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

ANNUAL REPORT

2020

VISION

To be a world class regulator that ensures availability of quality and safe Food, Drugs and other regulated products.

MISSION

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

CORE VALUES

Our PRIDE Core Values are:

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

Muhammadu Buhari, GCFR

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

Prof. Yemi Osinbajo *GCON*

Vice President of the Federal Republic of Nigeria

Dr Osagie Ehanire *MD, FWACS*

Honourable Minister of Health

Dr. Adeleke Olorunnimbe Mamora

Honourable Minister of State for Health

Alhaji Abdulaziz Mashi Abdullahi

Permanent Secretary, Federal Ministry of Health

Inuwa Abdul - Kadir ESQ, MCIArb, FICMC

Chairman Governing Council, NAFDAC

Prof. Christianah Mojisola Adeyeye

Director General, NAFDAC

NAFDAC MANAGEMENT STAFF

Dr. Monica Eimunjeze
Director R&R

Prof. Samson Adebayo
Director PID

Professor Mojisola Christianah Adeyeye PhD, FAS
Director General

Dr. Abubakar Jimoh
Director Public Affairs

Dr. Musa Umar, fsi
Director NCS

Dr. Bukar Ali Usman
Director VMAP

Barr. Kingley Ejiofor
Director I& E

Mrs. Ngozi Onuorah
Director CER

Alh. Ali O. Ibrahim
Director PV/PMS

Mrs. I.J. Nwankwo
Director DER

Mr. Sherif A. Olagunju, fsi
Director FSAN

Mrs. Clementina U. Anyakora
Director FCT

Fori M. Tatama fsi
Director PR & S

Mrs. Olajumoke O. Ojetokun
Director South East Zone

Edosa Ogbeide
DirectorLagos State Office

Isijola, C. O. Subulade
Director South South Zone

Dr. Charles Nwachukwu
Director, Lab Services (Food)

Mr. Victor Abiola
Director Lab Service (Drugs)

Mrs. Abayomi Bolaji
Director North Central Zone

Mr. William Effiok
Director FR and RA

Dr Rametu Omamegbe Momodu
FPSN FPC PharmDirector
Kaduna Laboratory Services

Mrs. Yedunni Adenuga
Director Agulu Laboratory Service

Mr. Joseph.A. Aina
Director Human Resource Management

Dauda D. Gimba
Director North West Zone

Ms. Preye Edotimi
Director South West Zone

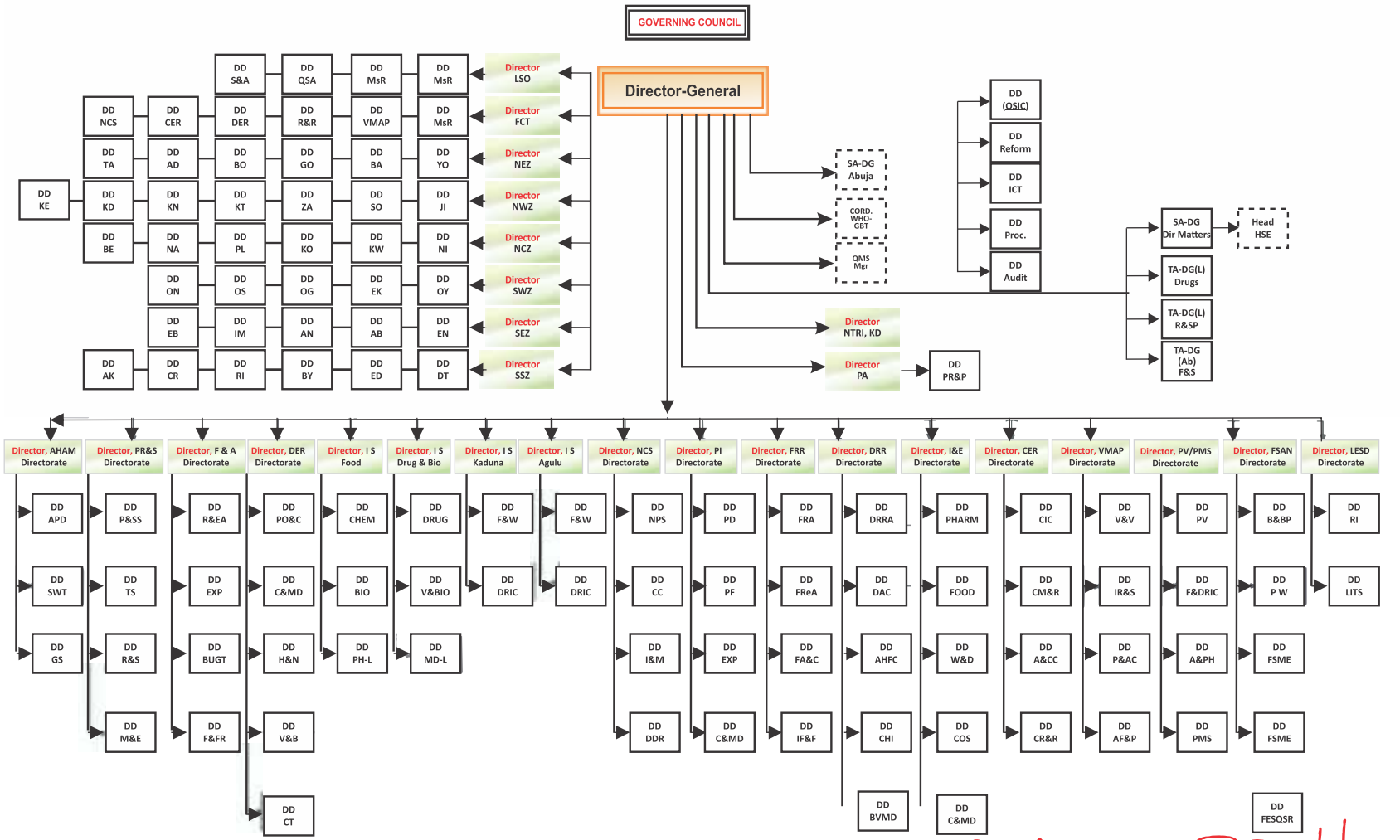
Ibrahim Sabo Adamu
Director North East Zone

Mr. Ayangbenga O. Ayanwande
Director Finance and Account

Barr. H. M. Bello
DD i/c Legal Services

ANNEXURE 3	NAFDAC-QMS-023-00	NAFDAC ORGANOGRAM

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



DIRECTOR-GENERAL'S SIGNATURE & DATE 3/3/2020

NAFDAC OFFICES AND LOCATIONS

Corporate Headquarters

Plot 2032 Olusegun Obasanjo Way
Wuse Zone 7, Abuja, Nigeria.
Tel. +234 709 821 2847 | Email. info@nafdac.gov.ng

Lagos Administration Office

Plot 1, Isolo Industrial Estate Estate Apapa/Oshodi Express Way,
Osolo Lagos.

ZONAL OFFICES

North East

NAFDAC Laboratory Complex
Biu Road, Maiduguri
Borno State

North West

Federal Secretariat
Zaria Road, Kaduna,
Kaduna State.

North Central

Federal Secretariat
6th Floor, Room 614
Jos, Plateau State

South East

Federal Secretariat
Independence Layout
Enugu Enugu State

South South

No. 5 Woji Road,
GRA Phase 2
Port Harcourt, River State

South West

Federal Secretariat
Jericho, Ibadan
Oyo State

ACRONYMS

A&HRM	-	Administration and Human Resources Management
APIs	-	Active Pharmaceutical Ingredients
CBN	-	Central Bank of Nigeria
CEO	-	Chief Executive Officer
CER	-	Chemical Evaluation & Research
CRIA	-	Clean Report of Inspection Analysis
CTD	-	Common Technical Documents
DER	-	Drug Evaluation and Research
DG	-	Director General
DHIS	-	District Health Information System
F&A	-	Finance and Accounts
FDA	-	Food and Drug Administration (United States)
FMoH	-	Federal Ministry of Health
FSAN	-	Food Safety and Applied Nutrition
FPPs	-	Finished Pharmaceutical Products
cGMP	-	Current Good Manufacturing Practices
HRM	-	Human Resource Management
HRMIS	-	Human Resources Management Integrated System
IA	-	Institutional Assessment/Analysis
ICT	-	Information Communication Technology
I&E	-	Investigation and Enforcement
ICH	-	International Conference on Harmonization
INGO	-	International Non-Governmental Organization
ISO	-	International Organization for Standardization
INCB	-	International Narcotics Control Board
LIMS	-	Laboratory Information Management System
LS	-	Laboratory Services
MAS	-	Mobile Authentication Service
MDGs	-	Millennium Development Goals
MDAs	-	Ministries, Departments and Agencies
M&E	-	Monitoring and Evaluation
MRA	-	Medicines Regulatory Agencies
MoU	-	Memorandum of Understanding
MSMEs	-	Micro, Small & Medium Enterprises
NAFDAC	-	National Agency for Food and Drug Administration and Control
NAPAMS	-	NAFDAC Automated Product Administration & Monitoring System
NCS	-	Nigerian Customs Service/Narcotics and Controlled Substances
NICIS	-	Nigerian Integrated Custom Information System

NGO	-	Non-Governmental Organizations
NHREC	-	Nigerian Health Research Ethics Committee
PA	-	Public Affairs
PID	-	Port Inspection Directorate
PRASCOR	-	Pharmacovigilance Rapid Alert System for Consumer Reporting
PR&S	-	Planning Research & Statistics
PV/PMS	-	Pharmacovigilance/ Post Market Surveillance
PQM	-	Product Quality Management
QA	-	Quality Assurance
QC	-	Quality Control
QMS	-	Quality Management System
R&R	-	Registration and Regulatory Affairs
SF	-	Strategic Focus
SFs	-	Substandard and Falsified Medicines
SO	-	Strategic Objective
SOP	-	Standard Operating Procedure
SWOT	-	Strengths, Weaknesses, Opportunities and Threats
TMC	-	Top Management Committee
UNICEF	-	United Nations Children Fund
UNIDO	-	United Nations Industrial Development Organization
USAID	-	United States Agency for International Development
VMAP	-	Veterinary Medicines & Allied Products
WHO	-	World Health Organization
WHO-GTB	-	World Health Organization-Global Benchmarking Too

Foreword

Foreword 2020 Annual Report

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

Our PRIDE Core Values are:
1. Professionalism
2. Resilience
3. Integrity (Transparency and Good Governance)
4. Dedication and Commitment
5. Excellence

The Agency has (18) Directorates namely:
1. Drug Registration and Regulatory Affairs
2. Food Registration and Regulatory Affairs
3. Drug Evaluation and Research
4. Narcotics and Controlled Substances
5. Chemical Evaluation and Research
6. Food Safety and Applied Nutrition
7. Veterinary Medicines and Allied Products
8. Ports Inspection
9. Laboratory Services (Food)
10. Laboratory Services (Drugs)
11. Agulu Laboratory Service
12. Kaduna Laboratory Services
13. Investigation and Enforcement
14. Pharmacovigilance and Post Market Safety Surveillance
15. Planning, Research and Statistics
16. Finance and Accounts
17. Administration and Human Resources Management.
18. Legal Services

In the office of the Director-General are also the Public Affairs, Federal Capital Territory (FCT), Lagos State, the Zonal offices headed by Directors and Information Communication Technology Unit.
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, Port Harcourt and Agulu.
NAFDAC has Port and Land border offices located in Lagos, Port Harcourt, Warri, Calabar, Abuja, Kano, Seme, Idiroko, Kamba, Ilella and Jibiya amongst others.
The Agency has a Desk Officer for Narcotics and Controlled Substances (NCS) due to the prevalence of drug abuse in the country and the need to control it. NAFDAC also has a desk at One Stop Investment Center (OSIC) to educate and enlighten prospective investors on the regulatory activities of the Agency.

The essence of regulation and control is to ensure that only quality regulated products that are safe, efficacious and wholesome 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.

