National Agency for Food and Drug Administration and Control (NAFDAC)

NAFDAC

2023 Annual Report

National Agency for Food and Drug Administration and Control (NAFDAC)

2023 Annual Report

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

National Agency for Food and Drug Administration and Control (NAFDAC) was established by decree 15 of 1993 as amended by decree 19 of 1999 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, chemicals, detergents, medical devices and packaged water (collectively known as regulated products).

The mission of NAFDAC is to safeguard public health by ensuring that only the right quality food, drugs and other regulated products are manufactured, imported, exported, distributed, advertised, sold and used in Nigeria.

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

The Agency has (20) Directorates namely:

1. Drug Registration and Regulatory Affairs (DR&RA)
2. Food Registration and Regulatory Affairs (FR&RA)
3. Drug Evaluation and Research (DER)
4. Narcotics and Controlled Substances (NCS)
5. Chemical Evaluation and Research (CER)
6. Food Safety and Applied Nutrition (FSAN)
7. Veterinary Medicines and Allied Products (VMAP)
8. Ports Inspection Directorate (PID)
9. Laboratory Services (LS Food and Chemicals)
10. Laboratory Services (Drug)
11. Laboratory Services (Vaccines, Biologics and Medical Devices)
12. Agulu Laboratory Services (ALS)
13. Kaduna Laboratory Services (KLS)
14. Investigation and Enforcement (I&E)
15. Pharmacovigilance (PV)
16. Post Marketing Surveillance (PMS)
17. Planning, Research and Statistics PRS
18. Finance and Accounts (F&A)
19. Human Resources Management (HRM)
20. Legal Services Directorate (LeSD)
21. 6 Zonal Offices, Lagos State and FCT offices headed by Directors

In the office of the Director-General are the Public Affairs Unit, Information Communication Technology Unit, Procurement Unit, Reforms Unit, Health Safety and Environmental Unit, Office of Research, Regulatory Innovations Unit, the Audit Unit, Quality Management System Office, WHO-GBT Unit, and the Office of Trade and International Relations.

The Agency has offices in the Thirty-Six States of the Federation and the FCT. The Laboratories of the Agency are strategically located in Oshodi-Lagos, Yaba-Lagos, Kaduna, Maiduguri-Borno State, Calabar -Cross Rivers State and Agulu-Anambra State.

NAFDAC has Port Inspection Offices in Lagos, Port Harcourt, Warri, Calabar, Abuja, Kano and land border outstations in Seme, Idiroko, Mfum, Kamba, Ilella and Jibiya.

The essence of regulation and control is to ensure that only quality, safe, wholesome and efficacious regulated products reach the market and ultimately the consuming public. This is achieved through various processes of the Agency including product registration, inspection of production facilities, laboratory evaluation, post marketing surveillance and enforcement activities.

The Agency recorded and sustained the successes attained in the past years to align itself with global best practices and stay amongst the world's top regulatory agencies. Some of the achievements recorded include:

1. **Global Benchmarking Tool (GBT)**

The WHO Benchmarking Programme which commenced in Nigeria in January 2018 has helped the Agency to imbibe a culture of self - audit as part of WHO-Global Benchmarking requirements and in line with International Best Practices.

WHO officially announced Nigeria's National Regulatory Agencies (NAFDAC and PCN) as a Stable, well-functioning and integrated regulatory system maturity level 3 rating scale of the Global Benchmarking Tool (GBT) with effect from 22nd March 2022.

The ML3 rating means NAFDAC has been found to function well,'is stable and eligible for inclusion into WHO Listed Authorities (WLA) after additional evaluation of their performance.

We are currently working assiduously towards the attainment of ML4 status.

2. **Quality Management System (QMS)**

The Agency has now fully embraced QMS principles with developed quality objectives and all processes are procedure-driven. The Agency received ISO 9001:2015 Certification in June 2019.

The Agency was successfully audited for ISO 9001:2015 re-certification in November 2023.

3. **Implementation of a Nationwide Track and Trace System using GS1 Standards.**

This was used to monitor COVID-19 vaccines and a defective batch was recalled within 24 hours (improved regulatory control).

The traceability system is being scaled up to other Product groups including Narcotic drugs, Aids, TB and Antimalarial drugs to support and improve Pharmacovigilance and Post Marketing Surveillance. 39 Health Facilities were enrolled in the Tracking and Tracing (Traceability) of Schedule 1 Finished Narcotic Medicines.

4. Curbing Substandard, Falsified (SF) and Counterfeit Medicines.

NAFDAC has been highly proactive and vigilant toward curbing SF in the country in all efforts to safeguard the health of the Nigerian populace. In a determined effort to combat falsified medicines, NAFDAC has deployed multifaceted strategies that destroyed Substandard and Falsified Medical Products, Unwholesome Processed Food Products, Unsafe Cosmetics, and other Expired and Counterfeit NAFDAC Regulated-Products worth **₦21,144,136.330.80** in 2023.

5. Information Communication Technology (ICT) Unit:

The following has been achieved through our ICT Unit:

- Procured and distributed 270 systems (89 laptops and 181 desktops with UPS) to Directorates, Zonal Offices, Laboratories, QMS, Dossier Review Team, Senior Officers, and IT Staff.
- Conducted preventive maintenance on 78% of the IT infrastructure.
- Hosted over 362 virtual meetings and trainings using Zoom and Microsoft Teams,
- Provided collaborative platform for WHO GBT Assessment
- 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.
- Analyzed website usage feedback, with 69% finding content useful.

Maintained and supported SAP ByD accounting solution for Finance & Account Directorate

6. Staff Development and Training

Management has continued to prioritize staff development in its bid to imbibe best practices. Various staff participated in Hundred and Twenty-Three (123) training programmes (both local and international) in the year under review.

Staff are equally being encouraged to undertake academic programmes to improve their expertise on the job provided it does not interfere with their official assignments.

7. Registration

The Agency has digitalized registration processes. Our clients can now register online. Digitalization of processes has been further enhanced with NAPAMS Version 2 being operationalized and more user-friendly.

Digitization has made the process more transparent and seamless with the reduction of registration time to 90 working days for food, simple cosmetics and water; while 120 working days for drugs and some cosmetics.

In 2023, NAFDAC registered a total of Six Thousand, Six Hundred and Fifteen (6,615) drug and drug-related products, Three Thousand Six Hundred and Twelve were imported (3,612) and Three Thousand and Three (3,003) were manufactured in Nigeria.

8. Good Manufacturing Practice (GMP)

Drug Evaluation and Research (DER) Directorate issued GMP Certificates to twenty-two (22) pharmaceutical companies whose operations were adjudged to comply with minimum GMP requirements in 2023.

DER conducted GMP Re-Assessment Inspections in thirteen (13) facilities in 2023 out of which twelve (12) facilities were found to be operating in compliance with requirements.

9. Compliance with Food Safety requirements

Food facility inspection activities were conducted nationwide by the Food Safety and Applied Nutrition (FSAN) Directorate covering the spectrum of inspection types (special, production, GMP-reassessment, routine, follow-up, warehouse, surveillance, Cold Chain Facilities monitoring).

From January to December 2023, a total of 22,694 inspections of establishments were conducted by FSAN Directorate.

10. Laboratory Services:

Laboratory Services migrated most of the analytical processes to the Laboratory Information System (LIMS). Migration of other parameters is under review.

The Central Laboratory Oshodi had an online surveillance audit for ISO17025:2017 Laboratory Accreditation by ANAB (ANSI National Accreditation Board) on the 18th October 2023.

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

The Laboratories processed Forty Thousand Eight Hundred and One **(**40,801**)** samples of which Thirty-Nine Thousand Two Hundred and Sixty-Six (39,266) samples were analysed and One Thousand Five Hundred and Thirty-Five (1,535) samples are pending. This represents 96.23 % overall performance.

11. Pharmacovigilance

The National Pharmacovigilance Centre (NPC) received Adverse Drug Reactions (ADR) reports from various stakeholders including patients, healthcare professionals, health institutions and Marketing Authorization Holders (MAHs) across the country. Two Thousand, Six Hundred and Nineteen (2,619) reports were received through MedSafety App, Four Hundred and Forty-Seven (447) reports through e-reporting, One Hundred and Ninety-Six (196) reports through Council for International Organization of Medical Sciences (CIOMS) forms, Ninety-Five (95) through NPC ADR Forms.

As of 31st December 2023, a total of Fifty-Two Thousand Six Hundred and Forty-Five (52,645) ICSRs/AEFIs were documented on the Vigiflow.

The reviewed and analyzed ADRs were uploaded on the Vigiflow, a web based Individual Case Safety Report (ICSR) management system that is specially designed for National Centres in the WHO programme for international drug monitoring.

Similarly, our Rapid Alert system for Food and Feeds (RASFF) information desk that reports on cross-border flow of food safety information on Nigerian export to EU recorded a total of 81 RASFF Alerts within the period.

87 public alerts were published on the NAFDAC Website and carried out 32 recalls on NAFDAC-regulated products.

12. Post-Marketing Surveillance

The Agency has developed and gazetted the necessary regulations for Good Distribution Practices. A baseline inspection started in May 2021 all over the country. Private, public and NGO wholesale and distribution facilities are being inspected. Eight Hundred and Five (805) facilities have been inspected. Currently, CAPA effectiveness verification inspection and categorization into high risk, medium risk and low risk is ongoing. Inspection of importers warehouses is also ongoing. Within the period under review, 635 Good Distribution Practice Inspections were carried out, 1148 Establishments visited for Mop-up, 23,459 of proactive (Routine) post-marketing surveillance carried out, and 102 GLSI Monitored

13. Ports Inspection

Automation of port clearance processes through the deployment of the Ports Inspection Data Capture and Risk Management System (PIDCARMS) a web-based, business process application in all the ports and land borders for e-clearance of regulated imports and exports has continued to effectively block leakages of revenue of the Agency and falsification of the Agency's security documents.

A total of Sixty-Three Thousand, Two Hundred and Sixteen (63,216) SGD forms comprising **1,270,598,904.93** metric tons of imported regulated products were processed with a CIF value of **₦28,708,695,424,062.30.**

A total of Two Thousand, Six Hundred and Seventy-Six (2,676) violations were recorded in the year under review.

14. Performance of NAFDAC Zonal Offices

The regulatory activities carried out in the Zones from January to December 2023 included inspections in establishments where regulated products such as foods, packaged water, drugs, cosmetics, chemicals and medical devices were manufactured, distributed, packaged and stored or sold. Inspections were carried out to ensure that Good Manufacturing Practice (GMP) was maintained where applicable and that whatever regulated product(s) in circulation for consumption or use by the public were wholesome.

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. The foundations have been laid for a more respected and accepted Regulatory Agency among the committee of Regulatory Agencies. Staff are being trained and retrained; More efficient equipment have been deployed to use by the Agency and increased prudence in the management of the limited financial resources.

From the building of State Offices in different states across the zones, vehicles for logistics, equipment and input materials in the laboratory, to devices for inspection and traceability, NAFDAC requires a continuous huge investment of financial resources in the aforementioned areas in order to safeguard the people from spurious, fake, unsafe, and counterfeited regulated products.

Counting on what the Agency has achieved so far and where we intend to be as a regulatory Agency, we are committed to taking NAFDAC to the next level where vaccines can be manufactured in the country. NAFDAC is now more customer-focused and Agency-minded in its quest to safeguard the health of the nation.

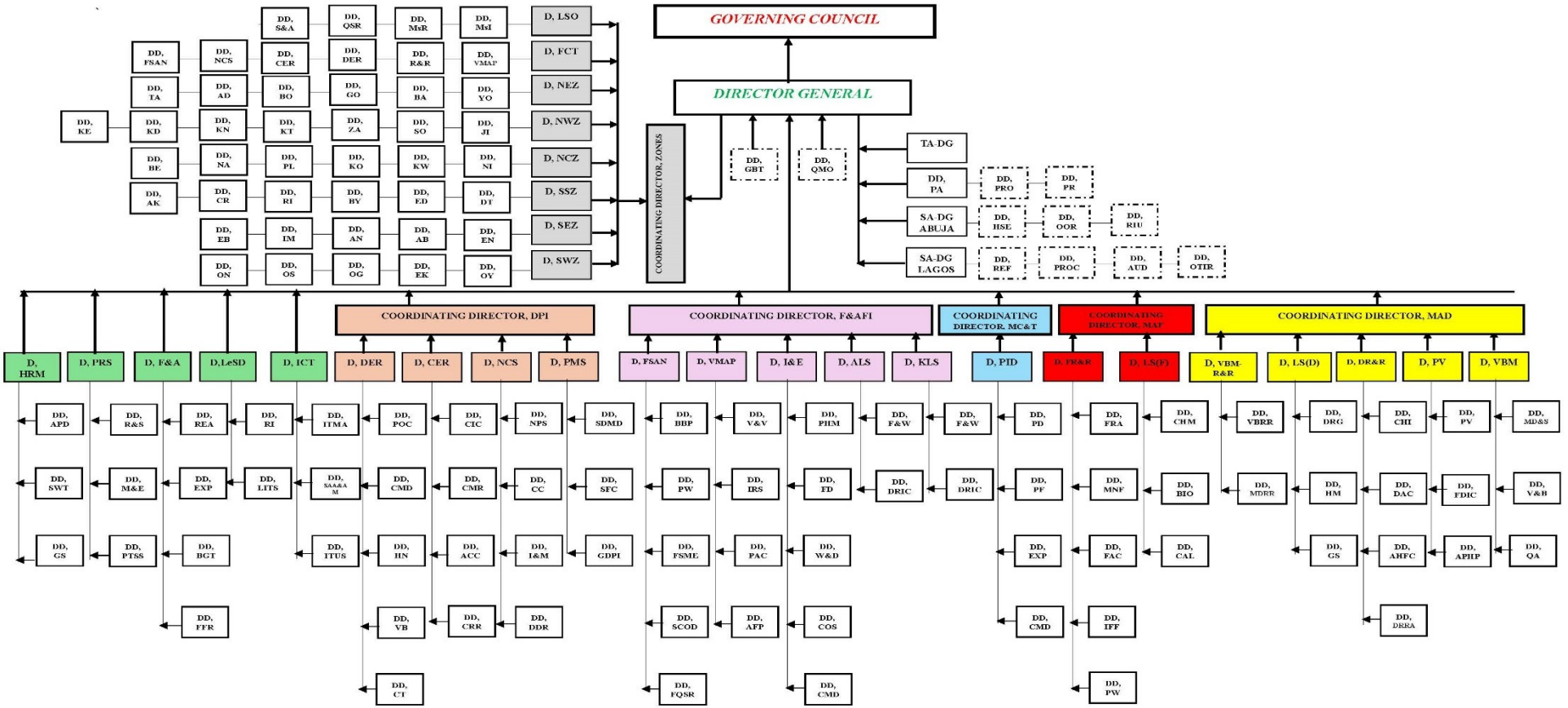
The Agency will continue to foster greater collaboration with government agencies, including the Nigeria Police Force (NPF), Nigeria Customs Service (NCS), Nigerian Institute of Pharmaceutical Research and Development (NIPRD), Nigerian Security and Civil Defense Corps (NSCDC), National Drug Law Enforcement Agency (NDLEA), Standards Organization of Nigeria (SON),Federal Competition and Consumer Protection Commission (FCCPC), Nigerian Immigration Service, Pharmacists Council of Nigeria (PCN), Pharmaceutical Manufacturing Group of Manufacturers Association of Nigeria (PMG-MAN) and Department of State Services.

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

NAFDAC Organogram

ANNEXURE 3	NAFDAC-QMS-023-01	NAFDAC ORGANOGRAM

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



October 19, 2024

DIRECTOR-GENERAL'S SIGNATURE & DATE

Table of Contents

Chapter One
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 promptly and decisively attend to these challenges.

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 Legal Services - Barr. Kingsley Ejiofor
- Director Laboratory Services (Food) – Dr. Charles Nwachukwu
- Director Laboratory Services (Drugs) – Mr. Victor Abiola
- Director, Food Registration and Regulatory Affairs - Mrs. Abayomi Bolaji
- Director Veterinary Medicine and Allied Product – Pharm. Rametu O. Momodu
- Director, Narcotics and Controlled Substances – Pharm. Yedunni Adenuga
- Director Human Resource Management – Mr. Joseph.A. Aina
- Director, Finance and Accounts – Mr. Ayangbenga O. Ayanwande
- Director, Ports Inspection Directorate – Dr. Abimbola Adegboye
- Director South West Zone –Mrs. Roseline Ajayi
- Director Food Safety and Applied Nutrition – Mrs. Eva Edwards
- Director Vaccines, Biologics and Medical Devices Directorate Mrs. O.O. Adekunle-Segun
- Director Federal Capital Territory – Mr. Abdulsalam Ozigis
- Director, Investigation and Enforcement – Pharm Francis Ononiwu
- Director North Central Zone – Pharm. Shaba Muhammad
- Director, Chemical Evaluation and Research – Dr. Patrick Omakpariola
- Director, Drug Registration and Regulatory Affairs – Pharm. Uche Sonny-Afoekelu
- Director North West Zone – Mrs. Josephine A. Dayilim
- Director, North East Zone – Mr. Kenneth Azikiwe
- Director, Lagos State Office – Mr. Kayode Fagboyo
- Director, Kaduna Laboratory Services, Pharm Babatunde Yusuf
- 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. Chukwuma Oligbu
- Director, Planning, Research and Statistics – Pharm. Chike Obiano

- Director, Drug Evaluation and Research – Pharm. Kayode Amuda
- Director, Pharmacovigilance – Pharm. Uche U. Elemuwa
- Service Units in the Office of Director General:
    - Special Assistant to DG NAFDAC (Abuja) – Mr. Nantim M. Dadi
    - 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 - Federal Secretariat, Zaria Road, 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, Port Harcourt, and Agulu - Anambra State. The Work in the Calabar Laboratory has reached an advanced stage.
- **Ports and Land Border offices**, located at Lagos (Tincan, Lilypond and Apapa), Port Harcourt, Warri, Calabar Seaports, Airports (Murtala Mohammed Lagos, Nnamdi Azikiwe Abuja, Aminu Kano International Airport Kano ,Akanu Ibiam International Airport Enugu) and Land border posts (Seme, Idiroko, Mfum, Jibiya, Kamba, Illela and Maigatari)
- One Stop Investment Center (OSIC) - NIPC Building Maitama, Abuja.

Chapter Two
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. In February 2018 the first self-benchmarking evaluation using the WHO-GBT was conducted. The outcome of the findings placed the Agency on maturity level One (ML1), symbolizing a weak regulatory system with no formal approach embedded on weak Regulatory processes, legal provisions, weak Organizational Structure, lack of accountability, transparency and communication.

On the 30th of March 2022, WHO officially ranked Nigeria's National Regulatory Agencies as Maturity level 3 upon the critical evaluation of the Eight Hundred and Sixty-Eight (868) evidences for system strengthening. This places it on a pedestal towards achieving ML4 and World Listed Authority (WLA) Status.

NAFDAC is putting in tremendous efforts to fulfill the requirements of the WHO Global Benchmarking of National Regulatory Authorities (NRAs) to reach Maturity Level 4 (ML4) for all regulatory functions including Vaccine Lot release function by 2024. This will enable our pharmaceutical industry to register their products faster in other countries, thus fast-tracking trade within Africa through African Continental Free Trade Area (AfCFTA) and across the globethus increasing our GDP and reducing unemployment.

Activities of NAFDAC WHO-Global Benchmarking Tool in 2023

The GBT activities in 2023 began positively with a thorough review of the previous year's activities and encouraging progress for 2023.

Work plan for 2023 was meticulously crafted, with extensive discussions held on execution strategies.
Additionally, all weekly meetings, including both physical and virtual gatherings for monthly and quarterly assessments, were diligently conducted as per the predetermined schedule.

- The GBT team had a meeting with PCN in Abuja to intimate and follow up on the activities of the Licensing function (LI) in preparation for the next assessment for ML4 and subsequently WLA.
- The GBT team reviewed the CAPA template given by WHO on the 37 recommendations for ML3 and ML4.
- The critical ML3 recommendations for Regulatory Inspection (RI), Registration and Marketing Authorization (MA), and Laboratory Testing (LT) were to be discussed and closed.
- RI to review Risk-based Inspection plan on foreign GMP.
- The GBT review of the critical sub-indicators for MA, LT, and RI.
- The continuous upload of evidence unto the SharePoint.
- The WHO lead informed the meeting that a review of the document will be carried out, and feedback will be sent to the NRA.
- The DG informed the meeting that next meeting will be virtual or physical, based on the feedback from WHO after the document review.

- Updates on the CAPA templates and upload of evidence to SharePoint were duly carried out by all function managers.
- Internal Benchmarking was scheduled to begin from 22nd – 30th August 2023.The following functions were benchmarked in Lagos, Registration and Marketing Authorization (MA), Regulatory Inspection (RI), Clinical Trial Oversight (CT), Laboratory Testing (LT), Lot Release (LR), and Vigilance function (VL).
- Reports of the internal benchmarking were generated to be sent to the DG.
- Market Surveillance and Control (MC) and Regulatory System (RS) in Abuja.
- Reports of the internal benchmarking were generated and forwarded to the DG, as well as all relevant directorates.
- Preparation for the National Regulatory Authority (NRA) follow-up and WHO Observed Audit in October is in top gear as all the critical sub-indicators are being finalized by the relevant functions and all narrative and evidence uploaded to the SharePoint.
- Focal persons engaged in the Upload of key quality document to WHO SharePoint in lieu of the follow-up assessment.
- Coordinated the National Regulatory Authority (NRA) IDP Follow-Up and WHO Observed Audit Scheduled From 23rd – 27th October 2023
- GBT Review Meetings for 5th December 2023
- The GBT weekly meeting for the period under review was held in-person at DG's Conference room while other team members connected virtually.
- Below are the highlights of the meeting:
    - All function managers were requested to bring up all ML 4 sub-indicators requiring DG's intervention, this will be in preparation for the benchmarking for ML4 next year 2024.
    - Sub-indicators requiring automation should be flagged for ICT's attention.

2.2 International Organization for Standardization (ISO) 9001:2015: Certification/0 Quality Management System (QMS) Activities

Having entrenched Quality Management System (QMS) in its operations, Agency received ISO 9001:2015 certification in June 2019.

2.3 Information and Communication Technology (ICT)

The Information Communication Technology (ICT) Unit operates under the Director General's Office, with a decentralized organizational structure and staff across various NAFDAC facilities. The Division is headed by the Deputy Director (ICT) at the NAFDAC Headquarters and comprises three management levels/subunits.

ICT Unit Achievements in 2023

1. IT Infrastructure

- Procured and distributed 170 systems (89 laptops and 181 desktops with UPS) to Directorates, Zonal Offices, Laboratories, QMS, Dossier Review Team, Senior Officers, and IT Staff.
- Conducted preventive maintenance on 78% of the IT infrastructure.
- Repaired135 faulty systems (90% of reported issues).

- Successfully performed routine quarterly network infrastructure maintenance. For major offices systems.
- Renewed 1,000 antivirus licenses via the Enterprise server and standalone
- Provided internet services (LAN and Wireless) at NAFDAC office locations.
- Hosted over 362 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.
- Analyzed website usage feedback, with 69% finding content useful.
- Ensured website security through routine updates, backups, and vulnerability analysis.
- Uploaded 234 new contents and reviewed/update 56 existing ones.

3. Supported IT Systems and Applications

- Maintained and supported SAP ByD accounting solution for Finance & Account Directorate.
- Provided e-permit system support and
- Provided NAPAMS support services.
- Clinical Trials Application support services
- 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. Project Management

- Initiated/completed projects:
  - 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 R&R, FR, DER and FSAN Directorates

Upgraded Laboratory Information Management System for Oshodi and Yaba laboratories

Chapter 3
Director General's office

3.0 Offices in Director – General's office

3.1 Public Affairs

Public Affairs is one of the offices created by Director-General, Prof. Mojisola Christianah Adeyeye following the restructuring of the Agency under her leadership. It was carved out of former Special Duties Office which later became Special Services, and now Public Affairs.
It is domiciled in the Office of the Director General and headed by a Deputy-Director in-charge with the primary responsibility of projecting the corporate image of NAFDAC, promoting its activities and programs, arrange International Trips and Foreign GMP Inspection for foreign companies and serve as an interface with the public. The office has two main units, namely Public Relations and Protocol.

3.1.1 Activities of Public Relations Unit Within Year Under Review

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

A. Media Coverage of Meetings, Press Conferences & Trainings

- Coverage and publicity of Second Tenure Press Conference and unveiling of workplan/Second Tenure Agenda by the NAFDAC, Prof. Adeyeye – 4th January, 2023.
- Coverage and publicity of Press Conference on the Joint International Destruction of Tramadol in Benin Republic -NAFDAC DG – 23rd January, 2023.
- Coverage and publicity of Interpol Courtesy Visit to NAFDAC Headquarters, Abuja – 6th February, 2023.
- Coverage and publicity of the DG's engagement with pharmaceutical industry stakeholders and solution providers on registration and Dossier, review, Vaccine manufacturing, good, manufacturing practiceand other issues affecting the pharmaceutical industry at Ikeja, Lagos on 6th February, 2023.
- Coverage and publicity of the signing of memorandum of understanding (MOU) with the University of Medical Sciences (UNIMED) Ondo state in Isolo Lagos on 7th February, 2023.
- Coverage and publicity of the launch of the international Narcotics control board (INCB) Annual and precursors reports for 2022 at Isolo, Lagos on 9th February, 2023.
- Coverage and publicity of Commissioning of Coordinated Wholesale Drug Centre (CWC), Kano – 10th February, 2023.

- Coverage and publicity of NAFDAC Media Sensitization workshop on "Dangers of Bleaching Cream" organized for North-West Zone in Kano – 10th February, 2023.
- Coverage and publicity of the Indian-Nigerian pharmaceutical/health industry forum at Lagos on 2nd March, 2023.
- Coverage and publicity of NAFDAC, FRSC one day stakeholders meeting at NAFDAC lab complex Oshodi, Lagos on 5th March, 2023.
- Coverage and publicity of Award Presentation to the Director-General (NAFDAC), Prof. Moji Adeyeye by Indian High Commission on 7th March, 2023.
- Coverage and publicity of NAFDAC in collaboration with the United Nations Office on Drugs and Crime Control Board (UNODC) launching of the 2022 international Narcotics control board Report at NAFDAC Office Complex, Isolo Lagos on 9th March, 2023.
- Coverage and publicity of NAFDAC's 2022 staff award and retirement ceremony at 10 Degree Event Center, Ikeja, Lagos on 15th March, 2023.
- Coverage and publicity of Organization for the prohibition of chemical weapon (OPCW) and the finnish institute for verification of the chemical weapon convention (VERIFIN) working visit to the NAFDAC chemical lab Oshodi, Lagos on 16th March, 2023.
- Coverage and publicity of the commission of branded BRT buses to create awareness and discourage underage drinking of alcohol by Distilleries Association of Nigeria in partnership with the Federal Ministry of Health and NAFDAC at Mile 2 BRT Bus Terminal, Lagos on 28th March, 2023.
- Coverage and publicity of press conference on the provisional approval for R-21 malaria vaccine by the Director-General of (NAFDAC), Prof. Moji Adeyeye on 17th April 2023.
- Coverage and publicity of 2023 World Safety and Health Day at Isolo conference room on 25th April, 2023.
- Coverage and publicity of the commissioning of NAFDAC office complex at NAHCO, Murtala Muhammed international airport (MMA) Ikeja Lagos on 8th May, 2023.
- Coverage and publicity of Joint Press Briefing between NAFDAC and Swiss Pharma Nigeria limited on the WHO pre-qualification of Pediatric Zincc sulphate tablet manufactured by Swiss Pharma Nigerian Limited at Sheraton Hotel, Ikeja, Lagos on 9th May, 2023.
- Coverage and publicity of enforcement exercise in Nasarawa (Raids of Delas – Pharmacy limited, was sealed because of expired, unregistered and prohibited (Banned) drugs and injections on 10th May, 2023
- Coverage and publicity of the commissioning of GSL experience center in Ikeja Lagos on 13th May, 2023.
- Coverage and publicity of courtesy visit/ meeting with National Coordinator, National Counter Terrorism Center on 1st June 2023.

- Coverage and publicity of NAFDAC, FSAN DVFA workshop held in Isolo Lagos office on 12th June, 2023.
- Coverage and publicity of the press conference on arrest and seal off of Baban Aisha Herbal factory for producing and selling unregistered and hazardous herbal products by the Director-General of NAFDAC prof. Mojisola Adeyeye on 19th June, 2023
- Coverage and publicity of NAFDAC media sensitization workshop on the Danger of Drug Hawking and Ripening Fruits with Calcium Carbide at NAFDAC Office Complex Isolo, Lagos on the 19th June, 2023.
- Coverage and publicity of Press Briefing on Food Fraud and Counterfeit Medicine and the Status of Nigerian Noodles at NAFDAC Office Complex Isolo, Lagos on 22nd June, 2023.
- Coverage and publicity of DG NAFDAC and other Top Management Team inspection visit to SAGAR Pharmaceuticals Nig limited at Ogun state on 8th August, 2023.
- Coverage and publicity of DG NAFDAC and other top management team inspection visit to Emzor Pharmaceuticals Industries group at Ogun state on 8th August, 2023.
- Coverage and publicity of DG NAFDAC and other top management team inspection visit to AFRI medical company at Ogun state on 8th August, 2023.
- Coverage and publicity of NAFDAC (FSAN) stakeholders' workshop for Hoteliers and Quick Service Restaurant Operators at Oshodi NAFDAC Laboratory complex Lagos on 11th August, 2023.
- Coverage and publicity of National institute for security studies in collaboration with the Directorate of Medical Services (DMS) Department of state services (DSS) on 29th August 2023
- Coverage and publicity of training on Performance Management System at Digital Bridge Oshodi on the 6th September, 2023.
- Coverage and publicity of the Inauguration of NAFDAC Freedom of Information Committee Desk on 6th of September, 2023.
- Stakeholders Meeting organized by Chemical Evaluation Research Directorate at NAFDAC Office complex Isoko Lagos on the 26th of September 2023.
- NAFDAC workshop on Local Manufacturing of APIs and Excipients at Marriot hotel Ikeja Lagos on the 3rd and 5th of October 2023.
- Coverage and publicity of joint press conference on production of branded NHIA Drugs on 12th October, 2023.
- Coverage and publicity of joint press conference with National Primary Healthcare Development Agency on 17th October, 2023.
- Coverage and publicity of destruction exercise in Kuje dumpsite on 18th October, 2023.
- DG NAFDAC Prof Christiana Adeyeye factory tour at ColexaBiosensor Limited at Ilupeju Lagos on the 25th of October 2023.

- DG NAFDAC Prof. Christiana Adeyeye delivered a keynote address at the 23rd edition of NECCI PR Roundtable, themed "fighting the scourge of illicit Trade in the pharma Industry '' at victoria Island Lagos.
- Coverage and publicity of courtesy visit of the Chairman PSN and PCN Enugu state to seek synergy and cooperation with NAFDAC SEZ by the Director SEZ with his management team on 26th October, 2023.
- Coverage and publicity of courtesy visit of Comptroller of Nigerian Immigration Service Enugu Commandant to seek synergy and cooperation with NAFDAC SEZ by the Director SEZ with his management team on 27th October, 2023.
- Coverage and publicity of press conference on Global fund by the Director-General (NAFDAC) Prof. Mojisola Adeyeye on 7th November, 2023.
- Coverage and publicity of courtesy visit of the commissioner of Police Enugu state to seek synergy and cooperation with NAFDAC SEZ by the Director SEZ with his management team on 7th November, 2023.
- Coverage and publicity of courtesy visit of the commander NDLEA, Enugu state command to seek synergy and cooperation with NAFDAC SEZ by the Director SEZ with his management team on 9th November, 2023.
- Coverage of Narcotics and controlled substance (NCS) Directorate and GSI Stakeholders meeting at NAFDAC office complex isolo Lagos on the 9th of November.
- Coverage of veterinary medicine and Allied products Directorate training for the staff and stakeholders to commemorate the 2023 World Anti-Microbial Resistance Awareness at NAFDAC Office complex isolo Lagos on the 20th of November 2023.
- Coverage and publicity of the Director SEZ organized a stakeholder's engagement forum for stakeholders: water, bread, beverages, cosmetics and patent medicine store dealers on the 23rd November, 2023 and for chemical, medical devices, pharmaceuticals and importers (all categories) stakeholders on the 24th November, 2023.
- Coverage of the Directors of NAFDAC Anti-corruption and leadership training in the 21st century at isolo Lagos on the 4th of December 2023.
- Coverage of Anti- corruption and leadership at the 21st century for the top management of NAFDAC at Isolo office complex on the 4th-6th of December 2023.
- Coverage of the National fortification Alliance (NFA) Meeting at Ikeja, Lagos on the 6th of December 2023.
- Coverage of courtesy call of the CEO Nigerian Export Promotion Council (NEPC) to the DG NAFDAC Prof. Christiana Adeyeye to NAFDAC at Isolo/Oshodi Lagos on the 7th of December 2023.
- Coverage and publicity of the raiding and temporary shutdown of the cemetery/Eziukwu Market Aba, Abia for proper sanitization following the huge discovery of fake products manufacturing centers. The operation was led by the

Director SEZ in collaboration with other sister security agencies on the 11th – 13th December, 2023.

- Coverage and publicity of DG NAFDAC's Media Parley and briefing on the closure of Eziukwu Market in Abia state for production of counterfeit wines and soft drinks at NAFDAC office, Lagos on the 18th of December 2023.
- Coverage and publicity of Coordinating Minister of Health and Social Welfare, Prof. Mohammed Ali Pate's visit to NAFDAC at Yaba- Lab Lagos on the 19th of December 2023.

B. 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 and in 36 states FM stations at different time schedules (52 episodes annually) respectively.
- Interviews, Special Features and Guest appearances on Radio and TV.
- Syndicated articles in major national dailies.

C. 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 updates.

3.1.2 Protocol Unit (48 Foreign GMP Inspection in 2023)

A total number of One Hundred and Ninety-Five (195) International trips comprising Forty-Eight (48) GMPs and One Hundred and Forty-Seven (147) Trainings, workshops and Meetings and conferences.

Table 3.1

SN	**Public Affairs Activities in 2023**

1	NAFDAC Information Disseminated Through Social Media	107
2	NAFDAC & Your Health Tv Programme (NTA, International Channel 151 DSTV)	52
3	NAFDAC & Your Health Tv Programme (TVC - Channel 418 ON DSTV)	52
4	NAFDAC & YOUR Health Radio Programme (Radio Nigeria and 36 FM Stations Across the Country) in Standard English, Pidgin English, Hausa, Igbo And Yoruba Languages (52 Episodes Respectively).	52
5	NAFDAC Information Disseminated Through Conventional Media (Television, Radio, Print).	107
6	Number of Sensitization Workshops Conducted	22
7	Number of Foreign GMP Inspections Conducted	48
8	Number of Foreign Trainings, Meetings, Conferences and Workshops Attended	147

3.2 Office of Trade and International Relations (OTIR)

NAFDAC Desk at OSIC

Table 3.2.1: Summary of Activities from January - December 2023.

