2024

NAFDAC ANNUAL REPORT

NAFDAC: Customer-focused; Agency-minded.

NAFDAC Vision, Mission and Core Values

Vision

To be a world-class regulator that ensures availability of quality and safe food, drug and other NAFDAC regulated products

Mission

To protect and promote the public health by instituting an effective and efficient regulatory system that ensures only the right quality Food, Drugs and other regulated products are manufactured, exported, imported, advertised, distributed, sold, and used.

Core Values

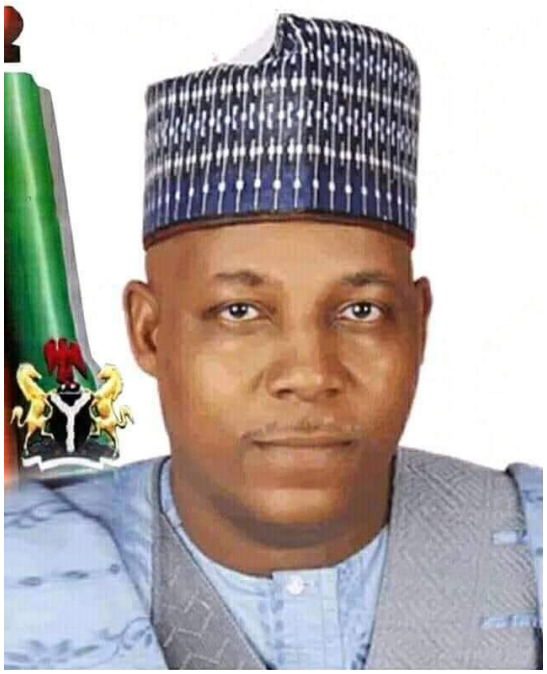
NAFDAC staff members are Customer-focused, Agency-minded and are guided by the following core values 'PRIDE':

1. Professionalism
2. Resilience
3. Integrity (Transparency & Good Governance)
4. Dedication & Commitment
5. Excellence

His Excellency

Bola Ahmed Tinubu *GCFR*

President and Commander in Chief of the Armed Forces of the Federal Republic of Nigeria



His Excellency

SEN. KASHIM SHETIMA *GCON*

Vice President of the Federal Republic of Nigeria

PROF. ALI PATE

Coordinating Minister of Health and Social Welfare

Dr. TUNJI ALAUSA

Honourable Minister of State for Health and Social Welfare

DAJU KACHOLLOM *mni*

Permanent Secretary, Federal Ministry of Health and Social Welfare

Prof. Christianah Mojisola Adeyeye *FAS*

Director General, NAFDAC

Foreword

It is my pleasure to present the 2024 Annual Report of NAFDAC, highlighting our efforts to ensure the safety and quality of food and drugs for the nation's well-being.

As a regulatory Agency, NAFDAC has continued to sustain its ISO 9001:2015 Certification since 2019 and has also attained the Maturity Level 3 of the WHO Global benchmarking for regulatory authorities and is working towards Level 4. Our Central Drug Control Laboratory (Yaba, Lagos) has also continued to sustain its WHO Pre-qualification since 2023.

This report showcases our achievements, challenges, and future directions in regulating the food and pharmaceutical industries. Our work is crucial in protecting public health, promoting compliance, and fostering trust in the products that reach our markets.

I commend our dedicated staff for their tireless efforts in enforcing regulations, conducting inspections, and engaging stakeholders. Their commitment to excellence has been instrumental in advancing our mission of protecting and promoting the public health by instituting an effective and efficient regulatory system that ensures only the right quality Food, Drugs, and other regulated products are manufactured, exported, imported, advertised, distributed, sold, and used.

As we reflect on the past year and look ahead, we remain committed to our mandate of safeguarding public health and promoting a safe and healthy environment for all.

Key Highlights

- Regulatory oversight and enforcement.
- Product registration and approval.
- Inspections and compliance monitoring
- The successful conduct of the first Benchmarking of a National Regulatory Agency (NRA) in Africa on Medical Devices and IVDs Benchmarking toward the attainment of ML3 Status
- Public education and awareness
- Global Collaboration and Reliance
- Efficient Financial Management
- Training and retraining of staff.
- Gazetting of Seventeen (17) Regulations within the period under review
- Provision of infrastructure, equipment and working tools

Looking Ahead

- Strengthening regulatory frameworks
- Enhancing enforcement capacity
- Achievement of WHO Listed Authority Status (WLA) and ML4.
- Improving public engagement and awareness
- Sustained efficient financial management
- Sustained collaboration with local and international stakeholders
- Provision of more infrastructure and working tools

Conclusion

NAFDAC has recorded significant success in its quest for compliance with international standards and ensuring the people of Nigeria have access to safe and efficacious products.

Counting on what the Agency has achieved so far and where we intend to be as a regulatory Agency, we are determined to remain customer-focused and Agency-minded in our quest to safeguard the health of the nation.

Prof. Christianah Mojisola Adeyeye, *PhD, FAS*
Director-General

List of Abbreviations/Acronyms

ADR: Adverse Drug Reaction
AEFI: Adverse Events Following Immunization
AFBTE: Association of Food, Beverage and Tobacco Employers
AfCTA: African Continental Free Trade Area
APIs - Active Pharmaceutical Ingredients
ATM: HIV/AIDs, Tuberculosis and Malaria
AMR: Anti-Microbial Resistance
AMU: Anti-Microbial Usage
BMS: Breast-Milk Substitutes
BCMS: Business Continuity Management System
CAPA: Corrective and Preventive Action
CBN - Central Bank of Nigeria
CEO - Chief Executive Officer
CER - Chemical Evaluation & Research
CRIA - Clean Report of Inspection Analysis
CCLAC: Coordinating Committee for Latin America and the Caribbean
CCNE: Coordinating Committee for Near East Region
CCCF: Codex Committee on Contaminants in Foods
CT: Clinical Trials Oversight
CTD - Common Technical Documents
CTAC: Community Treatment and Care
CWG: Country Working Group
DER - Drug Evaluation and Research
DFQT+: Digital Fortification Quality Traceability Plus
DVFA: Danish Veterinary and Food Administration
DG - Director General
DMS: Dossier Management System
D, LS (F&C): Director Laboratory Services Food and Chemicals
D, LS (Drug): Director Laboratory Services, Drug
D, ALS: Director, Agulu Laboratory Services
D, KLS: Director Kaduna Laboratory Services
D, VBM-LS: Director Vaccines, Biologics and Medical Devices Laboratory Services
D, DER: Director, Drug Evaluation and Research Directorate
D, DR&R: Director, Drug Registration and Regulatory Affairs
D, FR&R: Director, Food Registration and Regulatory Affairs
D, PRS: Director Planning Research and Statistics Directorate
D, VMAP: Director Veterinary Medicines & Allied Products
D, HRM: Director, Human Resource Management Directorate
D, PID: Director, Ports Inspection Directorate
D, PA: Director, Public Affairs Unit
D, NCS: Director, Narcotics and Control Substances Directorate
D, LSO: Director, Lagos State Office
D, FCT: Director, Federal Capital Territory
D, I&E: Director, Investigation and Enforcement Directorate
D,LeSD: Director, Legal Services Directorate
D, CER: Director Chemical Evaluation and Research Directorate

DHIS - District Health Information System
EPMS: Employee Performance Management System
F&A - Finance and Accounts
FDA - Food and Drug Administration (United States)
FMoHSW - Federal Ministry of Health and Social Welfare
FSAN - Food Safety and Applied Nutrition
FPPs - Finished Pharmaceutical Products
GAAP: Generally Accepted Accounting Principles
GRIDS: Global Rapid Interdiction of Dangerous Substances
GDP: Good Distribution Practices
cGMP - Current Good Manufacturing Practices
GS1: Global Standard
GMP: Good Manufacturing Practices
GHP: Good Hygienic Practices
HRM - Human Resource Management
KPIs: Key Performance Indicators
HRMIS - Human Resources Management Integrated System
IA - Institutional Assessment/Analysis
ICT - Information Communication Technology
IDPs: Institutional Development Programs
IEC: Information and Education Communication Materials
iTFAs: Industrially Produced Trans Fatty Acids
INFOSAN: International Food Safety Authorities Network
ICSRs: Individual Case Safety Reports
I&E - Investigation and Enforcement
ICH - International Conference on Harmonization
INGO - International Non-Governmental Organization
IPSAS: International Public Sector Accounting System
ISPTO: International Strategic Partnership and Trade Office
ISO - International Organization for Standardization
ISMS: Information Security Management System
INCB - International Narcotics Control Board
IVDs: In Vitro Diagnostics
LAN: Local Area Network
LI: Licensing Establishment
LIMS - Laboratory Information Management System
LS - Laboratory Services
LSFF: Large-Scale Food Fortification
LT: Laboratory Testing
LR: Lot Release
MA: Registration and Marketing Authorization
MC: Market Surveillance and Control
MAHs: Marketing Authorization Holders
MAS - Mobile Authentication Service
MDGs - Millennium Development Goals
MDAs - Ministries, Departments and Agencies
MIYCN: Maternal Infant and Young Child Nutrition
MNDC: Micronutrient Deficiency Control

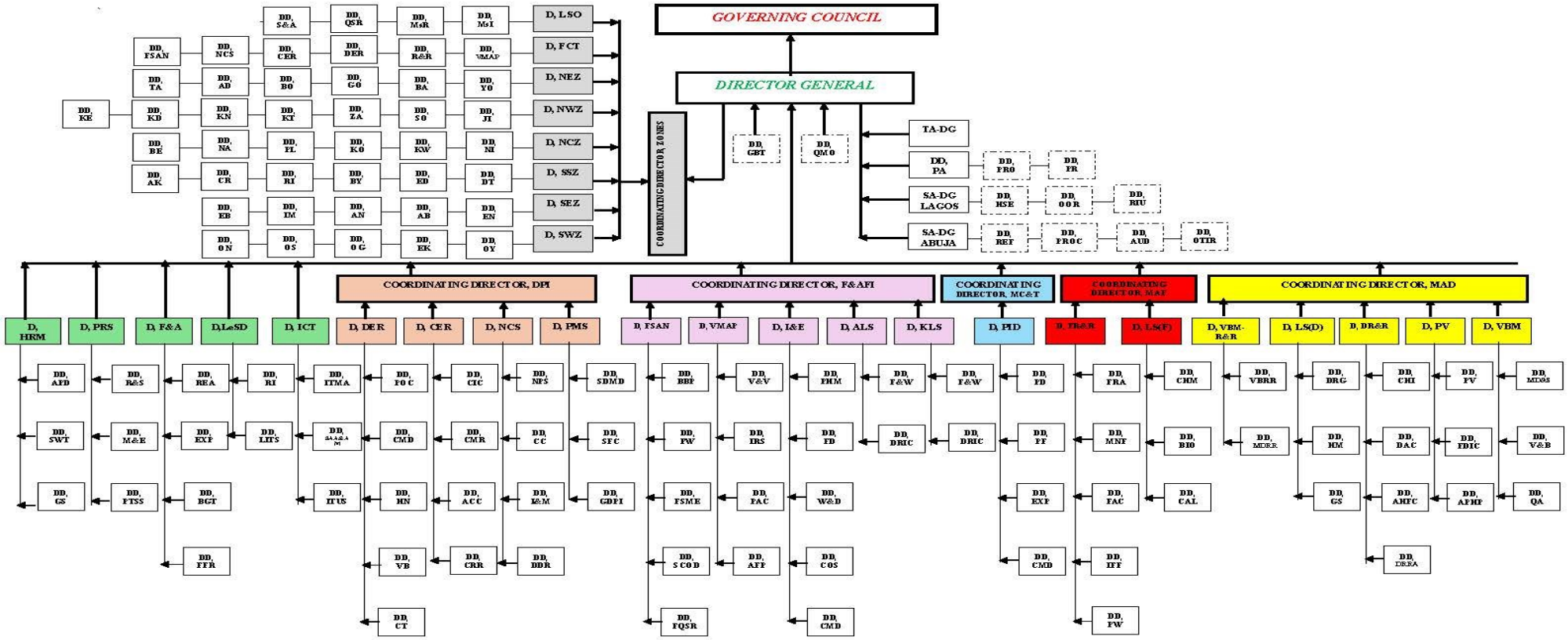
M&E - Monitoring and Evaluation
MRA - Medicines Regulatory Agencies
MoU - Memorandum of Understanding
MSMEs - Micro, Small & Medium Enterprises
NARPAD: NAFDAC Registered Products Automated Database
NAFDAC - National Agency for Food and Drug Administration and Control
NAPAMS - NAFDAC Automated Product Administration & Monitoring System
NCS - Nigerian Customs Service/Narcotics and Controlled Substances
NHLMIS: National Health Logistics Management and information system (NHLMIS)
NFCMS: National Food Consumption and Micronutrient Survey
NRCOC: National Recognition of community origin committee
NFSMC: National Food Safety Management Committee
NICIS - Nigerian Integrated Customs Information System
NGO - Non-Governmental Organizations
NHREC - Nigerian Health Research Ethics Committee
NCC-TC: National Codex Committee – Technical Committee
NHREC: National Health Research Ethics Committee
NICIS: Nigeria Integrated Customs Information System
NDEPS: National Economy Policy and Strategy
NDPR: Nigeria Data Protection Regulation
NGEA: Nigeria Government Enterprise Architecture
NGFHP: NAFDAC Guidelines for Food Hygienic Practices
NIPC: Nigerian Investment Promotion Commission
NOTN: Nigerian Office of Trade Negotiation
NFA: National Fortification Alliance
PA - Public Affairs
PEBEC: Presidential Enabling Business Council
PPEs: Personal Protective Equipment
PO: Purchase Orders
PID - Port Inspection Directorate
PIDCARMS:
PRASCOR - Pharmacovigilance Rapid Alert System for Consumer Reporting
PRS - Planning Research & Statistics
PV - Pharmacovigilance
PMS - Post Market Surveillance
PQM - Product Quality Management
Q1: Quarter one
Q2: Quarter two
Q3: Quarter three
Q4: Quarter four
QA - Quality Assurance
QC - Quality Control
QMS - Quality Management System
RA: Regulatory Systems
R&R - Registration and Regulatory Affairs
RMP: Remote Patient Monitoring
REMITA: Payment gateway for Federal Government Funds generated from levies, taxes and tariffs
RI: Regulatory Inspections

SF - Strategic Focus
SFs - Substandard and Falsified Medicines
SMEDAN: Small and Medium Enterprises Development Agency of Nigeria
SO - Strategic Objective
SOP - Standard Operating Procedure
SWOT - Strengths, Weaknesses, Opportunities and Threats
SPS: Sanitary and Phyto-Sanitary
SSC: Strategic Sector Cooperation
TMC - Top Management Committee
TRS: Time Release Study
UNICEF - United Nations Children's Fund
UNIDO - United Nations Industrial Development Organization
UNODC: United Nations Office on Drugs and Crime
USAID - United States Agency for International Development
USAT: User Satisfaction survey
VAT: Value Added Tax
VMAP - Veterinary Medicines & Allied Products
VL: Vigilance
WCO: World Customs Organization
WLA: World Listed Authority
WHO - World Health Organization
WHO ML4: World Health Organization Maturity Level Four
WHO-GBT - World Health Organization-Global Benchmarking Tool
YEP: Youth-Entrepreneurship Program

NAFDAC Organogram

ANNEXURE 3	SOP Ref. No.: NAFDAC-QMS-023-02	Title of Annexure: NAFDAC ORGANOGRAM

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC) ORGANOGRAM



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Chapter 1
Historical Background

1.0 Introduction

NAFDAC was established as a parastatal of the Federal Ministry of Health to give a frontal attack to health problems arising from food, drugs, chemicals and other similar regulated products without the inhibition of the civil service setting.

Until 31st December 1992 the responsibility of preventing the hazards arising from unwholesome foods, ineffective, substandard and adulterated drugs, toxic and corrosive cosmetics and chemicals as well as contaminated packaged water was vested on Department of Food and Drugs Administration and Control (FDAC) of the Federal Ministry of Health. However, with the rising incidences of counterfeit and substandard drugs, unwholesome food, etc., as well as the need to overcome bureaucratic bottlenecks of the Ministry, NAFDAC was created to attend to these challenges promptly and decisively.

The National Agency for Food and Drug Administration and Control (NAFDAC), established by Decree No. 15 of 1993 as amended and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004.

The Act mandates the Agency to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of Food, Drugs, Cosmetics, Medical Devices, Bottled Water, Chemicals and Detergents (known as regulated products).

Vision:

To be a World Class Regulator that ensures availability of quality and safe Food, Drugs and other regulated products.

Mission

To protect and promote the public health by instituting an effective and efficient regulatory system that ensures only the right quality Food, Drugs and other regulated products are manufactured, exported, imported, advertised, distributed, sold, and used.

Core Values:

The PRIDE core values of the Agency are:
1. Professionalism
2. Resilience
3. Integrity (Transparency & Good Governance)
4. Dedication & Commitment
5. Excellence

1.1 Brief History of NAFDAC and Organizational Structure

NAFDAC pioneer Governing Council was inaugurated on 31st December 1992 with Prof. G.E. Osuide as the Director-General. In April 2001, Prof. (Mrs.) D.N. Akunyili (OFR) was appointed the Director-General to replace The Interim Management Committee (IMC). She left the services of NAFDAC in December 2008 following her appointment as a Federal Minister and was replaced by

Pharm. (Mrs.) D.I. Amlai as the Acting Director-General until the appointment of Dr. P.B. Orhii (Ph.D, FAS, OON) on the 9th of January, 2009. Following the removal of CEOs of Government Agencies by President Muhammadu Buhari (GCFR), Mrs. Yetunde O. Oni assumed office as Acting Director-General in February 2016 until her retirement in September 2017. Mr. A.A. Mogbojuri (FCA) assumed the helm of affairs of the Agency until the appointment of a substantive Director-General, Prof. Mojisola Christianah Adeyeye (Ph.D, FAS) on 3rd November 2017.

The Top Management: The Top Management Staff of NAFDAC comprises:

Director General - Prof. Mojisola Christianah Adeyeye, PhD, FAS

- Director Veterinary Medicine and Allied Product – Pharm. Rametu O. Momodu
- Director, Narcotics and Controlled Substances – Pharm. Yedunni Adenuga
- Director, Finance and Accounts – Mr. Ayangbenga O. Ayanwande
- Director South West Zone –Mrs. Roseline Ajayi
- Director Food Safety and Applied Nutrition – Mrs. Eva Edwards
- Director Federal Capital Territory – Mr. Kenneth Azikiwe
- Director North Central Zone – Pharm. Francis Ononiwu
- Director, Investigation and Enforcement – Pharm Shaba Muhammad
- Director, Drug Registration and Regulatory Affairs – Pharm. Uche Sonny-Afoekelu
- Director, Chemical Evaluation and Research – Dr. Patrick Omakpariola
- Director Laboratory Services (Food) – Pharm Babatunde Yusuf
- Director, Food Registration and Regulatory Affairs - Mr. Kayode Fagboyo
- Director Agulu Laboratory Services – Pharm. Ngozi Onuigbo
- Director, Post Marketing Surveillance – Pharm. Bitrus D. Fraden
- Director South East Zone – Pharm Iluyomade Martins
- Director South South Zone – Pharm. Chukuma Oligbu
- Director, Planning, Research and Statistics – Pharm. Chike Obiano
- Director, Drug Evaluation and Research – Pharm. Kayode Amuda
- Director, Pharmacovigilance – Pharm. Uche U. Elemuwa
- Director Human Resource Management – Mr. Augustine Oboli
- Director North West Zone – Mr. Nantim M. Dadi
- Director, Ports Inspection Directorate – Dr. Olakunle D. Olaniran
- Director National Vaccine Control Laboratory, Mrs. Eunice Iyabowale Adegoke
- Director, Kaduna Laboratory Services, Pharm Unoma Asomugha
- Director Laboratory Services (Drugs) – Pharm. Nkem Ifudu
- Director, Lagos State Office – Pharm. Stephanie Adeoye
- Director, Vaccine, Biologicals and Medical Devices Registration and Regulatory Affairs – Pham. Khadijah Ade-Abolade
- Director, Director General's Office - Dr. Festus Ukadike
- Ag. Director Legal Services - Barr. Muhammad Habib Bello
- Deputy Director i/c, North East Zone – Mr Bashir Muazu
- Deputy Director i/c Information and Communication Technology – Mr. Olufemi O. Balogun
- Service Units in the Office of Director General:

✓ Special Assistant to DG NAFDAC (Lagos) – Dr. Gbenga Fajemirokun

1.2 Functions of NAFDAC

The functions of NAFDAC as provided in the enabling law that establishes it are to:

- Regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water, Chemicals and detergents (Regulated Products).
- Conduct appropriate tests and ensure compliance with standard specifications designated and approved by the Council for effective control of the quality of food, drugs, cosmetics, medical devices, bottled water and chemicals (regulated products) and their raw materials as well as their production processes in factories and other establishments.
- Undertake appropriate investigations into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water and chemicals (regulated products) and establish relevant quality assurance systems, including certification of the production sites and of the regulated products.
- Undertake inspection of imported food, drugs, cosmetics, medical devices, bottled water and chemicals (regulated products) and establish relevant quality assurance systems, including certification of the production sites and of the regulated products.
- Compile standard specifications and guidelines for the production, importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water and chemicals (regulated products);
- Undertake the registration of foods, drugs, cosmetics, medical devices bottled water, Chemicals and detergents.
- Control the exportation and issue quality certification of food, drugs, cosmetics, medical devices, bottled water and chemicals intended for export.
- Establish and maintain relevant laboratories or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions.
- Pronounce on the quality and safety of food, drugs, cosmetics, medical devices, bottled water and chemicals after appropriate analysis.
- Undertake measures to ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes.
- Grant authorization for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances.
- Collaborate with National Drug Law Enforcement Agency (NDLEA) in measures to eradicate drug abuse in Nigeria.
- Advise Federal, State and Local Governments, the private sector and other interested bodies regarding the quality, safety and regulatory provisions on food, drugs, cosmetics, medical devices, bottled water and chemicals (regulated products).
- Undertake and coordinate research programmes on the storage, adulteration, distribution and rational use of food, drugs, cosmetics, medical devises, bottled water and chemicals.
- Issue guidelines on, approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals.
- Compile and publish relevant data resulting from the performance of the functions of the Agency or from other sources.
- Sponsor such national and international conferences as it may consider appropriate.
- Liaise with relevant establishments within and outside Nigeria in pursuance of the functions of the Agency.

- Determining the suitability or otherwise of medicines, drugs, food products, cosmetics, medical devices or chemicals for human and animal use.
- Carry out such activities as are necessary or expedient for the performance of its functions.

1.3. NAFDAC Offices and Location

The Agency operates from various offices across the country. These offices consist of:

- **Corporate Headquarters** located at Plot 2032, Olusegun Obasanjo Way, Wuse Zone7, Abuja. In addition to the Director General's office, the head office houses the following Directorates: Pharmacovigilance/Post Marketing Surveillance, Planning, Research & Statistics, Admin & Human Resources Management, Finance & Accounts, the office of Public Affairs and FCT Office.

- **Lagos Operational Office** located at Block D, Plot 2, Isolo Industrial Estate, Oshodi-Apapa Express Way, Lagos

- **Six Zonal Offices** located as follows.
  - North East - NAFDAC Laboratory Complex Biu Road, Maiduguri.
  - North West – No. 2, Hospital Road, Narayi High-Cost, Kaduna.
  - North Central - Federal Secretariat, 6th Floor, Room 614, Jos.
  - South East - Federal Secretariat, Independence Layout Enugu.
  - South West - Federal Secretariat, Jericho Ibadan.
  - South South – Federal Secretariat, PH, River State.

- **Thirty-Six (36) State Offices** located in all States of the Federation and FCT Office.
- **Six Laboratories** at Oshodi - Lagos, Yaba - Lagos, Kaduna, Maiduguri, Calabar, and Agulu - Anambra State.
- **Ports and Land Border offices**, located at Lagos (Tincan, Lilypond and Apapa), Port Harcourt, Warri, Calabar, Seaports, Airports (Murtala Mohammed Lagos, Nnamdi Azikiwe Abuja and Aminu Kano) and Land border posts (Seme, Idiroko, Mfum, Jibiya, Kamba, Illela and Maigatari)

- One Stop Investment Center (OSIC) - NIPC Building Maitama, Abuja.

Chapter 2
Strengthening of the Regulatory Framework of NAFDAC

2.1 WHO Benchmarking

In November 2017, the management was driven with the passion to Strengthening Nigeria Regulatory System using the WHO Global Benchmarking Tool (GBT) approach.

On the 30th of March 2022 upon the critical evaluation of the Eight Hundred and Sixty-Eight (868) evidence to review for system strengthening, WHO officially ranked Nigeria's National Regulatory Agencies as Maturity level 3, meaning a Stable, well-functioning and integrated regulatory system and eligible for inclusion into the transitional WHO Listed Authorities (WLA) after additional evaluation of their performance to be globally recognized as meeting WHO and other international standards.

The Agency is now working assiduously towards the Attainment of WHO ML4 and World Listed Authority (WLA) Status. Attainment will enable:

- Global trade of Nigerian-made pharmaceuticals through collaborative registration with other regulatory agencies
- Local Pharma manufacturers to be more competitive in AFCTA

Activities of NAFDAC WHO – Global Benchmarking

The GBT 2024 work plan was fully implemented to meet all targets and goals in 2024.

1. A total of 26 WHO Assessors arrived in Nigeria for 5 days and conducted a formal Re-Benchmarking of the Eight Regulatory Functions on Medicines and Vaccine ML3 Status (25-29th November 2024)
2. The first ever Medical Devices and IVDs Formal Benchmarking was carried out by WHO co-currently within the same period.
3. The NAFDAC GBT Conducted two (2) internal Mock Benchmarking for all 9 Regulatory functions including Lot Release
4. Conducted 10 monthly CAPA review follow up meeting after the internal Benchmarking.
5. Carried out quarterly assessment of all regulatory functions to review and address all recommendations toward ML4 Sub-indicators across regulatory functions.
6. A total of 75 weekly review meetings in line with the 2024 work plan were carried out.
7. Held one week Residential in-person joint NAFDAC-PCN IDPs review meetings with WHO Country office.

The Re-benchmarking started from 25th November 2024 with an opening ceremony at NAFDAC headquarters Isolo, Lagos where all functions were being assessed except for LT at Yaba and RS and VL in Abuja.

At the end of the re-benchmarking, the draft report of the re-benchmarking was presented by the assessors on Thursday 28th November 2024 at Isolo, Lagos while the closing ceremony took place on Friday 29th November 2024 in Abuja.

Status of WHO recommendations Re -benchmaking

Functions	Number of sub-indicators needed to be implemented to keep ML 3	Number of Recommendations to keep ML 3
01-NATIONAL REGULATORY SYSTEM (RS)	1	1
02-REGISTRATION AND MARKETING AUTHORIZATION (MA)	2	7
03-VIGILANCE (VL)	0	0
04-MARKET SURVEILLANCE AND CONTROL (MC)	2	8
05-LICENSING ESTABLISHMENT (LI)	6	13
06-REGULATORY INSPECTION (RI)	5	16
07-LABORATORY TESTING (LT)	2	7
08-CLINICAL TRIAL'S OVERSIGHT (CT)	0	0
Total	**18**	**52**

2.2 Information Communication Technology (ICT) Directorate

The Information Communication Technology (ICT) Directorate is headed by Deputy Director i/c with office in NAFDAC Headquarters and comprises three divisions.

The following are the Key Achievements of the Directorate under the period of review:

1. **IT Infrastructure**

- Procured and distributed 75 systems (60 laptops and 15 desktops with UPS) to Directorates, Zonal Offices, Laboratories, QMS, Dossier Review Team, Senior Officers, and IT Staff.
- Conducted preventive maintenance on 88% of the IT infrastructure.
- Repaired 85 faulty systems (80% of reported issues).
- Successfully performed routine quarterly network infrastructure maintenance. For major offices systems.
- Provided and supported Cloud hosting of critical Regulatory Systems for 8 applications.
- Renewed 1,000 antivirus licenses desktops and laptops.
- Provided internet services (LAN and Wireless) at NAFDAC office locations.
- Hosted over 322 virtual meetings and trainings using Zoom and Microsoft Teams,
- Provided collaborative platform for WHO GBT Assessment

2. Website and Information Security Services

- Re-developed and upgraded the Website for better information dissemination Enhanced the website with additional sections and improved design.
- Implemented Web Page Search functionality for WHO Global Benchmarking Tool and Quality Management System requirements.
- Uploaded 221 new contents and reviewed/update 116 existing ones.
- Implemented Information Security Management System and Business Continuity Management System

3. **Supported IT Systems and Applications**

- Managed and supported corporate email services.
- Maintained and supported SAP ByD accounting solution for Finance & Account Directorate.
- Provided NAPAMS support services.
- Clinical Trials Application support services
- Provided e-permit system support.
- Maintained Laboratory Information Management System (LIMS) services in NAFDAC Laboratories across the country.
- Supported video conferences via Zoom and Microsoft Teams.
- Managed email services and renewed Microsoft 365 licenses.

4. IT Project: IT project Initiated/completed:

- Migrated staff mails from Galaxy backbone services to Microsoft 365 cloud services.
- Deployed full Microsoft 365 to 2100 staff.
- Upgraded NAFDAC GreenBook - Registered Drug Database
- Upgraded Dossier Management System (DMS) for R&R (Drug) Directorate
- Upgraded NAFDAC Automated Product Administration and Monitoring Services version 3 for product registration and inspection.
- Upgraded Laboratory Information Management System for Oshodi and Yaba laboratories.

Overall, the ICT Directorate has made significant progress in enhancing IT infrastructure, improving website and information security services, supporting critical IT systems and applications, and driving IT projects forward.

Chapter 3
Offices In Director -General's Office

3.1 Public Affairs

Public Affairs is one of the Units in the Director-General's Office with the primary responsibility of projecting the corporate image of NAFDAC, promoting its activities and programs, arranging International Trips and Foreign GMP Inspections for foreign companies and serve as an interface with the public.
The office has two main divisions, namely: Public Relations and Protocol.

3.1.1 Activities of Public Relations Unit

Publicity of NAFDAC activities: This includes enforcement, destruction exercises, prosecutions/convictions, workshops, advocacy meetings/visits and town hall/stakeholder's forum. Some of the activities covered and publicized by the office within the period under review are highlighted below.

1. **Media Coverage of Meetings, Press Conferences, Enforcement Activities, Sensitization and Trainings in 2024.**

- Publicity of NAFDAC Alert Notice on substandard and contaminated Syrups (Alergo Syrup, Emidone Suspension, Mugorid Syrup, Ulcofin Suspension and Zincell Syrup) from Pharmix Laboratories Ltd. Pakistan – 7th January 2024.
- Coverage and publicity of the Director General's Press Conference on the enforcement activities to enforce ban on production of alcohol beverages in sachet and small volume PET bottles below 200ml. - 5th January 2024.
- Publicity of the seal-off of Pizza Outlets in FCT for using expired seasoning – 9th February 2024.
- Publicity of the enforcement operation against substandard drugs at Area 1 motor park – 12th February 2024.
- Publicity of the enforcement operation on drug hawkers within FCT– 13th February 2024.
- Publicity of the DG's Press Statement on Nigeria's attainment of self-sufficiency in medicine production - 14th February 2024.
- Coverage and publicity of the Director General's press conference on the Relocation of Open Drug Marketers to Coordinated Wholesale Centre (CWC) in Kano: Fight against Substandard and Falsified Medicines – 28th February 2024.
- Coverage and publicity of enforcement operation at Sahad Stores and H-Medix in Abuja - 17th April 2024.
- Coverage and publicity of enforcement operation within FCT – 15th May 2024.
- Coverage and publicity of enforcement exercise in Abuja – 23rd May 2024.
- Coverage and publicity of enforcement exercise in Dei Dei and Zuba in FCT – 24th May 2024.
- Coverage and publicity of the visit of the Nation Coordinator of National Counter Terrorism Centre – Office of the National Security Adviser, Maj. Gen. Laka to DG NAFDAC in her office in Abuja 18th July 2024.
- Coordinating the South-South Director's appearance on Channels TV to discuss safety of bread – 3rd September 2024.

- Coverage of sensitization visit to the Council of Traditional Rulers by the Director (South-South Zone) and Rivers State Coordinator – 24th September 2024.
- Coverage and publicity of the Flag-off of "NAFDAC Catch Them Young Initiative" A campaign against illicit drug in Schools – 20th September 2024.
- Coverage of Sensitization and Awareness Campaign on Substandard and Falsified Medical Products in Port-Harcourt 26th September 2024.
- Coverage and publicity of a one-day sensitization and awareness on Substandard and Falsified Medical Products – 30th September 2024.
- Coverage of the meeting of the National Codex Technical Committee - 3rd October 2024.
- Coverage and publicity of exclusive interview with the DG NAFDAC, Prof. Moji Christianah Adeyeye in Lagos for NAFDAC & YOUR HEALTH Programme – 11th October 2024.
- Coverage and publicity of the seal-off of The Place Restaurant in Wuse 2 Abuja for unhygienic practice - 24th October 2024.
- Coverage and publicity of NAFDAC Sensitization of campaign in collaboration with Chemical Dealers Association – 24th October 2024 at NECA, Lagos.
- Coverage and publicity of handing over of Counterfeit Drugs and other regulated products seized by the Nigeria Customs service, Oyo/Osun Command to NAFDAC South-West Zone, Ibadan – 30th October 2024.
- Coverage and publicity of Pharmaceutical and Medical Devices companies in Ilorin, Kwara State – 30th October – 1st November 2024.
- Collation of materials in Lagos for the production Jingle on Alcohol Abuse by underage.
- Co-produced NAFDAC & Your Health TV Programme
- Coverage and publicity of the shutting down of illegal wine factory in FCT 13th November 2024.
- Coverage and publicity of NAFDAC-NDLEA Signing of MoU for improved collaborations - 13th November 2024.
- Coverage and publicity of NAFDAC-Nigeria Customs Service Signing of MoU for improved collaborations - 14th November 2024.
- Coverage and publicity of sensitization campaign at Kado Fish Market, Abuja and the destruction of illegally produced sachet water in Gwarinpa, Abuja. - 27th November 2024.
- Coverage and publicity of surveillance operation around Abuja on the sale of fake rice - 12th December 2024.
- Coverage and publicity of destruction exercise of expired and illicit drugs and other regulated products by South-West Zone, at Moniya Dump site in Ibadan, Oyo State - 11th December 2024.
- Coverage and publicity of enforcement operation at Eziukwu Market, Aba, Abia State - 14th December 2024.
- Coverage and publicity of enforcement activities in Oshogbo, Osun state – 16th December 2024.

2. Sustained Media Enlightenment Programmes on Television & Radio.

The PR Unit has continued to sustain the following programmes in the media.

- NAFDAC & YOUR HEALTH TV Programme on TVC and NTA stations – Mondays (6:30pm-7:00pm) and Tuesdays (8:00-8:30pm) 52 episodes annually respectively.

- NAFDAC & Your Health Radio programme on the Federal Radio Corporation of Nigeria (FRCN) Network by 4:30pm on Mondays (English Version), and in the 36 states FM stations at different time schedules (52 episodes annually) respectively.
- NAFDAC HALF HOUR on CITIZEN FM every Thursday at 5:30pm – 5:00pm
- Interviews, Special Features and Guest appearances on Radio and TV.
- Syndicated articles in major national dailies.

6. Increased Visibility in the Digital and New Media, namely:

- Facebook, Twitter, Instagram, YouTube
- Regular update of information on the activities of NAFDAC on the Facebook and Twitter
- Increased followership and recognition through stakeholders' engagement and regular posts.

3.1.2 Protocol Unit

In the year under review, a total number of One and Eighty-Eight (188) staff travelled for GMP inspection which represents 94 groups.

3.2 International Strategic Partnership and Trade Office ISPTO)

This report covers the activities of ISPTO (formerly OTIR) of the Director General's office for the year 2024.

A. Investors/Visitors at OSIC – NIPC:

Table 3.2.1: Investors/Visitors at OSIC Desk

S/N	Date	Name of Enquirer/ Company/ Purpose	Country	Sector	Remarks
1.	23/5/2024	Ms. Mary Adedaminiola	Nigeria	Pharmaceuticals	The client was briefed and given copy of the relevant guidelines.
2.	6/6/2024	Barr. Opiah Emmanuel	Nigeria	Pharmaceuticals	The client was briefed and given copy of the relevant guidelines.
3.	17/9/2024	Mr. Justice	Nigeria	Agro - Chemical	The client was briefed and given copy of the relevant guidelines.
4.	6/11/2024	Mr. Dominiek Viaene and his team	Belgium	Pharmaceuticals	The clients were briefed with the required information and given copy of the relevant guidelines.

B. Meeting/Workshop/Conference/Training:
The Unit participated in Seventy-Four (74) Meetings/ Workshops/ Conference/ Training and other programmes in 2024. Some of the programmes are highlighted below:

- Interactive Meeting of OTIR with the Nigerian Office of Trade Negotiation (NOTN) on the status of Africa Continental Free Trade Agreement (AfCFTA) and level of the Implementation on Import and Export on 04/01/2024.
- Interactive meeting of OTIR with Dr. Olutayo Olusegun of (AfCFTA) National Action Committee Secretariat on the status of Africa Continental Free Trade Agreement (AfCFTA) and Level of the Implementation on Import and Export.
- The launch of the World Customs Organization to (WCO) assisted Time Release Study (TRS) on 08/02/2024.
- Preparatory meeting to host British Secretary of State UK department for business and trade (DBT), Rt Hon. Kemi Badenoch, MP to Nigeria, 25–26/ 02/2024
- The Nigeria-India joint trade committee meeting in Abuja on 14/03/2024
- Inspection of factories by the National Recognition of Community Origin Committee (NRCOC) ON (ETLS), 21-28/ 03/2024.
- Meeting in preparation for the 6th World Trade organization (WTO) on Trade Policy Review (TPR) of Nigeria on08/04/2024.
- Inter-ministerial meeting in preparation for the first Nigeria-Afro Asia (SMEs) Exhibition in Abuja on 30/05/2024
- Policy Dialogue and Notification of the visit of World Bank to Seme Border Post (Nigeria-Benin Border), Onne Port, Rivers Port on 13/09/2024
- The 6th WTO Trade Policy Review at Geneva, Switzerland, 13/11/2024.
- Sensitization Training & empowerment program organized by MSMEs and SMEDAN
- The 7th International Biosafety Conference 202406/12/2024

C. Trade Fairs/ Business Investment Forums

The Unit participated in Twenty-One (21) Trade Fairs/ Business Investment Forums'in 2024. Some are listed below.

- The expanded National MSME clinics for viable enterprises at Benue State, 08-09/ 01/2024.
- The Africa Intl Trade fair Expo 202423/02/2024
- Participated and exhibited at Africa International Trade Fair Expo, 2024 at NICON luxury Hotel Abuja, 07-09/ 05/2024
- Youth-Entrepreneurship Program (YEP) on 27/08/2024.
- Nigeria-Italy Economic and Industrial forum organised by Ministry of Foreign Affairs and Nigeria – Italy Engineering and Solutions (NITA) at Lagos. 28-29 /10/2024.
- The 3rd National Conference on Non-Oil Export12/11/2024.
- The Nigeria-India Investor's Forum and Business Expo at the margin of the Prime Minister's state visit to Nigeria. 17/11/2024.

D. Presidential Enabling Business Council (PEBEC) M&E Report.

- The Desk collated and vetted the M&E monthly reports from 36 states including FCT for submission to PEBEC through regular phone calls, Text messages and emails to State/Zonal Coordinators and Desk Officers to remind them to update and promptly submit their reports.
- Analysis of collated reports from the states to ensure compliance to product registration timelines is carried out.
- Statistical analysis of compliance from the states is carried out by PRS and the reports are forwarded to the Zonal Directors and State Coordinators respectively.

Table 3.2.2: Summary of Activities for January to December 2024.

No. of Visitors at the Desk	Trade Fairs/ Exhibition /Business & Investment Forum	Meetings/ Workshops/ Conference/ Training	Others	Total
4	21	70	4	**99**

3.3 Reforms Unit

The Reforms Unit was set up to sustain an effective service-oriented Agency void of corruption and gender discrimination and to maintain a harmonized environment for adequate staff input and welfare.

Since inception, the Unit has endeavored to appropriately respond to customer complaints daily from the public bordering on adverse drug reactions, suspected poisonous food and drug products, import, export and registration enquiries, amongst others.

This has increased the confidence level of the Agency's customers and stakeholders.

Below are some of the activities of the Unit for the period under review.

1. **Customer Complaints:**

The SERVICOM Desk of the Unit receives email complaints daily from the public bordering on suspected substandard food and drug products, import, export and registration concerns, amongst others. To these mails, we send acknowledgement to the complainants and address their areas of concern and where necessary, forward them to the appropriate technical unit/department/directorate to take regulatory action and revert to the Unit while we in turn report back to the complainant with the actions taken and result.

This has increased the confidence level of the Agency's customers and stakeholders. Though to some of these mails, the Unit await feedback from some of the Directorates on actions taken. From January to December 2024, Four Hundred and Fourteen (414) mails were received by the Unit, Three Hundred and Forty-Five (345) were enquiries while Sixty-Nine (69) were complaints. Also, the Unit received Seven Hundred and Ninety-Four (794) calls in the year 2024.

2. **Customer Service Forms:**

The Unit received a total of Two hundred and Thirty-Six (236) forms administered from the Agency's front desk. The clients who were unsatisfied were contacted via phone calls and issues resolved.

3. **Monitoring of the Agency's Front Desk:**

To ensure Customers have a pleasant experience whenever they come to take service, the Reforms Unit as part of her responsibilities monitors the front desk daily to ensure its effectiveness.

4. **SERVICOM Monthly Resource Centre:**

The SERVICOM desk officer attended the monthly SERVICOM Resource Center for the period under review at the SERVICOM National office, Federal Secretariat which is handled by some team members from the SERVICOM Presidency Office, Federal Secretariat, and Abuja.

5. **SERVICOM MSU/PSU Breakfast Meeting:**

The Head Reforms Unit attended the quarterly reporting breakfast meeting on performance of Ministerial /Parastatal SERVICOM Units. The meeting is to assess service delivery performance in MDA's as well as to assess Customer service status and report same to the Presidency. The Head of the Unit made a presentation on the activities of the Unit for the third quarter. The meeting was held at the SERVICOM Presidency office Federal Secretariat, Abuja.

6. **Customer Satisfaction Survey:**

The Unit also carried out her quarterly Customer Satisfaction Survey for the year 2024 from all formations of which data is being collated and analyzed.

7. **2024 International Women's Day Celebration**

The day was marked at the Full Gospel Businessmen Fellowship behind NAFDAC Headquarters. Two schools namely School for the gifted Gwagwalada and Government Secondary School Tudunwada Wuse 2, consisting of ten students each and their teachers participated in a debate competition titled 'Adolescent Motherhood' who is to curb the menace? The Society or the Government? A debate that the School for the Gifted took the first position. The theme for the IWD celebration was **#INSPIREINCLUSION.**

8. **ECOWAS-Ecobank Empowerment Programme for Women Traders.**

The Head Reforms Unit attended the above program from 29 – 30 October 2024

9. **ACTU Meetings**.

The ACTU committee of NAFDAC had two monthly meetings and one training on the newly developed whistle-blower policy recently by the Director General.

10. **NAFDAC Policy on Whistle Blowing.**

The NAFDAC ACTU developed a policy on whistle blowing for all NAFDAC stakeholders. This was approved by the Director-General NAFDAC with effect from 27th March 2024.

11. **SERVICOM Stakeholders' Engagement Meeting 2024**

The Head, Reforms Unit attended the 2024 SERVICOM stakeholders' engagement at the Mambila Barack Abuja on the 23rd September 2024.