1. International Organization for Standardization (ISO) 9001:2015: Certification Quality Management System (QMS) has been entrenched in the Agency with all our processes procedure driven. Staff of the Agency have now embraced QMS principles with the developed quality objectives. The Agency thus, received ISO 9001:2015 certification in June 2019. NAFDAC has been received recertification in 2020.

2. Global Benchmarking Tool (GBT) Road Map:
WHO-GBT Assessment
In preparation for WHO virtual follow up assessment of GBT program, a Mock Virtual Assessment of all Regulatory Functions was held by the Agency. The Directorate participated in assessment of 4 key areas as follows; Regulatory systems, Market Surveillance & control, Regulatory Inspection and Vigilance.
To further strengthen the International Best Practice in NAFDAC, we have imbibed a culture of self - audit as part of our benchmarking in compliance to WHO and improve our maturity level as stipulated. The WHO Benchmarking Programme commenced in NAFDAC in January 2018 and the Audit took place between June 17-21, 2019. We are currently working towards attaining Maturity Level 3.

3. Institution of Strong Governance:
The Agency has been restructured and expanded in structure from fourteen (14) Directorates to eighteen (18) Directorates The five newly created Directorates are Laboratory Services; 1) Legal, 2) Kaduna Area Laboratory, 3) Agulu Zonal Laboratory and 4) Food Registration and Regulatory Affairs.

4. Zinformation Communication Technology (ICT)
ICT now drives most processes in NAFDAC. With COVID 19 restrictions more ICT tools were deployed. The followings are some of the achievements recorded through our ICT Unit during the period under review:
   a. Conduct of virtual trainings.
   b. Staff working remotely.
   c. Videoconferencing between NAFDAC formations.
   d. Regular update of the reconstructed NAFDAC website and populating it with needed information that is accessible to stakeholders for imminent online registration.
   e. More staff were connected to government backed mail system for improved security in communication.

5. Staff Development and Training
Under the current Administration, staff training, and capacity development has been given great priority. A total of 4,081 staff attended 65 various train ing programmes in the year under review. (i.e 4,116 staff participated in 52 local programmes mostly online while 68 staff went for 13 international programmes). 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.

6. Registration
Digitalization of processes has been further enhanced with NAPAMS Version 2 being operationalized and more user friendly. Our clients can now register online. The Agency has entrenched the elements of QMS in its operations and all regulatory processes have been positively impacted. The registration processes have benefitted from this with guidelines and operating procedures being more defined and adding clarity and transparency to processes and regulatory expectations. As a result of these, we have reduced registration time to 90 days for food, simple cosmetics and water and 120 days for drugs and some cosmetics. Consequently, NAFDAC registered a total of 9,890 products (5,208 Drugs and related products and 4,682 food products) from January to December 2020.

7. Decentralization of Registration Process
The Agency has since decentralized products registration of some regulated products with minimal risk associated with them manufactured by MSMEs to be processed and handled at the zonal offices thereby reducing the timeline to sixty (60) working days for Micro, Small and Medium Enterprises. As a result of the initiative and consciousness, there has been a significant increase in the number of MSMEs products registered.

The Agency has instituted the following palliative program for micro and small businesses in order to respond to the challenges of COVID 19 Pandemic.

- Zero tariffs for first 200 micro and small companies to register their products on the launch of 15th May 2020.
- Eighty percent (80%) reduction in tariffs for registration of micro and small enterprises products for a period of six (6) months from the date of the launch
- Giving waivers on administrative charges for renewal of expired licenses for products of micro and small businesses for three (3) months.

8. Drug Evaluation and Research

Following the challenges posed by the COVID 19 pandemic outbreak, Good Manufacturing Practices (GMP) inspections were suspended except for COVID 19 related products. Companies that were previously scheduled for onsite CAPA effectiveness verification inspections were requested to submit USB flash drive devices containing (scanned documents, short videos, pictorials etc.) indicators for completion of their CAPA plans. Desk review of data was done by Inspectors in Lagos & other states. Twenty-Five (25) companies submitted electronic copies of their CAPA plans for review, out of which Eleven (11) companies were adjudged satisfactory. Those with inadequate submissions were advised to review their plans and resubmit more effective plans within stipulated timelines.

9. Laboratory Services:

NAFDAC Laboratories are changing rapidly with improvement in new laboratory equipment pieces and supplies. The Central Laboratory, Oshodi was re-assessed virtually on the 11th and 12th November 2020 by ANAB for ISO 17025:2017 Laboratory accreditation of the previously accredited scopes and extended its accreditation scopes. The Laboratory currently have thirty-nine (39) scopes accredited and received its Certificate of recognition of Accreditation from ANSI-ASQ National Accreditation Body (ANAB) in December 2020.

A virtual surveillance for ISO 17025:2017 was also conducted for various NAFDAC laboratories with Central Drug Control LAB (CDCL) as the Parent Laboratory while others are Satellite sites. The audit lasted for Two weeks which was between November 2nd to 13th November 2020. All the various laboratories concerned retained their accreditation status in their different scopes.

10. Pharmacovigilance and Post Market Surveillance (PV/PMS)

The National Pharmacovigilance Centre (NPC) received Adverse Drug Reactions (ADR) reports from various stakeholders including patients, health care professionals, health institutions and Marketing Authorization Holders (MAHs) across the country. One Thousand Two Hundred and Thirty-Seven (1,237) ADR reports were received within the period of January-December 2020 comprising Seven Hundred and Eighty-One (781) Individual Case Safety Reports (ICSRs) and Four Hundred and Fifty-Six Council for International Organization of Medical Science (CIOMS) Forms. This brings the total number of ADRs received 25,445. 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) deployed to ensure cross-border flow of information to swiftly act when risks to public health are detected in the food chain recorded a total of 32 RASFF Alerts within the period.

The mobile App for reporting of adverse drug reactions was launched on 4th November 2020 in the Director-General's Conference room, Abuja. The Benefits of the Med Safety App include the following:

- it is convenient for ADR reporting
- it promotes awareness & increased ADR reporting
- it gives instant access to stakeholders via NAFDAC social media platforms
- it is free to download & use on Android and iOS devices
- it gives NRAs news feed
- Summaries of ADR data are available in graphical form and
- It can be used in 3 languages: English, Russian or Armenian.

11. Ports Inspection

The Deployment of the Ports Inspection Data Capture and Risk Management System (PIDCARMS) Online System as a web-based, online, fully automated business process application used across all PID formations Nationwide and enables importers conduct documentation and clearance processes from the comfort of the homes and officers, within and outside Nigeria. This has led to an effective blockage of leakages of revenue of the Agency and falsifying the Agency's security documents.

A total of Twenty-Five Thousand, Seven Hundred and Forty-Four (25,744) SGD forms, 21,999,644.22 weight in metric tons were treated, and a total of Two Thousand, One Hundred and Seven (2,107) violations were treated in the year under review.

12. Performance of NAFDAC Zonal Offices

The Agency has since decentralized products registration of some regulated products with minimal risk associated with them manufactured by MSMEs to be processed and handled at the zonal offices thereby reducing the timeline to sixty (60) working days for Micro, Small and Medium Enterprises.

As a result of the initiative and consciousness, there was a significant increase in the number of MSMEs products registered in the year under review.

The regulatory activities carried out in the Zones in January to December 2020 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 practices (GMP) was maintained where applicable and that whatever regulated product(s) in circulation for consumption or use by the public were wholesome.

Conclusion

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

For all the stated regulatory controls, and successes that were highlighted above, the need for utility vehicles or transportation cannot be over-emphasized. More vehicles are urgently needed for inspection, Investigation, enforcement, laboratory services, pharmacovigilance and post-marketing surveillance and enhancement of MSMEs across the nation.

We are working assiduously towards consolidating the successes the Agency has recorded thus far and taking it seamlessly to the next level where vaccines can be manufactured locally.

NAFDAC has remained 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), Consumer Protection Council (CPC), 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

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Chapter 1

HISTORICAL BACKGROUND

1.1 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, Drug, 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, drug and other NAFDAC regulated products.

Mission

NAFDAC promotes quality and safety of food, drug, chemicals, cosmetics, detergents, medical devices and bottled water by ensuring adherence to global best practices to protect public health.

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

1.2 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 9 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-Gen**2020**

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

- Director General - Prof. Mojisola Christianah Adeyeye, PhD, FAS
- Director, Drug Registration and Regulatory Affairs – Dr. Monica Eimunjeze
- Director, Ports Inspection Directorate – Prof. Samson B. Adebayo
- Director, Public Affairs (Office of the Director General) – Dr. Abubakar Jimoh
- Director, Narcotics and Controlled Substances – Dr. Musa Umar
- Director, – Dr. Bukar Usman VMAP
- Director, Investigation and Enforcement – Barr. Kingsley Ejiofor
- Director, Chemical Evaluation and Research – Pharm. (Mrs.) Ngozi U. Onuorah
- Director, Pharmacovigilance and Post Market Surveillance PV/PMS Alh. Ali O. Ibrahim
- Director, Drug Evaluation and Research – Pharm. (Mrs.) Ijeoma Nwankwo
- Director Food Safety and Applied Nutrition – Mr. Sherif A. Olagunju
- Director Federal Capital Territory – Pharm. (Mrs.) Clementina Anyakora
- Director, Planning, Research and Statistics – Pharm. Fori M. Tatama
- Director South East Zone – Pharm. (Mrs.) Olajumoke Ojetokun
- Director, Lagos State Office – Pharm. (Mrs.) Edosa Ogbeide
- Director South South Zone – Pharm. Caroline O.S. Isijola
- Director Laboratory Services (Food) – Dr. Charles Nwachukwu
- Director Laboratory Services (Drugs) – Mr. Victor Abiola
- Director North Central Zone – Mrs. Abayomi Bolaji
- Director Food Registration and Regulatory Affairs – Mr. William Effiok
- Director Kaduna Laboratory Service – Dr. Rametu Momodu
- Director Agulu Laboratory Service – Mrs. Yedunni Adenuga
- Director Human Resource Management – Mr. Joseph.A. Aina
- Director North West Zone – Pharm. Dauda Gimba
- Director South West Zone – Ms. Preye Edotimi
- Deputy Director North East Zone – Ibrahim Sabo Adamu
- Director, Finance and Accounts – Mr. Ayangbenga O. Ayanwande
- Deputy Director i/c, Legal Services - Barr. Mohammad H. Bello
- Service Units in the Office of Director General:
    - Special Assistant to DG NAFDAC (Abuja) – Pharm. Thomas O. Ilupeju
    - Special Assistant to DG NAFDAC (Lagos) – Dr. Gbenga Fajemirokun

1.3 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.

1.4 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-Seven (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 and Aminu Kano) and Land border posts (Seme, Idiroko, Mfum, Jibiya, Kamba, Illela and Maigatari)
- One Stop Investment Center (OSIC) - NIPC Building Maitama, Abuja.

Chapter 2

STRENGTHENING OF THE REGULATORY FRAMEWORK OF NAFDAC

2.1. I SO 9001:2015 Quality Management System Certification:

Quality Management System (QMS) has been entrenched in the Agency with all processes procedure driven. The Agency has been able sustain the ISO 9001:2015 Certification. We are encouraging the Pharmaceutical Industry to attain the same feat through training and capacity building.

2.2 Global Benchmarking:

We have imbibed a culture of self - audit as part of WHO-Global Benchmarking requirements and in line with International Best Practices. We have continued to improve our maturity level since the first WHO Audit in June, 2019. Currently, we are working towards attaining Maturity Level 3 to enable Nigeria to manufacture vaccines. But our goal is to reach Level 4 which will make Pharmaceutical Companies in Nigeria attain WHO Prequalification

2.3 Deployment of Electronic Platforms and Encouragement of MSMEs:

The digitalization of our registration processes allows our clients to register online through NAPAMS V2.0. The Agency also implemented assisted e- registration of regulated products and palliative program for MSMEs in 2020.

