RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FOOD AND DRUGS AUTHORITY ANNUAL REPORT FY 2021-2022

September, 2022

ODG/QMS/REP/A/FDA/05/2022

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LIST OF ABBREVIATIONS

1. **AEFI**	Adverse events following Immunizations
2. **ADR**	Adverse Drug reactions
3. **BOD**	Board of Directors
4. **CHCAR**	Cosmetics and Household Chemicals Assessment and Registration
5. **CHOGM**	Commonwealth Heads of Government Meeting
6. **DG**	Director General
7. **DFAR**	Drugs and Food Assessment and Registration
8. **FDIEC**	Food and Drugs Import and Export Control
9. **FDISM**	Food and Drugs Inspection and Safety Monitoring
10. **FDIC**	Food and Drugs Inspection and Compliance
11. **GMP**	Good Manufacturing Practice
12. **GDP**	Good Distribution Practice
13. **GCP**	Good clinical practices
14. **HMDAR**	Human Medicine and Devices Assessment and Registration
15. **MA**	Marketing Authorization
16. **NRA**	National Regulatory Authority
17. **PV-SM**	Pharmacovigilance & Food Safety Monitoring
18. **PBRER**	Periodic Benefit Risk Evaluation Report
19. **RNEC**	National Ethics Committee
20. **Rwanda FDA**	Rwanda Food and Drugs Authority
21. **SOPs**	Standard Operating Procedures
22. **UMC**	Uppsala Monitoring Centre
23. **WHO**	World Health Organisation
24. **QMS**	Quality Management System
25. **QCL**	Quality Control Laboratory
26. **GMP**	Good manufacturing Practices
27. **HACCP**	Hazard Analysis Critical Control Point
28. **RCA**	Root Cause Analysis
29. **CAPA**	Corrective and Preventive Action
30. **API**	Active Pharmaceutical Ingredient
31. **ISO**	International Standard Operation
32. **EAC MRP**	Easter African Countries Mutual Recognition Procedure

FOREWORD

On behalf of Rwanda Food and Drugs Authority (Rwanda FDA) and on my behalf, I am delighted to submit the authority's Annual report for the fiscal year 2021-2022. This report presents the achievements recorded in the fiscal year mentioned by the authority with pleasant cooperation from stakeholders and other public institutions on the way to protect public health from use of defective, falsified and substandard products.

In the course of the fiscal year 2021-2022, the authority has an ascending trajectory performance with budget execution rate of 83%. This is credited to commitment and professionalism in service delivery, Integrity, Accountability and teamwork spirits of the authority's staff to achieve common objectives of access to safe, quality, and efficacy of regulated products on the market. The general public has progressively noticed the importance of the Authority and has collaborated effectively in reporting of suspected substandard regulated products, product registration and market authorisation and control of different regulated products.

Rwanda FDA has a practical communication approach to the public using a well-designed website, different forms of media, TV's and Radio shows, toll free to connect to the public, professionals and the stakeholders. It is worth to note that the fiscal year 2021-2022 ends with 188 staff recruited and placed out of 195 as per organizational structure and therefore recruitment of 7 staff for remaining positions for fully staffing of the authority is planned in the fiscal year 2022-2023.

I would like to extend my honest appreciation to the government of Rwanda for the continued support and provision of the necessary resources for the implementation of plans in reaching the set goals and targets. Our special thanks also goes to Rwanda FDA Board of Directors for their sustained technical and managerial support that has always been considerable for regulatory decisions in the implementation strategies of the authority. we are looking forward to continued productivity in protecting public health through profound surveillance on the quality and safety of the regulated products on the market

Dr. Emile BIENVENU
Director General

EXECUTIVE SUMMARY

Rwanda FDA's mission is provided under Law N° 003/2018 of 09/02/2018, which is to protect public health by regulating human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products, and the conduct of clinical trials. The authority normally submits its annual report to the supervising ministry and with a copy thereof to other relevant public institutions provided the need arise.

This report particulars Rwanda FDA achievements for the fiscal year 2021/2022 on the planned interventions abiding to broad objective of ensuring a quality healthy population under social transformation pillar of the NST 1. The report details target attainment in areas of; Product Registration, Inspection and Premise Licensing, Import and Export Control, Clinical Trial oversight, Adverse Drug Reaction analysis, Post Marketing Surveillance, Pharmacovigilance and laboratory quality control testing.

The fiscal year 2021-2022 has left the authority with a tremendous performance and involved signing European Union twinning fiche agreement and a Memorandum of Understanding with Ghana FDA. Around 1077 food premises inspected, 1227 of pharmaceutical premises inspected and 208 strategic documents developed. In addition to the routine quality control of different products, the authority analysed various samples from restaurants, hotels and supermarkets for CHOGM readiness and most of those samples were submitted to microbiology tests to take evidence-based regulatory decisions and guidance provision to the concerned service providers.

In inference, Rwanda FDA worked with various categories of stakeholders to the accomplishment of the institutional mandate. The authority is further committed to working with partners and stakeholders to ensure protection of public health from consumption of defective, falsified and substandard products

RWANDA FDA PERFORMANCE HIGHLIGHTS FY 2021-2022

1.1. Human Medicine Assessment

Out of 2293 applications of human medicine for registration cumulatively received, 1724 were assessed which is 75% and 153 products which is 9% registered and received Market Authorisation.

1.2. Medical Devices Assessment

Out of 118 applications of medical devices for registration received, 35 of them which is 30% were assessed and 1 product which is 3% registered and received Market Authorisation.

1.3. Veterinary Medicine Assessment

Out of 153 applications of veterinary medicine for registration received, 110 of them which is 72% were assessed and 8 of them (7%) registered and received Market Authorisation.

1.4. Cosmetics and Household Chemicals Assessment

Out of 253 applications of Cosmetics and Household Chemicals for registration received, 214 of them, 85% were assessed and 59 products, 28% were registered and received Market Authorization

1.5. Food products Assessment

Out of 1507 food products applications for registration received, 1470 which is 98% were assessed and 485 which is 33% were registered.

1.6. Food Facility Licensing

203 licenses were issued to different categories of food establishments which include; 121 for food manufacturing industries, 4 for food supplement shops, 31 for food wholesaler/outlets and 47 for food importers. It is worth to note that since establishment the authority has in total licensed 235 food manufacturing facilities, 93 food wholesalers/ outlets, 28 food supplement shop and issued 7 GMP certificates.

1.7. Pharmaceutical licensing

101 licenses issued to different categories of pharmaceutical establishments. They include; 76 for human retail pharmacies, 15 for wholesale pharmacies, 6 for optical shops, 1 for veterinary retail pharmacy, 1 for cosmetic shop, and 2 wholesale of medical equipment

Rwanda FDA has in total licensed 7 manufacturing facilities of medical products, 14 small scale manufacturing facilities, 735 human retail pharmacies, 3 online pharmacies, 172 human wholesale pharmacies, 24 wholesale of medical device, 23 wholesale veterinary pharmacies, 15 retail veterinary pharmacies, 26 optical shops, 3 orthopaedic shops and 14 cosmetic shops.

1.8. Visa issued

Out of 12,818 received applications for import VISA, 12,372 which is 97% were issued, while 3% failed to comply with importation requirements

1.9. Import licensed

Out of 10,839 applications for import licenses, 10,371 which is 96% of them were granted, and 4% failed to comply with importation requirements.

1.10. Inspected underseal

Rwanda FDA has inspected 36,068 consignments which comprise 23,829 which have been inspected at ports of entry and 12,239 which have been released under seal and inspected at clients' premises.

1.11. ADR report reviewed

1,037 ADR reports received cumulatively, 693 (67%) of the received ADR/AEFI reports were reviewed and the remaining ADR reports were reported by internationally recognized regulatory authorities and 184 with complete data were reported to Uppsala Monitoring centre via Vigiflow.

1.12. Post Marketing Surveillance

41 suspected poor quality pharmaceutical products received and investigated in which Ten (10) batches of Pharmaceutical products and 6 batches of cosmetics products were recalled from market

113 suspected poor quality food products received, 79 were investigated and 62 sampled for laboratory control test which resulted in two (2) recalls of food products from the market

1.13. Clinical trial oversight

Ten (10) clinical trial applications received and reviewed and 7 complied requirements and approved.

Thirteen (13) clinical trial amendment applications received and reviewed and 11 were approved within the prescribed timeline

2. RWANDA FDA OVER VIEW

2.1. Strategic Overview

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

2.1.1. Vision

Become a world class regulatory Authority effectively protecting and promoting public health

2.1.2. Mission

To regulate medical products, processed foods, house-hold 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.

2.1.3. Core values

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

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.

2.1.4. Rwanda FDA Quality Policy Statement

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

2.2. The Authority Management

Rwanda FDA is managed by Board of Directors (BoD) and Executive Organ. The BoD of Rwanda FDA is the supreme management and decision making organ and has full powers to make and oversee the functioning of the Executive Organ and provides strategic guidance in the fulfilment of the Authority's mission. The Authority is affiliated and reports to the Ministry of Health

2.2.1. Rwanda FDA Board of Directors

The BoD is composed of seven (7) members which comprises chairman, vice chairperson and other five (5) members. The BoD has among others a key responsibility of overseeing the functioning of the executive organ and providing strategic guidance for the realisation of its mission. It has full powers to make decisions regarding administration of human resources and Rwanda FDA property in line with the relevant laws.

2.2.2. Rwanda FDA Executive Organ.

Rwanda FDA Executive Organ is comprised of Seven (7) members. They include; Director General (DG), Deputy Director General (DDG), Two (2) Heads of Department (HOD), Chief Finance Officer (CFO), one (1) Division Manager (DM) in charge of Quality Control Laboratory as a standalone division and a Legal Analyst.