12. **Evaluation of Ministerial/Parastatal SERVICOM Unit**

The NAFDAC Reforms Unit was evaluated by the SERVICOM in line with the President's quest for effective service delivery in all MDAs. The team visited the Agency on the 4th of December 2024, the exercise was based on MSU/PSU performance evaluation form. At the end of the exercise NAFDAC SERVICOM got a recognition Award, "NAFDAC STANDSOUT AT SERVICOM"

13. **ACTU Workshop**.

The NAFDAC ACTU members attended an anti-corruption workshop on "Confronting Corruption in MDAs through collective action" from the 4th to 6th of November 2024 at the Anti-corruption academy of Nigeria Keffi, Nasarawa State.

14. **2024 International Anti-Corruption Day Celebration:** NAFDAC's ACTU members attended a one-day roundtable talk event to mark 2024 International Anti-corruption Day, a program organized by the House of Representatives committee on Anti-corruption at the National Assembly Complex Abuja on the 18th of December 2024.

3.4 Reports from the Zones

3.4.1 North Central Zone

Introduction

The North Central Zonal Office is one of the Six (6) zonal offices of the Agency. The office is headed by the Director NCZ who oversees the affairs in the zone and is deputized by the Deputy Director in the NCZ. The office supervises the activities of Six (6) states in the zone which include Kwara, Kogi, Niger, Nasarawa, Benue and Plateau States respectively.

All the Offices in the zone carry out the functions of all other Directorates of the Agency except the Laboratory Service.

Highlights

1. **Regulatory Activities**

   In the year 2024, a total of Five Thousand Seven Hundred and Seventy-Nine (5,876) Regulatory activities were effectively carried out in the zone including sanction activities. Below is the breakdown.

   i. Routine: 1,282
   ii. Production: 671
   iii. Renewal of product registration licences: 540
   iv. Surveillance: 2,175
   v. Sanction activities: 1,208

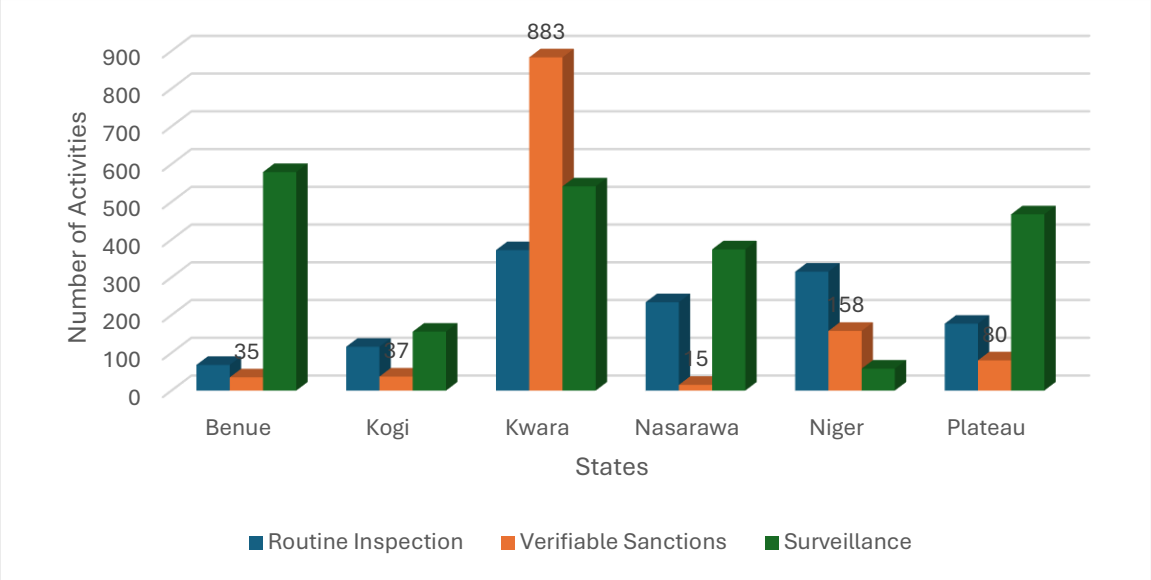
Table 3.4.1.1: Regulatory Activities in North Central Zone by Directorates

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1	DER	120	31	0
2	CER	5	1	0
3	R&R	0	30	0
4	PVPMS	0	1,010	1,720
5	VMAP	82	1	28
6	FSAN	1,075	135	427
7	NCS	0	0	0
8	Others	0	0	0
	Total	**1,282**	**1,208**	**2,175**

Table 3.4.1.2: Regulatory Activities in North Central Zone

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1	Benue	68	35	579
2	Kogi	116	37	156
3	Kwara	372	883	541
4	Nasarawa	234	15	374
5	Niger	315	158	58
6	Plateau	177	80	467
	Total	**1,282**	**1,208**	**2,175**

Figure 3.4.1.1: Regulatory Activities in North Central Zone



Other activities carried out in the zone in the period under review include.

i. GSDP monitoring activities in Supermarkets with GLSI certification.
ii. Raid operation on alcoholic beverages and sealing of pharmaceutical premises involved in revalidation of expired drugs, abortion.
iii. Sanction activity at various production facilities, supermarkets and stores, pharmacy and patent medicine outlets in the zone.

2. Approved Products

A total of 1001 products were approved in the Year 2024 and notifications were issued. The categories of products include, food, water, cosmetics, bread, GHP certificate for QSR.

3. Courtesy Visits

i. The Director NCZ had a courtesy visit to from Commissioner of Police, Plateau State Command as a way of strengthening the relationship the Agency has with other sister Agencies and also to further seek for more security support when the need arises when carrying out regulatory activities in the state.
ii. The Director also had a courtesy visit from Association of Patent Medicine of Nigeria, Plateau State.
iii. Courtesy call by NAPPMED Nasarawa State Chapter executives to the Nasarawa State Coordinator on 14th May, 2024.
iv. Courtesy call to the Nasarawa State Police commissioner by the State Coordinator and his team on 23rd May, 2024.

4. Meetings

Several meetings were held with stakeholders in all the offices in the zone and they include.

i. Stakeholders for GDP
ii. Focus Group meetings on Cosmetics Management
iii. Meeting with Nigeria Shippers Council
iv. Nigeria Immigration Service
v. Nigeria Police Force
vi. NYSC
vii. Nigeria Export Promotion Council
viii. ACPN

ix. Association of Patent Medicine Dealers
x. APPMAN
xi. Association of Master Bakers
xii. Supermarket owners
xiii. Meeting of NSOP Staff with the Director (NCZ) at NSOP Conference Hall Karu Nasarawa State on 30th September 2024

5. **Trainings/Workshops**
Staff in the NCZ were trained both virtually and physically in the year 2024. Some of the trainings and workshops attended include the following.
i. GDP Training (both physical and virtual).
ii. Training on Risk Based PMS Sampling of Anti Diabetic, Anti-Hypertensive and Maternal health Products in Nigeria (virtual).
iii. Performance Management System (physical).
iv. Virtual Training on NAPAMS Inspection Module: How to assign application for inspection. Presented by Dr. Dunoi Afam on the 9th of January 2024.
v. Virtual Training on NCS current Warehouse/Hospital/Pharmacy inspection reporting templates attended by Pharm. (Mrs.) Salome I. Aina on the 11th of January 2024
vi. NAFDAC SOP format.
vii. Labeling Regulations and Requirements
viii. Workshop with MDAs organized by Federal Ministry of Health.
ix. Sensitization workshop for the public on dangers of using chemicals in food storage.
x. Workshop organized by Nigeria Shippers Council on Cybersecurity.
xi. NAFDAC/ATWAP Stakeholders Workshop was conducted successfully on the 26th of September,2024

3.4.2 North West Zone

The North West zone comprises of seven states namely Jigawa, Kaduna, Kano, Katsina, Kebbi, Sokoto and Zamfara.

The total number of regulatory activities carried out by the States in the zone was Eleven Thousand Three Hundred and seven (11,307).

Highlight of Activities:

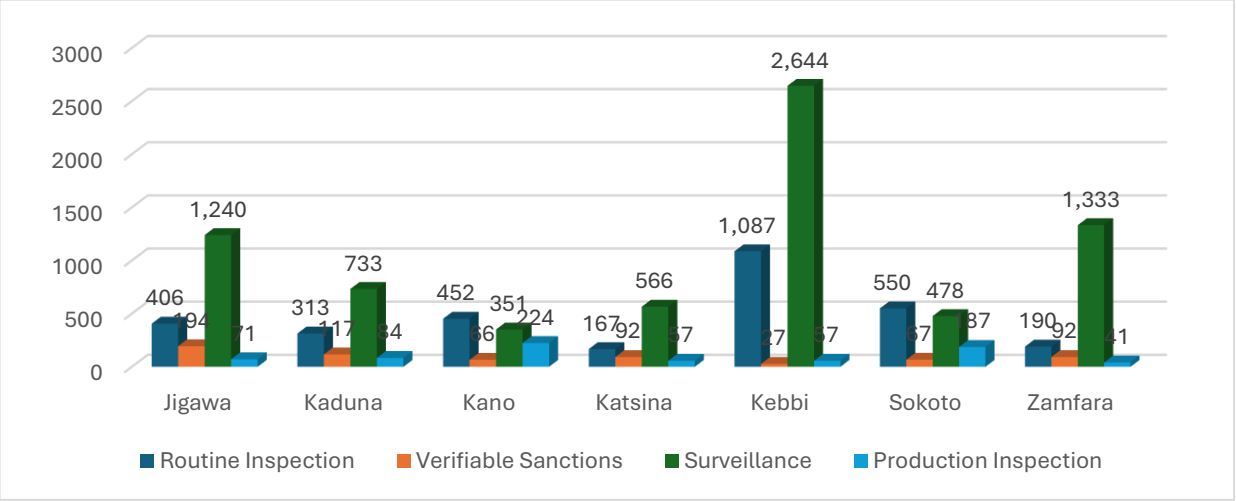
The report summarizes the regulatory activities carried out by the States within the zone in the Year under review as highlighted below:

1. **Routine Inspections**
One Thousand, Three Hundred Six Hundred and Seventy-Two (1,672) Routine inspections were carried out in the Zone during the period under review.
2. **Surveillance**
Seven Thousand Eight Hundred and Seventy-Nine (7,879) Surveillance were carried out in the Zone during the year under review.
3. **Sanctions**
One Thousand and Eleven (1,011) sanctions were imposed on various establishments in the Zone during the year under review.
4. **Production Inspection**
A total of Seven Hundred and Forty-Five (745) Production activities were carried out within the zone in 2024

Table 3.4.2.1: Regulatory Activities in North West Zone by States

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Production Inspection
1	Jigawa	406	194	1,240	71
2	Kaduna	313	117	733	84
3	Kano	452	66	351	224
4	Katsina	167	92	566	57
5	Kebbi	1,087	27	2,644	57
6	Sokoto	550	67	478	187
7	Zamfara	190	92	1,333	41
	Total	3,165	655	7,345	721

Figure 3.4.2.1: Regulatory Activities in North West Zone by States



5. North West Zonal FDRC Approval Meetings:

A total of Nine (9) Zonal FDRC approval meetings were held of which Five Hundred and Forty-One (541) approvals were issued, these include Two Hundred and Forty-Five (245) new food registration, Forty-Six (46) food renewals, Two Hundred and Twenty Nine (229) water renewals, Fifteen (15) new cosmetic products registration and Six (6) cosmetic product renewals.

Table 3.4.2.2: Summary of Northwest Zonal FDRC Approvals Granted for the Year 2024

States	Food		Water	Cosmetics		Total
	Registration	Renewal	Renewal	Registration	Renewal	
Jigawa	13	4	19	1		37
Kaduna	108	17	29	3		157
Kano	63	14	10	8	3	98
Katsina	14	5	11			30
Kebbi	7		66		2	75
Sokoto	26	5	79	1		111
Zamfara	14	1	15	2	1	33
Total	**245**	**46**	**229**	**15**	**6**	**541**

3.4.3 North East Zone

Introduction

The Northeast Zone (NEZ) comprises of Six (6) states namely, Adamawa, Bauchi, Borno, Gombe, Taraba and Yobe State.

The Zone is still experiencing security challenges. Some Local Government Areas Particularly in Borno, Yobe and Adamawa are not readily accessible due to insurgency.

During the period under review staff were trained on QMS. Nine Thousand, Three Hundred and Thirty-Nine (9,339) regulatory activities i.e., Routine, Sanction and Surveillance, were carried out.

(Adamawa (1,040), Bauchi (495), Borno (3,093), Gombe (2,890), Taraba (913), Yobe (908))

Despite the insecurity challenges officers in the zone have not relented in discharging their responsibilities.

Highlights of Activities

Breakdown of activities carried out during the period under review are highlighted below:

1. **Routine Inspections**
   Three Thousand, Two Hundred and Sixty-Six (3,266) Routine inspections were carried out in the Zone during the period under review.
2. **Surveillance**
   Five Thousand, Two Hundred and Ninety-Nine (5,299) Surveillance were carried out in the Zone during the year under review.
3. **Sanctions**
   Seven Hundred and Seventy-Four (774) sanctions were imposed on various establishments in the Zone during the year under review.
4. **Production Inspection**
   On Hundred and Fifty-Two Production inspections were conducted in the Zone during the period under review.

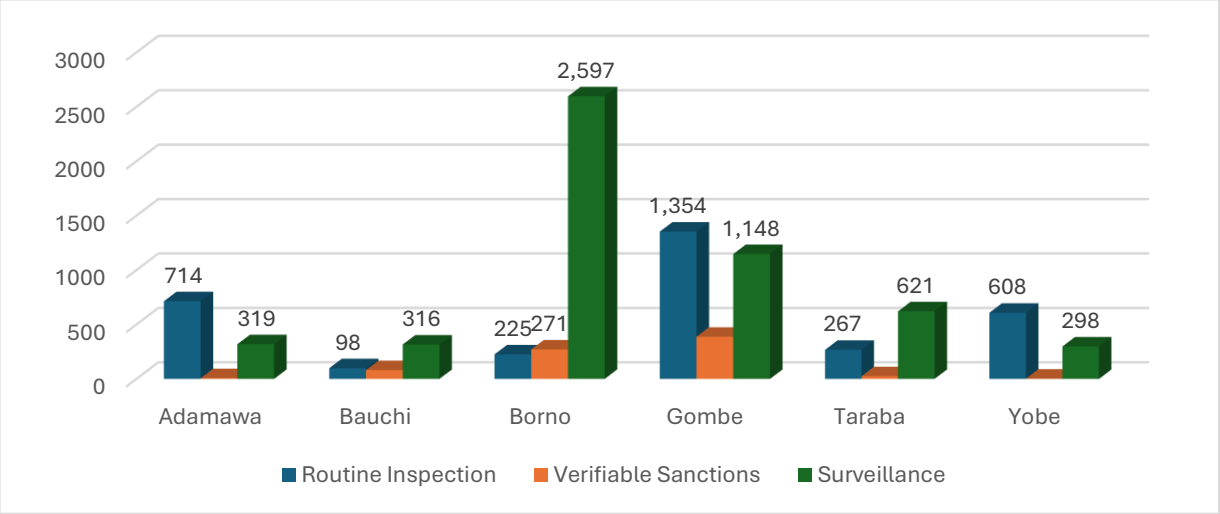
Table 3.4.3.1: Regulatory Activities in North East Zone by Directorates

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1	DER	253	173	453
2	CER	10	17	6
3	R&R	0	0	0
4	PMS	1,072	109	3,834
5	VMAP	351	156	285
6	FSAN	1,555	319	629
7	NCS	25	0	92
8	I&E	0	0	0
	Total	**3,266**	**774**	**5,299**

Table 3.4.3.2: Regulatory Activities in North East Zone by States

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1	Adamawa	714	7	319
2	Bauchi	98	81	316
3	Borno	225	271	2,597
4	Gombe	1,354	388	1,148
5	Taraba	267	25	621
6	Yobe	608	2	298
	Total	**3,266**	**774**	**5,299**

Figure 3.4.3.1: Regulatory Activities in North East Zone by States



Notable Regulatory Activities:

1. Fake and unregistered veterinary drugs containing banned drugs were identified in the zone during surveillance activities during the year 2024. This has resulted in the issuance of an alert by the post marketing surveillance directorate for the mop-up of those products. Among the drugs identified are.

i. B-GAG HEALTHY MEDICINE mist. Pot Cit.
ii. Nove Super Neoxy-care.
iii. Antibacterial powder Antibiotic
iv. Reofuramydine poultry antibiotic

2. Discouraging the use of calcium carbide in fruit ripening. Fruit marketers involved in the use of calcium carbide in fruit ripening were identified, sanctioned and the public were sensitized on the dangers involved in its use and to report marketers involved in such unwholesome practices.
3. Drugs that were damaged by flooding in Maiduguri which were worth about 5 billion naira were mopped up from Gamboru market and destroyed.

4. Destruction exercise was successfully carried out at Gombe state which involved substandard, expired and counterfeit regulated products from states in the Zone. The value of the destroyed products is worth about 10 billion.
5. A cosmetic marketer involved in Illegal recombination of cosmetic and bleaching agents was sanctioned during the year 2024.

Press Briefing

The zone has held 4 press briefings to disseminate information to the public on the following:

i. The ban on the use of calcium carbide in fruit ripening.
ii. Sale and use of banned cosmetics.
iii. Prohibition of drying, sale and use of drugs damaged by flood water.
iv. Illegality of sale of unregistered Pharmaceutical Products.

Meetings A total number of Sixty-Nine (69) meetings were conducted in the zone during the period under review.

Stakeholders Engagement.

The zone had engagement with stakeholders during the year under review. A total of Fifty-Six (56) stakeholders' engagements were held during the year under review.

Training: A total of Seventy (70) training courses were conducted during the year under review.

Renewal Inspections: A total of Forty (40) renewal inspections were conducted during the year under review.

Monitoring of Narcotics and Psychoactive Drugs: A total of Thirty-Four (34) monitoring activities were carried out during the year under review.

Plan of Action

Implementation of Quality Management System in the Agency's Operations.

The zone will improve on implementation of the Quality Management System requirements into its daily activities through continuous training on QMS and development of SOPs for the various operations.

FOCUS:

- Intensifying of enforcement and surveillance activities.
- Encourage registration of products, especially MSME's, by working closely with relevant stakeholders.
- Stepping up of other regulatory activities like GSP/GDP inspections and GHP certification.

Visit to States in the Zone

Sustained visits to states in the zone will be maintained to improve supervision of states in the zone which will ultimately lead to enhanced regulatory oversight.

The visit will make staff to put in their best and contribute meaningfully towards the success of the Agency. It will also provide the opportunity to identify challenges, Strength, weaknesses, and Opportunities with a view to improving regulatory operations in the states.

3.4.4 SOUTH WEST ZONE

Highlights of activities

The states in the South-West Zone carried out various activities during the year under review. below;

1. Routine Inspection: 838 routine inspections were carried out.
2. Surveillance: 548 surveillance activities were carried out
3. Sanctions: 324 sanction activities were carried out.
4. Production Inspection: 1,005 production inspection were carried out.
5. Renewal: 939 renewal inspection were carried out.

Table 3.4.4.1: Regulatory Activities in South West Zone by Directorates

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Production Inspection	RENEWAL INSPECTION
1	DER	43	18	10	92	33
2	CER	2		5	36	57
3	R&R		12			
4	PV	26		20		
5	PMS	137	106	476		
6	VMAP	1	1	19	6	1
7	FSAN	629	186	17	871	848
8	NCS			1		
9	PID		1			
	Total	**838**	**324**	**548**	**1,005**	**939**

Table 3.4.4.2: Regulatory Activities in South West Zone by States

SN	States	Routine Inspection	Verifiable Sanction	Surveillance	Production Inspection	Renewal Inspection
1	Ekiti	224	55	47	33	38
2	Ogun	23	14	24	218	187
3	Ogun II	77	56	14	238	295
4	Ondo	149	43	175	130	84
5	Osun	266	100	263	137	192
6	Oyo	99	56	25	249	143
	Total	**838**	**324**	**548**	**1,005**	**939**

Figure 3.4.4.1: Regulatory Activities in South West Zone by States

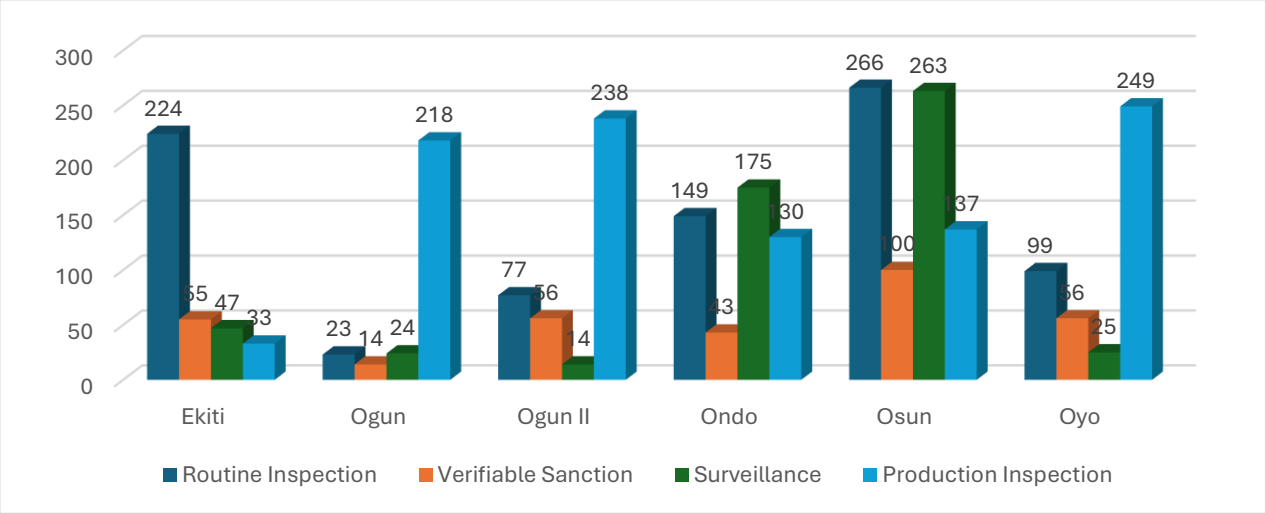


Table 3.4.4.3. Product Registration

SN	States	Water Products presented	MSME Products presented	Bread products presented	Cosmetics	Total products presented	Stepped down	Approved
	Ekiti	58	35		2	95	2	93
	Ogun	152	197	10	10	369	8	361
	Ondo	109	43		3	155		155
	Osun	118	71	4	3	196	1	195
	Oyo	117	185	33	20	355	1	354
	Total	**554**	**531**	**47**	**38**	**1,170**	**12**	**1,158**

Table 3.4.4.4: Products Approved at the Zonal Approval Meeting

Month	Number of Products Approved
Feb	52
March	96
May	76
June	93
July	56
August	126
October	122
December	138
Total	759

Other Activities and Achievements

- The total products approved in the Zone for the period under review is **Seven Hundred and Fifty-Nine (759).**
- Directorate and regulatory meetings were held every month.
- The Zonal Task force carried out a night raid in Lafenwa market in Ogun State (during the Directors' visit to Ogun I office) which was dominated by drug hawkers.

Sensitization

- Scheduled visit to Oyo State NYSC orientation camp in Iseyin for sensitization on the dangers of drug abuse and registration requirements for regulated products.
- A community Sensitization on Substandard & Falsified Medicine in Nigeria sponsored by Bill & Melinda Gate was held on 25th September at Ibadan Business School.

1. Stakeholders' Engagement

Stakeholders' engagement in all States during the oversite functions to the States.

There were stakeholder meetings with different sectors of stakeholders (Food and drink, Herbal producers, ATWAP) in Oyo State at House of Chiefs Hall, State Secretariat Ibadan and Federal Secretariat Complex Conference room. On 15th and 16th August respectively

2. Advocacy Visits

Following Stakeholders engagement on substandard and falsified medicine in Nigeria sponsored by Bill & Melinda Gate, Traditional rulers of Hausa and Yoruba community were visited on 14th and Igbo community on 15th November to solicit for their support in the campaign.

3. **Oversite Functions**

All the States were visited at least once during the year

- Ondo State between 18th and 21st March.
- Ekiti State between 27th and 28th May.
- Ogun I office between 9th and 12th September.
- Ogun II office between 18th and 22nd November.
- Osun State between 25th and 28th November.

During the visit the following activities were conducted

- Staff training and retraining
- Facility tours to confirm the reports from the States.
- Stakeholders' engagements to sensitize participants on the direction the agency is going and the Regulatory concerns.
- Interaction with staff

Nigerian Custom Service (NCS) Handover/Takeover of Confiscated Regulated Products

- The NCS (Oyo & Osun Command) handed over a consignment of seized substandard and falsified medicinal products and other unwholesome Regulated products to NAFDAC on 2 occasions in 2024 (April and October). The total worth is estimated to be about 4 billion naira.

4. Presentation of Listing certificate to West Africa Input Dealers Association (WAIDA).

The maiden certificate presentation to 34 members of West Africa Input Dealers Association (WAIDA) was done at the Federal Secretariat on 17th May, 2024.

Destruction Exercise

- Destruction of Substandard and falsified medicinal products and other unwholesome Regulated products exercise of illicit and fake drugs at Moniya dump site on 10th July.
- Another destruction exercise was carried between 9th and 14th December at Akinyele dump site.

The destruction of items are worth **Ten Billion Nine Hundred and Ninety-One Million Four Hund Red and Fifty-Eight Thousand Three Hundred- and Seventy-Four-Naira Sixty Kobo (₦10,991,458,374.60)** from the five States of the Zone and Kwara State which included expired products that were voluntarily forfeited by those in the drug distribution channels, unregistered and unwholesome products that were raided from different outlets and warehouses, fake and counterfeit as well as unregistered imported products smuggled into the Country.

5. Media Engagement

- NAFDAC AND YOUR HEALTH team visited the South West zone on 5th January to interview the Director on the NAFDAC activities in the zone.
- The Director granted an interview at Fresh FM on 26th February on the ban of sachet alcoholic drinks.
- Federal Radio Cooperation was in the zonal office on 22nd February to interview the Director on the ban of sachet alcoholic drinks.
- CHANNELS TV was also in the zone on 4th March to interview the director on the fake and counterfeit drugs seized by NAFDAC.
- Wells radio invited the Director for an interview in their station on 19th April.
- The Director granted an interview with Vintage FM in her office on 24th April.
- The Director granted a documentary interview with RXAll on 21st May 2024 in Ibadan.
- The Director granted interview on phone with Glow FM Akure on 23 August 2024

6. **Courtesy Visits**

- The Director of the National Productivity Center paid a courtesy visit to the Director in her office on 16th April.
- The Director paid a courtesy visit to Nigeria Police Force, Oyo Command, Ibadan Oyo State on 16th May 2024.
- The Director paid a courtesy visit to the GOC 2 Division, Odogbo Barracks Ojo Ibadan, on 26th September.

3.4.5. South South Zone

Summary of All Regulatory Activities for South-South Zone Jan- Dec 2024.
The number of regulatory activities (routine, sanctions & surveillance) carried out in the State from January - December 2024 was Two Thousand, Eight Hundred and Twenty-Four (2,824).

Table 3.4.5.1: Regulatory Activities in South South Zone by Directorates

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1	DER	73	45	156
2	CER	7	0	0
3	R&R	0	0	0
4	PV	18	0	0
5	PMS	413	145	1068
6	VMAP	0	0	35
7	FSAN	684	139	41
8	NCS	0	0	0
9	I&E	0	0	0
	Total	**1,195**	**329**	**1,300**

Table 3.4.5.2: Regulatory Activities in South South Zone by States

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1	Akwa Ibom	278	62	194
2	Bayelsa	89	43	586
3	Cross Rivers	173	47	287
4	Delta	326	47	119
5	Edo	105	49	75
6	Rivers	224	81	39
	Total	**1,195**	**329**	**1,300**

Figure 3.4.5.1: Regulatory Activities in South South Zone by States

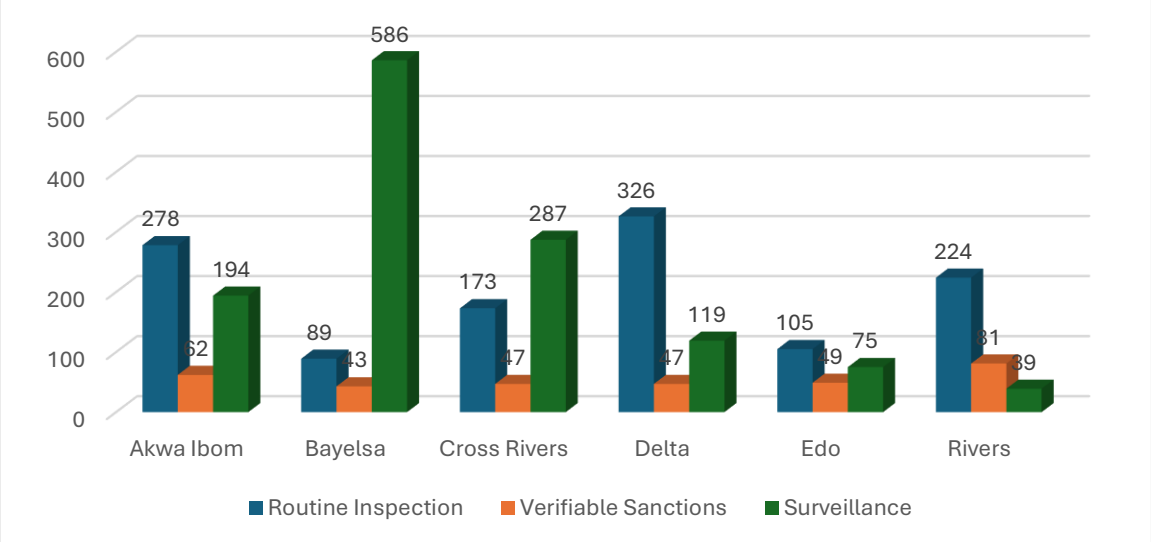


Table 3.4.5.3: Product Registration

SN	States	Total Number of Products presented	Water (Renewal)	Food	Cosmetics	Bread
	Zonal Total	668	204	296	24	144
	Akwa Ibom	119	42	47	9	21
	Bayelsa	54	8	36	3	7
	Cross Rivers	35	26	8	1	0
	Delta	110	67	31	2	10
	Edo	56	23	31	2	0
	Rivers	294	38	143	7	106

- The State Office participated in the destruction of used vials from routine immunization in the State on Friday 26th January, 2024 at the premises of Delta State Drug Revolving Fund, Asaba. The exercise (boil and bury) was organized by Delta State Primary Health Care Development Agency
- The DSSZ Pharm C.P Oligbu, State Coordinator Pharm Onogwu E.I.(DD) and a NAFDAC Staff during the Sensitization visit to the Chairman, Rivers State Council of Traditional Rulers, HRM Eze Chike Worlu Wodu.
- The State Coordinator Pharm Onogwu E.I.(DD), DSSZ Pharm C.P Oligbu and other NAFDAC Staff/Sister Agencies group during the Sensitization Workshop on Counterfeit and Unwholesome Medicinal products.
- The State Coordinator, Mr. Ihekire V.C.(DD) Sensitizing marketers at Swali market, Yenagoa, Bayelsa State on the sales of NAFDAC Regulated products on 7th March, 2024.
-

3.4.6: South East Zone

1. **Highlight of Activities:**
   The regulatory activities carried out by the States within the zone in the Month under review as highlighted below:

   a. **Routine Inspection**: A total number of Eight Hundred and Ten (810) routine activities were carried out within the zone in the year under review.
   b. **Verifiable Sanction**: A total of Four Hundred and Thirty-Eight (438) verifiable sanctions were meted out within the zone in the year under review.
   c. **Surveillance**: A total number of One Thousand, Six Hundred and Two (1,602) surveillance activities were carried out within the zone in the year under review.
   d. **Production Inspections:** A total of Seven Hundred and Fifty-Nine (**759**) production inspections were carried out.

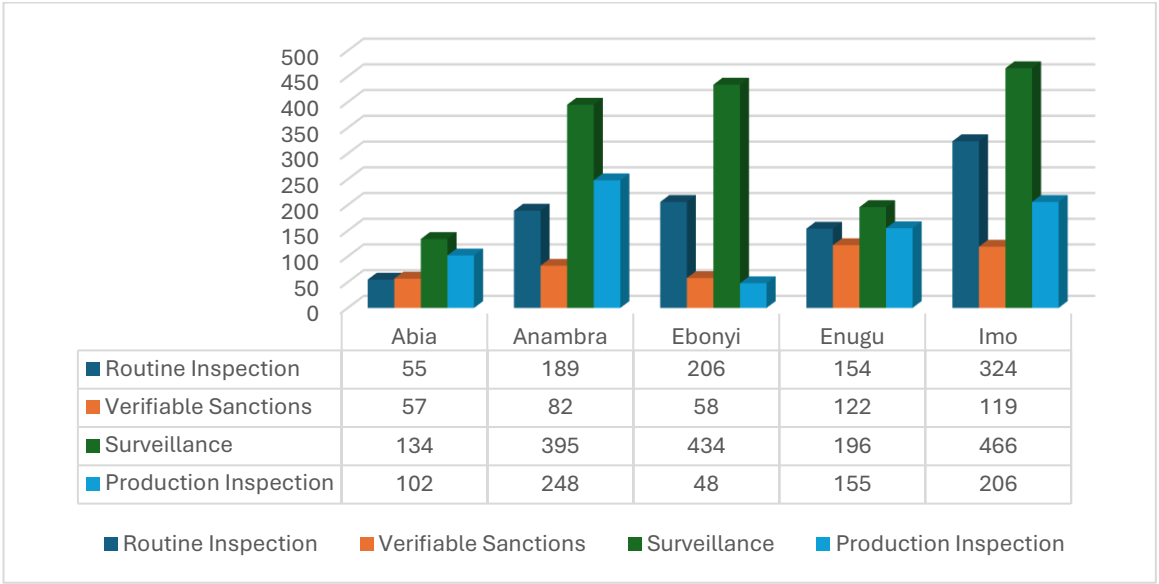
Table 3.4.6.1: Regulatory Activities in South East Zone by Directorates

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	
1	DER	99	123	256	44
2	CER	6	0	30	0
3	R&R	93	0	0	0
4	PV/ PMS	190	0	1185	0
5	VMAP	0	0	0	0
6	FSAN	515	315	131	715
7	NCS	0	0	23	0
8	I&E	0	0	0	0
	Total	**810**	**438**	**1602**	**759**

Table 3.4.6.2: Regulatory Activities in South East Zone by States

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Production Inspection
1	Abia	55	57	134	102
2	Anambra	189	82	395	248
3	Ebonyi	206	58	434	48
4	Enugu	154	122	196	155
5	Imo	324	119	466	206
	Total	**810**	**438**	**1,602**	**759**

Figure 3.4.6.1: Regulatory Activities in South East Zone by States



2. **Product Approval/MSME Activities**: The total products approved in the zone for the year 2024 was Nine Hundred and Thirty-Nine (939).

Table 3.4.6.3. Product Approval in South East Zone by State.

S/N	Category of Products	Type of Registration	NUMBER of Products Registered by State					
			Abia	Anambra	Ebonyi	Enugu	Imo	**Total**
1	Bread Products	New Registration	29	42	24	53	48	196
2	Bread Products	Renewal	21	37	17	27	2	104
3	Cosmetics Products	New Registration	4	13	1	21	9	48
4	Cosmetics Products	Renewal	2	9	0	0	2	13
5	MSME Food Products	New Registration	37	76	16	84	63	276
6	MSME Food Products & Packaged Water	Pack Size Extension	0	0	0	0	0	0
7	Bread Products Registered	Pack Size Extension	9	0	0	0	1	10
8	MSME Bread Products	Renewal	21	0	0	0	0	21
9	MSME Food Products	Renewal	18	28	14	29	6	95
10	MSME Water Products	Renewal	19	74	14	37	31	175
11	MSME Water	Factory Extension	0	0	0	0	0	0
12	MSME Food & Water	Factory Relocation	0	0	1	0	0	1
13	MSME Food	Change of Package/Label Design	0	0	0	0	0	0
	Total Number of Products Registered		**160**	**279**	**87**	**251**	**162**	**939**

3. **Meetings:**
    - The zonal office held monthly approval and pre-approval meetings; all states within the zone joined these meetings.
    - There were also weekly meetings between the Director and State Coordinators as well a monthly meeting between DSEZ and all staff of the zone.

4. **Stakeholder Forum:**
    - The SEZ held Stakeholder's meetings in all states of the zone.
    - The SEZ directorate also collaborated with Croplife Nigeria to hold a joint training and certification program for agro-dealers in all states within the Zone.

5. **Trainings:** Staff of the zone attended various trainings both virtual and physical including:
    - FSAN training for all regulatory officers
    - VMAP virtual training for regulatory officers.
    - Some Regulatory officers from the zone participated in PMS training.

6. **Report On Adherence to Timelines:** The Zone has been in adherence to the timelines given.

3.4.7: Federal Capital Territory (FCT) Office

Introduction:

The Federal Capital Territory Office has Nine (9) Units namely: -

1. Chemical Evaluation and Research (CER)
2. Food Safety and Applied Nutrition (FSAN)
3. Registration and Regulatory Affairs (R&R)
4. Veterinary Medicine and Allied Products (VMAP)
5. Drug Evaluation and Research (DER)
6. Narcotics and Controlled Substances (NCS)
7. Finance and Accounts (F&A)
8. Human Resource Management (HRM)
9. One Stop Shop (OOS) domiciled at the Abuja Enterprise Agency

Highlight of Activities

1. **Inspections**

The FCT Office, through the various inspecting Units-FSAN; DER; CER; VMAP and NCS carried out different types of inspections as highlighted below:

Table 3.4.7.1: Inspection Activities.

The FCT Directorate, through its various inspection divisions, conducted a series of inspections as detailed below.

SN	Units	Sanction	Routine Inspection	Other Inspection	Total
1	FCT Inspection Food	11	10	637	658
2	FCT Inspection, Medical Products and Cosmetics	4	47	65	116
3	FCT Inspection Veterinary	6	200	4	210
4	FCT Inspection Chemical	1	43	49	93
5	FCT Inspection Controlled Substances	0	7	11	18
	Total	**22**	**307**	**766**	**1,095**

Table 3.4.7.2: Summary of Activities Carried out by FCT Registration Division

SN	Activities	Importation	Local Products	Total
1	Counselling of clients	150	0	150
2	MSME new registration (Food & cosmetics)	Nil	146	146
3	MSME Renewals (Food, cosmetics, & water)	Nil	84	84
4	MSME Pack size extension/Change in package design	Nil	6	6
5	MSME Factory Extension/Additional Manufacturing Site	Nil	4	4
6	MSME Factory Relocation/Change in Manufacturing Site	Nil	6	6
7	Number of bread and bakery products registered	Nil	202	202
8	Number of bread and bakery products renewed	Nil	48	48
9	Other activities	301	8,683	8,984
	Total	451	9,179	9,630

Table 3.4.7.3: Other Office/Regulatory Activities

SN	Activities	LOD	FCT Inspection Food	FCT Inspection Med. Products & Cosmetics	FCT Inspection Veterinary	FCT Inspection Chemical	FCT Inspection Controlled subs	OSS	Total
1	Surveillance	0	0	24	0	0	0	0	24
2	Other regulatory/office activities	8,976	746	477	69	331	50	306	10,955
	Total	8,976	746	501	69	331	50	306	10,979

- **Sensitization Program/Exercise:** Five (5)
- **Meetings:** One Hundred and Two (102)
- **Workshop/Training:** Fifty-Five (55)
- **Foreign GMP Inspection:** Nil
- **Cold Chain Monitoring:** Twenty (20)
- **Mop-up:** Nil
- **Destruction & Seizure:** One (1)
- **Sanctions :** Twenty-Two (22)
- **Investigation :** Seven (7)
- **Surveillance:** Twenty-Two (22)

- **Counselling:** One Thousand, Seven Hundred and Fifty (1,750) clients received counseling on NAPAMS registration processes and other related guidelines and procedures.

3.4.8. Lagos State Office (LSO)

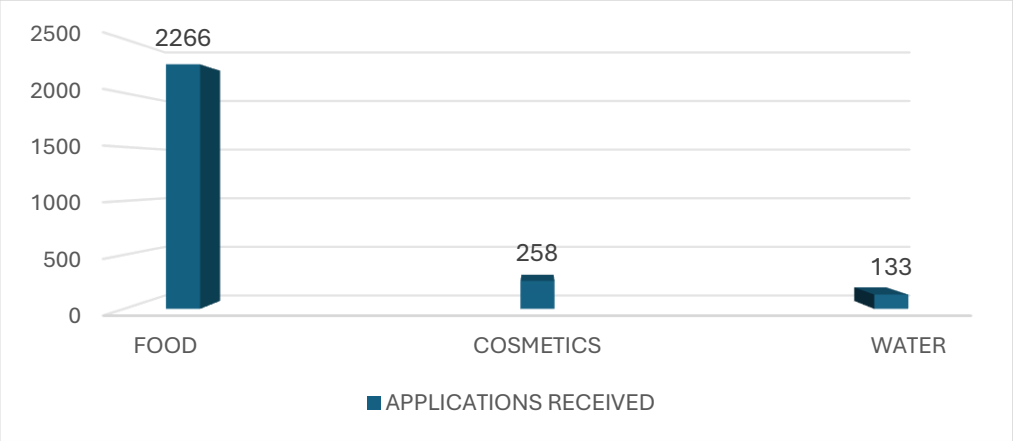
1. Introduction:

The year 2024 in Lagos State Office had activities carried out as part of the registration and inspection processes. Some of the registration and inspection activities carried out included - New registration, Renewals, GMP Re-assessment, and Routine processes for Food (including Bread), Cosmetics and Renewal of Licence for Bottle and Sachet Water in Lagos State .
Product registration under LSO purview and inspection activities within the year under review are as follows –

2. General Highlights:

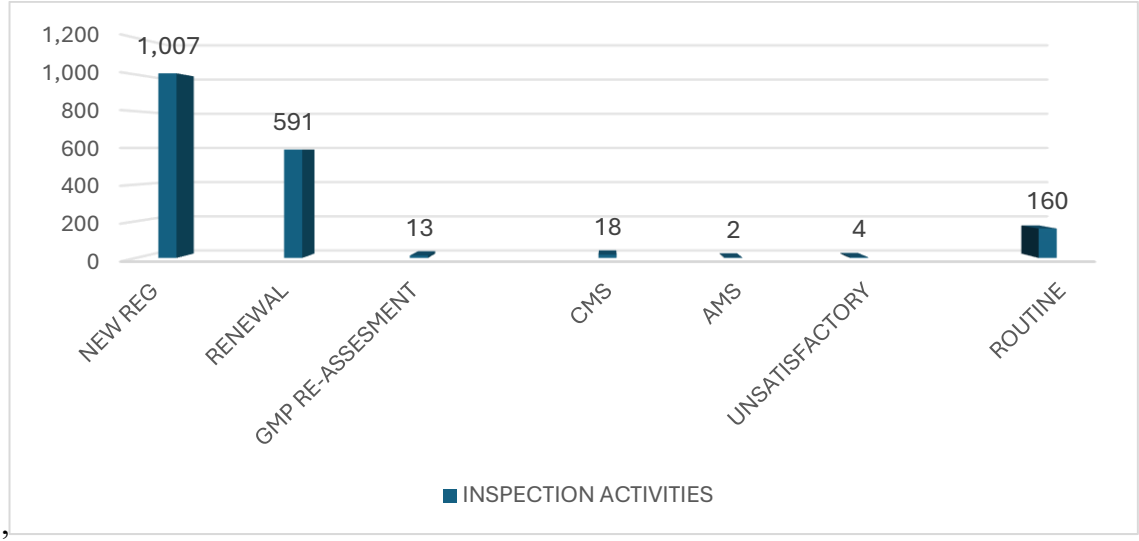
A. Summary of Applications Received:
A total of Two Thousand Six Hundred and Fifty-Seven (2,657) applications were received on NAPAMS in the year 2024. Two Thousand Two Hundred and Sixty-Six (2,266) applications were Food products including Bread, (New registration, renewal, pack-size extension and variations) while Two Hundred and Fifty-Eight (258) applications were cosmetic products including new registration, renewal applications and pack-size extension. One Hundred and Thirty-Three (133) application(s) were for the renewal and pack size extension of water (bottle and sachet).