No. of Visitors at the Desk	Trade Fairs/ Expo	Meetings	Workshops/ conference	Training	Business & Investment Forum	Others	Total
2	5	54	18	6	7	12	106

A. Investors/Visitors to NAFDAC Desk at OSIC

The following investors visited the Desk and were attended to by issuing the relevant guidelines and asked to visit NAFDAC website or nearest NAFDAC Office for more information: -

- Mr. Chinedu Nwokedi/ E-Force Agro Development Ltd, 873 Lodigiani, Life Camp Abuja/ enquiry on the importation and registration of corn beef
- Mr. Toritse Ikomi/ Sebore Farm, Mayo Belwa, Adamawa State/ enquiry on process and guideline on bringing in Opundia Ficus Indica (Cactus) for sustainable livestock farming.

B. Meeting/Workshop/Training:

The NAFDAC OSIC desk participated in numerous meetings, Workshops and training programmes in 2023 some of which are highlighted below.

- SMEDAN MSMEs Stakeholders meeting held in Grand Mirage Hotel, Opposite SMEDAN Office, Area 11, Garki, Abuja on 23/01/2023.
- Inter-ministerial meetings preparatory to convocation of the Nigeria-Japan business forum to be held in Tokyo, Japan, 23 - 27/ 01/2023.
- COLEAD Rapid SPS assessment tool (R-SAT) workshop on leafy vegetables, 24-27/ 01/2023.
- NACCIMA Digital Economy Conference in collaboration with JICA on 31/01/2023.
- Participation at the trade policy and market access technical working group on Nigeria-UK enhanced trade and investment partnership (ETIP) on 8/03/2023
- Attended a meeting of Nigeria – South Africa Trade Finance working group held at Federal Ministry Industry, Trade and Investment on 20/3/2023.
- Participation at the WTO National Workshop on the agreement on the application of sanitary and Phytosanitary (SPS) measures and the Technical Barriers to Trade (TBT) Agreement, 25-27/ 04/2023.
- Attended a meeting of the Pan African Competitiveness Forum (PACF)-Nigeria Chapter National steering committee held at ALGON Secretariat WAEC Building Maitama Abuja on 23/5/2023.
- Participation at the Trade policy and market access technical workshop group meeting on Nigeria-UK enhanced trade and investment partnership on 14/09/2023.
- Participation at the high-level sensitization workshop on the African Continental free Trade Area (AfCFTA), 18-19/ 10/2023.
- Meeting with representatives of British Standards Institution (BSI), 09/11/2023.

C. Trade Fair/Expo/Conference/Exhibition/Business & Investment Forum

- Participation at the Maiden Edition of NACCIMA Digital Economy Conference. 31/01/2023
- Participation at the 63rd AGM/ Conference/Investiture of Barrister Kelvin Dele Oye as the 22nd National President of NACCIMA in Ekiti State 08/06/2023
- Attended the PINK TRADE FAIR 4th edition organized by Federal Ministry of Women Affairs Abuja. 23 – 25/ 10/2023
- Participation at the inaugural Nigeria-Cote d'Ivoire Business roundtable and Exhibition. 09/12/2023
- Participation at a One-day exhibition and capacity development for micro, small and medium Enterprises (MSMEs) operators on Quality, Standard and Best practise in packaging for Made-in-Nigeria products. 12/12/2023

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.

3.3 Reforms Unit 2023 Annual Report

The Reforms Unit was set up to sustain an effective service-oriented Agency devoid 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 on a daily basis from the general 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 on a daily basis from the general public bordering on suspected substandard food and drug products, import, export and registration, amongst others. These mails are acknowledged and their areas of concern are forwarded to the appropriate technical unit/department/directorate to take action and revert to the Unit while we in turn report back to the complainant with the actions taken and final result.

   This has increased the confidence level of the Agency's customers and stakeholders. Though to some of these mails, we await feedback from some of the Directorates on actions taken.
2. **Customer Service Forms:** The Unit received forms administered on a daily basis from the Agency's front desk. The clients who were unsatisfied were contacted via phone calls and issues resolved immediately.
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 on a daily basis 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 Abuja.
5. **SERVICOM MSU/PSU Breakfast Meeting:** 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 ascertain Customer service status and report same to the Presidency.
6. **Customer Satisfaction Survey:** The Unit also carried out her quarterly Customer Satisfaction Survey for the third quarter from all formations of which data is being collated and analyzed.
7. **Reforms Unit In-House Quarterly Training:** In line with Quality Management System, the Unit had her in-house training held at the Unit's office, by the SERVICOM desk officer –Mrs Tamunonimi H. Adegbite on Environmental Anxiety and Head Reforms Unit on Excellent Customer Service with all staff of the Unit present.

8. **2023 International Women's Day Celebration:** The Event took place at the NAFDAC car park on the 8th of March, 2023 with theme: **#EmbraceEquity#DigitALL: "Innovation and technology for Gender equality".**

9. **Training on Empowerment of Women in Management, Arusha, Tanzania.**
The Head Reforms Unit attended the above training organized by Danida Fellowship Centre (DFC) in collaboration with Tana Copenhagen from April 24 to May 5, 2023. The course aimed at building the capacities of Danida supported organizations to strengthen their work towards achieving gender equality especially at management level.

10. **A One-Day Stakeholders Forum for Directors of Reforms, Nodal Officers, Public Relations Officers and CSOs:** The Head Reforms Unit attended the above event which was organized by SERVICOM Presidency for all MDAs as a strategic engagement of citizens, Government and media for optimal realization of good Governance.

    The event took place at A-Class event center, Wuse 2, Abuja on the 30th May,2023

11. **NAFDAC ACTU Inauguration**: The Agency officially inaugurated her Anti-Corruption and Transparency Unit (ACTU) on the 13th of June, 2023 at the Director General's Conference Room by a team of ICPC officials.

12. **ACTU Meetings**. Members of the just inaugurated ACTU had her first meeting on the 20th June followed by 18th July and 19th September 2023 at the Reforms Unit office in accordance to the ACTU Standing Order of ICPC. This meeting according to the Standing Order is to be held once every month.

    To this end the ACTU of NAFDAC has had three monthly meeting since her inauguration in the months of June and July respectively.

13. **Bureau of Public Service Reforms Lunch Time Seminar:**20th of July, 2023 at the Conference Hall, Federal Capital Development Authority (FCDA) Engineering Building, Abuja.

14. **Nodal Officers Meeting:** At the Federal Ministry of Health on the 9th of September, 2023.

15. **Celebration of 2023 Customer Service Week** from October 9th to 12th 2023, with the theme **"Team Service".** It was a week full of activities from road show/awareness to Wuse market –Abuja; visits to some service points for Customer engagements, Customer satisfaction survey and several others. Feedbacks for the week were collated and analyzed with recommendations forwarded to the Director General.

16. **A One Day Business Facilitation Act 2022/Reportgov.Ng Refresher Sensitization Workshop for MDA's:** The SERVICOM desk officer Mrs. Adegbite Tamunonimi together with the Agency's Reforms champions attended a one-day refresher sensitization workshop on the reportgov App organised by Presidential Enabling Business Environment Council for all MDAs on the 23rd of October,2023 at the NEPC Building Maitama, Abuja.

17. **Pink Trade Fair:** Reforms Unit attended the 4th edition of pink trade fair organised by the Federal Ministry of Women Affairs, a 50million African Women Speak Platform

Project with theme **"Equity in Unity: Bridging Dreams Through Collaboration And Partnerships for Women Entrepreneurs"** which was held at the Tobix Garden, Jahi, Abuja from the 23rd -25th October ,2023. The presence of the Reforms was impactful. Some Customer concerns were satisfactorily addressed.

18. **NAFDAC SERVICOM Focal Officers Meeting:** The Unit organised a virtual meeting for all focal officers via zoom on the 10th November 2023 and in attendance were the SERVICOM Presidency Desk officer for NAFDAC Mr Shittu, NAFDAC Quality Manager - Miss Nkem Ifudu, Head Reforms Unit-Mrs Ugochi Christie Favour . Staff of the Unit -Mrs Joan Abaagu, Mrs Halima Chatta, Mrs Tamunonimi Adegbite and 46 other Focal officers from all formations.
19. 2023 International Anti-Corruption Day Celebration: NAFDAC's ACTU members attended a one-day event to mark 2023 International Anti-Corruption Day Celebration organized by Inter Agency Task Team(Anti-Corruption Agencies),UNODC, European Union, Center for Democracy & Development, International Institute for Democracy & Electoral Assistance and MacArthur Foundation with theme "UNCAC at 20:Uniting The World Against Corruption at the Shehu Musa Yar'Adua Centre, CBD, Abuja on the 8th December,2023.
20. SERVICOM Exchange Programme: Mrs Joan Abaagu and Mrs Tamunonimi Adegbite attended the above programme organized by SERVICOM Presidency on ISO 10667-1 2020-Procedures and methods in work and organizational settings which took place at the Royal Tulip Hotels, Nairobi Kenya, from 10th-16th December, 2023.

3.4 Reports from The Zones

3.4.1 North Central Zone

The North Central Zone comprises of six states namely Benue, Nasarawa, Niger, Kogi, Kwara and Plateau States.

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, Two Hundred and Thirty-Three (1,233) routine inspections were carried out in the Zone during the period under review.
2. **Sanctions**
   One Thousand, Four Hundred and Eighty-Two (1,482) sanctions were imposed on various establishments in the Zone during the year under review.
3. **Surveillance**
   Four Thousand, Two Hundred and Forty-Eight (4,248) surveillance were carried out in the Zone during the year under review.

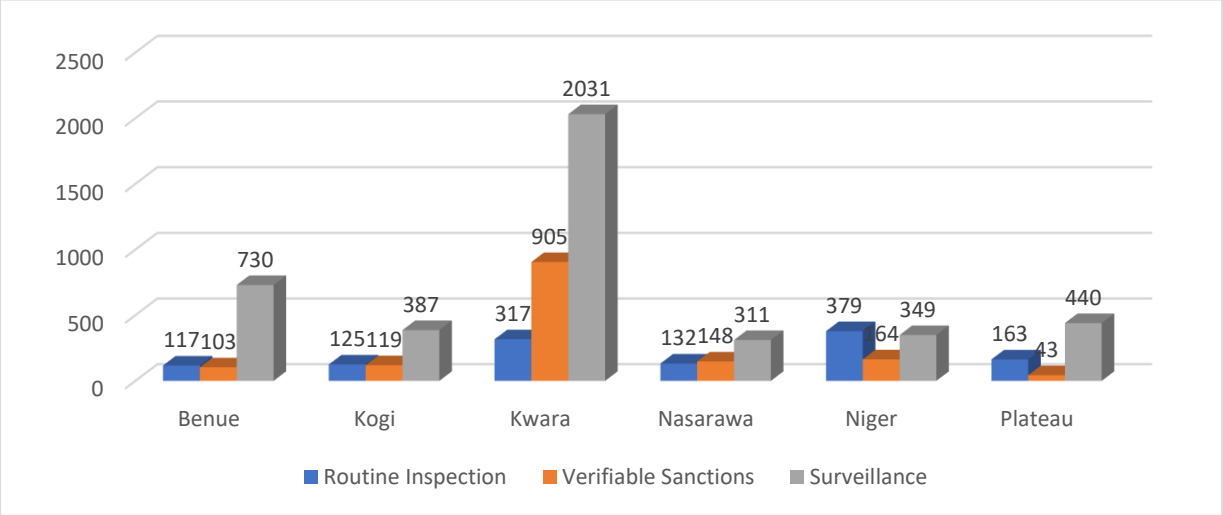
Table 3.4.1.1: Regulatory Activities in North Central Zone by Directorates

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1.	DER	21	4	0
2.	CER	7	13	0
3.	R&R	0	75	0
4.	PVPMS	0	1,012	3,766
5.	VMAP	11	6	13
6.	FSAN	1,194	372	469
7.	NCS	0	0	0
8.	Others	0	0	0
	Total	**1,233**	**1,482**	**4,248**

Table 3.4.1.2: Regulatory Activities in North Central Zone

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1.	Benue	117	103	730
2.	Kogi	125	119	387
3.	Kwara	317	905	2031
4.	Nasarawa	132	148	311
5.	Niger	379	164	349
6.	Plateau	163	43	440
	Total	**1,233**	**1,482**	**4,248**

Figure 3.4.1.1: Regulatory Activities in North Central Zone



3.4.2 North West Zone

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

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**
   Two Thousand, Six Hundred and Sixty-Eight (2,668) Routine inspections were carried out in the Zone during the period under review.
2. **Surveillance**
   Six Thousand, Two Hundred and Sixty- One (6,261) Surveillance were carried out in the Zone during the year under review.
3. **Sanctions**
   Seven Hundred and Forty-Nine (749) sanctions were imposed on various establishments in the Zone during the year under review.

4. **Production Inspection**
   A total of Eight Hundred and Two (802) Production activities were carried out within the zone in 2023

5. **Key Achievements:**
   a. Working visit to Kano State Office during which stakeholder engagement and facility tours took place.
   b. Courtesy visit to Department of State Services (DSS) Kaduna State Command to strengthen inter-Agency collaboration.

c. Courtesy visit to Nigeria Police Force (NPF) Kaduna State Command to strengthen inter-Agency collaboration.
d. Handover of seized unregistered

Table 3.4.2.1: Regulatory Activities in North West Zone by Directorates

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Production Inspection
1.	DER	69	45	924	36
2.	CER	45	19	172	25
3.	R&R		9		3
4.	PV	72	188	1,568	131
5.	PMS	196	200	2,052	
6.	VMAP	1,214	169	608	63
7.	FSAN	1,089	104	620	525
8.	NCS		18	318	19
9.	Others				
	Total	**2,685**	**752**	**6,262**	**802**

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.

For the past Twelve (12) years, the Zone has been tormented by security challenges. Still 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. Five Thousand Five Hundred and Twenty-Six (5,526) regulatory activities i.e., Routine, Sanction and Surveillance were carried out.

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**
   Two thousand nine hundred and eighty-nine (2,989) Routine inspections were carried out in the Zone during the period under review.
2. **Surveillance**
   Three thousand, six hundred and ten (3,610) Surveillance were carried out in the Zone during the year under review.
3. **Sanctions**

Six hundred and Fourteen (614) 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	Production Inspection
1.	DER	225	278	460	3
2.	CER	35	16	13	1
3.	R&R	0	0	0	0
4.	PVPMS	865	71	2,245	2
5.	VMAP	206	55	336	9
6.	FSAN	1,601	183	490	131
7.	NCS	55	10	65	6
8.	I&E	2	1	1	0
	Total	**2,989**	**614**	**3,610**	**152**

Table 3.4.3.2: Regulatory Activities in North East Zone by States

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Production Inspection
1.	Adamawa	725	4	193	22
2.	Bauchi	154	68	379	28
3.	Borno	26	290	1,358	29
4.	Gombe	1,315	222	1,092	59
5.	Taraba	144	28	424	14
6.	Yobe	625	2	357	0
	Total	**2,989**	**614**	**3,610**	**152**

Figure 4.3.1: Regulatory Activities in North East Zone by States

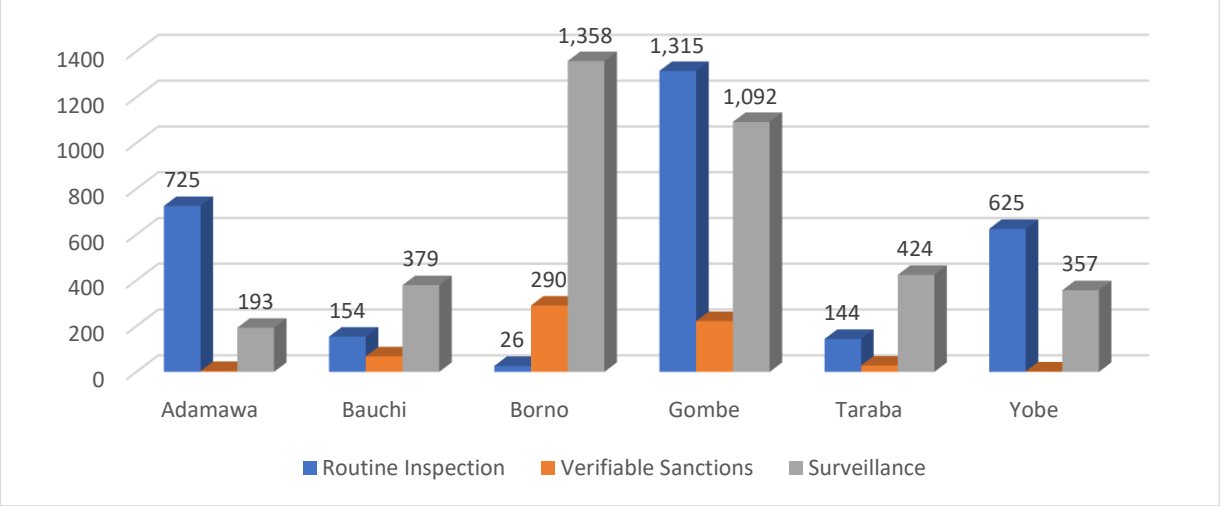


Table 3.4.3.3: Product Registration

SN	States	No. of Approved products
1.	Adamawa	
2.	Bauchi	
3.	Borno	4
4.	Gombe	
5.	Taraba	4
6.	Yobe	
	Total	**8**

Meetings

MEETINGS: A total number of thirteen meetings (13) meetings were conducted in the zone during the period under review.

Stakeholder Forum: A total number of nine (9) stakeholders forums were conducted during the period under review.

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

The zone will improve the Quality Management System requirement into its daily activity through continuous trainings in QMS and development of SOPs for the various operations.

Focus:

- Intensified enforcement and surveillance activity.
- Encourage registration of products, most especially MSME's by working closely with relevant state MDA's.
- Introduction of other regulatory activities eg issuance of GSP/GDP and GHP certification.

Visit to States in The Zone

Sustained visits to states in the zone will be maintained to increase/supervise regulatory activity.

These 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 problems, challenges. Strength, weakness, and opportunities with a view of enhancing staff performance. It will also fill in the gap between the management and staff, thus curbing rumor mongering and employee dissatisfaction in the workplace.

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 as highlighted below;

1. Routine Inspection: 1,044 routine inspections were carried out.
2. Surveillance: 578 surveillance activities were carried out
3. Sanctions: 357 sanction activities were carried out.
4. Production Inspection: 1,024 production inspection were carried out.
5. Renewal: 773 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	139	7	6	58	12
2.	CER	7	1	1	80	
3.	R&R					
4.	PV	160	11	200		
5.	PMS	167	93	304		
6.	VMAP	5	7	7	18	
7.	FSAN	566	238	60	868	761
8.	NCS					
9.	I&E					
	Total	**1,044**	**357**	**578**	**1024**	**773**

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	336	18	159	46	60
2.	Ogun	118	177	28	171	258
3.	Ondo	208	31	219	104	126
4.	Osun	127	92	119	156	190
5.	Oyo	255	39	53	247	139
	Total	**1,044**	**357**	**578**	**1,024**	**773**

Figure 3.4.4.1: Regulatory Activities in South West Zone by States

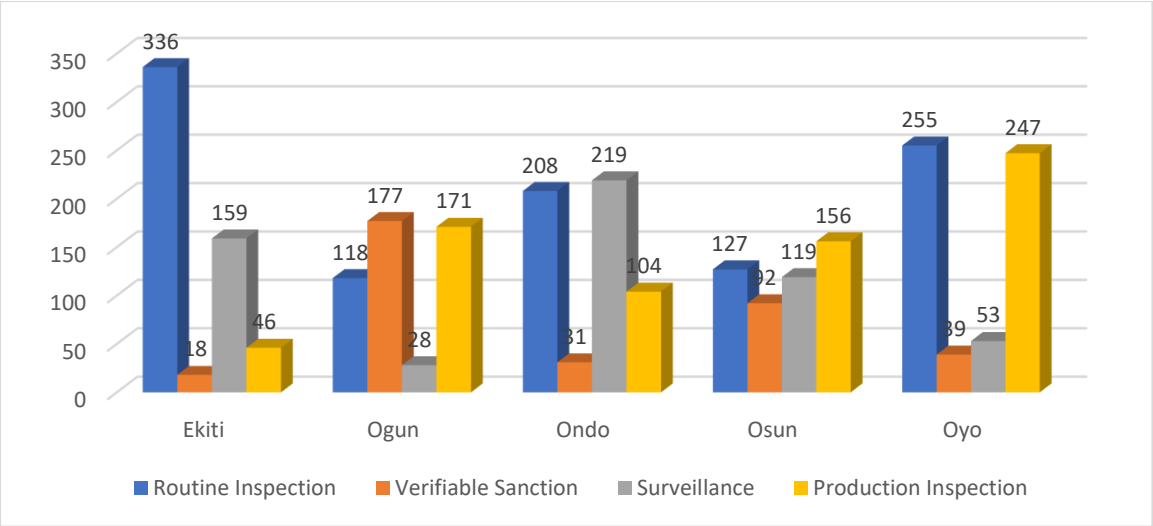


Table 3.4.4.3. Product Registration

SN	States	Water Products presented	MSME Products presented	Bread products presented	Cosmetics	Total product presented	Stepped down	Approved
1.	Ekiti	58	35		2	95	2	93
2.	Ogun	152	197	10	10	369	8	361
3.	Ondo	109	43		3	155		155
4.	Osun	118	71	4	3	196	1	195
5.	Oyo	117	185	33	20	355	1	354
	Total	**554**	**531**	**47**	**38**	**1170**	**12**	**1,158**

Achievements Recorded in South West Zone

1. A total of Eight Hundred and Fifty-Nine (859) products were processed and approved at the zone from January to December 8, 2023
2. With the support and approval of the DG and the Board members, Ogun II office was created and commenced operation in June 2023. This has brought regulatory activities closer to stakeholders operating in the Ogun West axis. This development has led to uncovering of several infractions in that axis and of course recovering of Revenue for the Agency.
3. Several major infractions were uncovered across the State of the zone including Oyo State and some are listed below.

    - Unregistered herbal products premises in Ibadan leading to publicity on NAFDAC regulatory control.
    - Revalidation of expired raw materials in Ibadan leading to sanctions and administrative charges
    - Incidences of faking and adulteration of Agrochemical in Ogunpa market (near Agbeni market) in Ibadan.
    - Detection of fake NAFDAC licenses and notifications across the States of the zone.

- Mutilation and alteration of date markings on drugs in pharmacy shops.
- Uncovering of fake and non-existing contract manufacturing outfit for crusader soap in Imeko of Ogun I axis.
- Several cases of relocation without approval.

4. Landed property

With the intervention of the Director General and follow-ups, The zone has secured the land for the office complex in Oyo, Ondo and Ekiti State which has been communicated to the Admin & Human Resources Directorate as required.

5.Constitution of Joint Zonal Task force.

Director South West Zone constituted a joint Task force to investigate the incidence of expired licenses in Ogun I office in July 2023. The outcome of the investigation with 60 out of the 74 facilities visited operating with expired licenses was escalated to the DG who gave a directive for further routine exercises.

The DG directive was implemented from the 7th of November to 5th of December and additional 93 facilities were visited during the period.

In all 167 facilities that were visited by the taskforce 120 of them had expired licenses. They were closed and mandated to initiate renewal which has led to the increase in Revenue recorded by Ogun I axis.

6. Stakeholders Engagements

Stakeholders were engaged in all the State offices of the zone accordingly. Director South West Zone was physically present in all the engagements except the Ondo State that is outstanding.

I.	Oyo State in April	Water producers and master bakers
II.	Ekiti State in July	All NAFDAC stakeholders
III.	Ogun I in August	Water producers and master bakers
IV.	Osun State in September	All NAFDAC stakeholders
V.	Ogun II axis in November	All NAFDAC stakeholders

7. Oversight Functions to the States

- All the States were visited at least once during the year for the purposes of;
- Staff training and retraining
- Facility visits 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.

8. NAPAMS Training

3.4.5. South South Zone

The number of regulatory activities (routine, sanctions & surveillance) carried out in the Zone for the year 2023 is Three Thousand, Five Hundred & Fifty-Two (3,552).

Table 3.3.5.1: Regulatory Activities in South South Zone by Directorates

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1.	DER	125	14	291
2.	CER	1	0	0
3.	R&R	0	0	2
4.	PV	561	130	749
5.	PMS		12	
6.	VMAP	6	0	1
7.	FSAN	880	163	350
8.	NCS	0	0	0
9.	I&E	0	0	0
	Total	**1,614**	**319**	**1,624**

Table 3.4.5.2: Regulatory Activities in South South Zone by States

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance
1.	Akwa Ibom	393	45	405
2.	Bayelsa	100	35	506
3.	Cross Rivers	136	14	230
4.	Delta	359	86	109
5.	Edo	125	31	10
6.	Rivers	501	108	364
	Total	**1,614**	**319**	**1,624**

Figure 3.4.5.1: Regulatory Activities in South South Zone by States

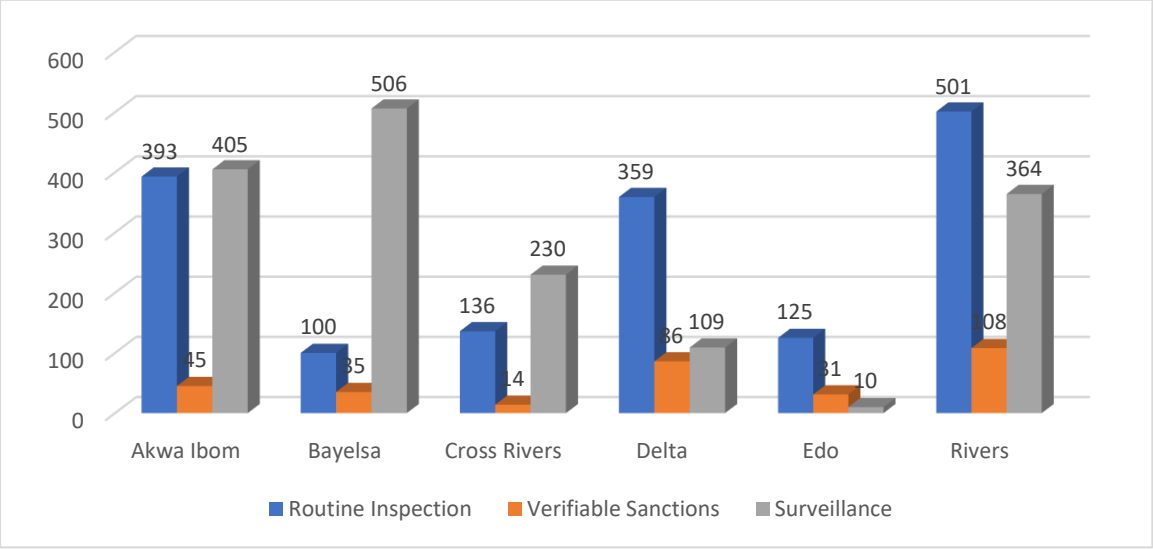


Table 3.4.5.3: Product Registration

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

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:

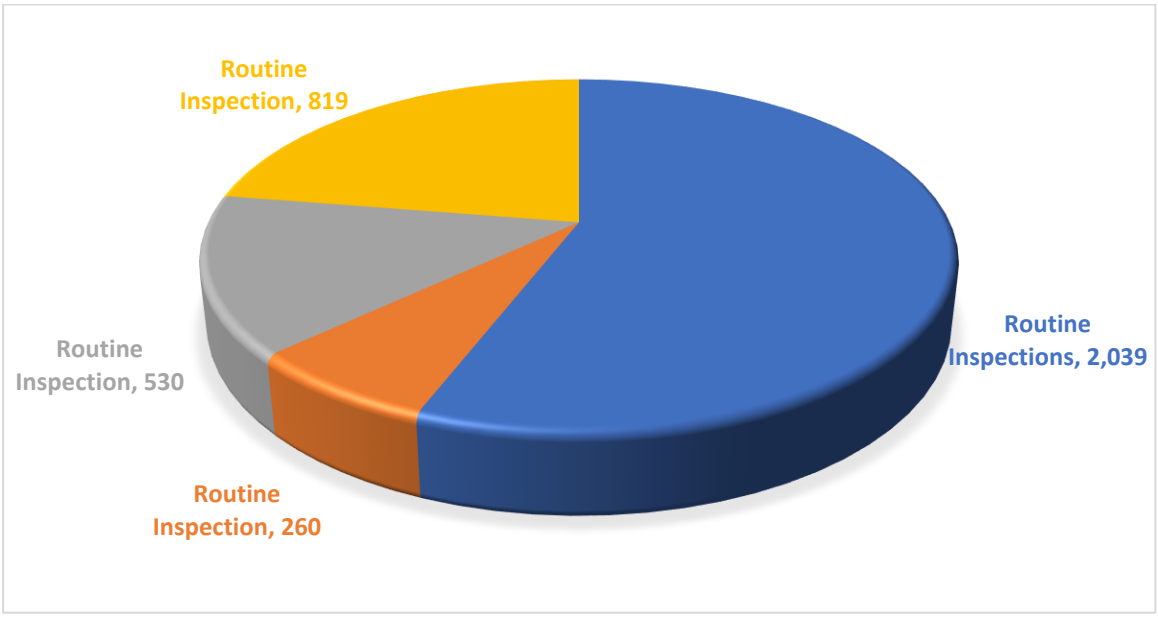
a. **Routine Inspections**: A total number of **Two Thousand and Thirty-Nine (2,039)** routine activities were carried out within the zone in the year 2023 under review.

b. **Verifiable Sanctions**: A total of **Two Hundred and Sixty (260)** verifiable sanctions were meted out within the zone in the year under review.

c. **Surveillance**: A total number of **Five Hundred and Thirty (530)** surveillance activities were carried out within the zone in the year under review.

d. **Production Inspections:** A total of Eight Hundred and Nineteen (**819**) production inspections were carried out.

Figure 3.4.6.1: Activities in South East Zone



2. **Product Approval/MSME Activities:** The total products approved in the zone for the year 2023 was **One Thousand, Six Hundred and Sixty-Four (1,664).**

Table 3.4.6.1. 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	22	57	20	55	24	178
2	Bread Products	Renewal	0	0	0	0	0	0
3	Cosmetics Products	New Registration	0	0	0	3	4	7
4	Cosmetics Products	Renewal	36	143	45	122	101	447
5	MSME Food Products	New Registration	38	57	40	100	70	305
6	MSME Food Products & Packaged Water	Pack Size Extension	0	0	0	0	0	0
7	Bread Products Registered	Pack Size Extension	0	0	0	0	0	0
8	MSME Bread Products	Renewal	22	58	12	55	34	181
9	MSME Food Products	Renewal	22	58	12	55	34	181
10	MSME Water Products	Renewal	83	96	23	100	70	372
11	MSME Water	Factory Extension	0	0	0	0	0	0
12	MSME Food & Water	Factory Relocation	0	0	0	0	0	0
13	MSME Food	Change of Package/Label Design	0	0	0	0	0	0
	Total Number of Products Registered		**223**	**469**	**152**	**487**	**333**	**1,664**

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 as monthly meetings between DSEZ and all staff of the zone.

4. **Stakeholder Forum:**
   - The SEZ held Stakeholder's meetings in all states of the zone.
   - The Director held meetings with executives of Eziukwu market in Aba and signed an MOU to rid the market of fake alcoholic beverages and other registered products.

5. **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: Regulatory Activities of FCT Office in 2023

S/N	Division/ Unit	No. of Routine Inspection	No. of Other Inspections	Verifiable Nos. of Sanctions	No. of Other Activities	Total No. of Activities
1.	CER	60	43	0	372	475
2.	DER	47	80	5	447	579
3.	FSAN	43	590	35	644	1.312
4.	VMAP	260	9	9	77	355
5.	R&R	N/A	N/A	0	9,873	9,873
6.	NCS	10	13	0	42	65
7.	LOD	N/A	N/A	N/A	11,811	11,811
8.	OSS	N/A	N/A	N/A	186	186
	Total	420	735	49	23,452	24,656

Figure 3.4.7.1: Regulatory Activities of FCT Office in 2023

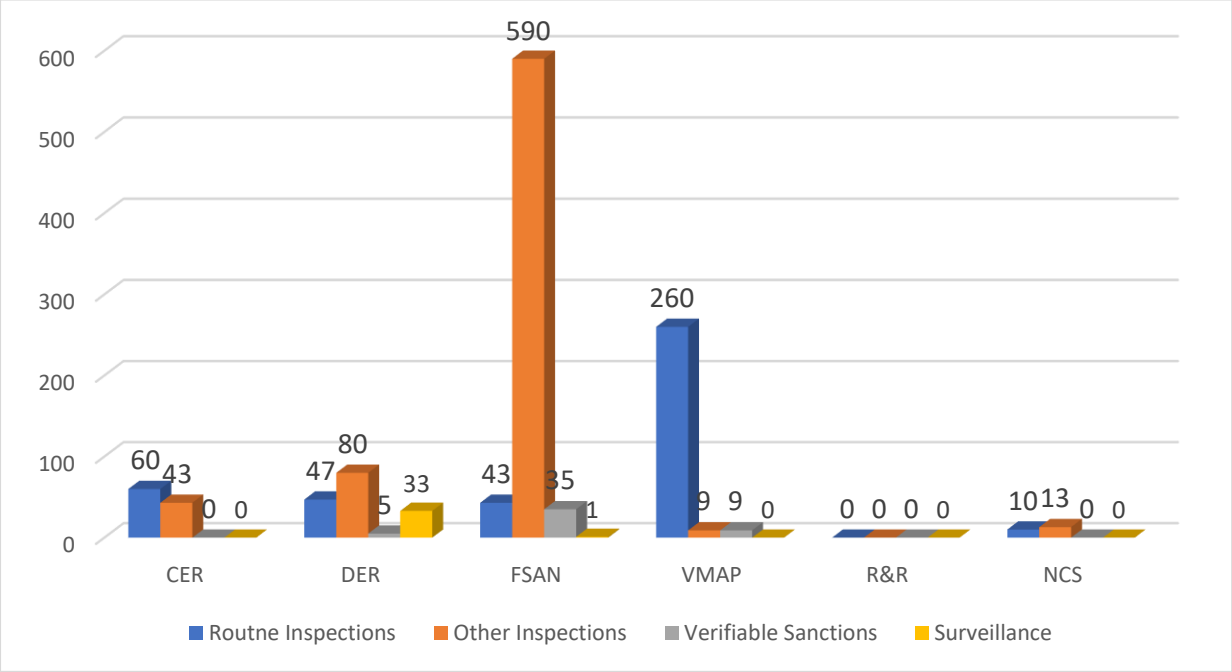


Table 3.4.7.2: Summary of Activities Carried Out by Registration and Regulatory Affairs Unit

SN	Activities	Importation	Local Products	Total
1	Counselling of clients	175	430	605
2	MSME new registration	0	556	556
3	MSME Renewals	0	389	389
4	MSME Pack size extension	0	25	25
5	MSME Factory Extension	0	0	0
6	MSME Factory Relocation	0	3	3
7	Number of bread and bakery products registered/Renewed	0	336	336
8	Other activities	319	7,640	7,959
	Total	**494**	**9,379**	**9,873**

Highlight of Activities

a. Inspections

The FCT Directorate, through the various inspecting Divisions (FCT-FSAN, FCT-DER, FCT-CER, FCT-VMAP and FCT-NCS) carried out different types of inspections as tabulated below:

Table 3.4.7.3: Inspections FCT Office in 2023

SN	Units	No of surveillance inspection	Routine Inspection	Other Inspection	Total
1	FSAN	1	43	590	634
2	DER	33	47	80	160
3	VMAP	0	260	9	269
4	CER	0	60	43	103
5	NCS	0	10	13	23
	Total	**34**	**420**	**735**	**1,189**

Table 3.4.7.4: Other Regulatory Activities

SN	Activities	Director's Office/Liaison Office	FSAN	DER	VMAP	CER	NCS	OSS	Total
1	Sanctions	0	35	5	9	0	0	0	49
2	Other activities	11,811	644	447	77	372	42	186	13,579
	Total	**11,811**	**679**	**452**	**86**	**372**	**42**	**186**	**13,628**

b. Sensitization Program/Exercise: Five (5)
c. Meeting: Fifty-Six (56)
d. Workshop/Training: Seventy-Three (73)
e. Foreign GMP Inspection: Four (4)
f. Cold Chain Monitoring: Thirty-Four (34) Cold Chain Monitoring was conducted.
g. Mop- up: Nil
h. Destruction & Seizure: One (1)
i. Investigation: Eighteen (18)
j. Surveillance: Thirty-Four (34)
k. Counselling: Two Thousand and Eighty-Four (2,084) clients were counselled on NAPAMS, registration processes, and other related guidelines and procedures.
l. Other activities: Twenty-Three Thousand, Five Hundred and One (23,501) other regulatory activities were carried out within the Directorate.