The Director General has the power to take financial and administrative regulatory decisions for the authority in accordance to relevant laws. Rwanda FDA Executive Organ has the responsibility to monitor and coordinate daily duties and activities of the authority and perform any other duty as may be assigned by the Board of Directors falling within the mission of the Authority.

2.3. The Functioning of the Authority

Rwanda FDA has two (2) technical active departments namely; Drug and Food Assessment and Registration, Food and Drugs Inspection and Safety Monitoring. These technical departments are supported by the Chief Finance officer that coordinates all financial arrangements for the implementation of the authority plans. The authority also has a Quality Control Laboratory (QCL) standalone division that help to take evidence based regulatory decisions by testing different parameters as may be requested.

2.3.1. Food and Drugs Inspection and Safety Monitoring (FDISM) Department

The FDISM department oversees the inspection activities and safety monitoring of all food and medical products manufactured locally and imported into the country as well as their inspections at all major ports of entry to stop the entry of substandard and counterfeit products into Rwanda.

In addition, FDISM also oversees the inspection and licensing of all foods and drugs handling premises and 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 public receive the right information on the regulated products. It also ensures the verification, monitoring and certification of food and drug promotion materials to ensure that misleading, biased and inaccurate information about regulated products is not disseminated.

2.3.2. Drugs and Food Assessment and Registration (DFAR) Department

The FDAR role is to assess dossiers submitted to Authority and recommend for registration/ marketing authorization (MA) of products that comply to the Rwanda FDA regulatory requirements. The issuance of marketing authorizations/ product registration is critical and the basis to any National Regulatory Authority (NRA)'s operations.
The Department contributes to the overall mission of the Authority by protecting and promoting human and veterinary public health through conducting assessment and evaluation 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.

2.3.3. Quality Control Laboratory (Standalone Division)

The Quality Control Laboratory (QCL) is mandated to analyse different categories of food and food products, medicines, medical devices and Public health products, 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 enables the Authority to make evidence-based regulatory decisions

Quality Control laboratory derives its directive from the article 8 of the law establishing the Rwanda FDA, paragraph (6) that mandates the Authority to establish the quality assurance and quality control of regulated products and paragraph (14) that mandates the Authority to conduct research and studies on food and pharmaceutical products and publish the findings in order to promote investment

2.3.4. Office of the chief Finance officer

The Chief of Finance Officer is responsible for planning, enabling implementation of plans, managing and running all financial matters of Rwanda FDA. The office duties involve managing the Authority cash flows and financial planning, reporting as well as analysing the institutional performance in relation to budget execution and recommend corrective actions for improvement and high yielding

3. INSTITUTIONAL PERFORMANCE FY 2021-2022.

Rwanda FDA performance for the fiscal year 2021-2022 is enlightened and observant to reaching her mission. The authority's performance considered strategic guidance from her strategic plan, health sector priorities, National Transformation Strategy (NST1) priority areas and other relevant strategic guidance at national and sector levels. The implementation status as detailed below per regulatory function has entirely and objectively protected the general public from consumption of unsafe regulated products;

3.1. Product registration and Market Authorisation

3.1.1. Assessment and Registration of Human Medicine;

Rwanda FDA since its establishment has in total received two thousand two hundred and ninety-three (2293) applications for human medicine demanding market authorisation and registration in which one thousand seven hundred and twenty-four (1724) 75% were assessed and a total of one hundred fifty-three (153) products registered.

The authority however in the fiscal year 2021-2022 received a total of four hundred and nineteen (419) applications and one thousand one hundred thirty-eight (1138) were assessed including the backlog from the previous year 2020-2021 and thirty- four (34) products registered. The authority ends the fiscal year 2021-2022 with five hundred and sixty-nine (569) applications of human medicine pending assessment for registration.

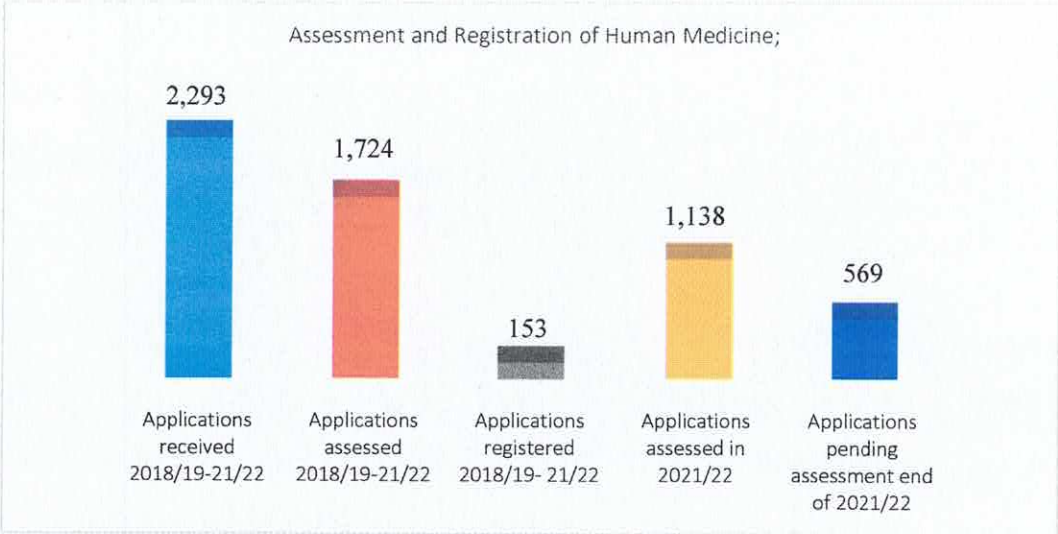

Figure 1: Assessed & Registered Human Medicine

3.1.2. Assessment and Registration of Medical Devices

The fiscal year 2021-2022 ended with a total of one hundred and eighteen (118) product applications for medical devices requesting market authorisation and product registration in record since authority establishment and thirty-five (35) which is 30% of product applications assessed and one (1) product registered on the market

In the fiscal year 2021-2022 however, the authority received seventy-four (74) applications and twenty-seven (27) were assessed and none registered. The financial year ends with eighty-three (83) product applications pending assessment.

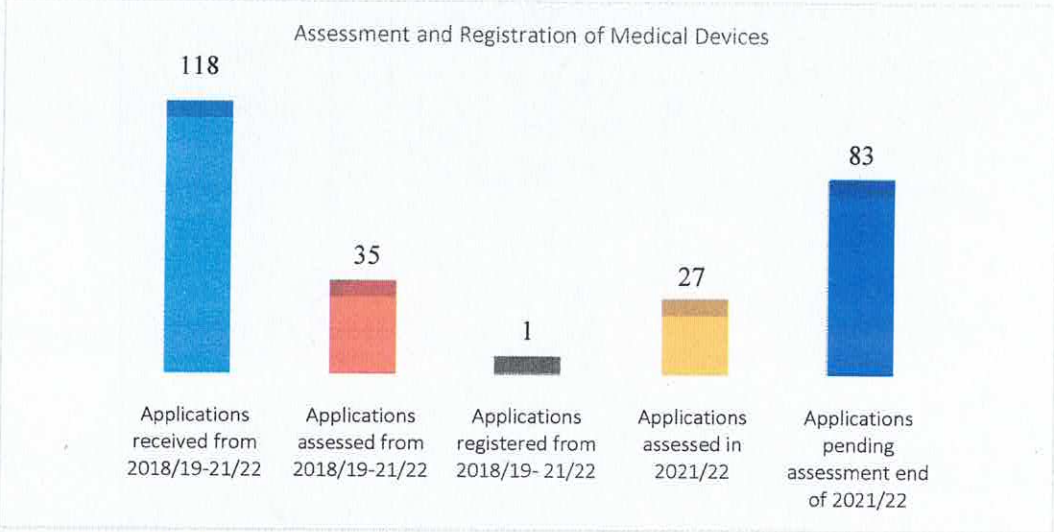

Figure 2: Assessed & Registered Medical Devices

3.1.3. Assessment and Registration of Vaccines and Biological products

A total of sixty-six (66) applications for registration of vaccines and biologicals were received with effect from 2018/2019 when the authority came into existence and sixty-four (64) 97% of these applications were assessed and ten (10) of them registered and granted market authorisation by the end of the fiscal year 2021-2022.