Figure 3.4.8.1: Applications Received



B. Summary of Inspection Activities:
A total of **One Thousand and Seven hundred and Seventy-Eight (1,778)** inspections were conducted in the month under review, New Registration inspection – One Thousand and Seven **(1,007),** Renewal inspection – Five Hundred and Ninety-One **(591),** GMP Re-assessment- Thirteen **(13),** Change of Manufacturing Site - Eighteen **(18)**, Additional Manufacturing Site - Two **(2)**, Unsatisfactory inspection - Four **(4)**, and Routine inspection - One Hundred and Sixty **(160)**.

Figure 3.4.8.2: Inspection Activities



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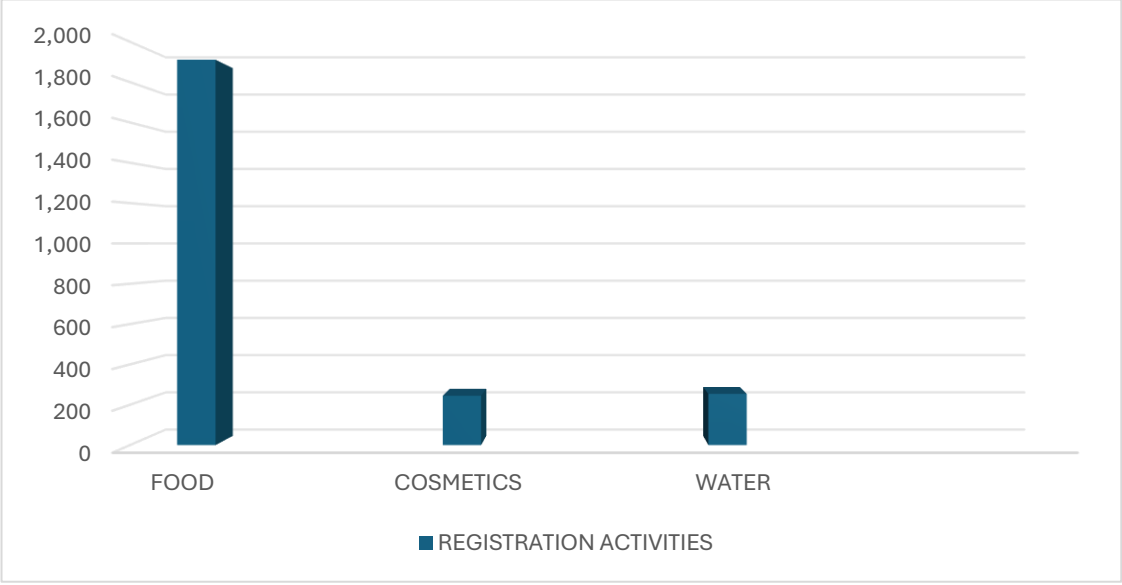
C. Summary of Registration Activities:

A progressive number of products where registered in the month under review. A total of Two Thousand Four Hundred and Ten **(**2,410) products were approved/Registered (New Registration, Renewal and Additional Variant) – One Thousand Nine Hundred and Eleven (1,911) Food products (including Bread), Cosmetic products – Two Hundred and Forty-Five (245) and water renewal – Two Hundred and Fifty Four (254).

Figure 3.4.8.3: Registration Activities



The bar-chart shows that the amount of products registered in LSO for year 2024 states that Food products (including Bread) had the highest number of products registered, followed by the Renewal of Water (Bottle & Sachet) and finally Cosmetics.

C. Meetings, Sensitization Programs and Trainings in 2024

Lagos State Office (LSO) 32 conducted inhouse meetings. Some of them are as follows.

- Directorate meeting and training was conducted on the 15th of January 2024 at the Central Laboratory Auditorium, Oshodi.
- NAFDAC-LSO Sub Food and Cosmetics Approval Meeting for the month of December, 2023 was held on the 29th of January, 2024 at the Central

D. External Sensitization Activities

There were Fourteen (14) External sensitization in 2023. Some are as follows.

- Consultative Meeting with foodotcomacademy services on 14th January 2023.
- Consultative Meeting with Honey Value Chain and Export Exhibition on 14th February 2023
- Consultative Meeting with National Association of Cakes and Sugar Craft Professionals (NASCP) 15th February 2023.
- Stakeholders Sensitization Program held at Central Laboratory complex Auditorium Oshodi 16th March 2023
- Training program for manufacturers on product labelling and requirements for kitchen scale accreditation at Technology Incubation Centre Conference Hall, Agege, Lagos

Chapter 4
The Food Safety and Applied Nutrition (FSAN) Directorate

4.0 Overview

The Food Safety and Applied Nutrition (FSAN) Directorate is one of the technical Directorates of NAFDAC created to refocus and further strengthen the Agency's mandate of regulatory oversight in the food sector to reduce, to the barest minimum, food safety related public health issues. The Directorate began operations in April 2013 and has its headquarters in Lagos, a Satellite Office in the Federal Capital Territory (FCT) Abuja, and activities that span the 36 States of the Federation and the Federal Capital Territory (FCT) Abuja.

Our core mandate is to ensure that food manufactured, imported, exported, distributed, advertised, sold, and used in Nigeria meet the highest standards of food safety and quality reasonably achievable while offering good nutrition to the population.

The FSAN headquarters is located on the second floor of the NAFDAC Office Complex at Plot 1, Isolo Industrial Estate, Oshodi-Apapa Expressway, Isolo, Lagos.

4.1 Structure

The Directorate is headed by a Director operating from the headquarters, supported by a professional team covering management, regulatory and administrative staff. To carry out her functions effectively and efficiently, the Directorate operates six (6) Divisions, the Satellite Office and the Director's Office:

i. Food Inspection, Medium Enterprises and Agricultural Products Division
ii. Food Safety, Codex and Regulations Division
iii. Food Evaluation, Food Storage & Quick Service Restaurants Division
iv. Packaged Water Division
v. Bakery & Baked Products Division
vi. Nutrition Division
vii. Satellite Office
viii. Director's Office

4.2 Functions of the Directorate

In the interest of safeguarding public health through a fair and effective food safety regulatory and control regime, the FSAN Directorate engages in several functions, which include the following:

i. Conduct Good Manufacturing Practice (GMP)/Good Hygiene Practice (GHP) assessments of food and water establishments, supermarkets (and their warehouses), and monitor continued compliance with relevant regulations, standards, and guidelines through unannounced (routine) inspections.
ii. Conduct inspection of production/packaging facilities (and warehouses) of processed and semi-processed agricultural food commodities and verify that products intended for export meet the required safety and quality parameters that assure food safety as a prerequisite for issuance of export certificate.
iii. Initiate development of, and participate in, review and revision of food regulations.
iv. Develop, review, and revise food guidelines.

v. Issue authorization/permit for importation of bulk food raw materials and ingredients.
vi. Implement the provisions of the International Code of Marketing of Breast-milk Substitutes (BMS) and the national BMS marketing regulations.
vii. Provide relevant regulatory information on the Sanitary and Phyto-Sanitary (SPS) measures of the World Trade Organization Agreement to intending exporters of processed and semi-processed agricultural food commodities as the National Enquiry Point on Food Safety.
viii. Coordinate activities of the International Food Safety Authorities Network (INFOSAN) as the INFOSAN Emergency Contact Point for Nigeria.
ix. Coordinate and anchor the activities of the Codex Alimentarius Commission (Joint FAO/WHO Food Standards Programme) for the Agency in the development of international and regional food standards, guidelines, and codes of practice to protect the health of consumers and ensure fair practices in food trade.
x. Participate in national nutrition programmes and activities in collaboration with relevant Ministries, Departments and Agencies (MDAs), as well as Development Partners, to contribute to improving national nutrition indices.
xi. Organize industry outreach, consumer education and stakeholders' engagements to provide information on food safety and nutrition for positive impact.

4.3 Regulatory Activities

Table 4.1: Summary of FSAN Regulatory Activities For Year 2024

S/N	FSAN Activities	Outcome	NCZ	NEZ	NWZ	SSZ	SWZ	SEZ	Lagos	Total
1	Routine Inspections	Satisfactory	661	1,196	1,003	489	720	515	44	4,628
		Unsatisfactory	369	125	593	252	163	53	3	1558
2	Special Inspections	Satisfactory	11	37	47	51	56	1	6	209
		Unsatisfactory	5	1	8	2	1	0	0	17
3	GMP Reassessment	Satisfactory	11	37	16	5	7	1	21	98
		Unsatisfactory	0	0	2	4	0	0	0	6
4	Production Inspection	Satisfactory	383	281	562	774	734	733	467	3,934
		Unsatisfactory	22	10	18	136	3	4	9	202
5	Follow-up Inspection	Satisfactory	26	32	18	4	97	11	20	208
		Unsatisfactory	2	0	10	0	1	0	0	13
6	GMP Reassessment (Renewal)	Satisfactory	280	67	304	422	725	357	58	2,213
		Unsatisfactory	24	0	5	52	2	4	3	90
7	Inspection of warehouses for Global Listing	Satisfactory	37	22	7	9	19	11	106	211
		Unsatisfactory	6	13	0	0	0	0	6	25
8	Cold Chain Facilities monitoring	Satisfactory	26	66	22	8	1	1	1	125
		Unsatisfactory	6	51	3	0	0	0	0	60
9	No. of Surveillance activities carried out	Compliant	291	995	324	49	1	271	0	1,931
		Non-compliant	53	173	113	18	5	83	0	445
10	No. of compliance directives issued		208	287	582	443	97	610	34	2261
11		Concluded	25	78	31	16	8	28	4	190

	No. of Investigation activities carried out	Ongoing	14	22	14	14	1	61	0	126
12	Sanctions imposed on companies		254	151	324	137	100	318	0	1,284
13	No. Put on Hold		0	46	0	0	8	0	0	54
14	No. of Hold Removed		0	14	0	0	4	0	0	18
15	No. of Establishments visited for Mop-up.		15	133	15	42	8	159	0	372
16	No of Products mopped up		7	42	348	22	89	5,178	0	5,686
17	No. of Consumer Complaints received		8	7	3	2	7	5	0	32
18	Number of consumer complaints investigated	Concluded	2	7	7	1	3	2	5	27
		Ongoing	9	1	2	2	2	2	5	23
19	No. of Product Alerts received		0	23	329	19	0	7	0	378
20	No. of Institutions visited for annual water monitoring		0	18	8	0	0	95	0	121
21	Breast Milk Substitutes (BMS) Monitoring		0	1,198	334	8	28	6	0	1,574
22	No. of Salt Iodization Survey carried out	Concluded	48	20	10	0	0	84	0	162
		Ongoing	0	0	0	0	0	0	0	0
23	No. of Vitamin A/Premix Survey carried out	Concluded	0	33	48	0	0	204	0	285
		Ongoing	104	0	206	0	0	0	0	310
24	GPS Marking of location		0	1	0	0	0	0	0	1
25	Change of Location		0	5	0	0	6	0	7	18
26	Pack size Extension		0	19	0	0	0	0	0	19
27	cGMP Certification		0	0	0	2	5	0	11	18
28	No. of Sampling Inspection		0	806	0	0	0	1085	9	1900
29	Others		12	62	41	0	152	409	88	764
Total			2,919	6,079	5,357	2,983	3,053	10,298	907	31,596

Table 4.2: Comparison of FSAN Regulatory Activities for Years 2022, 2023 And 2024

Zones	FSAN Activities		
	2022	2023	2024
NCZ	5,533	4,579	2,919
NEZ	2,507	3,498	6,079
NWZ	3,940	4,092	5,357
SSZ	2,687	3,743	2,983
SWZ	2,175	2,617	3,053
SEZ	1,736	3,091	10,298
Lagos	1,262	1,074	907
Total	**21,862**	**22,694**	**31,596**

Figure 4.1: Comparative Analysis of FSAN Regulatory Activities for Years 2022, 2023 And 2024

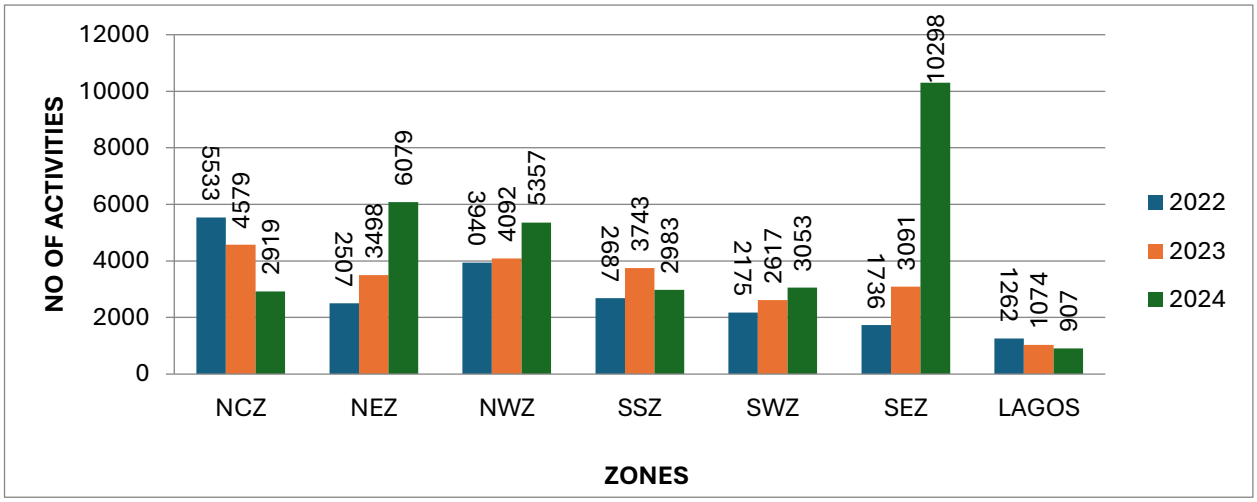


Figure 4.1 gives a graphical representation of regulatory activities in 2024 compared with 2022 and 2023. Overall, there was a significant increase (40%) in FSAN activities across the country in the year 2024 in comparison with 2023 and 2022. Specifically, the NEZ, NWZ, SWZ and SEZ recorded increased regulatory activities in 2024 when compared with 2022 and 2023, while the SSZ and Lagos FSAN Headquarters recorded a slight decrease in regulatory activities when compared with 2023. For FSAN Headquarters, this can be attributed in part to the transfer of some inspection activities for water establishments (inspections for renewal of product licences) and all inspection activities for bakery (bread) establishments to fully align with the Agency's nationwide structure for food establishment inspections.

Table 4.3: Number of GMP And GHP Certificates Issued

No. of Certificates Issued in 2024		Total
GMP	GHP	
18	15	33

In 2024, the year under review, the FSAN Directorate issued 18 Good Manufacturing Practice (GMP) certificates to indigenous manufacturers and 15 Good Hygiene Practice (GHP) certificates to food service operators.

Table 4.4: Permit for Importation of Bulk Food Raw Materials in 2024

Type of Permit	**Permit to Import Bulk Food Raw Materials as Manufacturer**		**Permit to Import Bulk Food Raw Materials as Supplier**		**One off Permit to Import Bulk Food Raw Materials**	
Month	No. of Applications	No. Approved	No. of Applications	No. Approved	No. of Applications	No. Approved
January	13	32	3	1	0	0
February	9	22	7	5	2	0
March	7	9	3	0	0	0
April	2	8	1	4	1	0
May	8	3	1	0	0	0
June	12	2	3	0	0	0
July	11	3	2	0	1	0
August	8	2	3	3	1	0
September	11	3	3	1	0	0
October	23	5	4	2	0	0
November	49	3	5	0	2	0
December	28	30	5	1	3	0
Total	181	122	40	17	10	0
Total Number of Applications Received:231						
Total Number of Applications Approved: 139						

Figure 4.2: FSAN Bulk Food Raw Materials Import Permit Activities for 2024

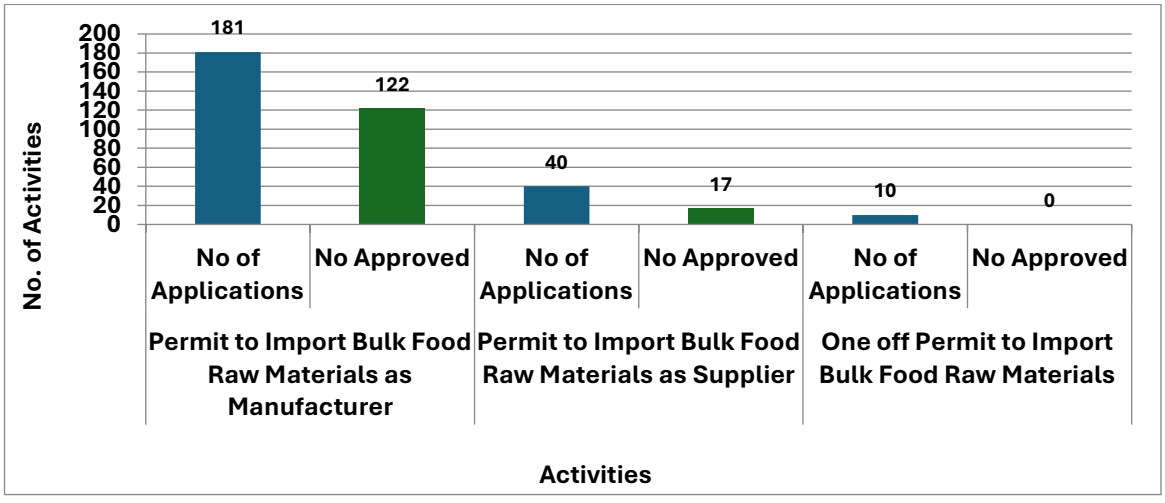


Table 4.5: FSAN Foreign GMP Risk Categorization Activities for 2024

No. of Applications		
Cleared	**Pending**	**Total**
184	**42**	**226**

Figures from **Table 4.5** show that in the year under review, Two Hundred and Twenty-Six (226) applications for foreign GMP clearance were treated out of which 184 were cleared with 42 pending due to issues of non-conformance with requirements for the service.

4.4 Other Activities of FSAN

The Food Safety and Applied Nutrition (FSAN) Directorate holds the Secretariat of several national committees, notable among these is the Secretariat of the National Fortification Alliance (NFA) and the Country Working Group (CWG) on Bouillon Fortification, the Secretariat of the National Food Safety Management Committee (NFSMC), the Secretariat of the National Technical Committee on the International Code of Marketing of Breast-milk Substitutes and the National Regulations. Below are highlights of some of the other activities undertaken by the Directorate in the year under review.

A. BMS Code Activities

The FSAN Directorate anchors the activities of NAFDAC on Breast-Milk Substitutes (BMS) and their appropriate marketing in line with the International Code of Marketing of Breast-milk Substitutes (BMS) and the national regulations in her capacity as the Secretariat of NAFDAC BMS activities. The Directorate is also currently implementing the National Strategy for the Implementation of the International Code of Marketing of Breast milk Substitutes in Nigeria (2021–2025). In the year under review, the Directorate participated in the underlisted BMS activities.

i. Provided resource person and participated in the capacity building of FMoHSW staff on the International Code of Marketing of Breastmilk Substitutes (BMS) and inauguration of FCT Multi-sectoral BMS Committee held at Karu, Nasarawa State on 19th to 21st February 2024.
ii. National Training of Trainers (ToT) on Maternal Infant and Young Child Nutrition (MIYCN) 4th to 12th March 2024, Keffi, Nasarawa.
iii. Regional workshop on Strengthening Monitoring and Implementation of Legal Measures to Protect Breastfeeding in West and Central Africa held on 12th to 14th March 2024, Abidjan, Cote d'Ivoire.
iv. National Training of Trainers (ToT) on Maternal Infant and Young Child Nutrition (MIYCN) 8th to 17th July 2024, Imo State.
v. 2024 World Breastfeeding week Flag-off under the theme "Closing the gap: Breastfeeding support for all" and the World Breastfeeding Record Attempt hosted by FMoHSW & UNICEF held on 1st August 2024, Abuja.
vi. Hosted the inauguration of the Lagos State BMS Multisectoral Technical Committee on 6th August 2024 as part of the 2024 World Breastfeeding Week activities at the NAFDAC Auditorium, Isolo, Lagos.
vii. Virtual inauguration by the DG (NAFDAC) of 32 States BMS Multi-Sectoral Technical Committees and capacity building in furtherance of efforts to implement and enforce the International Code of Marketing of Breast-milk Substitutes and the National BMS Regulations on 24th October 2024.
viii. Participated in a review meeting as resource (facilitator) on adaptation of the National Maternal, Infant and Young Child Nutrition (MIYCN) training modules for Lagos State Ministry of Health for ease of use at service delivery points, held in Lagos from 11th to 13th November 2024.

B. Food Fortification with Micronutrients

The FSAN Directorate, on behalf of the Agency, serves as the Secretariat of the National Fortification Alliance (NFA), a platform of relevant Ministries, Departments and Agencies (MDAs), industry, and development partners where issues on the national food fortification programme are deliberated upon. The NFA meets biannually and the FSAN Directorate successfully anchored and participated in the two (2) meetings and Steering Committee meetings of the NFA in July and December 2024. The FSAN Directorate participated actively in the development and co-creation of the Digital Fortification Quality Traceability Plus - DFQT+ platform, a digital monitoring and traceability system for the micronutrients used in large-scale food fortification, as well as the fortified foods, to improve the efficiency of compliance monitoring, currently in its pilot phase. In the period of this report, the FSAN Directorate participated in the following activities for the advancement of the National Large-Scale Food Fortification (LSFF) programme.

i. World Food Programme policy-driven analysis of food consumption and access data to improve micronutrient intakes from 11th to 15th March 2024 in Rome and delivered a presentation on the *"Overview of the Nigerian Fortification Context"*.
ii. Monthly user engagement for the Digital Fortification Quality Traceability + (DFQT+) platform held on 20th March. 2024, Lagos.
iii. LSFF Partner Convening 2024, Cape Town, South Africa, 17th April 2024 and delivered a presentation on '*Reinforcing National Fortification Alliances (NFAs): Sustaining Public-Private Sector Coordination (Nigeria NFA)'.*
iv. On-boarding of inspectors on to the DFQT+ platform at NAFDAC Auditorium, Isolo, Lagos on 24th April 2024 and 6th December 2024.
v. 1st and 2nd bi-annual National Fortification Alliance Steering Committee meetings on 2nd July and 16th December 2024, Lagos.
vi. 1st and 2nd bi-annual National Fortification Alliance meetings on 3rd July and 17th December 2024, Lagos.
vii. DFQT+ Digital Laboratory workshop was held on 5th December 2024, Lagos.
viii. Nutrition Dialogue on Workforce Nutrition and Large-Scale Food Fortification was held on 10th December 2024, Abuja.

The FSAN Directorate is a critical actor in the implementation of the national mandatory food fortification programme and conducts national compliance monitoring of the selected food vehicles at the retail/distributor levels to assess the content of the micronutrients to verify compliance with national standards and regulations. In 2024, in preparation for the compliance monitoring exercise, a pre-survey training for field officers was successfully conducted and sampling for food fortification compliance monitoring at the retail/market level across the 6 geopolitical Zones of Nigeria was undertaken in November 2024.

The FSAN Directorate also serves as the Secretariat of the Country Working Group (CWG) on Bouillon Fortification, an offshoot of the National Fortification Alliance (NFA). In furtherance of the consideration of bouillon as a food vehicle for fortification the Directorate participated in the CWG meetings on 28th February and 20th June in Abuja, and 6th December 2024 in Lagos.

Harmonization of food fortification efforts across the sub-region is of importance to the Agency considering her role as the NFA Secretariat, anchored by the FSAN Directorate. The Regional Fortification Alliance was established and launched by the West African Health Organization (WAHO) in March 2024 in Cotonou to strengthen regional coordination of food fortification and NAFDAC, through the FSAN Directorate, is contributing her quota to national efforts in this regard and participated in the regional consultative meeting on Food Fortification in the ECOWAS region held in Cotonou, Republic of Benin from 19th to 21st March 2024. The Directorate also participated

in the 1st Coordination meeting of the West Africa Regional Fortification Alliance in Abuja on 30th and 31st July 2024 and delivered a presentation on country updates on fortification for Nigeria as the NFA Secretariat. From 28th to 30th October 2024, FSAN was represented at the Africa Regional Workshop on Salt Iodization/Food Fortification organized by UNICEF in Ghana.

The FSAN Directorate continues to leverage her knowledge and experience on large-scale food fortification to contribute positively to supporting national efforts for the realization of rice fortification through participation in the 1st Quarter Technical Advisory Committee/ Rice Fortification Central Coordination Committee (TAC/RF3Cs) meeting held on 30th and 31st May 2024, Lagos.

In recognition of the critical place of quality data for regulatory decision-making, the FSAN Directorate participated in the launch of the report of the 2021 National Food Consumption and Micronutrient Survey (NFCMS) held in Abuja on 29th - 30th April 2024 and participated in the Data Utilization Workshop for the NFCMS Report from 12th -15th August 2024 in Abuja.

C. CODEX Activities

The FSAN Directorate anchors the activities of Codex Alimentarius (Joint FAO/WHO Food Standards Programme) for the Agency in the development of international food standards regarding safe food and ensuring fair practices in food trade. The Director General (NAFDAC) is the Chair of three (3) National Codex Committee (NCC) Technical Committees (NCC-TC) tasked, amongst other functions, with hosting and anchoring meetings of the NCC-TC which prepares Nigeria's delegates and develops national positions in readiness for promoting Nigeria's interests in the international food standards development process. In the period under review, the FSAN Directorate hosted relevant Ministries, Departments and Agencies (MDAs) and other members of the NCC to the three (3) NCC-TC meetings assigned to NAFDAC in line with the revised National Codex Committee NCC Procedural Manual (4th edition):

i. National Codex Committee – Technical Committee (NCC-TC) Preparatory meeting for the 17th session of Codex Committee on Contaminants in Foods (CCCF17) on 21st March 2024.
ii. National Codex Committee – Technical Committee (NCC-TC) Preparatory meeting for the 55th session of Codex Committee on Pesticide Residues (CCPR55) on 15th May 2024.
iii. National Codex Committee – Technical Committee (NCC-TC) Preparatory meeting for the 48th session of Codex Committee on Food Labelling (CCFL48) on 3rd October 2024.

The Directorate facilitated the participation of NAFDAC delegates drawn from relevant Directorates to form part of Nigeria's delegation to two (2) international Codex Committee meetings in 2024: Codex Committee on Pesticide Residues (CCPR55) and Codex Committee on Food Labelling (CCFL48), as well as participation in the meeting of the Codex Alimentarius Commission.

Other Codex activities participated in include:

a. National Codex Committee -Technical Committee (NCC-TC) meeting on Spices and Culinary Herbs on 22nd January 2024.
b. National Codex Committee -Technical Committee (NCC-TC) meeting on Fats and Oils held on 12th February 2024.
c. National Codex Committee -Technical Committee (NCC-TC) meeting on Food Hygiene held on 5th March 2024.

d. Virtual colloquium by CCCAFRICA, FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC), Coordinating Committee for Near East Region (CCNE) and US Codex considering agenda items for the 17th session of Codex Committee on Contaminants in Foods (CCCF) 17 held on 19th March 2024.

e. Participated in the virtual National Codex Committee –Technical Committee (NCC-TC) preparatory meeting convened by the Association of Food, Beverage and Tobacco Employers (AFBTE) to prepare the national delegates for the 54th session of Codex Committee on Food Additives (CCFA 54) on 18th April 2024.

f. Participated in the virtual National Codex Committee –Technical Committee (NCC-TC) preparatory meeting to prepare the national delegates for the 44th session of Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) on 21st September 2024.

As Secretariat of the National Food Safety Management Committee (NFSMC), the FSAN Directorate represented NAFDAC in the first quarter meeting of the NFSMC held on 15th February 2024 to launch and deliberate on the implementation of the revised National Policy on Food Safety and Quality and Its Implementation Plan, FMoHSW Conference Room, Abuja. World Food Safety Day 2024 was celebrated under the theme *"Food safety: prepare for the unexpected"* and the Directorate participated in several activities in commemoration of the international day.

i. 2024 World Food Safety Day webinar by FMoHSW on 3rd June 2024 and delivered a presentation titled '*Developing a Food Safety Emergency Response Plan: Implementation of the National Guidelines for Foodborne Disease Surveillance and Response'*.
ii. Inaugural workshop for the Technical Working Groups on Food and Feed Safety in Nigeria from 5th – 7th June 2024, Abuja.
iii. 10th Regional Food Summit (Refost 2024) convened by the Nigerian Institute of Food Science and Technology (NIFST) and deliberated on the current issues affecting Global Food Safety, Security and Sustainability held on 6th June 2024, Abuja.
iv. 2024 World Food Safety Day celebration held at NAFDAC Auditorium, Isolo, Lagos on 7th June 2024.
v. World Health Organization (WHO) webinar on ranking of Food Safety Risks at the National level held on 10th June 2024.

D. Stakeholders' Engagement

Engagement with stakeholders is recognized as an important activity to improve service delivery. In 2024, the FSAN Directorate actively engaged her stakeholders in the food sector (infant and young child foods, food manufacturing, food service, and edible oil sectors), using the platform for continued advocacy, building capacity, and fostering deeper collaboration through delivery of technical presentations on important aspects of the Directorate's regulatory activities while receiving valuable feedback on industry challenges and proffering solutions. These activities were all geared towards strengthening the food regulatory and control system. The following are some stakeholders' engagement activities undertaken in the period under review:

i. Stakeholders' engagement with Marketers and Sellers of Edible Oil Association of Nigeria to create awareness on hygienic practices for the transport of food held on 14th March 2024, Lagos.
ii. Stakeholders' engagement/Open dialogue/feedback session with Association of Infant Food Manufacturers and Marketers in Nigeria (AIFMN) on 22nd March 2024, Lagos.

iii. Stakeholders' engagement with the AFBTE. The Director (FSAN) delivered a presentation on the Concept of Food Safety and its Impact in the Food and Beverage Industry: Regulatory Perspective on 22nd July 2024, Lagos.
iv. Stakeholders' engagement with the DG NAFDAC and Executives of the Food Industry and Hoteliers was held at NAFDAC Auditorium on 13th August 2024. Isolo, Lagos.
v. Stakeholders' engagement/end-of-year dialogue and feedback session with the Association of Food, Beverage and Tobacco Employers (AFBTE) on 13th December 2024 at the NAFDAC Auditorium, Isolo, Lagos.

The consumer is recognized as a critical stakeholder of FSAN. In the period under review, this recognition of the consumer informed the activities of the Directorate in consistently contributing content on food safety and nutrition to awareness and sensitization programmes of the Agency through NAFDAC and your Health media programs (and other information outlets) to empower consumers with appropriate information to guide their decisions on healthy and nutritious food choices.

E. Sodium Reduction Strategies

The FSAN Directorate, in line with her role in national nutrition programmes represented the Agency at the following activities on sodium reduction strategies geared towards reduction of sodium in diets for better health outcomes.

i. Inauguration and inception workshop of the National Technical Working Group on Sodium Reduction (NTWG-SR) on 13th – 14th February 2024, Abuja.
ii. Inaugural meeting of the sub-Committee on sodium benchmark/target setting established during the inauguration of the NTWG-SR to set benchmarks for sodium levels in different food categories in Nigeria held on 25th - 26th March 2024. Abuja.
iii. Second meeting of the sub-Committee on sodium benchmark/target setting held on 8th - 10th May 2024, Mararaba, Nasarawa State.
iv. Commemoration of 2024 Salt Awareness Week with the theme *'It's Time to Shine the Spotlight on Salt'* on 21st and 22nd May 2024, Abuja.
v. Advocacy dialogue with industry representatives on sodium benchmark/target setting held from 5th to 6th September 2024 in Abuja.
vi. Stakeholders' review workshop on the draft National Guideline for Sodium reduction held from 10th to 12th September 2024 in Nasarawa.

F. Reduction of Industrially Produced Trans Fatty Acids (TFA)

In the bid to effectively implement the regulations (Pre-packaged Food (Labelling) Regulations 2022 and Fats, Oils and Foods containing Fats and Oils Regulations 2022) for the reduction of Industrially Produced Trans Fatty Acids (iTFAs) in the national food supply, in 2024, a Task Team under the Chairmanship of the FSAN Directorate, developed a Strategy and Roadmap document. This is a positive stride towards contributing to the successful implementation of reducing the consumption of industrially produced trans fatty acids (iTFAs) in line with the REPLACE Action package of the World Health Organization.

G. International Collaboration

Collaboration and learning exchanges with international organizations and peer regulatory authorities is a strategy the Agency has adopted for continual improvement as evidenced by the Memorandum of Understanding (MoU) on Strategic Sector Cooperation (SSC) with the Danish Veterinary and Food Administration (DVFA) and NAFDAC titled *"Cooperation in the Field of Food Safety"* and

anchored by FSAN as the focal Directorate. In furtherance of the collaboration the FSAN Directorate participated in the following activities.

i. Strategic Sector Cooperation (SSC) workshop organized by NAFDAC and the DVFA from 27th – 28th May 2024, Lagos.
ii. Learning/study visit organized by the DVFA and the Danish Embassy for deeper collaboration on the SSC project with NAFDAC from 25th to 31st August 2024.
iii. Joint workshop of NAFDAC, Federal Ministry of Agriculture and Food Security (FMAFS), and the DVFA for alignment and collaboration on areas of work for Nigeria under the Strategic Sector Cooperation (SSC) projects of the MDAs from 7th to 10th October 2024, Lagos.

H. Regulations and Guidelines

The task of initiating draft regulations, as well as developing and reviewing food guidelines, are activities undertaken by the FSAN Directorate as a means of keeping abreast of trends and developments in the regulated sector. In the reporting period, the under-listed were successfully accomplished:

Draft Regulations:

i. Draft Regulations on Non-Retail Containers of Foods (Labeling)
ii. Draft Regulations on Wheat Semolina & Durum Wheat Semolina
iii. Draft Regulations on Tomato Mix

New Guidelines:

i. Guidelines and Requirements for Inspection of Food Storage Facilities/Warehouse and Issuance of E-Permit for Bulk Food Raw Materials in Nigeria. Hosted on the website).
ii. Guidelines for Production Inspection of Small-Scale Food Enterprises in Nigeria (New Applicants)
iii. Guidelines for Production Inspection of Micro Scale Food Manufacturing Facilities in Nigeria (New Applicants)
iv. NAFDAC Guidelines for Food Hygienic Practices (NGFHP)

Reviewed Guidelines:

i. Current Good Manufacturing Practice Guidelines for Food and Food Products (Revised)

I. Nutrition Programmes

The FSAN Directorate is engaged in the coordination and implementation of food and nutrition programmes and projects of government within the Agency in collaboration with relevant Ministries, Departments and Agencies (MDAs), industry, Development Partners (UNICEF, WFP, GAIN, Technoserve, Gates Foundation, Helen Keller International, Save the Children Nigeria, etc.) and relevant non-governmental organizations and civil society organizations.

In the period under review, the Directorate participated actively in several nutrition programmes and Committees including National Council on Nutrition, National Committee on Food and Nutrition, Committee on Nutrition and Food Security, National Food Systems Transformation Pathways, Committee on Spirit Drinks Regulation, Micronutrient Deficiency Control (MNDC), National Taskforce on Maternal, Infant and Young Child Nutrition, National Nutrition Technical Working Group (FMOHSW), National Technical Advisory Group (NTAG) on Food Fortification, Regulatory Agencies Core Group on Food Fortification, National Multisectoral

World Breastfeeding Week Celebration Committee, and State Multisectoral Technical Committees on the Code of Marketing of Breast-milk Substitutes.

The FSAN Directorate also participated in the 54th Annual General Meeting and Scientific Conference of the Nutrition Society of Nigeria held from 15th - 21st September 2024 and the 48th Annual General Meeting and Scientific Conference of the Nigerian Institute for Food Science and Technology from 14th to 17th October 2024, both in Kano.

Building local capacity for nutrition commodities is one of the identified interventions to improve availability and access to maternal and child health commodities and this activated several activities in 2024.

i. The FSAN Directorate participated in the joint UNICEF/NAFDAC assessment visits to five (5) manufacturers of multiple micronutrient supplements (MMS) and micronutrient powders (MNPs) in Lagos and Ogun States from 27th to 29th May 2024.
ii. Participated at a one-day Inception meeting of the Multiple Micronutrient Supplement Landscape Analysis in Nigeria hosted by FMoHSW on 9th August 2024. Abuja.
iii. Participated in the Dissemination meeting on the implementation research findings on Multiple Micronutrient Powder (MMP) and the Multiple Micronutrient Supplement (MMS) held in Ondo and Adamawa States in 2022 convened by FMoHSW on 4th September 2024, Abuja.
iv. Participated in the meeting of zero draft review of the National Training Manual for Health Workers on Multiple Micronutrient Supplementation (MMS) Programme in Nigeria from 10th-12th September 2024, Protea Hotel, Ikeja, Lagos.
v. Participated in a 3-day Stakeholders' Technical review meeting on the draft National Training Manual for Health Workers on Multiple Micronutrient Supplementation (MMS) Programme held on 3rd October 2024 at Golden Tulip Hotel, Ikeja, Lagos.
vi. Participated in the stakeholders' finalization and validation workshop on the draft National Training Manual for health workers on Multiple Micronutrient Supplementation (MMS) Programme from 14th - 15th November 2024, Sheraton Hotel, Ikeja, Lagos.
vii. Participated in a regional dialogue on improving access to locally produced nutritious and safe complementary foods in low and middle-income countries from 2nd to 3rd December 2024, Dakar, Senegal.
viii. Participated in a One-Day Meeting of the National Task Force for Multiple Micronutrient Supplements (NTF4MMS) in Nigeria on the 14th of December 2024 at The Wells Carlton Hotel & Apartments, Asokoro, Abuja.

Chapter 5
Drug Evaluation and Research (DER) Directorate

5.0 Introduction

The Drug Evaluation and Research (DER) Directorate, under the leadership of Mr. Amuda Kayode, ensures the promotion and protection of public health in Nigeria by continually improving the quality of clinical research, product evaluation, document review and GMP inspections of manufacturing facilities for drugs, vaccines and other biologics, herbal medicines, nutraceuticals, cosmetics and medical devices, IVDs and related products.

The Directorate is also committed to the development and continued improvement of its Quality Management System (QMS) to ensure a robust and effective Inspectorate that will guarantee quality, safe and efficacious pharmaceuticals including biologics, herbal medicines and nutraceuticals as well as quality cosmetics and medical devices are consumed by the Nigerian public.

The Directorate is structured into the following five Divisions as well as the Director's Office and the QMS Unit:

- Clinical Trials, Vaccines and Biologics
- Cosmetics and Medical Devices
- Herbal Medicines and Nutraceuticals
- Pharmaceutical Compliance
- Pharmaceutical Operations

5.1 Summary of Regulatory Activities of the Directorate in 2024

Table 5.1: Summary of Inspections carried out in 2024 by Inspection Type.