3.4.8. Lagos State Office (LSO)

Introduction:

Lagos State Office has consolidated in the modest achievements made in the areas of NAPAMS end to end registration of products, sensitization, awareness campaigns, monitoring, and sectorial meetings. The outcome of these brought a lot of NAFDAC regulated businesses (micro & small) from the informal sector to the formal sector of the economy, thereby boosting the number of applications received which is currently on the increase at Lagos State Office.

1. Highlights of Activities:

Within the period under review, we achieved the following:

a. **Routine Inspection:**
Three Hundred and Fifty-Three (353) routine inspection were conducted.
b. **Verifiable Sanctions.**
Ninety-One (91) establishments were sanctioned in line with the Agency's guidelines. This could be attributed to the sensitization programs the formation has embarked on. Warning letters were issued because most of them are first offenders.
c. **Good Hygiene Practice (GHP):**
Twenty-Six (26) GHP notifications were issued within the period under review.

d. **Production Inspections:**
One Thousand, One Hundred and Eighty-Six (1,186) production inspections were conducted within the period under review. Continuous training of stakeholders has brought a major boost on the number of applications received from Nine Hundred and Ninety-Eight (998) in 2022 to One Thousand, One Hundred and Forty-Three (1,143) in 2023.

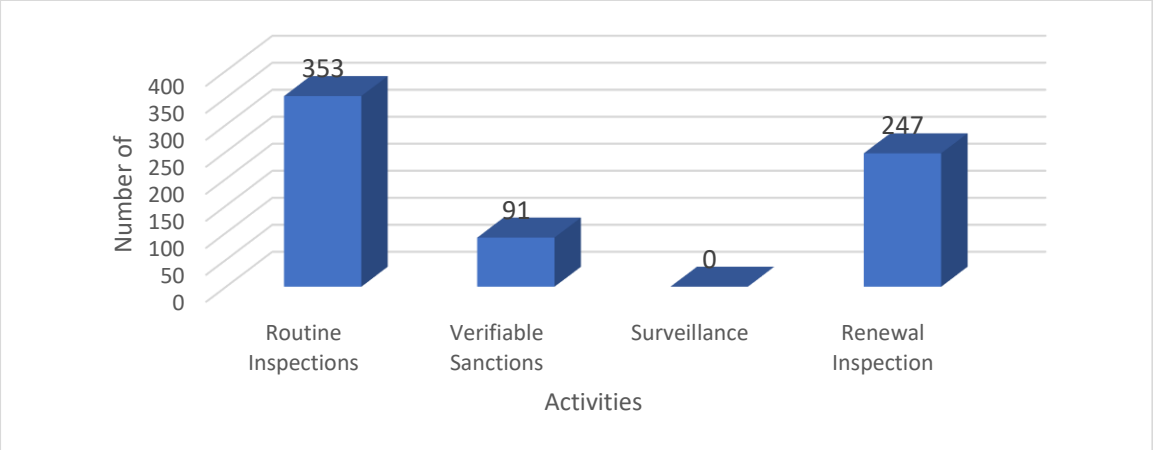
e. **Renewal Inspection:**
Two Hundred and Forty-Seven (247) renewal inspections were conducted.

A total of One Thousand Five Hundred and Sixty-Three (1,563) inspections were conducted in the formation throughout the year.

Table 3.4.8.1. Summary of Activities of LSO From January to December 2023

SN	Month	Routine Insp.	Verifiable Sanctions Imposed	Surveillance	GHP Insp. Conducted	Production Inspections	Renewal Inspection	Total
1.	Jan.	10	1	-	1	88	12	
2.	Feb.	17	1	-	-	122	1	
3.	March	21	-	-	4	90	24	
4.	April	18	-	-	6	66	14	
5.	May	23	4	-	15	103	26	
6.	June	38	6	-	1	95	33	
7.	July	40	9	-	-	101	14	
8.	Aug.	36	8	-	-	218	9	
9.	Sept.	50	18	-	-	89	27	
10	Oct.	45	15	-	-	82	7	
11	Nov	36	20	-	-	89	30	
12	Dec	19	9	-	-	43	40	
	Total	**353**	**91**	**0**	**27**	**1,186**	**247**	**1,904**

Figure 3.4.8.1. Summary of Activities of LSO From January to December 2023



2. External Sensitization Activities

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

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

a. Meetings Conducted

Lagos State Office (LSO) 22 conducted inhouse meetings. Some of them are as follows.

I. NAFDAC-LSO Sub-Food and Cosmetics Approval meeting for the month of December 2022 held on 25th of January 2022 at Central Laboratory Auditorium Oshodi.
II. Final Food and Cosmetics Approval meetings were held monthly at Oshodi Auditorium.
III. Staff meetings with Director LSO was held on the 17th April 2023.

Chapter Four
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 her 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 (as applicable), and monitor continued compliance with relevant regulations, standards, and guidelines through unannounced (routine) inspections.
ii. Initiate development of, and participate in, review and revision of food regulations.
iii. Develop, review, and revise food guidelines.
iv. Issue authorization for importation of bulk food raw materials/ingredients.

v. Implement the provisions of the International Code of Marketing of Breast-milk Substitutes (BMS) and the national BMS marketing regulations.

vi. 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.

vii. Coordinate activities of the International Food Safety Authorities Network (INFOSAN) as the INFOSAN Emergency Contact Point for Nigeria.

viii. 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.

ix. Participate in national nutrition programmes and activities in collaboration with relevant Ministries, Departments and Agencies (MDAs), as well as Development Partners, to contribute in improving national nutrition indices.

x. 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 2023

S/N	FSAN Activities	Outcome	NCZ	NEZ	NWZ	SSZ	SWZ	SEZ	Lagos	Total
1	Routine Inspections	Satisfactory	909	1186	988	572	503	819	117	5,094
		Unsatisfactory	488	14	415	263	173	0	45	1,398
2	Special Inspections	Satisfactory	18	117	35	49	7	1	7	234
		Unsatisfactory	2	0	6	11	0	0	0	19
3	GMP Re-assessment	Satisfactory	27	27	6	15	36	4	24	139
		Unsatisfactory	6	0	0	10	0	0	1	17
4	Production Inspection	Satisfactory	381	250	467	474	879	560	433	3,444
		Unsatisfactory	17	2	24	146	5	0	2	196
5	Follow-up Inspection	Satisfactory	22	14	9	18	5	7	14	89
		Unsatisfactory	1	0	9	50	0	0	4	64
6	GMP Re-assessment (Renewal)	Satisfactory	465	84	368	235	767	250	240	2,409
		Unsatisfactory	30	0	14	97	2	0	2	145
7	Inspection of warehouses for Global Listing	Satisfactory	12	38	18	21	12	16	91	208
		Unsatisfactory	8	6	0	0	0	0	15	29
8	Cold Chain Facilities monitoring	Satisfactory	11	14	10	12	17	2	11	77
		Unsatisfactory	14	0	5	5	0	29	0	53
9	No. of Surveillance activities carried out	Compliant	463	633	182	197	5	288	0	1,768
		Non-compliant	179	13	221	56	29	25	0	523

10	No. of compliance directives issued		348	184	524	514	55	771	2	2,398
11	No. of Investigations activities carried out	Concluded	55	127	14	8	6	28	3	241
		Ongoing	22	2	12	14	4	0	5	59
12	Sanctions imposed on companies		335	105	174	175	77	119	0	985
13	No. Put on Hold		0	1	1	0	2	1	0	5
14	No. of Hold Removed		34	0	0	0	1	1	0	36
15	No. of Establishments visited for Mop-up		135	51	10	78	1	1	0	276
16	No of Products mopped up		554	3	296	659	1	7	0	1,520
17	No. of Consumer Complaints received		14	15	60	4	3	2	22	120
18	Number of consumer complaints investigated	Concluded	5	5	1	2	1	0	17	31
		Ongoing	8	1	3	3	3	0	0	23
19	No. of Product Alerts received		0	13	13	13	0	8	0	47
20	No. of Institutions visited for annual water monitoring		0	0	0	11	0	0	0	11
21	Breast Milk Substitutes (BMS) Monitoring		9	403	207	31	0	3	0	653
22	No. of Salt Iodization Survey carried out	Concluded	0	0	0	0	0	0	0	0
		Ongoing	0	0	0	0	0	0	0	0
23	No. of Vitamin A/Premix Survey carried out	Concluded	0	0	0	0	0	0	0	0
		Ongoing	0	0	0	0	0	0	0	0
24	GPS Marking of location		0	0	0	0	0	0	0	0

25	Change of Location		1	1	0	0	5	0	3	10
26	Pack size Extension		0	8	0	0	3	0	1	12
27	cGMP Certification		0	0	0	0	0	0	5	5
28	No. of Sampling Inspection		0	64	0	0	1	42	4	111
29	Others		6	117	0	0	14	107	6	250
Total			4,579	3,498	4,092	3,743	2,617	3,091	1,074	22,694

Table 4.2: Comparison of FSAN Inspection Activities in 2023 with 2022

Zones	**FSAN Inspection Activities**	
	2022	**2023**
NCZ	5,533	4,579
NEZ	2,507	3,498
NWZ	3,940	4,092
SSZ	2,687	3,743
SWZ	2,175	2,617
SEZ	1,736	3,091
LAGOS	1,262	1,074
Total	**21,862**	**22,694**

Figure 4.1: Comparative Analysis of FSAN Inspection Activities for the Years 2022 and 2023

Figure 4.1 gives a graphical representation of inspection activities in 2023 compared with 2022. Overall, there was a four percent (4%) increase in FSAN inspection activities in year

2023 when compared with 2022. This increase was recorded in spite of the generally challenging economic environment experienced in the country in 2023, coupled with the fact that the first 2 quarters of the year were marked with heightened tension of political activities being an election year.

Table 4.3: Number of cGMP and GHP Certificates Issued

No. of Certificates Issued in 2023		Total
cGMP	GHP	
24	9	33

In the year 2023, FSAN Directorate issued 24 Current Good Manufacturing Practice (cGMP) certificates to indigenous manufacturers and 9 Good Hygiene Practice (GHP) certificates to food service operators.

GMP Reports Evaluation

A total number of four thousand, three hundred and six (4,306) GMP inspection reports of Food, Water and Global listing from the six Zones (Abuja and Lagos inclusive) were evaluated during the year.

Table 4.4: Permit for Importation of Bulk Food Raw Materials in 2023

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	14	35	7	3	2	0
February	8	18	3	5	1	0
March	4	10	0	2	0	2
April	6	4	3	2	0	0
May	2	2	0	2	0	0
June	11	1	0	1	0	0
July	4	3	3	0	0	0
August	9	1	1	2	1	0
September	8	1	1	0	1	0
October	23	1	1	0	0	0
November	41	5	3	1	0	0
December	12	15	3	0	0	0
Total	**142**	**96**	**25**	**18**	**5**	**2**
Total Number of Applications Received: 172						

Total Number of Applications Approved: 116	

Figure 4.2: FSAN Bulk Food Raw Materials Import Permit Activities for 2023

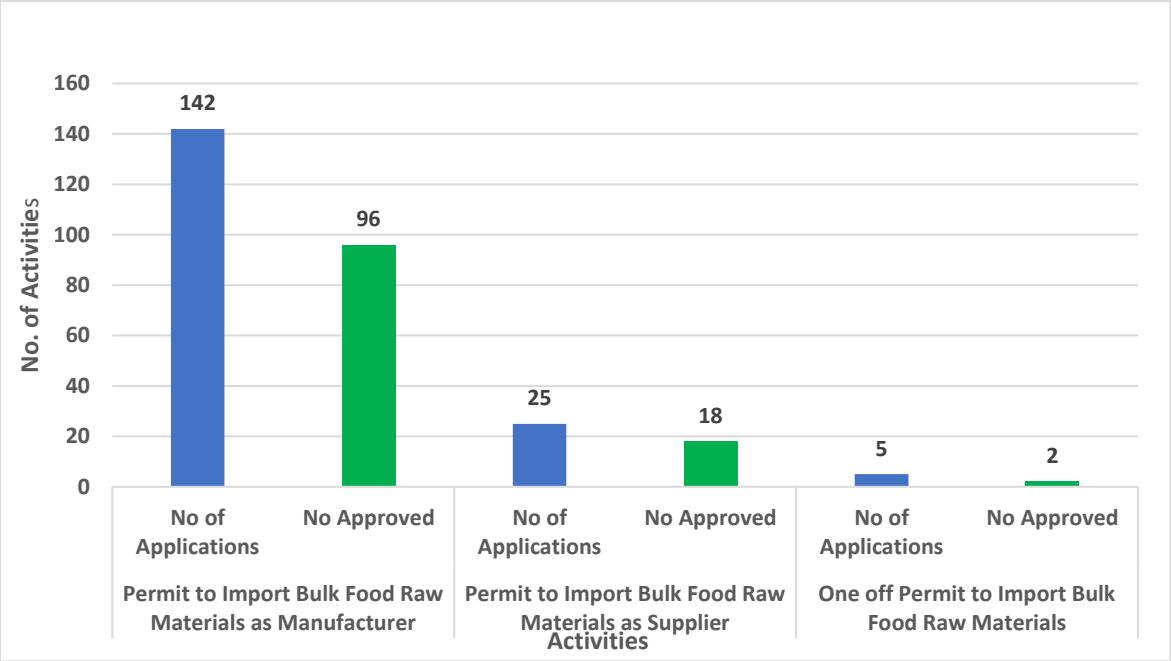


Table 7: FSAN Foreign GMP Risk Categorisation Activities For 2023

No. of Applications		
Cleared	**Pending**	**Total**
169	69	238

In the year under review, **Two Hundred and Thirty-Eight (238)** applications for foreign GMP clearance were treated out of which **169** were cleared with **69** 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 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, the Secretariat of the National Fortification Alliance (NFA) and the Country Working Group on Bouillon Fortification. Below are highlights of some other activities undertaken by the Directorate.

4.4.1 BMS Code Activities

The FSAN Directorate anchors 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 in the implementation phase of 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. Interactive meeting with State Nutrition Officers (SNOs) from the 36 States and the Federal Capital Territory for sustained collaboration in areas of effective monitoring of BMS violations on 12th - 13th July 2023, Abuja.
ii. National Training of Trainers on Maternal Infant and Young Child Nutrition (MIYCN) 19th to 26th July 2023, in Kano and 16th to 23rd August 2023, Lagos.
iii. Flag-off Ceremony for 2023 World Breastfeeding Week with the theme *"Let's make breastfeeding and work, work"* held in Abuja on 1st August, 2023.
iv. Hosted a workshop/training with presentations around the theme: *Enabling Breastfeeding – Making a Difference for Working Mothers* on 3rd August 2023.
v. World Breastfeeding Week webinar with University of Port Harcourt on 7th August 2023.
vi. BMS Technical Committee capacity building, inauguration and training of health workers in Yobe State on 22nd August, 2023 and in Borno State from 4th to 6th September 2023.
vii. Global Congress on Implementation of the International Code of Marketing of Breast-milk Substitutes (BMS) from 20th to 22nd June 2023 at WHO Headquarters, Geneva, Switzerland.

4.4.2 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 considered. 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 June and December 2023.

In the period of this report, the FSAN Directorate represented NAFDAC in the NFA delegation to the Nigeria Customs Service (NCS) on 26th October 2023 seeking clarification for the food fortification industry on HS Codes for specified vitamins and minerals that would translate to correct application of tariffs. The activity recorded huge success in the form of proper interpretation and application of the HS Codes for premix importers from the previously charged 20% to 5%.

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 Technical Committee Meeting for revision of Bouillon Standards and Code of Practice for Bouillon Fortification from 1st to 2nd November 2023 in Lagos.

The FSAN Directorate continues to leverage knowledge and experience on food fortification to contribute positively to supporting national efforts for the realization of rice fortification through participation in the underlisted activities.

i. Technical Committee meeting on the draft Code of Practice for Fortified Milled Rice on 27th July, 2023, Lagos.

ii. Training on Quality Assurance, Quality Control and Compliance Monitoring on Rice Fortification, 23rd to 25th August 2023, Lagos.

iii. Meeting of the National Rice Fortification Technical Advisory Committee on 7th December 2023, Lagos.

4.4.3 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 effective date of implementation (2023) of the revised National Codex Committee NCC Procedural Manual (4th edition):

i. National Codex Committee – Technical Committee (NCC-TC) Preparatory meeting for the 16th session of Codex Committee on Contaminants in Foods (CCCF16) on 28th March 2023.

ii. National Codex Committee – Technical Committee (NCC-TC) Preparatory meeting for the 53rd session of Codex Committee on Food Labelling (CCFL53) on 18th April 2023.

iii. National Codex Committee – Technical Committee (NCC-TC) Preparatory meeting for the 54th session of Codex Committee on Pesticide Residues (CCPR54) on 1st June 2023.

Being a major stakeholder in Codex work for Nigeria, FSAN Directorate participated in the four (4) quarterly meetings of the National Codex Committee (NCC) hosted by the Codex Contact Point for Nigeria and attended a 5-day Capacity Development Training on Scientific Basis of Codex and Food Safety Risk Analysis facilitated by NCC and FAO from 25th to 29th September 2023. The Directorate also facilitated the participation of NAFDAC delegates drawn from relevant Directorates to five (5) Codex Committee meetings in 2023: Codex Committee on Residues of Veterinary Drugs in Foods; Codex Committee on Methods of Analysis and Sampling; Codex Committee on Food Import and Export

Inspection and Certification Systems; Codex Committee on Pesticide Residues; Codex Committee on Food Labelling (virtual participation).

4.4.4 Stakeholders' Engagement

Engagement with stakeholders is recognized as an important activity to improve service delivery. In the period under review, the FSAN Directorate actively engaged stakeholders in the food and water sectors, building capacity and fostering further 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. The following are some stakeholders' engagement activities undertaken in the period of this report:

i. Engagement and training of operators of hotels and Quick Service Restaurants (Eateries) on 11th August 2023 in Lagos.
ii. Engagement and training of stakeholders across the food sector on 14th August 2023 in Lagos.
iii. Engagement with stakeholders in the baking industry delivering an address on *"Overcoming Baking Industry Challenges: Regulator's Perspective"* on 9th November 2023 in Lagos.
iv. Open dialogue session with stakeholders of the Association of Food, Beverage, and Tobacco Employers (AFBTE) on 8th December 2023 in 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.

4.4.5 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 with trends and developments in the regulated sector. In the reporting period, the under-listed were successfully accomplished:

Draft Regulations:

i. Draft Regulations on Tomato Concentrate

New Guidelines:

i. Guidelines for Registration of Packaged Edible Vegetable Oil by Dispensers under Micro-scale in Nigeria (Hosted on the website).

Reviewed Guidelines:

i. Guidelines for Inspection and Requirements for Bread and Baked Products Manufacturing Facility.

ii. Guidelines for Inspection and Requirements for Packaged Water Facility in Nigeria (Fresh Applications).
iii. Guidelines for Inspection and Requirements for Pre-Packaged Food Manufacturing/Packaging Facilities in Nigeria.

4.4.6 Nutrition Programmes

The FSAN Directorate is engaged in the coordination and implementation of food and nutrition programmes and projects of government in collaboration with relevant Ministries, Departments and Agencies (MDAs), Development Partners (UNICEF, WFP, GAIN, Technoserve, Alive and Thrive, Helen Keller International, USAID Advancing Nutrition, Bill and Melinda Gates Foundation, 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, 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), Nutrition Society of Nigeria, ECOWAS Nutrition Forum, National Technical Advisory Group (NTAG) on Food Fortification, Nigerian Institute for Food Science and Technology, National Multisectoral World Breastfeeding Week Celebration Committee, State Multisectoral Technical Committees on the Code of Marketing of Breast-milk Substitutes, Reproductive, Maternal, Newborn Child, Adolescent and Elderly Health plus Nutrition (RMNCAEH+N) Coordination platform, Front-of-Pack Nutrition Labelling (FOPNL) and Sodium Reduction Programme.

In furtherance of the positive strides 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, the FSAN Directorate in collaboration with development partners, Network for Health Equity and Development (NHED) and Resolve to Save Lives (RTSL) participated in a planning meeting for the constitution of a Task Team for the development of a framework for the implementation of the Fats, Oils, and Foods containing Fats and Oils Regulation 2022 in Lagos on 27th November 2023. The FSAN Directorate was subsequently assigned the role of Chair to drive further activities towards implementation.

The FSAN Directorate has continued to actively participate in activities towards implementing the Memorandum of Understanding (MoU) between NAFDAC and the Danish Veterinary and Food Administration (DVFA) for a Strategic Sector Cooperation (SSC) Project on cooperation in the field of food safety. Under this collaborative platform, two (2) FSAN staff were trained on sustainable food system, resource efficiency: food loss and food waste in November 2023 while two (2) joint workshops were held in Lagos with the Danish team from 12th to 14th July 2023 and 17th to 19th October 2023.

Chapter Five
Drug Evaluation and Research (DER) Directorate 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. 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

5.0 Pharmaceutical Operations
Summary of Regulatory Activities of the Directorate in 2023
Table 5.1 Summary of Inspections carried out in 2023 by Inspection Type.

S/N	Types of Inspection	Herbal Medicines & Nutraceuticals	Clinical Trials, Vaccines/ Biologics	Drugs	Cosmetics & Medical Devices	Total
1.	Routine Inspection	69	31	47	134	281
2.	Pre-Production Inspection (Drug companies only)	0	0	3	0	3
3.	Special Inspection	5	0	26	23	54
4.	Pre-Registration Inspection	0	0	2	1	3
5.	GMP Re-assessment Inspection	12	1	7	17	37
6.	Production Inspection	107	0	2	203	312
7.	Follow-up Inspection	1	4	15	9	29
8.	Inspection of Warehouses/Retail Outlets for Global Listing	0	0	10	85	95
9.	Global Listing Renewal	0	0	0	0	0
10.	Cold Chain Facilities Monitoring for Vaccines & Biologics	0	391	0	0	391
11.	Coding Inspection	0	0	16	0	16
12.	Surveillance Inspection	1	0	0	0	0
13.	Co-packaging Inspection	0	0	0	0	0
14.	GMP Assessment on change of factory site	0	0	0	0	0
15.	No. of Overseas GMP Inspections carried out	0	0	0	0	0

16.	MAS Coding Inspection	0	0	9	0	9
17.	No. of Investigation /For Cause (GMP & GCP) Inspections Conducted	0	0	0	0	1
18.	No. of GCP Inspections Conducted	0	15	0	0	15
	Total	**195**	**442**	**137**	**472**	**1,246**

5.1 Summary of DER Directorate Regulatory Activities carried out in 2023

The summary of all regulatory activities carried out nationwide in the year 2023 as they relate to the Divisions in the Directorate is as shown below:

- Clinical Trial, Vaccines & Biologics - 1,209
- Herbal Medicines & Nutraceuticals - 1,113
- Pharma Operations - 953
- Pharma Compliance - 6,096
- Cosmetics & Medical Devices - 3,129
- Quality Management System - 418

Total - 12,918

Table 5.2: Sanction Activities carried out by DER in 2023

SN	Sanction Activities for the Year 2023	
1.	Warning of offenders	43
2.	Compliance Directives (CDs)	86
3.	Admin Charges on Offenders	35
4.	Seizure/ withdrawal/ Mop Up of Products	43
5.	Destruction of Products	2
6.	Products Put on Hold	0
7.	Outfits put on hold	1
8.	Closure of Outfits	0
	Total	**210**

a. Issuance of Authority to Manufacture

Authority to manufacture products on different product lines in pharmaceutical manufacturing facilities was issued to Four (4) companies in 2023.

ii. Issuance of GMP Certificates and Notification of Satisfactory Inspection

GMP Certificates were issued to Twelve (12) companies whose operations were adjudged to comply with minimum GMP requirements and Seven (7) letters notification of satisfactory inspections were issued in 2023.

iii. Summary of Inspection Reports

A review of Four Hundred and Sixty-Eight (468) reports of inspections conducted nationwide in 2023 as captured under the relevant product categories listed below:

S/N	Product Category	Number
1.	Drug	103
2.	Herbal & Nutraceuticals	34
3.	Cosmetics & Medical Devices	331
	Total	**468**

iv. Regulations, Guidelines and Other Quality Documents

Thirty-Nine (39) operational SOPs were reviewed and developed in the reporting period and Thirty-Two (32) 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.
Two (2) guidelines were finalized, approved, made effective through training of DER staff nationwide.

Activities of the Divisions

5.2.1 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. Five (5) were issued Authority to Manufacture.

ii. **Pre- Registration Inspection** was carried out in Ten (10) pharmaceutical companies. Nine (9) were found to be operating within minimum NAFDAC GMP requirements therefore their products were recommended for registration while one (1) was unsatisfactory.

iii. **Routine inspections** were conducted in One Hundred and Forty-Seven (147) pharmaceutical manufacturing facilities nationwide in 2023.

iv. **On-Site CAPA Effectiveness Verification Inspections:**
Following a satisfactory outcome of review of their CAPA plans, On-Site CAPA Effectiveness Verification Inspections were conducted in Nineteen (19) facilities in 2023. 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 Ten (10) pharmaceutical facilities in 2023 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-Three (53) companies submitted electronic copies of their CAPA Plans for review in 2023. Twenty (20) were reviewed out of which Nine (9) were found satisfactory and effective in addressing the observed non-conformances. The remaining Eleven (11) CAPA plans require re-submission by the companies while review of Thirty-Three (33) CAPA plans are ongoing.

c. Review of Factory Designs and Layouts

Thirty-Nine (39) companies submitted proposed pharmaceutical manufacturing facility layouts for review during the period under review. Thirty-Five (35) have been approved having met the requirements while review of the remaining Four (4) are ongoing.

d. Sampling of Products for Laboratory Analysis

Fourteen (14) products were sampled for laboratory analysis in the year under review out of which 0ne (1) was an investigation sample, Ten (10) of the samples were for registration while Three (3) were renewal products.

e. Special Inspection

One (1) special inspection was carried out and s did not meet the minimum GMP requirement, hence it was unsatisfactory.

v. Pharmaceutical Compliance Division

i. Foreign Facility Verification Applications

A total number of Two Thousand Seven Hundred and Twenty-Four (2,724) applications were received in the reporting period. Two Thousand, Five Hundred and Thirteen (2,513) facilities were reviewed while Two Hundred and Eleven applications were not processed due to inability to payments not verified and some applicants were not forthcoming.

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

A total of Two Hundred and Seventeen (217) applications were received and processed for issuance of API permit in 2023. 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.

iii. Monitoring of Overprinting of NAFDAC RegistrationNumber and Affixing MAS Labels

Sixteen (16) Companies made requests for overprinting of NAFDAC registration number or affixing of Mobile Authentication Service (MAS) labels in 2023 and their requests were all granted after satisfactory monitoring of the activity.

iv. Other Activities

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

ii. A workshop for local manufacture of API and excipients with regulators, industries and academia. To sensitize the industry of the opportunity that lies within the industry. 3rd – 6th October 2023.

vi. Clinical Trial, Vaccines & Biologics Division

i. New Clinical Trial Applications

A total of Forty-Seven (47) New Clinical Trial Applications (CTA) were received out of which Forty-One (41) Applications were reviewed and 35 Authorizations issued in 2023. Forty-Nine (49) Protocol Amendment applications were received and Twenty-Eight (28) were treated. Seventy-Five (75) progress reports were received during the reporting year, out of which Forty-Six (46) were reviewed.

ii. Import Permit of Investigational Medicinal Products

Fifty-Five (55) applications for importation of Investigational Medicinal Products were received and Forty-Two (42) were reviewed and approved within the reporting period.

iii. Cold Chain Storage Facility Inspections

Twenty-Two (22) Cold Chain Facility Inspection Applications were received and scheduled; 17 Cold chain Facility inspections were carried out during the reporting period as the remaining 5 facilities were not ready for inspection as at the reporting period.

iv. GCP Inspection:

Out of the Forty-Nine (49) GCP Inspections scheduled for the year 2023, Sixteen (16) 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.

v. Clinical data:

A total of Forty-Eight (48) clinical data were received for drug registration/renewal out of which 45 were reviewed within the reporting period. About 38 were approved while 7 were yet to satisfactorily respond to the Compliance Directives served within the reporting period.

vi. Other activities

- Seven (7) Pre-Clinical Trial Application (CTA) consultation meeting were scheduled and conducted in the year 2023.
- The division participated in Thirteen (13) DER internal GMP/GCP trainings
- Seven (7) External trainings/workshops

vii. Herbal Medicines & Nutraceuticals Division

a. Applications for Inspection of Facilities

Twenty-Five (25) applications were received within Lagos State and were all treated and found to be satisfactory.

b. Inspection Requests Received

The Division received Twenty-One (21) requests for GMP inspection.

c. Number of Inspections Conducted

In the year under review, Twenty-Five (25) inspections were conducted out of which Nineteen (19) were satisfactory and Six (6) are unsatisfactory within Lagos State.

d. Routine Inspections

Four (4) routine inspections were conducted in 2023 and were all adjudged unsatisfactory as at the time of inspection.

e. Review of Inspection Reports from NAFDAC States offices

A total of One Hundred and Forty-Six (146) GMP inspection reports were received from NAFDAC State offices nationwide in 2023. One Hundred and Twenty-Three (123) have been treated while Twenty-Three (23) were still being reviewed as at the time of this report.

f. Other Activities

Five (5) audits were conducted in the Division during the year in view. The details are: Divisional Self-Assessments (February 14th and August 22nd, 2023), Directorate Internal Audit (March 28th, 2023), Follow Up Audit (May 9th, 2023) and Agency Internal Audit (26th June 2023).

viii. Cosmetics and Medical Devices Division

a. Production Inspections

Production Inspections were carried out in Sixty-Three (63) companies within Lagos State. Fifty-Nine (59) were adjudged satisfactory while four (4) were found to be unsatisfactory.

b. Warehouse/Outlet Inspection for Global Listing of Cosmetics

Warehouse/outlet inspections for global listing of cosmetic products were carried out in Thirty-Four (34) Supermarkets for Good Hygiene/Good Storage practice

c. Registration of Medical Devices

Seven (7) applications for registration of various medical devices were recommended for registration.

d. Risk-Based Sampling of Products for Laboratory Analysis

Two Thousand, Nine Hundred and Eighty (2,980) cosmetics out of which One Hundred Eighty-Eight (188) were high risk, Two Thousand, Seven Hundred and One (2,701) were categorized as medium risk while Ninety-One (91) were categorized as low risk. Products were recommended to Drug Registration and Regulatory Directorate for registration based on risk assessment and samples of the products were also sent to the laboratory for analysis and retention purposes as applicable.

e. Document Review

A total of One Hundred and Nineteen (119) documents were reviewed out of which One Hundred and Thirteen (113) were satisfactory and Six (6) are unsatisfactory.

ix. Quality Management System (QMS) and Other Activities Related to WHO-Global Benchmarking (WHO-GBT) 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 Forty-Seven (47) SOPs were reviewed through the year. Additionally, a new SOP, specifically the SOP for Importation of Bulk Regulated Products (DER-308-00), was successfully developed during the third quarter of 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. **Review and Approval of Obsolete Guidelines**:

A total of Two (2) guidelines namely, Guidance to Sponsors of Clinical Trials in Nigeria including COVID-19 Related Trials (DER-GDL-018-01) and the NAFDAC Inspectors Guide were reviewed during the year. All the stated guidelines including the NAFDAC Good Manufacturing Practice for Herbal Medicinal Products Guidelines 2022 (DER-GDL-024-00) were forwarded to the NAFDAC ICT team for onward hosting on the NAFDAC website.

d. **Self-Assessment and DER Internal Audit**:
A total of Five (5) 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 2023.

e. **Customer Complaints**:
A total of 3 customer complaints were received, 2 were investigated and closed, while 1 was still pending.

f. **Preparation of DER Quality Documents**:
A total of Thirty-Six (36) 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.

g. **Meetings:**
A total of Ninety-Five (95) meetings were attended by staff of the unit throughout the year. In the 1st quarter, a total of 19 meetings were attended which includes.

- Participation in the meeting between NAFDAC, Nippon Chemiphar, Japan and International Finance Corporation.
- Participation in the meeting on the establishment of NAFDAC Desk offices in the Local Government Areas.

In the 2nd quarter, a total of 24 meetings were attended by members of the QMS unit which includes.

- Participated in the inauguration of the mRNA Technology Transfer Hub in South Africa (virtual participation)
- Participated in the Workshop on Achieving Quality and Sustainable Local Vaccine Production in Africa to Improve Access, Kigali, Rwanda.
- Represented the Agency in the workshop on Improving the Availability of Quality Uterotonics to Reduce Pregnancy-Related Deaths in Nigeria.
- Represented the Agency in the training on MRNA Vaccine Drug substance manufacturing at Afrigen Biologics South Africa.

In the 3rd quarter, a total of Twenty-Eight (28) meetings were attended by staff of the Unit which includes.

- Participation in meeting on International Coalition of Medicines Regulatory Agencies (ICMRA) Product Quality Knowledge Management System (PQKMS)
- Participation in meeting between NAFDAC and United Nations Office of Project Services (UNOPS)
- Represented the Agency in meeting on MOU with South African Health Products Regulatory Authority (SAHPRA)
- Participated in the Seminar by USFDA on Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
- Participated in the meeting between DG-NAFDAC and selected Local Drug manufacturers & Designated inspectors in lieu of upcoming WHO observed audit.