The authority however, in the year 2021-2022 received nine (9) applications for registration and market authorisation, seven (7) of them were assessed, and three (3) registered. The fiscal ends with two (2) product applications pending for assessment

3.1.4. Assessment and Registration of Veterinary Medicine and Devices

Rwanda FDA has right from the start received cumulatively a total of one hundred and fifty- three (153) applications for registration and market authorisation of Veterinary Medicine and Devices among which one hundred and ten (110) which is 72% of applications assessed and eight (8) products registered and market authorised

Throughout the fiscal 2021/2022, a total of seventy-two (72) applications were received, eighty-five (85) assessed and five (5) registered. The fiscal year ends with fort-three (43) product applications pending for assessment

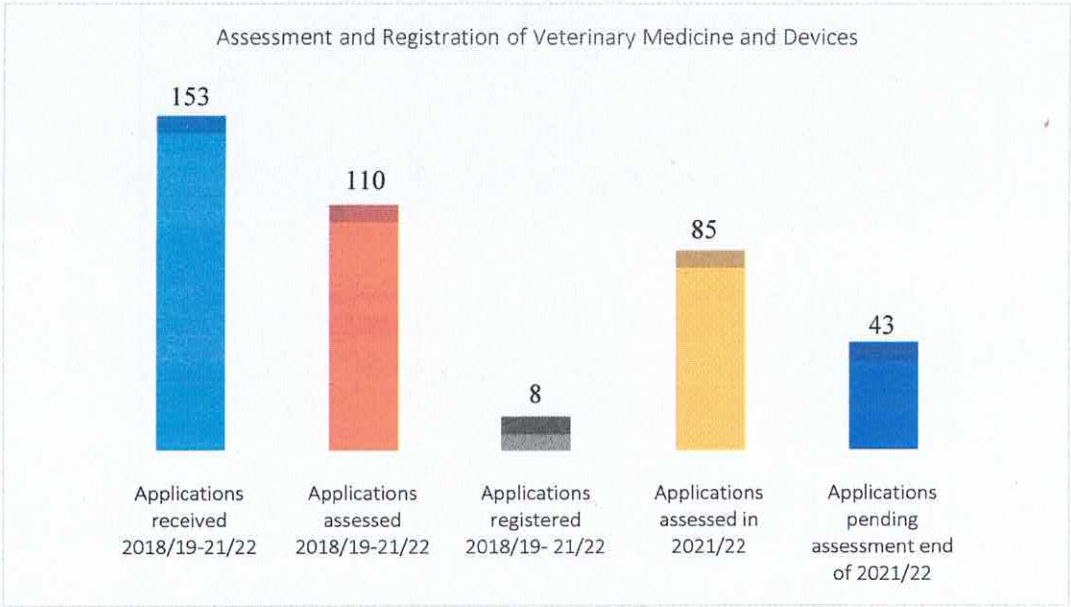

Figure 3: Assessed & Registered Veterinary medicine & Medical devices

3.1.5. Assessment and Registration of in Cosmetics and Household Chemical Products

For a total of two hundred and fifty-three (253) received applications for registration of Cosmetics and Household Chemicals right from the beginning of the authority to deliver its mandate, the Authority assessed two hundred and fourteen (214) 85% applications, and fifty-nine (59) which is 28% were cumulatively registered by the end of fiscal year 2021/2022.

In the fiscal year 2021-2022 a total of sixty-nine (69) applications were received, eighty-eight (88) assessed and forty (40) registered and received the Market Authorisation. The fiscal ends however with thirty-nine (39) applications pending for assessment

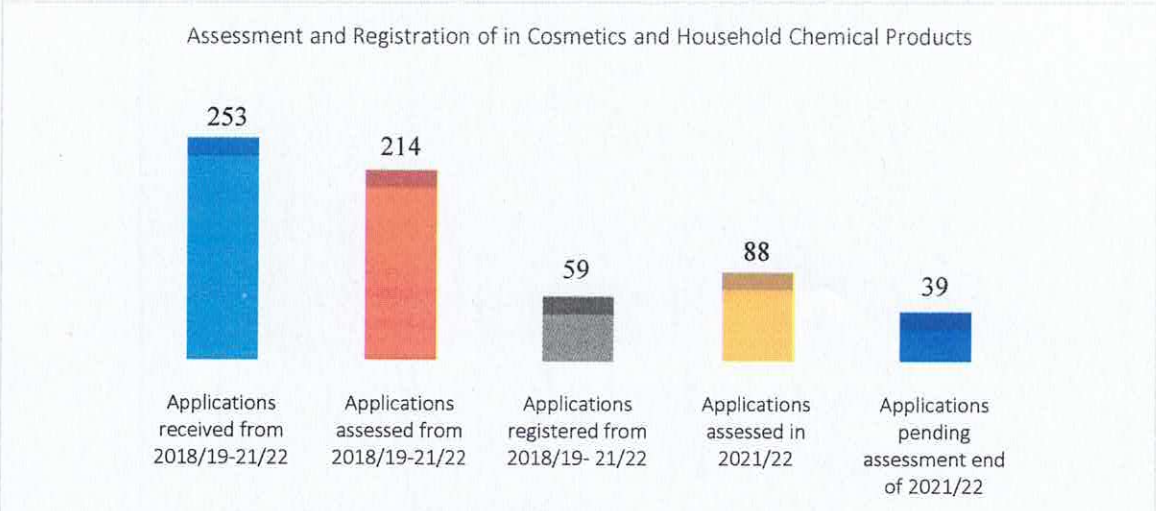

Figure 4: Assessed &Registered Cosmetics &Household Chemicals

3.1.6. Assessment and Registration of food products

Rwanda FDA right from the start received a total of one thousand four hundred and forty-seven (1,447) food products applications for registration. Around one thousand four hundred and nineteen (1,419) 98% applications were assessed and four hundred ninety-three (493) were registered cumulatively.

In the fiscal year 2021-2022 however, the authority received two hundred and twenty- one (221) applications, assessed one hundred and eighty-four (184), registered two hundred and fort-five (245). Year closes with thirty-seven (37) applications pending assessment and with nine hundred eighty-five (985) assessed but not yet complied for registration and market authorisation.

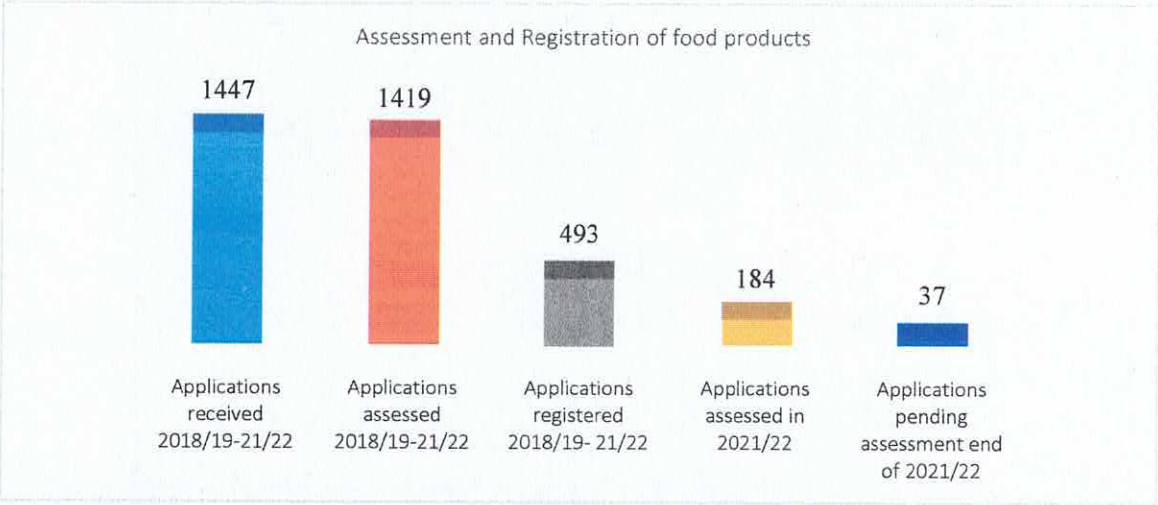

Figure 5: Assessed &Registered Food Products

3.2. Regulatory inspection and licensing

3.2.1. Inspections conduced

3.2.1.1. Food Facility Inspection

Normally the authority does inspection on new applicants for premise licensing, license renewal and relocation requests, Incineration, and additional warehouse to ensure compliance of the set standards by the authority in protection of public health. Mostly the food facilities that apply for the service include; Food manufacturers, Food importers and food supplement shops.

In the fiscal year 2021/2022, the authority received a total of nine hundred and eleven (911) applications and in response the authority carried out one thousand seventy-seven (1077) inspections including the re-inspections, and enforcements. Rwanda FDA also received a total of

one hundred and five (105) applications for GMP inspection of food manufacturing facilities and has throughout the year conducted thirty-seven (37) GMP inspection including thirty-six (36) physical and one (1) desk assessment review among which six (6) were awarded GMP certificate.

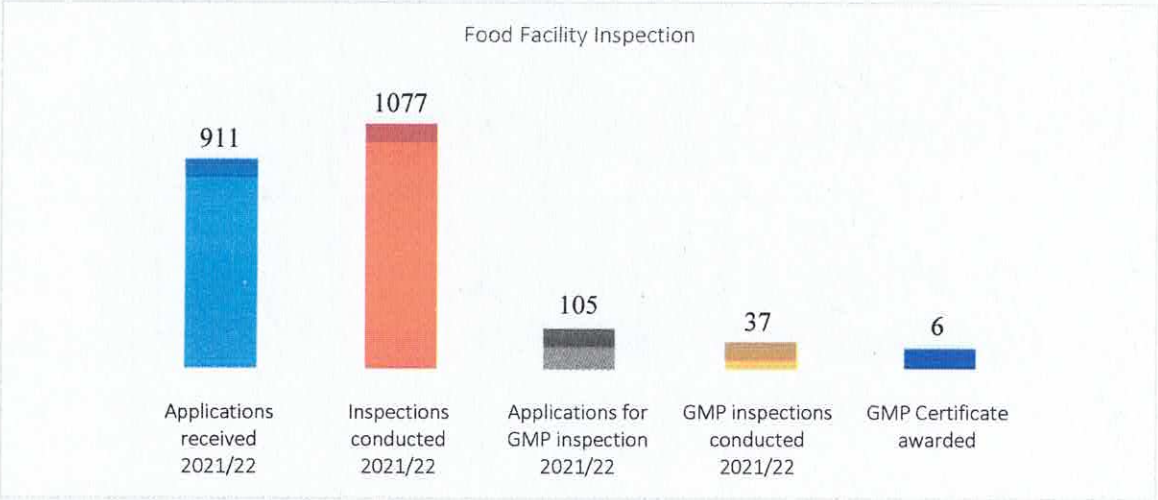

Figure 6: Inspected Food Facilities

3.2.1.2.Pharmaceutical Inspection

Rwanda FDA does inspection following the applications for premise licensing, license renewal and relocation requests, Incineration, and additional warehouse. The authority also conducts re-inspection of the inspected facilities and does enforcement inspections to ensure compliance to standards set prior license approval. Throughout the fiscal year 2021/2022, around one thousand two hundred and forty-four (1244) applications received and the authority inspected nine hundred thirty-seven (937) of new premises demanding license, two hundred and five (205) enforcement inspections and fifteen (15) re -inspected premises.