Relatedly, NAFDAC being an active member of the Presidential Enabling Environment Council (PEBEC) has continued to support the job creation agenda of the Federal Government in line with the provisions of Executive Order No.1. One of the provisions is to create an enabling environment for businesses, entrench measures and strategies aimed at promoting transparency and efficiency. Thus, the Agency carried out a lot of reforms of its activities to create an enabling environment for MSMEs businesses to thrive, focusing on micro and small companies. NAFDAC has achieved the following:

- Creation of Small Business Support Desk (SBSD) to facilitate registration processes for micro and small business operators.
- Reviewed guidelines for registration of products and uploaded them unto the website.
- Reduced requirements for registration of some food and cosmetics products.
  Granting 50% discount on tariffs for product registration.
- Expedited laboratory analysis for samples.
- Allowing micro companies with similar products to share production facility.
- Non engagement of consultants by companies for product registration and instructed them to visit NAFDAC offices directly.
- Ninety (90) working days timeline for product registration.
- Registration of micro enterprises products at the zonal offices nationwide.
  Prompt treatment of complaints/enquiries from companies.

In furtherance to compliance with the Executive Order on the Ease of Doing Business as well as proactive response to the challenges of COVID-19 pandemic, NAFDAC has instituted the following palliatives for the micro and small businesses:

- Offering zero tariffs for first 200 micro and small companies to register their products on the launch day.

- Eighty per cent (80%) reduction in tariffs for the registration of micro and small enterprises products for a period of three months.
- Giving waivers on administrative charges for late renewal of expired licenses for products of micro and small businesses.

2.4 Upgrade of NAFDAC Laboratories to International Standard:

NAFDAC laboratories are changing rapidly with improvement in new laboratory equipment and supplies. The National Control Laboratory for Vaccines and Biologics and the the Kaduna Area Laboratory got ISO-17025 Re-Accreditation. The Yaba Laboratory Complex has been renovated and refurbished.

2.5 Eliminating Substandard and Falsified medicines (SFs), unsafe or illicit drugs, unwholesome foods, chemicals, and other products

The Agency has evolved strategies to combat the ever-increasing challenge of regulated product counterfeiting, but the ever-innovative world of counterfeiting demands that new regulatory strategies be deployed to keep out these harmful products.

Some of the strategies which among others include enforcement of regulation and control of APIs imported into the country to ensure they meet the required standards for manufacturing of drugs; reduction in number of registered imported products and encouraging local manufacturing and innovation and overhaul of Pre-Shipment Clean Report of Inspection and Analysis of Imported Medicines and other NAFDAC Regulated Products

Others are; building Traceability and Supply Chain Security into regulated products from plant to patient or from farm to fork. Safeguarding the health of the Nation is a daunting task in the face of the chaotic drug distribution system currently existing in Nigeria. The falsification and diversion of health commodities carry very serious health and economic consequences. The consideration of these consequences vis-à-vis the mandate of NAFDAC to regulate and control among other things, the distribution of drugs and other regulated products is sufficient motivation to adopt and implement strategies that can assist in the fight against menace of substandard and falsified medicines and improve the regulatory control of the medicines supply chain in Nigeria.

The Nigeria Pharmaceutical Traceability Strategy presents NAFDAC's priority objectives that guided the development of a comprehensive operational plan and, contributes to strengthening the existing regulatory and legal frameworks required to publish and enforce a Traceability Regulation and related guidelines. NAFDAC is therefore committed to the implementation of pharmaceutical traceability in Nigeria as part of the regulatory strengthening and underscoring of its mandate. NAFDAC has developed a 5-Year Traceability Implementation plan in line with the objectives of the Nigeria Pharmaceutical Traceability Strategy to achieve supply chain visibility and strengthen its pharmacovigilance activities against the scourge of Substandard and Falsified Medicines and Medical Devices by the end of the year 2024. The Agency has also established a Traceability Office (GS1 Desk) and a Technical Working Group to drive the activities in the 5-year implementation plan.

In addition to the above, NAFDAC has linked up with the WHO Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre) as well as other National Medicines Regulatory Authorities, National Pharmacovigilance Centres across the world in web-based and social media campaigns that raises awareness on reporting of adverse drug reactions and other medicines-related problems. To this end, the Agency has procured and deployed Med Safety App for improved ADR reporting. The mobile phone application enables users to; report ADRs and other drug-related products experience, track drug-related safety information, build watch list of medications and view numbers of reports received in WHO database of suspected ADRs. But those are not enough, we are still in the process of procuring more detection gadgets to monitor SFs at the Zonal/State levels in addition to the several trainings our staff have undertaken over the past years. The Application is one of the tools that is being used for Covid-19 vaccines in collaboration with other sister agencies in Nigeria.

The provision of the Med Safety App which is available to download for free on android or apple smartphone devices provides a medium for users to seamlessly report incidences of ADRs from the comfort of their mobile phone devices. Reports can be created offline without internet connectivity and submitted once connection is established. Since it is directly linked to WHO database platforms, a lot of man hours are saved from manual input of the information on Individual Case Safety Reports (ICSRs) using the hard copy ADR forms.

To effectively harness the benefits of the Med Safety App, NAFDAC has intensified efforts on sensitization campaigns for the public leveraging on conventional and social media platforms, organized quarterly zonal and state level trainings for healthcare providers and health professionals and make provision of internet-enabled tablets for Zonal Pharmacovigilance Centres and selected health facilities in Nigeria.

Conditional Emergency Use Approval of Medical Devices (COVID-19 Antibody and Antigen Test Kits, PPEs, etc.)

The current COVID-19 pandemic has necessitated that NAFDAC put measures in place to ensure access to health commodities that have the potential to impact positively on public health outcomes. These include, but are not limited to, diagnostics necessary to support public health infrastructure and guide the response necessary to combat and address the pandemic.
The Agency has in 2020 processed many requests for Emergency Use Authorization for some of such diagnostic test kits to support the national response and ensure expanded testing capabilities. The Agency also put in place regulatory measures to ensure quality, safety and efficacy criteria are assessed.
These measures are supported by documentation which include the following:

1. Prior registration and approval by reference regulatory authorities such as those of Japan, USA, Germany, Canada, European Medicine Agency, etc.
2. Registration by the Regulatory Authority in the Country of Manufacture
3. Declaration of Conformity
4. Validation/performance evaluation /Clinical Evaluation Report

NAFDAC will continue to stay abreast of current best global practices in this area and monitor updates to the WHO collated list of medical devices being used by different countries.

NAFDAC has reduced the “registration to approval” time from 120 working days to 10 working days due to the COVID-19 pandemic. Thus far, the Agency has processed seventeen (17) applications using the expedited review process but has only granted Emergency approval to seven (7) companies using the criteria listed above.

The availability of Personal Protective Equipment (PPE) for health care providers is a critical component of the effort to stem the COVID 19 pandemic. These PPEs include gloves, protective goggles, face shields, protective gowns, and masks in the form of particulate respirators and surgical masks. These must meet certain technical requirements and specifications to achieve the objective and offer some measure of protection to health care providers and limit their exposure to infection.

Chapter 3

GLOBAL COLLABORATION AND RELIANCE

3.0 Global Collaboration and Reliance:

Some of the international collaborations and partnership which have developed over the past years include World Health Organization Global Benchmarking; Swiss Medic Marketing Authorisation for Global Health Products and the African Medicines Regulation Harmonization (AMRH), which elected me (NAFDAC DG) in April 2018 as the Steering Committee Chair. AMRH is the precursor organization for the African Medicines Agency.

Others are: International Conference of Drug Regulatory Authorities (ICDRA) and International Coalition of Medicines Regulatory Authorities (ICMRA) among others

3.1 3rd Annual African Medicines Quality Forum (AMQF) - Technical Working Group of AMRH Transcorp Hilton, Abuja, Nigeria February 24 - 28, 2020

The AMQF was established in 2017 in collaboration with AUDA-NEPAD and West Africa Health Organization (WAHO) to build and strengthen the capacity of African countries in medicines quality control and regional post market surveillance which in turn, will contribute significantly to reducing sub-standard and falsified medical products in circulation on the African markets.

NAFDAC successfully hosted the third annual meeting for the African Medicines Quality Forum (AMQF) in collaboration with the African Union Development Agency-New Partnership for Africa's Development (AUDA- NEPAD), the United States Pharmacopeial Convention (USP) and the World Health Organization (WHO). The meeting which held at Transcorp Hilton, Abuja, Nigeria 24th- 28 th February 2020 convened all members of the AMQF including its Technical Committee (TC), leadership from USP, AUDA-NEPAD, WHO, Regional Economic Communities (RECs), Regional Health Organizations (RHOs) as well as other partners and key stakeholders with the theme “Perfect Vision for Quality Medicines in Africa”.

The objectives of the 3rd AMQF meeting are to:

- Finalize the draft 2019 AMQF report including implementation of the 2019 AMQF workplan and present this in plenary.
- Reinforce the importance of quality control laboratories in post marketing surveillance by drawing up a proposal for regional/cross border survey of medicines of Public Health Importance in Africa.
- Complete the roadmap for strengthening NQCL infrastructure and systems to help make informed, reliable and consistent regulatory decisions.
- Emphasize the importance of instrumentation and analytical techniques in quality control for the entire drug approval process: Manufacturing to Post-marketing.
- Sensitize NQCLs on the importance of drafting laboratory strategic and business plans as well as having the right legal mandate to ensure continual provision of QC testing that meet international standards of quality.
- Generate a discussion with international partners for future funding of AMQF meetings and activities.
- Review result from 2019 ILT and plan for 2020 round of ILT.
- Finalize, present and advocate for the 2020 AMQF workplan including cataloguing lessons learned from 2019, focusing on the challenges and how they can be overcome in 2020.

3.2 9th Meeting of the Member State Mechanism on Substandard and Falsified Medical Products

The 9th plenary session took place virtually from 28-30 October 2020 with representatives of 82 Member

States from all WHO regions. The plenary meeting was preceded by a technical session on detection technologies and a Steering Committee meeting.

The WHO Deputy Director General opened the meeting and recognized the burden of SF medical products as an unacceptable global public threat. Efforts to ensure access to safe, quality, affordable and effective medical products are undermined if patients and end-users receive products that are substandard or falsified. She reiterated her support for the WHO Member State mechanism as a forum for developing global approaches to the prevention, detection and response to SF medical products.
Member States discussed ongoing progress to complete the 2020-2021 List of Prioritized Activities, including work on risk-based post-marketing surveillance, global focal point network, traceability of health products, detection technologies, links to access, risk communications, education and awareness, impact and outreach, medical products in transit, and internet supply and distribution. The full meeting report and relevant documentation are available on the WHO website.
A number of working groups have been opened to progress the work of the prioritized activities. Working groups are led by and principally composed of Member State representatives, however, some independent experts may be invited as appropriate.
There was an open-ended expert briefing session on detection technologies, methodologies and tools for WHO Member States, on 26 October 2020 by webinar.

The following presenters made submissions on behalf of their organization;

1. **Stephen Kimatu** from United States Pharmacopeial Convention (USP) presented on the work of USP to develop standards and guidelines for evaluation of medicine quality screening technologies. Three detection/screening technologies were evaluated by USP in 2019-2020; Fourier-transform infrared (FTIR) spectrometer (Target-ID ®), GPHF-Minilab™ and Paper analytical device (PAD). Details of the USP Technology Review programme, including evaluation report can be found here.
2. **Rutendo Kuwana** from WHO's Laboratory Networks and Services presented on WHO Global Medicines Spectral Data Analysis Solution (MeSDAS). He also presented on a WHO-led study is underway to evaluate acceptability and usability of 2D matrix codes for accessing medicines information by patients, healthcare workers, regulators and procurers in LMICs. Lastly, he presented using Machine Learning (a subset of Artificial Intelligence) as a promising approach to leverage Big Data for market surveillance.
3. **Paul Newton** from University of Oxford presented on Medicine Quality Monitoring Globe which maps and summarizes newspaper articles from Google News (in English, French, Chinese, Vietnamese, and Spanish), as well as the Medicine Quality Scientific Literature Surveyor which maps published scientific data on the quality of medicines for communicable diseases, non-communicable diseases, veterinary medicines and vaccines. Lastly, he presented on efforts to repurpose spatially-offset Raman spectroscopy (SORS) and matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF) for authentication of vaccines with specific interest on vaccines for COVID-19.