- Attended all GBT meetings held within the period under review with focus on addressing the ML4 sub-indicators.

In the 4th quarter, a total of Twenty-Four (24) meetings were attended by members of the QMS unit. They include:

- Participation in the API & Excipients workshop.
- Participation in meetings of ICHQ1/Q5C Sub teams, Regulators and Full Expert Working Group meetings.
- Participation in the ICH meeting in Prague, Czech Republic
- Attended and represented NAFDAC at the Afrisummit on PharmaReg at Cairo Egypt, 8th-9th October 2023.
- Participation in MOU signing ceremony between NAFDAC and Egyptian Drug Authority.

Ad-Hoc Duties:

- The unit was saddled with the task of preparing and providing key information to other Divisions, Directorates and DGs office directly. A total of sixty-seven (67) key information were generated by the unit and provided to the required users.
- A total of Nine (9) papers/presentations were prepared by the unit for different programs of the Agency within the year 2023.
- Staff of the Unit participated in/conducted Eleven (11) Agencywide QMS activities in the year 2023. Some of such activities includes participating in the Agencywide management review meeting, participating in the Agencywide internal audit and follow-up audits.
- The unit coordinated the NAFDAC WHO GBT assignments, gathered required evidences for the IDPs from RI and CTO functions and onward submission of evidences to the WHO Share-Point, coordination of the submission of evidence for the critical and new recommendations to address IDPs raised by WHO for the sustenance of WHO ML 3 for NAFDAC; and participation in all GBT meetings, GBT internal self-benchmarking exercise and focusing on addressing the ML4 sub-indicators leading to the advancement to WLA.

Chapter Six
Ports Inspection Directorate (PID)

6.1 Introduction

In the year under review, the Ports Inspection Directorate was responsible for verifying that all products subject to regulation by NAFDAC, whether imported into or exported from Nigeria, complied with the necessary quality and safety standards. The directorate's duties encompassed various statutory functions, including:

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

The Directorate conducted these tasks through its various divisions, port offices, outstation offices, and checkpoints at land borders.

6.2 PID Formations

a. Divisions: The Directorate comprises Six (6) divisions: the Director's Office Division, the Port Chemical, Cosmetics, and Medical Devices Division (CCMD), the Port Drug Division, the New Technologies/Port Clearance Division, the Port Food Division, and the Export Division.

b. Port Offices: NAFDAC operated 10 port offices across Nigeria, comprising six seaports (Apapa, Lekki Deep Sea, Tincan, Kirikiri Lighter Terminal, Lilypond, Ikorodu) and four airports (Murtala Mohammed International Airport in Lagos, Aminu 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.

6.3 Activities Summary

6.3.1 Transaction Summary

In 2023, the Port Inspection Directorate (PID) handled a range of port clearance transactions, encompassing inspection, analysis, radiation charges, administrative approvals, and penalties for violations.

- In 2023, a total of **1,270,598,904.93** metric tons were processed, with a CIF value of **₦28,708,695,424,062.30.**
- In addition, 2,676 violations were treated, which is about a 13% **increase** compared to the 2,376 cases reported in 2022.

- In the year under review, 63,216 SGD were processed, compared to 57,392 SGD processed in 2022, marking a 10.15% **increase** in the number of SGD processed in 2023.

Table 6.1: Transaction Summary Table for 2023

PID Office Locations	**No. of Transactions**
Lagos Ports	48,872
Land Borders	479
Outstations	13,865
Director's Office	625
Export	-
Totals	63,841

Table 6.2: Details of Export Activities

Product Group	Applications Received	Weight (MT)	*Certificates Issued*						
			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)	68	4286.377	51	-	17	-	13	-	25
Food Commodities (processed & semi processed)	15	342.674	-	2	2	-	4	1	1
Bulk Food Commodities	-	-	-	-	-	-	-	-	-
Drugs (Finished Pharmaceutical & Cigarettes)	35	182.889	15	8	-	15	1	2	9
Cosmetics	4	31.4784	5	2	-	-	-	-	-
Chemical	23	1286.891	3	2	-	-	-	17	4
Totals	**145**	**6,130.31**	74	14	19	15	18	20	39
			Total Certificates issued: 142. Total Export Approval: 18						

6.4 Treated SGDs

In the year under review, a total of 63,216 SGDs were processed. Among these, 48,872 SGDs were processed at the Lagos offices, 479 at land borders, and 13,865 at outstation offices.

Table 6.3: SGDs Treated in 2023

PID Formations	SGD Treated
Lagos Office	48,872
Land borders	479
Outstations	13,865
Total	63,216

6.5 Violation Reports

A total of 2,676 violations were addressed. The most common violation type was non-endorsement with 1,075 violations representing 40%. No permit had 484 violations representing 18%, Clean Report of Inspection and Analysis (CRIA) had 244 violations represent 9%, and Labeling lapse had 529 violations represent 19%.

Table 6.4: Violation Type

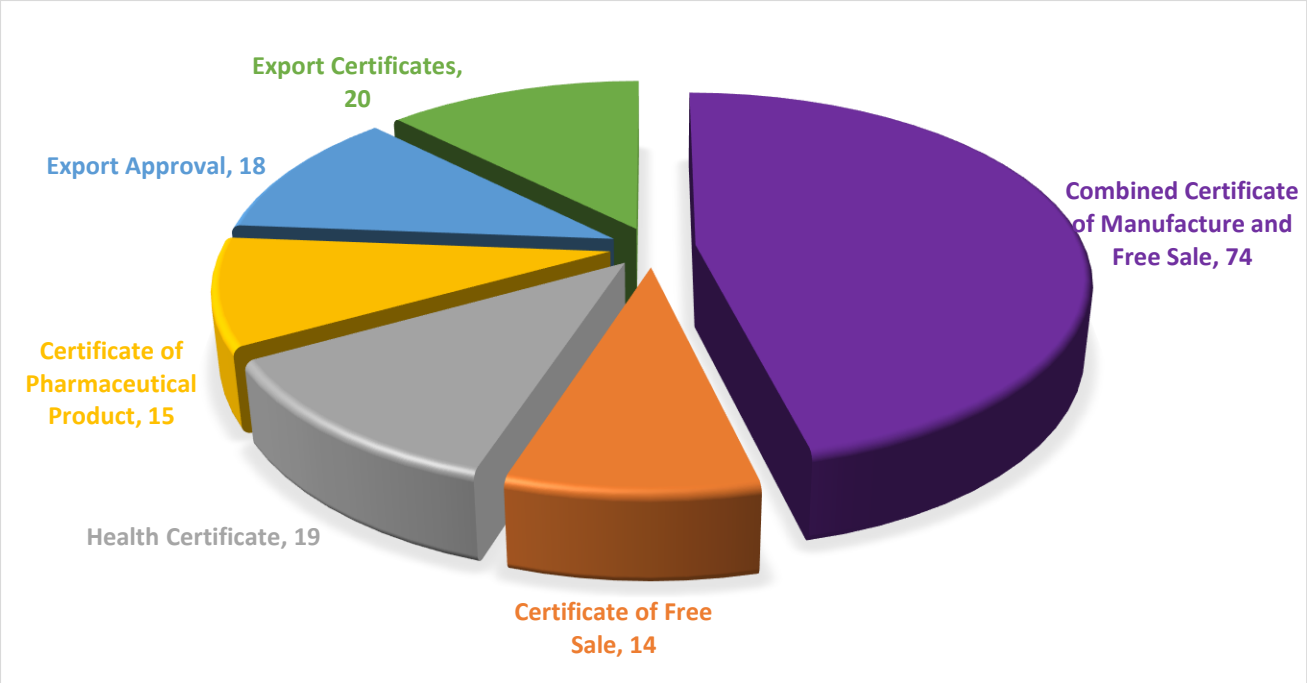
Types of Violation	No. of Violations
Change of Source	10
Concealment and False Declaration	5
Expired Certificate	27
Importation above Approved Quantity-Permit	43
Incomplete Packaging	2
Labelling Lapse	529
Mobile Authentication Service	18
No CRIA	244
No Permit	484
Non-Endorsement-Drugs	91
Non-Endorsement-Food	89
Non-Endorsement-Others	1,075
Removal of Seal before Inspection	8
Unapproved Pictorials	9
Unauthorized labelled packaging materials	1
Unauthorized Parallel Importation	2
Unregistered Pack Size	5
Unregistered Products	12
Others	22
Grand Total	2,676

6.6 Divisional/Outstations Report

6.6.1 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 Forty-Five **(145)** with One Hundred and Forty-Two **(142)** Certificates issued and Eighteen **(18)** Export Approvals given. Thirty-nine (39) compliance directives were issued.

Figure 6.1. Export Certificates Issued



6.6.2 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 Seven (7) holds were placed and twenty (20) holds were removed during the year in review.

6.6.3 Director's Office

During the reviewed year, e-licence unit in the Director's office issued ;

- **116** Letters of Non-Objection, **412** Authorizations to Open Form M,
- **48** Approvals for Materials for Machine Trials and Research Purposes,
- **33** Approvals to Import Donated Items by NGOs, and
- **16** Approvals to Import Products by Government Agencies, Multinational Organizations, and International Bodies.

6.6.4. Report of Samples for Laboratory Analysis

A total of 9,373 samples were sent to the laboratory for analysis during the year, of which 6,364 samples were satisfactory and 40 were unsatisfactory.

Table 13: Samples sent for Laboratory Analysis in 2023

Types of Samples	No. of Samples
Food	3,065
Drug	5,719
CCMD	589
Total	9,373

Chapter Seven
Drug Registration and Regulatory Affairs (DR&RA)

7.1 Introduction

The Drug R&R 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 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.

7.1.1 Divisions and Units of the Directorate

The Directorate now 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. Technical Services which comprises:
    - Regulations
    - Quality Management System
    - Dossier Review Team

7.2 Highlights of Activities:

The Directorate participated in a total of One Hundred and Five (105) meetings, stakeholders Engagement, training, media sensitization, workshops throughout the year.

1. Stakeholder engagement to discuss the draft Pharmaceutical Products (Traceability) Regulations, 2023 held 25th to 28th January 2023.

2. Training of North East Zone on the Registration and Inspection Modules of the NAFDAC Automated Product Administration and Monitoring System (NAPAMS) held 7 to 9th February, 2023.
3. Training of North West Zone on the Registration and Inspection Modules of the NAFDAC Automated Product Administration and Monitoring System (NAPAMS) held 13th to 15th February, 2023.
4. Participation at the Media Sensitization Workshop North West Zone, On the Dangers of Bleaching Creams and Regulatory Controls, Fed Secretariat Kano, Kano State on 9th February, 2023.
5. Training on Rudiments of Dossier Assessment/ Review for Drug R&R Dossier Assessors held 15th February 2023 at NAFDAC Auditorium Isolo, Lagos.
6. Training of all staff of Drug R&R on the Overview of Nutraceuticals held 14th March 2023 at the Drug R&R General Office, Isolo.
7. Participation at the Stakeholders Workshop for the Development of National Policy on Cosmetics Safety at Grace Hill Hotel Suite 5 Prof Obekpeya, Street, Opposite Mayday Hospital, Mararaba, Nasarawa State 14th to 17th March 2023.
8. Practical Training of Dossier Screening and Review on the Dossier App by DRT members held 15th and 22nd March 2023 respectively.
9. Stakeholder engagement with Federal Ministries of Health and Justice to discuss 10 draft Regulations held 20th to 24th March 2023 at Kebbi, Nasarawa State.
10. held 19th April 2023.
11. Participation in the Self Benchmarking of Vaccines, Biologicals and Medical Devices Laboratory services Directorate (VBM-LSD), Yaba on Lot Release Function held 23rd March 2023.
12. Participation at the Virtual Meeting of NAFDAC Expert Vaccine Advisory Committee (NEVAC) and NAFDAC Vaccine Committee Members to discuss the review outcome to the R21 Malaria Vaccine held 14th April 2023
13. Participation at the Stakeholders Engagement with SRA Dev On invitation from CER Directorate Towards Strengthening Enforcement of Mercury Added Products (Cosmetics) in Nigeria on 18th April 2023 DGs Conference Room, NAFDAC Complex, Isolo, Lagos.
14. Training of all Drug R&R staff on Good Review Practices held on 15th August 2023 at the Drug R&R Office, Isolo, Lagos.
15. Participation at the Africa Medical Devices Forum (AMDF)/ USFDA Workshop on Medical Device Regulatory Convergence held in Nairobi, Kenya between November 6th to 10th November 2023.
16. Participation at the Risk Assessment Capacity Building Workshop for West and Central Africa Sub-Region held in Grand Bassam, Cote D' Ivoire between 7th to 8th November, 2023
17. Virtual participation at the Webinar on "Modern Approaches to mRNA Manufacturing organized by USP Education held 8th November 2023.
18. Visit to Legal Drafting Department of Federal ministry of justice to follow-up on NAFDAC Regulations on 13th November 2023
19. Participation at the Training on deployment of Traceability scanners held between 14th
20. 2023 held at the Leola Hotel, Ikeja, Lagos between 22nd to 23th November, 2023

21. Representing the Director -General at the Corporate Wellbeing & Beauty Technologies Expo held in Lagos between the 23rd to 24th November, 2023
22. Stakeholder Engagement with the Pharm Industry on the Dossier Review Pathway held 24th November, 2023
23. Participation at the Task Force meeting on Medicinal Products Pediatrics Regulation (MPPR) Held on Thursday, November 28, 2023, at NAFDAC Office Isolo, Lagos
24. Co-ordination of the Meeting of Pediatric Medicines Regulations Committee to discuss draft Pediatric Medicines Regulations held 28th November 2023
25. Training of the Dossier Review Team (DRT) on the New Screening Checklist for Screening Dossiers on Dossier Management System (DMS) and Drop Box held 29th November 2023 at the NAFDAC Auditorium, Isolo, Lagos.
26. Virtual Participation at the Webinar on Wider Stakeholders Engagement on the Continental Pilot of Medicinal Products Listing Organized by AMRH, AUDA-NEPAD on 2nd December 2023
27. Virtual Participation at the 6th Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA VI) Organized by AUDA-NEPAD in Collaboration with WHO between 5th to 7th December 2023

***(A)* Statistical Analysis of Applications received and approved at the Divisions.**

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

A total of Six Thousand, Six Hundred and Fifteen applications were processed for Registration (57.5%), Renewal (36.1%) and variation (6.4%) and as listed below:

Table 7.1: Number of applications treated based on application type in 2023

Number of applications based on Application type in 2023			
S/No	**Application Type**	**Nos**	**%age**
1	Variation	426	**6.4**
2	New Registration	3,803	**57.5**
3	Renewal	2,386	**36.1**
	Total	**6,615**	

Figure 7.1: Application type

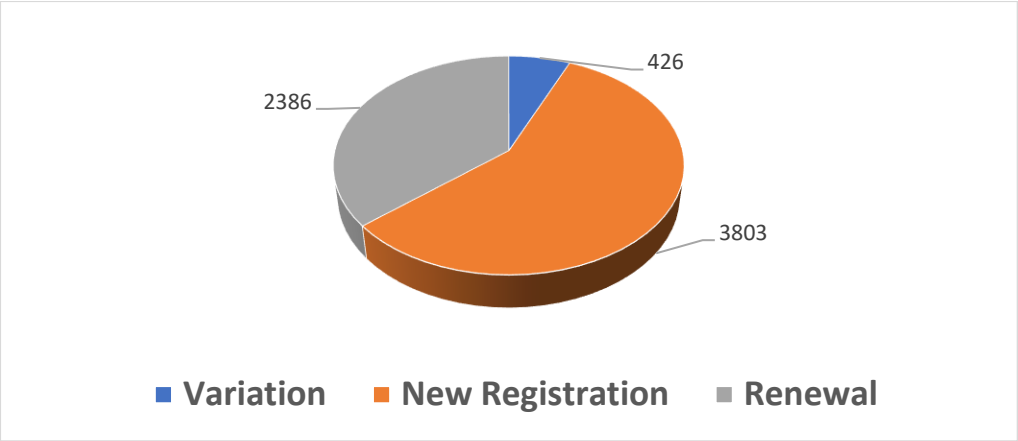
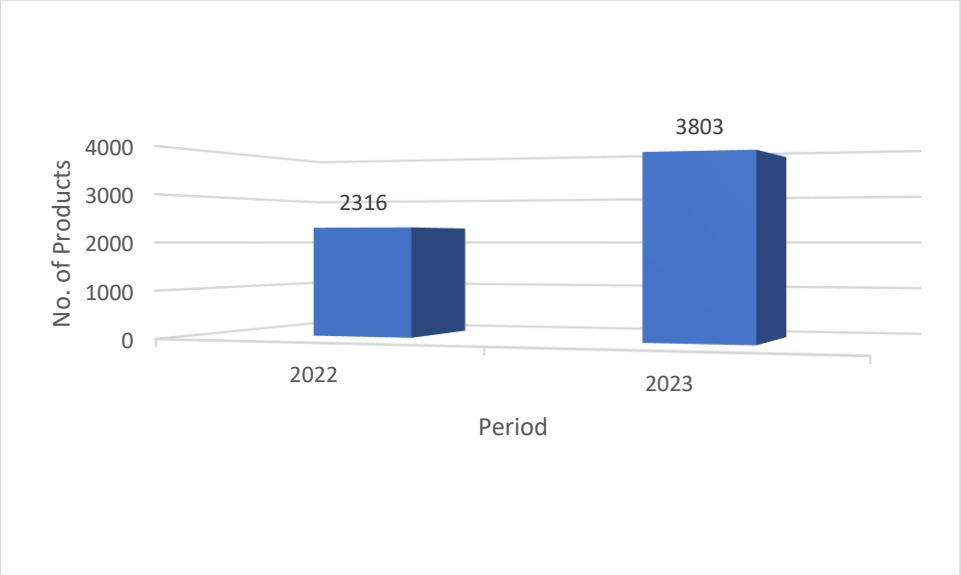


Table 7.2: Percentage of Registration/Renewal and Variation Approvals in 2023

S/No	Product Category	Nos	%age
1	Agro-Chemicals	358	5.4
2	Cosmetics	1,928	29.1
3	Drugs	2,062	31.2
4	Herbal and Nutraceuticals	1,084	16.4
5	Medical Device	439	6.6
6	Vaccines & Biologicals	165	2.5
7	Veterinary Products	579	8.8

Comparative Analysis of Registered NAFDAC Regulated Products 2022-2023

Figure 7.2: Comparative Analysis of New Product Registration in 2022 and 2023



This represents a 61% increase over the figures of the same period in year 2022 (Two Thousand, Three Hundred and Sixteen (2,316) Products.

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

S/No	Product Category	2022	2023
1	Agro-Chemicals & Pesticide	321	358
2	Cosmetics	1,445	1,928
3	Drugs	1,085	2,062
4	Herbal and Nutraceuticals	738	1,084
5	Medical Device	356	439
6	Vaccines & Biologicals	63	165
7	Veterinary Products	330	579
	Total	**4,338**	**6,615**

Figure 7.3: Total Applications (Registration, Renewals and Variation Approvals) processed in 2023

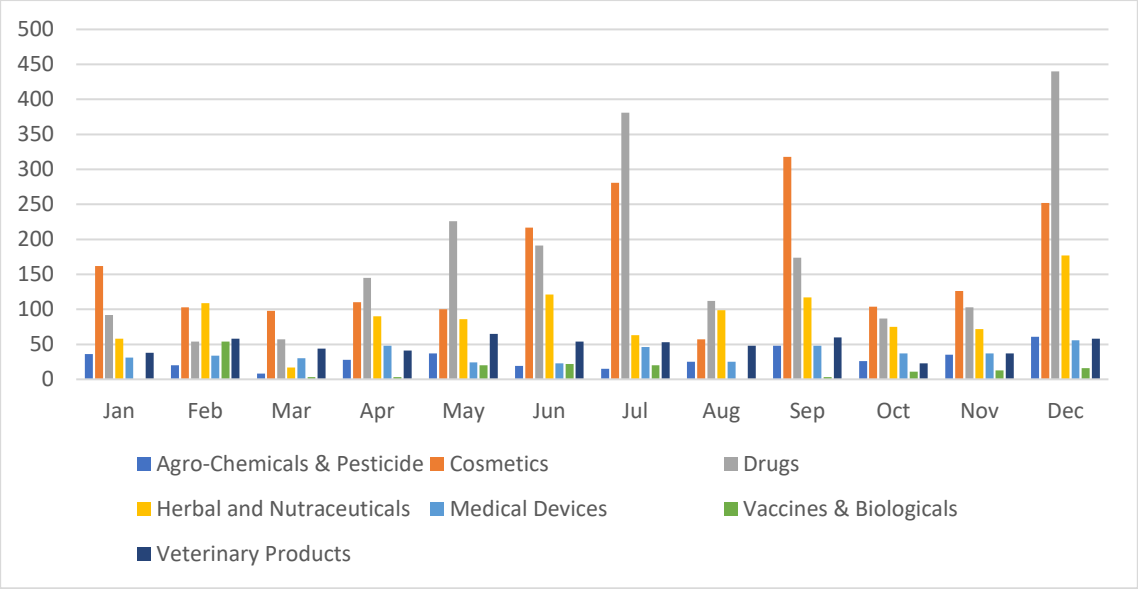


Table 7.5: Summary of the Activities of Drug and Related Products Registration Divisions

Data on Total Applications (Registration, Renewals and Variation Approvals) processed in 2023								
Month	Product Category							
	Agro-Chemicals & Pesticide	Cosmetic	Drugs	Herbal and Nutraceuticals	Medical Devices	Vaccines & Biologicals	Veterinary Products	Total
Jan	36	162	92	58	31	0	38	417
Feb	20	103	54	109	34	54	58	432
Mar	8	98	57	17	30	3	44	257
Apr	28	110	145	90	48	3	41	465
May	37	100	226	86	24	20	65	558
Jun	19	217	191	121	23	22	54	647
Jul	15	281	381	63	46	20	53	859
Aug	25	57	112	99	25	0	48	366
Sep	48	318	174	117	48	3	60	768
Oct	26	104	87	75	37	11	23	363
Nov	35	126	103	72	37	13	37	423
Dec	61	252	440	177	56	16	58	1,060
Total	**358**	**1,928**	**2,062**	**1,084**	**439**	**165**	**579**	**6,615**

Table 7.6: Summary of Applications Submitted, Approvals and Sources for 2023

S/No	Product Category	Product Source	No of Applications Submitted	No Approved	Total Application Submitted	Total Approved
1	Agrochemicals	Imported	138	278	176	358
		Local	38	80		
2	Cosmetics	Imported	206	356	735	1,928
		Local	529	1,572		
3	Drugs	Imported	498	1,492	744	2,062
		Local	246	570		
4	Herbal and Nutraceuticals	Imported	316	715	469	1,084
		Local	153	369		
5	Medical Devices	Imported	147	377	174	439
		Local	27	62		
6	Vaccines and Biologicals	Imported	24	164	24	165
		Local	0	1		
7	Veterinary Products	Imported	75	230	236	579
		Local	161	349		
	Grand Total	**Grand Total**			**2,558**	**6,615**

Please note that the number of applications received may be lower than the number of approvals because applications may be approved from previous submissions

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

- Five Thousand, Three Hundred and Sixteen (5,316) drugs and related products applications were received and sent to the Legal Unit for perusal.
- Nine Thousand, Five Hundred and Fifteen (9,515) 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 with 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).

- Three Thousand, Seven Hundred and Sixty-Five (3,765) certificates were prepared in the period under review. Breakdown: Drug (151), Cosmetic products (0), packaged water (150), Food products (3231), Medical devices (5), Herbal (69), Veterinary products (0), Pesticides (0) and correction & omissions (159).
- Three thousand, one hundred and six (3,106) products were keyed into the NAFDAC Registered Products Automated Database (NARPAD).
- Two Thousand, Three Hundred and Sixteen (2,316) Registration and Listing certificates were issued in the period under review. Breakdown: drug (669), food (450), cosmetics (231), pesticides (54), veterinary drugs (116), medical devices and biological & vaccines (62), herbal (103) and water (587).
- Six thousand, One Hundred and Eighty-Nine (6,189) products were uploaded on the NAFDAC Green book by the Unit.

(D) Regulations:

Three (3) Regulations were sent to NAFDAC Council for approval. They are:

- Pharmaceutical Products (Traceability) Regulations 2023
- Vaccine and other Biological Products (Lot Release) Regulations 2023
- Cosmetics Products Registration Regulations, 2023

Chapter Eight
Food Registration and Regulatory Affairs (FR&RA)

8.0 Introduction

The Food R&R Directorate is one of the Directorates of the Agency whose functions are anchored on the provisions of the Food, Drugs and Related Products (Registration, etc.) ACT Cap F33 Laws of the Federation of Nigeria (LFN) 2004 viz:

- Registration of food and packaged water. Other functions are as follows:
- Formulating, updating, compiling and periodic review of Regulations and Guidelines for the production, importation, exportation, sale and distribution of food and bottled water
- Approval and control of advertisements of food, and packaged water to ensure that advertisements are not exaggerated, deceptive or detrimental to the consumer.
- Monitoring of advertisements to ensure compliance.

8.1 Divisions and Units of FR&R Directorate

The Directorate comprises the following Divisions and Units:

1. **Food Registration Division (FRD):**
    i. Unit I (Lagos & Oyo States)
    ii. Unit II (South-South, South-East & Ogun State)
    iii. Unit III (North-Central, North-East, North-West & Other South-West States)

2. **Imported Food and Feeds Division (IF&F):**
    i. Imported Food Unit I (Europe & America)
    ii. Imported Food Unit II (Asia, Africa & Oceania)
    iii. Feeds (Imported& Made in Nigeria)

3. **Food Regulations Division (FReD)**
    i. Regulations Unit
    ii. QMS Unit

4. **Advertisements Control Division (AC):**
    i. Advert Registration Unit
    ii. Advert Monitoring & Control Unit

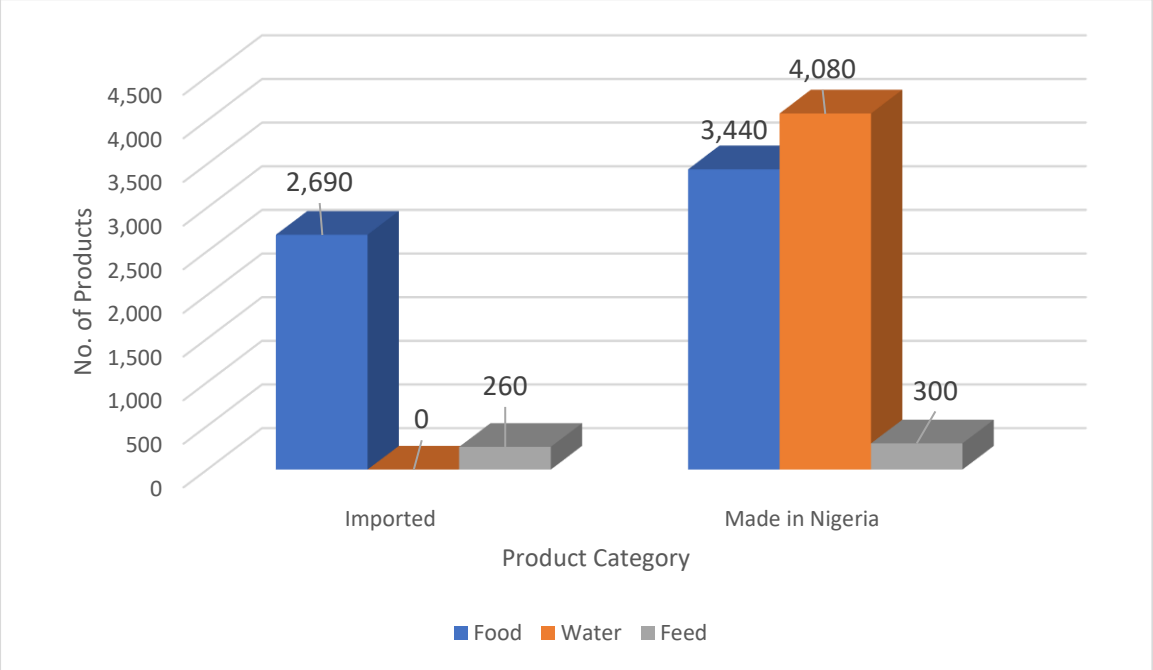
5. **Packaged Water Division (PWD):**

6. **The Director's Office** consists of**:**
    i. Liaison Office of the Director (LOD)
    ii. Global Listing of Supermarket Items & Fast Foods

Table 8.1: Number of Products Registered by Category

Number of Products Registered				
	Food	**Water**	**Feed**	**Total**
Imported	750		40	790
Made in Nigeria Foods	2,690		260	2,950
Water		4,080		4,080
Total	3,440	4,080	300	7,820
Remarks	A total of 7,820 Food Products were registered in 2023			

Figure 8.1: Number of Products Registered by Category



Highlight of Activities

A. The Directorate registered a total of Seven Thousand, Eight Hundred and Twenty food products during the year under review.
B. Twelve (12) sub-FDRC Approval Meetings for food product registration were conducted.
C. Officers in the Directorate participated in:
    1. FR&RA Management Review Meeting held on 3rd November 2023 at NAFDAC Auditorium.
    2. FR&A Committee Members attended various NAPAMS Reversioning Committee Meetings to enable improvement in internal processes.

3. Directorate Quality Management System (QMS) Internal Audit.
4. Monthly Directorate Meetings.
5. In-house review of Eleven (11) draft Regulations by Regulations Technical Committee, now hosted on the Agency website for public comments. The Regulations included the Three (3) draft Food, Bread, Malt and Sugar Confectionery Regulations.
6. Two (2) new guidelines developed and hosted on NAFDAC website; Guidelines for Change of Formulation of Food and Feeds Product and Guidelines for Registration of Bulk/Semi Processed Food Products for Export.
7. Fats and Oils and Food Containing Fats and Oils Regulation 2022 and Pre-Packaged Food Labelling Regulations 2022 are now gazetted and launched by the DG (NAFDAC) and currently at the phase of implementation.
8. Stakeholders Engagement: DG's Meeting held with Chief Executives of Association of Food, Beverages and Tobacco Employees.
9. Tripartite Internal stakeholders Meeting held quarterly with Directors of Laboratory Services (Food) and Food Safety and Applied Nutrition (FSAN) to foster Food Product Registration and Harmonize food processes in the Agency.
10. Staff participation in the ISO-22301 Business Continuity Management System (BCMS) meeting organized by Philips Consulting Limited in collaboration with NAFDAC ICT held at NAFDAC Isolo Auditorium.
11. Deployment of Three (3) Deputy directors to the Directorate.
12. Dialogue Meeting with Stakeholders on Online Advertisement.
13. Consultative Meeting with WAPAN.
14. Hosted internal stakeholder meeting via Google Meet with Zonal directors to strengthen collaboration and bridge information gap.
15. Marked World Food safety and Health day
16. Held various briefing and debriefing meetings with stakeholders on registration issues.
17. Strengthening end to end processes on NAPAMS and digitization of all our processes.
18. Ongoing development and review of Guidelines and SOPs.

Chapter Nine
Chemical Evaluation and Research (CER) Directorate

8.1 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:

I. Chemical Import Control (CIC)
II. Agrochemicals and Controlled Chemicals Division (AC/CC)
III. Chemical Monitoring and Risk Assessment (CM&RA)
IV. Chemical Research and Review (CR&R)

b. Functions of CER

I. Ensure availability of chemicals to bonafide 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)
II. Undertake and co-ordinate research programs on the storage, adulteration, distribution and rational use of chemicals
III. Carry out the Risk Assessment of Chemicals
IV. Issue Authorizations/Licenses to Chemical Marketers and Manufacturers
V. Inspect Warehouses for Storage of Chemicals
VI. Generate relevant reports & statistics on Chemicals
VII. Investigate breach of regulations on chemicals by companies and individuals.
VIII. Safeguard the health of the populace and environment by ensuring sound chemical management
IX. Ensure conformity to International Standards for controlled and restricted Chemicals
X. Conduct surveillance and monitor hazardous and harmful Chemicals in circulation

8.2 Summary of Activities

In 2023, a total of Twenty-Seven Thousand and Ninety-Two (27,092) regulatory activities were carried out by CER Directorate nationwide. Twenty-Four Thousand, One Hundred and Sixty-Seven (24,167) 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, Three Hundred and Thirty-Three (8,333) 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, One Hundred and Forty-Five (3,145) permits to import were approved for both general and restricted Chemicals while One Thousand One Hundred and Ninety-Six (1,196) permits to clear were issued for restricted chemicals. Eight Hundred and Eight (808) facilities were listed as chemical marketers and manufacturers and issued Listing Notifications. A total of One Thousand, Five Hundred and Thirty-Eight (1,538) satisfactory inspection activities were carried out in the year under review.

One Hundred and Thirty-One (131) routine monitoring inspections were carried out in Lagos. Nine Hundred and Ninety-Seven (997) Compliance Directives were issued for various inadequacies and incomplete documentations.

Table 8.2: Activities of CER in 2023

S/N	Type Of Activities	Total
1	No of applications received for Permit to Import	4,367
2	No of applications received for Permit to Clear	1,196
3	No of applications received for Warehouse inspection	1,046
4	No of applications received for Listing Certificate	891
5	No of applications received for LPO verification	388
6	No of applications received from outstation for permits to import/clear, warehouse inspection, LPO verification and Listing certificates	445
7	No. of applications treated for Permit to import	844
8	No. of applications treated for Listing Certificate	523
9	No. of applications treated for Permits to Clear	1,196
10	No. of applications treated within timeline	2,511
11	No. of applications in progress	1,255
12	No of E-permits to Import issued	3,145
13	No of E-permits to Import issued within timeline	3,145
14	No of approved permits to Clear	1,196
15	No of approved permits to Clear issued within timeline	1,196
16	No. of Listing Notifications issued to Chemical Marketers	797
17	No of Listing Notifications issued to Chemical Manufacturers	11
18	No. of Listing Certificates prepared for DG'S endorsement	0
19	No of inspections conducted (Satisfactory reports)	1,399
20	No. of follow - up inspections	8
21	No. of routine monitoring inspections	131
22	No of surveillance inspections	0
23	No. of LPO verification treated	393
24	No. of LPO verification untreated	5
25	No. of Queries/CDs issued	997
26	No. of consultative meetings/seminar and workshop held	0
27	No. of Violations	7
28	No. of Warehouses/Products/Consignments put on Hold	0
	Total	**27,092**

Table 8.2: Comparative Analysis of Key CER Regulatory Activities 2021-2022

SN	Activities	2022	2023
1	Number of Regulatory activities recorded	25,249	27,092
2	Number of Applications received	8,382	8,138
3	Number of Permits to Import issued for General and Restricted Chemicals	3,260	3,260
4	Number of Permits to Clear issued for Restricted chemicals	1,271	1,196
5	Number of Inspections Conducted	1,387	1,399
6	Number of Listing notifications issued to Chemical Marketers	619	797
7	Number of Queries/CDs issued	550	997

The Chemical Evaluation and Research Directorate recorded huge level of success in 2023. A significant higher number of regulatory activities were recorded in 2023 as compared to 2022. The Directorate also recorded a significant higher number of queries and compliance directives. This may be attributed to monitoring exercises carried out in Lagos and outstation offices within the year.