The authority also received one hundred and fifteen (115) GMP applications of Pharmaceutical manufacturing facilities and has throughout the year conducted a total of seventy-four (74) GMP inspection comprising of ten (10) physical, sixty-three (63) desk assessment review and one (1) virtual inspections among which twenty-five (25) were granted GMP certificate.

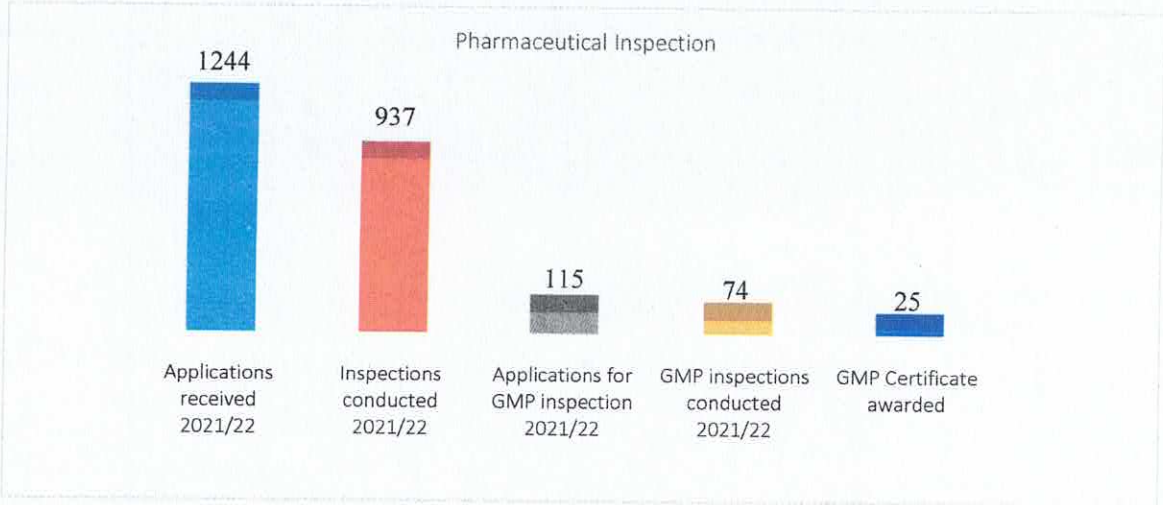

Figure 7: Inspected Pharmaceuticals

3.2.2. Licensing

3.2.2.1.Food Facility Licensing

Throughout the fiscal year 2021-2022, the authority with due diligence issued and granted two hundred and three (203) licenses to different food facility categories. They include; one hundred twenty-one (121) for food manufacturing industries, four (4) for food supplement shops, thirty-one (31) for food wholesaler/outlets and forty-seven (47) for food importers.

The authority has since establishment licensed a total of two hundred thirty-five (235) food manufacturing facilities, ninety-three (93) food wholesalers/ outlets, twenty-eight (28) food supplement shop and issued seven (7) GMP certificates.

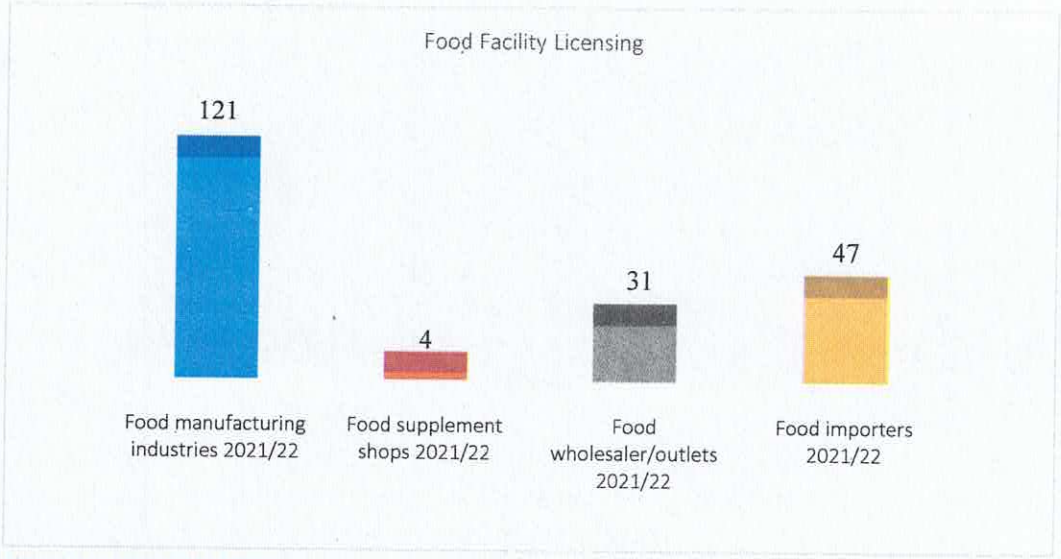

Figure 8: Licensed Food Facilities

3.2.2.2.Pharmaceutical Licensing

In the fiscal year 2021-2022, the authority issued and allowed a total of one hundred and one (101) licenses to different applicants which complied to the requirements for license approval. They include; seventy-six (76) for human retail pharmacies, fifteen (15) for wholesale pharmacies, six (6) for optical shops, one (1) veterinary retail pharmacy, one (1) cosmetic shop, two (2) wholesale of medical equipment

Rwanda FDA has in total licensed seven (7) manufacturing facilities of medical products, fourteen (14) small scale manufacturing facilities, seven hundred thirty-five (735) human retail pharmacies, three (3) online pharmacies, one hundred seventy-two (172) human wholesale pharmacies, twenty-four (24) wholesale of medical device, twenty-three (23) wholesale veterinary pharmacies, fifteen (15) retail veterinary pharmacies, twenty-six (26) optical shops, three (3) orthopaedic shops and fourteen (14) cosmetic shops

Figure 9: Licensed Pharmaceuticals

3.2.3. Import and Export Control

3.2.3.1.Import Visa Provision

Rwanda FDA received a total of twelve thousand eight hundred and eighteen (12,818) applications for import visa of human pharmaceutical products, veterinary pharmaceutical products, Food products, medical devices, tobacco & tobacco products, cosmetics, chemicals, Food supplements, Animal feeds, and Packaging materials in which twelve thousand three hundred and seventy-two (12,372) 97% import visas were issued to the applicants throughout the fiscal year.

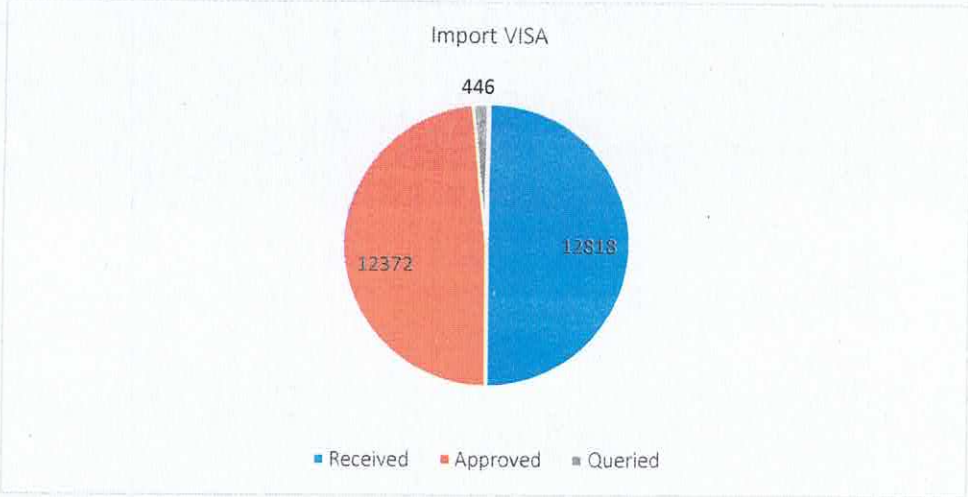

Figure 10: VISA approvals

3.2.3.2.Import Licenses Issued

Throughout the fiscal year 2021/2022, the Authority received ten thousand eight hundred and thirty-nine (10839) applications for import licenses among which ten thousand three hundred and seventy-one (10,371) 96% were issued to the applicants. These applications include human medicine, tobacco & tobacco product, food product, food supplements, animal feeds, packaging materials, raw mat for food, cosmetic product, chemical products, food processing devices, disinfectants, labelling materials, human vaccines, and biosimilar, raw mat for animal feeds, raw mat for medicine, raw mat for medical devices, food testing devices, veterinary medicine, and food reagents

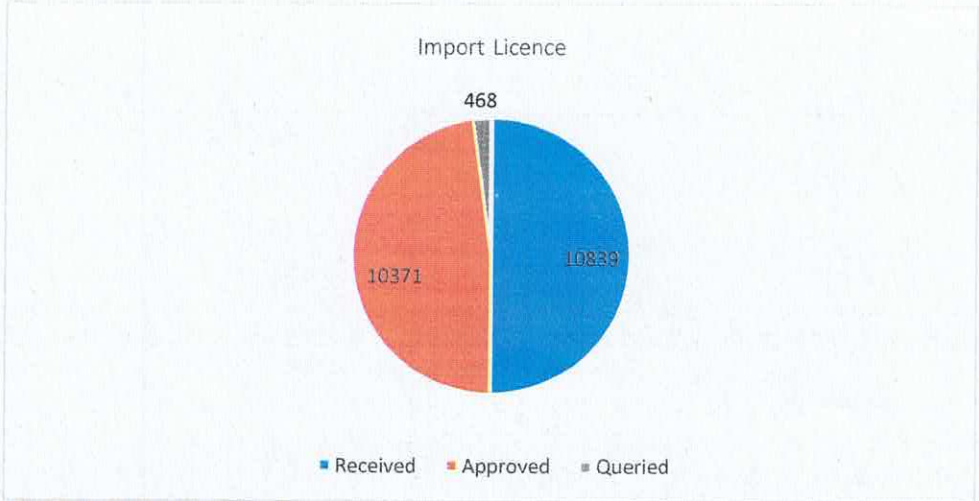

Figure 11: Import License issued

3.2.3.3.Export licenses issued

The Authority received five hundred and fourteen (514) applications for export license on various regulated products such as human pharmaceutical products, medical devices, food products, cosmetics, animal feeds and food supplements. With the fulfilment of the requirements for export license approval, five hundred and thirteen (513) licenses were issued and granted to the applicants throughout the year in question.