WHO's participation in relevant global and regional initiatives.
The Secretariat provided an update on WHO engagement in relevant global and regional initiatives, highlighting linkages with the Member State mechanism. The Member State mechanism supported WHO's continued engagement in these initiatives. To avoid duplication of work and ensure greater strategic coordination, wherever possible, it was agreed that both the Secretariat and Member States play a role in engaging in regional, cross-regional and global initiatives that would help elevate the profile of the WHO Member State mechanism to the highest levels. Member States discussed the possibility of creating a dedicated working group aiming to coordinate input and strategic impact in such various forums.

Update on governance issues
Following up on the request made by the Member State mechanism at its eighth meeting, the Secretariat provided an update on progress on informal discussion with interested Member States regarding the drafting of

a scoping paper and the need to establish a similar network on medical devices.
Member States acknowledged that COVID-19 has highlighted the need for safe, quality and effective medical devices, in particular for personal protective equipment. It was clarified that the working definitions for substandard, falsified and unregistered medical products endorsed by the Seventieth World Health Assembly provide that "a medical product is defined as a medicine, vaccine or in vitro diagnostic and it may also include medical devices at an appropriate time in the future." It was agreed that medical devices other than IVDs, at present fall outside the scope of the Member State mechanism and it was decided that the Secretariat to convene with interested Member States to discuss how to take this work forward.

Chapter 4

DIRECTOR-GENERAL'S OFFICE

4.1 Public Affairs

Public Affairs is one of the recently created offices following the restructuring of the Agency under the current leadership. It was carved out of 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 director with the primary responsibility of projecting the corporate image of NAFDAC, promoting its activities and programs, and serve as an interface with the public. The office has two main units, namely Public Relations and Protocol.

4.1.2. Summary of Activities in 2020

Publicity of NAFDAC activities. This includes enforcement, destruction exercises, prosecutions/convictions, workshops, advocacy meetings/visits and town hall/stakeholders' forum. Some of these activities are highlighted below.

a. Meetings, Conference & Training

- DG NAFDAC, Prof. Mojisola Christianah Adeyeye induction lectures to the newly employed NAFDAC staff at the NAFDAC Oshodi Lagos, January, 2020.
- 2nd phase of DIBAN's Advocacy Campaign Responsible Drinking & Discourage Alcohol consumption by minors/underage drinking at MAN House Ikeja, Lagos January,2020.
- Training of NYSC Corp members at the NAFDAC Laboratory Auditorium Oshodi, January, 2020.
- Coverage of Codex meeting at the Oshodi Laboratory Auditorium Lagos, February 2020.
- Prof. Adeyeye, Dg NAFDAC's lecture at the faculty of Pharmacy Olabisi Onabanjo's University Shagamu during the Oath taking and Induction into the Pharmacy profession, Shagamu Ogun State, February, 2020.
- Common Technical Document (CTD) Training, NAFDAC'S Requirement of dossier submission held at NECA House Ikeja Lagos
- Press briefing by DG NAFDAC to refute employment rumours.
- International Narcotics Board (INCB) 2019 Report held at NAFDAC Oshodi laboratory complex Lagos, February ,2020
- DG NAFDAC's press briefing on the recent activities of the Agency at the Oshodi Lab complex Lagos, March, 2020
- Coverage of DG NAFDAC virtual press briefing on the recent activities of NAFDAC, in Abuja, August, 2020.
- Coverage of press conference hosted by DG NAFDAC on Covid -19 in Abuja, August, 2020.
- Organising / Coverage of Press Conference hosted by DG NAFDAC in Abuja, September, 2020.
- Coverage of training on COVID19 at yaba Lab. Lagos, September, 2020.
- NAFDAC's Orientation Course Lecture at the NYSC camp Lagos, November, 2020.

b. Destruction, Raids & Enforcement Activities

- Raid of illegal/fake alcoholic and nonalcoholic wine producers at Eket, Akwa Ibom State on January, 2020.

- Investigation & Enforcement activity at Pandar Supermarket (Chinese Supermarket) Jahi – Abuja, January, 2020.
- Coverage of surveillance checks on pharmaceutical and packaged water factories at Abakpa-Nike and Emene in Enugu, January, 2020.
- Raiding of illegal sachet water producers in Diobu, Portharcourt and mop up of fake/unregistered Vaseline products in supermarkets in Portharcourt with agents of PZ Company, February, 2020.
- Coverage of investigation / sealing- off of a water factory (J-Forst) for illegal production in Abuja by FCT, March ,2020.
- Destruction of imported unwholesome 2x20 feet and 1x10 feet containers of imported frozen fish and sweet potato respectively at Aluu dump site, Port Harcourt, April, 2020.
- Surveillance and mop up activities of unregistered hand sanitizers in Delta State, May, 2020.
- Destruction of 2x20 feet container load of frozen fish at Aluu dump site, Port Harcourt, July, 2020.
- FSAN inspection and seal of pure water factory at Akoka Yaba Lagos, March, 2020
- Coverage of returned banned Codeine cough syrup to NAFDAC warehouse Oshodi Lagos, July, 2020.
- Hand-over of unwholesome drugs worth #150m to NAFDAC by the Nigeria Customs Services in Kaduna on August 11, 2020
- Coverage of sealing –off of illegal packaging and selling of confectionaries by FCT Directorates in Gwarimpa, Abuja, Semptember, 2020.
- Illegal closure of factory in Kano producing agrochemical in Kano on October 15, 2020.
- DG NAFDAC and the Minister of Health's visit on October 26, 2020 after the vandalization of NAFDAC formations in Kaduna.
- Coverage of raid of illegal bread facility (Bakery) in Karmo, Abuja, November, 2020.
- Coverage of the seiling – off of illegal Rice mill in Idu, Abuja, November ,2020
- Coverage of consultative meeting with Master Baker in Nsukka, 8th December, 2020.

c. Advocacy Visit, Workshop/ Sensitization, and Interviews

- Coverage of African Medicines Quality Forum in Abuja, February, 2020.
- Coverage of sensitization programme for Master Bakers at Nsukka Zone of the State on February, 2020.
- Coverage of inspection of water factories at Trans Ekulu Enugu on February, 2020.
- Coverage of inspection of bread factories at 9th Mile Corner Udi Local Government Area and Trans Ekulu Enugu State on 12th and 23rd March 2020 respectively.
- Coverage of herbal medicine company for the production of NAFDAC and Your Health program in Lagos, July, 2020.
- Coverage of inspection of supermarkets operations at Agbani Road and Kenyatta in Enugu, July, 2020.
- Coverage of DG NAFDAC interview on Vaccine and fake hand sanitizer for the production of NAFDAC and Your Health program, August, 2020.
- Coverage of DG NAFDAC, Prof Adeyeye's interview on falsified and substandard medicine for the production of NAFDAC and Your Health program, August, 2020.
- Coverage of inspection of supermarkets at Timber shed, and Garikki Market Enugu, August, 2020.
- Coverage of Director FSAN on fruit ripping, September, 2020.
- Coverage of a stakeholder workshop organised by Cassava Cottage Processing and Marketing Association of Nigeria at IAR&T, Ibadan, Oyo state, March, 2020.
- Coverage of stakeholder meeting organised by Master Bakers, Ondo state chapter, March, 2020.
- Coverage of the Launch of MSMEs assisted E – Registration (Job Creation) by NAFDAC in Abuja, May, 2020.
- Coverage of sensitization of health care practitioners on code of marketing of Breast Milk Substitute (BMS) held in Ondo State, November, 2020.

- Inspection of Cross River State's Garment Factory; producers of face mask and protective personal equipment (PPE) in Calabar, July, 2020.
- Coverage of the launch of Traceability Plateform by the Hon. Minister of Health at the FMOH, Abuja in collaboration with NAFDAC, October, 2020.
- Coverage of AMR- Week (VMAP) in Abuja, November, 2020.
- Coducting of interviews for the production of NAFDAC & YOUR HEALTH programme with DG and Directors in Abuja, November, 2020.
- Conducting of interview on DG's 3 Years Scorecard with Director (Admin & HRM), and the DDi/c Finance & Account for NAFDAC & YOUR HEALTH programme with DG and Directors in Abuja, November, 2020.
- Production of Documentary for the launch of Med Safety APP. in Abuja, November, 2020.

d. Press Releases in Major National Dailies (Examples Listed Below)

- Stop cooking Meal with paracetamol, NAFDAC tells Nigerians, February, 2020.
- NAFDAC Alerts Nigerians on circulation of fake chloroquine Tablet, April, 2020.
- COVID -19 NAFDAC warns companies against donation of infant foods, May, 2020.
- NAFDAC Authorizes for use of Antibody Test kits on patients, April, 2020.
- Moving Herbal Medicine Research forward NAFDAC Inaugurates the Nigerian Herbal Medicinal products committee (HMPC) June 2020.

e. Publications

- NAFDAC News. Quarterly News magazine of NAFDAC activities.
- The Scorecard. A chronicle of activities and achievements of NAFDAC
- Information Brochure

f. Mass Media Programmes.

The unit sustained the production and airing of the following programmes in the media.

- NAFDAC & Your Health radio programme on the network service of the Federal Radio Corporation of Nigeria (FRCN).
- Interviews, Special Features and Guest appearances on Radio and TV.
- Syndicated articles in major national dailies.
- Production and airing of quarterly TV documentary on NAFDAC.

g. 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
- Participated and uploaded information on various activities such as:
  - ✓ Event information
  - ✓ Safety information
  - ✓ Photographs
  - ✓ Videos
  - ✓ Customer services
  - ✓ Director-General's presentations and addresses.
- Increased followership and recognition through stakeholders' engagement and regular updates.

h. Protocol Activities

The Annual Report of Protocol Unit comprises of all activities of the Unit, as it relates to processing of international engagements and other Protocol activities to meet up with the Agency's mandate of safeguarding the health of the Nation.

Issuing of Introduction Letters to Staff

S/N	Activities	No. of Requests Received	No. 0f Letters Issued	Remarks
1.	Issuing of Introduction Letter	32	32	Completed

Airport Protocol Management

S/N	Activities	No. of Requests Received	No. of Passage	Remarks
1.	Airport Protocol Management for Director General	12	International – 2 Local- 10	

4.2. NAFDAC OSIC Desk

a. Introduction

As part of efforts to fast-track investment and boost the nation's economy, the Federal Government established and domiciled the One Stop Investment Centre (OSIC) in the Nigerian Investment Promotion Commission (NIPC), to serve as a "One Stop Shop" for investment facilitation and business entry by both foreign and local investors. There are 26 (twenty-six) MDAs at the Centre including NAFDAC. These MDAs maintain existing their organizational mandates and responsibilities within the structure of OSIC.

b. NAFDAC Desk at OSIC

NAFDAC Desk at OSIC is one of the units under the Director General's Office, though domiciled at the Nigerian Investment Promotion Commission (NIPC), Maitama, Abuja.

- NAFDAC's services at OSIC deal mainly with Investment Promotion (IP), Trade Facilitation (TF) and other trade-related matters in relation to the Agency's mandate.
- The Desk provides relevant information on NAFDAC activities especially product registration requirements to investors, potential investors and the public at Trade Fairs/Exhibitions, Business & Investment Forums (BIFs) and other forums.
  - ✓ Trade Fairs/Exhibitions always provide the Agency with ample opportunities to track down fake, substandard, expired and unregistered regulated products which are hitherto difficult to detect in the open markets.
  - ✓ They also serve as avenues for informal public enlightenment as well as getting feedback from stakeholders and consumers.
  - ✓ Through participation at committee meetings, conferences, Business & Investment Forums (BIFs), Trade Fairs/Expos NAFDAC through OSIC Desk encourages local manufacturers of regulated products to willingly proceed to register their products thus promoting their sale.
  - ✓ NAFDAC through the Desk at OSIC collaborates with all MDAs relevant to trade facilitation in various committees
  - ✓ The Desk works harmoniously with the other MDAs at the Centre to support all Nigeria-bound investment/trade decisions.