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 8.3: Performance Outlook for January – December 2023

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	95%
3	Prompt issuance of Permit to Clear restricted chemicals to marketers within timeline	100%

Table 8.4: CER Outstation Activities 2022

S/N	Outstation	Number of Activities
1	South West	351
2	South East	589
3	South South	786
4	North West	342
5	North East	67
6	North Central	156
7	Fct Abuja	618
	Total	2,925

8.3 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.

8.4 Other Activities and Meetings Attended

1. Development of Chemical and Chemical Products Regulations
2. 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)
3. Digitalization of processes for permits to clear for restricted chemicals and listing certificates for chemical manufacturers.
4. Deployment of guidelines for production Inspection of chemical manufacturing facilities in Nigeria and guidelines for NAFDAC Good Manufacturing. Practice for chemicals and chemical products.
5. Organization of stakeholders' sensitization Meeting for Chemical stakeholders on recent development in chemical industry.
6. Organization of sensitization campaign for South East Zone on Sound management of Chemicals
7. In-house Human Capacity Building Program on Chemical Monitoring of CER Regulatory Officers.
8. Organization of 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)

Routine

One Hundred and Thirty-One (131) surveillance Inspection activities were carried out in the year under review.

Surveillance

Two Hundred and Seventy-Eight (278) surveillance inspection activities were carried out in the year under review.

Local Purchase Order Verifications

Three Hundred and Ninety-Three (393) 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 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 Nine
Narcotics and Controlled Substances (NCS) Directorate

9.1 Introduction

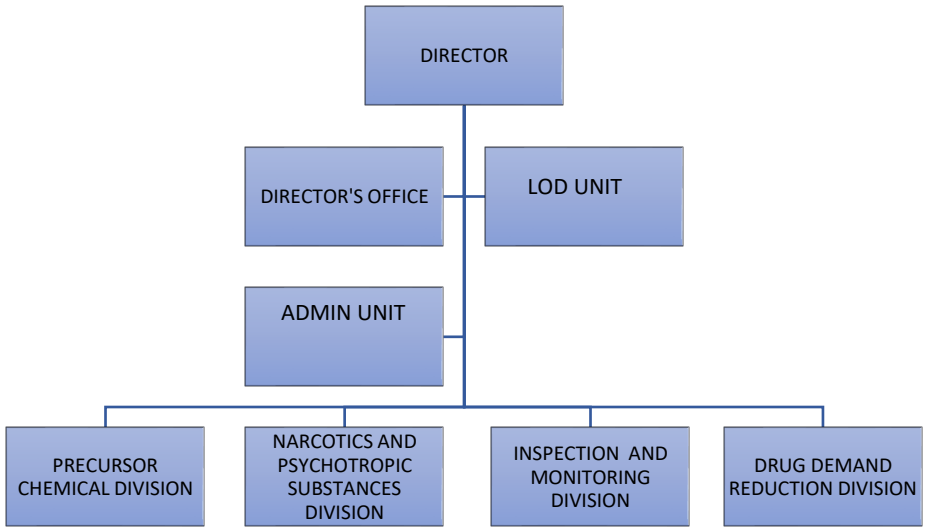
The Directorate has the mandate to carry out the following functions,

- 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



Activities of the Narcotics and Controlled Substances Directorate in 2023.

Routine activities which include the following:

i. Processing of applications for permits & authorizations to import and clear;

ii. Response to Pre-export Notification (PEN) and Export Authorization;

iii. Inspection 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 Directorate carried out the following programs:

A. NCS Stakeholders Meeting:

As part of the agency's mandate to engage our stakeholders with the responsibility of ensuring that narcotic drugs, psychotropic substances and precursor chemicals are not diverted to illicit use but available only for medical, scientific and industrial use, Stakeholders Engagement was organized and held 22nd June, 2023 at Manufacturers Association of Nigeria (MAN) House. The meeting was well attended with over four hundred and fifty (450) participants. Stakeholders were trained on observed regulatory issues: Regulation on Controlled Substances, Good Documentation and Warehousing Practices and Traceability.

B. National Technical Working Group on Harm Reduction

An NCS staff participated in the National Technical Working Group on Harm Reduction program held between 3rd-5th July, 2023 in Maiduguri, Borno State. Participants were drawn from the following organizations - FMOH, NACA, NDLEA, NHRC, NCS, NPF, NSCDC, NAFDAC, and experts from FNPH across the Country, Academia, CCM, FHI360, CSOs etc. Considering the uniqueness of the country's implementation of harm reduction, it was resolved to expand WHO's 10 Comprehensive Harm Reduction package to 11 to include provision of Psychosocial and Economic support to Substance Users. A major take home from the meeting was the need to ensure the provision of additional services for PWID (People Who Inject Drugs) from IPs (Independent Partners) and CSOs involved in screening activities for related co-morbidity such as HIV and Hepatitis. These additional services are basically vaccination, counselling and treatment depending on the outcome of screening.

C. Meeting to Validate Strategy for Cannabis Research and Value Chain Development in Nigeria:

NCS participated in the above meeting organized by the raw Materials Research and Development Council (RMRDC) held in Abuja, FCT on the 26th May, 2023. The Agency was invited to the meeting to participate in the validation of strategy and document for value chain development in Nigeria. The RMRDC and relevant stakeholders were proposing for legalization and regulation of cannabis for medical and industrial use.

However, the participant recommended that inter-directorate committee be set up by the Agency to review the draft documents before further action bearing in mind the extant Indian Hemp ACT and NDLEA ACT1.

D. Stakeholders' Forum for South East Facilities/Clients:

In a bid to ensure frequent engagement with stakeholders in compliance with ISO 9001 2015 specifications, Narcotics and Controlled Substances Directorate sent an officer to the stakeholder meeting in the zone held between 26th-27th July, 2023. The officer anchored presentation on Documentation in NCS processes and was well attended by key stakeholders.

E. World Drug Day 26th June, 2023 with NYSC, Oshodi, Lagos:

NCS marked the International day against drug abuse and illicit trafficking to strengthen action that foster cooperation in achieving a society free of Drug Abuse/Misuse. The Sensitization was carried out on the need to treat drug users with respect and empathy. The campaign also called for collaborative effort of everyone especially the youth to combat stigmatization and discrimination against drug addicts by promoting humane language, attitudes, respect and being non-judgmental.

F. Traceability Pilot Meeting with the Solution Provider, New Soft PLC:

The meeting held on 19th July 2023. It was extensively discussed in the meeting the modus operandi for implementation of traceability program. The Director-General had directed that importers of tramadol whose products are not yet in the country should obtain Global Trade Identification Number (GTIN) and Global Location Number (GLN) before permit to clear is issued. Letters are being sent to concerned importers.

G. Regional Expert Group Meeting (EGM) On Prevention Of New Psychoactive Substances (NPS) and Non-Medical Synthetic Opioid Trafficking Through Logistic Services in Central and West Africa:

NCS participated in the above meeting organized by the International Narcotics Control Board (INCB) held in Lagos between 2nd - 5th August, 2023.

The INCB's Global Rapid Interdiction of Dangerous substances (GRIDS) Programme convened a regional Expert Group Meeting (EGM) on the prevention of NPS and synthetic opioid trafficked through Logistic services in Central and West Africa. The convener, INCB was calling for cooperation between national regulatory authorities and private sectors to prevent trafficking in dangerous substances (NPS and synthetic opioid) in the region. Experts from governments, logistics and transport services companies and international organizations from the region were in attendance.

H. National Drug Control Master Plan (NDCMP) Technical Working Group (TWG)

The meeting was held on 31st August 2023 to review and finalize the 2022 report in preparation for the next Inter Ministerial Committee Meeting in which 2023 work plan implementation and sundries would be discussed. NAFDAC and FMoH are directly responsible for Pillar 3 of the NDCMP which addresses Access and Control of Controlled medicines.

I Technical Working Group on Access and Control of Controlled Medicines.

The Director (NCS) led the NAFDAC team to the meeting that took place between 5th to 7th September 2023.

J. Heads of National Drug Law Enforcement Agencies (HONLEA) Africa (HONLAF)

The 31st meeting of HONLEA, Africa organized by the United Nations Office on Drugs and Crime (UNODC) and hosted by the Government of Nigeria was held in Abuja, between 26th-29th September 2023. The Director, Narcotics and Controlled Substances (NCS), alongside officers of NDLEA, represented Nigeria at the regional conference.

K. NCS Stakeholders Meeting on Traceability:

A Stakeholders Engagement was organized and held on 9th November 2023 at NAFDAC auditorium, Isolo, Lagos in preparation for the pilot test on traceability project for narcotic medicines. The hybrid meeting was well attended with over two hundred (200) participants both on-site and on-line. Stakeholders were trained by the GS1 on how to obtain and use GTIN and GLN in Traceability. There were also series of engagements with public and private health facilities utilizing schedule 1 narcotics for the traceability pilot.

L. Meeting Between INCB GRIDS AND NAFDAC Held at NAFDAC Office In October 2023

NCS participated in the meeting-

The Director General, NAFDAC- Prof. Mojisola Adeyeye with her NFDAC team and the regional Technical Officer, INCB GRIDS- Mr. Bedi, O. Amare and Mr. Fumio Ito were in attendance.

- The **INCB GRIDS** meeting was held on 24th October to deliberate on overview of the INCB and GRIDS programmes and raising awareness for voluntary cooperation with private sectors and Proposal for a national awareness.

M. Meeting Between Secretariat of INCB AND NAFDAC Held at NAFDAC Office in October 2023

The Director General, NAFDAC- Prof. Mojisola Adeyeye with her NAFDAC team and the regional Technical Officer, INCB GRIDS- Mr. Bedi, O. Amare and Mr. Fumio Ito were in attendance.

- The **Secretariat of INCB** meeting held 25th October, 2023 was organized by INCB for sensitization on voluntary contribution of stakeholders to raise awareness on emerging New Psychoactive Substances (NPS) using carrier service logistics.

N. Hospital inspection:

NCS Inspected Seven (7) private Hospitals to ascertain their sources of schedule 1 narcotics and its utilizations. Findings revealed that the private health institutions were sourcing from illegal sources.

O. Trainings

Seventeen (17) officers of the Directorate including D-NCS and other NCS management staff attended a total of Forty-Two (42) trainings on different subjects. Twenty-Four (24) were virtual and eighteen (18) were physical trainings.

Table 9.1. Summary of the Activities of NCS Directorate in 2023

S/N	Activities	Inspection and Monitoring	Narcotics and Psychotropic Substances	Precursor Chemical	Drug Demand Reduction	Total
	No. of Applications Received	164	1,131	709	-	2,004
1	Permit to import Controlled/Precursor Chemical	-	358	223	-	581
2	Permit to clear Controlled/Precursor Chemical	-	768	486	-	1,254
3	Permits to Import Psychotropic/other controlled drugs	-	358	223	-	581
4	Permits to Clear Psychotropic/ other controlled drugs	-	768	486	-	1,254
5	Authorizations to Import Narcotics (Bulk and Finished Schedule 1 Narcotics)	-	5	-	-	-
6	Authorizations to Clear Narcotics (Bulk and Finished Schedule 1 Narcotics)	-	1	-	-	-
7	Authorizations to Purchase finished Narcotics	-	66	-	-	66
	No. of Inspections		-	-	-	-
8	Schedule/routine Warehouse Inspections	164	-	-	-	164

	I. Satisfactory	150	-	-	-	150
	II. Unsatisfactory	4	-	-		4
	III. Inspection not held	10	-	-	-	10
9	Hospital Inspections	11	-	-	-	37
	I. Satisfactory	9	-	-	-	31
	II. Unsatisfactory	2	-	-	-	2
	II. Inspection not held	4	-	-	-	4
10	No of outstation inspection Reports Received	70	-	-	-	70
	I. Satisfactory	65	-	-	-	65
	II. Unsatisfactory	4	-	-	-	4
11	LPO/Sales Verification	190	-	-	-	190
	I. Satisfactory	87	-	-	-	87
	II. Unsatisfactory	75	-	-	-	75
	II. Verification not held	28	-	-	-	28
12	Surveillance	-	-	-	-	-
13	No of investigations conducted	-	-	-	-	-
14	No of investigations conducted (Outstation)	-	-	-	-	-
15	Outstation verification report received	-	-	-	-	-
16	**Total Permits/Authorisations Issued**	-	-	-	-	-
17	Permit to import Precursor chemicals, Psychotropic and other controlled drugs	-	358	223	-	581
18	Permit to clear Precursor chemicals, Psychotropic and other controlled drugs	-	768	486	-	1,254
19	Permit to import Precursor chemicals, Psychotropic and other controlled drugs within timeline	-	358	223	-	581
20	Permit to clear Precursor chemicals, Psychotropic and other controlled drugs within timeline	-	768	486	-	1,254
21	Authorizations to Import Narcotics (Bulk and Finished Schedule I Narcotics)	-	-	-	-	-
22	Authorizations to Clear Narcotics (Bulk and Finished Schedule I Narcotics)	-	-	-	-	-
23	Authorizations to Purchase finished Narcotics	-	66	-	-	66
	Export Authorizations		14			
	No of Export Authorizations non objected		14			

	No of Export Authorizations objected to		-			
24	Pre-export Notification (PEN)	-	46	85	-	131
	No of Pre-export Notification objected to	-	46	77	-	123
	No of Pre-export Notification non objected	-	-	8	-	8
25	No of schools, clinics, markets, NYSC Camps visited	-	-	-	39	39
26	Training (In-house/External)	15	10	9	5	39
27	Statutory Meeting/ Workshop/Stakeholder Consultative meeting	4	7	6	3	20
28	No of Violations	-	2	2	-	4

Chapter Ten
Veterinary Medicines and Allied Products (VMAP) Directorate

10.0 Highlights of Activities
10.1 Meetings/ Trainings/Workshops:

The Directorate has conducted/participated in the following trainings/workshops/meetings of the year 2023.

S/N	Meetings/ Trainings/Workshops
1.	Top Management Committee meeting held on 11th January, 2023
2.	Directorate Meeting held on 16th January, 2023.
3.	Training on Listing as Agrochemical Marketer; A Regulatory tool in Pesticides and Agrochemicals held on 23rd January 2023.

10.2 Inspections Conducted

A total of Eight Hundred and Seventy-Nine (879) inspections were conducted.

Inspection	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	ANNUAL TOTAL
Warehouse	29	19	5	25	78
AMR Monitoring	0	4	1	1	6
Production	2	2	5	2	11
Routine	32	21	18	25	96
Cold Chain	5	0	1	1	7
Surveillance	40	79	79	227	425
Removal of Hold Label	0	1	1	1	3
GMP Renewal	2	0	2	0	4
Advisory/ Outreach	15	0	4	15	34
GMP Risk Categorization	48	42	22	64	176
GMP Assessment	1	0	4	2	7
Risk Assessment	0	1	0	0	1
Pre-Production	2	0	2	0	4
Farm Verification	1	0	0	0	1
Courtesy Visit	1	0	0	0	1
Pre-Registration	5	1	0	1	7
Follow up	1	0	0	0	1
Investigation Inspection	0	1	0	0	1
Permit monitoring	0	0	10	6	16
Listing as toll-miller	0	0	3	1	4
Total	**202**	**176**	**172**	**369**	**879**

10.3 e-Licence/Permit/Certificate Issued:

A total of Three Hundred and Twenty-Five (325) e-License were issued in the Second Quarter.

Permit issued/Certificate	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Biannual Total
Import permits for Animal feeds, Concentrates, Additives, Premixes, and Fish meals.	177	44	22	94	243
Import permits for Bulk Pesticide and Agrochemicals.	20	6	5	15	31
Listing as Toll Miller	1	0	5	9	6
Permit for active Veterinary Pharmaceutical Ingredients	0	1	0	0	1
Listing license for Agrochemical Marketer	3	4	0	1	7
Authority to Clear	9	11	9	5	29
One-off Permit for importation of Pesticides and Agrochemical	3	2	3	4	8
Total	**213**	**68**	**44**	**128**	**325**

10.4 Sanction Activity

Type of Sanction	1st Quarter	2nd Quarter	3rd Quarter	4thQuarter	Biannual Total
Compliance Directive	10	20	10	10	50
Warning of Offenders	10	2	8	3	23
Seizure	15	48	3	6	72
Place on Hold	0	3	1	7	11
Admin Charges	26	5	2	6	39
Total	61	78	24	32	195

- Product Registration Samples sent to lab - 105
- Summary of Local GMP Inspection Sent to R&R– 65

Table 10.5: NAPAMS Inspection Applications-

NAPAMS Inspection Application treated at LOD	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Annual Total
	134	**1,049**	**349**	**348**	**1,880**

Table 10.6: VMAP Activities for the Year, 2023.

S/NO	Types of Activity	Veterinary Drug	Veterinary Vaccine	Veterinary Devices	Veterinary Cosmetics	Pesticides	Agrochemicals	Animal Feeds	Feed Additives /Concentrates/ Supplements and Premixes	Pet/ Companion Food	Others	Total
1	Advisory Inspection	0	0	0	0	0	0	0	1	0	0	1
2	Routine Inspection	13	0	0	1	4	40	35	3	0	0	96
3	Pre-production Inspection	0	0	0	0	0	0	0	13	0	0	13
4	Production Inspection	1	0	0	0	0	3	7	0	0	0	11
5	Pre-Registration Inspection	0	0	0	0	4	3	0	0	0	0	7
6	Follow-up Inspection	0	0	0	0	0	0	1	0	0	0	1
7	Cold Chain Facilities Inspection	5	2	0	0	0	0	0	0	0	0	7
8	Surveillance Inspection	199	6	1	4	28	119	61	4	3	0	425
9	Warehousing Inspection	0	0	1	1	0	3	15	53	5	0	78
10	Permit Monitoring	2	0	0	0	1	0	2	7	4	0	16
11	Renewal Inspection	2	0	0	0	0	0	1	1	0	0	4
12	Investigations Inspection	0	0	0	0	0	0	0	0	0	1	1
13	GMP Assessment	0	0	0	0	2	1	3	1	0	0	7
14	GMP Risk Categorization Assessment	57	1	0	0	44	60	6	0	8	0	176
15	Change of Formulation	0	0	0	0	0	0	0	0	0	0	0
16	Field Trial Monitoring	0	0	0	0	1	0	0	0	0	0	1
17	Toll Miller Inspection	0	0	0	0	0	2	0	0	0	0	2
18	Pet Store Inspection	0	0	0	0	0	0	0	0	0	0	0
19	Complaint Inspection	0	0	0	0	0	0	0	0	0	0	0
20	Farm verification Inspection	0	0	0	0	0	0	0	0	0	0	0

21	AMR Monitoring	6	0	0	0	0	0	0	0	0	0	6
22	Total no. of Inspection	285	9	2	6	84	231	131	83	20	1	852
23	GMP Certificate issued	0	0	0	0	0	0	0	0	0	0	0
24	Import Permit issued	0	0	0	0	20	15	43	157	1	0	236
25	Listing certificate issued	0	0	0	0	1	22	0	0	0	0	23
26	Authority to Clear	0	0	0	0	6	14	3	0	0	0	23
27	Overseas GMP inspection reports received/reviewed	0	0	0	0	4	0	0	0	0	0	4
28	Adverse drug event report	0	0	0	0	0	0	0	0	0	0	0
29	Alerts received	0	0	0	0	0	0	0	0	0	0	0
30	Dossier evaluation	0	0	0	0	0	0	0	0	0	0	0
31	Clinical Trial protocol reviewed	0	0	0	0	0	0	0	0	0	0	0
32	Clinical Trial supervisions	0	0	0	0	0	0	0	0	0	0	0
33	Fields trials Report Evaluation	0	0	0	0	0	0	0	0	0	0	0
34	Supervision of field trial	0	0	0	0	0	0	0	0	0	0	0
35	Regulations developed	0	0	0	0	0	0	0	0	0	0	0
36	Guidelines Developed/Reviewed	0	0	0	0	0	0	0	0	0	0	0
37	SOPs developed/Reviewed	0	0	0	0	0	0	0	0	0	0	0
38	Guidance documents developed	0	0	0	0	0	0	0	0	0	0	0
39	Consultative meetings held	4	0	0	0	0	0	0	0	0	0	4
40	Seminars/Workshops Attended	10	0	0	0	0	0	0	0	0	4	10
41	Stakeholders meeting attended	0	0	0	0	0	0	0	0	0	0	0
42	Advocacy/Outreach	0	0	0	0	1	0	0	1	0	0	2

43	Courses/Training, seminars, meetings, conferences and workshop attended	1	0	0	0	9	2	7	0	0	94	113
44	Collaboration with other agencies & stakeholders	0	0	0	0	0	0	0	0	0	0	0
45	Co-ordination of activities with other directorates	0	0	0	0	0	0	0	0	0	1	1
46	Investigation of prohibited / banned veterinary medicines	0	0	0	0	0	0	0	0	0	0	0
47	No of violative veterinary drug residue in food.	0	0	0	0	0	0	0	0	0	0	0
48	NAPAMS Inspection Application received	0	0	0	0	0	0	0	0	0	1880	1880
	Total/Products	300	9	2	6	125	284	184	241	21	1980	3152

Chapter Eleven
The Laboratory Services Directorate (Food & Chemicals)

Introduction

The Laboratory Services Directorate (Food & Chemicals) performs its activities through enhanced facilities, maintenance and capacity development of personnel in two Laboratories listed below:

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

1. Goals

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

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

2. Analytical Performance

The Laboratory Services Directorate (Food) received Twelve Thousand Eight Hundred and Thirty-Eight (**12,838**) samples in 2023. Three Hundred and Sixty-Eight (**368**) samples were carried over from 2022 bringing it to a total of Thirteen Thousand Two Hundred and Six samples (**13,206**) handled in 2023. Out of these, Twelve Thousand Nine Hundred and Seventy-Six (**12,976**) samples were analysed which represents **98.3%** output in 2023.

Table 11.1 below shows the summary of activities for the period under review with profile of samples handled in **Figure 11.1,** while **Figure 11.2** shows percentage of samples analysed. Of the analysed samples, **97%** of the samples were satisfactory as shown in **Figure 11.3. Figure 11.4** shows the Individual Laboratory performances. **Table 11.2** represents the samples received according to categories which are illustrated in **Figure 11.5**. The summary of Food samples received according to categories are further illustrated in **Figures 11.6**.

Table 11.1: Summary of Analytical Performance in the Year 2023

	No. of Samples Brought Forward	**No. of Samples Received**	**Total Number of Samples**	**No. of Samples Analysed**	**Number of Satisfactory Samples**	**Number of Unsatisfactory Samples**	**No. of Samples Pending**	**Percentage Performance**
Oshodi	368	12,838	13,206	12,976	12,553	423	230	98.3%
Calabar	0	0	0	0	0	0	0	0
Total	**368**	**12,838**	**13,206**	**12,976**	**12,553**	**423**	**230**	98.3%

Overall Performance = 98.3%

Figure 11.1: Profile of Samples Handled in 2023

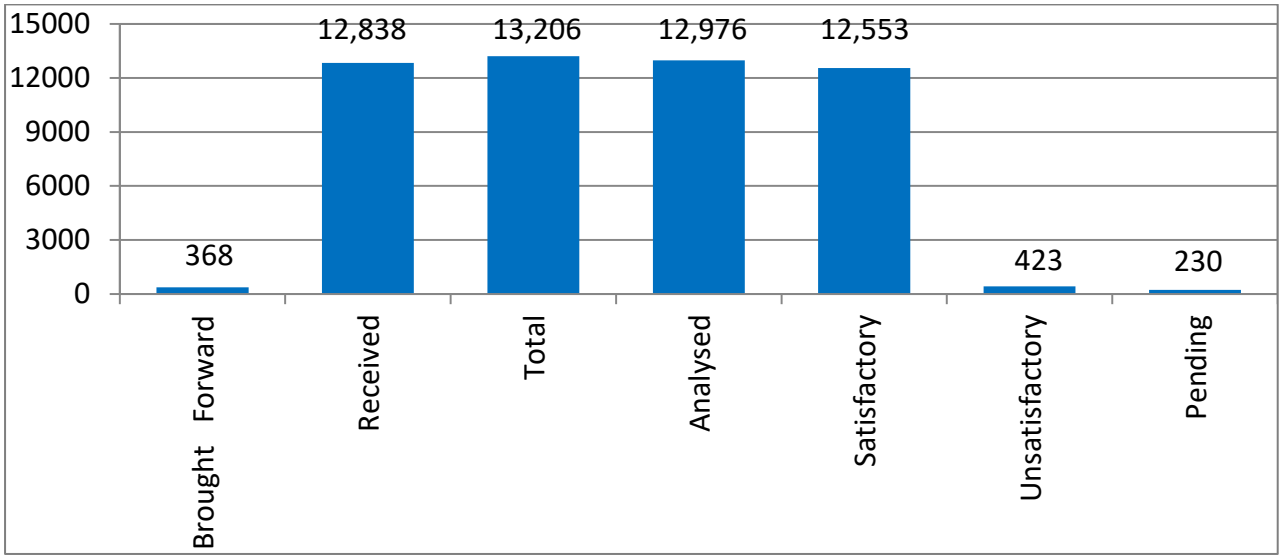


Figure 11.2: Percentage of Samples Analyzed in 2023

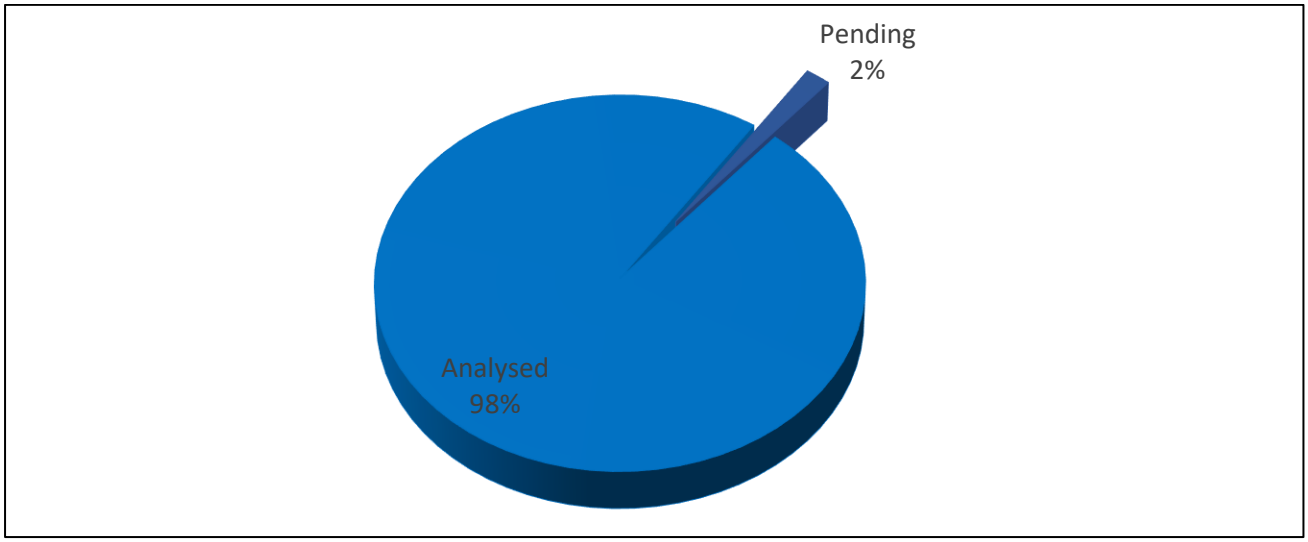


Figure 11.3: Percentage of Satisfactory/Unsatisfactory Samples

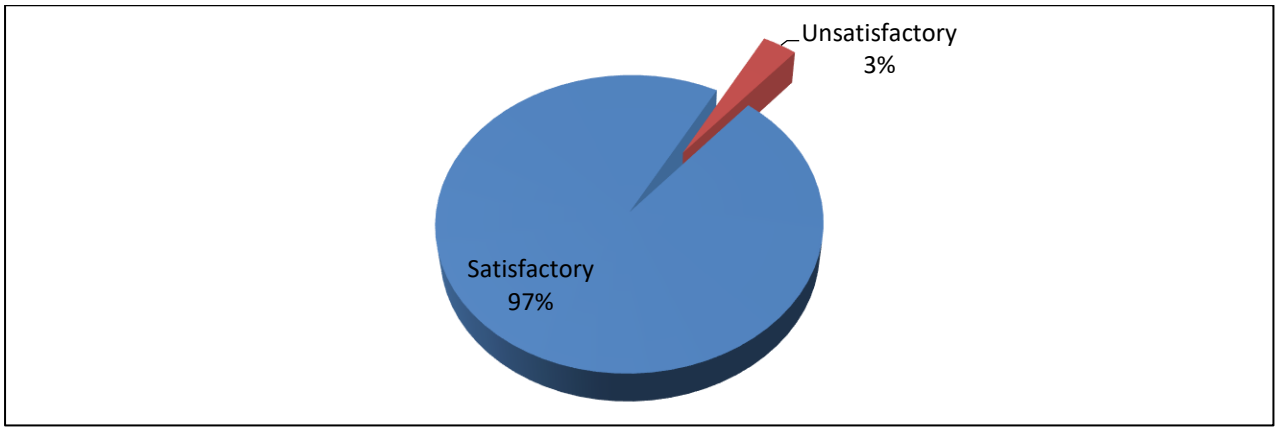


Figure 11.4: Individual Laboratory Performance

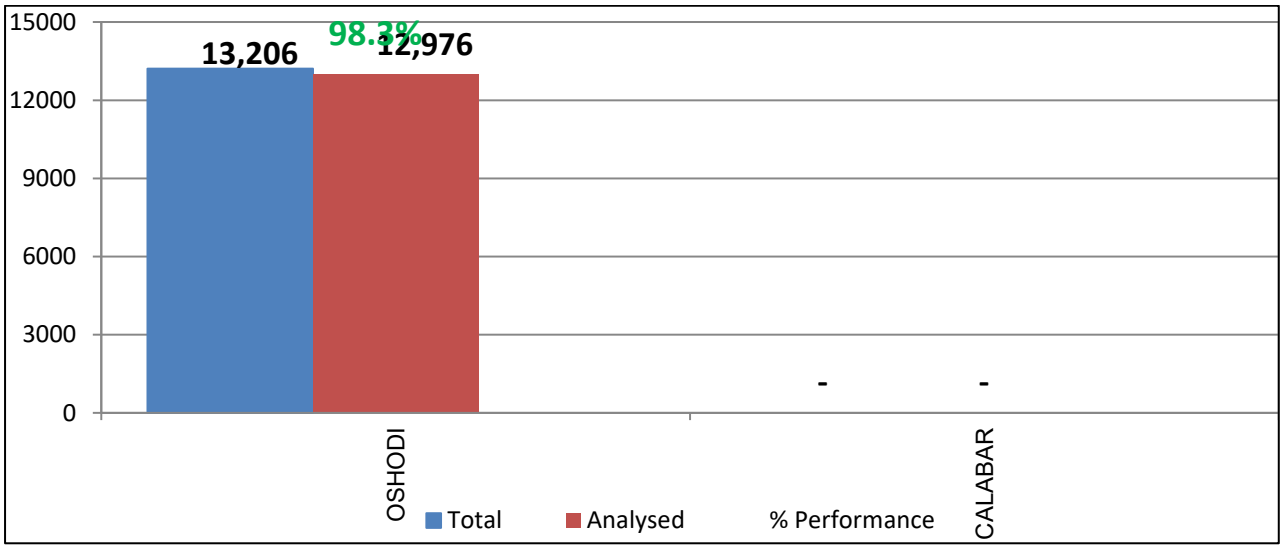


Table 11.2: Sample Received According to Categories In 2023

January- December	Registration	Compliance	Investigation	Enforcement	Others	Total
Food	5535	2222	186	27	12	7982
Dairy and Milk Product	307	490	23	0	0	820
Non Dairy Products	0	0	0	0	0	0
Baby and Infants Foods	25	179	0	0	0	204
Fat and Oils	190	195	19	2	2	408
Cereal and Cereals Product	204	550	100	1	3	858
Bread	1184	0	0	0	0	1184
Tea, Coffee and Cocoa Product	147	148	0	0	2	297
Fruits and Fruits Products	212	42	3	0	0	257
Carbonated Drinks	133	54	16	2	0	205
Meat and Meat Products	98	80	0	0	0	178
Fish and Fish Products	122	53	4	1	5	185
Salt	5	0	0	0	0	5
Seasoning and Flavouring Products	375	122	14	10	0	521
Sugar and Sugar Products	29	51	0	0	0	80
Beverages and Malt	0	26	3	0	0	29
Nut and nut products	123	20	0	0	0	143
Legume and legume products	182	13	0	0	0	195
Egg and egg products	25	1	0	0	0	26
vegetable and vegetable products	11	17	0	0	0	28
root and tuber products	269	25	0	0	0	294
Flavoured Drinks	80	7	0	0	0	87
Ready to Eat	64	23	0	3	0	90
Food Supplements	0	65	2	0	0	67
Food Additives	429	857	11	0	0	1297
Alcoholic Beverages	803	129	41	17	74	1064
Water	1758	0	0	0	2	1760
Pesticides F.	389	326	0	0	0	715
Animal feeds	20	0	0	0	0	20
Miscellaneous (Food Samples)	1750	61	2	8	0	1821
TOTAL	8934	3534	238	44	88	12838

Figure. 11.5: Categories of Samples Received In 2023

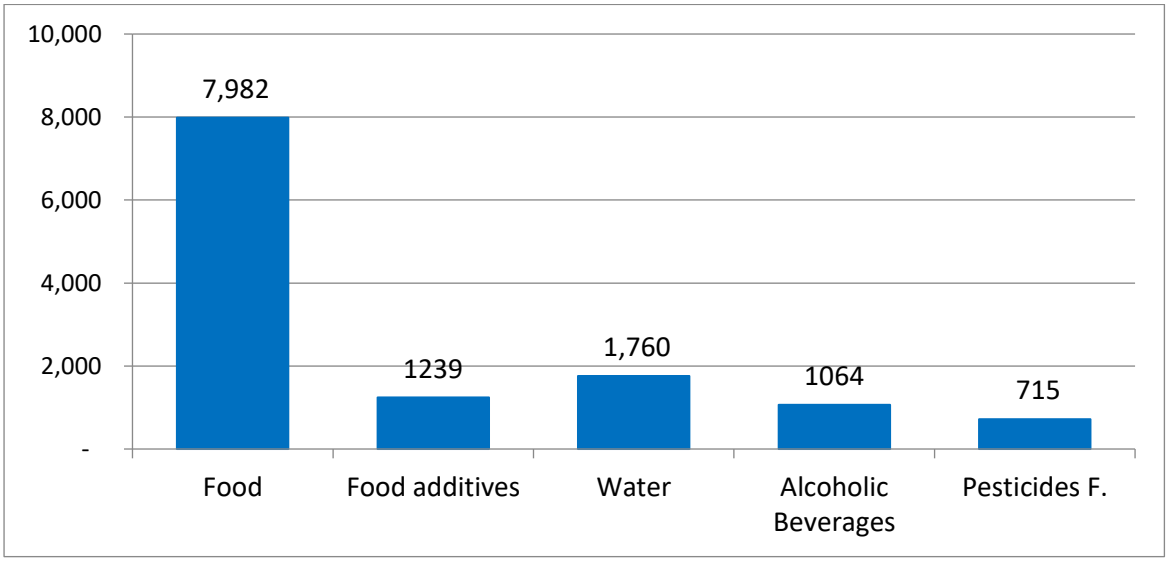
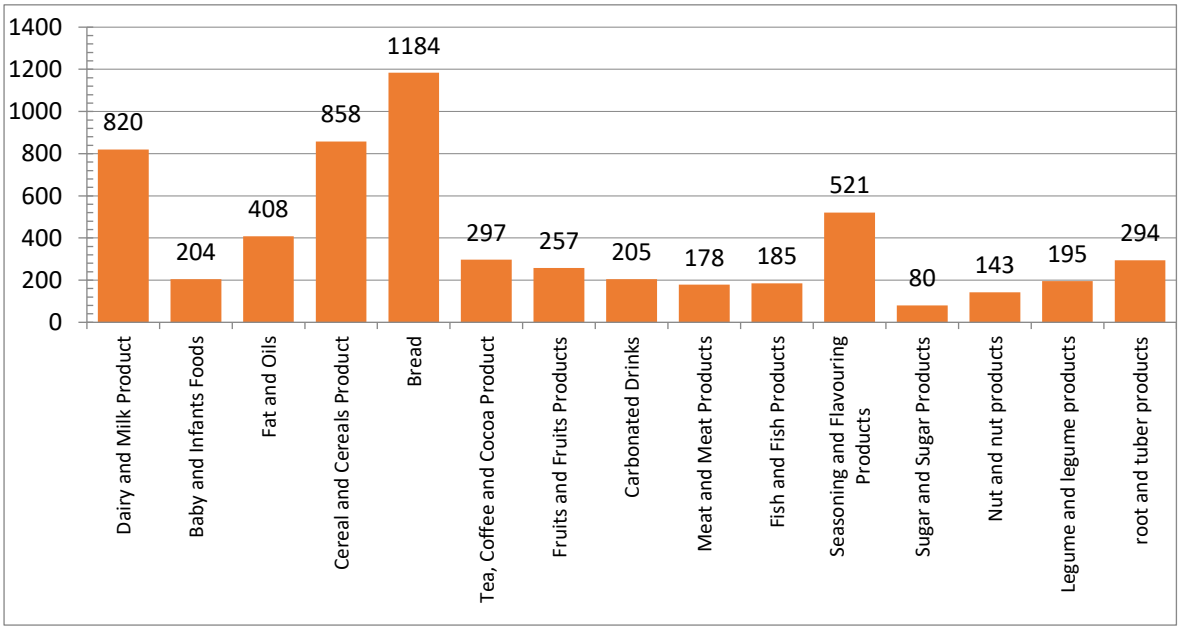


Figure 11.6: Summary of Food Samples Received According to Categories



Trend in Assessment of Regulated Products (2020 - 2023)

70% of samples received for analysis in the Laboratory Services Directorate (Food & Chemicals) were for registration purposes while the compliance samples account for 27% of the samples received.

