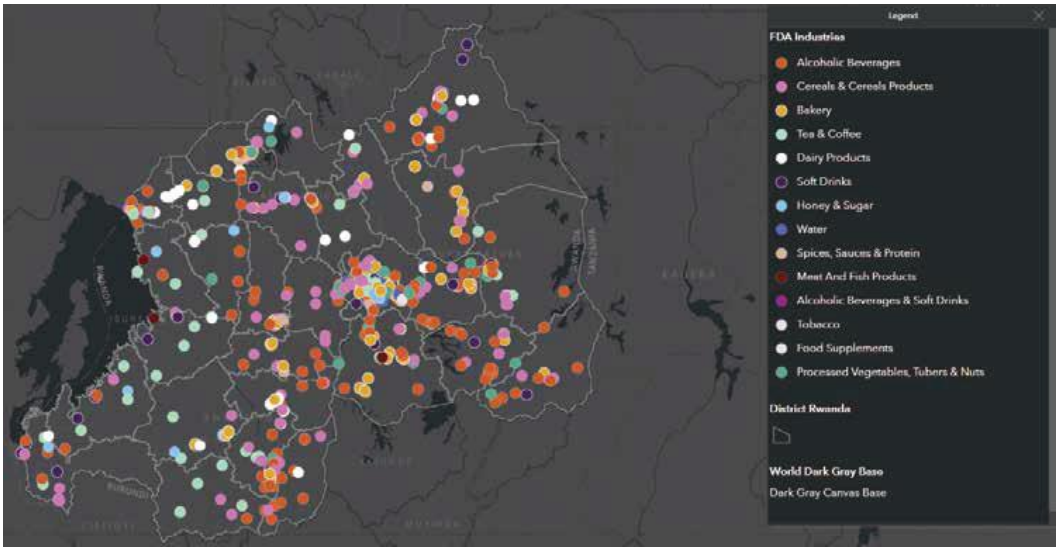
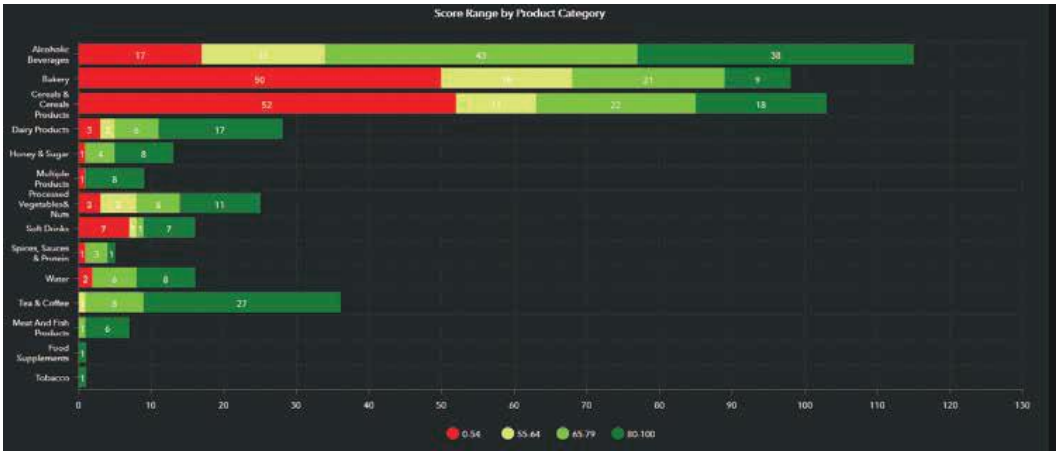


Figure 6 Score range by product company



5.6 Registration and Marketing Authorization

The Law establishing Rwanda Food and Drugs Authority empowers the Authority to carry out its mandate in the area of Registration and Marketing Authorization. Significant progress towards assurance of quality, safety and efficacy of food, drugs and health technologies available for sale on the Rwandan market is made through establishing technical regulations and guidelines.
Assessment process of food, drugs and health technologies requires submission of dossiers application in accordance with the requirements available in the related guidelines. The Authority has actively participated in East African Community joint assessment and World Health Organization Collaborative Registration Procedure.

After receiving the application, there is first and second assessment. When one or more items are missing or the samples tested have failed to meet the standard requirements, a query response is sent to the applicant. When no queries, the product is registered and it is assigned a unique registration number.