During the year 2020, the following activities were carried out by NAFDAC Desk at OSIC

c. Investors/Visitors That Visited the Desk

During the period under review, thirty-five (35) investors/visitors were attended to at the Desk or given copies of relevant guidelines or asked to visit NAFDAC website or nearest NAFDAC Office.

Table 4.2.1 Trade Fair/Conference/Exhibition/Business & Investment For m attended

S/N	Event	Date	State	Venue
1.	National Stakeholders' Engagement on Youth Export Development Programme (YEXDEP)	30th January, 2020	Abuja	NEPC Conference room, Maitama, Abuja.
2.	MSMEs Clinics	1. 10th February, 2020 2. 6th March 2020	1. Nassarawa 2. Ebonyi	1. Ta'al Conference Center, Lafia. 2. Ecumenical Centre, Akanu Ibiam roundabout, Abakaliki.
3.	PEBEC/EBES Stakeholders Forum (Lituation)	4th February, 2020	Abuja	NAF Conference Center, Jahi, Abuja.
4.	Web Conference for Businesses in Food Processing organized by NIFST with theme "Staying ahead of COVID-19 in Nigeria, perspectives for Food processing MSMEs"	30th April, 2020	Virtual	Virtual
5.	50 million African Women Speak Out Project (SOMAWSP) Pink Trade Fair	4th - 5th December 2020.	Abuja	Tobix Gardens , Opposite Alibert, Jahi, Abuja.
6.	Ministry of Health Media Parley	7th December 2020.	Abuja	Ladi Kwali Hall, Sheraton Hotels, Abuja.
7.	Lagos International Trade Fair	6th -15th December 2020	Lagos	Tafawa Balewa Square, Lagos

d. Meeting/Workshop/Training Attended:

The Unit participated in 25 Meeting/Workshop/Training during the period under review. Some of them are as follows:

- Roundtable on promotion of transparency and efficiency in the business environment at Frasier Suites, Central business district, Abuja on 21st January, 2020.
- QMS training on reviewed/developed Management SOPs for Director General's Office NAFDAC training room, Wuse zone 7, Abuja 27th – 28th February, 2020.
- Program Implementation committee Virtual meeting on the launch of MSMEs assisted e-registration by NAFDAC on 4th May 2020.
- Virtual training on NAPAMS vs 2 on 8th May, 2020
- AfCTA Workshop on Non-tariff Barriers, Technical Barriers to trade, Sanitary and Phyto-Sanitary measures Virtual 12th August, 2020
- FGN Survival Fund for MSMEs at BOI building Central Business District, Abuja.1st 1 October, 2020, 15th October, 2020 and 21st October, 2020
- PEBEC Virtual Stakeholder's Forum of Omnibus Bill on Business Facilitation 26th November, 2020

e. Presidential Enabling Business Council (PEBEC) M&E Reports.
Collation and vetting of M & E monthly reports from the 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 of update and prompt submission of reports.

f. Summary Of Activities for Year 2020

The year 2020 recorded a total of 77 (Seventy-Seven) activities at the Desk as summarized below:

No. of Visitors at the Desk		Trade Fairs/ Expo	Meetings	Workshops	Trainings	Business & Investment Forum	Others	Total
Local	Foreign							
33	2	4	22	3	5	4	4	77

g. Challenges

- The low record of activities was due to the Covid-19 pandemic.
- Frequent breakdown of official car even on the road and leaving the staff stranded.
- Lack of laptops for staff use especially when needed during critical hours.
- Inadequate stationeries.
- OSIC staff need to be trained to enhance their career progression since the staff are from different disciplines that are not related to investment promotion.

4.3 Reform Unit

The Reforms Unit was set up to sustain an effective service-oriented Agency void of corruption and gender discrimination and to maintain a harmonized environment for adequate staff input and welfare.
The Unit has endeavored to appropriately respond to customer complaints daily, 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.

Activities in Year Under Review

a. Customer Complaints

The Unit receives email complaints daily from the public bordering on suspected poisonous food and drug products, import, export and registration, amongst others. To these mails, we send acknowledgement to the complainants and address their areas of concern and where necessary, forward them to the appropriate technical unit/department/directorate to act 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. The Unit also received some mails from PEBEC APP (The Presidential Enabling Business Environment Council) which were also treated accordingly.

In 2020, a total of 114 complaints were received and the break down are as follows:

- PEBEC APP: 4 and all resolved
- Reforms Unit email: 110
- Resolved: 50
- Unresolved:21
- Closed: 42 (as a result of lack of information from complainant)
- Total number of calls from the Unit's hotlines: 558 all resolved

b. SERVICOM Monthly Resource Centre:
NAFDAC Parastatal SERVICOM Unit (PSU) attended the monthly SERVICOM resource center at the SERVICOM National office, Federal Secretariat which is handled by some team members from the SERVICOM office. NAFDAC PSU was represented in the months of January and February,2020 due to the Pandemic by – Mrs. Tamunonimi H. Adegbite.

c. Gender Town Hall Meeting:
NAFDAC Parastatal Gender Unit attended National Accountability Town Hall Meeting to commemorate the 16 DAYS OF ACTIVISM to end the violence against women and girls on the 27 November ,2020 at the Federal Ministry of Finance, Budget and National Planning. NAFDAC Gender Unit was represented by Mrs. Tamunonimi H. Adegbite.

d. **SERVICOM Nodal Officers Meetings**:
NAFDAC Parastatal SERVICOM Unit (PSU) attended the Council of Nodal officers meeting held at the SERVICOM National office, Federal Secretariat Complex, Abuja on the 21of December 2020 and NAFDAC PSU was represented by Mrs. Tamunonimi H. Adegbite.

Chapter 5

FOOD SAFETY AND APPLIED NUTRITION (FSAN) DIRECTORATE

5.0. Introduction

Food Safety and Applied Nutrition (FSAN) Directorate is responsible for:

1) ensuring that food manufactured, imported, exported, distributed, sold, advertised, and used in Nigeria meet the highest standard of Food Safety reasonably achievable,
2) ensuring that food business operations are in line with NAFDAC regulations and with international best practices.

5.1 Structure

The Directorate is headed by a Director and it is made up of seven (5) Divisions, each headed by a Deputy Director, and Office of the Director. The five Divisions are:

1. Food Inspection & Medium Scale & Agric Produce
2. Food Evaluation & Global Listing
3. Packaged Water
4. Bakery & Baked Products
5. Food Safety/Codex & Regulations

5.2. Functions of the Directorate

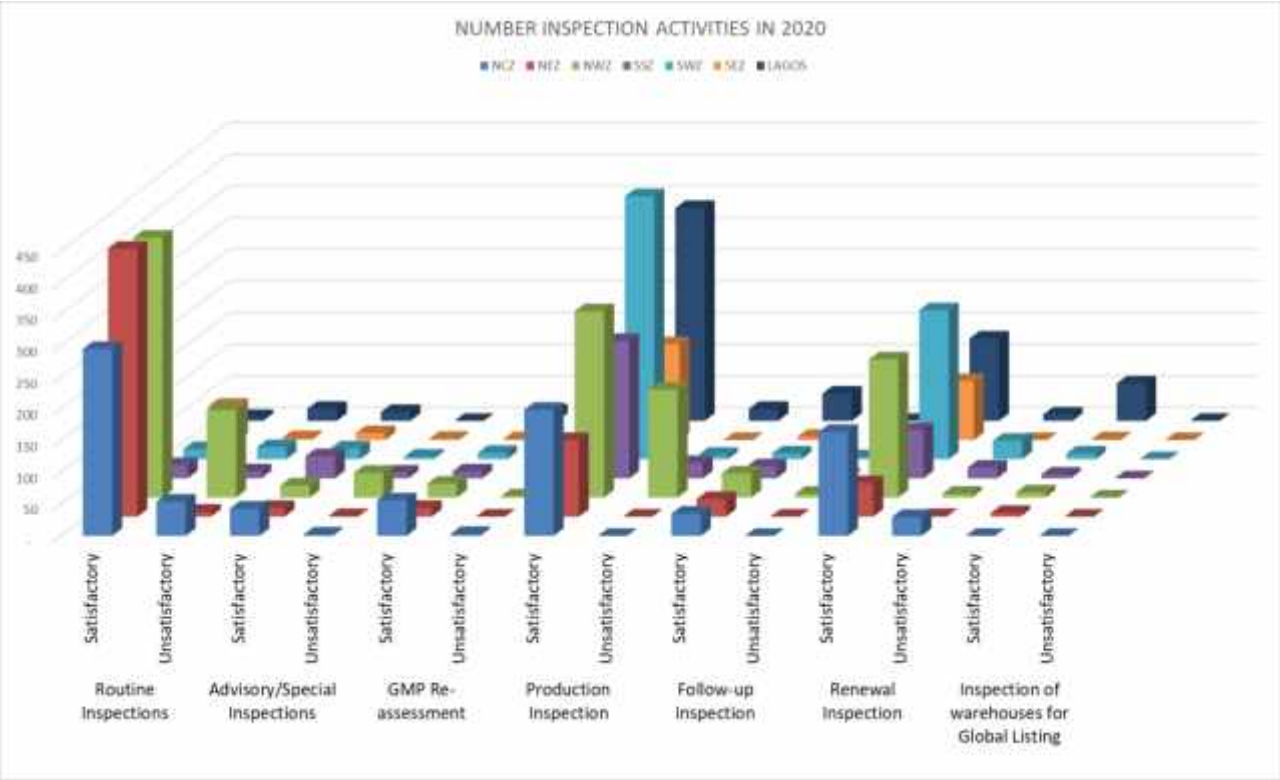
1. Safeguarding public health through a fair and effective food, water and related products regulatory regime that focus on out Good Manufacturing Practice (GMP) inspections of food and water establishments, Quick Service Restaurants, bakeries, etc.
2. Safety evaluation of all processed foods, food supplements, water, food additives and related products to ensure they meet the highest standards before marketing authorization or use.
3. Conducting health risk and benefit assessments of food, water, related products, and additives.
4. Engage in regulatory and research programs to address health risk associated with Food borne ailment, physical, chemical, and biological contaminants in Food and related products.
5. Strong collaboration and consultation with all relevant stakeholders in the food value chain from farm to table.
6. Industry Outreach, Consumer Education and stakeholders meeting to provide information and for meaningful engagement.
7. Coordination and promotion of Codex Alimentarius Commission activities, WTO Sanitary and Phyto-Sanitary (SPS) measures, International Food Safety Authorities Network (INFOSAN), National Fortification Programmes and International Code for Marketing of Breastmilk substitutes (BMS).