The volume of samples received for Investigation and enforcement purposes were quite low compared to previous years.

Table 11.3: Trend of Samples Received Based on Purpose of Analysis

Purpose of analysis	Number of samples 2021	Percentage 2021	Number of samples 2022	Percentage 2022	Number of samples 2023	Percentage 2023
Registration	10,922	65.69%	8,617	56.7%	**8,934**	**69.6%**
Compliance	5,256	31.61%	6,110	40.0%	**3,534**	**27.5%**
Investigation	380	2.29%	299	2.0%	**238**	**1.9%**
Enforcement	63	0.38%	104	0.7%	**44**	**0.3%**
Others	6	0.04%	60	0.4%	**88**	**0.7%**
Total	**16,627**		**15,190**		**12,383**	

3. Trend In the Categories of Regulated Products Received In the Directorate

- Food samples constituted the highest number (7,982; 62.2%) of samples received in the Directorate.
- Of the Food samples received, Bread samples constituted the highest (1,184; 14.83 %)
- Of the 1,760 water samples received, 1,758; 99% were for registration purpose
- Two Hundred and Thirty-Eight (238) samples were received for investigation purposes with Cereal and cereal products constituting the highest percentage (100; 42%)
- Only Forty-Four (44) samples were received for enforcement purposes with Alcoholic beverages being the highest (17; 39%)

4. ISO Accreditation

A. ISO 17025:2017 Laboratory Accreditation

- The Central Laboratory Oshodi had an online surveillance audit for ISO17025:2017 Laboratory Accreditation by ANAB (ANSI National Accreditation Board) on the 18th of October 2023.
- The Laboratory currently has Thirty-Nine (39) scopes accredited.

B. ISO 9001:2015 Quality Management System

- The Central Laboratory Oshodi was reassessed by Association Francaise de Normalisation (AFNOR also known as French Standardization Association) on the 22nd of November 2023 towards renewal of the Agency's ISO 9001:2015 QMS accreditation.

Partnership with Governments and Organisations

a. Organisation for Prohibition of Chemical Weapons (OPCW)

- The OPCW supports the Laboratory unit in Central Laboratory Oshodi dedicated for testing of Chemical Weapons.
- Sequel to the satisfactory performance of the Laboratory in the CWC Chemical Analysis Competency Test (CCACT) 15, the Laboratory has been upgraded to

also participate in conventional Proficiency Tests (PT) samples along with the CCACT.

- The Unit participated in CCACT 16 and PT for 2023. The results were successful
- A staff of the unit participated in the OPCW/VERIFIN training on Enhancement of Laboratory Skills in the use of LCMS to analyse chemicals related to CWC in Helsinki-Finland from 11th- 22ndSeptember 2023.
- Another staff attended the OPCW International Seminar 2023 at Helsinki-Finland from 14th – 16thNovember 2023.

b. Industrial Trans Fatty Acid (TFA) Analysis

The Laboratory is undertaking the analysis of industrial Trans/fatty acids in hydrogenated oil.

5. Relocation of Area Laboratory, Port Harcourt, Rivers State to Calabar, Cross River State

The Area Laboratory, Port Harcourt has been relocated to Calabar. This is to give room for the construction of a more befitting Laboratory at Port Harcourt.

6. Special Activities

a. Proficiency Testing/ Certified Reference Material

The Proficiency Testing/ Certified Reference Material Laboratory Unit established in the NAFDAC Central Laboratory Oshodi conducted a Proficiency Testing Scheme on two parameters; saponification value of oil samples and moisture/ash in cereal products. A total of eighteen (18) Laboratories including five NAFDAC Food Laboratories participated in the scheme.

70% of the laboratories had a z-score within limit.

b. Inter-Laboratory Audit of NAFDAC Laboratories

NAFDAC Laboratories Inter-laboratory Audit for Central Laboratory Oshodi was carried out from 24th to 27th July 2023 by Mrs. Chindo from Kaduna Laboratory Service in line with the harmonization of Laboratory documents.

c. Meetings

- The annual Management Review Meeting held virtually on the 9th of October 2023 with the Director General and all Laboratory Services Directors in attendance.
- General Meeting: The Director met with all staff of the Central Laboratory Oshodi on the 2nd of March 2023 at the NAFDAC Auditorium, Oshodi to discuss improving the analytical process in the Laboratory using the QMS as well as the newly institutionalized KPI for the annual performance evaluation.
- Quality Assurance Meeting: The Quality Assurance officers of the Central Laboratory Oshodi held a meeting with the Quality Assurance Manager on the 15th February 2023 to harmonise the Quality SOPs for NAFDAC Laboratories

d. Micronutrient Monitoring Survey

Central Laboratory Oshodi

The Laboratory actively participated in the fortification survey of ten thousand food vehicles embarked upon by the Agency. The samples were received and analysed in the Laboratory in the year under review.

e. Proficiency Testing

All Laboratory Units in Central Laboratory Oshodi with accredited scopes participated in Proficiency Testing Schemes and inter-Laboratory testing. The results were satisfactory.

7. Conclusion

The Laboratory Services Directorate (Food & Chemicals) achieved much in terms of analyses of samples despite pertinent challenges. The Directorate successfully sustained the previously accredited analytical scopes in the Central Laboratory Oshodi. The state-of-the art of equipment received were a great booster to our activities. The Directorate hopes to obtain accreditation of some test scopes in Area Laboratory Port Harcourt.

Chapter Twelve
Lab Services Directorate (Drugs)

Introduction

The Drugs Laboratory Services (LS) Directorate was established by the Director General to enable the Drugs Laboratory to be more prudent and more productive in achieving its mandate and that of the Agency. The Directorate currently has two functional laboratories viz:

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

Highlights

A) Second WHO Prequalification Audit of the Central Drug Control Laboratory, Yaba 15th – 17th February 2023

Exactly three years from the 1st Audit, WHO PQ Inspectors led by Dr. Dimitros Catsoulacos and supported by Mr. Solomen Onen visited the Laboratory from 15th – 17th February 2023 for the 2nd WHO PQ Audit. This Audit aimed to assess the laboratory's compliance to the laboratory quality system and physiochemical processes with the WHOGPPQCL requirements. During the three-day visit some of the areas assessed include Document management, reference standard management, equipment management, personnel training and qualification, validation of analytical methods, sample management etc

B) RCORE Training Update – Visit by the Liberia Medicine Regulatory Authority 17th -28th April 2023

In 2014, NAFDAC Laboratory was designated by the African Union NEPAD as a Regional Center for Regulatory Excellence in Quality Assurance and Quality Control of Medicines. This is in line AU-NEPAD's mandate of strengthening regulatory capacity development in Africa. With its capacity as an RCORE for QA/QC, many organizations, CDCL has delivered several training/ capacity building programs in Quality Control of Medicines; both classroom and hands-on style, to several organizations. Over the years some beneficiaries include; Official medicine control laboratories (Sierra Leone, Burkina Faso), government Agencies/ parastatals (NIPRD, The Nigerian Military etc), Educational institutions, just to mention a few.

In line with this mandate, CDCL received three (3) personnel from the Liberia Medicine Health Regulatory Authority (LMHRA) for a two-week training program in Laboratory Quality Management, Laboratory Management and Quality Control testing using HPLC, UV/VIS, Karl Fischer, LOD and other key processes. The three personnel are the Acting Laboratory Director, Quality Manager, and a QC Analyst.

C)**WHO-GBT follow –up +Observed audit, October 23rd-October 27th, 2023**

The purpose of the Audit was to conduct a follow-up on all the High Institutional Development Plan implemented towards NAFDAC obtaining Maturity Level 3.During the audit, the team carried out a tour/assessment of the recently constructed/Expanded Laboratory. They also looked at the equipment procured.

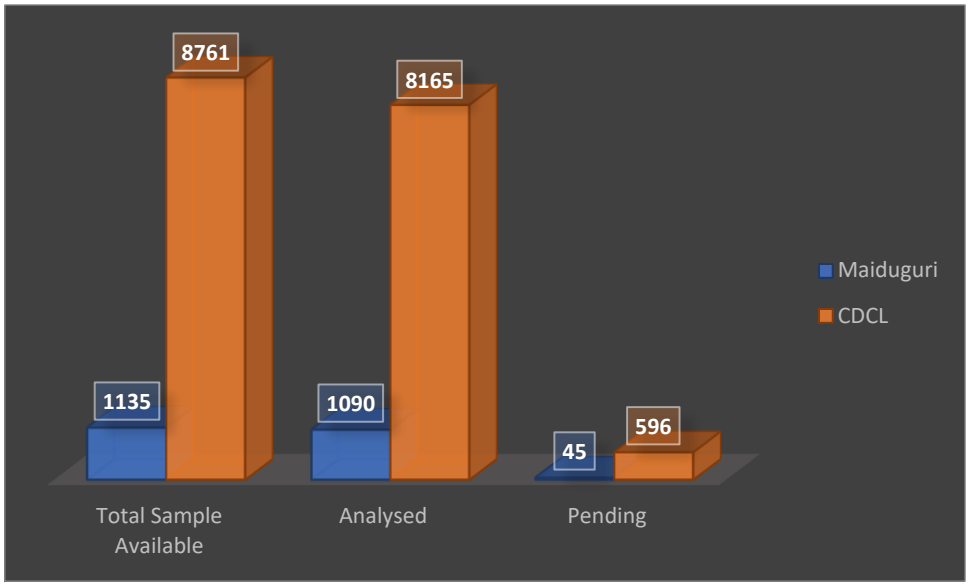
12.1Analytical Performance of the Directorate

January 2023– December 2023, Drugs Laboratory Directorate received a total **9,391 samples**. The number of samples brought forward (carried over) from December 2023 was **505.** This implies that a total of **9,896 samples** were available for analysis during this period. However, from this number**,** a total of **9,255 samples** were finally analysed representing **93.52 %**

Table 12.1: Summary of Analytical Performance for 2023

Labs	No. of Samples Brought Forward	No. of Samples Received	Total Number of Samples Available	No. of Samples Analysed	No. of Samples Pending
Maiduguri Area Lab	45	1,090	1,135	1,090	45
CDCL	460	8,301	8,761	8,165	596
Total	505	9,391	9,896	9,255	641

Figure 12.1. Graphical Representation of Analytical Performance for 2023



The Directorate wish to express her gratitude to the Management and Governing Council of NAFDAC for the support the laboratories have received in the recent past especially in the areas of bulk purchase of chemicals and reagents, consumables, new equipment and vehicles.

Chapter Thirteen
Laboratory Services Directorate (VBM-LSD)

13.1. Introduction

The vaccine, biological and medical device laboratory services directorate (VBM-LSD) has recorded outstanding improvements over the years.

The laboratory made exceptional positive developments in line with keeping the Agency's mandate in ensuring the safety and efficacy of Vaccines, Biologicals and Medical Devices were achieved during the year 2023. The laboratory was audited for scope extension in medical devices and consolidation of the existing scopes and VBM-LSD came out without a non-conformance.

13.2. Goals:

The goals of the Laboratory Services Directorate (VBM) are:

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

13.3 Analytical Performance

The laboratory received a total of One Thousand Three Hundred and Ninety-Eight (1,398) samples. A total of One Thousand, Six Hundred and Thirty (1,630) were to be analyzed. A total of One Thousand One Hundred and Three Hundred and Ninety-Eight (1,398) samples were analyzed and Two Hundred and Thirty-Two (232) carried over to the next year.

Table 13.1: Summary of Analytical Performance in Year 2023

Number of samples carried over from 2022	Number of Samples Received	Total number of samples	Total Samples Analyzed	Number Satisfactory	Number of Unsatisfactory Samples	Number Pending	Percentage Performance
232	1,398	1,630	1,398	1,398	0	232	85.77%

Figure 13.1. Analytical Performance for Year 2023

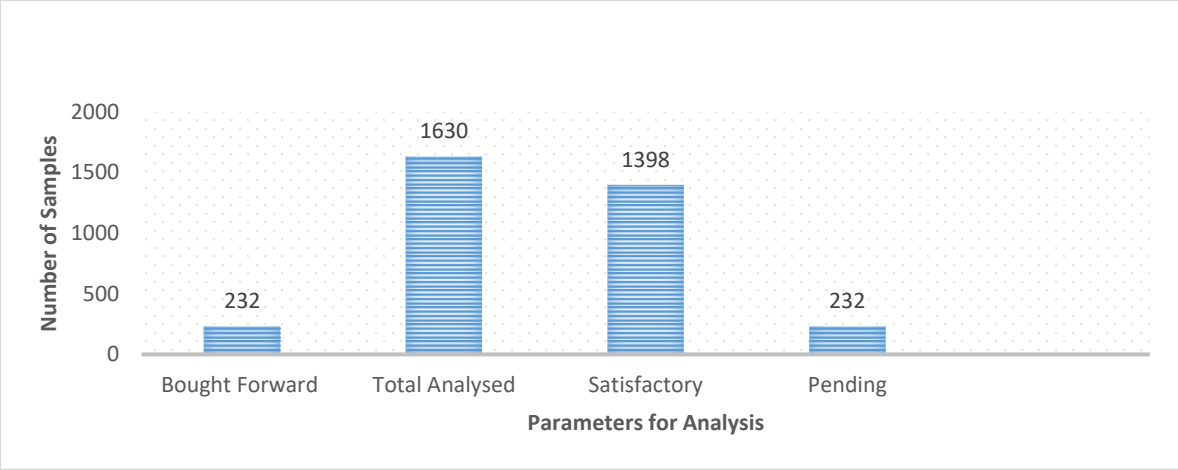


Figure 13.2. Percentage of Samples Analysed In 2023

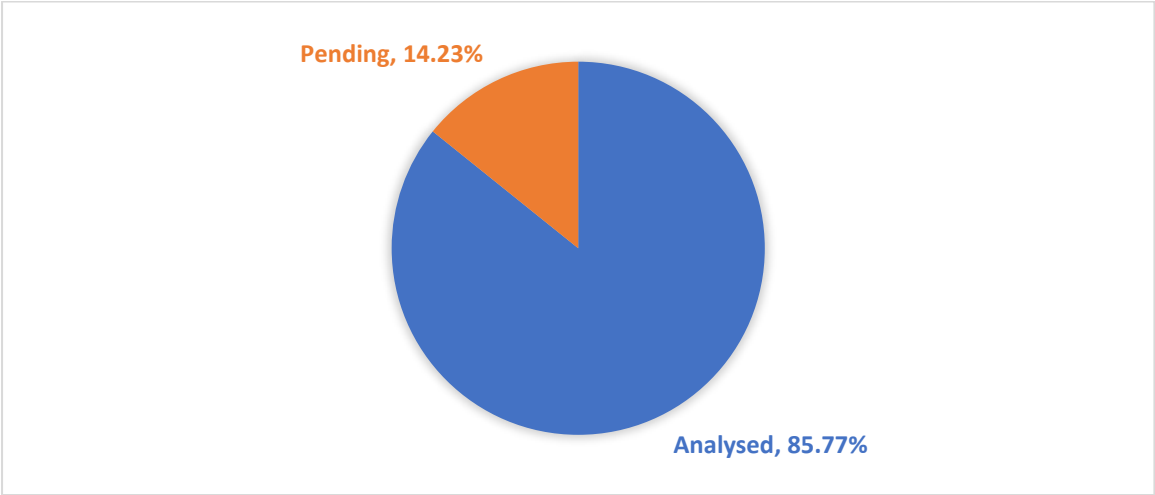


Table 13.2: Breakdown of Samples According to Category and Source

Types of Products	Registration	Compliance	Investigation
Vaccine (Human)	6	137	0
Vaccine (Vet)	26	132	0
Biologicals	7	192	0
Medical Devices (Biological)	118	113	0
Medical Devices (Diagnostics)	266	398	3
Total Samples Received	423	972	3
Grand Total For 2023		1,398	

Figure 13.3: Breakdown of Samples According to Category and Source

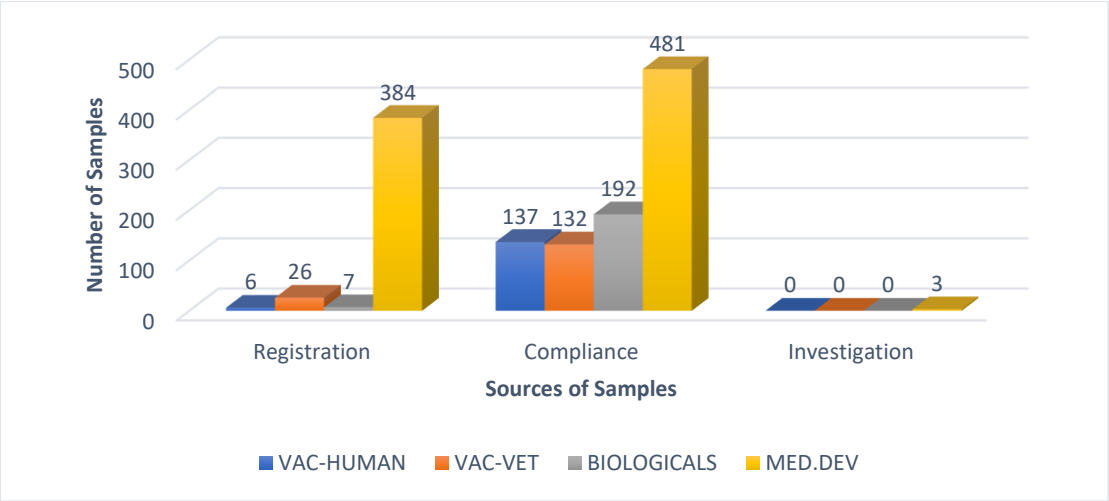
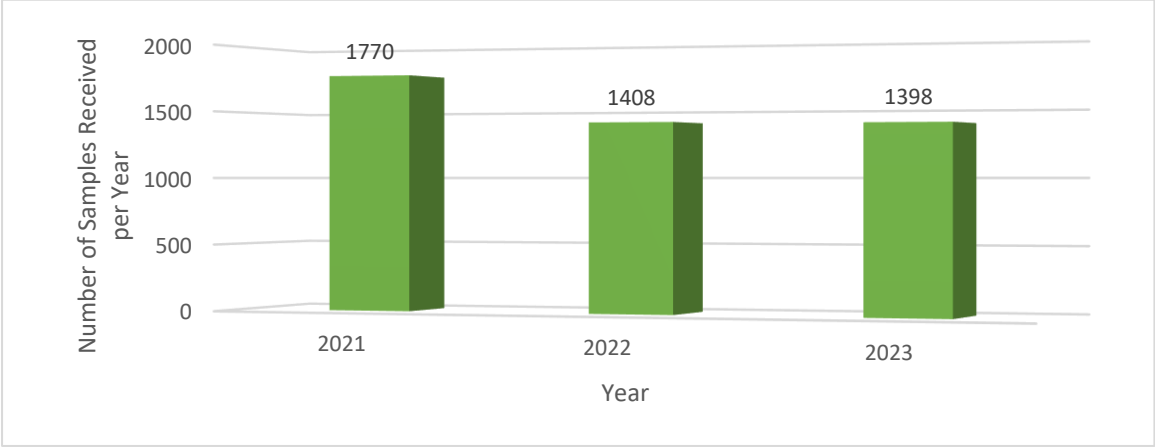


Table 13.3: Trend in Assessment of Regulated Products (2021-2023)

Purpose of Analysis	Number of samples 2021	Percentage 2021	Number of samples 2022	Percentage 2022	Number of samples 2023	Percentage 2023
Registration	575	32.49	438	31.11	423	30.26
Compliance	1,182	66.80	951	67.54	972	69.53
Investigation	13	0.71	19	1.35	3	0.21
Total	1,770		1,408		1,398	

Most of the samples analyzed in year 2021,2022 and 2023 were received from compliance source. There is a slight decrease in the number of samples received for analysis in the laboratory over the years. These may be due to the risk-based sampling been implemented in the Agency.

Figure 13.4: Trend in Assessment of Regulated Products (2021-2023)



13.4. Joint Sampling with PID at Cold Storage Areas

For the period of January – December 2023, Vaccines and Biologicals for compliance were jointly inspected and collected with the Ports Inspection Directorate at various Cold Stores across the Country. Samples were also received from Registration & Regulatory Affairs Directorate, Port Inspection Directorate and Enforcement Directorate.

13.7. 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 one (1) Post Market Validations of HIV Test Kits within the year under review, at the medical laboratory council laboratory Lagos.

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, some laboratory documents were developed and reviewed to strengthen the quality management system.

A total of Forty-Four (44) procedures were reviewed. Two (2) procedures were developed in the year under review.

D. **Outcome of recent internal audits**

In the period under review internal audits were conducted according to the Laboratory's approved audit plan that captures the requirements of ISO/IEC17025:2017. All the laboratory units were audited in March, while three rounds of self-assessment were carried out by various units in February, June, and September.

E. **Non-conformances raised and treated.**

A total of fifty-four non-conformances were identified in the laboratory during the year under review. Out of fifty-four non-conformances identified Fifty -three were successfully treated.

F. **Quality Control Checks (QCC).**

The laboratory conducted five (5) quality control checks for pH, UV-Visible, Titrimetric, and Gravimetric analysis.

G. Customer and Personnel Feedback

The laboratory received a total of fifteen (15) responses from the customer satisfaction survey conducted this year of the twenty-five (25) distributed survey forms. Out of the fifteen (15) responses, one (1) gave a dissatisfied response and this has been addressed by the laboratory.

H. Proficiency Testing.

The laboratory planned to participate in PT/ILC for 16 test scopes in 2023.However, the laboratory was only able to successfully participate in ten (10) out of the planned 16 test scopes.

I. Equipment and Maintenance

Availability of necessary equipment is requisite to accomplish testing accuracy. Equipment calibration was achieved for the year under review.

J. Results of Risk Identification

The laboratory risk management team identified risks, treatment actions and provided risk mitigation strategy for the year under review.

K. Laboratory Annual Supplier Evaluation

The evaluation of the laboratory supplier was conducted for year 2022 and Serum institute India had the highest score of (94.6%) followed by Untied States Pharmacopeia (USP) with (94.2%) based on the quality of goods and services.

L. Environmental Monitoring:

Three-hundred and thirty-six reports of environmental (temperature and humidity) were reviewed by the unit in 2023.

13.8 Assessment by External Bodies: ISO Accreditation

The Laboratory had its multi-site's assessment for ISO-17025:2017 in November 2022 and the laboratory received its certificate of compliance in December 2020.

The laboratory was reassessed for ISO 9001:2015 compliance on the 12th October 2022.

13.9 Laboratory Security & Safety Health and Environment (SHE)

The laboratory has a committee on Safety, Health and Environment. Trainings on safety, HSE inspection were conducted twice in all the unit, awareness and fire evacuation drill were conducted under the year of review. However, more is to be done in the area of awareness and training programmes.

13.10 Activities of Animal Facility

The Animal facility serves both the Vaccine and Drug laboratories.
The number of animals in the facility as at 31st December 2023 is as follows:
Mice = 901 Rabbits = NIL Rats = 2 Guinea pig= NIL
Animal feed 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.

13.11 New Office Complex

The Directorate is planning to move to its new permanent site in the year 2024 to optimize its efficiency and effectiveness.

Conclusion

The Biologics laboratory has made excellent progress. More samples are now being received which includes all medical devices. The state-of-the art of equipment received were a great booter to our activities. The Directorate successfully maintained previously certified analytical scopes.

Chapter 14
Agulu Laboratory Service

Analytical Performance

A. No of Samples Received

The Laboratory received Five Thousand, Seven Hundred and Forty-Five (5,745) samples. One Hundred and Eight (108) samples were brought forward from 2022, bringing to a total of Five Thousand, Eight Hundred and Fifty-Three (5,853) samples for analysis within the period under review.

B. No of Samples Analyzed

Five Thousand, Six Hundred and Fifty-Nine (5,659) samples were analyzed. This represents 96.69% of samples analyzed. Out of the number analyzed, Five Thousand, Four Hundred and Sixty (5,460) samples were analyzed within the timelines. This represents 96.50%.

C. No of Pending Samples

One Hundred and Ninety-Eight (198) samples were pending within the year under review.

D. No of Satisfactory and Unsatisfactory Samples

Four Thousand, Four Hundred and Thirty-Three (4,433) samples were satisfactory while Two Hundred and Twenty-Six (226) samples were unsatisfactory.

Table1, 2 & 3 show the statistics of activities within the year.

14.2 Staff Matters

As of 31st December 2023, the Laboratory had a total of Thirty-Six (36) staff comprising Thirty (30) senior staff and Six (6) junior staff. In addition, there were Six (6) Corp members, Four (4) Intern Pharmacists, and Sixteen (16) IT Students.

14.3 Accreditation

Internal Audit of the Laboratory was held from 18 – 21st July 2023. Monitoring and evaluation of the accredited scopes continued within the year under review. Intra-audit followed-up for LSA took place from 20th – 22nd of September 2023.

The Reassessment of the Laboratory by ANAB took place on the 20th of October 2023. The assessment was successful as there was no non-conformance recorded.
Monitoring and evaluation of the accredited scopes continued within the year under review.

14.4 Special Events

The Laboratory witnessed the evacuation and destruction of counterfeit, unwholesome, unregistered, expired products seized from several distribution outlets by Investigation and Enforcement Directorate.

Table 14.I: Summary of Activities in the Year 2023

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	87	2,910	2,997	2,901	96.80	2,704	93.21	2,806	95	96
Water	0	1,524	1,524	1,500	98.43	1,500	100.00	1,449	51	24
Pesticides	3	31	34	34	100.00	34	100.00	34	0	0
Drugs	18	574	592	518	87.50	516	99.61	489	29	74
Cosmetics	0	487	487	487	100.00	487	100.00	437	50	0
Medical Devices	0	73	73	73	100.00	73	100.00	72	1	0
Herbal Preparation	0	146	146	146	100.00	146	100.00	146	0	0
Total	**108**	**5,745**	**5,853**	**5,659**	**96.69**	**5,460**	**96.50**	**5,433**	**226**	**194**

Table 14.2: Profile of Samples Received in the Year 2023

Products	Imported	Local		Total
		MSMEs	Others	
Food	222	1,405	154	1,781
Bread	0	1,023	6	1,029
Water	0	629	898	1,524
Pesticide Formulation	31	0	0	31
Drug	540	0	34	574
Cosmetics	3	0	484	487
Medical Devices	51	0	22	73
Herbal Preparation	0	0	146	146
Fertilizer	0	0	0	0
Animal Feed	69	0	31	100
Others (Specify)	0	0	0	0
Total	916	3,054	1,775	5,745

Table 14.3: Sources of Samples Received in the Year 2023

		Imported			Local						
					MSMEs			Others			
Product		**Registration**	**Renewal/ Compliance**	**Others**	**Registration**	**Renewal/ Compliance**	**Others**	**Registration**	**Renewal/ Compliance**	**Others**	**Total**
Food		0	222	1	1,339	117	0	62	35	5	1,781
Bread	Medium	0	0	0	211	3	0	0	0	0	214
	Medium/Large	0	0	0	722	93	0	0	0	0	815
Water	Sachet	0	0	0	654	418	0	0	0	0	1,072
	Bottle	0	0	0	267	185	0	0	0	0	452
Pesticide Form.		0	31	0	0	0	0	0	0	0	31
Drugs		4	530	1	0	0	0	15	16	8	574
Cosmetics		0	3	0	0	0	0	478	2	4	487
Medical Devices		0	50	0	0	0	0	12	0	11	73
Herbal Preparation		0	0	0	0	0	0	146	0	0	146
Fertilizer		0	0	0	0	0	0	0	0	0	0
Animal Feed		69	0	0	0	0	0	31	0	0	100
Others (Specify)		0	0	0	0	0	0	0	0	0	0
Total		**73**	**836**	**2**	**3,193**	**816**	**0**	**744**	**53**	**28**	**5,745**

Chapter Fifteen
Kaduna Laboratory Services

Executive Summary

The Kaduna Laboratory Services receives samples from 13 states (Northwest states: Kaduna, Kebbi, Katsina, Kano, Sokoto, Jigawa and Zamfara. North Central states: Niger, Kogi, Benue, Plateau, Nasarawa, Katsina and Kwara and the FCT). Occasionally samples come from the Lagos State and Borno State as well.

In 2023, the laboratory received a total of Seven Thousand, and Forty-Seven (7,047) samples including four (04) PT samples. Six Thousand, Three Hundred and Sixteen (6,316) samples were locally produced while the remaining Seven Hundred and Thirty-One (731) were foreign samples. From the year 2022, Three Hundred and Sixty-Nine (369) samples were brought forward. The Laboratory also received Three Thousand and Thirty-Three (3,033) survey samples in the year under review making total number of samples for analysis to stand at Ten Thousand, Four Hundred and Forty-Nine (10,449).

The laboratory analyzed Ten Thousand, Two Hundred and Twelve (10,212) samples, out of which Six Thousand and Nine Hundred and Thirty-Three (6,933) samples were satisfactory and Three Thousand, Two Hundred and Seventy-Nine (3,279) samples were unsatisfactory. Two hundred and Thirty-Seven (237) samples are pending analysis.

Table 15.1: Summary of laboratory analysis for the year 2023

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	No of Pending Samples
Food	166	3,598 3033(survey) 1 (PT)	6,798	6,759	3,994	2,765	39
Chemistry	85	872 1 (PT)	958	892	782	110	66
Water	73	2,057	2,130	2,075	1,716	359	55
Cosmetics	25	415	440	384	340	44	56
Pesticides	20	101	121	100	99	01	21
Microbiology*	296	5248 2 (PT)	5544 2 (PT)	5,501 (2)	4653 (2)	848	43
Mycotoxin*	0	1,587	1,587	1,587	1,581	06	0
HPLC	14	99	113	111	110	01	02
Total	**369**	**10,080**	**10,449**	**10,212**	**6,933**	**3,279**	**237**

#Key: Figures in red (soft copy) and asterisked*are from supporting labs and are therefore not used in obtaining the total number of samples treated, they have been already captured by the main labs namely Food, Chemistry, Water, Cosmetics and Pesticides.

The Laboratory Performance Evaluation Index (KPI) stands at 97.7 %.

Details of Activities

A. Technical

I. Investigation

In the year under review, the Laboratory received a total of Two Hundred and Five (205) investigation samples comprising of Seventy-Four (74) drugs, Four (04) cosmetics, Twenty-One (21) water, Eighty-Eight (88) food and Eighteen (18) pesticide samples.