Rwanda FDA has registered the following achievements in the area of assessment and registration of regulated products

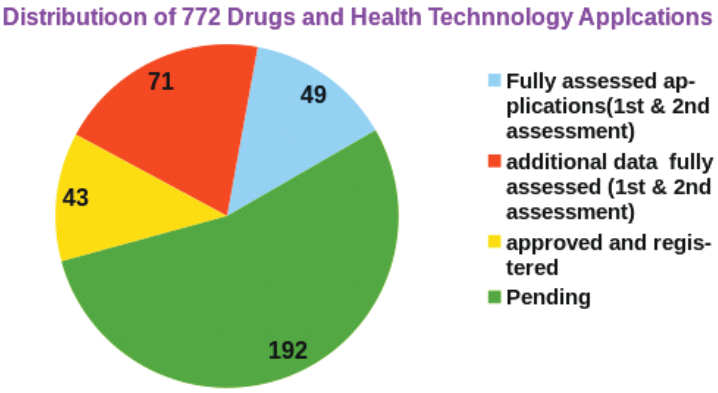
5.6.1 Drugs and Health Technologies

Rwanda FDA received a total of 772 requests for drugs and health technologies marketing authorization. the Authority has screened 417 applications with feedback to the applicants, 49 new applications were fully assessed (first and second assessment), 71 additional data or query responses were fully assessed (first and second assessment) and 43 products were approved and registered while 192 applications are pending approvals

In addition, the Authority has conducted six (6) EAC joint reviews whereby ten (10) applications requesting for medicines marketing authorization have been assessed by Rwanda FDA.

The Authority has also conducted assessment of Ten (10) applications requesting medicines registration through World Health Organization Collaborative Registration Procedure (WHO-CRP).

Figure 7 Status of the applicant's dossiers



5.6.2 Food products

Rwanda FDA received a total of 373 requesting for processed food registration. The Authority has assessed 301 Applications, 234 were requested for Additional data and query responses have been sent while 140 processed foods were assessed and approved and registered

5.7 Quality Control of regulated products

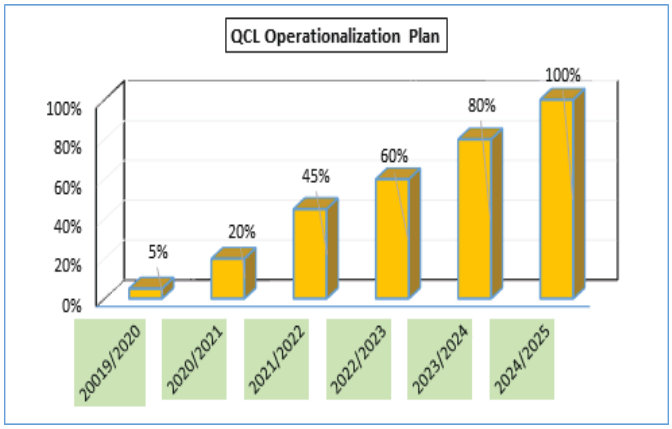
The following achievements were registered in the Quality Control of regulated products

5.7.1 Testing equipment

•The Authority acquired equipment that test milk and milk products, alcoholic drinks and animal feed, two High Performance Liquid Chromatography (HPLCs) was also acquired for quality testing of drugs and medicated cosmetics.

•The Five-year plan for operationalization of Quality Control Laboratory was prepared and approved by Rwanda FDA Board of Director and then submitted to the Ministry of Finance and Economic planning for consideration. It is expected that Quality Control Laboratory will be 100% operationalized in the 2025.

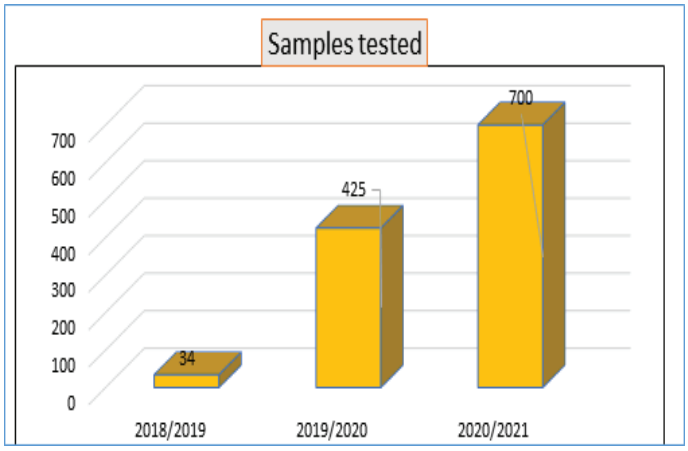
Figure 8 Current status and plan to the full operationalization of Quality Control Laboratory



5.7.2 Test reports

The Authority tested and reported 425 samples of in different categories that includes medicines, hand sanitizers, rice, alcoholic drinks and maize flour and other food samples from pre market, post shipment and Post Market Surveillance, when with the 34 samples that were tested in 2018/2029, we find a big increase in number of samples attributed to the fact Rwanda FDA Quality Control Laboratory was handed over from Rwanda Standards Board in March 2019 with only few equipment that needed important upgrade, it is also planned that in the 2020/2021 the number of samples to be tested reach 700 samples.