S/N	Type of Inspection	Herbal Medicines & Nutraceuticals	Clinical Trials, Vaccines/ Biologics	Drugs	Cosmetics & Medical Devices	Total
	Routine Inspection	75	16	153	147	391
	Pre-Production Inspection (Drug companies only)	0	0	9	0	9
	Special Inspection	3	0	6	8	17
	Pre-Registration Inspection	0	0	9	0	9
	GMP Re-assessment Inspection	11	0	9	44	64
	Production Inspection	103	0	0	250	353
	Follow-up Inspection	9	0	16	9	34
	Inspection of Warehouses/Retail Outlets for Global Listing	3	0	23	63	89
	Cold Chain Facilities Monitoring for Vaccines & Biologics	0	114	0	0	114
	Coding Inspection	0	0	42	0	42
	Co-packaging Inspection	0	0	0	0	0
	No. of Overseas GMP Inspections carried out	0	0	102	0	102
	MAS Coding Inspection	0	0	19	0	19
	No. of Investigation /For Cause (GMP & GCP) Inspections Conducted	0	0	2	0	2
	No. of GCP Inspections Conducted	0	13	0	0	13
	Total	204	143	390	521	1,258

Figure 5.1: 2024 Herbal Products Inspections carried out in 2024

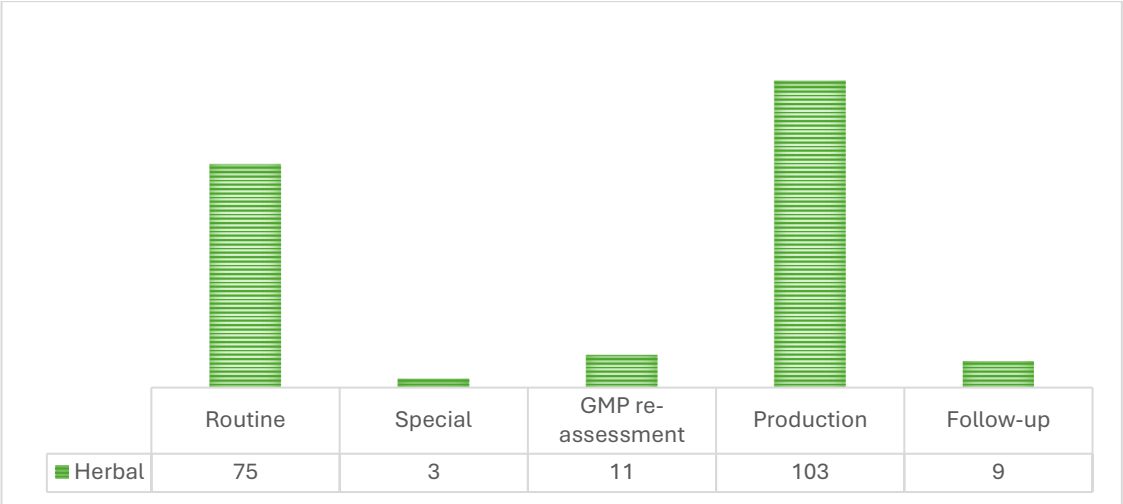


Figure 5.2: Clinical Trial, Vaccines & Biologics Inspections in 2024

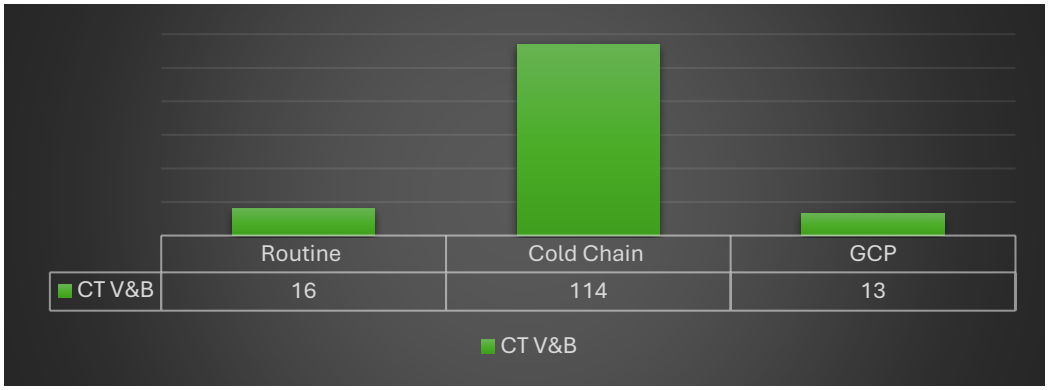


Figure 5.3: Drug (Pharma Operations & Pharma Compliance (local)) Inspections carried out in 2024

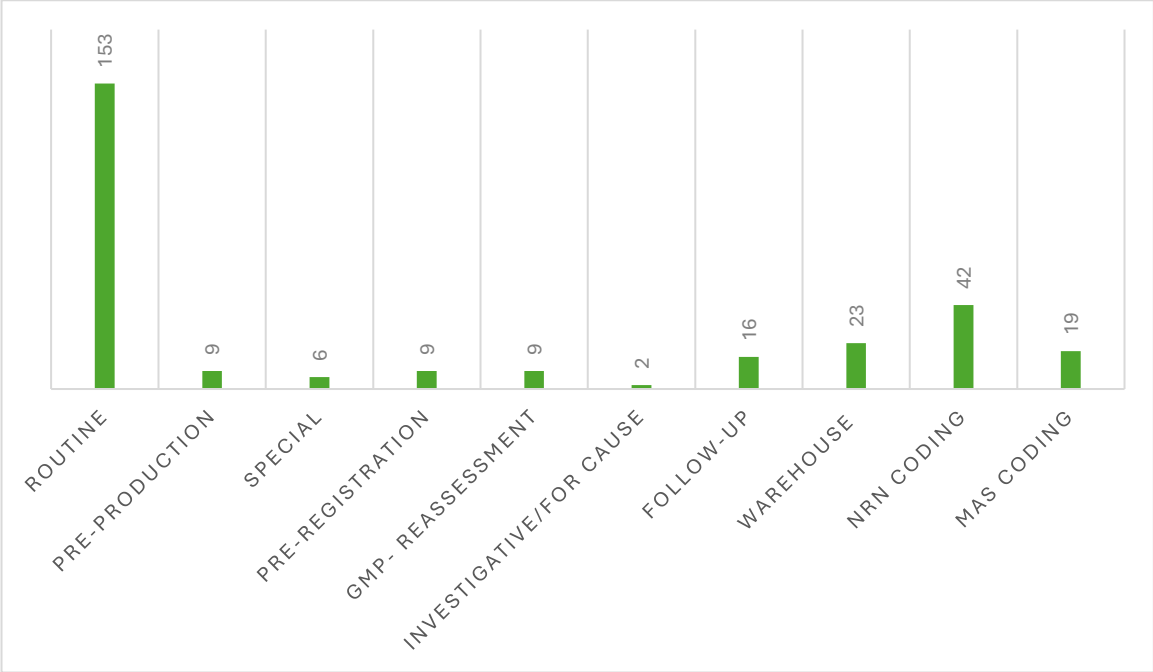
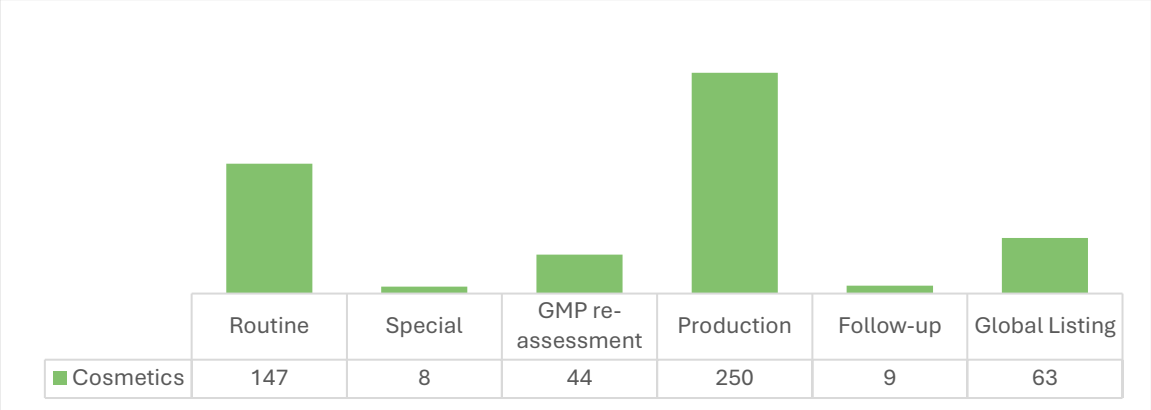


Figure 5.4: Cosmetics & Medical Devices Inspections carried out in 2024



5.2 Summary of DER Directorate Regulatory Activities carried out in 2024

The summary of all regulatory activities carried out nationwide in the year 2024 as they relate to the Divisions in the Directorate is as shown below:

- Clinical Trial, Vaccines & Biologics - 1,017
- Herbal Medicines & Nutraceuticals - 987
- Pharma Operations - 1,024
- Pharma Compliance - 14,536
- Cosmetics & Medical Devices - 5,650
- Quality Management System - 404

Total - 23,618

Figure 5.5: Number of activities carried out by Division/Unit in 2024

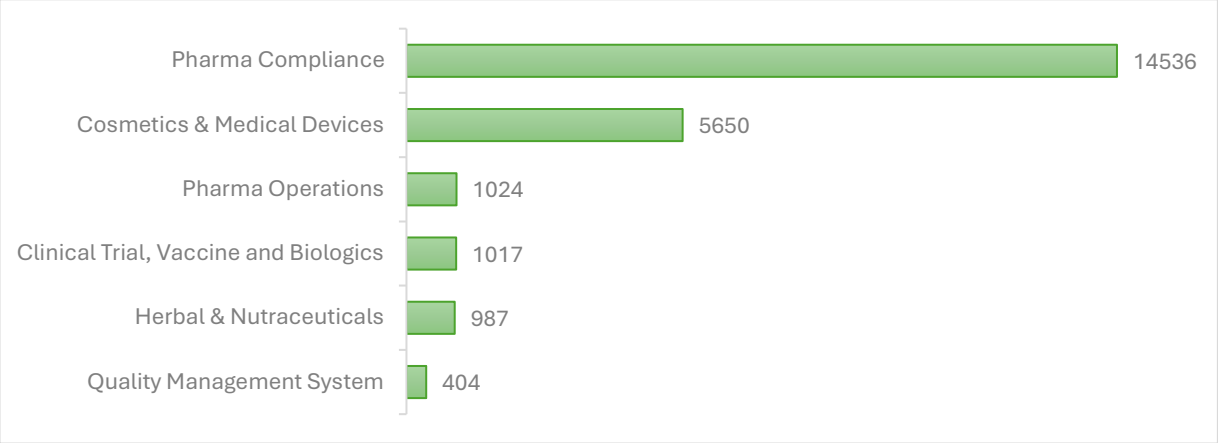
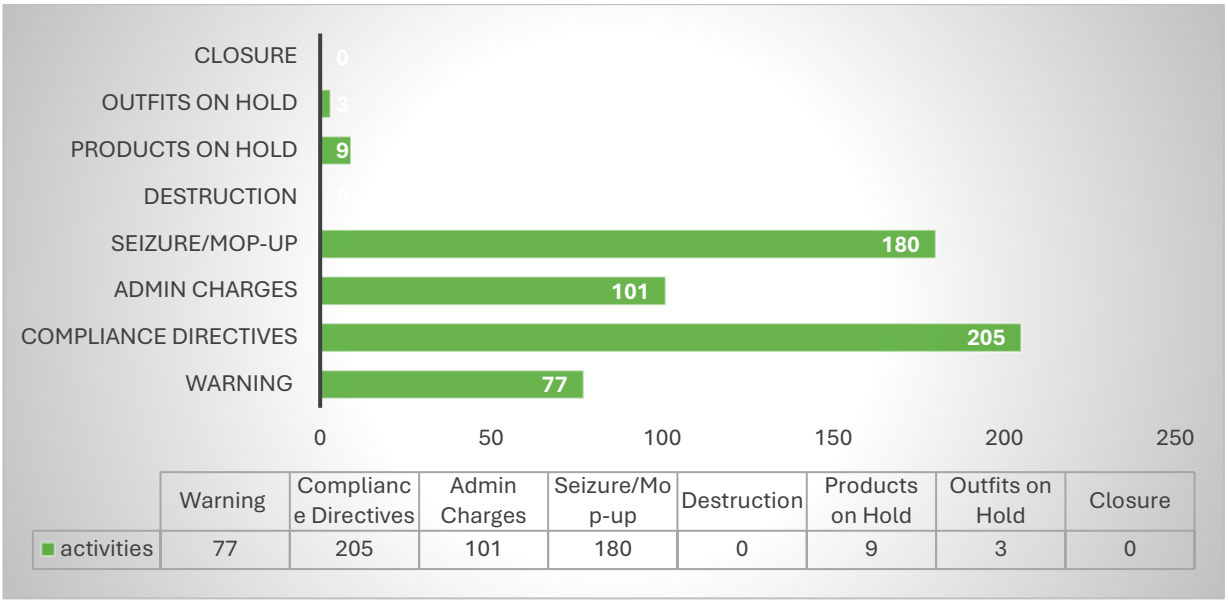
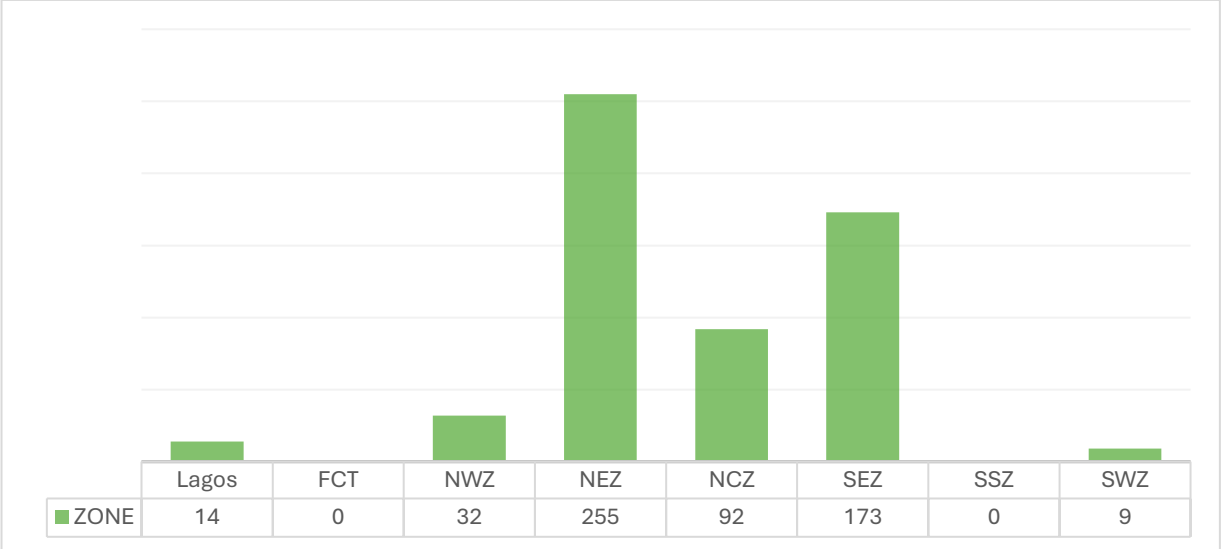


Figure 5.6: Sanctions Carried out in 2024 by Activities



	Warning	Compliance Directives	Admin Charges	Seizure/Mop-up	Destruction	Products on Hold	Outfits on Hold	Closure
activities	77	205	101	180	0	9	3	0

Figure 5.6: Sanctions Carried out in 2024 by Zone



	Lagos	FCT	NWZ	NEZ	NCZ	SEZ	SSZ	SWZ
ZONE	14	0	32	255	92	173	0	9

A. Issuance of Authority to Manufacture

Authority to manufacture products on different product lines in pharmaceutical manufacturing facilities was issued to six (6) companies in 2024.

B. Issuance of GMP Certificates and Notification of Satisfactory Inspection

GMP Certificates were issued to seven (7) companies whose operations were adjudged to comply with minimum GMP requirements.

C. Regulations, Guidelines and Other Quality Documents

Twenty-Nine (29) operational SOPs were reviewed and developed in the reporting period and Twenty-Nine (29) SOPs were approved, made effective by training the relevant personnel and deployed for use of staff. Deployment of relevant QMS forms for effective implementation of the SOPs within the directorate was also done.

Twelve (12) guidelines were finalized, approved, made effective through training DER staff

nationwide. Some of which include: Guideline for Clinical Trial Process Timelines (DER-GDL-011-01) and NAFDAC Good Manufacturing Practice for Pharmaceutical Products Guideline 2024 (DER-GDL-019-03).

5.3. Activities of the Divisions

A. Pharmaceutical Operations Division

a. Inspections

i. **Pre-Production Inspections**
Pre-Production Inspections were carried out in nine (9) facilities nationwide and all met the minimum GMP requirements.

ii. **Pre- Registration Inspection** was carried out in nine (9) pharmaceutical companies. Nine (9) were found to be operating within minimum NAFDAC GMP requirements therefore their products were recommended for registration.

iii. **Routine inspections** were conducted in one hundred and fifty-three (153) pharmaceutical manufacturing facilities nationwide in 2024.

iv. **On-Site CAPA Effectiveness Verification Inspections:**
Most of the facilities were seen to have made significant improvement and were operating within minimum GMP requirement and as such their applications were recommended for further processing.

v. **GMP Re-Assessment Inspections** were conducted in seven (7) pharmaceutical facilities in 2024 nationwide. Seven (7) were adjudged satisfactory while three (3) did not meet the minimum GMP requirement, hence were unsatisfactory as at the time of inspection.

b. Review of CAPA Plans

Fifty-Two (52) companies submitted electronic copies of their CAPA Plans for review in 2024. Nineteen (19) were reviewed.

c. Review of Factory Designs and Layouts

Fifty-Four (54) companies submitted proposed pharmaceutical manufacturing facility layouts for review during the period under review. Forty-One (41) have been reviewed.

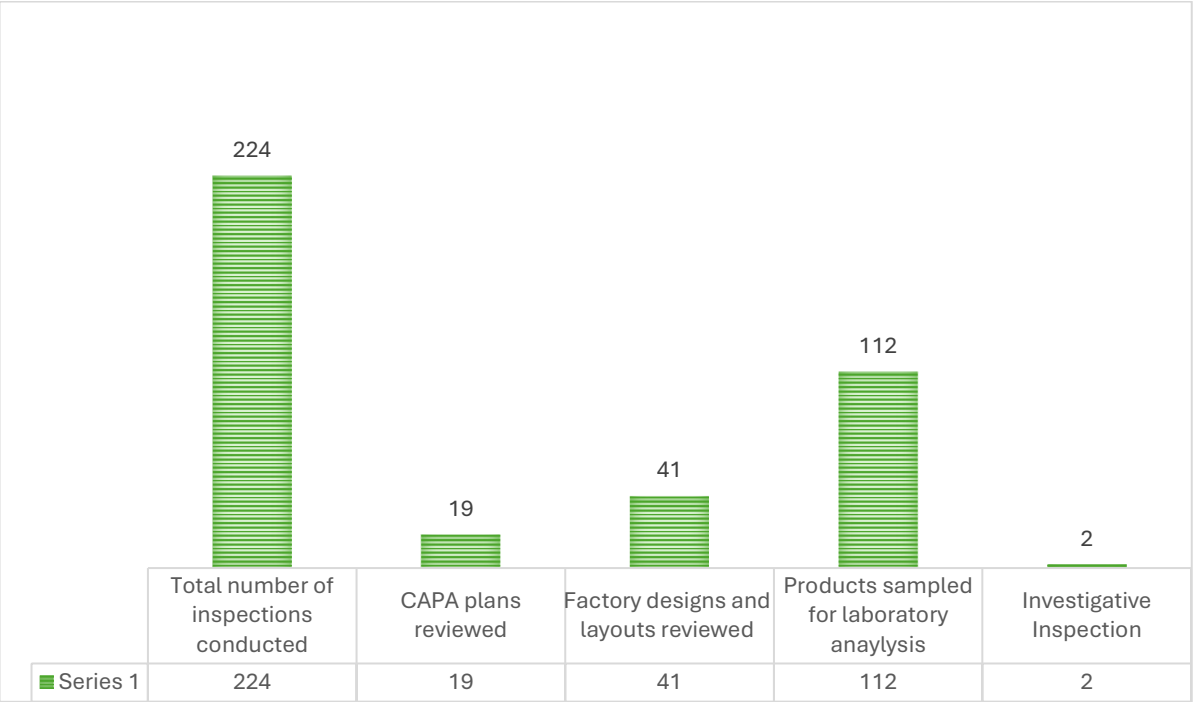
d. Sampling of Products for Laboratory Analysis

One Hundred and Twelve (112) products were sampled were sampled for laboratory analysis in the year under review.

e. For Cause/ Investigative Inspection

Two (2) investigative inspections were carried out in 2024

Figure 5.8: Key Activities of Pharma Operations Division 2024



B. Pharmaceutical Compliance Division

a. Foreign Facility Verification Applications

A total number of Six Thousand, One Hundred and Twenty-Seven (6,127) applications were received and reviewed in the reporting period.

b. Issuance of Permit to Import Active Pharmaceutical Ingredient (API)

A total of One Hundred and Five (105) applications were received and processed for issuance of API permit in 2024. All applications were made on the single window trade portal. Some were renewal, some additional items. All payments were made, inspections conducted, and permit issued.

c. Monitoring of Overprinting of NAFDAC Registration Number and Affixing MAS Labels

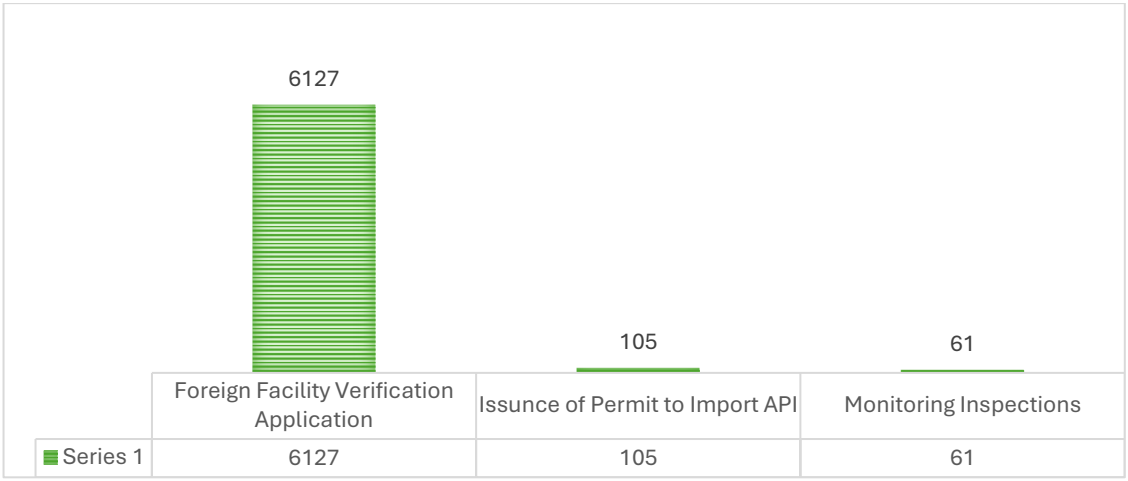
Sixty-One (61) Companies made requests for overprinting of NAFDAC registration number or affixing of Mobile Authentication Service (MAS) labels in 2024 and their requests were all granted after satisfactory monitoring of the activity.

d. Other Activities

i. Participation in the training on inspection module of NAPAMS for integration of GMP inspection processes in the e-registration platform.

ii. Second Regional Workshop on Manufacturing of Active Pharmaceuticals Ingredients and Excipients in Nigeria: Developing Guidelines and Regulations. 29th-31st July, 2024.

Figure 4.9: Key Activities of Pharma Compliance Division 2024



C. Clinical Trial, Vaccines & Biologics Division

a. New Clinical Trial Applications

A total of Sixteen (16) New Clinical Trial Applications (CTA) were received and reviewed and 10 Authorizations issued in 2024.

b. Import Permit of Investigational Medicinal Products

Seventy-one (71) applications for importation of Investigational Medicinal Products were received and Sixty-Eight (68) were reviewed and approved within the reporting period.

c. Cold Chain Storage Facility Inspections

Ten (10) Cold Chain Facility Inspection Applications were conducted in Lagos. A total of One Hundred and Fourteen (114) Cold chain Facility inspections were reported to be carried out across the country during the reporting period.

d. GCP Inspection:

Out of the Twenty-Nine (29) GCP Inspections were scheduled for the year 2024, thirteen (13) inspections were conducted, and Notices of Inspection Findings sent accordingly to the inspected sites. The remaining sites were not inspected due to non-release of funds for the inspections and unavailability of the Principal Investigators.

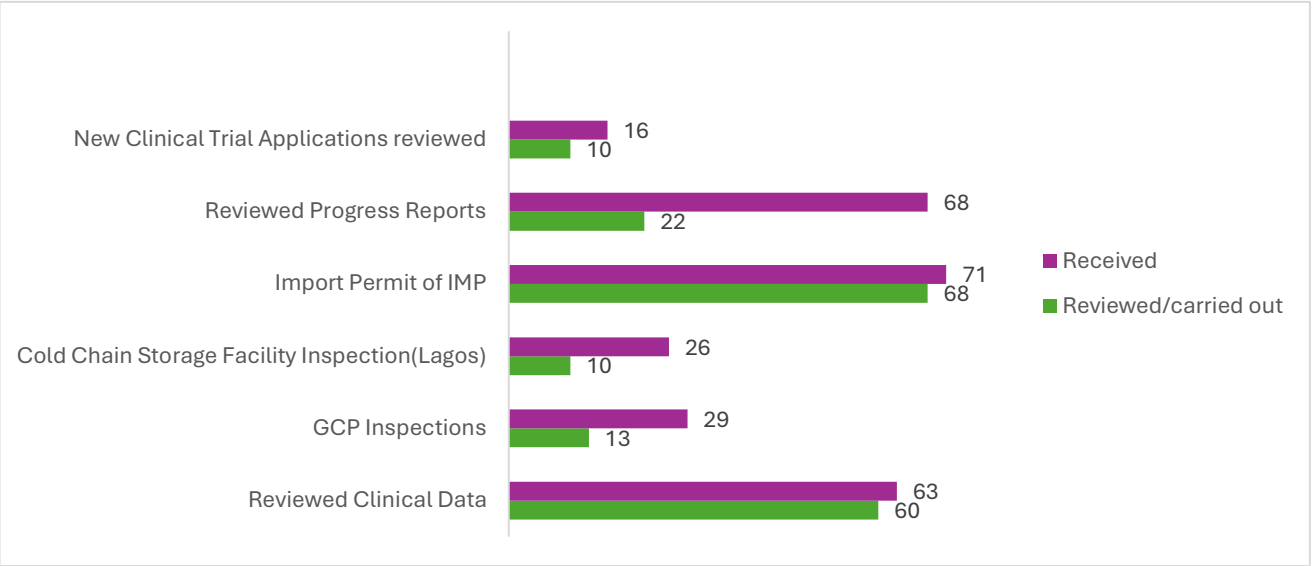
e. Clinical data:

A total of Sixty-Three (63) clinical data were received and Sixty (60) were reviewed within the reporting period. Some reviews were backlogs of Clinical data that were received in preceding year(s).

f. Other activities

I. Seven (7) Pre-Clinical Trial Application (CTA) consultation meeting were scheduled and conducted in the year 2024.
II. The division participated in Twelve (12) DER internal GMP/GCP trainings
III. (7) External trainings/workshops

Figure 5.10: Key Clinical Trial Vaccines and Biologics Division Activities



D. Herbal Medicines & Nutraceuticals Division

a. **Applications for Inspection of Facilities**
Thirty-Eight (38) applications were received within Lagos State and were all treated and found to be satisfactory.

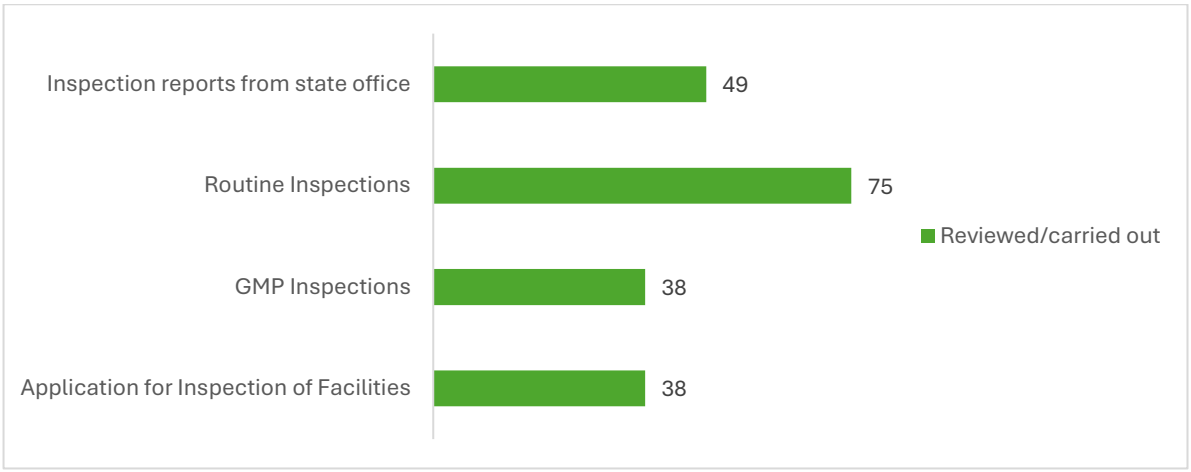
b. **Number of inspections conducted.**
In the year under review, Thirty-Eight (38) inspections were conducted out of which Twenty-Eight (28) were satisfactory within Lagos State.

c. **Routine inspections**
Seventy-Five (75) routine inspections were conducted in 2024.

d. **Review of Inspection reports from NAFDAC States offices**
A total of Sixty-Eight (68) GMP inspection reports were received from NAFDAC State offices nationwide in 2024. Forty-Nine (49) have BEEN reviewed at the time of this report.

e. **Other Activities**
Five (5) audits/self-assessments were conducted in the Division during the year in view.

Figure 5.11: Key Herbal and Nutraceuticals Division Activities



E. Cosmetics and Medical Devices Division

a. Production Inspections

Two Hundred and Fifty (250) Production Inspections for cosmetics & medical devices were carried out across Nigeria.

b. Warehouse/Outlet Inspection for Global Listing of Cosmetics

Warehouse/outlet inspections for global listing of cosmetic products were carried out in sixty-three (63) Supermarkets for Good Hygiene/Good Storage practice.

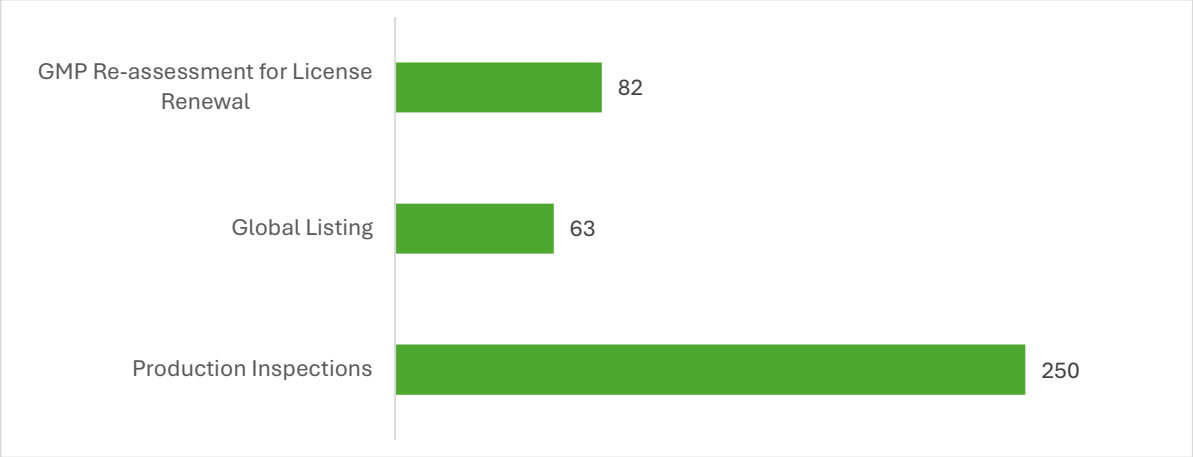
c. GMP Re-assessment for License Renewal

Eighty-two (82) GMP Re-assessment Inspections for cosmetics & medical devices were carried out across Nigeria.

d. GMP Inspection Requests

One Hundred and Fifty-Two (152) GMP requests were received and one hundred and forty-eight (148) were conducted. Out of which, One Hundred and Thirty-Six (136) had a satisfactory GMP.

Figure 5.12: Key Cosmetics and Medical Devices Activities



F. Quality Management System (QMS) and Other Activities Related To WHO-Global Benchmarking (WHO-GB) of NAFDAC

a. **Development of New and Review of Obsolete SOPs**:

The Unit has been actively involved in the comprehensive development and review of the Directorate Standard Operating Procedures (SOPs) throughout the year. A total of twenty-nine (29) SOPs were reviewed through the year.

b. **Deployment of Effective SOPs:**

The unit was also responsible for the approval and deployment of the approved SOPs. All the approved SOPs were distributed and deployed to the process owners within the stipulated timelines.

c. **Self-Assessment and DER Internal Audit**:

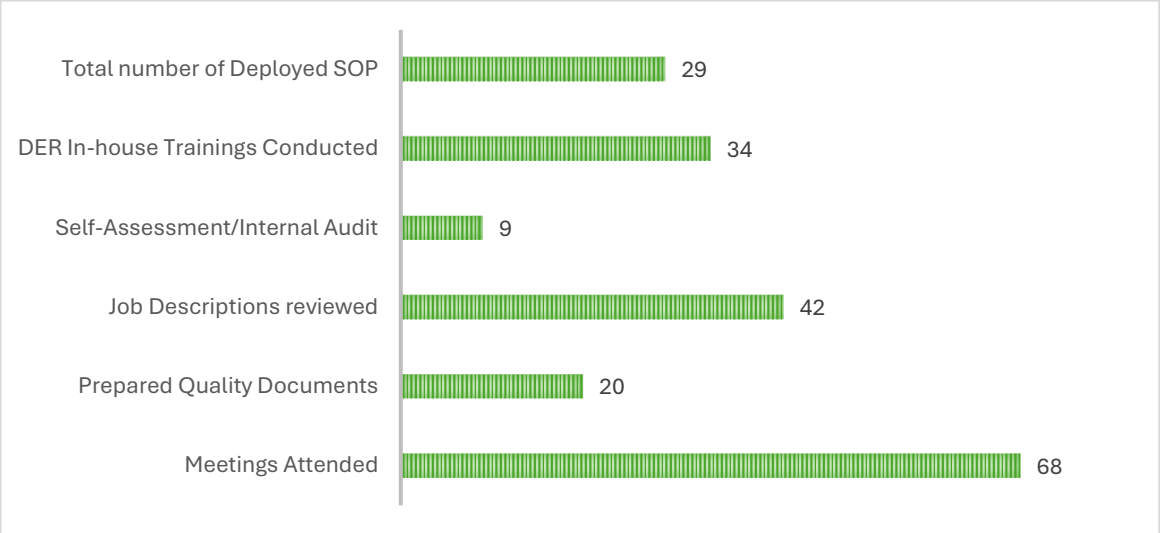
A total of Nine (9) Internal Audits/Self-assessments conducted in the Directorate were coordinated by the unit as scheduled throughout the year. All non-conformances raised were adequately addressed and completely closed out by 4th quarter 2024.

d. **Preparation of DER Quality Documents**:

A total of Twenty (20) quality documents including the List of Directorate Stakeholders, DER Organogram, DER Operational Process Flow Charts, and Minutes of Directorate meetings held within the period under review were prepared and approved accordingly.

e. **Meetings:**
A total of Sixty-Eight (68) meetings were attended by staff of the unit throughout the year.

Figure 5.13: Key Activities of the QMS Unit



f. WHO- Global Benchmarking for NAFDAC

Following the WHO re-benchmarking assessment conducted from 25th - 29th November 2024, a total of 15 Institutional Development Plans (IDPs) for Regulatory Inspections (RI) were identified, all of which have been successfully closed by the time of this report. Additionally, the Clinical Trial Oversight (CTO) function has successfully maintained its ML 3 status.

Chapter 6
Ports Inspection Directorate (PID)

6.0 Introduction

In the year under review, the Ports Inspection Directorate sustained its drive towards efficient and effective control of the channels through which regulated products were imported and exported. The Directorate's duties were as embedded in its various statutory functions, including:

- Overseeing and managing the importation of drugs, food, medical devices, cosmetics, and other regulated products, ensuring compliance with regulatory standards.
- Reviewing import documents prior to issuing pre-release stamps.
- Examining imported food, drugs, medical devices, cosmetics, chemicals, detergents, other regulated products at entry ports prior to release.
- Regulating the exportation of regulated products and providing quality certifications for such items.

The Directorate carried these tasks through its various Divisions, Port offices, Outstation offices, Checkpoints at land borders and airports.

A. Divisions:

The Directorate comprises five (5) divisions and the units under Director's Office headed by the Deputy Directors. The divisions are the Port Chemical, Cosmetics, and Medical Devices Division (CCMD), the Port Drug Division, the New Technologies/Post Port Clearance Division, the Port Food Division, and the Export Division.

B. Port Offices:

NAFDAC PID maintained a total of 11 port offices across Nigeria, strategically located at six seaports and four airports. The seaport offices included Apapa, Lekki Deep Sea, Tincan, Kirikiri Lighter Terminal, Lilypond, Ikorodu, and Onne Port at PortHarcourt. The airport offices were situated at Murtala Mohammed International Airport in Lagos, Aminu Kano International Airport in Kano, Nnamdi Azikiwe International Airport in Abuja, and Akanu Ibiam International Airport in Enugu.

C. Outstation Offices:

The Ports Inspection Directorate operates outstation offices in Port-Harcourt, Warri, Calabar, Kaduna, Kano, Abuja, Enugu, and Onitsha.

D. Land Borders:

NAFDAC's Ports Inspection Directorate oversees operations at the following six (6) land borders: Idiroko, Seme, Kamba, Jibiya, Maigatari, and Illela.

E. Staff Strength

PID has a total of Two Hundred and Twenty-One (221) staff members in a total of twelve (12) locations. Below is a Table and Chart showing PID officers' staff distribution and composition across various PID offices and locations.

6.2 Activities Summary

A. Transaction Summary

In 2024, the Ports Inspection Directorate (PID) managed various port clearance transactions, including inspection charges, analysis, radiation charges, administrative approvals, and penalties for violations. The total revenue generated from these activities is outlined as follows:

Table 6.1: ***Transaction Summary Table for 2024***

PID Office Locations	**No. of Transactions**
Lagos Ports	58,527
Land Borders	
Outstations	
Director's Office	665
Export	-
Totals	59,192

B. Violation

The most reported types of violations in the year under review were non-endorsement (45.07%), No permit (20.12%), Labeling lapses (14.76%), No CRIA (11.20%), unapproved pictorial (0.21%), Importation Above Approved Quantity (3.42%) and mobile authentication service (0.87%). Table 7 below gives the statistics report of types of violations.

Table 6.2: Violation Types

Violation Types Reported	Total Cases
Change of Source	2
Concealment and False Declaration	8
Expired Certificate	17
Importation above Approved Quantity-Permit	51
Labeling Lapse	220
Mobile Authentication Service	13
No CRIA	167
No Permit to Clear-Controlled Drugs, Chemicals, Precursors, Solvents	16
No Permit to Clear-Restricted Chemicals	11
No Permit to Import-Controlled Drugs, Chemicals, Precursors, Solvents	4
No Permit to Import-General Chemicals	212
No Permit to Import-Others	53
No Permit to Import-Restricted Chemicals	4
Non-Endorsement-Drugs	90
Non-Endorsement-Food	102
Non-Endorsement-Others	480
Others (Specify in Remark)	12
Removal of Seal before Inspection	1
Unapproved Pictorials	3
Unauthorized labelled packaging materials	1
Unauthorized Parallel Importation	3
Unregistered Pack Size	6
Unregistered Products (Excl. Medicines)	15
Total	**1,491**

C. Quantity of Imported Items

A total of 11,088,211,509.3 Quantity in Metric Tons and 8,200,283,930,191,660 Cost Insurance Freight were treated in the year under review.

Table 6.3: Quantity Metric Ton (MT) and Cost Insurance Freight (CIF)

Product class	Quantity (MT)	CIF Value
Agarbatties	678,595.44	1,697,522,603.15
Agrochemicals	74,540,102.21	700,792,556,777.08
Autocare	2,101,615.95	515,521,563,125.64
Baby Foods	26,320,945.60	136,385,327,604.60
Bakery Wares	10,640,891.78	50,909,134,423.49
Beverages	235,562,506.75	842,095,460,586.58
Cereals	3,630,777.69	125,927,564,606.35
Cereals & Cereal Products	3,993,294.47	877,207,626,231.97
Composite Foods	185,771,155.81	413,466,138,867.08
Confectionery	745,662.94	27,934,185,106.05
Controlled Solvents	184,768,167.30	530,641,462,574.24
Cosmetics & Household	19,425,746.55	22,056,664,724.60
Dairy Products	51,763,782.11	3,643,605,102,846.12
Edible Ice	1,160.00	4,640.00
Eggs & Egg Products	43,425.00	653,863,082.00
Fats & Oils	3,736,163.22	1,654,081,467,174.36
Finished Pharmaceuticals	4,675,891,475.21	1,284,298,187,268.19
Fire Extinguisher	63.00	29,041,209.00
Fish & Fish Products	336,204,814.86	3,967,383,056,809.31
Food Raw Materials	726,626,517.78	34,617,077,923,741.10
Fruits & Vegetables	24,716,838.88	17,550,746,432.77
Industrial Chemicals	3,829,661,023.44	8,575,598,654,607.98
Meat & Meat Products	171,454.13	4,540,640,103.09
Medical Devices	54,786,178.74	1,770,331,629,814.50
Nutritional Foodstuff	29,637,470.97	1,055,098,381,397.47
Raw Materials	541,550,412.90	8,127,834,949,051,730.00
Ready-To-Eat Savourings	730,383.60	7,456,065,012.71
Reagents	221,976.72	59,306,391,807.57
Refrigerant Gas	123,710.86	,715,026,193.68
Salt	377,749.00	771,876,718,238.00
Salts & Spices	20,563,674.42	84,982,324,876.91
Shoe Polish	1,318,198.00	807,720,677.00
Sugar	8,867,949.44	10,559,656,169,539.90
Supermarket Items	3,140,420.30	28,928,922,979.89
sweeteners	164,656.75	3,221,177,107.10
Vaccines & Biologicals	2,518,692.01	19,682,755,676.64
Veterinary Products	27,213,855.50	73,463,961,457.58
Total	**11,088,211,509.30**	**8,200,283,930,191,660.00**

Table 6.4: Details of Export Activities

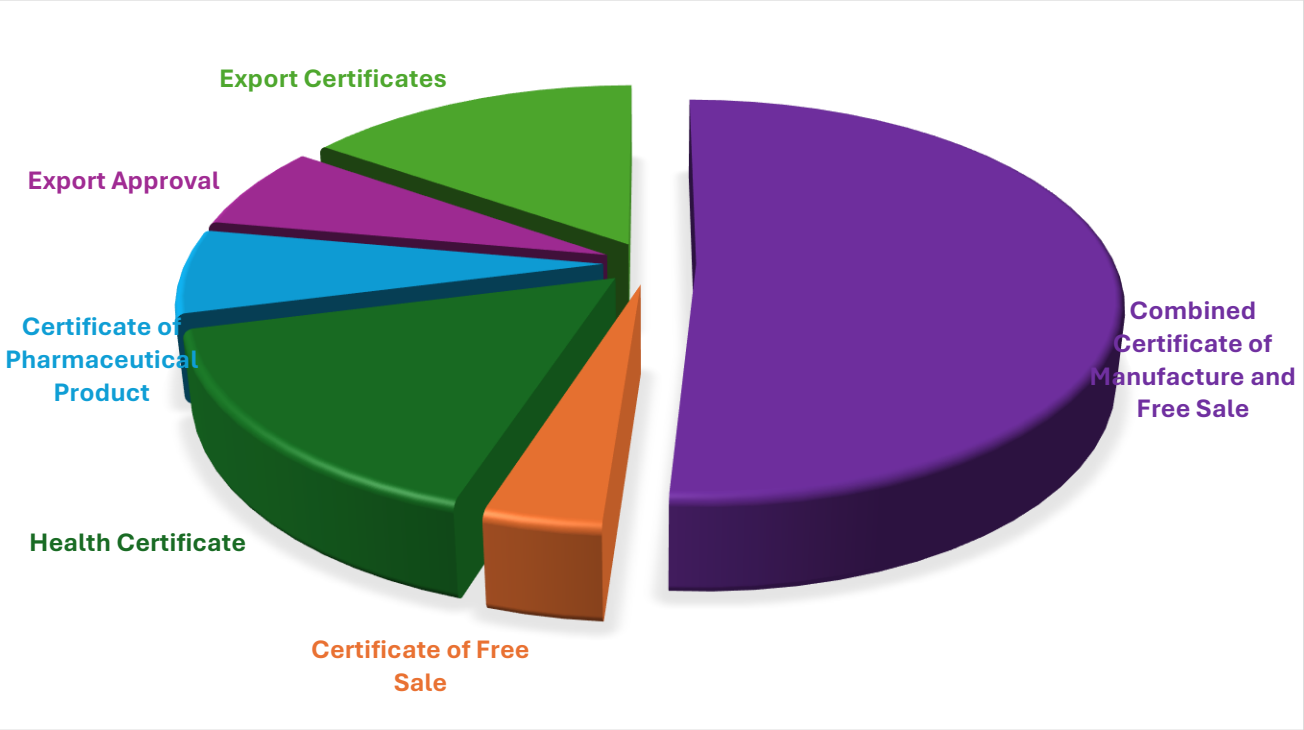
Product Group	Applications Received	Weight (MT)	Combined Certificate of Manufacture and Free Sale	Certificate of Free Sale	Health Certificate	Certificate of Pharmaceutical Product	Export Approval	Export Certificates	Compliance-Directive
Food (Finished Products)	64	2,578,842.088	38	-	8	-	6	2	**8**
FOOD COMMODITIES (Processed & Semi Processed)	29	381,970.207	14		9	-	-	-	3
Bulk Food Commodities	4	18	-	-	3	-	-	-	1
Drugs (Finished Pharmaceutical & Cigarettes)	21	24,763.394	6	3	-	9	-	1	1
Cosmetics	6	27,010.696	6	-	-	-	-	-	1
Chemical	11	225,410.071	3	2	1	-	3	7	1
Totals	**135**	**3,400.406.545**	**67**	**5**	**21**	**9**	**9**	**10**	**15**
			Total Certificates issued: 113.			**Total Export Approval: 9**			

6.3 Divisional/Outstations Report

A. Export Activities

Activities in the Export Division are online which involve review of submitted documentation, Inspection, Laboratory Analysis, and e-certification. These operations are usually carried out in collaboration with relevant Directorates of the Agency and other stakeholders. Applications received were One hundred and thirty-five **(135)** with One hundred and thirteen **(113)** Certificates issued and Nine **(9)** Export Approvals given. Fifteen (15) compliance directives were issued.

Figure 6.1: Pie Chart of Export Certificates issued in 2024.



B. New Technology/Post-Port Clearance Division (NT/PPC)

The division is responsible for overseeing all aspects of post-port clearance operations. This includes managing inspections, release procedures, HOLD placements, and the removal of HOLDs at the importers' warehouse.

Placement/ Removal of Hold Label Report

A total of four (4) holds were placed and ten (10) holds were removed during the year in review.

C. Director's Office

During the reviewed year, e-licence unit in the Director's office issued **135** Letters of Non-Objection, **409** Authorizations to Open Form M, **50** Approvals for Materials for Machine Trials and Research Purposes, **35** Approvals to Import Donated Items by NGOs, and **36** Approvals to Import Products by Government Agencies, Multinational Organizations, and International Bodies.

Table 6.5: Breakdown of e-licence Activities.