3.2.3.4.Inspected Consignment

Rwanda FDA inspected a total of thirty-six thousand and sixty-eight (36,068) consignments which comprises twenty-three thousand eight hundred and twenty-nine (23,829) at ports of entry and twelve thousand two hundred thirty-nine (12,239) released under seal

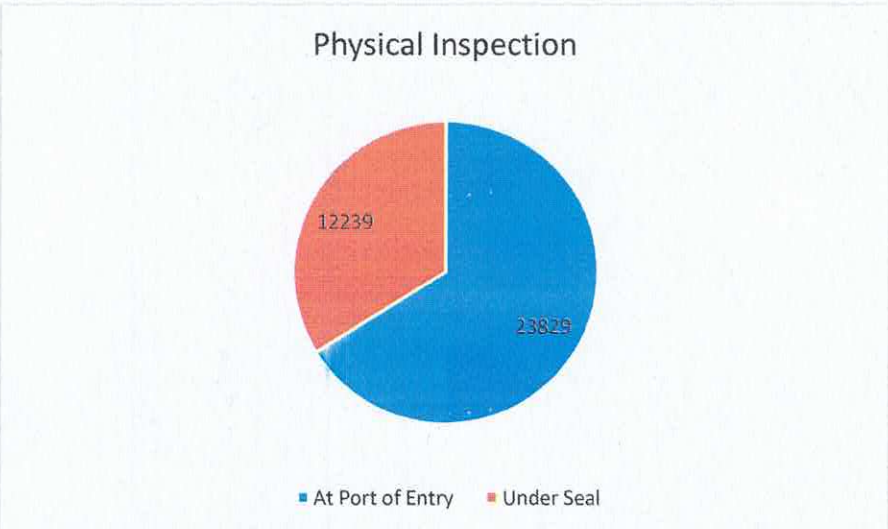

Figure 12: Inspected Consignments

3.2.4. Pharmacovigilance and food Safety Monitoring

3.2.4.1.ADR/AEFI reports and safety information

In the year 2021/22, the authority received a total of one thousand and thirty-seven (1,037) ADR/AEFI reports from both local and international sources; out of which six hundred ninety-three (693) which is 67% of the received ADR/AEFI reports were reviewed and one hundred eighty-four (184) with complete data were reported to Uppsala Monitoring centre via Vigiflow.

These reports come from different sources mainly the International Pharmaceutical companies, Health facilities, Public Health programs, Local Technical representatives and Patients. ADR reports from international companies are considered in aggregated analysis for signal detection but

not individual case safety analysis to avoid the duplication as they are already analysed and reported by marketing authorization holders to WHO-UMC (Uppsala monitoring Centre)

As the safety reports received, the pharmacovigilance staff record in the specific database, then the causality assessment is conducted especially for the local safety reports and feedback are prepared accordingly. Also sixty-eight (68) Periodic benefit risk evaluation report (PBRER) were received from marketing authorization holders for the authorized medicine

3.2.4.2.Post marketing surveillance

Throughout the fiscal year 2021/2022, the authority received and investigated forty-one (41) suspected poor quality pharmaceutical products reported in which ten (10) batches of pharmaceutical products and 6 batches of cosmetics products were recalled from market based on laboratory control test results.

Furthermore, the authority received one hundred and thirteen (113) suspected poor quality food products among which seventy-nine (79) were investigated and sixty-two (62) samples taken for laboratory control test which resulted to two (2) recalls of food products which could not justify the market authorisation.

3.2.4.3.Products information, promotion and advertisement control

3.2.4.3.1. Food safety information

Rwanda FDA developed two (2) food safety information on *Escherichia coli* and Listeria. The Authority also did awareness on food product labelling to the general public throughout the country by distributing Information, Education and Communication (IEC) materials including sixty (60) banners and one hundred (100) posters prepared by Rwanda FDA in collaboration with WHO and RBC. Those materials were posted in places where the public gather like on the market, on the car parks and on the district offices.

3.2.4.3.2. Food products promotion and Advertisement Control

Seventeen (17) applications requesting for food products promotion and advertisement authorization were received and analysed, nine (9) applications met requirements for food promotion and advertisement authorization were approved and eight (8) applications were queried additional data from the applicants. Technical guidance on the requirements for approval of food products promotion and advertisement was provided to 4 companies.

The Authority also inspected twenty-eight (28) food establishments and made awareness on requirements for food product promotion, marketing and advertisement authorization. In addition, three (3) warning letters were sent to companies that were found advertising food products without the authorization from Rwanda FDA.

3.2.4.3.3. Medicine safety information.

The Authority Published four (4) safety communications on Sofosbuvir, Valproate, serotonin reuptake inhibitors (SSRIs), Diclofenac and serotonin-noradrenaline reuptake inhibitors (SNRIs).

No	Medicine	New Safety Information
1	Sofosbuvir	Potential risk of severe cutaneous adverse reactions (SCAR) in patients using Sofosbuvir namely Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme (EM), and bullous dermatitis (BD)
2	Valproate	Risk of teratogenicity and/or lower IQ in babies born to mothers who took valproate products including valproate sodium and related products, and valproic acid (brands) like (Depacon, Depakenine) when pregnant.
3	Diclofenac	Risk of cardiovascular events (heart attack and stroke) associated with inappropriate use or overdose of Diclofenac such as high dose (150mg daily) and for long-term treatment
4	Selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs)	Increased risk of postpartum hemorrhage when selective SSRIs and SNRIs are used by mothers during the month before delivery.

3.2.4.3.4. Promotion and Advertisement Control

Rwanda FDA provided technical guidance on the requirements for approval of promotion of medical products to nine (9) companies including two (2) for traditional medicines and food supplements, two (2) for veterinary medicines, four (4) for human medicines and one (1) for cosmetics. The Authority also received and analyzed twenty-three (23) applications for promotion control of regulated medical products among which sixteen (16) of them were approved and seven (7) were sent back to applicants requesting additional data.

3.2.4.3.5. Clinical trial oversight

Rwanda FDA has since establishment received twenty-eight (28) clinical trial applications and were all (28) 100% reviewed in the set timeline. In the fiscal year 2021-2022, the authority received and reviewed ten (10) clinical trial applications and seven (7) applications that outstandingly complied with the requirements for authorization were approved totalling to twenty-one (21) approved in the prescribed timelines effective inauguration of the authority. There is also thirteen (13) clinical trial amendment applications received and were all reviewed and eleven (11) of them were approved within the prescribed timeline.

Rwanda FDA also inspected thirty-two (32) clinical trial sites including; CARAES Ndera RH, Kibuye Referral Hospital Rwamagana Hospital, Remera, Nyarugunga and Busanza Health Centers, Rinda UBUZIMA, Kigali Rwanda, Nyamata District Hospital, Nyamata Health Center, Rukara Health Center, Masaka Health Center, Bugarama Health Center among others. The Authority also updated and published the register of authorized and withdrawn clinical trials. It is also worth noting that a Joint Institutional Collaboration Framework between Rwanda FDA and RNEC was developed and signed.

In addition, the authority participated into Parliament Commission sessions for validation of the new Law on research on human beings and establishment of the National Research Ethics Committee. Furthermore, a joint Rwanda FDA-RNEC GCP Inspection at trial site for INGABO trials targeting reported serious adverse events was done and resulted in a fatal outcome. The authority also conducted a joint review of RNEC indicators to verify implementation status, identify gaps, and chart a course of action.

3.2.5. Laboratory Access and Testing

Rwanda FDA laboratory tested different categories of samples that includes food samples (like juice, mineral water, yogurt, tomatoes; canned beef, chicken luncheon meat, maize, etc.) medicines and cosmetics (tablets, syrup, pomade, creams and lotions, etc.), and medical devices (condoms and gloves). Samples were obtained from pre-market, post shipment and Post Market Surveillance.

In addition to samples testing, the Authority also conducted different activities to ensure that the generated laboratory test results are accurate and precise in compliance with relevant international standards and requirements.

3.2.5.1.Samples tested for Quality Control

Throughout the fiscal year, the Authority tested twenty seven thousand and seven hundred and nine (27,709) samples including twenty six thousand eight hundred forty (26,840) condom samples, three hundred fifty nine (359) medicine and cosmetics samples, and five hundred and ten (510) food products which comprise rice, alcoholic beverages, soft drinks or /and juices, honey, salt, flours, vegetable cooking oils, coffee, mineral water, raw meat, sausage and food samples from hospitality entities among others. The test results from these samples were accurately generated and certificate of analysis (CoAs) issued.