Figure 9 compares the samples tested in 2018/2019, samples tested in the current financial year being reported and the plan of samples to be tested in 2020/2021.



Rwanda FDA Registered and successful participated in the 2019 African Medicines Quality Forum (AMQF USP Ghana) inter laboratory comparisons (ILC) for paracetamol (assay and Dissolution) and registered for 2020 AMQF (USP Ghana) inter laboratory comparisons (ILC) for Azithromycin (pH) Amodiaquine tablets (related substances) and Ibuprofen assay

5.8 Office of the Chief Finance

For proper coordination and management of human and financial resources, Administration and Finance Department supported in the development of Rwanda FDA Manuals, regulations and guidelines, strategic plan (draft), action plan, checklist packages.

•The Authority through its Departments coordinated the recruitment of 127 staff and facilitated the acquisition of laboratory equipment; office furniture, computer consumables and ICT related devices and web development among others to make the Authority achieve its mandate.

•The Authority also availed staff to support in the COVID-19 pandemic command centres. The Rwanda FDA products regulatory information management system (PRIMS) is a system used by the Authority to issue its regulatory services online.

•During the FY2019/2020, the Authority has automated the premise registration and licensing, inspection processes and import and export control processes now fully operational. Other modules have been developed and yet to be deployed.

•The Authority has coordinated the development of the One Health Policy and fully participated in the development of the pharmaceutical products pricing containment policy.

•The Authority overall annual performance was at 89.93% and the ordinary budget of 2, 964,992,411 Rwandan francs executed at 88%.

Rwanda FDA Income generation status

Table 4 Revenues collected between two fiscal years

REVENUE COLLECTION		
Fiscal year	2018/2019	2019/2020
FRW	1,426,010,204	2,223,433,669
USD	817,318	1,402,043.17

The Authority's revenue generated for 2019/2020 was Two Billion two hundred twenty three million four hundred thirty three thousand six hundred sixty-nine Rwandan Francs (2,223,433,669 FRW); an increase of approximately 56% compared to 2018/2019 and, One Million four hundred two thousand and forty three United State Dollar (1,402,043.17 USD); an increase of approximately 71.5% compared to 2018/2019. as shown in the table above.

Rwanda FDA Coalition of the interested Partners (CIP) meeting was convened January 2020 to creating a network of supporters for Rwanda FDA to implement the Institutional Development Plan (IDP) and mobilize resources for regulatory system strengthening in Rwanda to achieve WHO maturity level 3.

5.9 DOCUMENTATION

One of the goals of Rwanda FDA is to have a functioning Quality Management System (QMS) in accordance with national and internationally recognized standards.

To deliver on its mandate, the Authority needs to have documentation in place which responds to ISO 9001:20215 QMS requirements and there was a need to demonstrate how all process are carried out in well-structured documented manner

•The Authority has developed, validated and published on website 2 regulations and 4 guidelines for pharmaceutical and Medical devices imports and exports control, export & import control of medicated cosmetics and 3 stakeholder's consultation meetings on current implemented procedures (Premise licensing, import and export control and fees regulations). All these fall in the area of Food and Drugs Inspection and Safety Monitoring practices.

•Four (4) technical regulations, nine (9) guidelines containing forms and formats, three (3) Standard operating procedures were developed and approved to facilitate the assessment and registration of both medicines and health technologies before they are placed on the Rwandan market.

•Five (5) documents have been developed in response of the COVID -19 pandemic to mitigate and guide the implementation of regulatory functions. These includes Guidelines on specifications of coverall protective clothing, guidance on manufacturing and use of barrier masks, guidelines on requirements and specifications of eye protectors and face shields, guidelines on requirements and specification of ventilators and guidelines on preparations of hand sanitizers.

•The Authority has also successfully established authorized lists of Human Medicinal products; Veterinary and Medicated Cosmetics as reference lists for importation and export purposes.

•In addition, one regulation relating to food fortification and the regulation related to regulatory services tariff/ fees and fines have been developed and published on website. These regulatory documents were developed in the area of Food and Drugs Assessment and Registration.

•five (5) guidelines related to processed foods were developed and approved.

•In the area of Quality control laboratory, Quality manual was developed as per World Health Organization (WHO) Good practices for pharmaceutical quality control laboratories (GPCL) and ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories; 5 Standards Operating Procedures (SOPs); 5 Standards test methods (STM) and 5 work Instructions (WI) were developed).

•Five years plan for operationalization of Quality Control Laboratory was also developed, approved by the Board of Directors and submitted to Ministry of Finance and Economic planning for consideration. The division also participated in development of 5 guidelines that will assist in protection and fighting COVID-19 (2 for masks, 1 for Coverall, 1 ventilator and 1 for face shield).