Month	Approval of letter of non-objection	Authorization to open form M	Materials for machine trials & Research purposes	Approval to import donated items by NGO'S	Approval to import products by Government agencies, multinational organizations, and international bodies
January	28	84	6	2	2
February	26	76	2	6	26
March	19	67	5	3	6
April	9	35	2	4	1
May	4	15	4	1	1
June	10	17	4	3	1
July	7	12	4	2	nil
August	6	13	6	4	2
September	7	14	3	5	2
October	3	14	4	3	nil
November	5	28	6	nil	nil
December	11	34	4	2	1
Total	**135**	**409**	**50**	**35**	**36**

6.4 Achievements

1. Optimization of PIDCARMS and Training of Priority Clients: The Ports Inspection Data capture and Risk Management System (PIDCARMS) was optimized for sustained virtual processing of clearance activities. Despite the strike action embarked on by the staff Union, the Directorate maintained its port operations. Similarly, Priority Clients on the PIDCARMS Platform underwent a successful on-site training on the optimized and existing modules on the platform. Awards were made for organizations that performed well during the year.

2. Sustained Regulatory Operations: Despite the hiccups on the economy and the consequences on regulatory operations, the Ports Inspection Directorate staff showed exemplary dedication through their sustained and effective manning of the ports and land borders. This was evident in the modest achievements in the face of our challenges and in the sustained revenue generated during the year.

Chapter 7
Drug Registration and Regulatory Affairs (DR&RA) Directorate

7.0 Introduction

The Drug Registration and Regulatory Affairs Directorate is one of the Directorates of the Agency, whose functions are anchored on the provisions of the Drugs and Related Products (Registration, etc) Decree No. 19 of 1993 as amended now Act. Cap N1 Laws of the Federation of Nigeria (LFN) 2004, vis:

- Registration of drugs, cosmetics, medical devices, chemicals, detergents.
- Other functions are as follows:
  i. Formulating, updating, compiling and periodic review of standard specifications, regulations and guidelines for the production, importation, exportation, sale and distribution of drugs, cosmetics, medical devices and chemicals.
  ii. Approval and control of advertisement of drugs, cosmetics, medical devices, and chemicals to ensure that advertisements are not exaggerated, deceptive or detrimental to the consumer.
  iii. Monitoring of advertisement to ensure compliance and identify illegal advertisements.
  iv. Assessment of technical requirements for local and imported drug dossier on Dossier Management System.
  v. Assessment of technical requirement for PQR for local and imported pharmaceutical products.
  vi. Assessment of technical requirements for the different types of variations for pharmaceutical products viz; (Annual Notifications, Immediate Notifications, Minor & Major Variations).
  vii. Issuance of Variation Clearances and Variation Approvals to complement NAPAMS applications for registration processes.

Divisions and Units of the Directorate

The Directorate has Five (5) Divisions with several Units to enable it carry out its regulatory functions:

1. Drugs Registration Division
2. Biologics, Vaccines and Medical Devices Division (BVM)
3. Drug Adverts Control Division (AC)
4. Animal Health Products and Finished Chemicals (AHFC)
5. Cosmetics Division

The Director's office is made up**:**

i. Liaison Offices to the Director (LOD Drug)
ii E-Registration & Data Management Unit
iii. Global Listing Office
iv. Service & Orphan Drugs and Donated Medical Products
v Technical Services which comprises:
- Regulations
- Quality Management System
- Dossier Review Team

7.1 Highlights of Activities:

The Directorate, with her core functions and other responsibilities, has undertook and participated in many relevant activities to build staff knowledge capacity and to strengthen the Agency mandate. These activities/responsibilities are enumerated below:

- Participation in the Stakeholders workshop on the Pilot of the Collaborative Registration Procedure (CRP) for Vector Control Products in Tanzania from 30th Jan - 1st February,2024.
- Participation in National policy on cosmetics safety 7th September 2023 to March 2024.
- Participation in 15th WAMRH Steering Committee Meeting in Lomé Togo, from 18th and 19th March 2024.
- Reception and processing of the pilot CRP/VCP product by AHFC Division (Applicant is yet to meet all statutory requirements).
- Participation in the West African Pesticides Registration Committee (WAPRC) information and awareness raising meeting as part of the Regional Harmonization project. This was held in Cabo Verde from 11th -13th June 11th -13th 2024.
- Participation in Pilot Assessment Sessions for In-Vitro Diagnostics Geneva, Switzerland June 2024.
- Stakeholder engagement on Service drugs and Service Medical Devices held on July 15th 2024.
- Advocacy and Consolidation Workshop on Collaborative Registration Procedure (CRP) for Medical Products attended in Kigali, Rwanda from 9th – 11th July 2024. Collaborative Registration Procedure (CRP) is a regulatory reliance mechanism initiated by the World Health Organization (WHO) to make risk-based regulatory decisions to accelerate the granting of National Marketing Authorization for Drugs, Vaccines, and In-Vitro Diagnostic devices that had been prequalified by WHO or approved by a Stringent Regulatory Authority (SRA).
- NAFDAC is a member of of the Quality Working Group (QWG) in International Pharmaceutical Regulators Program (IPRP). IPRP is a forum for regulatory bodies to exchange information on issues of mutual interest and enable regulatory cooperation. This forum assists in maximizing potential efficiencies in addressing the increasingly complex global regulatory environment, facilitates the implementation of ICH and other internationally harmonized technical guidelines for pharmaceuticals for human use,

promotes collaboration and regulatory convergence, and contributes to the coordination of a range of international efforts related to the regulation of medicinal products for human use.

- Stakeholder engagement on Export Regulations on 12th August 2024.
- Presentation of 2 Regulations to NAFDAC Governing Council on 5th September 2024.
- Virtual participation of DR&RA at the cGMP training marathon for vaccine manufacturing, Principles into practice held between 12th September – 10th October 2024.
- Creation of Vaccine, Biologics and Medical Device Registration and Regulatory Affairs Directorate in 13th September, 2024
- Creation of a new division Nigeria Drug Registration Division and renaming of the Drug Registration Division to Imported Drug Division ,4th November 2024
- Participation in the Antimicrobial Resistance /One health programme on the Antimicrobial Use and Antimicrobial Consumption organised by the WHO/NCDC/NAFDAC in Abuja from the 25th- 295th November 2024.
- Inauguration of Regulatory Affairs Committee (RAC) on 10th December 2024
- Twelve (12) Approvals meetings (SubFDRC & FDRC

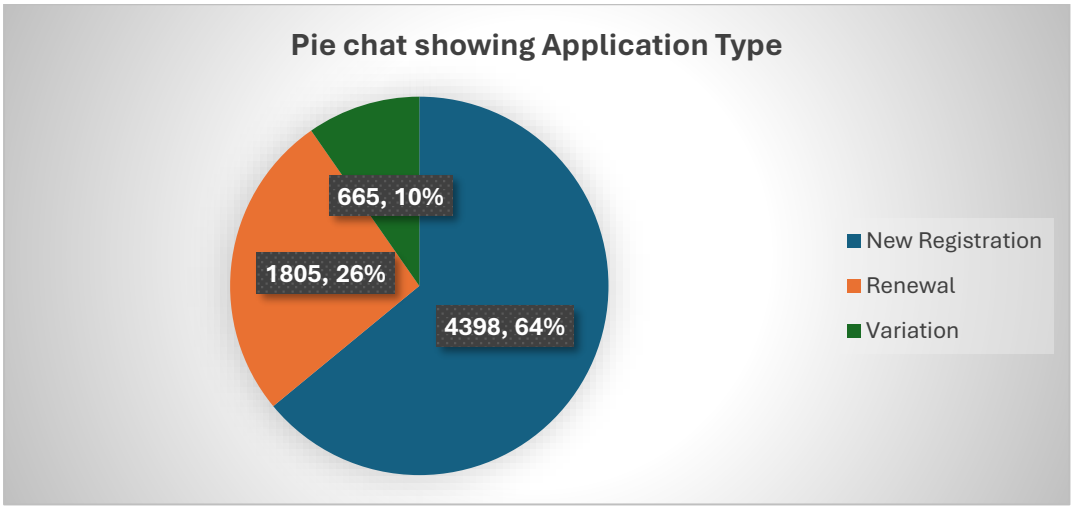
The Directorate processed applications for registration, renewal and variation which are summarized below:

A total of Six Thousand, Eight Hundred and Sixty-Eight applications were processed for variation (9.7%), Registration (64%) and Renewal (26.3%) as listed below:

Table 7.1: Number of Applications Treated Based on Application Type in 2024.

Number of applications based on Application type in 2024			
S/No		Nos	Percentage
1	Variation	665	9.7
2	New Registration	4,398	64.0
3	Renewal	1,805	26.3
	Total	6,868	

Figure 7.1: Percentage of Registration/Renewal and Variation Approvals in 2024



A total of Six Thousand, Eight Hundred and Sixty-Eight applications were processed for Registration. Cosmetics had a total number of 3,178 (46.2%). This is followed by Drugs with a total number of 1,318 *(19.19%).* Vaccines and Biologics have the least t number of registered products of 46 (0.67%) as listed below:

Table 7.3: Category of Products Registered in 2024

Product Category	No Registered	Percentage
Agro-Chemicals & Pesticide	433	6.30%
Cosmetics	3,178	46.27%
Drugs	1,318	19.19%
Herbal and Nutraceuticals	984	14.33%
Medical Device	368	5.36%
Vaccines & Biologicals	46	0.67%
Veterinary Products	541	7.88%
Grand Total	6,868	

Figure 7.2: Category of Products Registered in 2024

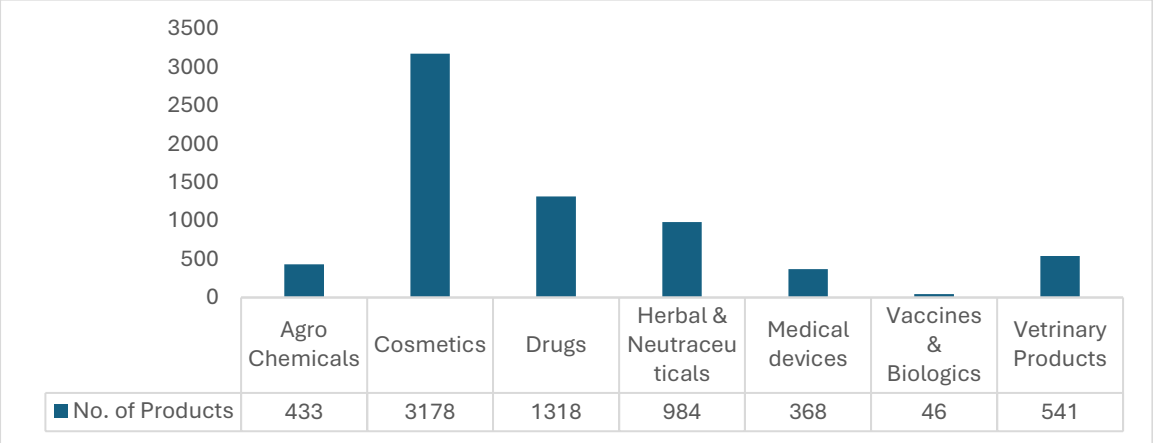


Table 7.3: Category of Products Registered in 2024

Product Category	Imported	Local	Grand Total
Agro-Chemicals & Pesticide	345	88	433
Cosmetics	278	2,900	3,178
Drugs	958	360	1,318
Herbal and Nutraceuticals	611	373	984
Medical Device	291	77	368
Vaccines & Biologicals	45	1	46
Veterinary Products	247	294	541
Grand Total	**2,775**	**4,093**	**6,868**

Figure 7.3: Application Type

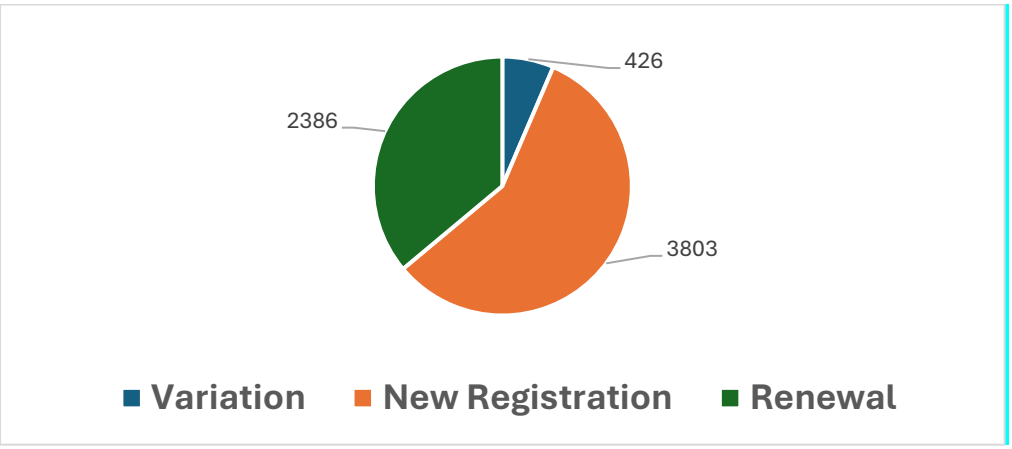


Figure 7.4: Category of products by origin status registered in 2024

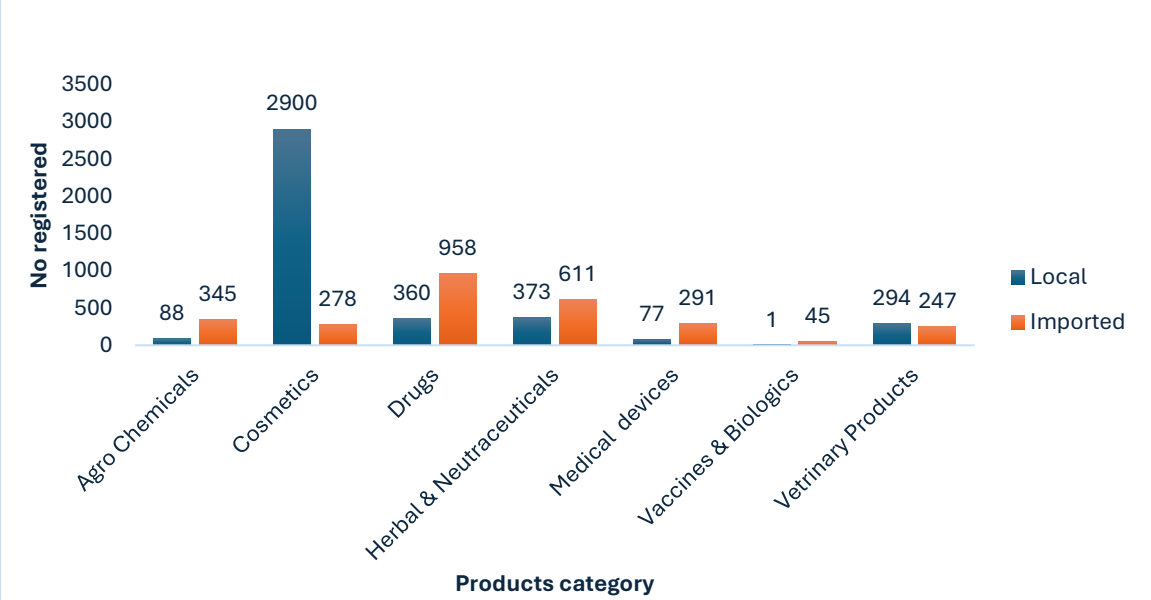
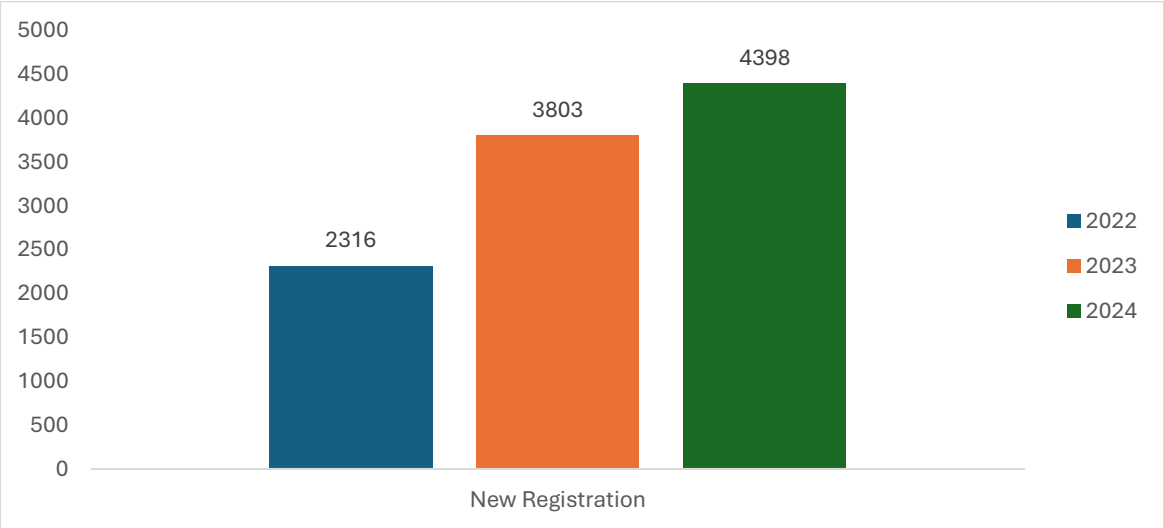


Figure 7.5: Comparative Analysis of New Product Registration in 2022 to 2024



This represents a 86.5% increase over the figures of the same period in year 2023 and (Three thousand, eight hundred and three (3,803) products.

Table 7.4: Comparative Analysis of Registration/Renewal and Variation Approvals in 2022 2023 and 2024.

Comparative Analysis of Number of Registered products between 2022 and 2024				
S/No	Product Category	2022	2023	2024
1	Agro-Chemicals & Pesticide	321	358	433
2	Cosmetics	1,445	1,928	3,178
3	Drugs	1,085	2,062	1,318
4	Herbal and Nutraceuticals	738	1,084	984
5	Medical Device	356	439	368
6	Vaccines & Biologicals	63	165	46
7	Veterinary Products	330	579	541
	Total	**4,338**	**6,615**	**6,868**

Figure 7.6: Products Registered Between 2022 and 2024

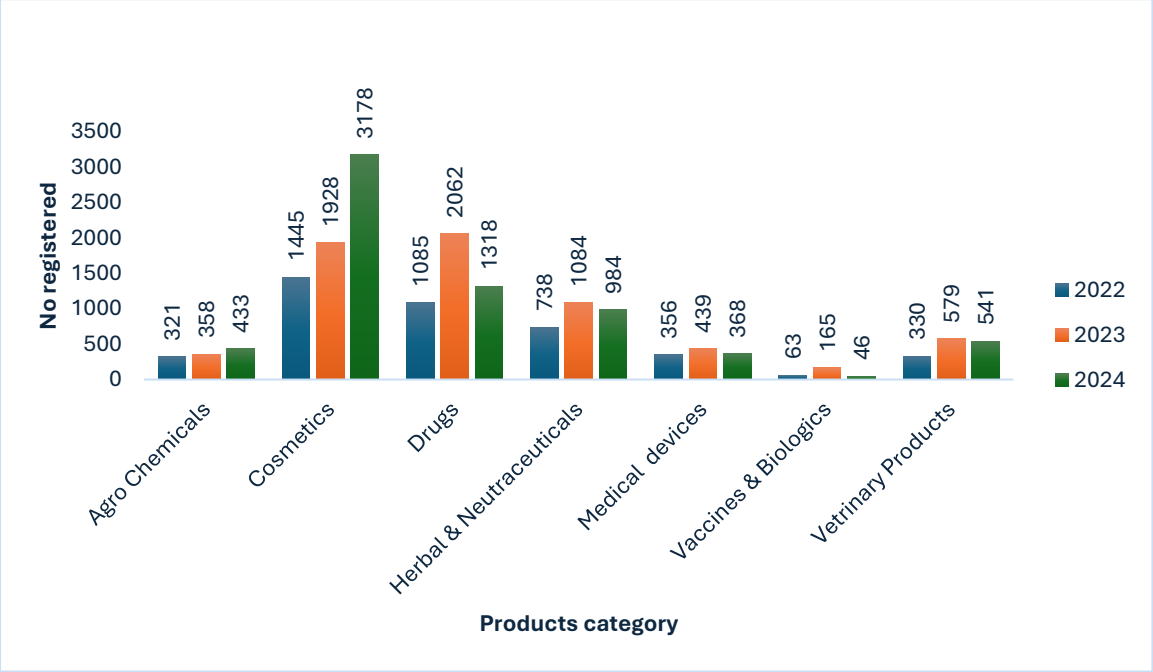


Table 7.5: Summary of the Activities of Drug and Related Products Registration Divisions

Data on Total Applications (Registration, Renewals and Variation Approvals) processed in 2024								
Month	**Product Category**							
	Agro-Chemicals & Pesticide	Cosmetic	Drugs	Herbal and Nutraceuticals	Medical Devices	Vaccines & Biologicals	Veterinary Products	Total
Jan	1	76	6	39	0	0	5	127
Feb	67	496	118	72	33	2	52	840
Mar	65	497	117	73	33	2	52	839
Apr	0	123	93	22	0	0	24	262
May	63	350	175	88	33	0	81	790
Jun	33	108	148	81	39	0	29	438
Jul	43	368	205	162	75	4	52	909
Aug	61	466	226	153	113	5	104	1,128
Sep	28	334	95	126	17	16	61	677
Oct	1	39	27	21	0	0	2	90
Nov	23	101	46	39	10	5	22	246
Dec	48	220	62	108	15	12	57	522
Total	433	3,178	1,318	984	368	46	541	6,868

Figure 7.7: Average Timelines for Registered Products

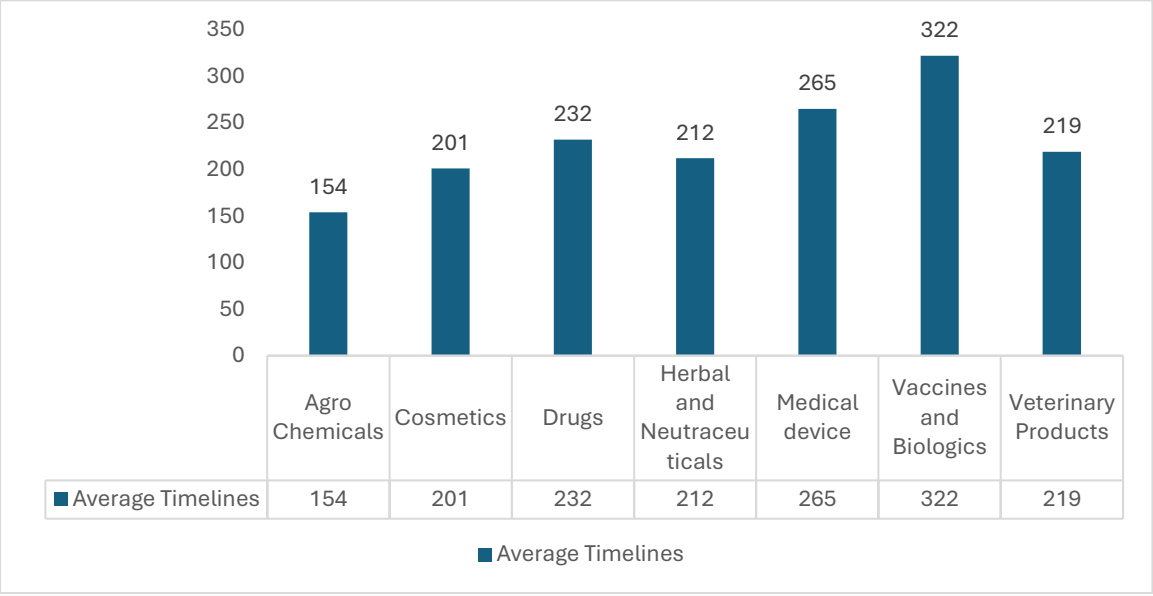
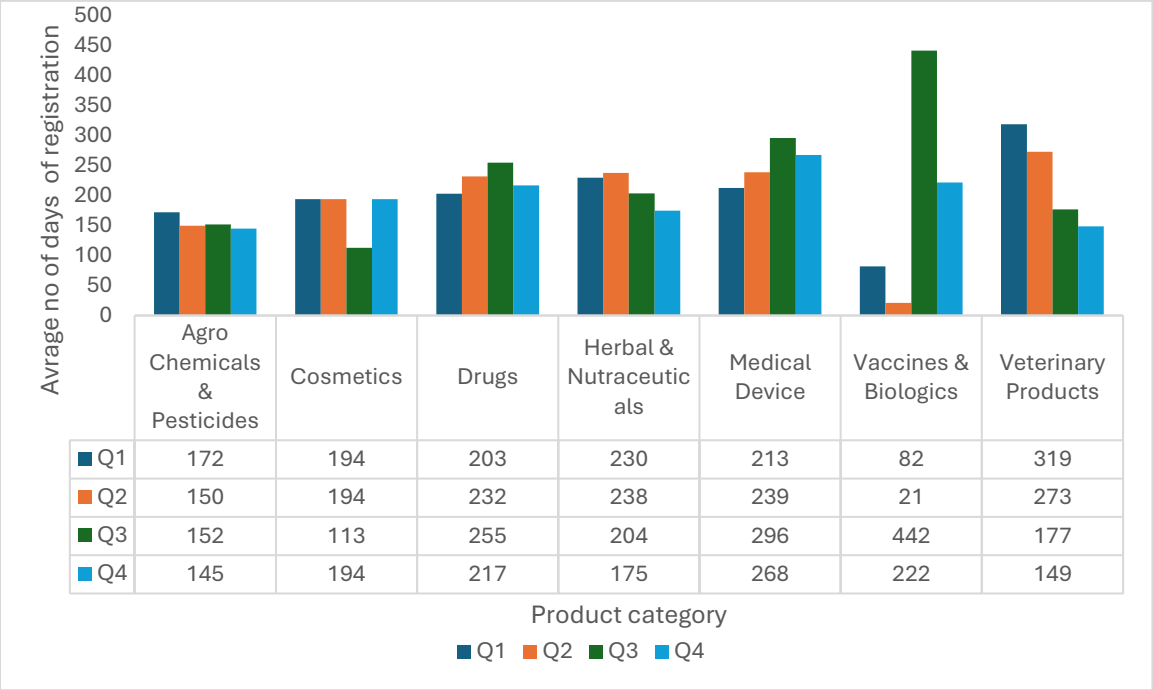


Figure 7.8: Quarterly Analysis of Timelines of Registered Products



	Agro Chemicals & Pesticides	Cosmetics	Drugs	Herbal & Nutraceuticals	Medical Device	Vaccines & Biologics	Veterinary Products
Q1	172	194	203	230	213	82	319
Q2	150	194	232	238	239	21	273
Q3	152	113	255	204	296	442	177
Q4	145	194	217	175	268	222	149

(B) Liaison Office to the Director (Drugs and related products)

- Six Thousand, Four Hundred and Thirty-Four (6,434) drugs and related products applications were received and sent to the Legal Unit for perusal.
- Twelve Thousand, Three Hundred and Thirty-Three (12,333) applications of drugs and related products were processed and sent to relevant Divisions.

(C) E-Registration and Data Management

This Unit is charged with the responsibility of administration of NAPAMS and preparing Registration and Listing Certificates of products that have successfully completed the registration process and processed manually. It is also charged the upload of registered products on the NAFDAC Green book for publishing by the Food and Drug Information Centre. The unit is also saddled with the responsibility of keying in registered products into NAFDAC Registered Products Automated Database (NARPAD). It is also saddled with the responsibility of developing NAPAMS Version 3 and migration from version 2 to 3 come first (1st) quarter 2025.

- Six Thousand, Eight Hundred and Sixty-Eight (6,868) Registration and Listing certificates were issued in the period under review. Breakdown: drug (1,318), cosmetics (3,178), pesticides (433), veterinary drugs (541), medical devices (368), biological & vaccines (462), and herbal (984)

- One Thousand, Two Hundred and Ninety-Nine (1,299) drug products were uploaded on the NAFDAC Green book by the Unit.

(D) Regulations:

Seventeen (17) Regulations were gazetted in 2024. They are:

- Chemical and Chemical Products Regulations 2024
- Fertilizer Registration Regulations 2024
- Fertilizer Labelling Regulations 2024
- Fertilizer Advertisement Regulations 2024
- Bio-Fertilizer Registration Regulations 2024
- Bio-Fertilizer Labelling Regulations 2024
- Bio-Fertilizer Advertisement Regulations 2024
- Bio-Pesticide Registration Regulations 2024
- Bio-Pesticide Labelling Regulations 2024
- Bio-Pesticide Advertisement Regulations 2024
- Vaccine and Other Biological Products (Lot Release) Regulations 2024
- Traceability of Pharmaceutical Products Regulations 2024
- Animal Feed Premix Registration Regulations 2024
- Animal Feed Premix Labelling Regulations 2024
- Animal Feed Premix Advertisement Regulations 2024
- Animal Feed Additive Labelling Regulations 2024
- Animal Feed Additive Advertisement Regulations 2024

Chapter 8
Food Registration & Regulatory Affairs (FR&RA) Directorate

The Food Registration and Regulatory Affairs (FR&RA) Directorate is one of the Directorates in NAFDAC responsible for Food registration in Nigeria, carved out of the old Registration and Regulatory Affairs Directorate in the year 2019.

The Directorate comprises of Five (5) Divisions and the Office of the Director.

1. Imported Food and Feeds (IF&F) Division.
2. Made in Nigeria Food (MNF) Division.
3. Food Advert Control (FAC) Division.
4. Food Regulations (FRe) Division.
5. Packaged Water (PW) Division.

Products Treated

Summary of FR&RA Directorate Activities in the Year 2024				
No. of Products Registered				
	Food	**Water**	**Feed**	**Total**
Imported	648		19	667
Made In Nig. Foods	2,089		273	2,362
Packaged Water		2,268		2,268
Total	**2,737**	**2,268**	**292**	**5,297**
Remarks	**A total of 5,297 Food products were registered within the Period January to December 2024.**			

Remarks: A total of Five Thousand Two Hundred and Ninety-Seven (**5,297)** Food Products were registered within the period under review.

1. **Summary of Product Registered**

Months	Number of Product Registered
January	551
February	417
March	318
April	359
May	370
June	366
July	489
August	451
September	477
October	388
November	344
December	767
Total	5,297

Summary of Activities- Highlights.

a. The Directorate, during the period under review, registered a total of Five Thousand Two Hundred and Ninety-Seven **(5,297)** Food Products registered.

b. During the period Twelve (12) Sub-FDRC and Twelve (12) FDRC Approval meeting for Food product registration was conducted.

c. Officers in the Directorate participated in:
   1) Ongoing development and review of Guidelines and SOPs
   2) Webinar Symposium on Honey Production and Quality in Nigeria: Setting the Standards, organized by the Polynological Association of Nigeria (PAN) in Conjunction with the Department of Botany, Faculty of Science, University of Lagos November 27, 2024.
   3) Training on: Good Regulatory Practice (GRP) and Good Review Practices (GRevP) Confirmation organized by QMS NAFDAC Steering Committee.
   4) Food Regulations lunched by the DG-NAFDAC, and currently at the phase of implementation.
      a. Cocoa and Cocoa Products Regulations, 2021
      b. Food Additives Regulations, 2021
      c. Food Fortification Regulations2021
      d. Food Grade (Table or Cooking) Salt Regulations, 2021
      e. Food Irradiation Regulations, 2021
      f. Fruit Juice and Nectar Regulations, 2021
      g. Food Products Advertisement Regulations, 2021
      h. Fats and Oil and Food Containing Fats and Oil Regulations 2022
      i. Pre-packaged Food (Labelling) Regulations 2022
      j. BMS Regulations 2024
   5) Meeting on Partnership between NAFDAC and Nigerian Heart Foundation (2003 - 2024), at DG's Office NAFDAC Office Complex, Isolo Lagos on

Monday July 1st, 2024.

6) Tastin' France 2024 – Professional tasting of French Wine and Spirit. Event Organized by French Embassy of Nigeria at Diamond Suite, Eko Hotels and Suites Victoria Island, Lagos in June 14, 2024.
7) NAFDAC celebrates World Safety and Health Day, May 3, 2024.
8) Training on AU-SPS (Sanitary and Phytosanitary) measures April 18, 2024.
9) Two (2) new guidelines developed and hosted on the NAFDAC website:
   a. Guidelines For Change in Formulation of Food and Feeds Products, and
   b. Guideline for the Registration of Bulk/Semi Processed Food Products for Export.
10) Officers attended training on Policy implementation, monitoring and compliance.
11) Directorate Quality Management System (QMS) Internal Audit
12) Various briefing and debriefing meetings with stakeholders on registration issues.
13) Strengthen and enforce digitization of all our processes.

Chapter 9
Vaccines, Biologics, and Medical Devices Registration & Regulatory Affairs (VBM-R&RA)

9.0 Introduction

The Vaccines, Biologics, and Medical Devices Registration and Regulatory Affairs (VBM R&RA) Directorate was created from the Drug Registration and Regulatory Affairs (DR & R) Directorate and started operations on the 14th of October 2024. The Directorate is headed by Mrs. Khadijah Ade-Abolade and has a pool of highly motivated staff working to achieve the objectives of the Directorate.

The Directorate is responsible for the registration of human and veterinary vaccines, biologics, and medical devices including in vitro diagnostics. VBM –R&RA Directorate has the mandate to ensure that only quality, safe, and effective vaccines and biologics as well as medical devices including IVDs are approved for use by the Nigerian public.

A. Divisions & Offices in The Directorate

1. Medical Devices and In Vitro Diagnostics Registration Division
2. Vaccines and Biologics Registration Division
3. Advert Control and Regulatory Affairs Division
4. Liaison Office of the Directorate (LOD)
5. Technical Office of the Director (TOD)
6. Directorate Administrative Office

The Directorate also has a Quality Team headed by a Quality Manager who reports to the Director and other team members drawn from the Divisions and offices of the Directorate.

Table 9.1: Staff Strength

S/N	Division/Office	Number of staff
1.	Vaccines and Biologics	5
2.	Medical Devices and In Vitro Diagnostics Registration	6
3.	Advert Control & Regulatory Affairs Division	2
4.	Liaison Office of the Directorate (LOD	2
5.	Technical Office of the Director (TOD)	2
6.	Directorate Administrative Office	1
	Total	**18**

9.1 Summary of Market Authorization Activities

A. Applications Received at the Directorate

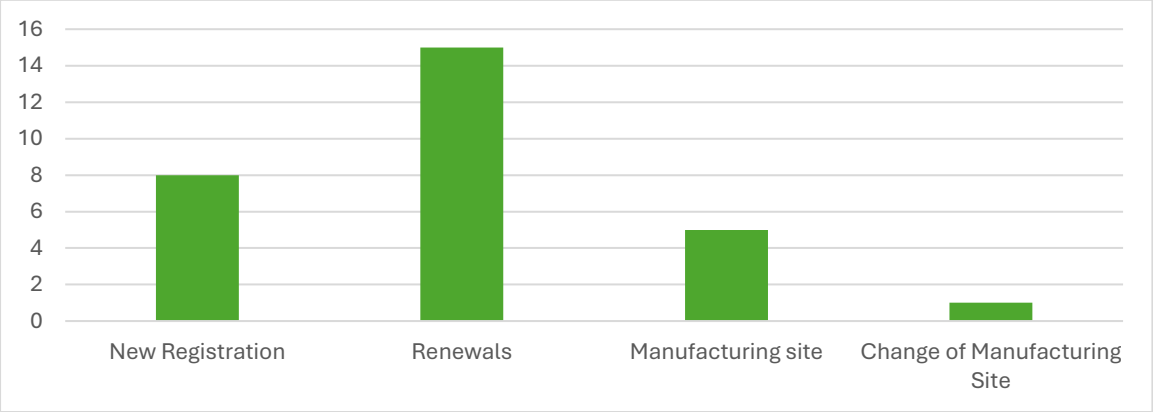
A total of One Hundred and Sixty-Two (162) applications (new registration, renewal, and variation) were received and One Hundred and Twenty-Eight (128) were found satisfactory for

further processing. The others were issued compliance directives which are yet to be satisfactorily addressed by the applicants.

B. Issuance of Market Authorization for Vaccines and Biologic Products

A total of Twenty-Nine (29) vaccines and biologic products were presented at the FDRC meetings from October to December 2024 with Eight (8) new applications, Fifteen (15) renewals, Five (5) additional manufacturing sites, and one (1) change of manufacturing site applications. All the products were approved by the FDRC. Processing of Eleven (11) applications is yet to be completed for different reasons like non-payment of inspection fees by the applicants and other compliance directives.

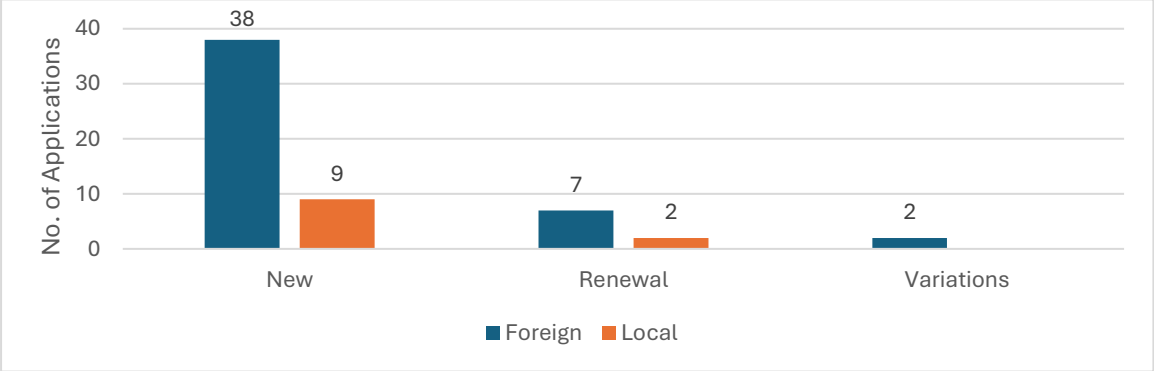
Figure 9.1: Issuance of Market Authorization for Vaccines and Biologic Products



B. Issuance of Market Authorization for Medical Device Products

A total of Fifty-Eight (58) medical devices were presented at the October, November, and December FDRC meetings with Nine (9) new and Two (2) renewal applications for locally manufactured medical devices; Thirty-Eight (38) new and Seven (7) renewal applications for imported medical devices; and two (2) applications for additional variants of imported medical devices. All the products were approved by the FDRC. Processing of Thirty (30) applications is yet to be completed for different reasons like non-payment of inspection fees by the applicants and other compliance directives.

Figure 9.2: Market Authorization Issuance



C. Issuance of Permits to Import Service Medical Devices

Only one (1) Service Medical Device application was approved, and the permit was issued during the period under review.

D. Issuance of Permits for Donated Items

Permits to import Donated Medical Devices were issued to two (2) applicants during the review period.

9.2 Summary of Advertisement Control & Regulatory Affairs Activities

A. Issuance of Advertisement Permits

Approval was granted for Five (5) advertisement applications during the period under review.

B. **Advert Control Sanctions**

No Advertisement control sanctions were issued during the period under consideration.

C. Regulatory Affairs Activities

Gazetting of the Medical Devices and Related Products Registration, Labelling, and Advertisement Regulations 2024

9.3 Summary of Activities Carried Out by Quality Management System (QMS) Unit and Other Activities Related to Who-Global Benchmarking (WHO-GB) of NAFDAC

The following QMS and GBT-related tasks were carried out by the QMS Unit and relevant Divisions of the Directorate in the reporting period:

A. Development and approval of the under-listed quality documents for the Directorate
   - Directorate Organogram
   - List of Internal and External Interested Parties of the Directorate
   - Directorate Competency Matrix
   - Directorate Communication Matrix
   - Job Descriptions for Staff of the Directorate

B. Induction training for all newly employed staff deployed to the Directorate.

C. Development of Three (3) new and review of Two (2) existing Standard Operating Procedures (SOPs) for the Directorate.

D. Development, review, and approval of Seven (7) new and Three (3) existing Medical Devices Guidelines in line with the International Medical Devices Regulators Forum (IMDRF) guidelines.

E. Training of all staff of the Directorate on the newly developed and reviewed guidelines and Standard Operating Procedures (SOPs)

F. WHO GBT Benchmarking Assessment of the Directorate for Vaccines, Biologics, and Medical Devices held between 25th to 29th November 2024 at NAFDAC Office, Isolo, Lagos.

Table 9.2: Summary of Other Registration-Related Activities of The Vaccines and Biologics Division

S/N	Activity	Number
1.	Dossier Reviewed	7
2.	APQR Reviewed	6
3.	Variation Reviewed	7
4.	Samples sent to the Lab	4

Figure 9.3: Summary of Other Vaccines & Biologics Activities

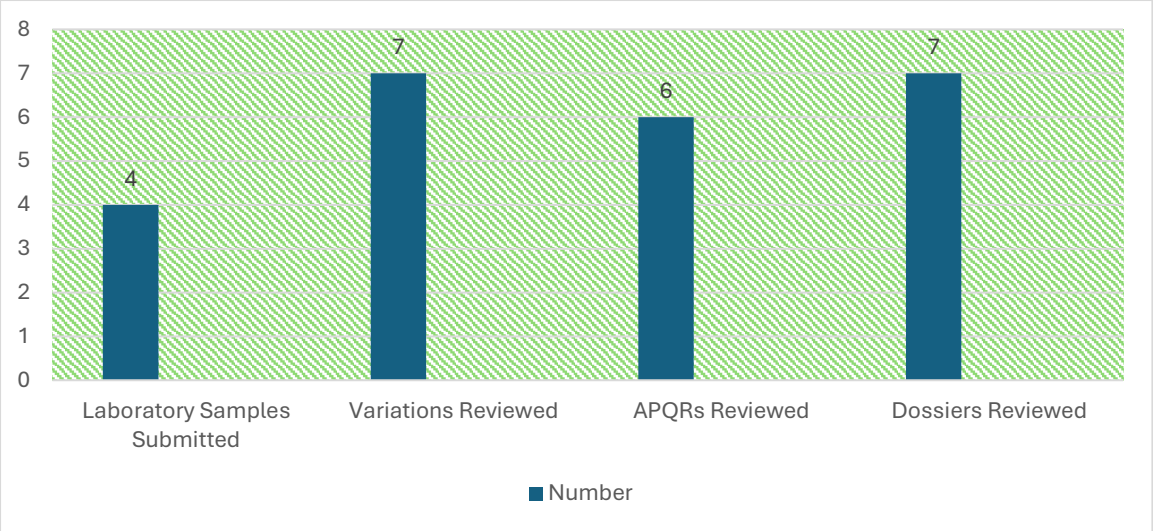
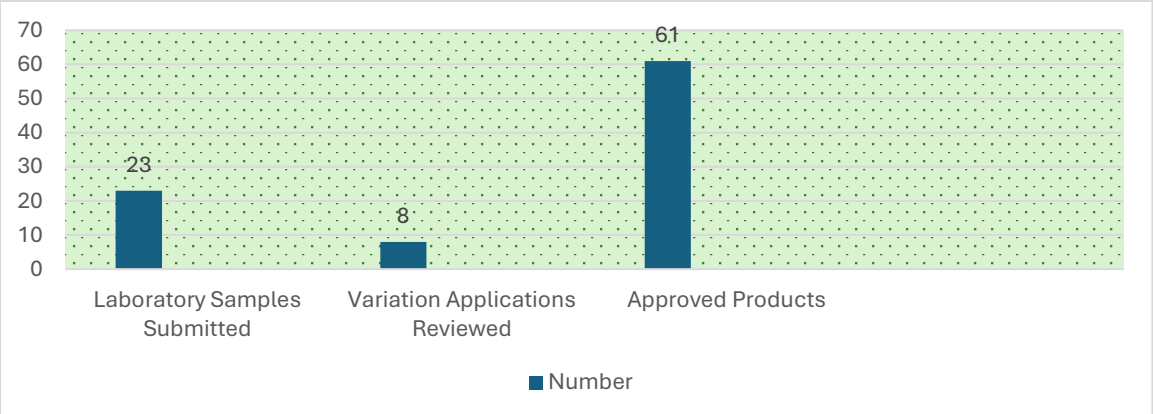


Table 9.3: Summary of Other Registration-Related Activities of The Medical Devices Division

S/N	Activity	Number
1.	Approved products	61
2.	Variation Applications Reviewed	8
3.	Samples sent to the Lab	23

Figure 9.4: Summary of Other Activities of Medical Devices Division



9.4: Summary of Other Activities Carried Out by the Directorate

- Participation at the First (1st) Session of the Continental Joint Review of Mpox In-Vitro Diagnostics facilitated by the AMRH African Medical Devices Forum (AMDF) held between 21st to 25th October 2024 at Gaborone, Botswana.
- Virtual participation at the NAFDAC Vaccine Committee meetings for October, November, and December 2024.
- Stakeholders' engagement on the regulation of Service Medical Devices held 31st October 2024 at NAFDAC Office, Isolo, Lagos.
- Virtual Stakeholders engagement on NAFDAC RoadMap for transition to the IMDRF-ToC format for submission of technical information for Medical Devices Dossier held 5th November 2024
- Participation at the Launch of Priority List of Diagnostics and Advocacy for the Continental Process for Regulation of In-vitro Diagnostics held between 26th to 29th November 2024 at Nairobi, Kenya
- Virtual participation in the WHO Workshop on Risk-Benefit Assessment of Snake Antivenoms in Dubai, United Arab Emirates, from 3rd - 4th December 2024.
- Establishment of smooth collaboration with other Directorates and NAFDAC State offices for efficient regulatory functions.
- Implemented seamless communication via email and NAPAMS portal with applicants by ensuring prompt dissemination of information to clients and expediting necessary regulatory functions on clients' applications.
- Development of procedures for a more efficient filing system of documents for ease of access and maintenance of confidentiality.