5.3: Regulatory Activities

Table 5.1: Summary of FSAN Activities for the Year, 2020

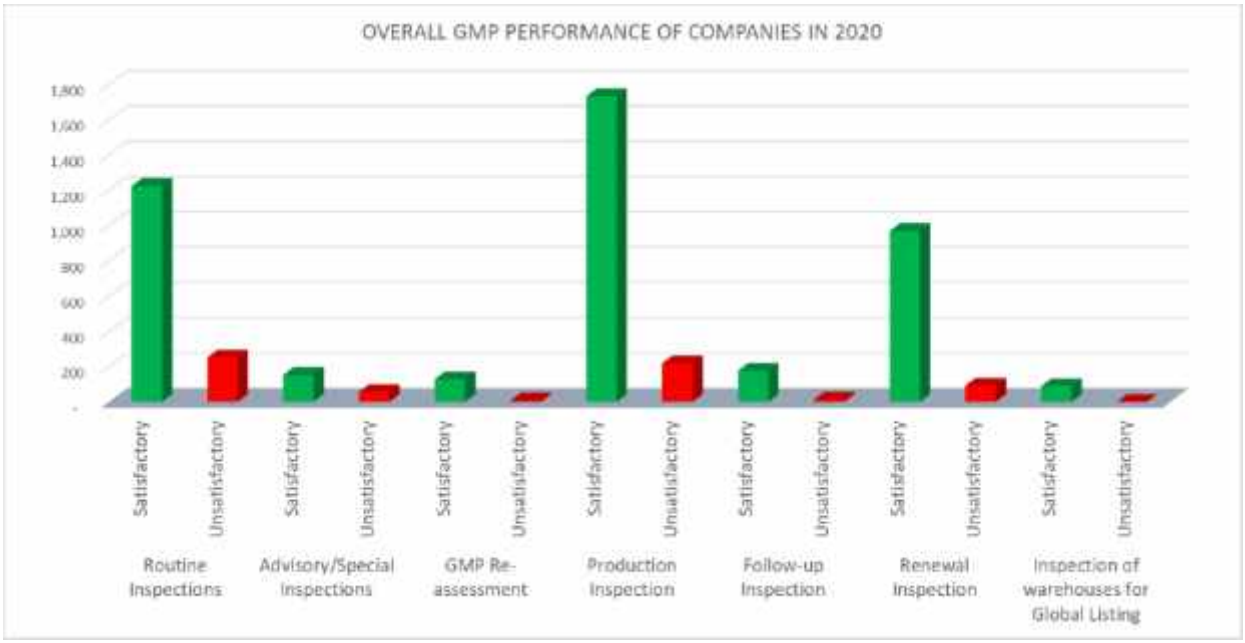
SN	FSAN ACTIVITIES	OUTCOME	TOTAL
1.	Routine Inspections	Satisfactory	1,225
		Unsatisfactory	252
2.	Advisory/Special Inspections	Satisfactory	153
		Unsatisfactory	57
3.	GMP Re-assessment	Satisfactory	129
		Unsatisfactory	8
4.	Production Inspection	Satisfactory	1,733
		Unsatisfactory	220
5.	Follow-up Inspection	Satisfactory	177
		Unsatisfactory	13
6.	Renewal Inspection	Satisfactory	969
		Unsatisfactory	93
7.	Inspection of warehouses for Global Listing	Satisfactory	89
		Unsatisfactory	-
8.	Cold Chain Facilities monitoring	Satisfactory	81
		Unsatisfactory	10
9.	No. of Surveillances activities carried out	Compliant	1,014
		Non-compliant	274
10.	No. of compliance directives issued		880
11.	No. of Investigations activities carried out	Concluded	65
		Ongoing	44
12.	Sanctions imposed on companies		554
13.	No. Put on Hold		25
14.	No. of Hold Removed		3
15.	No. of Establishments visited for Mop-up.		61
16.	No of Products mopped up		167
17.	No. of Consumer Complaints received		25
18.	Number of consumer complaints investigated	Concluded	9
		Ongoing	12
19.	No. of Product Alerts received		210
20.	No. Of Institutions visited for annual water monitoring		198
21.	Breast Milk Substitutes (BMS) Monitoring		120
22.	No. of Salt Iodization Survey carried out	Concluded	-
23.		Ongoing	24
24.	No. of Vitamin A/Pr emix S urvey carried out	Concluded	1
		Ongoing	132
	GPS Marking of location		2
25.	Change of Location		-
26.	Packsize Extention		3
27.	CGMP Certification		-
28.	No. of Sampling Inspection		20
29.	Others		1
	Total		**9,053**

Figure 5.1: Zonal Distribution of FSAN Inspection Activities in 2020.



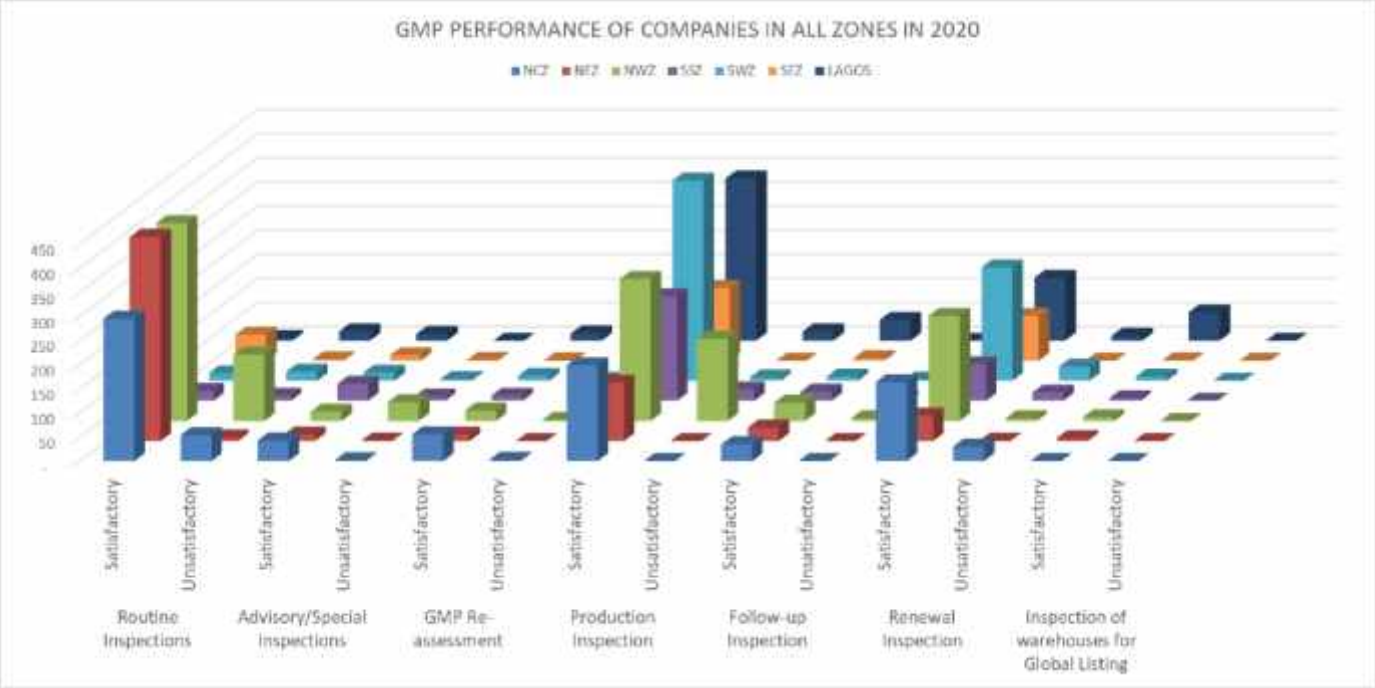
Unsatisfactory inspections are relatively high in the NWZ. Production inspections and renewal inspections are relatively high in SWZ while routine inspections are low. Warehouse and Global Listing Inspections are generally low in all the Zones.

Figure 5.2: GMP performance of companies in 2020.



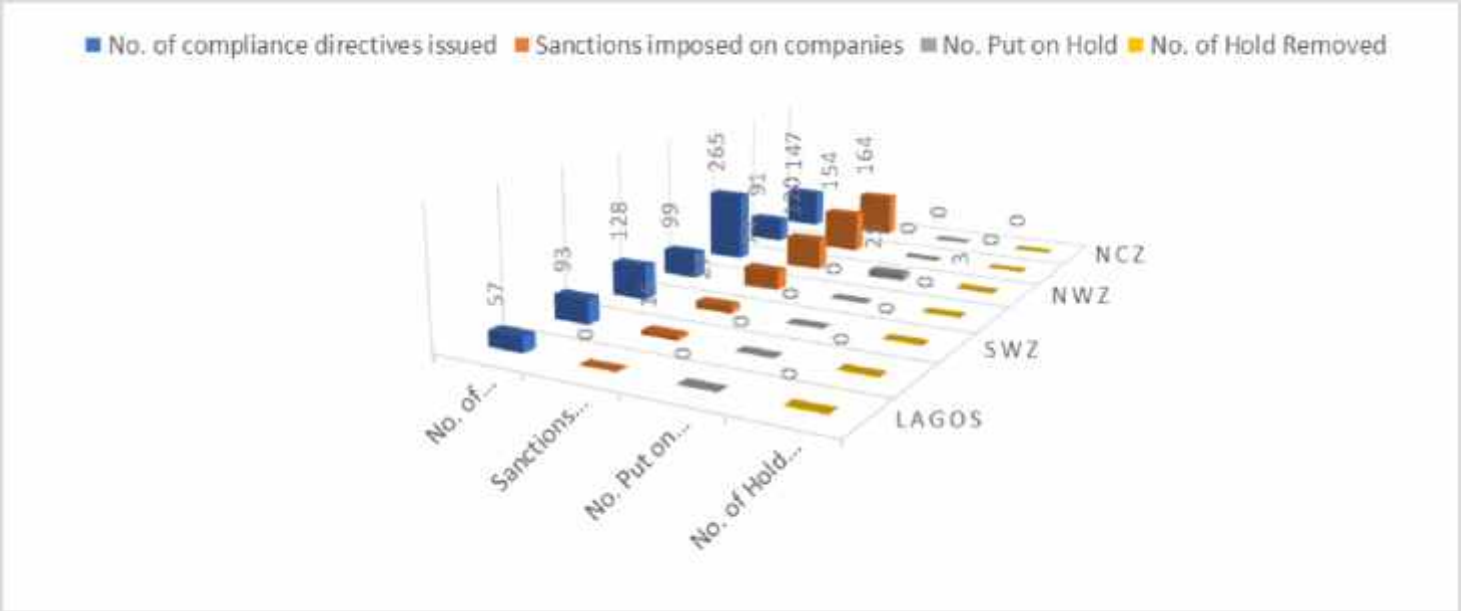
Performance of companies in terms of GMP are generally high in all types of inspections.

Figure 5.3: Zonal distribution of GMP performance of companies in 2020.



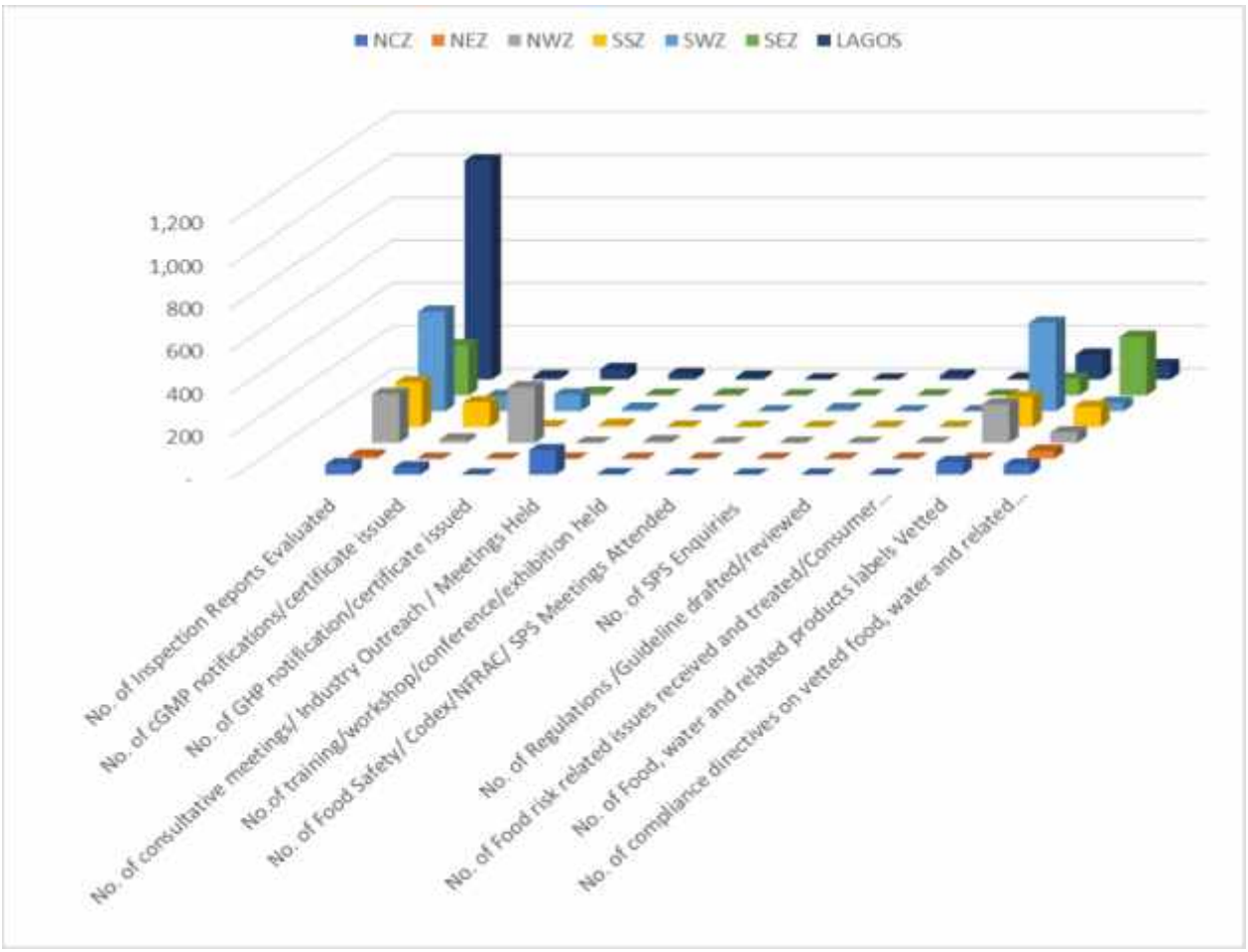
SWZ and Lagos are leading in production inspections while NEZ, NWZ, and Lagos are leading in routine inspections in that order.