During the Fiscal year 2019-2020, different documents including Regulations, Guidelines, Forms and Checklists have been developed to orient Clients on what are requirements for services rendered by the Authority either stakeholders or Rwanda FDA staff on how services are rendered.

Table 5 Summary of documents developed in the FY20219-2020

Department	Document name	Status
Drug&Food Assessment and Registration	Regulations Governing control of medicated cosmetics	Published
	Regulations Governing Registration of medicinal products	Published
	Regulations Governing Registration of medical devices	Published
	Regulations Governing Service Fees Tariff and Fines	Published
	Regulations Governing Food Fortification	Published
	Guidelines on submission of documentation for registration of medicated cosmetic Products	Published
	Guidelines on submission of documentation for registration of veterinary Products	Published
	Guidelines on submission of documentation for registration of Biosimular biotherapeutic products	Published
	Guidelines on submission of documentation for registration of Antiseptic and Disinfectant products	Published
	Guidelines on submission of documentation for variation of registered medicinal products	Published
	Guidelines on submission of documentation for registration of Human medicinal products	Published
	Guidelines for application and registration of processed food	Published
	Guidelines for Application and registration of Food Supplements	Published
	Guidelines for Good Manufacturing Practices of Food	Published
	Guidelines for importation and exportation of food	Published
	Guidelines for investigation and control of food borne diseases	Published
Food and Drug Inspection and compliance	Guidelines for registration and licensing of food premises	Published
	Regulation Governing Licensing to Pharmaceutical Products or to operate as wholesale or retail seller of Pharmaceutical products	Published
	Regulation Governing Control of Import& Export of Pharmaceutical products and medical devices	Published
	Guidelines for Post-marketing Surveillance of Pharmaceutical products	Published
	Guidelines on safety and vigilance of medical products and health technologies	Published
	Clinical Trial Documentation Requirements	Published
Quality Control Laboratory	QCL Quality Manual	Published
	Document Control for Quality Control lab	Published
Documents developed in Line with COVID 19 spread prevention	Guidelines on Requirements and Specifications of eye protectors and face shields	Published
	Guidelines on specifications of Coverall protective clothing	Published
	Guidelines on requirements and specifications of ventilators	Published
	Guidance on Manufacturing and use of barrier masks	Published
	Guidelines on Preparation of Hand sanitizers	Published

5.10 TRAININGS

Rwanda FDA has in its line of capacity building trained some of its staff and stakeholders from different fields to increase efficiency and effectiveness in service delivery. The following staff members and stakeholders were trained

•Two (2) laboratory officers attended four months training on Advanced Pharmaceutical Product Quality using Mass Spectrometry and other State of the Art Technique that was held in L.E.A.F. Pharmaceuticals LLC 216 West Cumming Park Woburn, Massachusetts 01801, USA

•Four (4) FDA staff members were trained on Pharmacovigilance tools

•One FDA staff member trained on Good Clinical Practices Conducted by WHO

•Twenty-eight (28) FDA staff members were trained on basic skills for food products assessment

•Three hundred thirteen (313) health professionals (Medical Doctors, Pharmacists and Nurses) from referral, provincial and District Hospitals, Retail pharmacies were trained in Pharmacovigilance tools.

Challenges

•Dossier Application submitted for product registration lack key information stipulated in Rwanda FDA product registration requirements

•Lack of appropriate technology in Food processing industries

•Accessibility and location of some Food Processing industries

•lack of appropriate packaging materials for food processing industries

•under reporting of ADR and suspected poor quality products

•lack of skilled personnel in the new area of regulation such as medical device

•lack of private laboratories to support growing industries and new innovations.

Way forward

•Awareness sessions with applicants for product registration on the requirements

•Work with Private and Government institutions to promote technology transfer and innovation

•Advocacy to facilitate accessibility of food processing industries and mobilise investors to relocate in industries designated areas

•Public awareness and establishment of online reporting system

•Mobilise local investors to establish private testing laboratories

•Establish working collaboration with advanced regulatory institutions to facilitate training attachments.

Concluding remark

In conclusion, the performance of Rwanda FDA as a new entity during the year 2019/2020 is inspiring. However, our efforts need to shift to a higher score if the Authority is to improve on the areas that did not price as well as expected.

We are looking forward to achieving higher in the financial year 2020/2021 in the usual operations of Rwanda FDA of product registration, premise licensing, Import and export control, Clinical trial, Post market surveillance, product testing and reporting, Adverse drugs reactions and follow-ups among others.

RWANDA FDA

Rwanda Food and Drugs Authority

August 2020