Chapter 10
Chemical Evaluation and Research Directorate (CER)

10.0 Introduction

The Chemical Evaluation and Research Directorate (CER) has the mandate to safeguard public health by ensuring that only the right **chemicals** are manufactured, imported, exported, distributed, sold and used in Nigeria.

A. Structure of CER

The Directorate is structured into 4 divisions. These are:

1. Chemical Import Control (CIC)
2. Agrochemicals and Controlled Chemicals Division (AC/CC)
3. Chemical Monitoring and Risk Assessment (CM&RA)
4. Chemical Research and Review (CR&R)

B. Functions of CER

- Ensure availability of chemicals to bona fide companies through prompt issuance of permits to import and clear Industrial and Restricted Chemicals. The process of obtaining import permits is electronic and can be done on the Nigeria Single Window Portal (www.trade.gov.ng/nafdac)
- Undertake and co-ordinate research programs on the storage, adulteration, distribution and rational use of chemicals.
- Carry out the Risk Assessment of Chemicals
- Issue Authorizations/Licenses to Chemical Marketers and Manufacturers
- Inspect Warehouses for Storage of Chemicals
- Generate relevant reports & statistics on Chemicals.
- Investigate breach of regulations on chemicals by companies or individuals
- Safeguard the health of the populace and environment by ensuring sound chemical management.
- Ensure conformity to International Standards for controlled and restricted Chemicals.
- Conduct surveillance and monitor hazardous and harmful Chemicals in circulation.

10.1 Summary of Activities

In 2024, a total of Twenty-Nine Thousand and Four hundred and Seven (29,407) regulatory activities were carried out by CER Directorate nationwide. Twenty-Six Thousand, Four Hundred and Eighty-Two (26,482) of these regulatory activities were carried out in Lagos state while Two Thousand, Nine Hundred and Twenty-Five (2,925) CER regulatory activities were recorded in NAFDAC offices in the other states.

A total of Eight Thousand and Forty-Four (8,044) applications were received for issuance of permits to import general and restricted chemicals, permits to clear restricted chemicals, Listing as a chemical marketer or chemical manufacturer and inspection of storage facilities for Chemicals.

Three Thousand, Four Hundred and Forty-Two (3,442) permits to import were approved for both general and restricted Chemicals while One Thousand Three Hundred and Eighty-**Eight** (1,388) permits to clear were issued for restricted chemicals. Seven Hundred and Seventy-One (771) facilities were listed as chemical marketers and manufacturers and issued Listing Notifications. A total of One Thousand, Five Hundred and Thirty-eight (1,305) inspection activities were carried out of which One Thousand, Three Hundred and Ninety-Nine (1,147) were satisfactory.

One Hundred and Thirty-One (158) routine monitoring inspections were carried out in Lagos. One thousand Seven Hundred and Thirty-One (1,731) Compliance Directives were issued for various inadequacies and incomplete documentations.

Table 10.1: Summary of Activities of CER Directorate in the Year 2024

S/N	TYPE OF ACTIVITIES	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC	TOTAL
1	No of applications received for Permit to Import	829	419	204	200	203	144	178	151	146	278	410	811	**3973**
2	No of applications received for Permit to Clear	104	101	78	78	123	103	112	133	93	123	123	123	**1294**
3	No of applications received for Warehouse inspection	116	144	51	124	163	43	36	44	27	80	194	160	**1182**
4	No of applications received for Listing Certificate	75	134	101	81	46	47	49	116	61	46	89	138	**983**
5	No of applications received for LPO verification	105	79	36	26	25	16	17	16	12	7	18	43	**400**
7	No. of applications treated for Permit to import	52	46	48	53	51	39	44	0	0	76	279	249	**937**
8	No. of applications treated for Listing Certificate	67	117	313	150	209	93	12	165	67				
9	No. of applications treated for Permits to Clear	93	101	78	78	123	103	112	133	93	123	123	123	**1283**
10	No. of applications treated within timeline	93	101	391	147	189	111	112	277	153	197	373	372	**2516**
11	No. of applications in progress	90	111	51	74	85	38	30	51	34	86	141	131	**922**
12	No of E-permits to Import issued	802	373	191	128	203	151	125	85	88	115	74	588	**2923**
13	No of E-permits to Import issued within timeline	802	373	191	128	203	151	125	85	88	115	74	588	**2923**
14	No of approved permits to Clear	104	101	78	78	123	103	112	133	93	123	123	123	**1294**
15	No of approved permits to Clear issued within timeline	104	101	78	78	123	103	112	133	93	123	123	123	**1294**
16	No. of Listing Notifications issued to Chemical Marketers	114	110	98	51	53	39	58	58	63	44	70	92	**850**
17	No of Listing Notifications issued to Chemical Manufacturers	0	6	3	1	1	3	1	0	0	1	1	4	**21**
18	No. of Listing Certificates prepared for DG'S endorsement	0	0	0	0	0	0	0	0	0	0	0	0	**0**
19	No of inspections conducted (Satisfactory reports)	167	211	107	78	81	77	52	59	44	133	157	217	**1383**
20	No. of follow - up inspections	0	0	0	0	0	0	0	0	0	0	0	0	**0**
21	No. of routine monitoring inspections	17	11	7	9	9	29	17	17	11	9	9	7	**152**
22	No of surveillance inspections	0	0	0	0	0	0	0	0	0	0	0	0	**0**
23	No. of LPO verification treated	102	79	36	26	25	16	16	16	11	7	18	50	**402**
24	No. of LPO verification untreated	0	0	0	0	17	15	0	0	0	0	0	0	**32**
25	No. of Queries/CDs issued	256	190	158	153	86	65	78	58	77	101	209	243	**1674**
26	No. of consultative meetings/seminar and workshop held	13	8	7	3	3	6	15	0	0	0	0	0	**55**
27	No. of Violations	0	0	2	1	1	0	0	0	1	0	0	0	**5**
28	No. of Warehouses/Products/Consignments put on Hold	2	0	4	4	0	0	2	0	0	0	0	0	**12**
29	**TOTAL**	4107	**2916**	**2,311**	**1,749**	**2145**	**1,495**	**1,415**	**1730**	**1,255**	**1,524**	**2712**	**4352**	**27711**

Table 10.2: Comparative Analysis of Key CER Regulatory Activities 2022-2024

S/N	Activities	2023	2024
1	Number of Regulatory activities recorded	27,092	29,407
2	Number of Applications received	8,138	8,044
3	Number of Permits to Import issued for General and Restricted Chemicals	3,145	3,442
4	Number of Permits to Clear issued for Restricted chemicals	1,196	1,388
5	Number of Inspections Conducted	1,399	1,305
6	Number of Listing notifications issued to Chemical Marketers	797	771
7	Number of Queries/CDs issued	997	1,731

The Chemical Evaluation and Research Directorate recorded huge level of success in 2024. A significantly higher number of regulatory activities were recorded in 2024 as compared to 2023. The Directorate also recorded a higher number of queries and compliance directives. This may be attributed to monitoring exercises carried out in Lagos and the new PIDCARMS portal initiated for permit to Clear process.

The Directorate also ensured that as much as possible, timelines were adhered to while also making the processes easy and seamless for the clientele.

Table 10.3: Performance Outlook for January – December 2024

S/N	Activities/Tasks	Actual Performance
1	Processing of applications for chemical/raw materials warehouse treated	100%
2	Processing of applications for Permit to import chemicals within stipulated timelines	88%
3	Prompt issuance of Permit to Clear restricted chemicals to marketers within timeline	100%

10.2 Quality Management Systems (QMS) and Internal Trainings

The CER QMS team organized and conducted trainings and workshops in the year under review. Guidelines and operational procedures were also reviewed. Trainings on Process Safety Management, Domestication of the chemical Weapons convention in Nigeria, NAFDAC Quality Documents, Scheduled Chemicals of Chemical Weapons Convention were conducted for all members of staff of CER.

10.3 Other Regulatory Activities and Meetings Attended

1. A meeting in conjunction with the Sustainable Research and Action for Environmental Development (SRADev) on the enforcement of phasing out Mercury Added Products (MAPs) in Nigeria with focus on Skin-Lightening Products (SLPs).
2. Initiation of the digitalization of Processes for Listing Certificates for Chemical Manufacturers
3. Deployment and Sensitization on guidelines for Production Inspection of Chemical Manufacturing Facilities in Nigeria and the guidelines for NAFDAC Good Manufacturing Practice for Chemicals and Chemical Products.
4. Organization of a stakeholder's Sensitization Meeting for Chemical Stakeholders on recent developments in Chemical Industry
5. Organization of an in-house Human Capacity Building Program on key Components of Chemical Monitoring for CER Regulatory Officers.
6. Inspection of Chemical Manufacturing sites and plants in Lagos State for compliance in activities.
7. Organization of a sensitization campaign for South East Zone on Sound Management of Chemicals in Nigeria in collaboration with the National Authority on Chemical and Biological Weapons Conventions (NAC&BWC)
8. Nationwide monitoring of Chemicals of Security Concern.

Routine

One Hundred and Fifty-Two (152) surveillance inspection activities were carried out in the year under review.

Local Purchase Order Verifications

Four Hundred and Two (402) Local Purchase Orders presented by Chemical marketers were verified from the bona-fide end-users.

Focus

1. Enhanced collaboration with International Chemical Control Organizations such as Organization for the Prohibition of Chemical Weapon, Montreal Protocol, Stockholm Convention etc.
2. Continuous sustenance of Quality Management System achievements through Monitoring and Evaluation to ensure continuous improvements.
3. Constant engagement with listed chemical marketers to ensure that they keep to the terms of their listing certificates with the overall objective of ensuring that chemicals do not get into wrong hands who may deploy them for clandestine purposes.
4. Establishment of a Chemical Laboratory in collaboration with the Laboratory Services Directorate for Chemicals.
5. Regular engagement with industries and other relevant stakeholders to ensure sound management of chemicals in Nigeria.

6. Continuous collaboration with MDAs like Office of the National Security Adviser (ONSA), Federal Ministry of Environment, Federal Ministry of Agriculture, NESREA, NCS, etc. on matters of common interest; like the issuance of end-user certificate; Mercury as a global pollutant, chemicals interaction with the ozone layer and the ozone depleting substances, chemical weapons etc.
7. Continuous monitoring (through enhanced routine inspections) of chemicals in Industries to check utilization and stock levels and possible diversion for unauthorized purpose; and also monitor disposal practices.

Chapter 11
Narcotics and Controlled Substances (NCS) Directorate

11.0 Introduction

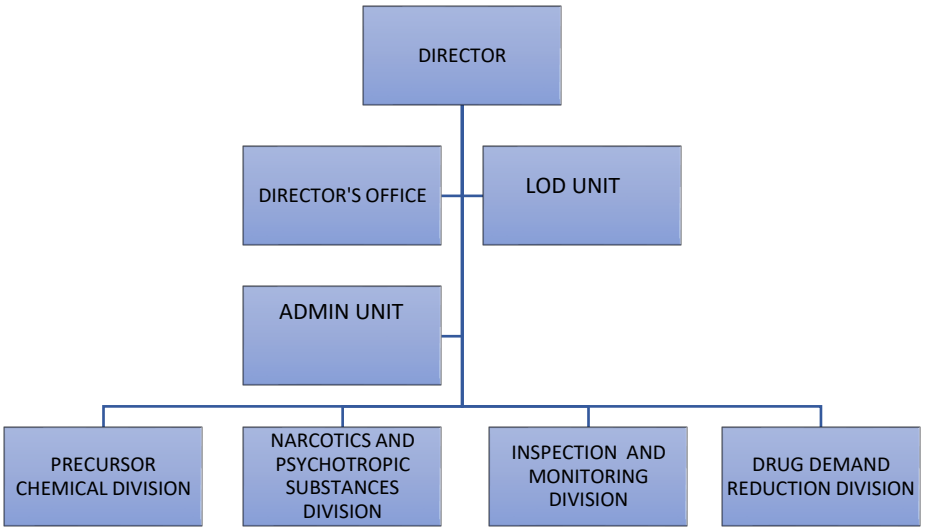
The Directorate has the mandate to carry out the following functions:

- Grants authorization for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances.
- Collaborates with National Drug Law Enforcement Agency (NDLEA) and other stakeholders in the bid to eradicate drug abuse in Nigeria.
- Takes measures to ensure that the use of narcotic drugs, psychotropic substances are limited to only medical and scientific purposes.
- Coordinates Drug Demand Reduction Activities.

In addition, the Directorate ensures Nigeria fulfills its obligations under the three-drug control conventions.

- ✓ **United Nations Single Convention on Narcotics Drugs (1961)**
- ✓ **United Nations Convention on Psychotropic Substances (1971)**
- ✓ **United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)**

Structure of the Directorate



11.1 Activities of the Narcotics and Controlled Substances Directorate From 1st January 2024 to 31st December 2024.

The routine activities of the Directorate include the following:

i. Processing of applications for permits to import and clear.
ii. Response to Pre-export Notification (PEN) and Export Authorization.
iii. Inspections of facilities/warehouses.
iv. Inspection of hospitals on source and utilization of schedule 1 narcotics

v. Issuance of authorization to procure schedule 1 narcotics; and
vi. Various targeted drug abuse sensitization activities

The activities of this year are reported under the relevant strategic pillars.

11.1 Strong Leadership and Governance (To sustain a Transparent Quality-Driven Management Structure for a Strong Regulatory Framework)

i. The total number of staff of Narcotics and Controlled Substances Directorate as at 31st December 2024 was Twenty-Six (26) comprising Nineteen (19) regulatory and Seven (7) non-regulatory officers. Three (3) new regulatory officers were posted to the Directorate.
ii. The working environment has improved with the repair/replacement/supply of new air conditioners and the supply of new worktables and chairs and printers.
iii. In line with the ISO 9001:2015 Quality Management of the Agency, the Directorate carried processes as required.
   - Quality meetings and the Directorate's Management (MRM) meeting took place as scheduled.
   - Internal audit and self-assessment were carried out by all the divisions in the Directorate. Corrective actions have been implemented effectively for all non-conformities identified. The Agency wide internal audit was successfully carried out. Documents affected were reviewed and approved as required,
   - 90% of the internal training scheduled for 2024 were carried out.
   - Risk Management: Identified risks which required top management attention have been addressed as stated in (ii) above.
   - Customer Satisfaction Survey for 2024: 97.3% Customer satisfaction was recorded. The 2.63% dissatisfaction arose from the delay in understanding the use of the new technology Ports Inspection Data Capture and Risk Management System (PIDCARMS)

Institutionalization of Best Practices (To improve the Corporate Image of the Agency and the Country)

Various capacity building programmes including Drug Demand Reduction activities took place during the year under review.

A. Capacity Development /Stakeholder Engagements and other activities

i. Launch of International Narcotics Control Board (INCB) 2023 Annual Report and Precursor Report: Narcotics and Controlled Substances Directorate hosted the launch of INCB on 5th March 2024 attended by our sisters' agencies, NDLEA, Nigerian Customs Services and other health bodies.
ii. Stakeholders' Forum For Anambra State Facilities/Clients: Narcotics and Controlled Substances Directorate participated in a stakeholders' meeting at Onitsha, Anambra State between 26th-27th July, 2024. There was a presentation on Documentation in Narcotics and Controlled Substances Processes. The programme was well attended by key stakeholders.
iii. Stakeholders' Engagement on Compliance Requirements and Updates On Regulating Precursor Chemicals: The Directorate organized a virtual session on 6th June 2024

engaging stakeholders involved in Precursor Chemicals. The meeting aimed to enhance the understanding of Precursor Chemicals promote compliance with regulations and ensure that stakeholders are well informed about the legal frameworks governing their use.

iv. The Director (NCS) was a speaker at the 27th Annual National Conference of the Association of Industrial Pharmacists of Nigeria (NAIP)on 7th June 2024 with the theme "The Role of Digital Technologies and Innovations in Achieving Universal Health Coverage: The Nigeria Industrial Pharmacy Perspective". The paper presented was titled "Controlled Substances and Promotion of Access to Medicines: The Meeting Point".

v. Sensitization On Traceability of Pharmaceutical Products For Distributors, Wholesalers, Retailers and Health Facilities: The virtual meeting that took place on 14th November 2024, aimed at stressing highlighted the need for manufacturers to integrate their products into the NAFDAC Traceability Information System (TIS). All stakeholders present where advised to register their Global Location Number (GLN) with GS1 to be able to trade in narcotic products. The meeting increased awareness among stakeholders, including wholesalers and retailers on traceability issues and the use of dedicated scanners to scan their products along the supply chain.

vi. A total of 33 statutory meetings/workshops/stakeholder consultative meetings.

vii. Signing of Memorandum of Understanding (MOU) between NAFDAC and NDLEA on matters relating to Narcotics and other controlled substances took place on 13th November 2024 at the NDLEA Headquarters Abuja

B. **Capacity Building/Development for Staff**

i. Global Rapid Interdiction of Dangerous Substances (GRIDS) Training: The International Narcotics Control Board (INCD)/United Nations Office of Drug and Crime (UNODC): Officers drawn from The Narcotics and Controlled Substances, Ports Inspection Directorate and Investigation and Enforcement (I&E) Directorates participated in the INCB training held in Lagos on the 24th May, 2024, The Project ION Incident Communication System (IONICS) is an INCB initiative and online tool dedicated to the communication of incidents involving suspicious shipments, seizures manufacture, processing, packaging, distribution and trafficking in, non-scheduled New Psychoactive Substances (NPS). The communication platform allows for real-time sharing of important information between relevant national authorities and participants who were added to IONIC platform for real-time reporting.

ii. The Agency represented by an officer of the Directorate participated at a training workshop in Dubai facilitated by the International Narcotics Control Board (INCB), in collaboration with the U.S. Drug Enforcement Administration (DEA) and the Dubai Police. The workshop was organized for the competent national authorities of different to discuss issues of substandard and illicitly sourced pharmaceuticals and share strategies on how to disrupt networks exploiting online platforms, logistics services, and re-shippers. Participants were drawn from the INCB, Dubai Police, Dubai Customs, World Customs Organization (WCO), Interpol, the UK Home Office intelligence Department and DEA officers from several state-offices within the US and their regional offices in Nigeria, Dubai, Ghana, India and Pakistan. Other participants include representatives of regulatory authorities from Nigeria (NAFDAC and NDLEA), Ghana, Tanzania, Morocco, India, Pakistan, Singapore, Germany and France; as well as members of the private sector companies (Aramex and FedEx.

iii. A total of Twenty (20) internal/external training were organized for staff of the Directorate. Some staff also participated in Good Manufacturing Practice Training (GMP) organized by Drug Evaluation and Research (DER) Directorate.

11.3 Drug Demand Reduction Activities

i. NCS Stakeholders Meeting: As part of the agency's mandate to collaborate with stakeholders in the measure to eradicate drug abuse in Nigeria, the Directorate organized and hosted stakeholders' engagement, titled "Preventing Drug Abuse and Addiction-The Best Strategy" on the 7th March 2024 at the NAFDAC auditorium, Isolo, Lagos where novel ideas to combat menace of drug abuse were birthed. The program was well attended by Non-Governmental Organizations, Civil Society Organizations, District Heads in Education, NDLEA, Federal Medical facilities.

ii. United Nations International Day against Drug Abuse and illicit Drug Trafficking (World Drug Day) 2024

- The Directorate marked the International Day against Drug Abuse and Illicit Trafficking (World Drug Day) on 25th June, 2024 at the NAFDAC Auditorium Isolo Lagos. The theme of the year's celebration was "The Evidence is Clear: Invest in Prevention". The programme was to raise awareness and develop an understanding of the effectiveness and cost-effectiveness of prevention strategies mitigating the harms of drug use.
- The Directorate participated in the National celebrations of the World Drug Day organized by the National Drug Law Enforcement Agency (NDLEA) to commemorate the 2024 World Drug Day on 26th June 2024. The Director (NCS) Mrs. Yedunni Adenuga represented the Director General NAFDAC where she gave a goodwill message on her behalf.
- The World Drug Day was also celebrated at Nestle Nig. PLC on 30th July 2024. The company hosted a virtual session at their office. There was a presentation on the topic "Prevention Strategies Mitigating the harm of Drug Abuse at the Workplace". About Thirty (30) staff of the company participated in the event.

iii. The Directorate participated at the 11thAll Africa Universities Games (FASU) on 23rd to 26th September 2024 at the Lagos State University, Lagos. An information stand where participants can visit and be informed about the harmful effects of substance abuse and its implication on the games. Information, Education and Communication (IEC) materials were distributed to participants of the All-Africa University games (FASU) and educate them on substance abuse. The Director (NCS) also made a presentation titled "Drugs in Sports" during the programme.

iv. The Flag off for the NAFDAC-Catch Them Young Programme a campaign on Drug Demand Reduction was flagged off on 20th September 2024 at Government Secondary School Tudun Wada FCT. It was aimed at sensitizing secondary school students against drug and alcohol abuse.

v. 23 Drug Demand Reduction activities were carried out in schools and other public locations.

11.4 Safety and Quality of Regulated products (Ensure strict utilization of narcotics, psychotropics and precursors for scientific and medical purposes.

i. The pilot phase of traceability of pharmaceutical products launched on 18th January 2024 using narcotics was successfully carried out during the year of review. Market Authorization Holders (importers and local manufacturers) were mandated to obtain Global Trade Item Numbers (GTINs) from GS1 Nigeria. All facilities including importers, local manufacturers, distributors and retailers were also mandated to obtain Global Location Numbers (GLN) also from GS1. A total number of 152 importers local manufacturers of narcotics have been onboarded to the NAFDAC traceability System. A total number of 144 distributors and retailers have obtained their GLNs. Subsequently, controlled medicines particularly tramadol, pentazocine, ketamine and flunitrazepam imported into or manufactured in the country must carry a 2D Matrix barcode to enable track and trace of the items along the supply chain.

ii. Risk Categorization of Local Manufacturers of Controlled Medicines: A nation-wide monitoring of local manufacturers of controlled medicines majorly tramadol and ephedrine/pseudoephedrine containing medicines was carried out in 2024. Twenty-Seven (27) facilities were visited. At the end of all the inspections, the local manufacturers of controlled medicines were categorized accordingly based on the outcomes of the warehouse inspection and verification of utilization of narcotics and psychotropic substances using the Risk Categorization Tool designed by the Directorate. Six (6) were categorized as low, Nineteen (19) medium and Two (2) categorized as high.

iii. A total of Four Hundred and Thirty-Eight (438) permits to import were issued for the importation of narcotics, psychotropics and precursors from January to December 2024 while One Thousand Two Hundred and Forty-Nine (1,249) permits to clear were issued.

iv. Two Hundred and Eight (208) warehouse inspections of facilities dealing with controlled substances were carried out from January to December 2024.

v. Two (2) special investigations were carried out and there was 1 violation recorded in a pharma facility in Kano.

vi. One Hundred and Thirty-Six (136) verifications of sales/utilization of controlled substances were carried out.

vii. Ninety (90) authorization letters were issued to health facilities to purchase Schedule 1 Narcotics from the Federal and Zonal Narcotic Stores from August 2023 to date.

viii. Twenty (20) Hospitals to ascertain their sources of schedule 1 narcotics and its utilizations. Fourteen (14) were satisfactory and six (6) were unsatisfactory.

ix. The Directorate made statutory returns of the utilization of Internationally controlled items to INCB on schedule during the year of review.

x. 67th Session of the Commission on Narcotic Drugs (CND): Narcotics and Controlled Substances Directorate participated in the Commission on Narcotics Drugs (CND) meeting organized by the Commission on Narcotics Drugs (CND) held in Vienna, Austria on the 13th to 21st March, 2024 attended by Director (NCS) and two (2) Deputy Directors.

xi. The Directorate participated in the meeting convened by the Secretariat of International Narcotics Control Board (INCB), to hold regional expert group meeting on the prevention of trafficking in dangerous substances by road transport in central and west Africa. The meeting took place at Lagos, Nigeria from 25th to 27th September 2024. Participants at the program were drawn from the West Africa region included Nigeria, Ghana, Senegal, Benin, Cote d'Ivoire, Sierra Leonne, ECOWAS mission and the USA.

xii. Successful two separate tripartite meetings to prevent and stop the illegal diversion of unauthorized doses of tramadol (above 100mg) and codeine containing cough syrup into Nigeria. The first meeting took place on 7th June 2024 between Pakistan, Nigeria and Ghana while the second took place on 12th November 2024 between Nigeria, Ghana and India. The meetings were facilitated by the United Nations Office of Drugs and Crime. It is expected that there will be a drastic reduction in the illegal importation of these items.

xiii. National Drug Control Master Plan (NDCMP) 2021 – 2025: The National Drug Control Master Plan (NDCMP) 2021-2025 which is a broad based, comprehensive and all-inclusive approach to addressing drug related issues. The plan policy-driven, result-based and planning tool for coordinating interventions against illicit drug use, trafficking and related organized crime in Nigeria. It was developed as part of strategic response to emerging trends and current challenges in illicit drug trade and consumption of drugs by Nigerians. NAFDAC, a lead Agency alongside the Federal Ministry of Health responsible for implementing strategic pillar 3 (Access to controlled medicines). In 2024, NAFDAC actively participated in implementing a lot the activities outline in the operation plan and provided the NDCMP coordinating secretariate domiciled with the NDLEA with quarterly report as at when due. The Director (NCS) also participated in the Inter-Ministerial Committee of the NDCMP on 7th March 2024.

xiv. Technical Working Group (TWG) Meeting on Access to Controlled Medicines: The 2024 TWG deliberated on strategies towards improving availability and access to controlled medicines while preventing diversion, implementation status of the national drug control master plan (NDCMP), onboarding of Schedule I narcotics inventory management on the National Health Logistics Management and information system (NHLMIS) of FMOH and the Methadone Assisted Therapy (MAT) for addiction treatment and the NAFDAC Traceability pilot of controlled medicines.

Table 11.1 The Summary of the Activities of NCS Directorate in 2024 are highlighted as follows.

S/N	Activities	Inspection and Monitoring	Narcotics and Psychotropic Substances	Precursor Chemicals	Drug Demand Reduction	Total
1	No of applications received	530	1,381	943		2324
2	No of Permits to Import issued	-	249	189		438
3	No of Permits to Clear issued		647	602		1249
4	Authorizations to purchase Schedule 1 Narcotics		90			
5	No of Inspections Schedule/routine Inspections	208				208
	Satisfactory	204				204
	Unsatisfactory	4				4
	Not Held	7				7
6	Hospital Inspections	20				20
	Satisfactory	14				14
	Unsatisfactory	6				6
	Not Held	3				3
7	Number of outstation reports received	140				140
	Satisfactory	140				
	Unsatisfactory					
8	LPO/Sales Verification	136				136
	Satisfactory	92				92
	Unsatisfactory	44				44
	Verification not held	20				20
9	Number of outstation verification received	3				3
10	Number of investigations conducted	2				2
11	Export Authorizations		9			9
12	Number of Export Authorizations non objected		9			9
13	Number of Export Authorizations objected to		0			0
14	Pre-export Notification (PEN)	-	28	23	-	51
15	Number of Pre-export Notification objected to	-	6	2	-	8
16	Number of Pre-export Notification non objected	-	22	21	-	43
17	Number of schools, clinics, markets, NYSC Camps visited	-	-	-	23	23
18	Training (In-house/External)	10	5	2	3	20
19	Statutory Meeting/ Workshop/Stakeholder Consultative meeting	24	4	3	2	33
20	No of Violations		1	2	-	3

Chapter 12
Veterinary And Medicines and Allied Products (VMAP) Directorate

12.0 Highlights of Activities from January to December 2024.

A. Meetings/ Trainings/Workshops:

The Directorate has conducted/participated in about Ninety-Eight trainings/workshops/meetings during the year 2024. Some are as follows.

- Participated in the updated virtual training on NAPAMS Inspection module on 9th January, 2024.
- Participated in the meeting of Technical Working Committee on Training and Certification of Agro-input Dealers on 24th January, 2024.
- Participated in the 17th International Feed Regulators Meeting (IFRM) hosted by IFIF and FAO held in Atlanta USA between 29th and 31st of January 2024.
- Participated in a meeting with COLEAD on *determining the effect of lower EU MRL on pesticide residue on regulatory capacity* on 16th February, 2024.
- Participated in a stakeholder meeting on *Drug Demand Reduction* organized by Narcotics
- and Controlled Substances (NCS) Directorate on 7th March 2024.
- Participated in the Danish Veterinary and Food Administration (DVFA) introductory meeting with DG NAFDAC on 15th and 17th April, 2024.
- Participated in The AU NEPAD AMRH Secretariat GMP Vaccine Subcommittees on the 29th May, 2024.
- Participated in Dossier Training on 5th – 9th August, 2024
- Conducted an In-house training on *"Zoonosis, a brief history"* on 4th October, 2024.
- NAFDAC World AMR Awareness Week WAAW event in collaboration with
- DVFA Denmark on 21st – 22nd 2024

B. Inspections Conducted

A total of Six Hundred and Seventy (670) inspections were conducted in the Jan-Dec 2024

Inspection	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Total
Warehouse	48	13	9	18	88
Production	4	3	30	7	44
Routine	7	1	67	3	78
Cold Chain	2	3	12	0	18
Surveillance	8	0	54	132	194
GMP Risk Categorization	17	21	56	9	103
GMP Inspection	5	5	4	4	18
Pre-Production	1	1	14	1	17
Overseas GMP Inspection	36	43	0	0	79
Farmstead Verification	0	1	1	0	2
Pre-Registration	0	1	12	0	13
Listing as toll miller	3	4	5	1	13
Shop Verification	3	0	0	0	3
Administration of Questionnaire	0	1	0	0	1
Listing certificate	2	0	0	0	2
Total	134	97	260	175	670

C. NAPAMS Inspection Application Received/Treated:

NAPAMS Application	**1st Quarter**	**2nd Quarter**	**3rd Quarter**	**4th Quarter**	**Total**
Application received at LOD	491	330	362	354	1,537
Application treated	225	442	435	384	1,486

D. e-Licence/Permit/Certificate Issued:

Permit issued/Certificate	PERMIT/certificate CODE	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Total
Import permits for Animal feeds, Concentrates, Additives, Premixes, and Fish meals.	8201	85	36	23	96	240
Import permits for Bulk Pesticide and Agrochemicals.	8202	17	10	7	19	53
One –off Permit for Pet Food	8203	6	3	2	3	14
Authority to Clear	-	7	0		2	9
Listing as Agrochemical Marketer(medium)	8204	3	0	2	1	6
Listing as Micro-agro input dealer	-	6	2	0	0	8
Permit to Import veterinary pharmaceutical active ingredient	8206	1	2	1	4	8
One-off permit for permit to Import pesticide and agrochemical	8208	1	1	0	0	2
Total		**126**	**54**	**35**	**125**	**340**

E. Sanction Activity

Type of Sanction	**1st Quarter**	**2nd Quarter**	**3rd Quarter**	**4th Quarter**	**Total**
Compliance Directive	7	2	2	0	**11**
Admin Charges	0	0	0	0	**0**
Total	**7**	**2**	**2**	**0**	**11**

F. Product Registration Samples sent to laboratory.

	1st Quarter	**2nd Quarter**	**3rd Quarter**	**4th Quarter**	**Total**
Number of samples sent to lab	**20**	**36**	**26**	**43**	**125**

Table 16.2: Profile of Samples Received in the Year 2024

Product	Imported	Local		
		MSMEs	Others	Total
Food	202	1,458	809	2,462
Bread	0	1,013	219	1,232
Water	0	44	1,446	2,090
Pesticide Formulation	52	0	0	52
Drug	213	0	163	376
Cosmetics	6	1	464	471
Medical Devices	50	0	16	66
Herbal Preparation	0	0	139	139
Fertilizer	0	0	0	0
Animal Feed	9	0	60	60
Others (Specify)	0	0	0	0
Total	532	3,116	3,316	**6,946**

Chapter 13
Laboratory Services (Food & Chemicals) Directorate

13.0 Introduction

The Laboratory Services Directorate (Food & Chemicals) has two functional laboratories viz:

- Central Laboratory, Oshodi, Lagos State
- Area Laboratory, Calabar, Cross River State

GOALS

The goals of the Laboratory Services Directorate (Food & Chemicals) are:

- To generate quality and timely test results that meet international standards.
- To fully deploy and maximize capacity to provide excellent customer service.

13.1 Analytical Performance

In 2024, the Laboratory Services Directorate (Food & Chemicals) handled a total Twelve Thousand Eight Hundred and Twenty-Three samples (**12,823**) out of which Twelve Thousand Six Hundred and Twelve (**12,612**) samples were analyzed.

Table 13.1: Summary of Analytical performance in the Year 2024

	Total Number of Samples Received	No. of Samples Analyzed	Number of Satisfactory Samples	Number of Unsatisfactory Samples	No. of Samples Pending	Percentage Performance
Oshodi	12,823	12,612	12,176	436	211	98.4%
Calabar	0	0	0	0	0	-
Total	12,823	12,612	12,176	436	211	98.4%

Figure 13.1: Profile of Samples Handled in the Year 2024

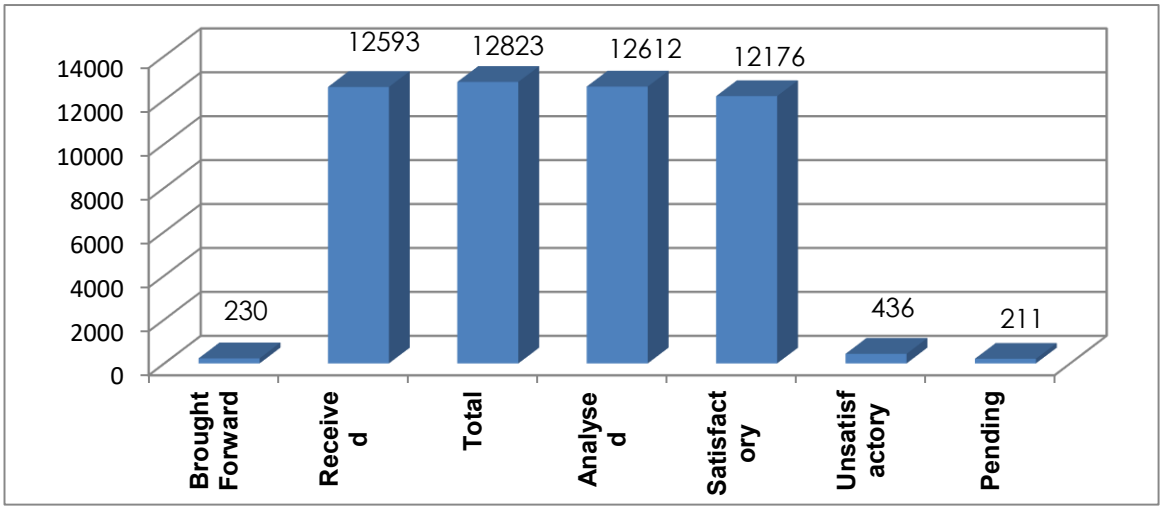


Table 13.2: Sample Received According to Categories in 2024

		ANNUAL				
	Registration	Compliance	Investigation	Enforcement	Others	Total
Dairy and Milk Product	202	232	14	0	3	**451**
Non-Dairy Products	31	17	0	0	0	**48**
Baby and Infants Foods	22	71	3	0	0	**96**
Fat and Oils	315	91	3	0	0	**409**
Cereal and Cereals Product	157	266	8	7	0	**438**
Bread	1541	0	22	0	0	**1563**
Tea, Coffee and Cocoa Product	137	67	2	0	12	**218**
Fruits and Fruits Products	337	47	0	0	0	**384**
Carbonated Drinks	70	41	0	0	0	**111**
Meat and Meat Products	117	44	0	0	0	**161**
Fish and Fish Products	149	56	0	0	0	**205**
Salt	5	0	0	0	0	**5**
Seasoning and Flavouring Products	417	68	0	0	0	**485**
Sugar and Sugar Products	60	38	0	0	0	**98**
Beverages and Malt	36	36	2	0	0	**74**
Nut and nut products	187	11	0	0	0	**198**
Legume and legume products	207	17	1	0	0	**225**
Egg and egg products	15	5	0	0	0	**20**
vegetable and vegetable products	62	2	0	0	0	**64**
root and tuber products	287	0	0	0	0	**287**
Flavoured Drinks	110	0	0	0	0	**110**
Ready to Eat	443	0	6	5	0	**454**
Food Supplements	0	0	0	0	0	**0**
Food Additives	52	1067	0	0	0	**1119**
Alcoholic Beverages	732	129	65	9	12	**947**
Water	1972	0	2	0	0	**1974**
Pesticides F.	388	192	18	0	0	**598**
Animal feeds	30	6	0	0	0	**36**
Miscellaneous (Food Samples)	1268	521	23	0	3	**1815**
TOTAL	**9349**	**3024**	**169**	**21**	**30**	**12593**

Figure 13.2: Summary of Food Samples Received According to Categories

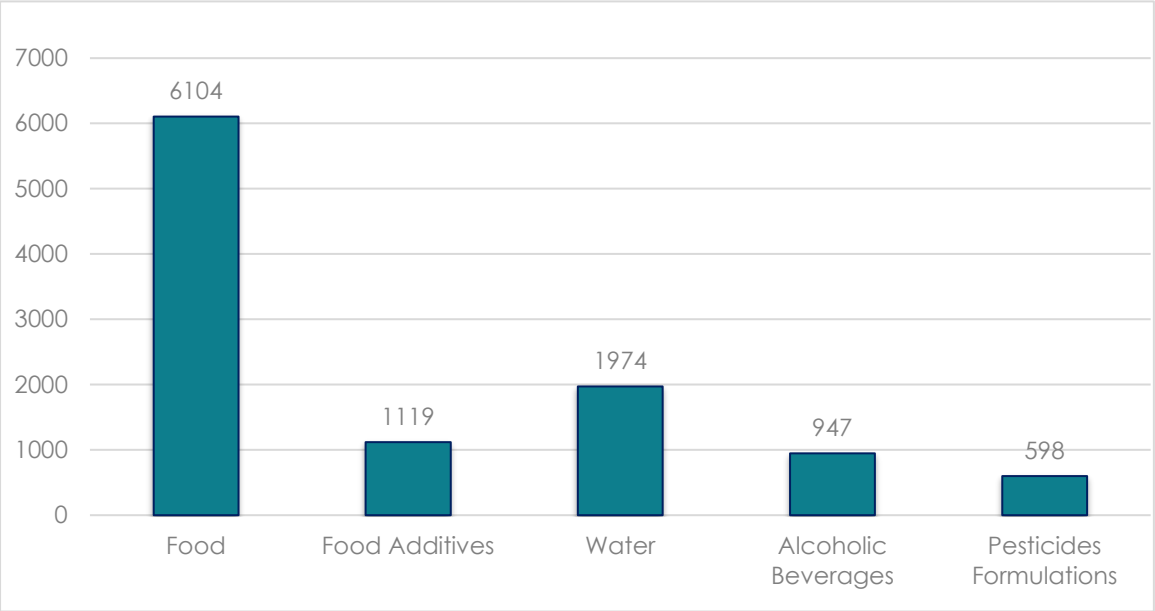
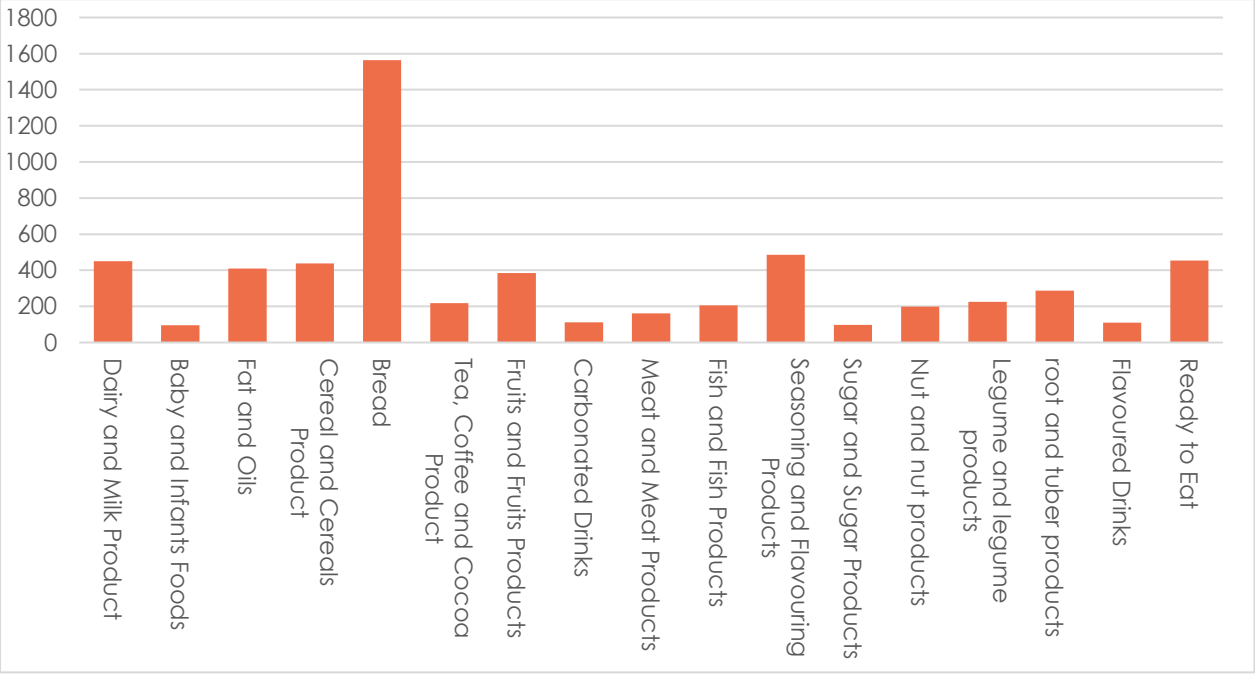


Figure 13.3: Breakdown of Food samples received according to categories



13.2 ISO 17025:2017 Laboratory Accreditation

The Central Laboratory Oshodi was scheduled to have a physical audit for ISO17025:2017 Laboratory Accreditation by ANAB (ANSI National Accreditation Board) in October 2024 but this was rescheduled due to February 2025

The Laboratory currently has Thirty-Nine (39) scopes accredited.