Figure 5.4: Sanctions on non-conformances by companies in 2020.



There is paucity of data on places put on hold in all the zones except NWZ. More attention should be given to data collation for violations in subsequent years.

Figure 5.5: Non inspection activities in 2020.



NCZ and SWZ are leading in non-inspect

Figure 5.6: Comparison of FSAN Activities for 2019 With 2020

There was significant decrease in the activities in 2020 compared with 2019 in all the zones. This is due to the COVID-19 pandemic and the resultant lockdown and restrictions.

5.4: Other Food Safety Activities

A Food Fortification Programmes

Training on fortification survey was carried out in Lagos by PRS. Nationwide Micronutrient monitoring survey to monitor levels of fortificants (Vitamin A and Iodine) in selected products was carried out during the year under review in all the six geo-political zones in the country. The food vehicles include flour, sugar, salt and vegetable oil.

B National Assignments

The Directorate serves as the secretariat of National Codex Committee – General Purposes Technical Committee (NCCGPTC) of which the Director General of NAFDAC is the Chair. Five NCC-GPTC meetings were held in the year under review to prepare delegates for Codex Meetings.

The Directorate serves as the National SPS Enquiry Point on Food Safety, as the INFOSAN Emergency Contact Point for Nigeria, and as secretariat to the National Fortification Alliance (NFA) which is public-private alliance on large scale food fortification in Nigeria. In the year under review, there were prompt notifications of regulations to the World Trade Organization (WTO) for enhanced trade facilitation. The Directorate also coordinates activities of the National Technical Committee on International Code for Marketing of Breastmilk Substitutes (BMS Code) on behalf of the Director General NAFDAC who is the Chair.

5.5 Challenges

1. Inadequate operational vehicles for facility inspections.
2. Lack of FSAN liaison office at Abuja for effective collaboration with development partners, MDAs, and other stakeholders.
3. Inadequate infrastructure to fully implement QMS.
4. Most food regulations are still in draft.

5.6. Way Forward

1. Open FSAN liaison office at Abuja.
2. Provide tools and equipment for optimal workflow.
3. All effort should be made to push for gazetting of all draft food regulations.
4. Provide 20 Hilux vans for effective monitoring of food facilities.

Chapter 6

DRUG EVALUATION AND RESEARCH (DER) DIRECTORATE

6.0. Introduction

The Drug Evaluation and Research (DER) Directorate 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. The Directorate is also committed to the development and continued improvement of its Quality Management System (QMS) to ensure a robust and effective Directorate that will guarantee safe, effective, and good quality medicinal, cosmetics and allied products.

The Directorate operated through the following Divisions in year 2020:

- Clinical Trial & Drugs
- Cosmetics and Medical Devices.
- Herbal and Nutraceuticals
- Pharmaceutical Operations
- Pharmaceutical Compliance
- Vaccines and Biologics

6.1 Summary of Regulatory Activities of the Directorate in 2020

• Drugs & Clinical Trial	-	339
• Herbal & Nutraceuticals	-	1,059
• Vaccines & Biologics	-	198
• Pharma Operations & Compliance	-	2,546
• Cosmetics & Medical Devices	-	1,782
• Quality Management System	-	134
Total	-	**6,058**

Table 6.1: Summary of Inspections carried out by DER in 2020 by Inspection Type.

S/NO	Type of Inspection	Herbal & Neutraceuticals	Vaccines/ Biologics	Drugs	Cosmetics & Medical Devices	TOTAL
	Routine Inspection	320	3	46	158	527
	Pre-Production Inspe ction (Drug companies only)	0	0	4	13	17
	Special Inspection	7	0	63	21	91
	Pre-Registration Inspection	0	0	8	0	8
	GMP Re-assessment Inspection	35	0	40	66	141
	Production Inspection	0	101	0	37	138
	Follow-up Inspection	0	11	0	28	39
	GMP Re -assessment for	0	17	0	2	19

	License Renewal Inspection					
	Inspection of Warehouses/Retail Outlets for Global Listing	0	0	20	4	24
	Global Listing Renewal	0	0	2	0	2
	Cold Chain Facilities Monitoring for Vaccines & Biologics	0	0	108	2	110
	Coding Inspection	5	0	7	2	14
	Surveillance Inspection	0	3	0	27	30
	Co-packaging Inspection	0	0	0	0	0
	GMP Assessment on change of factory site	0	9	0	0	9
	No. of Overseas GMP Inspections carried out	0	0	0	1	1
	MAS Coding Inspection	0	0	0	0	0
	No. of Investigation /for cause Inspections Conducted	0	1	0	3	4
	No. of GCP Inspections Conducted	0	0	16	0	16
						1190

Table 6.2: Sanction Activities carried out by DER in 2020

S/N	States	Warning of offenders	Compliance Directives (CDs)	Admin Charges on Offender	Seizure/ withdrawal/ Mopping Up of Products	Destruction of Products	Products Put on Hold	Outfit put on hold	Closure of Outfit	Total
1	Abia	0	23	1	13	0	0	1	0	38
2	Adamawa	0	0	0	0	0	0	0	0	0
3	Akwa-Ibom	0	0	0	0	0	0	0	0	0
4	Anamabra	0	20	21	32	0	0	1	0	74
5	Bauchi	0	19	0	0	0	0	0	0	19
6	Benue	0	1	0	0	0	0	0	0	1
7	Borno	0	21	0	0	0	0	0	0	21
8	Bayelsa	0	0	0	0	0	0	0	0	0
9	C/River	0	0	0	0	0	0	0	0	0
10	Delta	0	0	0	0	0	0	0	0	0
11	Ebonyi	0	0	0	0	0	0	0	0	0
12	Edo	0	0	0	0	0	0	0	0	0
13	Ekiti	0	0	5	0	0	0	0	0	5
14	Enugu	0	0	0	317	0	0	1	0	318
15	Gombe	0	4	0	0	0	0	0	0	4
16	Imo	0	0	0	0	0	0	0	0	0
17	Jigawa	0	1	0	0	0	0	0	0	1
18	Kaduna	0	28	0	0	0	0	0	0	28
19	Kano	0	13	0	60	0	0	3	0	76

20	Katsina	0	0	0	0	0	0	0	0	0
21	Kebbi	18	0	0	0	0	0	0	0	18
22	Kogi	0	0	0	0	0	0	0	0	0
23	Kwara	0	2	2	0	0	0	0	0	4
24	Lagos	0	10	1	0	0	0	7	0	18
25	Nasarawa	0	0	0	0	0	0	0	0	0
26	Niger	0	0	0	0	0	0	0	0	0
27	Ondo	11	12	1	2	0	0	0	0	26
28	Ogun	0	0	2	0	0	0	1	0	3
29	Osun	0	1	4	0	0	0	1	0	6
30	Oyo	0	0	1	0	0	0	0	0	1
31	Plateau	2	4	0	0	0	0	0	0	6
32	Rivers	0	0	0	0	0	0	0	0	0
33	Sokoto	9	0	0	6	0	0	0	0	15
34	Taraba	3	15	4	3	0	2	0	0	27
35	Yobe	0	0	0	0	0	0	0	0	0
36	Zamfara	81	0	0	73	0	23	0	0	177
37	FCT	0	1	0	8	0	0	0	0	9
	Total	**124**	**175**	**42**	**514**	**0**	**25**	**15**	**0**	**895**

6.1 Review of Inspection Reports.

A review of five hundred and fifty (550) local GMP inspection reports captured under product categories listed below was carried out in the year 2020. The breakdown is as follows.

Product Category		Nos.
Drug	-	56
Herbal & Nutraceuticals	-	68
Medical Devices	-	19
Cosmetics	-	326
Global listing of Cosmetics	-	9
Sanitizers	-	73
Total		**550**

6.2 Summary of Foreign Facility Verification Applications Received and Cleared Facility in 2020.

A total number of three hundred and eighty-seven (387) applications were received in the reporting period. Three hundred and Sixty-nine (369) were cleared and uncleared applications were eighteen (18) in number. Below is statistical information on product categories that are manufactured by the assessed facilities

Product Category		No.
Drug	-	229
Herbal & Nutraceuticals	-	62
Medical Devices	-	39
Cosmetics	-	39
Total	**-**	**387**

6.3 Regulations and Guidelines

The Directorate reviewed some existing guidelines as well as developed some new guidance documents as listed below;

- Review of NAFDAC Good Manufacturing Practice for Pharmaceutical Products Guidelines 2016.

- Review and update of the Guidelines for Importation of APIs.
- Review of NAFDAC Good Clinical Practice Guidelines (Adopted ICH-GCP E6 (R2) Guidelines).
- Development of Guidance for sponsors of COVID-19 Clinical Trial Applications in Nigeria.
- Development of draft guidelines for medical devices manufacturing facility
- A review of expired guideline on production inspection was carried out by the Directorate.

6.4 Collaboration Between NAFDAC and WHO on Eradication of Poor Quality Finished Pharmaceutical Products in Nigeria.

The World Health Organization (WHO) as part of its commitment to member countries to promote and ensure access to medicines that are safe, effective and of the desired quality partnered with NAFDAC to jointly conduct a post marketing surveillance exercise on some essential medicines for priority health diseases in Nigeria. The quality survey started with collection of samples in August 2019. Result of laboratory analysis started trickling in by November 2019 and continued alongside with the COVID-19 pandemic despite the enormous challenges to NAFDAC regulatory systems. The outcome of the surveillance exercise involved the sampling of finished pharmaceutical products from retail Pharmacy outlets within the country. The sampled finished pharmaceutical products were subjected to laboratory evaluation and the results presented to NAFDAC for appropriate regulatory action which was implemented as follows:

Communication to Manufacturers and MAH holders

- All affected manufacturers (local and foreign) were officially notified of the failure and directed to:
- Carry out a comprehensive investigation and report outcome of investigation to DG (NAFDAC) within 14 days.
- Recall batches of defective products and submit a detailed report to DG (NAFDAC) within 14 days.
- Closure of Local Manufacturers with Critical Quality Failures
- Local manufacturers with up to critical quality failures (5 in number) were shut down followed by series of regulatory interventions which include but not limited to for-cause inspection, Onsite CAPA effectiveness verification imposition of administrative charge and product recall.
- Imposition of Administrative Charge
- An administrative charge of one million naira was imposed on each of the manufacturers whose factories were shut down. The administrative charge has since been paid.

6.5 Collaboration Between NAFDAC and CBN/AFDB On Funding Intervention Program to Reduce Spread of COVID -19

The directorate compiled list of ten local (10) pharmaceutical manufacturers for special consideration by DG-NAFDAC for CBN/AFDB intervention programme to enable them to procure raw materials and equipment to boost local drug production in Nigeria. The selected companies include Fidson Healthcare Plc, May and Baker Plc, Neimeth International Plc, Unique Pharma, Swiss Pharma, Dana Pharma, Orange Drugs Limited, Sagar Vitaceuticals Nigeria limited, GSK Consumer Nigeria Plc. and Emzor Pharmaceutical Industries.