II. Report from Laboratory Units

a) **Food Unit**

The food unit received Six Thousand, Six Hundred and Thirty-Two (6,632) samples including one (1) PT and Three Thousand and Thirty-Three (3,033) survey samples. One Hundred and Sixty-Six (166) samples were brought forward from 2022; thus, the unit had a total of Six Thousand, Seven Hundred and Ninety-Eight (6,798) samples to work on. Six thousand, seven hundred and fifty-nine (6,759) samples were analyzed. Three Thousand, Nine Hundred and Ninety-Four (3,994) samples were satisfactory while the remaining Two Thousand, Seven Hundred and Sixty-Five (2,765) samples were unsatisfactory. Thirty-Nine (39) samples have been carried over into the month January, 2024.

b) **Chemistry Unit**

In the year 2023, the chemistry unit received Eight Hundred and Seventy-Three (873) samples including a PT sample. Eighty-Five (85) samples were brought forward. Thus, the unit had a total of nine hundred and fifty-eight (958) samples for analysis. Eight Hundred and Ninety-Two (892) samples were analyzed, out of which Seven Hundred and Eighty-Two (782) samples were satisfactory; One Hundred and Ten (110) samples were unsatisfactory. Sixty-Six (66) samples were carried over into the month of January, 2024.

c) **Water Unit**

The water unit received Two Thousand and Fifty-Seven (2,057) samples. Seventy-three (73) samples were brought forward from December 2022, making a total of Two Thousand, One Hundred and Thirty (2,130) samples. Two Thousand and Seventy-Five (2,075) samples were analyzed, out of which One Thousand, Seven Hundred and Sixteen (1,716) samples were satisfactory and Three Hundred and Fifty-Nine (359) samples were unsatisfactory. Fifty-Five (55) samples were carried over into the month of January 2024.

d) **Cosmetics Unit**

The cosmetics unit received Four Hundred and Fifteen (415) samples in 2023. Twenty-Five (25) samples were brought forward from the month of December 2022, making a total of Four Hundred and Forty (440) samples to work on. Out of the total, three hundred and eighty-four (384) samples were analyzed. Three Hundred and Forty (340) samples were satisfactory while the remaining Forty-Four (44) were unsatisfactory. Fifty-Six (56) samples were carried over into the month of January, 2024.

e) **Pesticide**

The pesticides unit received One Hundred and One (101) samples in 2023. Twenty (20) samples were brought forward from the month of December 2022, making number of samples for analysis to be one hundred and twenty-one (121). One Hundred (100) samples were analyzed out of which Ninety-Nine (99) were satisfactory, while the remaining one (01) sample was unsatisfactory. Twenty-One (21) samples were carried over into the month of January 2024.

f) **Microbiology Unit**

The microbiology unit acquires samples from various main labs namely: Food, Drugs, Water and cosmetics totaling Five Thousand, Two Hundred and Forty-Eight (5,248) samples and brought forward Two Hundred and Ninety-Six (296) samples from the month of December 2022. The unit also received two (02) PT samples. Total samples for analysis were Five Thousand, Five Hundred and Forty-Six (5,546). Five Thousand, Five Hundred and Three (5,503) samples were analyzed, out of which Four Thousand, Six Hundred and Fifty-Five (4,655) samples were satisfactory and Eight Hundred and Forty-Eight (848) samples were unsatisfactory. Forty-Three samples were carried over into the month of January 2024.

g) **Mycotoxin Unit**

The unit received One Thousand, Five Hundred and Eighty-Seven (1,587) samples in the year under review and no sample was brought forward from the month of December 2022. Total samples for analysis were One Thousand, Five Hundred and Eighty-Seven (1,587). All the samples were analyzed out of which One Thousand, Five Hundred and Eighty-One (1,581) were satisfactory and the remaining Six (06) were unsatisfactory. No sample was carried over into the month of January, 2024.

h) **HPLC Unit**

The unit received Ninety-Nine (99) samples in the year under review and Fourteen (14) samples were brought forward from the month of December 2022. Total samples for analysis were One Hundred and Thirteen (113); One Hundred and Eleven (111) samples were analyzed out of which One Hundred and Ten (110) were satisfactory and the remaining one was unsatisfactory. Two (02) samples were carried over into the month of January 2024.

Table 2: Total number of samples received in 2023

S\N	Product Type	Quantity
1.	Food	3,598
2.	Food Survey	3,033
3.	Chemistry	872
4	Water	2,057
5.	Cosmetics	415
6.	Pesticides	101
7.	PT (Proficiency Testing)	04
8.	Microbiology*	5,248
9.	Mycotoxin*	1,587
10.	HPLC	99
	Total	**10,080**

Figure 1: **Number of Samples Received in the Year 2023**

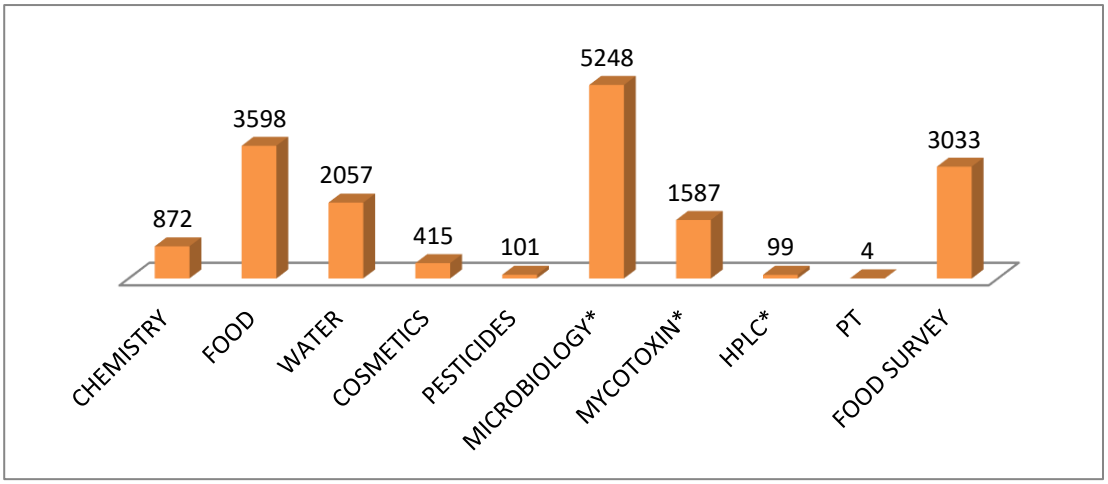


Table 3: Profiles of Local and Foreign Samples Received in 2023

S\N	Product Type	Samples Received	
		Local	**Imported (Foreign)**
1.	Food	3,546	52
2.	Chemistry	231	641
3.	Water	2,057	0
4	Cosmetics	414	01
5.	Pesticides	68	33
6.	PT	0	04
7.	Food Survey	3,033	0
8.	**Subtotal**	**9,349**	**731**
		Total	**10,080**

Figure 2: Local Samples Received in 2023

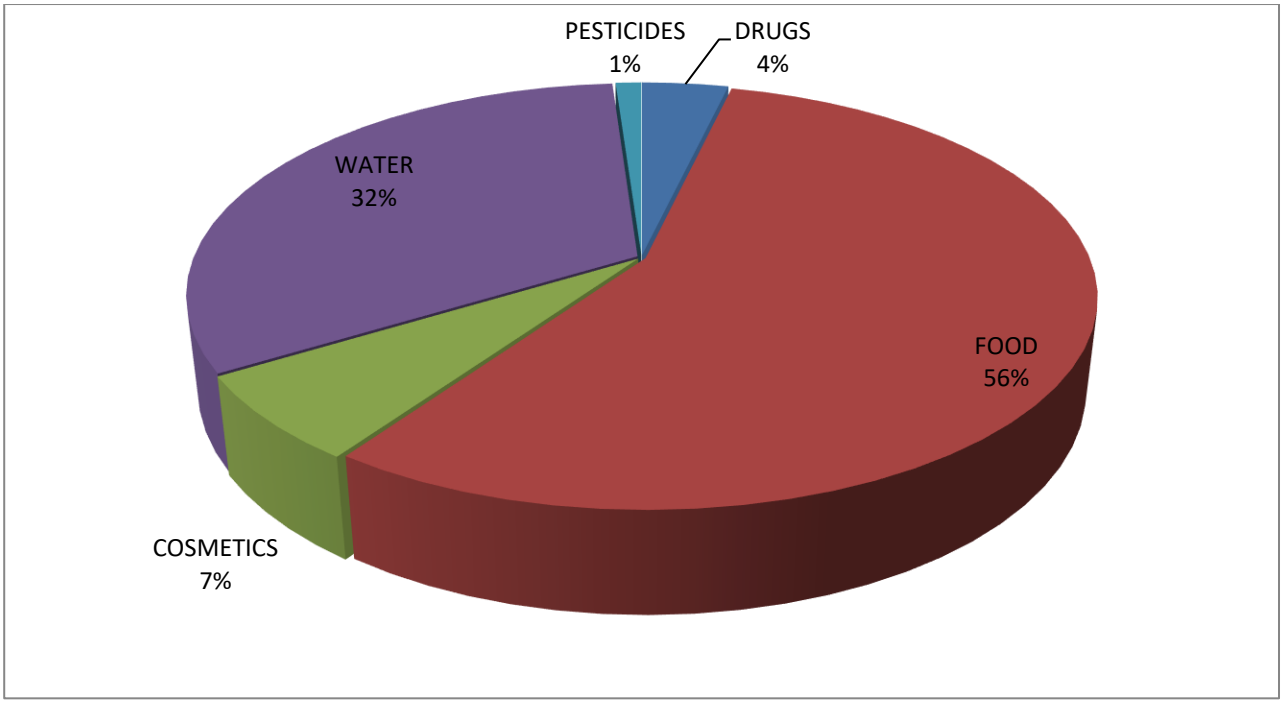


Figure 3: Foreign Samples Received in 2023

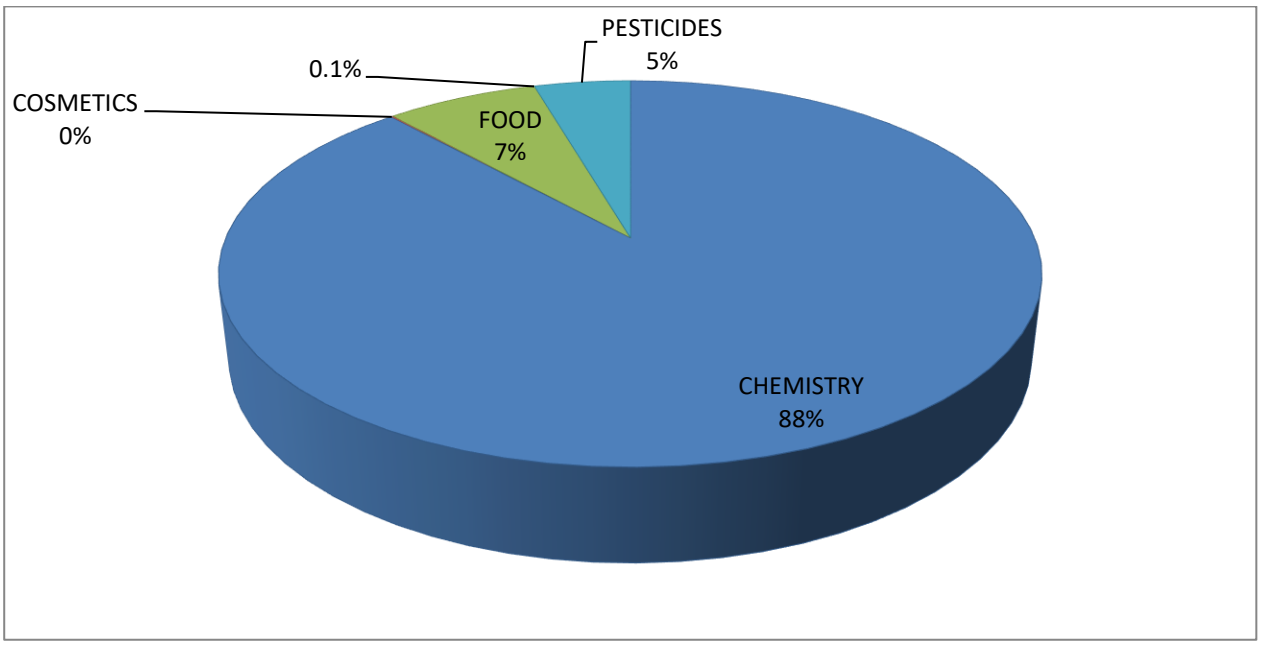


Table 4: Sample Classification Based on Purpose of Analysis.

Type of Sample	Water	Food	Drugs	Cosmetics	Pesticide	Total
Registration	1,046	2284	132	309	57	3,828
Renewal	990	1207	60	102	06	2,365
Compliance	-	19	606	-	20	645
Food Survey	-	3,033	-	-	-	3,033
Investigation	21	88	74	04	18	205
PT	-	01	03	-	-	04
Factory Extension	-	-	-	-	-	-
Pack Size Extension	-	-	-	-	-	-
Total Samples	**2,057**	**6,631**	**872**	**415**	**101**	**10,080**

Figure 4: Percentage of Samples Based on Purpose of Analysis

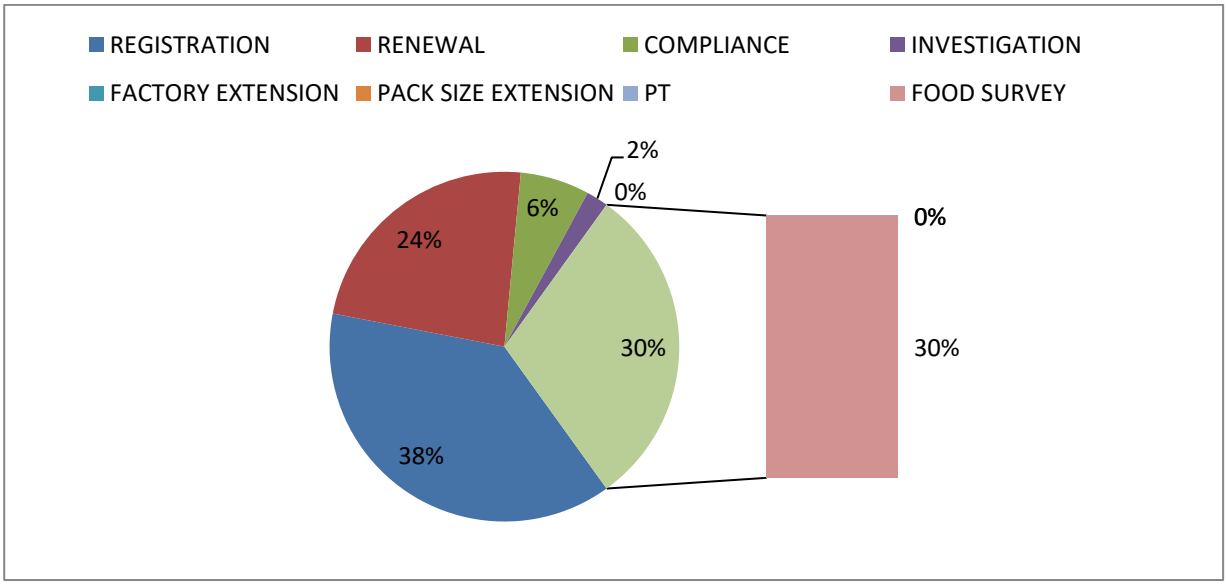


Table 7: Pending samples received for 2023

SN	Laboratory Unit	Number of Samples Pending	Reasons for Pending Samples
1.	Food	39	Work in progress
2.	Chemistry	66	Work in progress
3.	Water	55	Work in progress
4	Cosmetics	56	Work in progress
5.	Pesticides	21	
6.	Microbiology*	43	Work in progress
7.	Mycotoxin*	0	
8.	HPLC*	04	Work in progress
Total		**237**	-

B. Administrative Unit

In the year 2023 a new Director Pharm. Babatunde A. Yusuf was posted to the laboratory following the retirement of Mr. Sariel Sakomi Ankruma from service. As of December 2023, KLS has Sixty-Seven (67) permanent staff, comprising of Sixty-Two (62) senior staff and Five (05) junior staff. The lab also has a total of Forty-Six (46) temporary staff comprising of Eleven (11) Corp members, and Thirty-Five (35) IT/SIWES students.

C. Quality Assurance Unit

In 2023, the laboratory carried out (17) scheduled internal trainings for its entire staff.
All senior staff in the laboratory have undergone training on anti-corruption, leadership and ethical values in place of work.
The two (02) Deputy Directors in the laboratory have undergone training on performance evaluation.
Five (05) staff were trained on Step Wise Assessment Tool towards Accreditation (SATTA) and Internal Audit by USP PQM.
All audits were conducted as scheduled.

D. Instrument Maintenance Unit (IMU)

In the year under review the laboratory received the underlisted equipment:

1. Automatic Colony Counter Interscience LS Scientific/Scan 300 (QTY 1)
2. Glassware (Flask) Shaker VWR / SF1 (QTY) 1
3. Hot Plate with Stirrer IKA Germany / C-MAG HS10 (QTY 2)
4. Centrifuge with Rotor and accessories. OHAUS Switzerland / 30332131 – FC5706 (QTY 1)
5. Friability Tester Erweka / TAR 220P (QTY 1)
6. Hardness Tester Erweka / TBH-425 (QTY 1)
7. Heating Mantle (3-6 points) VWR / EME60250 / CEB (QTY 1)
8. Incubators 300C/370C LS Scientific / 102606204 – IN110 (QTY 2)
9. Analytical Balance OHAUS Switzerland /30429811-PX224/E (QTY 2)

10. Drying Cabinet VWR / 466-0231 (QTY 2)
11. Automatic Titrator Metrohm / 29162010 –TI-TOUCH 916 (QTY 1)
12. Top Loading Balance (5200 x 0.1g) OHAUS Switzerland / 30619385-PX6202 (QTY 2)
13. Moisture Analyzer OHAUS Switzerland / 30303303-MB90 (QTY 1)
14. HPLC/DAD/FLD VWR / Chromaster (QTY 1)
15. pH / Conductivity Meter Mettler Toledo / 30671567-SD23Kit (QTY 1)
16. Air Generator LS scientific / 60-3500-Zero Air (QTY 1)
17. Hydrogen Generator LS Scientific 63-0200 Hydrogen generator (QTY 1)
18. Nitrogen Generator LS Scientific / 61-0250 Nitrogen Generator (QTY 1)
19. Crucible VWR / 511-0289 (QTY 10)
20. Thermometer VWR / 620-2006 (QTY 3)
21. Karl Fischer Metrohm / KF-TI-TOUCH 915 (QTY 1)
22. pH Meter Mettler Toledo / 30671554-SD20 (QTY 2)
23. Waterbath with thermostat/shaker
VWR / 462-0519 – OLS 26 1
24. Ultrasonic bath VWR / 142-0110-USC 2600 THD

Laboratory Information Management System (LIMS)

Laboratory Information Management system (LIMS) has been deployed but Due to glitches in the software proper implementation has not been carried out. These glitches in the software include:

1. The system is unable to generate sample Reference numbers before allocation to the respective units for analysis.
2. The reports printed do not show the laboratory parameters rather, only sample information, even though the reports are in the completed status and ready for printing.

F. Health Safety and Environment (HSE)

All Fire Extinguishers have been serviced by the Federal Fire Service, Kaduna Command.

The cause of the leakage at the back of the laboratory resulting in mould on the walls in the main building has been identified and evaluated by the head of NAFDAC Engineering unit.

Chapter Sixteen
Investigation and Enforcement Directorate

16.1 Introduction.

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 2023, 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

16.2: Activities of I&E Directorate in 2023

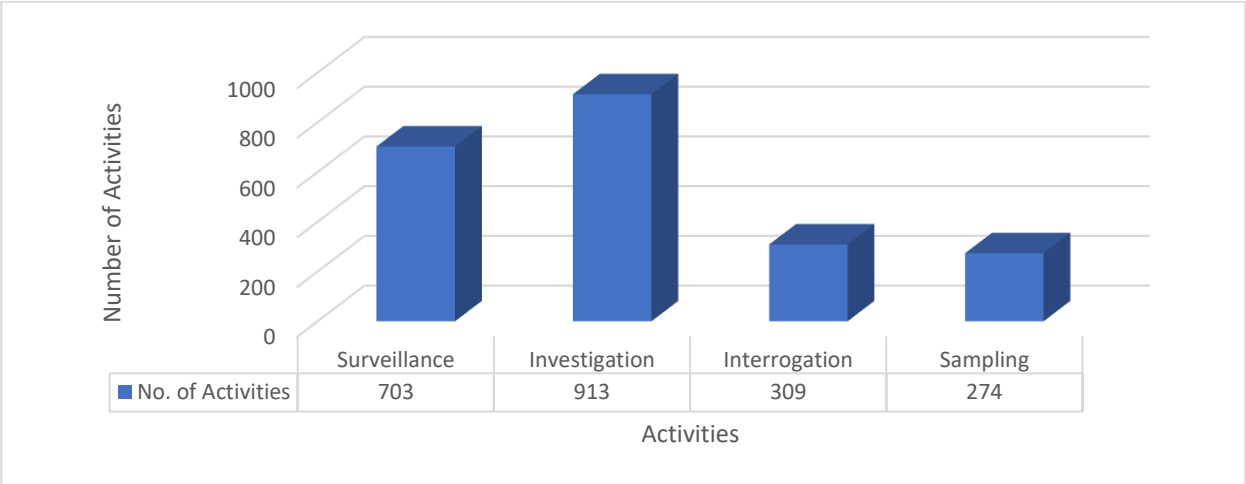
A. Surveillance: The Directorate carries out surveillance in order to identify or monitor threats and prevent/investigate criminal activities. A total of 703 surveillance activities were carried out in the year 2023.

B. 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 913 investigations were carried out in 2023.

C. Interrogations: The Directorate interrogates suspects, interview victims and witnesses of crimes related to NAFDAC Enactments. 274 Interrogations and interviews were conducted in the year 2023.

D. 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 309 investigative samples were forwarded during the period under review.

Figure 16.1: Activities of I&E Directorate in 2023



E. 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 12 raids, arrested 13 hawkers, and 193 wares were seized between January to December under review.

F. No of Hawkers Arrested: The Directorate conducted Twelve (12) raids, arrested Thirteen hawkers and One Hundred and Ninety-Three wares were seized in 2023.

G. Compilation of Case Files: The Directorate in conjunction with the Legal Services Directorate filed Four (4) cases in court.

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

Table 16.1: Destruction Exercises Carried out in 2023

Month	Zone	Value of Products Destroyed
January	-	-
February	1	N326,833,592.80
March	-	-
April	-	-
May	1	N4,282,302,738.00
June	-	-
July	-	-
August	-	-
September	-	-
October	2	N16,535,000,000.00
November	-	-
December	-	-
Total	**4**	**N21,144,136.330.80**

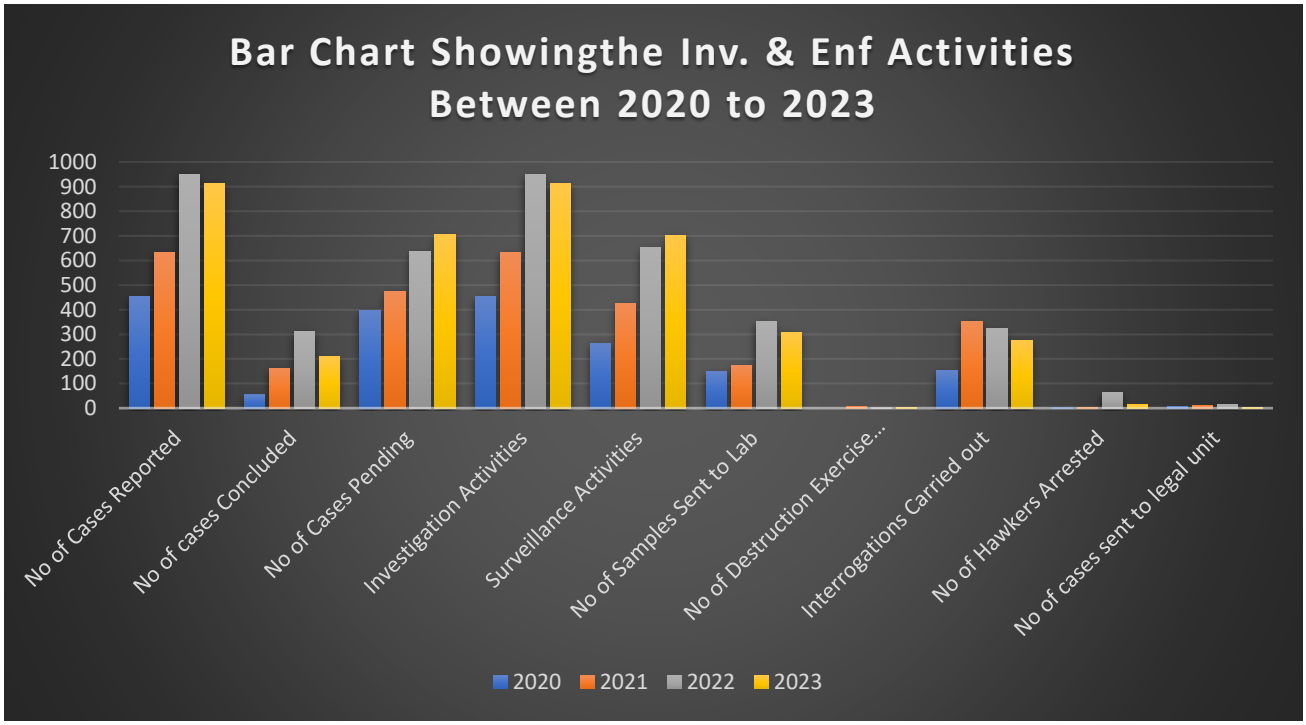
I. Other Activities

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

Table 16.2: Comparison of Enforcement Activities 2020 - 2023

	2020	2021	2022	2023
No of Cases Reported	452	634	948	913
No of cases Concluded	54	161	312	209
No of Cases Pending	398	473	636	704
Investigation Activities	452	634	948	913
Surveillance Activities	264	424	653	703
No of Samples Sent to Lab	148	172	351	309
No of Destruction Exercise Carried out	0	6	1	4
Interrogations Carried out	152	351	322	274
No of Hawkers Arrested	1	3	63	13
No of cases sent to legal unit	7	9	14	4
Total	**1,928**	**2,858**	**4,248**	**4,044**

Figure 16.3: Chart Showing Major Enforcement Activities for Year 2020, 2021, 2022 and 2023



Chapter Seventeen
Post Marketing Surveillance (PMS) Directorate

17.1 Introduction

NAFDAC has undergone several changes over the years, all towards strengthening the regulatory and operational efficiency of the Agency. In 2012, the Pharmacovigilance and Post Marketing Surveillance (PV/PMS) Directorate was created out of the defunct Establishment Inspection Directorate (EID), and last year on January 17th, 2023, the Post Marketing Surveillance (PMS) Directorate was separated from the Pharmacovigilance with the need to emphasize the Post Marketing Surveillance as well as Good Distribution Practices. The areas of focus of the new Directorate include:

- Routines surveillance of the supply chain system through monitoring of Distribution, wholesale, and sales outlets.
- Reactive surveillance and investigation of consumer complaints and alert notices.
- Monitoring of Supermarkets and other stores for compliance with the Global Listing of Supermarket Items.
- Inspection of Distribution, wholesale, and warehouses for holding, storing, and distributing pharmaceutical products and other regulated products.
- Coordination and dissemination of information on Rapid Alerts on Food and Feeds (RAFFs).
- maintaining a functional national database on Substandard and Falsified (SF) pharmaceutical products and other medicine-related problems.
- Conduct a risk-based survey on the quality of medicines and other regulated products.
- Collaborate with MAHs, Manufacturers, and other stakeholders to prevent, detect, and respond to Substandard and Falsified SF) products.
- Collaboration with Development partners such as WHO, UNODC, USAID, BMGF, USP
- Monitor Advertisements of NAFDAC-regulated products.

17.2 2023 Report of PMS Activities

A summary report of activities of the Directorate in 2023 is presented below.

1. Proactive Post Marketing Surveillance (PMS)

A summary of proactive (Routine) post-marketing surveillance carried out within the period under review (Jan. - Dec. 2023) is presented in the table below.

Table 17.1: Routine Surveillance

MONTH	No. of Routine Surveillance (Food, Drugs, Cosmetics)
January	628
February	1,635
March	964
April	1,326
May	1,835
June	1,108
July	2,234
August	2,216
September	3,259
October	1,698
November	5,579
December	977
Total	**23,459**

Table 17.2: Establishment Visits.

Month	Number of Establishment visited
January	284
February	446
March	416
April	477
May	562
June	683
July	802
August	954
September	1,148
October	861
November	930
December	607
Total	**8,170**

Table 17.3: Good Distribution Practice Inspections

Month	Number of GDP
January	1
February	32
March	58
April	42
May	66
June	72
July	117
August	63
September	61
October	35
November	54
December	34
Total	**635**

Table 17.4: GLSI Monitored

Month	Number of GLSI Monitored
January	5
February	4
March	8
April	14
May	16
June	12
July	10
August	23
September	1
October	7
November	0
December	2
Total	**102**

Reactive PMS

Table 17.5: Investigations carried out

Month	Number of Investigation carried
January	186
February	292
March	128
April	103
May	84
June	160
July	197
August	231
September	293
October	248
November	277
December	74
Total	**2,273**

Table 17.6: Products Mopped-Up

Month	Number of Products Mopped-Up
January	499
February	574
March	764
April	367
May	3,519
June	1,176
July	1,552
August	3,755
September	1,041
October	1,577
November	2,135
December	354
Total	**17,313**

Table 17.7: Sanctions Carried Out

Month	Number of Sanctions carried out
January	86
February	53
March	157
April	68
May	197
June	229
July	311
August	681
September	297
October	232
November	270
December	107
Total	**2,688**

Table 17.8: Consumers' Complaints.

Month	Number of Consumers' Complaints Treated
January	22
February	13
March	21
April	13
May	23
June	12
July	25
August	30
September	12
October	21
November	9
December	13
Total	**214**

17.3 Rapid Alert System for Food and Feeds (RASFF)

RASFF is a Rapid Alert System for Food and Feed. It is a key tool to ensure the cross-border flow of information to swiftly react when risks to public health are detected in the food chain. Border rejections are received from the European Commission Authentication Service and notifications are disseminated to the Nigeria Customs Service, Nigerian Agricultural Quarantine Service (NAQS), Nigeria Export Promotion

Council (NEPC), Ministry of Trade and Investment, The Central Bank of Nigeria, and other stakeholders in the food safety supply chain.

Table 17.9: Border Rejections Received from the European Commission Authentication Service May-December 2023.

Date Of Case	Ref. No	Contaminant
17/05/2023	2023.3276	Absence of health certificate and analytical report for sesame seeds from Nigeria
17/05/2023	2023.3277	Absence of health certificate and analytical report for sesame seeds from Nigeria
17/05/2023	2023.3279	Absence of health certificate and analytical report for sesame seeds from Nigeria
17/05/2023	2023.328	Absence of health certificate and analytical report for sesame seeds from Nigeria
17/05/2023	2023.3281	Absence of health certificate and analytical report for sesame seeds from Nigeria
31/05/2023	2023.3639	Absence of health certificate and analytical report for sesame seeds from Nigeria
31/05/2023	2023.3638	Absence of health certificate and analytical report for sesame seeds from Nigeria
26/06/2023	2023.4273	Sesame seeds from Nigeria with label/document mismatch
29/06/2023	2023.4383	Border rejection of Egusi seeds over the limits for Aflatoxins
22/06/2023	2023.422	Improper official certificate for sesame seeds from Nigeria. The official certificate was issued on 25.05.23, while the Consignment left the place of loading on 03.05.23. This is non-compliance with Art.11 Paragraph 2 letter(h) of R.2019/1793
22/06/2023	2023.4213	Improper Official certificate for Sesame seeds from Nigeria.
31/07/2023	2023.5152	No Identification Code on the packaging of the goods and poor hygiene conditions of transport in sesame from Nigeria
14/08/2023	2023.5487	Absence of health certificate for sesame seeds from Nigeria
25/08/2023	2023.5781	Cyanide in Cassava flour from Nigeria, via the Netherlands
01/09/2023	2023.593	Salmonella spp. in Sesame seeds from Nigeria
01/09/2023	2023.5932	Sesame seeds from Nigeria without a correct official statement
01/09/2023	2023.5933	Sesame seeds from Nigeria with the absence of original certificates
01/09/2023	2023.5934	Sesame seeds from Nigeria with the absence of original certificates
01/09/2023	2023.5956	Salmonella in Sesame seeds from Nigeria
01/09/2023	2023.596	Salmonella in Sesame seeds from Nigeria
27/09/2023	2023.6529	Sesame seeds from Nigeria with the absence of official certificates
27/09/2023	2023.653	Sesame seeds from Nigeria with the absence of official certificates
27/09/2023	2023.6533	Sesame seeds from Nigeria with the absence of official certificates
27/09/2023	2023.6534	Sesame seeds from Nigeria with the absence of official certificates
28/09/2023	2023.5152	No Identification code on the packaging of the goods and poor hygienic conditions of transport in sesame seeds
04/10/2023	2023.6708	Sesame seeds from Nigeria with document mismatch

25/10/2023	2023.6709	Sesame seeds from Nigeria with document mismatch
09/11/2023	2023.7714	Absence of health certificate for sesame seeds from Nigeria
09/11/2023	2023.7715	Absence of health certificate for sesame seeds from Nigeria
09/11/2023	2023.7716	Absence of health certificate for sesame seeds from Nigeria
09/11/2023	2023.7718	Absence of health certificate for sesame seeds from Nigeria
09/11/2023	2023.776	Presence of salmonella spp. in 1 out of 5 Shelled Sesame samples
14/11/2023	2023.7846	Sesame seeds with document mismatch
14/11/2023	2023.7849	Sesame seeds with document mismatch
14/11/2023	2023.7853	Sesame seeds from Nigeria with the absence of original official certificates.

Table 17.10 Products Recalled in 2023

S/N	Product	BN	MFD	EXPD	NRN
1	Polyforte Suspension	All batches			
2	Mesporin injection (CEFTRIAXONE 1000MG)	Z0086Z0114	01-05-2022	01-05-2022	04-5969
3	Tetracycline Hydrochloride Ophthalmic Ointment USP 1%				
4	Sprite 50CL Glass bottle	AZ6 22: 33	18/04/23	18/04/24	
5	Appendor Syrup 200ml	Change of formulation	-	-	-
6	Real Whippy Mayonnaise 245G/ 460G	OA2GP220614A, OA2GP220611A, 0A2GP22O617A	06- 2022	06- 2023	A8-0700
7	Krishat Diclofenac injection	KP23008	03-2023	02-2026	A11-100427
8	Abbott MPIMA HIV I/2VL				
9	Malven Ergometrine Injection	13792302	01-2023	12-2025	B4- 5295

Table 17.11: Training/ Meetings/Other Activities:

Months	No of Training/Meeting Attended
January	9
February	8
March	11
April	11
May	13
June	15
July	25
August	8
September	11
October	9
November	9
December	6
Total	**135**

Chapter 18
Pharmacovigilance Directorate

Introduction

In its strides to actualise the mandate of the Agency, which is to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of Food, Drugs, Cosmetics, Medical Devices, Packaged Water, Chemicals and Detergents (collectively known as regulated products), the PV Directorate has sustained its activities within its functions and has made necessary impact.

The activities of PV Directorate within the period under review are summarily be presented as follows:

18.1 Structure:

The Directorate is currently structured along the following divisions and offices;

I. Office of the Director headed by the Director
II. PV Liaison office Lagos headed by a Deputy Director
III. Pharmacovigilance Division headed by a Deputy Director
IV. Advocacy and Public Health Collaborations headed by an Assistant Director
V. Food and Drug Information Center (FDIC) headed by a Deputy Director
VI. Zonal and state Offices.