13.4 Proficiency Testing

- CWC Chemical Analysis Competency Test (CCACT) 15 and 2024 conventional Proficiency Tests (PT) scheme.
- VERIFIN and WHO Proficiency Tests (PT) schemes
- Inter Laboratory Comparison (ILC) international Proficiency Test Scheme

13.5 Visits Meetings and Surveys:

The laboratory attended the following meetings:

- OPCW Meeting for African and GRULAC Member States
- Meeting on Food Fortification Quality and Traceability
- National Fortification Alliance (NFA) meeting
- Mentorship Visit from Mississippi State University
- Meeting on Anti-Microbial Resistance (AMR)
- Meeting on Genetically Modified Organisms (GMO)
- 2024 Food fortification survey

13.6 Conclusion

The Laboratory Services Directorate (Food & Chemicals) is committed to optimizing service delivery regarding the fulfillment of the Agency's mandate despite pertinent challenges that need to be resolved.

Chapter 14
Laboratory Services Directorate (Drugs)

14.0 Introduction

The Laboratory Services Directorate Drugs was established by the Director General of NAFDAC, Prof. Mojisola Adeyeye, to carry out quality and timely regulatory testing of medicines, veterinary medicines, herbal preparations, cosmetics etc. The Directorate currently has two functional laboratories viz:

- Central Drug Control Laboratory (CDCL), Yaba, Lagos.
- Maiduguri Area Laboratory

The Central Drug Control Laboratory, Yaba is one of the seven official reference Laboratories established to undertake quality control testing of regulatory products submitted to NAFDAC for regulatory purposes such as Market Authorization, Investigation, Post-Market Surveillance etc. It commenced operation in 1978 under the department of Food & Drug Administration of Nigeria's Federal Ministry of Health. It later became the Central Drug Quality Control & Vaccine Lab when NAFDAC was established in 1993 and as a Central Drug Quality Control Laboratory (CDQCL) in 2009, with the vaccine unit established as a separate independent Laboratory. In 2013, it assumed its current nomenclature as CDCL.

A. Objectives/Purpose of the Laboratory

The objective of the Laboratory is to provide reliable analytical Laboratory Services to NAFDAC in line with ISO 17025:2017-General requirements for the competence of testing & Calibrating Laboratories, WHO Good Practices for Pharmaceutical Quality control Laboratory, WHO Global Benchmarking Tool Requirements and ISO 9001:2015 Standards.

B. Highlights of the Functions of the Laboratory

a. CDCL carries out sample management and generate test reports using a validated Laboratory Information Management Systems (LIMS).
b. CDCL specializes in quality control testing for finished pharmaceutical products & active pharmaceutical ingredients (APIs).
c. CDCL provides reliable & accurate analytical Laboratory services in line with WHO GPPQCL, WHO Global Benchmarking Tool (GBT) requirements, ISO 9001:2015 and ISO/IEC 17025:2017

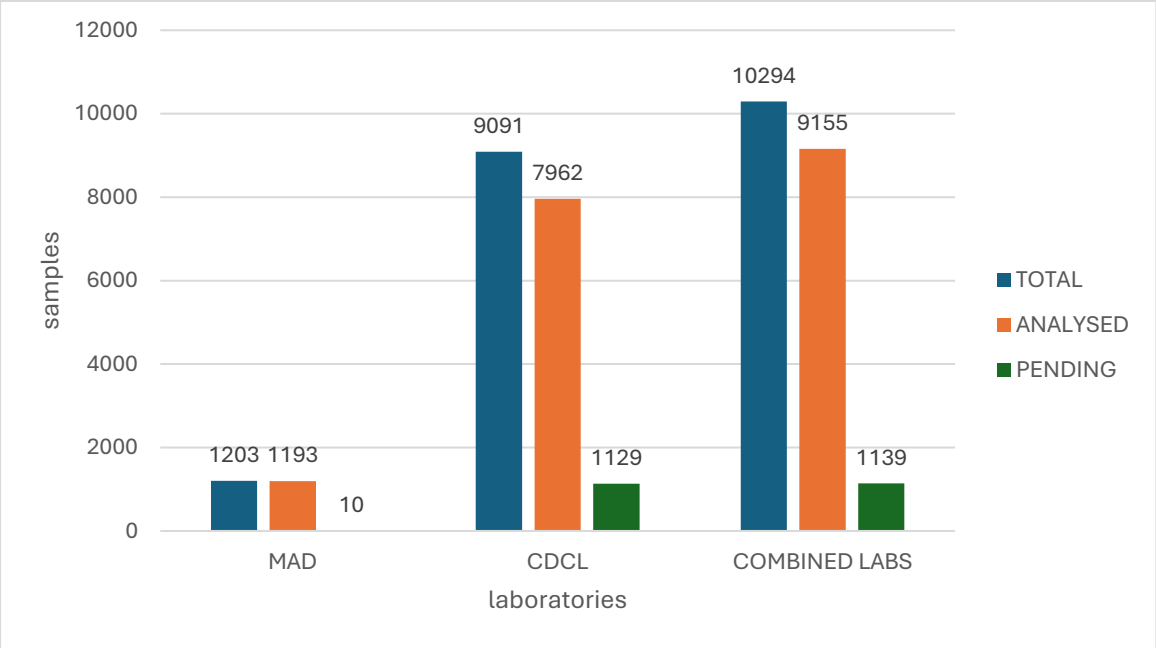
14.1 Analytical Performance

In the year 2024 being period under review, the Laboratory Services directorate (Drugs) received a total of **10,294** samples that were available for analysis. Table 1 and Figure 1 show the summary and chart of activities for the period under review, respectively.

Table 14.1: Summary of Analytical Performance In 2024

Labs	No. of Samples Brought Forward	No. of Samples Received	Total Number of Samples Available	No. of Samples Analysed	No. of Samples Pending
Maiduguri	45	1,158	1,203	1,193	10
Yaba Drugs	596	8,495	9,091	7,962	1,129
Total	641	9,653	10,294	9,155	1,139

Figure 14.1: Chart of Analytical Activities in 2024



14.2 Quality Management System (QMS)

A. Suitability of Policies and Procedures.

Thirty-Four (34) harmonized procedures, 19 QA and technical laboratory specific SOPs and 12 Work Instructions were reviewed.

B. Laboratory Annual Internal Audit

Two (2) phases of Internal Audit were implemented as prescribed by the Laboratory's Annual Internal Audit plan.

C. Laboratory Intra-Laboratory Audit

Intra-Lab Audit and Follow-up took place in line with the NAFDAC Laboratory Harmonization Program

D. External Audits

The Laboratory participated in Four (4) external audits thus.

i. **The WHO GBT Re-Benchmarking Assessment**

ii. ISO 17025:2017 Surveillance Audit and **ISO 9001:2015 Surveillance Audit** were rescheduled to hold in 2025.

E. Trainings

The Laboratory implemented training activities covering Forty (40) processes. One external training course was also undertaken in the year under review.

F. RCORE Training/ Information-Sharing Activities

In line with the laboratory's status as a regional center for regulatory excellence in Quality Assurance, the Laboratory hosted Medicine Control Agency of Gambia and Students from Dept of Mass Communication University of Lagos.

G. Capacity Building of Students, Intern Pharmacists

The laboratory onboarded One-Hundred and Eighty-Seven (187) students, Eleven (11) intern pharmacists and one (1) NYSC corps member for training and capacity building during the year under review.

H . Meetings/ Collaborations etc.

Several statutory meetings were held such as Quality Meeting, Risk Management Team (RMT) Meeting and Management Review Meeting (MRM).

I Safety Health and Environment Program

The laboratory commemorated the World Safety Day on 28th April 2024. Undertook several trainings, fire drills and inspections to assess the Laboratory compliance with safety practices.

J. Proficiency Testing

The laboratory participated in Inter-Laboratory Comparison schemes in three scopes, Karl Fischer, Optical rotation and MLT. Proficiency testing schemes are still in view.

14.3 Data Management System

A) Laboratory Information Management Systems (LIMS)

The Laboratory has an electronic system (LIMS) that manages sample receipt to the point of Issuance which ensures traceability and monitoring.

B) Temperature and Humidity monitoring Device

The Laboratory installed the Viasala Electronic Environmental System (Data Loggers for real time monitoring of temperature and humidity for the laboratory). This system ensures the integrity of samples submitted for analysis is maintained throughout the sample shelf-life.

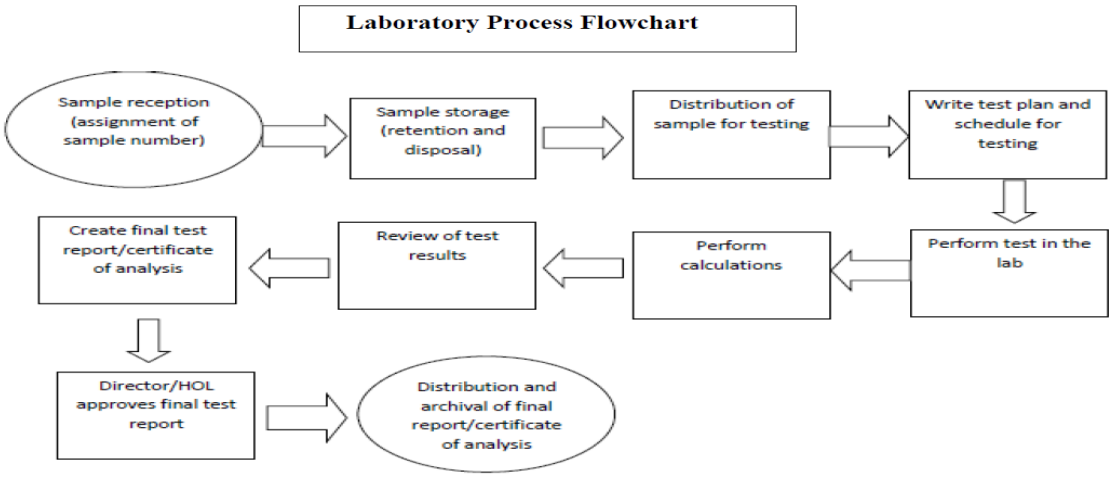
14.4 Laboratory Organizational Structure

The Laboratory's current organizational structure is as follows.

LABORATORY ORGANIZATIONAL STRUCTURE	
Testing Units	**Non-Testing Units**

• HPLC Laboratory I
• HPLC Laboratory II
• Analytical Chemistry I
• Analytical Chemistry II
• Pharmaceutical Control
• Cosmetics Lab
• Herbal Lab
• Microbiology Lab
• Pharmacology
• GC lab
• Fourier Transform Infra-Red Laboratory
• Veterinary Products Lab
	• Quality Assurance
	• Central Registry
	  • Sample Reception
	  • Specification Archive
	  • Store
	• Instrument Maintenance Unit
	• Director/ HOL Office

14.5 Laboratory Process flow



CONCLUSION

The Laboratory Services Directorate is committed to providing a robust service delivery and excelling in its responsibilities in meeting the Agency's mandate however the constraints need to be resolved.

Chapter 15
Laboratory Services Directorate (Vaccines, Biologicals and Medical Devices)

15.0 Introduction

The Laboratory Services Directorate (Vaccines, Biologicals and Medical Devices) is responsible for testing the safety and quality of vaccines, biologicals, and medical devices in Nigeria.

Goals

- To generate quality and timely test results that meet international Standards.
- To provide excellent customer service

15.1 Analytical Performance

The laboratory received a total number of One Thousand, Two Hundred and Eighty-One (1,281), samples in 2024. Out of these, One Thousand One Hundred and Twenty (1,120) samples were successfully analyzed, with 87.43% meeting quality standards.

Table 15.1: Summary of Analytical Performance for 2024

Number of Samples Brought Forward from 2023	Number of Samples Received	Total number of samples	Total Samples Analyzed	Number Satisfactory	Number of Unsatisfactory Samples	Number Pending	Percentage Performance
196	1,085	1,281	1,120	1,120	0	161	87.43%

Figure 15.1: Summary of Analytical Performance for 2024

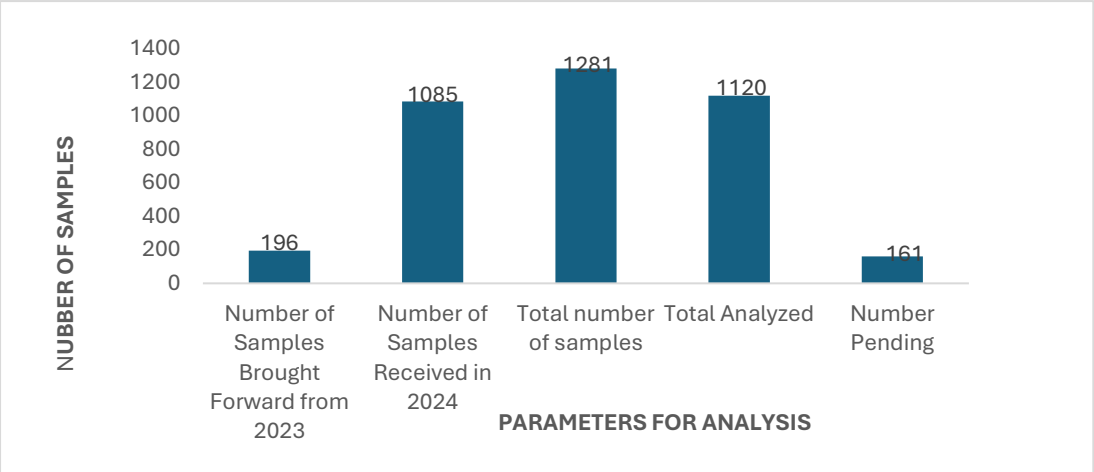
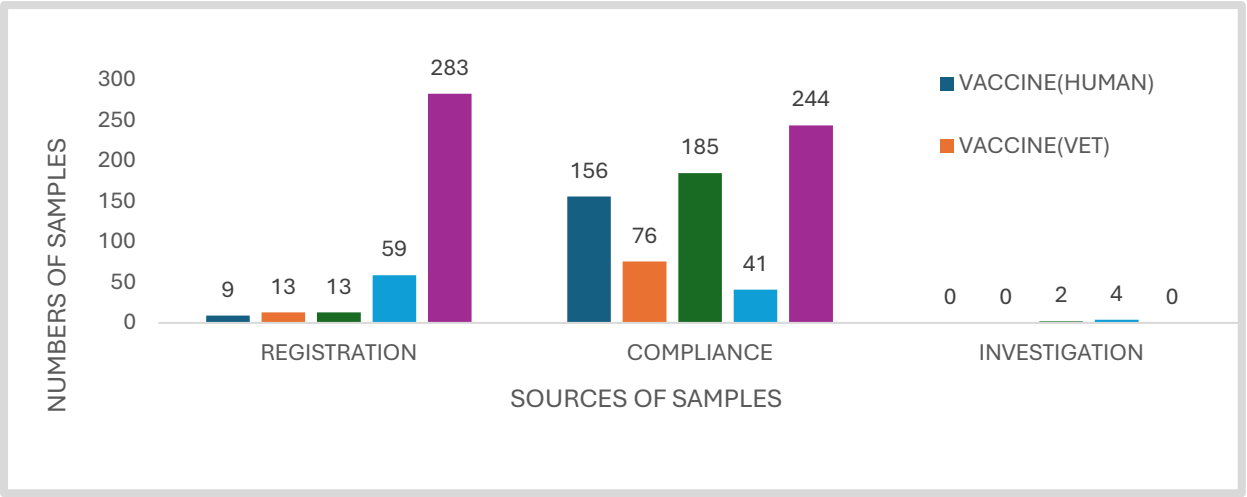


Figure 15.2: Breakdown of Samples According to Category and Source



15.2 Joint Sampling with Other Directorates

Eighty-Six (86) Vaccines and Biologicals for compliance were jointly inspected and collected with the Ports Inspection Directorate at various Cold Stores. Samples were also received from Registration & Regulatory Affairs and Enforcement Directorates.

15.3 Quality Management System:

A. National Quality Assurance Team on HIV Rapid Test Kits:

One (1) staff who is a member of the National Laboratory Quality Assurance Team (NALQAT) participated in Two (2) Sampling and Two (2) Post Market Validations of HIV Test Kits within the year under review.

B. Business Continuity Plan (BCP).

The laboratory has put in place a business continuity plan (BCP). The plan defines all activities and risks that can affect the laboratory's operations, making it an important part of the laboratory's risk management strategy.

C. Suitability of Policies and Procedures.

In the year under review, a significant effort was made to enhance the quality management system through the development and review of laboratory documents. A total of Fifty-Nine (59) procedures and Two (2) work instructions were reviewed, ensuring they meet current standards and requirements. Additionally, Four (4) new procedures were developed to further strengthen the system. These efforts reflect a commitment to continuous improvement and maintaining high-quality standards within the laboratory.

D. Outcome of Recent Internal and Intra-laboratory audits

During the period under review, the laboratory undertook several audit and self-assessment activities to ensure compliance with the requirements of ISO/IEC 17025:2017.

i. **Internal Audits and Self-Assessments**:
The laboratory conducted internal audits and self-assessments in line with the approved audit plan to ensure ongoing alignment with ISO/IEC 17025:2017.

ii. **Intra-Laboratory Audit**:
The laboratory also participated in an intra-laboratory audit following the approved intra-laboratory audit plan, based on the requirements of ISO/IEC 17025:2017. .

E. Customer and personnel feedback

The laboratory received 11 responses out of the 20 distributed customer satisfaction surveys. The analysis of these responses indicated a positive outcome in terms of customer satisfaction for the laboratory.

F. Proficiency Testing.

The laboratory successfully participated in Thirteen (13) test scopes.

15.5 Assessment By External Bodies: Who GBT Team

The laboratory underwent an assessment by the WHO GBT team, the focus was on medical devices, Lot Release procedure and regulations were also examined.

15.6 Laboratory Health Safety and Environment (HSE)

The committee on Health, Safety and Environment took proactive steps to ensure the safety and well-being of its personnel through regular safety awareness trainings, fire evacuation drills, and monthly HSE (Health, Safety, and Environment) inspections.

15.7 Trainings and Workshops

In the year 2024, a total of 45 training/workshops (including 23 unit-specific and safety trainings) were conducted for various personnel cadres. Additionally, the laboratory participated in two international meetings/conference.

15.8 Survey

The laboratory participated in performance evaluation survey on locally manufactured syringes and needles. Various batches of samples were collected from three different companies, namely,

i. Afrimedical Manufacturing and Supplies limited.
ii. HMA Medical limited
iii. El-Salmat Pharmaceutical Co. Limited

15.9 Activities of Animal Facility

The Animal facility serves both the Vaccine and Drug laboratories.
The number of animals in the facility as of 31st December 2024 is as follows:
Mice = 930; Rabbits = NIL; Rats = NIL; Guinea pig= NIL
The mice, which are the major animals used for laboratory analysis are further classified into different groups and the quantities available during the period under review.

Adult = 400m
Winner = 80
Litter = 300
New birth = 150
Death = 50

Animal feeds were regularly purchased to ensure adequate feeding of the available animals. There is need for purchase of Guinea pigs, Rabbits, additional rat cages and rabbit cages.

15.10 Conclusion

The Vaccines, Biologicals and Medical Devices Laboratory Directorate has experienced remarkable growth and improvement which has been pivotal in strengthening our testing capabilities. This is also highlighted by
maintaining our previously certified analytical processes and broadening our scope, which stands as a significant achievement. The introduction of state-of-the-art equipment is also a key enabler of these advancements.
Looking ahead, the Directorate is committed to building on these successes however, some constraints need to be resolved.

Chapter 16
Agulu Laboratory Services (ALS) Directorate

16.0 Introduction

The 2024 Annual Report for Agulu Laboratory Services (ALS) details the lab's activities and achievements throughout the year. ALS demonstrated high analytical performance, maintained a dedicated staff, and continued to uphold rigorous accreditation standards.

16.1 Accreditation

ALS conducted both an Internal Audit and an Intra-Laboratory and Follow-up Audit during the year to maintain its high standards.
The laboratory continued to monitor and evaluate its accredited scopes, ensuring ongoing compliance.

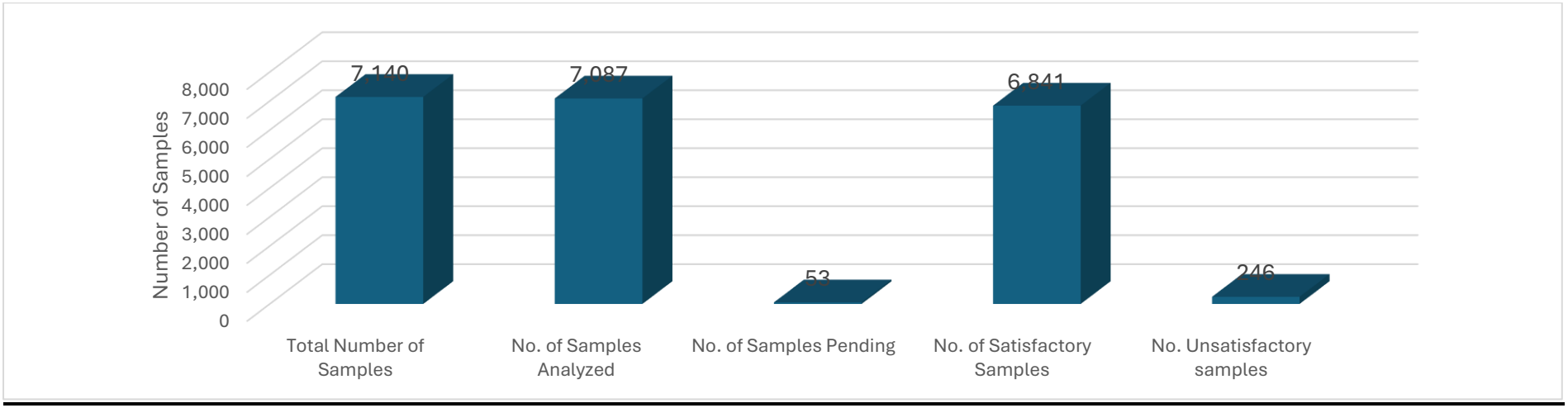
16.3 Analytical Performance

In 2024, ALS received a total of 7,140 samples for analysis in 2024, including 194 samples carried over from the previous year. The laboratory demonstrated high efficiency by analyzing 7,087 samples, representing 99.26% of the total. ALS handled a diverse range of samples, including food, water, pesticides, drugs, cosmetics, medical devices, and herbal preparations. The highest volume of samples came from the food category.

Table 16.1: Summary of Analytical Performance for the Year 2024

Product	No. Samples Brought Forward		No. of Samples Received	Total Number of Samples	No. of Samples Analyzed	% of Samples Analyzed	No. of Samples Analyzed Within the Timelines	% of Samples Analyzed Within the Timelines	No. of Satisfactory Samples	No. Unsatisfactory sample	No. of Samples Pending
Food	96		3,752	3,848	3,816	99.17	3,660	95.91	3,708	108	32
Water	24		2,090	2,114	2,114	100.00	2,102	99.43	2,034	80	0
Pesticides	0		52	52	52	100.00	52	100.00	52	0	0
Drugs	74		376	450	429	95.33	366	85.31	396	33	21
Cosmetics	0		471	471	471	100.00	471	100.00	447	24	0
Medical Devices	0		66	66	66	100.00	55	83.00	66	0	0
Herbal Preparation	0		139	139	139	100.00	139	100.00	138	1	0
Total	194		6,946	7,140	7,087	99.26	6,845	96.59	6,841	246	53

Figure 16.1 Analytical Performance for the Year 2024



16.3 Conclusion

The year 2024 was a successful year for ALS, marked by high analytical performance, a well-supported staff, and a commitment to maintaining accreditation. The laboratory's dedication to quality and efficiency is evident throughout the report. The Directorate is committed to ensuring that its operations meet the Agency’s mandate through rigorous analytical performance, dedicated staff development and unwavering.

Chapter 17
Kaduna Laboratory Services (KLS)

17.0 Introduction

The Kaduna Laboratory Services Directorate (KLS) ensures the safety and quality of food, drugs, and other regulated products through thorough analysis, supporting NAFDAC formations across 13 states and other stakeholders. As an ISO/IEC 17025:2017 accredited laboratory with 16 scopes of testing in medicines, KLS is pursuing food testing accreditation to enhance its credibility and reliability.

In 2024, the laboratory received a total of 8,488 samples of both local and imported products Table 1 shows a summary of the analytical performance for the period under review, while Figures 1 and 2 show the profile of samples received and distribution of samples based on purpose of analysis, respectively.

Table 17.1: Summary of Analytical Performance for the year 2024

Product type	No of samples brought forward	No of samples received	Total number of samples	No of samples analyzed	No. of satisfactory Samples	No of unsatisfactory samples
Food	39	4,792	4,831	4,784	3,657	1,127
Food Survey	0	960	960	960	377	583
Drugs	66	956	1,022	1,009	940	69
Water	55	1,977	2,032	1,965	1,721	244
Cosmetics	56	470	526	519	459	60
Pesticides	21	56	77	74	64	10
Microbiology*	43	5,219	5,262	5,058	4,547	511
Mycotoxin*	0	1,898	1,898	1,878	1,875	3
HPLC	02	272	274	274	248	26
TOTAL	**237**	**8,251**	**8,488**	**8,351**	**6,841**	**1,510**

#Key: Figures in red and asterisked* are from supporting labs and are therefore not relevant to the total number of samples.

17.1 Details of Activities

A. Technical

I. Investigation

During the year under review, the Laboratory analysed a total of 205 investigation samples.

II. Report from Key Laboratory Units

- **Food Unit**: The unit enhanced its capacity through food fortification sampling courses and inter-laboratory comparison exercises, analyzing 960 samples from five states for the National fortification survey.
- **Chemistry Unit**: This unit participated in proficiency testing and maintained its ISO/IEC 17025:2017 accreditation for various tests, including High Performance Liquid Chromatography (HPLC), UV-Visible Spectrophotometry, Dissolution Testing and Uniformity of Dosage Unit.
- **Water Unit, Cosmetics Unit** and **Pesticide Unit**: The units consistently met their targets with high proficiency, demonstrating exceptional accuracy and reliability in analyses.
- **Microbiology Unit**: Central to KLS service delivery, the unit analysed samples from various labs and received a Biosafety Class A cabinet, participating successfully in Proficiency Tests for Bacterial Endotoxin Test (BET).
- **Mycotoxin Unit**: Responsible for detecting the presence of aflatoxin, ochratoxin, and melamine, the unit consistently met its targets by analysing 100% of its samples demonstrating exceptional accuracy and reliability.
- **HPLC UNIT:** During the year under review, the unit carried out analyses of all samples received.

Figure 17.1: Profile of Sample received in 2024

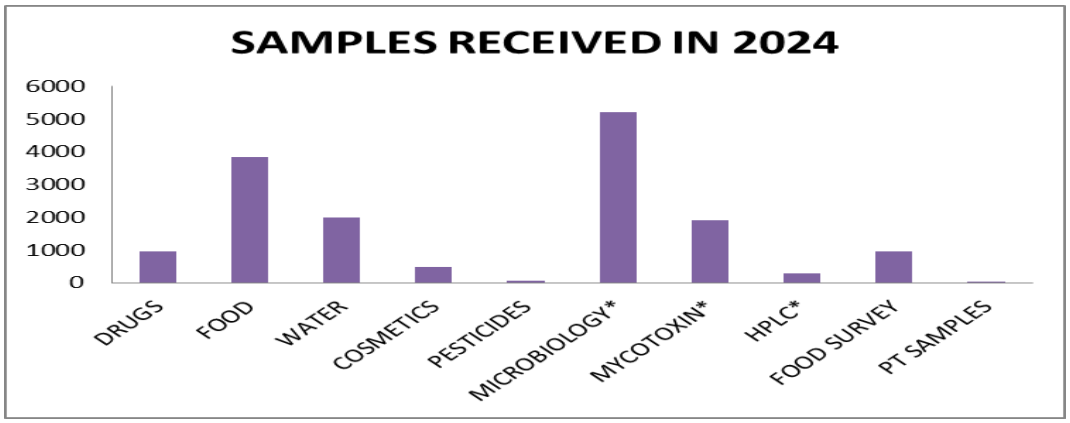
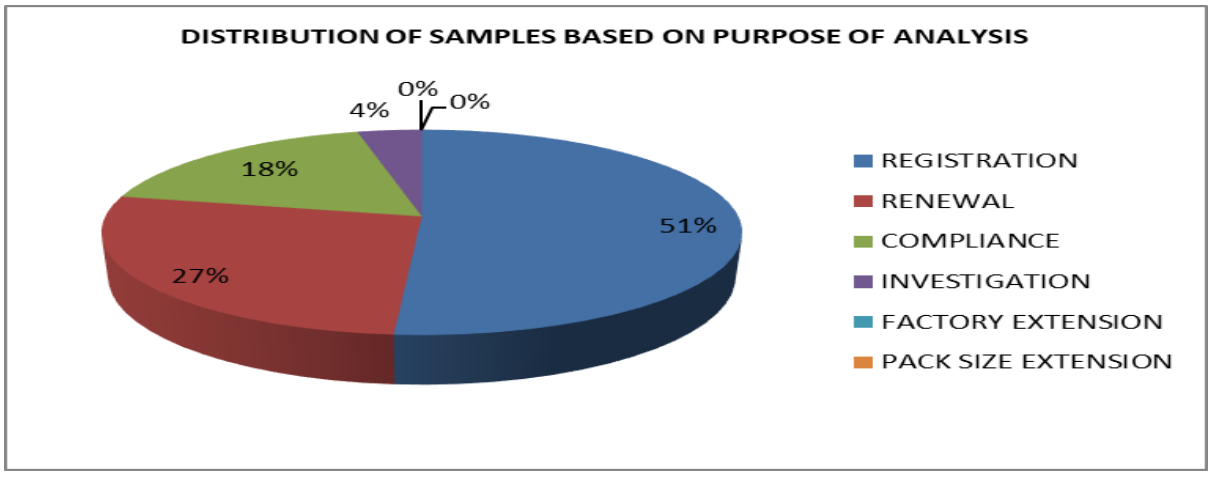


Figure 17.2: Distribution of Samples Received Based on Purpose of Analysis



17.2 Quality Assurance

To ensure quality assurance of processes and reports, and in accordance with ISO/IEC 17025:2017, the unit focused on the improving processes and quality of results by undertaking various activities including:

- Conducted all scheduled internal audits, including process audits and self-assessment audits.
- Carried out 17 scheduled internal training sessions for the entire staff.
- Participated in four proficiency tests in the areas of Dissolution, Polarimetry, BET, and Tablet Testing (Hardness, Friability, Disintegration).
- Supported the training of staff members on the organization of inter-laboratory comparisons and knowledge management organized by USP PQM/USAID.
- Developed 17 new Standard Operating Procedures (SOPs) and reviewed two existing ones; Created 16 new work instructions and reviewed ten existing ones
- Investigated and confirmed 31 Out of specifications (OOS) results.

17.3 Instrument Maintenance

The laboratory received a new 275KVA generator to ensure steady power supply. Additionally, a total of 64 pieces of equipment were calibrated, and all scheduled routine maintenance was conducted. Performance verification on the equipment was also carried out.

17.4 Information and Communication Technology

The laboratory's' capabilities were significantly improved with the implementation of an updated Laboratory Information Management System (LIMS) with user roles and permissions reconfigured. To boost efficiency, the LIMSREMOTE application was rolled out to various formations starting in December 2024, allowing stakeholders to initiate the sample submission process before arriving at KLS.

17.5 Health Safety and Environment (HSE)

The laboratory remains committed to safety by prominently displaying in-house emergency contacts, strictly enforcing the use of personal protective equipment (PPE) and ensuring Safety Data Sheets are easily accessible. In addition, the following measures amongst others were undertaken.

- Various devices were procured for monitoring staffs body fitness and regular health checks (Weighing scales, Sphygmanometer and Glucometer), to enhance staff health.
- Fire safety drills and assessment were carried out, the requirements for firefighting equipment were elicited and directed to the Engineering team for implementation.

17.6 Achievements

- Participation in Inter-Laboratory Competency (ILC) for both food and drug
- Full deployment of Laboratory Information Management System.
- Participation in 4 Proficiency Tests for drug analysis, national Food and Drug Surveys

17.7 Conclusion

The Kaduna Laboratory Services Directorate (KLS) has demonstrated significant progress and commitment to excellence in 2024. The laboratory's' achievements in sample analysis, internal training, and quality assurance underscore her dedication to maintaining high standards and supporting regulatory functions across multiple states.

KLS's focus on continuous improvement, capacity building, and customer satisfaction positions it well for future success.

Chapter 18
Pharmacovigilance (PV) Directorate

18.0 Introduction

The National Pharmacovigilance Centre (NPC) is responsible for promoting rational and safe use of medicines by sourcing, collating, analyzing and disseminating information on adverse drug events. Activities of PV Division within the period under review are hereby presented as follows:

18.1 Individual Case Safety Reports (ICSRs) Management

One of the major functions of NPC is to manage data collected from the individual case safety reports (ICSRs) sent to the NPC via different sources; CIOMS, NPC ADR Forms, e-Reporting and Med Safety App. The reports, irrespective of the source, are transcribed and entered VigiFlow which can further be transmitted to the VigiBase, the WHO International Drug Safety Monitoring Program database domiciled in Uppsala Monitoring Centre, Sweden after causality assessment. As of 31st December 2024, a total of Fifty-Seven Thousand, Six-Hundred and Eighty-One (**57,681**) ICSRs/AEFIs were documented on the Vigiflow.

Received Reports

A total number of Five Thousand and Ninety-Eight (**5,098**) ICSRs/AEFIs were received in 2024 via the various reporting platforms as shown in table below:

Table 18.1. Number of reports received in 2024.

Means of reporting	2024	Comments
MedSafety App	939	6 Review ongoing
e-Reporting	1736	1736 Assessed and shared with Vigibase
CIOMs	116	116 Uploaded, Assessed and shared with Vigibase
NPC ADR forms	187	187 Uploaded, Assessed and shared with Vigibase
AEFI forms (NEC)	112	112 Uploaded, Assessed and shared with Vigibase
Industry eReporting	22	22 Assessed and shared with Vigibase
Vigiflow e-forms	174	7 Review ongoing
Import	770	770 Assessed and shared with Vigibase
IHVN	1042	1042 Assessed and shared with Vigibase
Total received	**5,098**	13 Review Ongoing

Note: The Institute of Human Virology, Nigeria manually uploaded 1,042 reports before transitioning to the e-reporting platform. As a result, some of the reports from the e-reporting platform are from the IHVN.

Update on Manual Data entry to Vigiflow

ADR reports received at the NPC as CIOMS, NPC ADR forms and AEFI reports from the NEC on AEFI are manually uploaded to vigiflow by the NPC staff. In the year 2024, One Thousand Four Hundred and Fifty-Seven (**1,457**) ICSRs/AEFIs were manually uploaded to vigiflow as shown in Table below:

Table 18.2: Manual ICSR/AEFI data entry to Vigiflow in 2024

	Number uploaded	Number committed to Vigibase	Number pending review and committing
Manual data entry ICSRs	303	303	0
Manual data entry AEFI	1,154	1,154	0
Total	1,457	1,457	0

18.2 Review of Safety Documents

Four Hundred And Forty-Four Hundred (**444**) Periodic Safety Update Report (PSUR)/[Periodic Benefit risk Evaluation Report (PBRER) and Twenty-Two (**22**) Risk Management Plan (RMP) were received and reviewed in 2024.

18.3 PV State Level Trainings

The Pharmacovigilance Directorate has collaborated with various partners and stakeholders to implement pharmacovigilance activities in the states such as awareness creation, training of healthcare professionals, and supporting the establishment of Pharmacovigilance committees in health facilities. To further strengthen Pharmacovigilance in the states, training of healthcare professionals in selected healthcare facilities was conducted. Fifty-Three (53) and One Hundred and Thirteen (113) healthcare providers were trained in Zamfara and FCT respectively.

FDIC Division

D. Recall and Alert Notifications

Fifty-Seven (57) notifications were received and treated within January and December 2024

From January to December 2024, a total of Fifty-Seven (57) recalls and alerts were received and treated (14) DHCPL were disseminated to Healthcare Professional respectively and Forty-Three (43) Public alerts were sent for upload on NAFDAC website Review of Safety Submissions from January to December 2024

E. Review of Safety Submissions

Seven-Five (75) Safety submissions were received and reviewed within the period under review

.

F. PV Newsletter:

The FDIC prepares quarterly newsletters to inform stakeholders on current trends in pharmacovigilance. Four (4) pharmacovigilance newsletters were prepared and disseminated to stakeholders within the period under review. The newsletters prepared are as follows:

1. Facts about prescription opiods , risk and management. first quater
2. Best practices for disposal of antimicrobials amidst the escalating threats of Antimicrobial Resistance. second quarter.
3. Perils in preservation :exploring how inadequate storage conditions transform pharmaceuticals into menace. Third quarter 2024
4. Inspections to ensure Quality Pharmacogilance. Dissseminated by Fourth Quarter 2024

G. Poison Control Articles

1st quarter 2024 poison control article volume 3 titled Mercury poisoning in skin Lightening products (SLPs) and Clinical management of chronic Mercury intoxication has been disseminated to healthcare professionals titled on 28th March 2024.

2nd quarter 2024 poison control article VOLUME 4: Safe disposal of Old Medicines at Home, Tips for Parents and Caregivers has been disseminated to healthcare professionals on June 30th, 2024

3rd quarter Volume 5: Facts About Prescription Opioids, Risks of Addiction and Overdose (Opioid Use Disorder), Treatment And Management.disseminated on 28th oct 2024.

H. Advocacy and Public Health Collaboration

Advocacy and Public Health Collaboration Division is one of the divisions in Pharmacovigilance Directorate.

Table 18.3: Summary of Activities by Months:

	Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec.	Total
Number of Advocacy Visit carried out.	1	5	4	0	6	2	0	3	7	6	4	4	42
Number of Collaborative meetings attended	1	3	2	5	7	4	2	1	2	3	1	2	33

13.2 Report of Activities Undertaken by PV Directorate - Lagos Office (Jan – Dec, 2024)

The Pharmacovigilance (PV) Lagos Office carried out various regulatory activities throughout 2024, focusing on pharmacovigilance documentation, advocacy and public health collaborations, consultative meetings, training sessions, and regulatory inspections. This report presents a comprehensive review

of the activities undertaken, safety documents received, and key recommendations for future improvements.

The PV Lagos Office is headed by a Deputy Director, Pharm Uche Chidi Uzoma. It has a staff of five (5) people. Below is a summary of the office's activities within the year.

13.4 Achievements

A. Pharmacovigilance Activities

1) Good Pharmacovigilance Practice (GVP) Assessment of Healthcare Facilities

The PV Lagos officers visited Four (4) healthcare facilities for an awareness assessment of their pharmacovigilance systems and processes related to adverse event reporting, data management, risk assessment, and communication. Being the first-ever assessment visit to these facilities, it provided a baseline evaluation of its pharmacovigilance practices and identified areas for improvement.

Key findings included:

- Limited knowledge of GVP guidelines/standards
- Variability in ADR reporting practices among healthcare providers.
- Need for increased training on the MedSafety App and reporting procedures.
- Establishment of Pharmacovigilance Committees in some facilities.

The PV Lagos Office conducted GVP health assessments of the following healthcare facilities:

1.	National Orthopedic Hospital (NOHIL), Lagos
2.	Federal Medical Center (FMC) Ebute Metta, Lagos
3.	Federal Neuro-Psychiatric Hospital, Lagos
4.	Evercare Hospital LTD GVP, Lagos

Pharmacovigilance (GVP) Inspections

As part of regulatory oversight, PV officers in Lagos and Abuja collaborated to conduct pilot pharmacovigilance (GVP) inspections at healthcare facilities. The goal was to assess compliance with ADR reporting, data management, risk assessment, and communication protocols. These inspections helped identify strengths and areas needing improvement in pharmacovigilance practices.

1.	Johnson & Johnson Innovative Medicine
2.	Pfizer Specialties Ltd
3.	Fensyl MHP Consulting Ltd
4.	Novartis Nigeria Pharmaceuticals Ltd

Pharmacovigilance Documentation

Several safety documents were received and forwarded to the PV Headquarters, Abuja for further necessary action.

S/N	**PV** Documents	Nos**.**
1	PSUR/PBRER	137
2	CIOMS	-
3	SmPCs	2
4	RMP	-
5	PIL	-

PV Investigation(s)

Investigation of ADR Related to Omnipaque Iohexol Injection (350mg/ml) at Evercare Hospital

On May 24, 2024, an adverse drug reaction (ADR) was reported at Evercare Hospital following the administration of Omnipaque Iohexol Injection (350mg/ml). The patients experienced severe fatigue and rigor shortly after administration. The PV Lagos team conducted an on-site investigation to assess the hospital's pharmacovigilance practices and ADR reporting mechanisms. The findings highlighted deficiencies in staff training on contrast media safety and the need for enhanced monitoring protocols. Recommendations were made to improve ADR documentation and emergency response preparedness at the facility.

Investigation of ADR linked to Deekins Amoxicillin Capsules 500mg (Batch No: 46C39001)

In December 2024, PV Lagos officers investigated ADR reports associated with this product, including severe hypersensitivity reactions and generalized body weakness, reported among patients at KOWA Specialist Hospital and four students at St. Gregory’s College. Investigations revealed significant concerns regarding potential counterfeiting and critical lapses in the pharmacovigilance (PV) systems of Divine Kings Pharmaceuticals Ltd, the Marketing Authorization Holder (MAH).

These investigations highlight the critical need for strengthened pharmacovigilance systems and enhanced awareness of ADR reporting tools, such as the Med Safety app, across healthcare facilities. Addressing these gaps in pharmacovigilance and regulatory oversight is essential to safeguard public health and mitigate risks associated with counterfeit or substandard pharmaceutical products.

B. Advocacy and Public Health Collaborations (APHC) Activities

❖ PV Advocacy Visits /Sensitization

A total of **56** healthcare facilities were visited for advocacy and sensitization. The focus was on:

- Training healthcare professionals on ADR reporting mechanisms.
- Promoting the MedSafety App and E-Reporting tools.
- Encouraging the establishment of Pharmacovigilance Committees in healthcare facilities.

Follow-up calls were made to facilities where on-site visits were not possible to assess their compliance with PV reporting requirements.

Table Below Shows the Summary of PV Advocacy Visits/Sensitization Carried Out in the year 2024.

	Advocacy Visits
Healthcare Facilities (Hospitals, Clinics, Health Centers)	28
Pharmacy Outlets	28
PHP (Collaboration)	Southwest Zonal Pharmacovigilance Centre, LUTH, Lagos Damien Foundation, KNCV Nigeria – linkage partners of Damien Foundation, a non-profit organization for Tuberculosis and Leprosy program

C. Food And Drug Information Center (FDIC) Activities

❖ Alert Notices

Alert notices were received on NAFDAC-regulated products. Various Pharmacy outlets were visited for surveillance on alerts.

❖ NAFDAC Catch-Them-Young Teachers Training Modules:

The PV Directorate in collaboration with the Narcotics and Controlled Substance Directorate, has successfully relaunched the NAFDAC Consumer Safety Club (NCSC) through the training of secondary school teachers for the Catch-Them-Young Program. This initiative aims to eradicate drug abuse among secondary school students. Meetings are held a month, with Pharm. Egwuonwu Theophilus (DD PV Lagos) representing the PV Directorate.

D. Conferences, Trainings, Meetings, Presentations, Self-Assessment and Internal Audit.

PV Staff, Lagos participated in several meetings, training, and paper presentations within the period under review.