In compliance with the ISO/IEC 17025:2017 (general requirements for the competence of testing and calibration laboratories) the authority developed fifty-one (51) laboratory support documents (LSDs) for food and medicines testing laboratories. Apart from the routine quality control of different products, the laboratory analysed one hundred and thirty-five (135) various food samples from restaurants, hotels and supermarkets for the preparedness of CHOGM in Rwanda. Most of those samples were submitted to microbiology tests, and this allowed the authority to take evidence-based regulatory decisions and to provide guidance on preventive measures to concerned service providers.

3.3. Improvement status on underlined gaps in Rwanda FDA strategic plan

Rwanda FDA three year (2021-2024) strategic plan highlights the identified areas for improvement in November 2018, when the Authority's regulatory system was assessed using the WHO Global Benchmarking Tool (GBT). The Authority has tremendously registered a desired improvement on these areas which falls in National Regulatory Systems, Registration and Marketing Authorization, Regulatory Inspection, Vigilance, Market Surveillance and Control, Licensing Establishments, Clinical Trials Oversight and Laboratory Testing.

3.3.1. National Regulatory Systems (NRA) area for improvement

The identified areas of regulatory system for improvement using WHO global benchmarking tool include possessing a QMS which includes risk management principles, possess and maintain Mechanisms to promote transparency, accountability, and communication and reliable arrangement for effective organization and good governance.

3.3.1.1. National Regulatory Systems (NRA) area improved

Different documents were assessed to be in line with the approved QMS requirements and an internal quality Audit was conducted. The approved organisation structure of the institution is progressively implemented and the managerial levels (Board, Executive Organ) and technical staff are now appointed and recruited respectively. The authority has also developed different regulations and guidelines which are published on the institutional website. Internally, processes are effected in accordance to the established procedures in order to improve objectivity while taking decisions

3.3.2. Registration and Marketing Authorization (MA) area for improvement

Development of guidelines including; registration of products in emergency situations, timelines for processing of MA applications and related tracking system, and reliance on the Marketing Authorisation decision of other national medicines regulatory authorities and Human resource constraints hampering the effectiveness of activities

3.3.2.1. Registration and Marketing Authorization (MA) area improved

Guidelines for Authorization for Emergency Use was developed; Timelines for processing MA is defined in the guidelines and related tracking system was established, Guidelines for reliance on the MA decision making was also developed. Different guidelines and regulations were developed, approved and are on the authority website for use

The recruitment was done following the organisation structure and the performance on planned activities is progressively attained, however, the nature of the job and the increased need for service delivery has demanded more staff and thus the constraint is not yet solved.

3.3.3. Vigilance area for improvement

Establishment of National database for collating ADRs, Establishment of advisory committee to advise on causality assessment, Development of communication strategy on submission of ADR reports to the Uppsala Monitoring Centre, Designated staff to carry out PV activities Stakeholder and Engagement in PV activities, particularly with public health programs

3.3.3.1. Vigilance area improved

Rwanda FDA has established different database including the one for local ADR reports, database for AEFI reports and another one for ADR reports from international manufacturers or marketing authorization holders. As of today the authority recorded in the database around 3500 ADR report (both local and international) and also there is more than 630 AEFI reports in AEFI database

The Authority also established a national Pharmacovigilance committee with clear terms of reference and the committee is functional and trained. Secondly there is a national AEFI committee also which is functional and support agency in conducting investigation and causality assessment for serious AEFI. The Authority has in place a communication plan for safety issues. Currently has issued eighteen (18) medicine safety information to health professionals and four (4) safety signals which is also published to Rwanda FDA website

Furthermore, the Authority has reactivated the vigiflow account and report to Uppsala Monitoring Centre ADR/AEFI reports as of now the Authority submitted two hundred and ninety (290) ADR/AEFI. The Authority has in its division for pharmacovigilance and safety monitoring four (4) dedicated staff that conduct routinely pharmacovigilance activities

The Authority has started engaging different stakeholders including public health programs where there are some joints activities such as ongoing active surveillance on dolutegravir based regimen conducted jointly with HIV program, there are also some trained organized jointly with expanded program for Immunization

3.3.4. Market Surveillance and Control area for improvement

Guiding documents that facilitate transparency and communication of the market surveillance outcomes to the public, required staff to perform market surveillance and control activities

3.3.4.1. Market Surveillance and Control area improved

There are regulatory documents that include regulation and guidelines on post marketing surveillance and recalls. Based on that from the post marketing surveillance activities, as of now the Authority issued recalls for one hundred and eight (108) batches for the substandard products. Rwanda FDA has four (4) staff dedicated routinely to market control and surveillance activities. In addition, the Authority established the technical committee for post marketing surveillance that advises the Authority in matters related to market surveillance and control

3.3.5. Licensing Establishments area for improvements

Development of guidelines for inspection and licensing of premises, regulations on the variation of premises, Development of procedures, Inspections of public and private hospital pharmacies, Training of personnel and qualification, and Publishing of licensed establishment on the website as per the LI06 indicator in the GBT tool;

3.3.5.1. Licensing Establishments area improved

For Pharmaceutical Establishments licensing; one (1) Regulation governing licensing of public and private manufacturers, wholesaler, distributors and retailers of medical products has been revised and published on the website as the second revision signed on 26th January 2022. The 3rd revision is under revision process to be externally validated in end August 2022. The articles covering the substantial modifications and variations has been captured.

The Guidelines on licensing for public and private manufacturers, wholesalers, distributors and retailers of medical products has been revised and published on the website as the second revision effective from 22nd February 2022. The 3rd revision is under revision to capture all recommendations received in the last sessions with different experts and the validation by external stakeholders is expected end of August 2022.

SOP on licensing and inspections have been developed. Currently, being enhanced to improve the procedures on inspections and licensing activities. SOP on annual inspections plan has been developed and approved. However, Annual inspection plan is under revision to improve it based on the different types of inspections to be conducted. The publication of all licensed establishments dealing with medical products is done on monthly basis

A total of ninety (90) hospital pharmacies were inspected and given feedback letters to comply with the Rwanda FDA requirements for licensing.

3.3.5.2. Regulatory Inspection area for improvement

Training of personnel and qualification, Evaluation of the effectiveness of training, Drafted legal provisions need to be revised in accordance with the provisions of Law N° 003/2018 of February 9th, 2018, Regulatory documents need to be updated, reviewed; GMP Regulation, Guidelines and SOP's need to be completed and Validated, GDP regulation and guidelines need validation, SOP's need to be developed, Most regulatory inspection operations performed are not documented, especially procedures or documentation to show implementation of enforcement activities

3.3.5.3. Regulatory Inspection area improved

Regulation governing GMP and GDP and their respective guidelines and SOPs have been updated but there is still a need to have them incorporated with the WHO recommendation and validated internally and by validated during external validation in pharmaceutical sector.

To evaluate a training CFO/SOP/166 developing, maintaining training activities, staff records and evaluation of training effectiveness was amended and inputs from DM's FDIC were shared with DAHR for Revision. Currently effectiveness of training is done through pre/post testing, but more tools need to be developed to determine the training effectiveness of inspectors

Rwanda FDA has been participating in enforcement activities such as inspections of hospital pharmacies and report was generated and shared with the different stakeholders. In addition, Rwanda FDA has been participating to FAGIA – OPSON VI (March 2022), First Interpol – AFRIPOL Joint Operation Flash Illicit Pharmaceutical Products in Africa (Operation Flash-IPPA) (November 2021) and operations conducted with other partners and reports were shared

3.3.6. Clinical Trials Oversight area for improvement

Drafted legal provisions need to be revised in accordance with the provisions of Law N° 003/2018 of February 9, 2018, Limited number of human resources to carry out clinical trial oversight activities

3.3.6.1. Clinical Trials Oversight area improved

The Authority Published Regulations No CBD/TRG/015 Governing the Conduct of Clinical Trials in Rwanda which is aligned with the Law N° 003/2018 of February 9, 2018. The Authority also developed and published different guidelines to guide clinical trial activities

The Authority has two (2) staff dedicated for clinical trial activities and has trained other staff to support the clinical trial team. The Authority is still working on increasing the number of staff in clinical trial

3.3.7. Laboratory Testing area for improvement

Additional appropriately trained staff are needed for the development of microbiological testing. Moreover, the laboratory should be prepared to perform lot release process for vaccines to be produced in Rwanda. For that a vaccine unit has to be established in QCL. QCL should project to analyse herbal medicine samples since they are on the market and their quality is not guaranteed. There is a need for a regulation describing the mechanism of quality control of medicines including the official issuance of laboratory testing results. Memorandum of understanding defining the process of recognition and reliance on the results of other laboratories needs to be enforced. MA information needs to be made available to laboratory staff to ensure that testing is in accordance with the manufacturer's methods. Guidance on nonconformities and how to communicate with MA holders and other interested parties needs to be provided

3.3.7.1. Laboratory Testing area improved

At the time of planning, microbiological laboratory was not operational, but now it is functioning with two (2) staff. However, microbiology testing unit needs two (2) more staff to analysed not only food but also medicine samples.

The regulation for the analysis of products regulated by Rwanda FDA is available. There is Rwanda FDA law N° 003/2018 of 09/02/2018, article 9 which was issued in August 2021 and is globally including not only Quality control of medicines, but also all regulated products including food, medicine, cosmetics, medical devices, pesticides and poisonous. However, this law needed to be amended to cover some gaps already identified.