In addition to the various divisions within the PV Directorate, the Pharmacovigilance Zonal Centers situated in various tertiary health institutions complement the work of the directorate by creating PV awareness among healthcare providers as well as collation of completed Adverse Drug Reaction reporting forms. The host institutions of the Zonal Pharmacovigilance Centres are:

- ✓ Ahmadu Bello University Teaching Hospital (ABUTH) Zaria
- ✓ University of Ilorin Teaching Hospital (UITH)
- ✓ University of Maiduguri Teaching Hospital (UMTH)
- ✓ Lagos University Teaching Hospital (LUTH)
- ✓ University of Benin Teaching Hospital (UBTH)
- ✓ Federal Medical Centre (FMC) Owerri.

18.2 Functions of the Directorate

PV Directorate is saddled with the following responsibilities:

i. Implementation of National Policy on Pharmacovigilance and provision of science-based advice and information on safe use of medicines.
ii. Coordination of Pharmacovigilance activities Nationwide
iii. Implementation of Risk Management Plans (RMP) in collaboration with the Pharmaceutical Industry and MAHs as appropriate
iv. Pharmacovigilance Inspections
v. Supporting the establishment of active Pharmacovigilance Centers in healthcare institutions in the country
vi. Creation of awareness on Pharmacovigilance among health professionals, healthcare providers, Marketing Authorization Holders and the general public
vii. Promoting rational and safe use of medicines in Nigeria
viii. Medicine safety communication
ix. Coordinating the activities of the National Drug Safety Advisory Committee (NDSAC)

x. Sourcing, collating, preserving, storing, retrieving and dissemination of information on food, drugs, cosmetics, chemicals, and other NAFDAC regulated products.
xi. Establishing and maintaining a functional national database on ADRs and other medicine related problems
xii. Coordinating the activities of NAFDAC Consumer Safety Club NCSC in Secondary Schools and NAFDAC Consumer Safety Publications NCSP

18.3 Achievements:

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:

A. 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 2023, a total of Fifty Two Thousand Six Hundred and Forty-Five (52,645) ICSRs/AEFIs were documented on the Vigiflow.

Received Reports

A total number of Three Thousand Three Hundred and Fifty-Seven (3,357) ICSRs/AEFIs were received in 2023 via the various reporting platforms as shown in table below:

Table 18.1. Number of Reports Received in 2023.

Means of reporting	2023	Comments
MedSafety App	2,619	2,619 Assessed and shared with Vigibase
e-Reporting	447	447 Assessed and shared with Vigibase
CIOMs	196	196 Uploaded, Assessed and shared with Vigibase
NPC ADR Forms	95	95 Uploaded, Assessed and shared with Vigibase
Total Received	**3,357**	

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 2023, Three Hundred and Sixteen (316) ICSRs/AEFIs were manually uploaded to vigiflow as shown in Table below:

Table 18.2. Manual ICSR/AEFI Data Entry to Vigiflow in 2023

	Number Uploaded	Number Committed to Vigibase	Number Pending Review and Committing
Manual Data Entry ICSRs	316	316	0
Manual Data Entry AEFI	0	0	0
Total	316	316	0

B. Review of Safety Documents

Seventy-Six (76) Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report (PBRER) and 9 Risk Management Plan (RMP) were received and reviewed in 2023.

C. 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. **Healthcare professionals were trained in 2023 across 25 states namely: Taraba, Kano, Kogi, Kebbi, Sokoto, Kwara, Plateau, Kaduna, Nassarawa, Akwa Ibom, Cross-River, Osun, Ondo, Lagos, Adamawa, Katsina, Enugu, Ebonyi, Imo, Bauchi, Jigawa, Rivers, Gombe, Benue and Niger.**

D. Meetings/Trainings/Workshops.

The Directorate attended/participated in Sixty-Three (63) Meetings/Trainings/Workshops in 2023 Some of which are listed below.

- Biweekly Meetings of the AU 3S group
- Biweekly AEFI TWG meetings
- Directorate Meeting GBT Meeting 17th May 2023
- CEM Data Validation 22nd to 26th May 2023
- CEM Phase II Causality Assessment meeting with UMB 12th to 16th June 2023
- Inaugural meeting of National SRMTH Self-care Coordination group 20th to 21st July 2023
- Training on Health Safety and Environment SOPS 21st August 2023
- PV State Training 23rd 27th October 2023
- NTD Supply Chain Management TWG Inaugural Meeting 07th – 9th November 2023
- Situation Analysis Workshop for Multisectoral Public Health Events at Points of Entry 22nd to 23rd November 2023

E. Recall and Alert Notifications

Fifty-Seven (57) notifications were received and treated within January and December 2023. Some are listed below.

- Alert on Substandard (contaminated) METHOTREXTM 50mg identified in the WHO Eastern Mediterranean region.

- Corim Industries Issues Allergy Alert on Undeclared Peanuts in Peanut Butter hot Chocolate
- Alert on Substandard and Falsified Medical Products Seized in Cote D'Ivoire.
- Alert on Killer Cough Syrup Manufactured by Fraken in Cameroon.
- Alert on One Batch of Falsified Ozempic (Semaglute) Pen in Nigeria
- Alert on Substandard (contaminated) medicines syrup identified in WHO Region of the Western Pacific
- Alert on Foreign Unauthorized Sugar from Brazil and India
- Public alert on Presence of Suspected Counterfeit Artequin 600/750 Tablets in Circulation in Nigeria
- Recall of Dacarbazine 100mg, 200mg & 500mg powder for solution for injection vials by medac GmbH (t/a medac Pharma LLP)
- Alert on Substandard (contaminated) syrup and suspension medicines identified in the WHO Regions of the Americas, Eastern Mediterranean, South-East Asia and Western Pacific

Within January to December 2023, a total of Fifty-Seven recalls and alerts were received and treated, eighteen (18) DHCPL and Six (6) zonal notices were disseminated to Healthcare Professional and NAFDAC offices respectively, Thirty-Eight (38) Public alert were sent for upload on NAFDAC website.

F. Review of Safety Submissions for January to December 2023

Below is a breakdown of these products:

Fifty-Four (54) Safety submissions were received and reviewed within the period under review.

G. PV Newsletter:

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

1. Factors that affect the uptake of booster doses of COVID-19 vaccine
2. Pharmacovigilance in Public Health Programmes
3. Spontaneous Reporting in a hospital setting: barriers and solutions
4. Pharmacovigilance Practice by Community Pharmacists- Challenges & Solutions.

First quarter 2023 newsletter titled' 'Factors that affect the uptake of Booster doses of Covid-19 Vaccine'' was created and disseminated within March 2023. The second quarter 2023 Newsletter vol 16 No2 ` Pharmacovigilance in Public Health programmes" was prepared and disseminated to stakeholders in June 2023.

H. Poison Control Articles

First quarter articles volume 1: on harmful effects of chemicals and management of emergencies (Poisons/control) titled "An Overview of Ethylene and Diethylene Glycols Poisoning, Treatment and Management'' has been disseminated accordingly.

"Volume 2 titled Nitrosamine Impurities in Medicines, Acceptable Intake Limits, Hazardous Effects and Control" has also been disseminated accordingly.

Table 18.3 Summary of Activities per Month:

	Jan	Feb	Mar	April	May	June	July	Aug	Sep	Oct	Nov	Dec.	Total
Number of Advocacy Visit carried out.	1	2	2	2	3	3	4	3	8	15	14	0	**57**
Number of Collaborative meeting attended	3	2	1	3	3	3	2	2	1	2	3	2	**27**

Participants at the PAVIA Training

PV Staff at The Stakeholders Meeting

A cross section of participants at the NMEP multi-sectoral meeting

The Task Team on Effective Vaccine for Lassa Fever in Nigeria. (Perm Sec in the Middle, Flanked By ED-NPHCDA, NCDC,WHO, Rep From NAFDAC)

Kick-off of the world AMR awareness week 18-24 November, themed “preventing antimicrobial resistance together”.

J. Advocacy to the Six Zonal Pharmacovigilance Centre:
In the effort to strengthen pharmacovigilance systems in Zonal Pharmacovigilance Centres, the Agency through the Pharmacovigilance Directorate conducted Advocacy Visits to Six Zonal Pharmacovigilance Centre, State Ministry of Health, the CMDs of Tertiary Hospital where the ZPCs are located.

The objectives of the visit were:

ii. To conduct a high-level advocacy, visit to the State Ministry of Health and CMDs of the host institutions of the Zonal Pharmacovigilance Centres.
iii. To carry out needs assessment of the Zonal Pharmacovigilance Centers
iiii. Discuss the terms of reference and secure signature of ZPC Coordinators
iiv. To discuss challenges faced by the Zonal Pharmacovigilance Centers and collect the developed work plan
iv. To discuss upcoming training for health workers and LMCU staff on Adverse Event Reporting tools.
ivi. To discuss on Confidentiality Agreement/any conflict-of-interest agreement and secure signature of ZPC staffs

Table 18.4 The ZPC's visited:

S/N	Zone	Location	Head of ZPC
1.	South-South	University of Benin Teaching Hospital (UBTH)	Dr Abimbola Opadeyi
2.	North-West	Ahmadu Bello University teaching Hospital (ABUTH)	Pharm Foluke Garnett
3.	South- West	Lagos University Teaching Hospital (LUTH)	Dr. Adebowale Adewunmi
4.	South-East	Federal University Teaching Hospital Owerri (FUTH)	Dr Frank Onuoha
5.	North-Central	University of Ilorin Teaching Hospital (UITH)	Pharm Busayo Elegbede
6.	North- East	University of Maiduguri Teaching Hospital	Dr Bello Ibrahim

Activities Carried out during the Advocacy:

a. Advocacy Visit to Commissioners / Permanent Secretaries State Ministry of Health

The Commissioners and Permanent Secretary (in some states) of the State Ministry of Health, Director pharmaceutical service, and State Logistic Management Coordinating Unit, Executive Secretary of Hospital Management Board, ZPC Coordinator and other key staff of the ministry were on visited in all the Zones. The NAFDAC advocacy team included the two National Pharmacovigilance Staff and One NAFDAC State PV focal person. Highlights of the meeting in all the zones were as follows:

- Need for a strengthened pharmacovigilance system in the zones towards the achievement of ML4 currently being sought by the Agency in the WHO GBT assessment, emphasizing the place of increased reporting of ADRs.
- Training needs of Health Care providers in the state
- Increase and sustain collaboration between NAFDAC and State Ministry of Health

b. Meeting with the Chief Medical Directors/CMACs of the institutions and their team of health experts.

The NAFDAC team in all the zones met with the CMDs of the Hospitals in some cases the CMACs and for their efforts at ensuring PV is entrenched in their system was appreciated. They all pledged the institutions unwavering support for NAFDAC and its programs including strengthening PV systems in the other states in the Zone.

c. Assessment of Zonal Pharmacovigilance Centre in each Zones:

The advocacy team from the NPC and State PV focal persons carried out the assessment of the ZPC in each zone. Highlights of the meeting in all the Zones:

- The Terms of Reference, Conflict of Interest were reviewed with the ZPC Coordinator for better understanding, agreement and Signature.
- Training on the use of VigiFlow was carried out in some states
- Planning for PV training in the various states in the zones was also discussed.
- The need assessment in each state was also discussed as summarised in the table below:

Table 18.5 Statistical Summary of PV Activities Nationwide

S/N	GPZ	State	No of Institutions Visited for PV Advocacy and detailing	No of Adverse Events Reports Received	Pharmacovigilance Investigations
1	NC	Plateau	7	1	0
		Benue	25	0	3
		Nasarawa	10	0	0
		Kogi	0	1	0
		Kwara	0	11	1
		Niger	6	0	0
		FCT	4	1,171	0
	ST		52	1,184	4
2.	NW	Jigawa	84	0	0
		Sokoto	10	0	9
		Katsina	28	0	0
		Kaduna	42	0	0
		Kebbi	51	10	0
		Kano	23	0	0
		Zamfara	6	0	0

	ST		244	10	9
3.	SW	Osun	27	0	0
		Ondo	12	0	2
		Oyo	60	0	0
		Ogun	4	0	0
		Ekiti	15	0	2
		Lagos	37	1	4
	ST		155	1	8
4	NE	Taraba	29	0	0
		Adamawa	0	0	0
		Bauchi	0	0	0
		Borno	67	0	0
		Gombe	88	0	0
		Yobe	4	0	51
	ST		188	0	51
5.	SE	Abia	12	0	0
		Anambra	70	0	0
		Ebonyi	73	0	0
		Enugu	32	0	0
		Imo	57	0	0
	ST		244	0	0
6	SS	C/River	3	0	9
		A/Ibom	4	0	0
		Bayelsa	0	0	0
		River	21	2	55
		Delta	0	0	0
		Edo	9	0	0
	ST		37	2	64

Chapter 19
Legal Service Directorate (LeSD)

19.1. 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	46	15	61
February	42	10	52
March	64	42	106
April	53	20	73
May	66	35	101
June	71	32	103
July	30	35	65
August	155	31	186
September	80	26	106
October	86	32	118
November	114	10	124
December	71	21	92
		Total	**1,187**

19.2. Agreements

- A total of Sixty-Eight (68) Contract agreements were prepared for the months under review.
- A total of Eleven (11) Bond Agreement were prepared for the period's months under review.

19.3. Meetings

- Meeting held with the House Committee Chairman/Deputy Chairman on Healthcare Services, DG NAFDAC, LESD Abuja and the consultant working on CAP C34 on fine-tuning the Bill for Amendment.
- Review of the NAFDAC Fats, Oils & Foods Regulations 2022 and attending the stakeholders' strategic meetings on TFAs with the FMOH, FMOJ and other external stakeholders.
- National Workshop on the reform of Tax laws in Nigeria on 24th of May. reform the Capital Gains Tax Act, Cap. C1, LFN 2004. and NAFDAC was represented by a Staff of LeSD.
- LeSD and other MDAs attended the 12 years of implementation of Freedom of information (FOI) celebration held on the 31st of May 2023, at the Federal Ministry of Justice.
- The inauguration of FOI was held on the 6th of September 2023. The members were inaugurated in the presence of the DG NAFDAC and Directors and DDs in Abuja.

- Meeting held at FMITI on the 14th of September 2023 on the Nigeria-UK enhanced Trade and Investment partnership. The FMITI invited NAFDAC to attend a meeting to develop an MOU and the draft MOU sent by the UK government.
- LeSD attended a 2-day symposium from 24th -25th October 2023 organized by The Bureau of Public Service Reforms (BPSR), on Countering Organized Crime in Africa.
- LeSD, OTIR and Servicom attended a workshop organized by PEBEC on 23rd October 2023 on Highlights of the Business Facilitation Act, 2022.
- The Home of the Earth Foundation (HOMEF) invited legal practitioners and right groups for a training on pesticide hazards and human rights which was held on the 7th of November 2023 at Broadfield Hotel Apo Residence, Abuja.
- Meeting held at FMITI on the 14th of September 2023 on the Nigeria-UK enhanced Trade and Investment partnership. The FMITI invited NAFDAC to attend a meeting to develop an MOU and the draft MOU sent by the UK government.
- LeSD attended a 2-day symposium from 24th -25th October 2023 organized by The Bureau of Public Service Reforms (BPSR), on Countering Organized Crime in Africa.
- LeSD, OTIR and Servicom attended a workshop organized by PEBEC on 23rd October 2023 on Highlights of the Business Facilitation Act, 2022.
- The Home of the Earth Foundation (HOMEF) invited legal practitioners and right groups for a training on pesticide hazards and human rights which was held on the 7th of November, 2023 at Broadfield Hotel Apo Residence, Abuja.

19.4. Committees

The Directorate has had full representation on the following committees:

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

19.5. Public Hearings at The National Assembly

- Public Hearing on A Bill for An Act to Provide for the Establishment of Traditional Complementary and Alternative Medicine Council of Nigeria; and For Related Matters (HB.2L72) the public hearing was held on the 13th of April at the NASS.
- The Committee on Delegated Legislation of the House of Representatives invited the Agency for a meeting on the 6th December, 2023

19.6. New Cases

a) **FRN Vs IGWE EMMANUEL TOCHUKWU -** The Agency filed a charge against the defendant at the Federal High Court (FHC) Awka, Anambra State for the production of fake and unregistered Dettol and JIK.
b) **FRN Vs OBINNA OWEREKWE MACHEAL & ANOR-** The Agency filed a charge against the defendant for Sale, Distribution, and possession of unregistered Super Delicieur Cooking Margarine, at the FHC Umuahia.
c) **FRN Vs VALENTINE DURU NDUKWE (FHC/L/39C/2)-** The Agency filed a charge against the defendant for Importation and possession of Really Extra Tablets at the FHC Lagos.
d) **MUSIBAHU IDRIS MUHAMMAD Vs PROMASIDOR NIG. LTD & NAFDAC (FHC/KN/CS/213/2022)** – Instituted a civil action against the Agency for breach of his fundamental human right at the FHC Kano.

e) **FRN Vs SUNDAY CHIBIUKE & 2Ors (FHC/L/176C/2023) -** The Agency filed a charge against the defendant for Sale and Possession of Japata Alcoholic Bitters contaminated with Cannabis at the FHC Lagos.

f) **FRN Vs IDUME OKO EMMANUEL(FHC/L/374C/23)**. - The Agency instituted action against the accused for obstruction of a NAFDAC Staff at the Federal High Court Lagos.

g) **FRN Vs UCHENNA NWANCHI & ANOR (FHC/AWK/ C/268/23)** – The Agency instituted action against the accused for sale of unregistered GE Man Energy Power drink.

h) **FRN V Onyeka Christian Ibeh & ANOR (FHC/B/135c/2023)**

The Agency filed a three (3) count charge against the defendants at the Federal High Court, Benin City, and is to arraign them for the offence of sale, distribution, and possession of unregistered processed food to wit: Mivina Chicken Seasoning.

i) **FRN V Okoye Samson Anene & ANOR (FHC/B/136c/2023)**

The Agency filed a four (4) count charge against the defendants at the Federal High Court, Benin City, and is to arraign them for the offence of sale, distribution, importation, and possession of unregistered processed food to wit: Mivina Chicken Seasoning.

j) Ejiofor Lucky Adimkpaya & 5 Others v. NAFDAC & 8 Others Suit No: A/165/2023 - The Claimant filed a suit challenging the legality of the allocation of the Alabama Land to NAFDAC and praying the court to declare it null & void.

19.7. Judgment

a) **ADEMOLA MOBOJURI Vs NAFDAC** -Judgement was delivered on the 27th July, 2023 on the matter in favor of NAFDAC at the National Industrial Court FCT. The Court awarded costs in favor of the Agency while the plaintiff was told to return the official vehicle in his possession.

b) **LELASSCORN v. NAFDAC.**

On 23rd of September 2023, the Agency received judgement in its favor in the above-mentioned case. The applicant sought an order of court to compel the Agency (under Freedom of Information Act) to release the DG's report on the death of some persons in Kano allegedly from a flavored drink in Kano in 2021.

The Agency has presented preliminary report to the Kano State Government and the culprits have been arrested.

c) **Mohammad Ayaz & 1Or V. NAFDAC & 1Or**.

On the 5th of October 2023, the Agency received judgement in its favor in the above mentioned. The applicant had challenged NAFDAC's power to carry out enforcement activity on his premises and alleged breach of his right. He prayed the court to declare illegal all regulatory actions taken pursuant to the inspection. The court ruled that the applicant's right was not breached and ordered him to submit to NAFDAC for investigation.

d) **MUSBAHU IDRIS MUHAMMAD Vs. Promasidor Nig. Ltd & NAFDAC (FHC/KN/CS/213/2022)**

The Plaintiff brought a case of Malicious prosecution against the Agency at the Federal High Court, Kano. The Plaintiff claimed N44,000, 000.00 (forty-four million naira) as Damages. The Court however struck out the case for lack of diligent prosecution.

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

19.8. Training/Workshop/Conference

Legal officers attended the following trainings and workshops:

- Nigerian Bar Association Conference from 28th August to 1st September 2023.
- Countering illicit Trade Amid Expanding Trade Infrastructure Investment from 13th - 15th November 2023.
- Regional Workshop for Africa on Legislation Against the Manufacturing of and Trafficking in Falsfied Medical Products from 28th -30th November 2023. LESD presented a paper on Penalty and Sentencing.
- Consumer Protection Trade, Investment, Competition and Digital Economy Law Practice organized by (NAILS) from 5th – 7th December 2023

19.9. Laws

a) **AMENDMENT OF NAFDAC ACT, CAP N1 LFN 2004** - Amendment of certain sections of the Act to enhance the activities of the Agency is pending at the Senate for Concurrence.

b) **BILL FOR THE REPEAL AND RE-ENACTMENT OF THE COUNTERFEIT ACT, CAP C34 LFN 2004** - Work is ongoing at the Secretariat of the House committee of Healthcare in preparation for Third Reading at Plenary of the entire House.

19.10. FOI Committee

The inauguration of FOI was held on the 6th of September 2023. The members were inaugurated in the presence of the DG NAFDAC and Directors and DDs in Abuja.

19.11. Restructuring

Legal Services with the approval of the Director-General was restructured into the following divisions:

i. Regulatory and Alternative Dispute Resolution (ADR)
ii. Civil litigation
iii. Criminal Prosecution
iv. Legal Drafting

19.12. Regulations

Two (2) new regulations were submitted at Federal Ministry of Health for gazetting.

Chapter Twenty
Human Resource Management (HRM) Directorate

20.1 Introduction:

The Human Resources Management is involved in the 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 optimal productivity.

The Directorate has three (3) Divisions namely:

1. Appointment, Promotion, Discipline & Establishment
2. Staff Welfare and Training
3. General Services

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

- Staff recruitment/appointment, staff, promotion, transfer and posting in the Agency.
- Dealing with complaints of staff misdemeanors/misconduct and recommending proper disciplinary actions against erring staff.
- Documentation of new staff, preparation of staff nominal roll and issuing of staff identify cards.
- Custody of the Agency's rented and owned properties.
- Handling of insurance matters as they relate to staff and NAFDAC assets.
- In charge of security services, environmental matters and other corporate issues.
- Coordination of 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.

20.2. Appointment, Promotion, Discipline & Establishment

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

The 2023 promotion Interview was conducted successfully. A Total of 638 qualified staff members were invited to participate in the exercise.

- Promoted staff - 439
- Conversion - 26

a. **Discipline**

In the year under review, Disciplinary committee meetings were held, and different types of disciplinary measures were meted out to erring staff. These include query and warning of officers who were found culpable of various offenses, as detailed below:

- Issued query - 12
- Staff issued warning - 11
- Suspended staff - 1
- Dismissal - 19

b. **Records & Registry**

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

c. Leave Matters

During the period, majority of staff members enjoyed various types of leave, such as the Annual leave, sick leave, examination leave, and casual leave.

d. Exited staff grew up to 84 in the period under review as shown in the breakdown below:

- No of resignation - 23
- No of voluntary retirement - 28
- Staff death toll - 2
- Resignation – 23
- Tenured Directors- 4
- Statutory Retirement 27

20.3. Staff Welfare and Training

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

a. **Welfare**

- During the period under review, a total of 2 staff members benefitted from the support for staff involved in operational hazards, accidents, mishaps, other kinds of emergencies in the course of official duty.
- A total of 3 staff members benefitted from financial support with regards to health.
- During the period under consideration, a total of 86 staff members were paid transfer allowance.
- A total of 9 people were given repatriation allowance.
- 2 staff members were paid burial expenses.
- 141 staff members were paid warm clothing allowance.
- Annual allowances were paid as follows:

  i. 368 staff members benefited from Laboratory allowances in January 2023.
  ii. 2,121 staff members received the regulatory allowance.
  iii. 2,107 staff members were paid hazard allowance.
  iv. 373 staff members received the Lab allowance in August 2023.
  v. 2,081 staff members benefited from the productivity allowance.

- Welfare stipends for Sallah was paid to 2,086 while 2,062 staff members were paid Christmas bonuses.
- 82 staff members benefited from financial support for wedding of staff/child of staff and loss of child/spouse/biological parent of staff.

Note:

- The discrepancies in the number of staff regarding various payments is because of staff exits at various times in the year under review.

b. **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 trainings coordinated by HRM Directorate to enhance productivity of staff members as follows:

i. 44 staff members went for Pre-retirement training in June 2023.
ii. 55 staff members went for performance management system training in July 2023.
iii. 40 staff members went for performance management system training in August 2023.
iv. 40 staff members went for performance management system training in September 2023.

20.4. General Services.

This Division carries out the following activities:

- Handles insurance matters as they relate to staff and NAFDAC assets.
- Coordinated matters relating to NAFDAC Governing Council.
- Liaise 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.
- Handles Cleaning and Sanitation issues.
- Handles security of Offices in NAFDAC formations.

a. Insurance Matters

- Group Life Assurance in place for all staff of the Agency
- NAFDAC Properties and Vehicle were duly covered.
- Motor Insurance were duly covered.
- Building (Equipment/Fire & special peril/Burglary) insurance policy were all covered.

b. Council Matters

The NAFDAC Governing Council meetings held four (4) times during the year under review.

c. Transport & Maintenance

Activities of the Division are:

- The Agency currently has 218 functional vehicles,
- 41 non-functional vehicles were disposed through auction.

d. Service Providers (19)

i. Cleaning Services (14):

- Chrysolite Services – Agulu Lab. Complex
- Emobic Commercial Enterprises - Agulu Lab. Compound

- Am- Engineering Services& Consultancy - Maiduguri Lab. Building
- Brette Global Concept Ltd - Port-Harcourt Lab.
- High Hope Investment Ltd. - Corporate Hq, (Annex) Abuja
- Caminon Intergrated Services Nig. Ltd. – Yaba Laboratory & PID Block
- HOCK-BU Ltd. - Corporate HQ, Abuja
- ETS Oscars & Company (Nig) Ltd. – zonal lab complex Agulu
- Henritton Ventures Limited – Zonal/State Office Narayi, Kaduna
- Henritton Ventures Limited- Kaduna Area Laboratory
- Lizabell Nig. Limited – I & E Apapa Lagos
- Lizabell Nig. Limited- Kaduna Lab. Narayi Quarters
- Lizabell Nig. Limited – Isolo Office Complex
- Mr. Wash – Oshodi Lab.

ii. **Security Service (3)**

- Jual Security Services - NAFDAC Formations excluding FCT and Lagos offices, Southeast and Agulu Lab.
- Jupiter Security Services - Southeast Offices & Agulu Laboratory
- Kings Guards Nig. Ltd. – NAFDAC Corporate HQS, Abuja & Lagos Formations

Maintenance Services (2)

- BOBBY TECH. NIG. LTD. – Air Conditioners at NAFDAC Headquarters, Abuja
- AFAN PROJECTS – Fumigation & Pest Control at NAFDAC Headquarters, Abuja

Chapter Twenty-One
Planning Research and Statistics (PR&S) Directorate

The PR&S Directorate is a service Directorate that is charged with the responsibility of planning, researching, collecting, collating, storing and retrieving of data aon the activities and achievements of the Agency. The directorate also monitors and evaluates the implementation of plans,programmes and projects of the Agency.

21.1 Planning and Support Services (PT&SS)

A. Training

PT&SS Division collated staff training needs and successfully coordinated the participation of staff and stakeholders in various trainings/staff development programmes. A total of Two Thousand, Four Hundred and Seventy-Eight (2,478) staff of the Agency participated in One Hundred and Eighty-Six (186) training programmes. That is Two Thousand Three Hundred and Thirty (2,330) staff attended One Hundred (100) Local Programmes while One Hundred and Forty-Eight (148) staff attended Eighty-Six (86) various international programmes.

Table 21.1: Breakdown of staff participation at Local & Foreign Training Programmes in 2023.

Programme	Foreign		Local		Total	
	No of Programs	Staff participation	No of Programs	Staff participation	No of Programs	Staff participation
Trainings/Workshops	86	148	100	2,330	186	2,478

The Directorate also coordinated the hosting of One (1) TMC Meeting in year 2023.

B. Industrial Attachments

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 students on Industrial attachment, with courses relevant to the operations of NAFDAC in our various laboratories in Lagos, Agulu, Maiduguri and Kaduna. 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 Eighty-Three (2,083) application letters were received out of which Seven Hundred and Forty-Eight (748) applications were processed, Six Hundred and Forty-Seven (647) Assumption letters were received from the various laboratories and One Hundred and Eleven (111) certificates were issued at the end of 2023.

C. Excursion

During the year 2023, four excursions were conducted in the Agency.

21.4 Monitoring and Evaluation (M&E)

The Monitoring and Evaluation Division of PR&S is charged with the responsibility of;
I. Developing M&E systems that will aid in the implementation of the agency's Annual work plan.
II. Collection, validation, storing and analyzing of monthly, quarterly, bi-annual and annual reports of all Directorates in the Agency.
III. Collaborating with the Research and Statistics (R&S) Division in the development of an Annual report for the Agency.
IV. Providing supportive supervision by carrying out quarterly Field Visits of all Directorates to monitor and ensure that programmatic activities are being carried out as planned.
V. Coordinating the Internship programme in the Agency.
VI. Providing technical guidance to Directorates of the Agency by incorporating appropriate M&E systems into their programmes.

A. Monthly Reports

The Division reviewed the 2023 Monthly reports received from all the Directorates of the Agency. These reports were validated for detailed statistical analysis and finalized into the Quarterly, Bi-Annual and Directorate Annual Performance Evaluation Report.

The M&E Division received a total of **One Hundred and Fifty-Four (154) monthly reports** from the various directorates. Thirty-Nine (39) reports, **25%** were submitted within the specified timeline of 15th of preceding month while One Hundred and Fifteen (115), **75%** were submitted after the specified timeline. The reports were validated and analyzed using comparative analysis for Directorates performance.

B. Annual Report
3.0 The Division reviewed the 2022 Monthly reports received from all the Eighteen (18) Directorates of the Agency. These reports were validated and forwarded to the R&S Division of PR&S for detailed statistical analysis and finalization of NAFDAC 2022 Annual report.

C. Internship
4.0 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 of Nigeria approved internship centre. NAFDAC is one of the approved centres for training of Intern Pharmacists.
In the year under review, total of Five Hundred and Six (506) Internship Applications were processed, Fifty-Five (55) interns were engaged in 2023, Forty-One (41) interns previously engaged in 2022 were discharged in 2023, and Forty-Two (42) interns were given Internship certificate of completion while Fifty-Five (55) interns are still in the system.

D. Others
The Division coordinated the review of Agency's Strategic plan of 2018-2023 that will form the basis for the development of the four year Strategic plan of 2024-2027 of the Agency.

21.3 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 among others did the following: -

A. Surveys and Statistical Analysis.

- Carried out **123** statistical analyses covering: - Monthly Analysis of Presidential Enabling Business Environment Council (PEBEC) reports for the Office of Trade and International Relation (OTIR/OSIC), Analysis on monthly complaints received and Customer feedback system for Reforms Unit, Collated Monthly/Quarterly Zonal performance reports.
- Developed 8 survey protocols and questionnaires in year 2023.
- Rendered Statistical support to other Directorates.

B. Library Services.

NAFDAC Library is charged with the responsibility of providing 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 2023. The library carried out the following activities: -

- Rendered reference service to library users.
- Carried out user education.
- Provided 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 **489** users visited the library in the year under review.

Chapter Twenty-Two
Finance and Accounts Directorate

The Finance and Accounts Directorate is one of the non-technical Directorates in NAFDAC. It is saddled with the responsibility of managing the financial resources of the Agency. In the course of carrying out its functions it is guided in its day-to-day operation by Financial Regulations, Finance Act, Fiscal Responsibility Act 2007 and Circulars and Memos emanating from regulatory bodies.

In the year ended 31st December 2023, the following were the major operational activities of Finance and Accounts:

i. The office of the Auditor General for the Federation came for the statutory periodic checks in NAFDAC. At the end of the audit, they gave the clean sheet of records to the Agency. The report was basically on five issues which were sorted out amicably.
ii. The Agency's Account for the year ended 31st December 2022 was audited and both audited accounts and the management letters therein were submitted to the statutory bodies as required. The Audit was carried out by the firm of Messrs. Issa Shuaib & Co, Chartered Accountants who have been auditing the accounts for the Agency for the past few years.
iii. Within the year under review, a new Accounting Packaging Software, SAP Business By Design was fully installed and configured. It replaced the old Accounting System Sage Line X3. The new SAP Business By Design was introduced for accuracy, fastness and reliability.
iv. The Agency's Budget for year 2024 was prepared and defended before the Joint Senate and House of Representatives Committees on Health. The budget that was presented to the Joint Committee was prepared in line with the Medium-Term Revenue Expenditure Framework for years 2024-2026 earlier submitted to the Budget Office of the Federation as statutorily required but with minor adjustments.

Table 22.1: Summary of the Financial Information that was Uploaded to the BIMMS (Budget Information Management and Monitoring System) Platform:

	2024 (N)	2025 (N)	2026 (N)
Internally Generated Revenue	5,110,998,270.84	5,290,151,413.28	5,522,125,593.60
User Fee	16,719,066,479.23	17,555,019,803.19	18,432,770,793.35
Personnel Cost	7,797,140,484.00	8,186,997,508.20	8,596,347,383.61
Capital Allocation	233,833,939.50	245,525,636.48	521,338,719.67
Overhead Expenditure	11,809,982,477.63	12,400,481,601.51	13,020,505,681.59
Capital Expenditure	7,090,996,500.00	7,445,546,325.00	7,817,823,641.25

However, the Budget for year 2024 has the following highlights:

Proposed Internally Generated Revenue	-	N4,113,303,080.52
Proposed User Fee	-	N14,878,768,960.00
Estimated Overhead Expenditure	-	N12,744,645,165.67
Estimated Capital Expenditure	-	N11,757,188,876.48
Expected Personnel Allocation	-	N7,797,140,484.00
Expected Capital Allocation	-	N317,230,185.00
Expected Overhead Allocation	-	NIL

v. The Budget Performance of the Agency for year under review as at November 2023 stood as follows:

Actual Internally Generated Revenue	-	N3,412,003,427.00
Actual User Fee	-	N12,398,974,162.00
Actual Overhead Expenditure	-	N9,744,206,168.77
Actual Capital Expenditure	-	N3,395,868,983.72

vi. The sum of N2,754,082,409.66 Regulatory Allowance was paid to the staff of the Agency in 2023 in fulfilment of the agreement reached with Union sequel to the strike embarked upon by them in the past. In the same token, total amount of Hazard Allowance paid was N1,641,372,005.84 while the productivity allowance paid was N510,087,535.59. All these allowances constitute welfare packages paid to the staff in the year.

vii. The amount of operating surplus which was being deducted at source by the Federal Government from the total revenue of the Agency was increased to 40% from 25% in the year. This new trend has a negative effect on the revenue available for the use of the Agency. As of November 2023, the amount already deducted at source by the office of the Accountant General of the Federation was N2,875,255,075.30.

viii. The disposal of unserviceable assets of the Agency for year 2023 has started in earnest. Compilation has been concluded and the Council of the Agency has approved the exercise. The net book values of the unserviceable assets penciled down for disposal are as follows:

		N
Motor Vehicles	-	420.00
Office Equipment	-	1,870.00
Laboratory Equipment	-	380.00
Furniture & Fittings	-	2,880.00
Plant & Machinery	-	145,440.00

There are also obsolete items valued at N52,780,705.00