❖ PV State Level Trainings

The Pharmacovigilance Directorate has collaborated with various partners and stakeholders to implement pharmacovigilance activities in the states such as awareness creation, training of healthcare professionals, and supporting the establishment of Pharmacovigilance committees in health facilities. To further strengthen Pharmacovigilance in the states, training of healthcare professionals in selected

healthcare facilities was conducted. Fifty-Three (53) and One Hundred and Thirteen (113) healthcare providers were trained in Zamfara and FCT respectively.

❖ **GBT Meeting:**

Dr. Evelyn Anegbe participated in GBT weekly meetings in preparation for the WHO formal re-benchmarking of Nigeria's regulatory system, assessing Maturity Levels 1 to 3 sub-indicators, scheduled for November 2024. The Vigilance Function achieved Maturity Level 3, with some IDPs identified.

❖ **PV Detection Committee Meeting:**

Pharm. Uche Chidi, Pharm. Egwuonwu, T.O., and Dr. Evelyn Anegbe participated in committee meetings.

❖ **International Medical Devices Regulatory Forum (IMDRF)**

Pharm. Egwuonwu, T.O., DD (PV), Lagos represented the PV Directorate in the Clinical Evidence in-Vitro Diagnostic Working Group

E. Self-Assessment and Internal Audit

- **Self-Assessment:** The PV Lagos office conducted a self-assessment on 14th July 2024 in readiness for the Agency's internal audit scheduled for 17th July 2024. Mrs. Adewusi, Edna, CER Directorate observed the exercise.
- **2024 NAFDAC Internal Audit:** PV Lagos was audited by the Agency QMS team.

Chapter 19

Post Marketing Surveillance (PMS) Directorate

19.0 Introduction

The Post Marketing Surveillance (PMS) Directorate of NAFDAC is responsible for the Post marketing Surveillance of all Regulated Products in collaboration with Marketing Authorization Holders (MAHs).

The activities of the PMS Directorate within the period under review are hereby presented as follows.

19.1 Proactive PMS

1. The PMS Directorate and state offices planned and visited sales outlets and distribution facilities and screened the products. Violative products are identified, and regulatory actions are taken depending on the type of violations. Twelve Thousand, Eight Hundred and Eighty (12,880) outlets/facilities were visited from January to December 2024.

2. Good Storage Distribution Practice (GSDP) Scheduled and Inspected.
This activity for now is only carried out on medical products in wholesale and distribution facilities both private and public. Storage, handling, and transportation impact a lot on the quality of medical products. The facilities are inspected to ensure compliance and to track and trace substandard and falsified products for appropriate regulatory action and regulatory directives.
The total number of GSDP conducted in all the states in 2024 was stood at Four Hundred and Thirty-Five (435).

3.GLSI Monitored
In line with NAFDAC laws and regulations, no product should be manufactured, imported, exported, or distributed in Nigeria until it is duly registered. However, Supermarket operators are given special consideration under the Global Listing of Supermarket Items (GLSI) scheme to import and sell varieties not registered and sale on retail only in their supermarkets and not distributed to others. The Agency monitors compliance with the scheme. One Hundred and Ten (110) GLSI were monitored in 2024.

19.2 Reactive Post Market Surveillance

A. No. of Special Surveillance Carried Out (Alert Notices) Received
Summary of special surveillance received within the period under review (January-December 2024).
These are specific surveillance carried out on products identified as not compliant with regulations by other NRAs, MAHs, and others.
Therefore, this surveillance is targeted. The Three Thousand and Forty-Six (3,046) of such surveillances were carried during the period under review.

B. Consumers Complaints Received and Investigated
Consumers are encouraged to report any unusual discovery on a regulated product for prompt investigation and regulatory action.

The number of consumer complaints received was 204 of which 182 were successfully investigated in 2024.

C. Rapid Alerts System for Food & Feed Received (RASFF)
Feedback from the European Union and other nations indicates that Nigerian commodity products do not meet their standards. Most of the time these products were exported, not following the correct procedures. These reports are usually sent to the appropriate MDAs/ Directorates for necessary actions. **39** Rapid Alert System for Food and Feed were received in 2024.

D. Establishments Visited for Product Mop-Up.
The Directorate visited Five Thousand, Three Hundred and Five (5,305) facilities for Products mop-up in the year 2024.

E. Products mopped up.
These are substandard, falsified, unwholesome, and non-performing medical products, food, and medical devices respectively removed from circulation. Fifty-One Thousand, Five Hundred and Fifty-Nine (**51,559)** Products were mopped up in the year 2024.

F. Sanction
The Directorate carried out Three Thousand, One Hundred and Ninety (3,190) Sanction activities in the year 2024.

19.3 Other Activities in the Year

a. Risk-based post-marketing surveillance.
The products include Antimalarial medicines like Artemether/ Lumefantrine 80/480mg. 20/120mg tablets and dry powder for oral suspension. Also, there are Condoms, Sulphadoxine/Pyrimethamine, and Amoxicillin suspension and dispersible tablets in collaboration with USP. Pediatrics formulation of Artemether/lumefantrine, Azithromycin, and Amoxicillin dispersible tablets sampled from the coordinated wholesale center, Kano analyzed in the ISO-certified laboratories. The lab reports were evaluated, and appropriate regulatory actions were taken on the failed samples.
Notable among the discoveries in this activity is that Artemether/Lumefantrine suspension is unstable after reconstitution, therefor the formulation has to stop. A regulatory Directive has been issued to this effect.

b. Nation Action Plan (NAP) for Substandard and Falsified (SF) Products.
The Directorate coordinated the review of the NAP, it has been completed and signed by the coordinating minister for Health and Social Welfare.

c. Advocacy, sensitization, and Awareness campaigns on Substandard and Falsified Medical Products.
The Directorate developed and produced IEC materials like stickers, fliers, roll banners, and Jingles for awareness and sensitization campaigns. The directorate organized advocacy to opinion leaders and sensitizes communities in six states including FCT. The programs were well-aired for public attention through the print, electronic and social media.

Chapter 20
Investigation And Enforcement Directorate

The Investigation & Enforcement Directorate is the arm of NAFDAC, principally responsible for ensuring compliance with the Agency's mandate on regulatory activities related to Food, Drugs, Cosmetic, and Medical Device etc. It also coordinates the enforcement activities of all other Directorates, zonal and states offices of NAFDAC Nationwide. The Federal Taskforce on Counterfeit and Fake Drugs and Unwholesome Processed Foods is domiciled in the Directorate.

In 2024, the Directorate continued its enforcement activities with more vigor despite a number of challenges. The activities are summarized under the following headings:

- Surveillance
- Investigation
- Interrogation
- Sampling
- Compilation of case files
- Raid on drug hawkers

20.1 Surveillance-

The Directorate carries out surveillance in order to recognize or monitor threats and prevent/investigate criminal activities. A total of 902 surveillance activities were carried out between January to December 2024.

20.2 Investigations:

In order to ascertain the veracity of Cases under investigation, the Directorate examines all materials and available facts before reaching a conclusion; a total of 1,204 investigations were carried out between January to December.

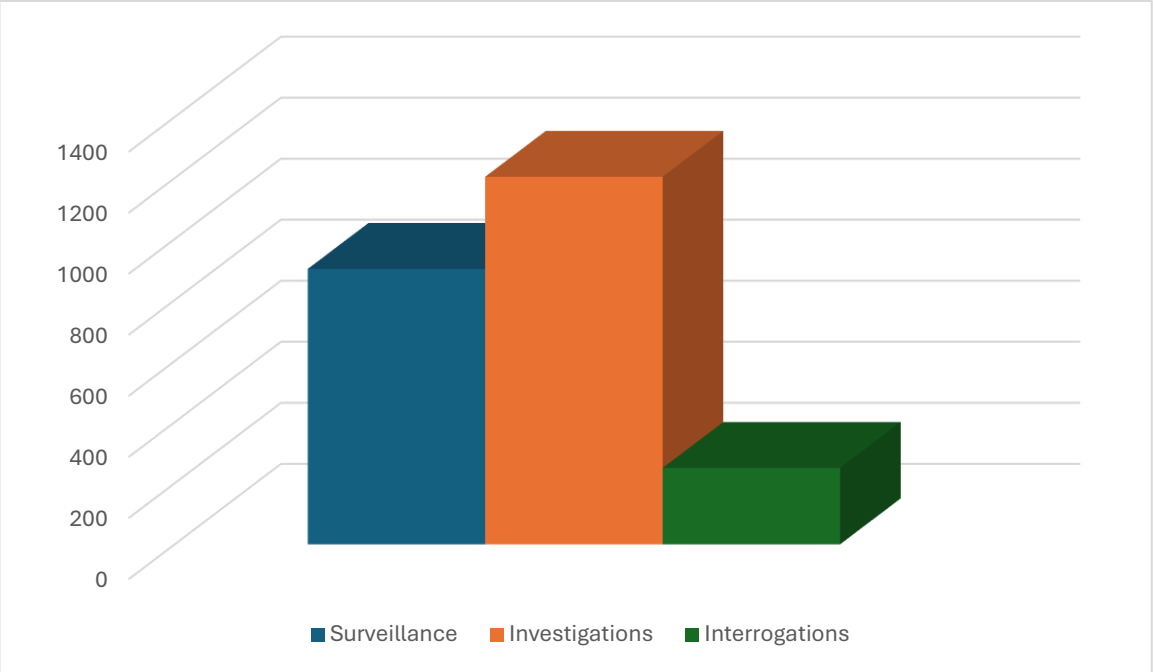
20.3 Interrogations.

The Directorate interrogated suspects interviewed victims and witnesses of crimes related to NAFDAC Enactments. 250 Interrogations and interviews were conducted between January to December 2024.

Table 20.1: Summary of Enforcement Activities Carried Out in 2024

Months	Surveillance	Investigations	Interrogations
January	65	79	11
February	52	63	5
March	84	99	9
April	100	127	44
May	110	124	9
June	61	81	27
July	105	184	20
August	43	56	15
September	102	137	12
October	16	30	6
November	126	168	57
December	38	56	35
Total	**902**	**1,204**	**250**

Figure 20.1: Enforcement Activities Carried Out in 2024



20.4 Sampling

During the process of investigation, all violative NAFDAC Regulated Products were sampled and forwarded to the laboratory for appropriate analysis and pronouncement. A total of 233 investigative samples were forwarded between January to December 2024 with the breakdown as follows:

20.5 Raid on Hawkers of Pharmaceutical Products

Raids are routinely carried out on hawkers of drugs in markets, streets and moving vehicles. The Directorate carried out a total of 84 raids, arrested 31 hawkers, and 158 wares were seized between January to December 2024 under review.

Table 5: No of Hawkers Arrested

Month	Raid	Hawkers Arrested	No of Wares Seized
January	0	0	0
February	1	0	0
March	1	0	0
April	39	1	56
May	38	26	97
June	0	0	0
July	2	4	5
August	0	0	0
September	0	0	0
October	0	0	0
November	3	0	0
December	0	0	0
Total	**84**	**31**	**158**

- **Compilation Of Case Files**

The Directorate, in conjunction with the Legal Services Directorate, filed Twenty (20) cases in court and secured 6 convictions.
The breakdown is as follows:

20.6 Destruction of Seized NAFDAC Regulated Products

The Directorate carried out the destruction of Substandard and Falsified Medical Products, Unwholesome Processed Food Products, Unsafe Cosmetics, other Expired and Counterfeit NAFDAC Regulated Products.

Table 6: Destruction Exercises Carried out in 2024.

Month	Zone	Value of Products Destroyed
January	-	-
February	-	-
March	-	
April	7	N675,378,431.00
May	-	-
June	1	N986,300,290.00
July	-	-
August	-	-
September	1	N43,000,000,000.00
October	-	-
November	-	-
December	-	-
Total	**9**	**N44,691,678.721.00**

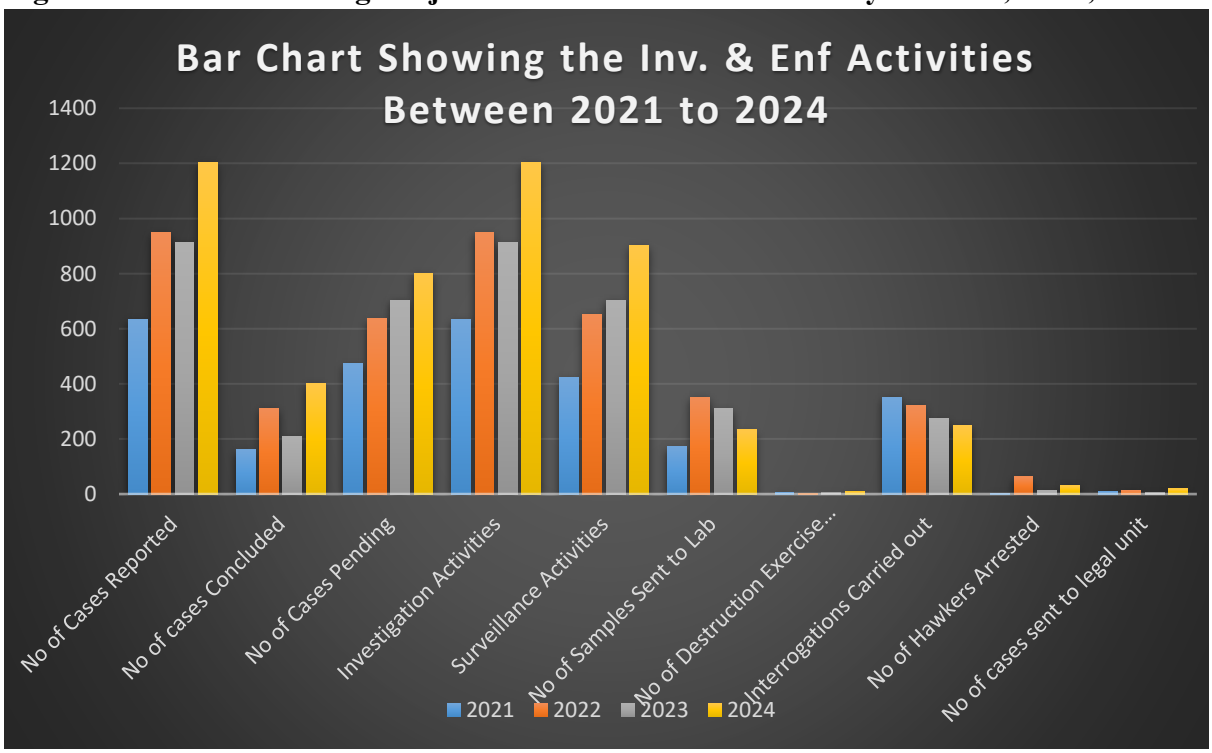
20.7 Other Activities

There was appreciable improvement in compliance by stakeholders with relevant Laws and Regulations particularly in the area of registration, due to enforcement activities.

Table 8: Summary of Enforcement Activities 2021 – 2024

	2021	2022	2023	2024
No of Cases Reported	634	948	913	1,204
No of cases Concluded	161	312	209	403
No of Cases Pending	473	636	704	801
Investigation Activities	634	948	913	1,204
Surveillance Activities	424	653	703	902
No of Samples Sent to Lab	172	351	309	233
No of Destruction Exercise Carried out	6	1	4	9
Interrogations Carried out	351	322	274	250
No of Hawkers Arrested	3	63	13	31
No of cases sent to legal unit	9	14	4	20
Total	2,858	4,248	4,044	5,057

Figure 2: Charts Showing Major Enforcement Activities for year 2021, 2022, 2023 and 2024



Chapter 21
Legal Service Directorate

21.1 Registration Documents

Below is a breakdown of registration documents treated by the directorate for the months under review.

Month	Drugs, Cosmetics & Medical Devices	Food	Total
January	48	23	71
February	69	21	90
March	130	23	153
April	65	18	83
May	71	27	98
June	54	19	73
July	73	15	88
August	96	14	110
September	102	19	121
October	-	3	3
November	131	28	159
December	134	16	150
		Total	**1,199**

1. Meetings

- Meeting held on 19/01/24 between NAFDAC and AMAC on the resolution of the charges for wrong parking/parking charges and fees issued to the Agency. In attendance were DD Admin, S A to DG, Legal and AMAC. Same AMAC meeting was also held on 19th February, 2024. AMAC came back with feedback as a resolution to the charges for wrong parking issued to the Agency. The resolution reached was that AMAC slashed the earlier amount of 16.5m charged against NAFDAC to 6m.
- Enhanced Trade and Investment partnership (ETIP) draft meeting held at the BOI Conference Room on the 24/01/2024 and 7/02/24. The meeting was arranged by Federal Ministry of Industry Trade & Investment (FMITI) on the draft memo. In attendance were MDAs, with dealings on trade & investment. NAFDAC, SON, FCCPC, NAQS, NEEDS, FMITI, FMOI and the organized private Sector.
- Enhanced Trade & Investment Partnership (ETIP) Inter-ministerial meeting held on 24th April, 2024 at Bank of Industry (BOI) Conference Hall, Abuja. The purpose of the meeting was to select members of the Technical Working Corps as captured in the MOU signed between the FRN and the Government of United Kingdom and Northern Island on 13th February, 2024. LeSD & OTIR were in attendance.
- POCA Regulation Validation meeting held for two days on 18 – 19 & 24th -25th of April, 2024. The Regulation was considered by MDAs in attendance and suggestions were made.
- Virtual Meeting on PEBEC 90 days RRA held on 26th April, 2024 to make adjustments for 90 days products registration to comply with the ease of doing business in Nigeria. Sub-Approval Meeting: Attended the 25th FCT Sub-Approval meeting on the 24th of April 2024.
- The Honourable Attorney General of the Federation (HAGF) organized a capacity building for legal advisers in public institutions on 2nd May, 2024 at Federal Ministry of Justice. The meeting

was attended by DD i/c LeSD & CLO (F0I Desk Officer). Participants were enlightened on the F01 Act, 2011 and an overview of the Act was the highlight of activities and the responses of MDAs to request for information brought pursuant to its Act.

- Meeting on validation of proceeds of crime (management and recovery at the Federal ministry of justice.
- Meeting between Kwesbatro & Procurement Evaluation Committee to get the Contractor (Kwesbatro) to agree on the general amount quoted in their bid to execute the project.
- Meeting between NAFDAC & the owner of the Nassarawa office space held on 23rd April, 2024. The Agency is letting in other to iron out certain clauses set out in the Tenancy Agreement.
- Meeting for proposed inspection of NAFDAC premises by AMAC held between AMAC and NAFDAC (A & amp; HRM, LeSD, Engineering and HSE) on the 18th of March 2024 for the purpose of discussing a proposed inspection of the Abuja facility. AMAC was asked to provide us with a report of the previous inspection they carried out in 2022, certificate of inspection, checklist for this inspection, legal basis for the inspection and legal basis for the fees being charged.
- Meeting at FCCPC Abuja office with NAFDAC & representatives from Chi Ltd. FCCPC was investigating a claim used by Chi Ltd on one of its products as "No added Sugar" 100% fruit juice. In attendance were DD (R & RA), AD (FSAN) & CLO.
- Meeting with Federal Ministry of Health (FMOH), NAFDAC and relevant stakeholders on a draft MOU, proposed by health. The meeting was held on 26/02/2024 and NAFDAC submitted its inputs to the ministry.
- PEBEC Reform meeting was held at NIPC building on the 12/03/2024 to deliberate on the reform's areas NAFDAC needs to comply to. In attendance were DD (ICT) and NAFDAC PEBEC reforms team led by Mrs Ajayi DD (OTIR)
- One-Day Information Roundtable and Official Launch of the Branding Project for SMEs in Nigeria organized by World Intellectual Property Organization (WIPO). The World Intellectual Property Organization (WIPO) held the maiden edition of its one-day training and information roundtable for the Branding Project for Small and Medium Enterprises (SMEs) in Nigeria on 24/09/2024 at the United Nations House, Abuja. The session was organized to introduce the initiative and provide insights on how Intellectual Property (IP) can boost market access for SMEs and address challenges in a post-pandemic economic environment.

21.2 Contract Agreements/Memorandum of Understanding

A total of Fifty-Three (53) contract agreements/MoU's were prepared for the period under review.

21.3 Committees

The Directorate has full representation on the following committees:

a) Food and Drugs Registration Committee (Final and Sub)
b) GBT Team
c) NAFDAC Traceability Office
d) POCA

2. Public Hearings at The National Assembly

- Public hearing on the 18th of April 2024 for a Bill for an Act to enact.
the Nigerian (Non-oil and gas sector) development (establishment) bill to establish the Nigerian Content (Non-oil and gas sector) development council.

- Public Hearing on a Bill for a Law to establish the Imo State Competition and Consumer Protection Council held on 24th May 2024 at Imo State.
- Public Hearing on the 23rd July, 2024 for a Bill for an Act to provide for the establishment of the National Safety Regulatory Board.

21.4 Cases

New Cases

a) **MUKTAR SA'ID AMIN VS NAFDAC & 3 OTHERS. - SUIT NO K/M307/2024.** The plaintiff sued the Agency for the enforcement of his fundamental rights to personal liberty under Section 34,35,36 & 41 of the 1991 Constitution, Article 5,6 & 7 of the African Charter on human & Peoples Rights (Ratification & Enforcement) Act, Cap A9 LFN 2004. The plaintiff is seeking N50,000,000.00 (fifty million naira).

b) **NAZIFI YSUF GORONDUTSE Esq Vs NAFDAC & 3 Ors - Suit No.** K/M/342/2024. The Plaintiff sought an Interim Injunction via Motion Exparte against the Agency to unseal, unlock, allow ease of movement of persons, goods, etc,, stop intimidating, arresting & harassing the applicant. The Court granted same. The matter was adjourned for hearing.

c) **NIGERIAN ASSOCIATION OF PATENT & PROPRIETORY MEDICINE DEALERS LTD (NAPPMED.** The plaintiff sued the Agency and others for breach of Fundamental Human Rights. The plaintiff is seeking for N1,000,000,000.00 (one billion naira) as general and exemplary damages.

21.5 Judgments:

1. **AMSON INELO V NAFDAC & 3 ORDERS - SUIT NSD/K19/2023**
   The Plaintiff filed this suit before the High Court of Justice, Keffi, Nasarawa state claiming the sum of thirty million naira (N30, 000, 000. 00) only against the Agency for unlawful destruction of chemical seized from his shop by NAFDAC Officers in Nasarawa State and cost of the suit. The Agency filed a defence and sought a dismissal of the suit for lacking in merit. The Agency also filed a Notice of Preliminary Objection challenging the jurisdiction of the Nasarawa State High Court to hear and determine the suit. The matter was struck out on 26th June, 2024.

2. **MUSIBAU BALLAM VS NAFDAC SUIT NO: FHC/ABJ/CS/1223/2019**.
   The Plaintiff filed this suit against the Agency before the Federal High Court, Abuja Division for breach of contract. The Plaintiff was engaged to auction Agency properties nationwide. His contract was terminated and later awarded to another company. He claimed the sum of Fifty-One Million Naira (N51, 000, 000. 00) as damages and cost of suit. The Agency filed a defence on the merit and a Notice of Preliminary objection in defence of the Agency. The Court struck out the suit on the ground that it was statute barred.

3. **NAZIFI YUSUF GORONDUTSE ESQ V PHARMACEUTICAL COUNCIL OF NIGERIA & 4 0RS, SUIT NO: K/M342/24**.
   The Applicant filed this suit at the Kano State High Court alleging breach of his Fundamental Rights guaranteed under the Constitution. He claimed the sum of Eighty Million Naira (N80, 000, 000. 00) Only against the Agency and 4 others. The applicant alleges that the act of sealing and locking down the entire Mai Karami Plaza where his law firm operates by the Agency and 4 others was a violation of his right to movement and to his property. The Agency filed a

Counter affidavit in opposition to the Applicant's suit. Parties adopted their processes before the court. The court dismissed the Applicant suit and entered judgment in favour of the Agency.

4. **FRN V MONDAY OKORIE (FHC/L/19C/2018)**
The Defendant was arraigned before the Federal High Court, Lagos Division in 2018 on a 3 count charge of sales and possession of fake and unregistered drugs to wit:- tramadol. 17 other fake and unregistered drugs products were recovered from the defendant. Upon arraignment, the defendant pleaded not guilty to the 3 counts. He later changed his "not guilty plea" to "guilty". NAFDAC Prosecutor tendered the 18 drugs recovered from the Defendant and other exhibits in the case. Judgment was delivered by the Court on the 25/9/2024 and the defendant was convicted and sentenced to an aggregate of 5 years imprisonment with an option of fine of an aggregate of One Million Naira (N1, 000, 000. 00) Only.

5. **FRN V BENARD CHINWEUBA & DURU VALENTINE NDUKWE(FHC/L/653C/2022)**
The Defendants were re-arraigned at the Federal High Court, Lagos Division on 28/11/2024 on a 2 count Amended charge for the importation of unregistered drugs and aiding the importation of unregistered drugs to wit: Diclofenac tablets, cold time tablets, sonjdrex tables collcap tablets. The defendants pleaded guilty to the 2-count charge. The court convicted and sentenced the two defendants with an option of fine of Five Hundred and Fifty Thousand Naira (N550, 000. 00).

6. **INCORPORATED TRUSTEES OF FREEDOM OF INFORMATION ADVOCATE INITIATIVES V A. G, FEDERATION (FHC/L/CS/60/2022**
The plaintiff filed this suit against the Agency before the Federal High Court, Lagos Division claiming various reliefs and costs of over N3,000,000 against the Agency and 7 others. The plaintiff alleged that it is wrongful and illegal for the Federal government to benefit from collection of taxes and levies from alcoholic drinks in the North while the same products were destroyed by the Northern State Government. Curiously, the plaintiff joined the Agency as party to the suit. The Agency filed a defence to the suit and a Notice of preliminary objection on ground that it is not a necessary party. Upon receipt of the Agency's defence and Preliminary objection, the plaintiff filed a Notice of Discontinuance before the court. On 17/10/2024, the name of the Agency was struck out from the suit with a cost of Eighty Thousand Naira (N80,000. 00) awarded against the Plaintiff in favour the Agency.

7. **FRN V OBINNA IGBO(FHC/L/257c/2022)**
The Defendant was charged on a 3 - count amended charge of possession, sale and distribution of fake drug – Amanta Forte and arraigned before the Federal High court, Lagos Division on 16/10/2024. The drugs were recovered from him. The defendant pleaded guilty to the 3 counts charge and the court convicted and sentenced him to a fine of Six Hundred Thousand Naira (N600,000. 00).

8. **FRN V PIUS EFFIONG EYOH & ANOR(FHC/L/333C/2024)**
The Defendant charged on a 3-count amended charge and re-arraigned at the Federal High Court, Lagos Division on 3/10/2024 of manufacturer and storing of unregistered cosmetics products to wit: - super white and 17 other cosmetics products recovered from the defendant.

The defendant pleaded guilty to the 3 counts amended charge and the court convicted and sentenced him to a fine of Three Hundred and Fifty Thousand (N350,000.00)

9. VALENTINE DURU CHINWEKE V. CHAIRMAN, NAFDAC & 2 ORS (FHC/L/CS/2295/2022)

The Applicant filed the suit against the Agency at the Federal High Court, Lagos Division for unlawful detention in violation of his Fundamental Right. The Agency filed a defence. However, the Applicant was not diligent in prosecuting the suit. On 24th June, 2024, the court struck out the suit for lack of diligent prosecution with a cost of N50,000 against the agency in favour of the Agency

10. MUKHTAR SA'ID AMIN VS PHARMACEUTICAL COUNCIL OF NIGERIA & 3 OTHERS. SUIT NO: K/M307/2024.

The Applicant brought this suit under the Fundamental Right Procedure at the High Court of Kano State to enforce his right to freedom of movement and to challenge the wrongful lockdown of his business premises (Mai Karimi Plaza). He claimed Fifty Million Naira (N50, 000, 000. 00) Only against the Agency. The Agency filed a defence denying any breach of the Applicant's right. The court dismissed the Applicant's suit and ruled in favour of the Agency on 13th June, 2024.

11. JOHN EHIJE V. NAFDAC – FHC/ABJ/CS/736/2021

The Applicant filed this suit against the Agency in 2021 at the Federal High Court, Abuja Division for the enforcement of his Fundamental Right under the Constitution and African Charter on human and Peoples' Right. The Applicant alleged that NAFDAC failure to properly regulate and control drug (Greentol Mentholyptus) has caused him health and financial injury. He claimed about Two hundred and Sixteen Million (216, 000, 000. 00) Only in damages. The agency filed a defence and a Preliminary objection on grounds that the matter cannot be maintained under Fundamental Rights Enforcement. The court agreed with the Agency and struck out the suit on 6th November, 2024

12. MUHAMMAD AYAZ & ANOTHER V. NAFDAC – K M582/2023

The Applicant brought this suit under the Fundamental Rights enforcement procedure at the Kano State High court, Audu Bako complex, Kano. The Applicant sought enforcement of his right to freedom of movement, liberty and human dignity and a restraining order restraining the Agency from arresting, intimidating, or investigating him. The Agency filed a defence in opposition.

13. ARI CONTINENTAL LTD & OTHER V. NAFDAC &1 OR. – ID/15094MFHR/23

The Applicant filed a Fundamental Rights action against the Agency at the High Court of Lagos State for the enforcement of his Fundamental Rights claiming the sum of Five Million, Six Hundred and Twenty-Five Thousand Naira (N15, 625, 000. 00) Only and the unsealing of his shop. The Agency filed a defence in opposition to the suit. The court delivered judgment in favour of the Agency on 16th January, 2024.

14. ERISCO FOODS LIMITED & 2 OTHERS V. NAFDAC – FHC/L/CS/ 967/2016

The plaintiffs brought this suit against the Agency at the Federal High Court, Lagos Division seeking order of mandamus to compel the Agency to implement its report on banned on imported tomato paste and to challenge the imposition of N1, 000, 000. 00 fine as penalty for breach of advert regulations. He also claimed damages in the sum of over Five Million Naira (over N5, 000, 000. 00). The Agency filed a defence to justify the fine and proffered argument against the grant of the order of mandamus. The Court held that the plaintiffs were not in violation of the advert regulation and declared the N1, 000, 000. 00 a nullity but decline to grant the prayer for mandamus. The court granted damages in favour of the plaintiffs in the sum of Two Hundred Thousand naira (N200, 000. 00) Only on 26th September, 2024.

15. AUCTION CLEARING NIGERIA LIMITED V. NAFDAC & 3OTHERS – FHC/KT/CS/38/2024

The Applicant filed this Fundamental Right suit at the Federal High Court, Katsina State Division for breach of his Fundamental Right to property – Peugeot J5 vehicle with Reg No. EDO, BENIN 51-ZU. The vehicle was impounded by NAFDAC officers on suspicion of distribution of unregistered sachet water. The Agency filed a defence relying on the NAFDAC Act and related legislation as justification and power to impound the vehicle in pursuit of our mandate. On 26th September, 2024, the court held that NAFDAC had no power to impound vehicle under the NAFDAC Act Cap N1, LFN 2004 and ordered the release of their vehicle and damages in the sum of Six Hundred Thousand Naira (N600, 000. 00) Only against the Agency in favour of the Applicant. The Legal Services Directorate is studying the need and implication of appealing the decision.

All other cases are still ongoing at the various Courts.

Note :Reports of court proceedings cannot be presented monthly as it is dependant on the Courts. Details of concluded cases will be submitted as at when due.

3. Regulations

A total of 19 new regulations were approved for gazette after tripartite meeting with FMHSW and FMOJ.

4. POCA

The Proceeds of Crime office has been created and comprises the Legal Services directorate, Investigation & Enforcement Directorate and the ICT Directorate. The office is domiciled in the Legal Services Directorate

Chapter 22
Planning Research and Statistics Directorate

The PR&S Directorate is a service Directorate charged with the responsibility of planning, researching, collecting, collating, storing and retrieving of data as well as coordinating the activities and achievements of other Directorates of the Agency. It functions as enumerated in enabling Act.

22.1 Training

The Training Unit of PRS Directorate is responsible for coordination of training programs for staff of the Agency. The Unit collects and collates staff training needs, coordinates their participation at training courses, conferences, seminars, statutory meetings etc documents the outcome as well as evaluates the impact of such programmes on staff.

During the year under review, the unit recorded a total of Sixty-Six (66) training programmes with One Thousand, Twon Hundred and Thirty-Six (1,236) staff participation**.**

The breakdown is shown on the table below:

Programme	**Foreign Training**		**Local Training**		**Total**	
Training	No of Programme	Staff Participation	No of Programme	Staff Participation	No of Programs	Staff Participation
Trainings	32	40	34	649	66	689
Virtual	14	547			14	547
Total	46	587	34	649	80	**1,236**

22.2 Industrial Attachment

The students' Industrial Work Experience Scheme (SIWES) was instituted by the National University Commission to ensure that what is taught theoretically to students in school is followed up with practical experience. The Agency has been engaging in the services of students on Industrial attachment, with courses relevant to the operation of NAFDAC to our various laboratories in Lagos, Agulu, Maiduguri and Kaduna. The successful IT students are exposed to the use of state-of-the-Art Laboratory equipment to enhance the practical experience.

During the year under review, a total of Two Thousand and Seventeen (2017) application letters were received out of which Nine Hundred and Sixty-Four (964) applications were processed, Three Hundred and Forty (340) Assumption letters were received from the various laboratories and Five Hundred and Ninety-Nine (599) certificates were issued at the end of 2024.

NOTE: Two Hundred and Fifty-Nine (259) certificate were brought forward from previous year (2023).

22.3 Excursion unit

During the year 2024, Five excursions were conducted in the Agency.

22.4 Monitoring and Evaluation (M&E)

A. Monthly Reports

The M&E Division received and collated a total of One Hundred and Twenty -Seven (127) monthly reports from the Twenty- One (21) Directorates of the Agency in the year 2024. However, only Thirty-Three (33) of these reports were received within specified timeline of 15th of the next month while Ninety-Four were outside the specific timeline. These reports were validated and used in developing the Directorate Performance Evaluation Report for the first, second and third quarters of 2024.

B. Annual Report

The Division reviewed the 2023 Annual reports received from all the (21) Directorates of the Agency. These reports were validated and forwarded to the R&S Division of PRS for detailed statistical analysis and finalization of the NAFDAC 2024 Annual report.

C. M&E Exercise

The Division participated in the development of the Agency's Strategic Plan for year (2024-2027) and also developed the M&E Data Collection Templates for the periodic monitoring and evaluation of the Agency's KPIs.

D. Internship

The M&E Division also coordinates the placement of Intern pharmacists in the Agency. Under the Pharmacists Council of Nigeria (PCN) Decree 91 of 1992, Pharmacy graduates are statutorily required to undergo a compulsory one-year continuous internship training programme in a registered Pharmacist Council approved internship centre.

NAFDAC as one of the approved centres for training Intern Pharmacists, coordinates this training for the agency through the M&E division of PRS.

In line with the agency's Internship policy, an aptitude test was conducted for Three Hundred and Fifty-Two (352) from the Six Hundred and Ninety-Nine (699) internship application received and processed.

After a transparent recruitment process that was conducted twice in 2024, Ninety-Five (95) Pharmacy Interns were selected and offered a one-year temporal appointment. However, only Eighty-One (81) Pharmacy Interns accepted the offer and resumed. Certificate of completion was issued to Fifty-Two (52) Interns engaged in the previous year who submitted the relevant documents.

22.5 Research and Statistics (R&S) Division

The Research and Statistics Division is charged with the responsibility of conducting scientific research on NAFDAC regulated products as well as other subjects of interest to the Agency and making recommendations based on the findings to management for evidence based regulatory decision making. The Division also provides Library Services to the staff of the Agency.
During the year under review, the Division did the following: -

A. Surveys

One (1) survey (survey on effectiveness of NAFDAC and your health program on radio) was designed in the first quarter of 2024 and the survey was conducted in the 2nd quarter of 2024.

B. Statistical Analysis.

- A total number of 63 FGMP report were Received and Filed in the year under review**.**
- Carried out 118 statistical analyses covering: - Monthly Analyzed of Presidential Enabling Business Environment Council (PEBEC) reports for the Office of Trade and International Relation (OTIR/OSIC),
- Analysis on quarterly complaints received and Customer feedback system for Reforms Unit.
- Collated Monthly/Quarterly Zonal performance reports.
- Rendered Statistical support to other Directorates.

C. Library Services.

NAFDAC Library is charged with the responsibility of providing and accurate information resources that would help staff in (Lagos, Abuja, and Kaduna) achieving the Agency's mandate. The library has been providing quality library services to staff of the Agency and researchers within the year 2024. The library carried out the following activities: -

- Rendered reference service to library users.
- Carried out user education.
- Provide current awareness service by constantly informing users of new information resources available in the library.
- Carried out Selective Dissemination of Information (SDI) so as to encourage the use of library resources.
- Collected, organized, and preserved newspapers and other periodicals of interest to the users.
- A total of 106 users visited the library in the year under review.

Chapter 23
Human Resource Management (HRM)Directorate

23.1 Introduction

The Directorate is one of the three Service Directorates and is involved in day-to-day administrative matters as well as all issues affecting the workforce of the Agency to ensure efficient and effective use of Human and material resources for improved productivity.

The Directorate has Four (4) Divisions namely:

1. Appointment Promotion & Discipline
2. Staff Welfare and Training
3. Corporate Services
4. Records & Registry

The day-to-day functions of the Directorate are:

- Handles staff recruitment/appointment, staff, promotion, transfer and posting in the Agency.
- Deals with complaints of staff misdemeanors/misconduct and recommend proper disciplinary actions to be taken by the Agency against erring staff.
- Documentation of new staff prepares staff nominal roll and issues of identify cards.
- Keeps records of all the Agency's rented and owned properties.
- Handles insurance matters as they relate to staff and NAFDAC assets.
- In charge of security services, environmental matters and other corporate issues.
- Coordinate matters relating to NAFDAC Council.
- Liaising with ministries, Government Departments and other Agencies (MDAs) in sourcing for and collecting all establishment circulars and relevant rules and regulations guiding the conduct of Government business.

23.2 Appointment, Promotion & Discipline Division

The division handles all matters relating to Recruitment, promotion of staff and discipline of erring staff.

The division carried out the 2023 recruitment exercise in September 2024, at the end of which 110 senior staff and 10 junior staff were engaged.

The 2024 promotion examination was conducted successfully. A Total of 265 senior staff and 7 Junior staff were promoted. Special promotion was also given to a senior member of staff who was outstanding during the year.

Also, 21 staff were upgraded and converted to different cadres.

23.3 Discipline

During the year under review, Disciplinary committee meetings were held, and different types of disciplinary measures were met up with staff. These include termination of appointments of officers who were on study leave and absconded eventually.

23.4 Records & Registry

The division keeps and updates records of all staff of the Agency.

Staff Position

- Staff strength -2106
- Females - 918
- Males - 1,188
- Senior Staff - 1,921
- Junior Staff - 185

Activities of the Directorate during the year under review are as follows:

23.5 Leave Matters

During the year, all staff of the Agency enjoyed various types of leave, such as Annual leave, sick leave or casual leave.

The Agency, however, encourages staff development and training, which enabled 6 staff to proceed on study leave to enhance their productivity on the job after the training.

23.6 Staff Welfare and Training

The Division is responsible for staff training and staff general welfare.

23.7 Welfare

During the year under review, a total of 70 staff benefitted from the staff welfare package of N100, 000 given to staff during wedding ceremonies or loss of close family members.

23.8 Training

Functions of the Training Unit of the division include:

- Identifying staff training needs of the various Directorates.
- Preparing annual training schedules for consideration.
- Processing and obtaining approvals for training.

There were various Local training courses coordinated by HRM Directorate in which 64 staff attended.

23.9 Corporate Services.

This Division carried out the following activities:

- Handled insurance matters as they relate to staff and NAFDAC assets.
- Coordinated matters relating to NAFDAC Governing Council.

- Liaising with Ministries, Government Departments and other Agencies (MDAs) in sourcing for and collecting all establishment circulars and relevant rules and regulations guiding the conduct of Government business. Such Government organizations include Federal Ministry of Health, Federal character commission, PENCOM, National University Commission, National Health Insurance Scheme, Federal Ministry of Finance among others.
- Cleaning and Sanitation issues were handled by the Division.
- Handles security of Offices in NAFDAC formations.

23.10 Insurance Matters

- Group life Assurance in place for all staff of the Agency.
- NAFDAC Properties and Vehicle are duly covered.

23.11 Council Matters

The NAFDAC Governing Council meetings were held quarterly during the year under review.

23.12 Transportation

Activities of the Division are:

- The Agency currently has 204 functional vehicles and 20 non-functional vehicles.
- New vehicles (6) Toyota Hilux

Chapter 24
Finance and Accounts (F&A) Directorate

The Finance and Accounts Directorate is one of the non-technical Directorate in the Agency. It has the responsibility of managing the financial resources of the Agency. It is guided in its day-to-day activities by Financial Regulations, Finance Act, Fiscal Responsibility Act 2007 and Circulars and Memos from regulatory bodies.

The year 2024 activities of the Directorate were encapsulated in the work plan drawn in January 2024 with the following:

I. The Audit of the 2023 Accounts of the Agency was completed by the firm Messrs. Issa Shuaibu & Co, Chartered Accountant, and the completion of Management Accounts for the year.

ii The Medium-Term Expenditure Framework for the years 2025-2027 was prepared and submitted to the Budget Office of the Federation. However, the summary of the financial information that was uploaded to BIMMS (Budget Information Management and Monitoring System) platform as follows:

	2025	**2026**	**2027**
Internally Generated Revenue	10,580,302,826.55	10,679,123,998.96	11,148,013,418.23
User Fees	35,110,039,606.39	36,865,541,586.71	38,708,818,666.04
Personnel Cost	8,186,997,508.20	596,347,383.61	9,026,164,752.79
Capital Allocation	333,091,695.30	349,746 280.07	521,338,719.67
Overhead	12,400,481,601.51	13,020,505,681.59	13,671,530,965.67
Capital	7,445,546,325.00	7,817,823,641.25	8,208,714,823.31

The total revenue collected for the year amounted to N27,083,332,661.25 The breakdown is as follows:

IGR N4,718,445,528.20

USER FEES N22,364,887,133.05

The Value Added Tax (VAT) collected and remitted to Federal Inland Revenue Service (FIRS) was N358,130,584.82, Withholding Tax N245,663,282.77 and Stamp duty N22,920,226.06

The amount of N2,700,983,947.62 being Regulatory Allowance was paid to the staff.

The 50 percent automatic deductions from the Agency's revenue account by the Federal Government has impacted negatively on our revenue available for the operational activities of the Agency.

The total number of staff promoted in 2024 were DD 32, AD 20, Chief 48, AC 110, Principal 28, Seniors 14, Level 8, 8. Which brought the number to 260 with salary arrears payment so far to N46,564,434.30. Also, National Youth Service Corp members were paid N52,519,086.85 and Intern Pharmacists were paid N131,869,911.59.

The budget allocation of N351,971,851.70 was disbursed to various Directorates during the year 2024.

In 2024 the budget performance shows the Key Performance Indicators highlighting the variances and areas for improvement.

S/N	Description N	2024 Budget	Performance	Percentage
1	Revenue	21,992,072,040.52	27,083,332,661.25	123.15
2	Overhead	12,844,645,165.29	12,332,678,389.15	96.01
3	Capital	11,757,188,876.48	2,532,520,548.84	21.54

Moreover, the budget for 2025 was prepared, presented, and defended before the Governing council of the Agency. It is awaiting the National Assembly approval.

S/N	Description	2025 Budget N	2024 Approved Budget N	Percentage
1	Revenue	45,732,944,042.18	21,992,072,040.52	208
2	Overhead	16,069,948,308.81	12,844,645,165.29	125
3	Capital	32,056,598,530.01	11,757,188,876.48	273

The Directorate conducted a budget retreat for Directors and State Coordinators to sensitize them about the workability of the budget in the agency.

The summary of capital and overhead expenditure for 2024 fiscal year amounted to N14,865,198,938.