Some MoUs are available but there is a need for the enforcement, and to be specific on the recognition and reliance. So far, QCL has established a procedure on non-conformities. The process to access MA file has been defined in collaboration with MA team. Then, when it comes to communicate with MA staff, this is done through departments by taking reference to laboratory certificate of analysis and expert reports issued by QCL. What is clear is that communication to the manufacturer is conducted in such manner that comply with Rwanda FDA procedure for communication.

3.4. QMS and Documentation

The Authority is ambitiously looking to put in place an online documentation platform which responds to ISO 9001:20215 QMS requirements and thus a number of documents were developed and they include; nine (9) regulations, nineteen (19) guidelines, one (1) manual, eighty-three (83) Standard Operating procedures and ninety-six (96) forms. The revised documents were forty-nine (49) including eight (8) regulations, three (3) guidelines, nine (9) standard operating procedures, and twenty-nine (29) formats.

The authority has QMS internal auditors of 27 members appointed and the team provide daily support to all functions and closely monitor the RS function IDPs and Recommendations. The QMS internal audit has been conducted from 4th January until 11th February 2022 and a final compiled report is proceeding. The authority also had Workshop of technical support on Gap Analysis for certification to the ISO 9001:2015 standards and through the MoU with TMDA, the gaps were identified and are currently being implemented

3.5. Regulatory and Harmonization affairs

Rwanda FDA signed memorandum of understanding with two (2) WHO maturity level 3 African National Regulatory Authorities; Ghana FDA and Tanzania Medicines and medical Devices Authority (TMDA). Rwanda FDA developed and initiated implementation of a joint implementation plan of the signed MoU with TMDA.

A joint action plan to implement the signed MoU between Rwanda FDA and Ghana FDA is under development. In addition, a Projects charter has been completed on Partnerships for African Vaccine Manufacturing (PAVM) and a project concept note is under development.

3.6. Capacity building and trainings

As stipulated in the strategic objective of Rwanda FDA strategic plan which brings emphasis on Strengthening organizational management and capacity building framework for developing, attracting, and retaining talent to ensure effective implementation of the Rwanda FDA's mandate. The authority has therefore prioritised capacitating its workforce as the engine for performance and result completion in different regulatory functions. Below are the details on trainings offered.

3.6.1. Trainings in HMDAR

In Human medicine and devices assessment & registration (HMDAR) a number of trainings were offered and laid a measurable achievement to the authority performance in the year 2021-2022. They include the following;

Training on;

1. Use of available documentation (policies, Laws, technical regulations, guidelines, SOPs, forms and formats, ongoing related initiatives, and use of WHO-GBT) which took place on 31st July 2021 with the aim of introducing staff to system of document development and approval processes, and their levels of applications and fourteen (14) staff were trained,

2. Assessment of Technical Files for Blood Screening In Vitro Diagnostic Medical Devices (IVDs) which took place from 27th to 30th of September 2021and two (2) staff were trained,

3. Quality Management System (QMS) which took place during Division meeting held on 22 November 2021 with the aim of having an overview and introduction on QMS to better understanding and implementing quality Management System and fourteen (14) staff were trained,

4. Assessment of medical devices and IVDs technical files, which took place from 15 to 19th, November 2021 and fourteen (14) staff were trained,

5. Marathon for Vaccine Manufacturing which took place from 5th October to 11th November 2021 for 2 days per week. This was attended by three (3) staff,

6. Evaluation of vaccines and Biological products dossier applications, which took place at Ubumwe Grand Hotel, Kigali from 17th to 21st January 2022 and fourteen (14) staff were trained,

7. Assessment of applications for registration of human and veterinary medicines that took place at Fatima Hotel, Musanze from 27th February to 4th March 2022 and thirteen (13) staff were trained,

8. Risk-Based Post Marketing Surveillance and online MedRS tool V2, which took place from 14th -25th February 2022 and two (2) staff attended training,

9. Assessment of Clinical Trials Applications and Vaccines for Emergency Use Authorization which took place from 14th to 18th February 2022 and seven (7) staff were trained,

10. Good Manufacturing Practices (GMP) and Dossiers Desk Assessment which took place from May 16th to 27th 2022 and three (3) staff attended the training,

11. Documentation format requirements and principles of assessment for the WHO prequalification and emergency use listing of vaccines from 27th June to 1st July 2022 and six (6) staff were trained,

12. 14th Annual PQT medicines quality assessment and 1st Bio therapeutics (BPT) and Similar Bio Therapeutics Product (SBP) assessment and four (4) staff attended the training, E-learning Capacity Building one (1) staff was trained.

3.6.2. Trainings in PV-SM

In pharmacovigilance and safety Monitoring (PV-SM); the authority capacitated its staff in the following areas in the year 2021-2022.

1. Training of Hospital (Public and Private) Focal Persons on Investigation of Serious Adverse Events following Immunization; All Rwanda FDA staff involved in AEFI surveillance and one hundred and twenty-nine (129) health professionals including medical doctors and nurses from all public hospitals and some private hospitals in Rwanda were trained

This training focused on pharmacovigilance system, vaccine safety, adverse event following Immunization (AEFI) reporting, Investigation of serious AEFI and Vaccine safety communication. It was conducted by Rwanda FDA and Rwanda Biomedical Center/Expanded Program for Immunization (RBC/EPI) supported by the WHO country office

2. Training on Risk based Post marketing surveillance of medical products; forty-five (45) participants including Rwanda FDA staff and different stakeholders in post marketing surveillance program mainly Ministry of Health, National Pharmacy Council, Hospitals, central medical stores, wholesale pharmacies, industries, Rwanda Community Pharmacy Union, Rwanda Investigation Bureau, Rwanda National Police, University of Rwanda and Rwanda Revenue Authority

The workshop was held at La Palisse Nyamata Hotel and was facilitated by experts from USAID/PQM+. The participants were trained on principles of RB-PMS and to establish the first Risk-based PMS technical working Group referred to as Risk based PMS technical Committee in Rwanda FDA

3. Training on Pharmacovigilance for the National Pharmacovigilance Advisory committee and Rwanda FDA staff; The training was attended by twenty (20) participants from pharmacovigilance advisory committee and Rwanda FDA.

The training aimed at capacitating members of the pharmacovigilance advisory committee and Rwanda FDA staff in pharmacovigilance and safety monitoring division on causality assessment, risk management, signal detection and investigation, MedDRA terms and reporting tools. The training was supported by USAID-MTaPS

3.6.3. Trainings in CHCAR

The authority also offered trainings to its staff working in Cosmetics and Household Chemicals Assessment and Registration (CHCAR) in the year 2021-2022 and these trainings include the following; the authority has six (6) staff in the field and were differently capacitated through the following trainings effective January to June 2021.
Training on;

1. Regulation of Medical devices including IVDs: Focus on technical files approaches and Post Market Surveillance for COVID-19 assays, Scientific assessment of Vaccines and Biological products, Assessment of Clinical Trials Applications and Vaccines for Emergency Use Authorization, Assessment of human medicinal products and veterinary medical products, Updating the WHO GBT Regulatory system strengthening

2. Human medicines dossiers assessment, Good Manufacturing Practices (GMP) and Dossiers Desk Assessment, Data migration of human medicines dossiers, Documentation Format Requirements and Principles of Assessment for the WHO Prequalification and Emergency Use Listing of Vaccines, Medical devices including IVDs: Focus on technical files approaches and Post Market Surveillance for COVID-19 assays

3. Introduction to Good Clinical Practice (GCP) eLearning, Rwanda FDA gap analysis to ISO 9001:2015, Medicine Dossiers Evaluation and Good Review Practices, validation of narrative report on IDPs, ISO 17025 QMS in Quality Control Laboratory, Report consolidation and Research proposal writing for cow value chain project that is implemented by NIRDA, Development of research proposal for cow value chain project that is implemented by NIRDA

3.6.4. Trainings in FDIEC

The authority also arranged and facilitated staff to attend trainings related to Food and Drugs import and export control (FDIEC) and below are highlights for the fiscal year 2021-2022.

1. Training on The Use of Regulatory and Technical Documents to refresh on different guiding documents used in control of the regulated products. Forty-two staff were trained in August 2021, Training of Vaccines and Biosimilar Assessment for Registration and six (6) staff attended in January 2022, Training of Assessment of Medicines for Registration and four staff trained in February 2022, Training On Testing Micronutrients in Fortified Food Using I-Check. Fifteen (15) staff got trained in May 2022

2. Training on Assessment of Medical Devices and IVDS and six (6) staff got trained in Nov 2021, Training on estimates of Annual Legitimate Requirements (ALRS) For Imports of Precursors of Amphetamine-Type Stimulants and one (1) staff trained in July 2021, Training on the Assessment System for Psychotropic Substances. One (1) staff trained in July 2021, Training on the estimates System for Narcotic Drugs. One (1) staff trained in July 2021, Training on Sluice Room (Bedpan Washers) And Instrument Washers, two (2) staff trained in Sept 2021

3. Virtual cGMP training Marathon for Vaccine Manufacturing Confirmation. One (1) staff trained in Oct 2021, Training On Appeal Against Regulatory Decisions. One (1) staff trained in Oct 2021, Risk Based Post Marketing Quality Surveillance and Medrs Tool and one (1) staff trained in Feb 2022, Iso Virtual Workshop On Stakeholder Engagement, With A Focus On Iso/Casco and two two (2) staff trained in Nov 2021

3.6.5. Trainings in FDIC

The authority also found it relevant and critical to train its staff in food and Drugs inspection and compliance in the year 2021-2022. The trainings offered and the affected staff include the following;

1. Authorisation and Licensing of Blood Establishments (Review of Quality Documentation of Blood and Blood Components)" training workshop 'JULY 2020-JULY 2021 and eight staff trained, 'Virtual cGMP Training Marathon for Vaccine Manufacturing' in response to Member States' requests for capacity building to address challenges and improve. eight (8) staff were traied

2. Assessment of Human Medicine and Assessment and Registration of product registration and three (3) staff trained, cGMP Training and one (1) staff trained, one (1) staff trained on Current GMP and General aspects of Aseptic manufacturing of Pharmaceutical products, Documentation Format Requirements and Principles of Assessment for the WHO Prequalification and Emergency Use Listing of Vaccines and eight (8) staff trained

3. East African Community- GMP for Veterinary Medicines environment and one (1) staff trained, From Good practices to the best practices in blood and blood components referring to GPG and GMP and five (5) staff trained, GMP Inspection - Medical Devices and nine (9) staff were trained, GMP Inspection and one (1) staff trained, GMP training and GMP desk assessment and thirty (30) staff were trained.

4. High check Rapid test kit for Iodine, Vitamine A, Iron Detection food products with nine (9) staff trained, ISO/IEC 17025/2017 and QMS training with one (1) staff trained, Leadership, Management and Governance for Health Systems Strengthening (eLMG-HSS) and one (1) staff trained, Overview of clinical trials in Rwanda: State of play, Regulatory provisions and approval procedure for clinical trials in Rwanda and one (1) staff trained.

5. Overview of clinical trials in Rwanda: State of play, Regulatory provisions and approval procedure for clinical trials in Rwanda and two (2) staff were trained, Pharmacovigilance training and one (1) staff attended, Study tour in Germany on strengthening NRAs one staff affected, Training on assessment of clinical trials applications and Vaccines for Emergency Use Authorization and seven (7) staff were trained, Training on Use of Aflatoxin and Moisture Rapid Test Kit and eight (8) staff were trained

6. Training workshop on Assessment of product registration dossiers for Human and Veterinary Medicines, Clinical Trials and assistance on implementation of IDPs from Self Benchmarking Assessment and six (6) staff were trained, Virtual training on scientific assessment of Vaccines and Biological products in which nine (9) staff were trained, webinar: Applying behavioural and cultural insights to tackle antimicrobial resistance and one (1) staff trained.

3.6.6. Trainings in VMDAR

A number of trainings were also offered to staff in charge of veterinary medicine and devices assessment and Registration. They include;

1. GMP training & GMP Desk Dossier review by USAID-PQM+ and three (3) staff attended from 16th up to 27th May, 2022 in Musanze.

2. Five days Training on application Assessment for registration of Human & Veterinary Medicine BY WHO and six 6) staff were trained from 28th February to 4th March, 2022 in Musanze.

3. Five days Training workshop on assessment of clinical trials applications & Vaccines for Emergency Use Authorisation BY WHO and six (6) staff were trained from 14th to 18th February 2022

4. EAC-MRP Virtual GMP Training on Veterinary Medicine Inspection by GIZ and five (5) staff attended from 15th to 23rd November, 2021.

5. Five days Capacity building workshop on evaluation of vaccines dossiers in Rwanda by MTaPS -USAID with six (6) staff were trained from 17th to 21st January 2022.

6. Four days Virtual Training Workshop on the Documentation Format Requirements and Principles of Assessment for the WHO Prequalification and Emergency Use and four (4) staff attended,
7. Quality Management System based on ISO 9001:2015 Organized by MMCL Africa and one (1) staff attended from 13th -17th September,2021 in Kigali.

8. EAC MRP Training on Veterinary Pharmaceutical Dossier Assessment by EAC MRP, GALVmed and two (2) VMDAR staff were trained from 09th to 12th May 2022 in Nairobi.

9. Training on HACCP Food Safety Management Systems Internal Auditors, Training based on ISO 19011:2018 guidelines on Auditing Management Systems organised by RSB &MMCL one (1) staff was trained from 08th to 12th November,2021 in Kigali.

10. Training on ISO/IEC 17025:2017 based QMS, Corrective action with root cause analysis and internal auditor organized by USAID, USP, PQM Plus and one (1) staff was trained from 13th to 17th June 2022.

11. Virtual training on Foundations of GMP: Training on Deviations, Root Cause Analysis (RCA) Tools and Corrective and Preventive Action (CAPA) - Sequence flow for handling of any non-conformance in the GMP environment offered by PQM+, USP and USAID and one (1) staff attended from 26th -27th May 2022

12. Virtual Foundations of GMP: Training on Medicinal Products, Part of the Foundations in Good Manufacturing Practices (GMP) offered by PQM+USP and USAID and one (1) staff was trained from 22nd to 23rd May 2022.

13. Virtual Foundations of GMP: Active Pharmaceutical Ingredient (API) Certificate awarded on Thursday, May 26, 2022 offered by PQM+USP and USAID with one (1) staff trained,

14. Virtual Basic principles of Supply chain management for Health system and attended by one (1) FDA staff,

15. Virtual training on Capacity building for assessment of Medical devices & in vitro diagnostics (IVDs) technical files that took place from 15th to 19th November 2021 offered by MTaPS and USAID and two (2) staff from VMDAR division were trained

3.6.7. Trainings in QCL

In Quality Control Laboratory, trainings were also organised for staff and they include among other for twenty-eight (28) staff in the field.

1. Training on ISO/IEC 17025 based QMS, Corrective action with Root Cause Analysis, UNFPA In-Country Laboratory Training for Requirements and Test Methods of Male Latex Condoms and Female Condoms, Quality Assurance in a Testing Laboratory (ISO/IEC 17025), ISO/IEC 17025:2017 Uncertainty Measurement

2. Quality assurance and quality management in the context of combating antimicrobial/antibiotic resistance held at The Federal Institute for Drugs and Medical Devices (BfArM) and The Institute for Pharmaceutical and Applied Analytics (InphA), Deviations, Root Cause Analysis (RCA) Tools and Corrective and Preventive Action (CAPA) - Sequence flow for handling of any non-conformance in the GMP environment, introduction to ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories" with focus on quality control laboratories in the pharmaceutical sector,

3. Introduction to ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories" with focus on quality control laboratories in the pharmaceutical sector, Training on Dissolution Apparatus Quantification: USP Guideline on procedures for Mechanical qualification and performance verification test: Apparatus 1 and Apparatus 2, Training on ISO/IEC 17025:2017 based QMS with PQM+, Corrective action with root cause analysis and internal audit

3.7. Revenues generated

Throughout the fiscal year 2021-2022, the Authority from its rendered services of registration, retention/renewal and variation of registered products, inspection, operational license/permit/certificate among others generated six billion one hundred and eighty million twenty three thousand and four hundred sixteen (6,180,023,416rwf) which is 0.6% increase as compared to six billion one hundred thirty-nine million and two hundred ninety-seven (6,139,897,297 frw) generated from the previous fiscal 2020-2021.

3.7.1. Annual Budget Execution

The budget execution rate is 83% when relating the allocated budget 8,435,678,120 frw to effected budget of 7,006,511,260 for the fiscal year 2021/202

3.8. Concluding Remarks

In the fiscal year 2021-2022, the authority's performance is earnest to acknowledge the efforts of the organizational staff in different regulatory and enabling functions. It has tremendously registered a desired improvement in National Regulatory Systems, Registration and Marketing Authorization, Regulatory Inspection, Vigilance, Market Surveillance and Control, Licensing Establishments, Clinical Trials Oversight and Laboratory Testing.

There are also good records in food safety and import-export market control of the regulated products. The authority however is focused on areas that did not weigh up as well as anticipated and achieving higher in the fiscal year 2022-2023 accounting to quality and quick service delivery and on time regulatory decisions.

Review of the performance on the annual plan.														
Indicators	**Baseline 2020-2021**	**Planned target 2021/22**					**Achieved Target 2021/22**					**On track (Y/N)**	**Observations**
		Q1	Q2	Q3	Q4	Annual	Q1	Q2	Q3	Q4	Annual		
% of drugs assessed (both vet and Human)	20	35	50	65	75	75	73	75	77	79	79	Yes	
% of assessed Medicated cosmetics and household chemicals	8	28	48	68	85	85	66	82	83	85	85	Yes	
% of processed food and food supplements registered	38	48	65	80	95	95	25	30	33	33	33	No	The applicants have not complied to registration requirements as they have not provided the additional data on queries raised during assessment
% of Health Technologies Assessed/ medical devices Assessed	5	20	40	60	80	80	16	18	20	29	29	No	More efforts were put in clearance of backlogs in human medicine and; Staffs were not trained on assessment of medical devices
% of ADR/AEFI reports received and analysed	60	65	70	75	80	80	47	61	62	67	67	Yes	The remaining ADR reports were analysed and reported by the internationally recognized regulatory authorities
# of Food safety	60	10	10	20	10	50	24	20	23	15	82	Yes	

inspections conducted													
# of samples tested for Post Marketing Surveillance(PMS)	35	40	20	20	20	100	15	66	29	20	130	Yes	
% of clinical trial applications reviewed within set timelines	80	82	84	86	90	90	100	100	100	100	100	Yes	
# of food premises inspected	120	60	80	80	80	300	405	251	232	189	1077	Yes	
# of pharmaceutical premises inspected	150	50	60	70	70	250	306	380	292	250	1227	Yes	
% of import licenses issued for regulated products.	100	100	100	100	100	100	100	100	98	96	96	Yes	4% failed to comply with importation requirements
% of export licenses issued for regulated products	100	100	100	100	100	100	100	100	100	100	100	Yes	
% of Rwanda FDA laboratory performance capacity	15	Tender procedures	Tender procedures	Contract management	48	48	0	0	0	0	15	No	No successful bidder acquired and accordingly tenders were Re-advertised