6.6 Expert Committee Participation

DER staff participated in WHO expert working group for the development of performance evaluation framework (PEF) of WHO listed authorities (WLA)

6.7 NAFDAC Mock WHO Global Benchmarking Assessment

The Directorate participated in the mock exercise of Global benchmarking Assessment. During the mock assessment on 7 and 9 September, 2020, the Regulatory Inspection function team and Clinical Trial Oversight (CTO) team participated both physically and virtually, and all the gaps associated with sub-indicators under the two functions were properly addressed.

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- Review and update of the Guidelines for Importation of APIs.
- Review of NAFDAC Good Clinical Practice Guidelines (Adopted ICH-GCP E6 (R2) Guidelines).

Description of Indicators	No	Percentage
Companies with satisfactory outcome	13 (25)	52%
Companies with unsatisfactory outcome	12 (25)	48%
Companies redesigning, re-modelling or erecting new GMP compliant facility	10 (25)	40%
Companies with potential for upward migration on risk categorization	16 (25)	64%
Companies with potential for downward migration risk categorization	9 (25)	36%

For CAPA plans that were found satisfactory, the companies were issued payment advice to make payments for onsite effectiveness verifications. Whereas those with inadequate submissions were advised to review their plans and resubmit more effective plans within stipulated timelines.

Companies that failed to submit their CAPA plan after GMP Roadmap inspection of Pharmaceutical Manufacturing sites

Fifteen (15)defaulting companies that failed to submit their CAPA plan after GMP Roadmap inspection of pharmaceutical manufacturing facilities in the country were scheduled for on-site GMP re-assessment inspection. The outcome of the inspections was as follows;

Description of Indicators	No. of affected companies
Companies with unsatisfactory outcome	6
Companies that were placed on HOLD	6
Companies that were inaccessible. To be re-scheduled for next inspection exercise.	1
Companies that stopped manufacturing of pharmaceutical products	1
Companies redesigning, re-modelling or erecting new GMP-compliant facility	1

- **Companies with product quality failure problems**
  The directorate placed on HOLD the Beta-lactam manufacturing lines of four (4) Pharmaceutical companies with quality failure problems. An on-site CAPA plan effectiveness verification was later carried out at the facilities. Three of the four companies that satisfactorily developed and implemented their CAPA were re-opened. The remaining one is yet to tackle objectionable conditions that led to the said product failure.

- **Review of Factory Designs and Layouts**
  Fourteen companies submitted factory layouts for review. Three of the designs have been approved with eleven (11) currently undergoing review.

- **Sampling of Products for Laboratory Analysis**
  Prior to the approval and implementation of the SOP for risk-based sampling of regulated products for laboratory analysis, eight (8) companies with satisfactory GMP outcomes were issued letters to submit their samples upon payment of prescribed fees.
  Upon deployment of the SOP, nine (9) companies with satisfactory GMP outcomes were sampled based on the SOP for Risk-based Sampling of regulated products for laboratory analysis after payment of the prescribed fees. Some products were recommended for laboratory analysis and others for laboratory retention considering their risk status.

Other Activities

a. Sampling of May and Baker Chloroquine Tablets for COVID-19 Clinical Trials.

6.9 Pharmaceutical Compliance Division

- **Active Pharmaceutical Ingredient (API) Import Permit**
  One Hundred and Nineteen (119) applications for permits to import APIs were received during the period with forty-four (44) applications already approved while others were at various stages of processing.
- **Other Activities**

  a. Receipt and screening of Drug Master Files (DMFs) for API import permit.
  b. Review of e-permit payment matrix/invoice for API permit processing
  c. Represented the Agency at the PSN council meeting and Nigeria Association of Industrial Pharmacists.
  d. Training of staff on screening of DMF for APIs
  e. Generation of budget estimates and articulation of all required areas of needed intervention for DER by support from Africa Development Bank
  f. Participation in the review of the inspection module of NAPAMS Version 2 for integration of GMP inspection processes in the e-registration platform
  g. Preparation and submission of list of ten (10) local manufacturers with their installed and capacity utilization to the DG-NAFDAC.

6.10 Clinical Trial and Drugs (CT & D)

- **New Clinical Trial Applications**
  Twenty-nine new clinical trial applications were received during the reporting period. Seven (7) of the applications were approved, fourteen (14) were rejected due to lack of required documentation, one (1) was cancelled by the applicant due to futility of the study while seven (7) were issued compliance directives and the responses are being awaited.
- **Clinical Trial Authorization Renewal Applications**
  The two applications received for renewal of Clinical Trial Authorization during the reporting period were approved.
- **Permit to Import Investigational Medicinal Products (IMP)**
  Four (4) applications for permits to import IMPs were processed and three (3) of these were approved while a response to the compliance directives issued for the last application is being awaited.
- **Clinical Data Review**
  Three clinical data submissions were reviewed in the Division and the three were rejected because they didn't meet the specification.
- **Guidance Documents Developed**
  The following guidance documents were developed for clinical trial stakeholders:
  a. Notes to Clinical Trials Researchers during the COVID-19 (Coronavirus) pandemic
  b. Additional Clinical Trial Frequently Asked Questions (FAQs)
  c. Disclaimer letter on WHO SOLIDARITY Vaccine Trials.
- **Other Activities**
  a. Development of Memorandum for Public Hearing on a Bill for an Act to Establish the National Blood Services Commission.
  b. Development of Proposal for the joint NAFDAC/NHREC GCP training workshop for clinical trial investigators.
  c. Development of Work plan for National Blood Regulatory System.
  d. Development of the criteria for the categorization of GCP inspectors.
  e. WHO-GBT CAPA closure.

6.11 Herbal & Nutraceuticals Division

The Division carried out a total of twenty - seven (27) inspections, fifteen (15) were satisfactory, seven (7) unsatisfactory while five (5) facilities were not accessed.

- **Review of CAPA Plans**
  CAPA Plan submissions received from two (2) companies were reviewed and one was adjudged satisfactory while the other was not and the company was issued a compliance directive. The remaining five (5) companies with unsatisfactory GMP outcome were yet to submit their CAPA plan as at the time of this report.
- **Other Activities**
  Drafted confidentiality agreement between herbal medicine practitioners/manufacturers and herbal research scientists in collaboration with Legal Services Directorate.
  Guideline for carrying out GMP inspections and review of inspection reports from the zones/state was reviewed by the division.
  Developed and approved minimum floor plan requirements for herbal medicine manufacturing facilities"
  Organized special inspection of herbal medicine manufacturing facility for airing on NAFDAC and Your Health Television program.

6.12 Cosmetics and Medical Devices Division

Three hundred and ten (310) applications for registration of cosmetics products were received out of which Three hundred (300) were recommended for registration and three (10) were not.

Two hundred and Sixty-four (264) applications were received for registration of sanitizers. One hundred and fifty (150) applications were recommended for registration while fifty-eight (58) applications were not because the applicants did not have ma nufacturing facilities.

All five (5) applications received for registration of surgical face masks were recommended for registration.

Five (5) applications were received for registration of non-surgical face mask and they were recommended for registration.

Three (3) applications were also received for registration of PPE (Overalls) and they were recommended for registration.

- **Other Activities:**
  Drafting of accelerated procedure for desk review of documentation and processing of hand sanitizer under COVID-19.

6.13 Vaccines & Biologics Division

- **Cold Chain Monitoring Inspection**
  Applications for Eight (8) cold chain facility monitoring inspections were received and two (2) of the facilities were approved for cold chain storage based on a desk review of submitted documents while the last application is still being reviewed.
- **Coding Inspection**
  Applications for thirty-two (32) Monitoring Inspections for overprinting of NAFDAC Registration Number/MAS Codes were received and all the requests were approved based on a desk review of submitted documents and other evidence provided.
- **Global Listing Inspection**
  Four (4) application for Global Listing Inspections was received and treated.

- **Dossier Review**
  Ten dossiers were received during the reporting period, and all were treated.

6.6 Trainings, Meetings and Seminars in period under Review

- **National Advisory Committee on Vaccines & Biologics (NACVB) Meeting**
  A meeting of the NACVB was held on 29 May 2020 and the Vaccines & Biologics Division represented the Directorate
- **African Organization for Standardization's Conformity Assessment Committee** (ARSO CACO)
  Following a workshop held in June 2018 at the 24 ARSO (an expert working group on African Traditional Medicines), General Assembly in Durban, South Africa, ARSO initiated, through the ARSO CACO program, regulatory cooperation between regulators from different Member States and standardization bodies. The ARSO Conformity Assessment Committee (ARSO CACO) aims at establishing various tools and capacity building for Good Conformity Assessment Practices (testing, certification, inspection, market surveillance, laboratory accreditation and calibration) and facilitating Mutual Recognition Arrangements, to ensure that products and services conforms to acceptable Standards and Technical regulations and thus facilitate intra-African Trade. Furthermore, the working Group seeks to leverage on the benefits of Mutual Recognition Agreements (MRMs) where African countries will recognize one another's testing and certification requirements as acceptable, thus limiting different testing or customs inspections to reduce the barriers imposed by differences in technical requirements. The use of MRAs with more trading partners is expected to cement bilateral relations among the African countries and alleviate some of the testing and conformity assessment issues encountered by African traders as MRAs will lead to free movement of Goods and services as is anticipated by the Africa continent free TA.
- **Nigeria Herbal Medicine Product Committee (NHMPC)**
  The division hosted the 3rd (virtual) meeting of Nigeria Herbal Medicine Product Committee (NHMPC) held on 7th May 2020.The meeting was spurred on by the low output of researched herbal medicines and challenges such as inadequate level of research, poor documentation, and inadequate number of standards for raw materials, lack of standardization of herbal medicines and lack of cooperation/collaboration of practitioners with scientists/researchers. In addition, the low level of understanding of protection of invention and the Intellectual Property Right Laws (IPR), secrecy, lack of incentive for complete disclosure of herbal actives in the products and lack of clinical trial of existing herbal medicines also form the basis for inauguration of the committee.
  The DG NAFDAC invited stakeholders from the academia to bring their ideas to bare whilst in the committee and various subcommittee created to address above challenges identified in that sector.

- DER staff Meeting on work protocol during COVID-19 pandemic/lockdown.
- Virtual meeting between NAFDAC and NHREC on solidarity trial protocol.
- Virtual meeting between NAFDAC and NHREC on areas of collaboration in fulfilment of WHO-GBT requirement.
- Meeting of Expert Committee on 1st Edition of The Nigerian Essential Herbal Medicines List which took place at PSH Conference Room, Federal Ministry of Health Federal Secretariat Complex, Abuja on the 10th - 11th March, 2020.
- ARSO CACO virtual leadership meeting on 29th July 2020.
- NAFDAC virtual training for stakeholders on regulatory requirements for registration of herbal products made in Nigeria Wednesday, 5th august 2020. H&N made a presentation on the topic - Preparing for GMP Inspection of Herbal Medicinal Products.
- Virtual Divisional Meetings to address applications during the COVID pandemic and effective management and communication with stakeholders.

- Virtual training of DER staff and Pharmaceutical GMP Inspectors on various GMP topics.
- Virtual training of DER staff and Pharmaceutical GMP Inspectors on both newly developed and revised Directorate and Agency SOPs and other quality documents.
- Meeting between D (DER) and Concept Pharmaceutical Pvt. Limited India on company's intention to start local manufacturing of API in Nigeria.
- Virtual meetings for the review and update of GMP guidelines for pharmaceutical products 2020.
- Virtual cGMP training Marathon from September 7th to November 30, 2020.

Chapter 7

DRUG REGISTRATION AND REGULATORY AFFAIRS

7.0 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:

- 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.
- 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.
- Monitoring of advertisement to ensure compliance and identify illegal advertisements.

7.1. 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
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 Post Registration Documentation /NAFDAC Registered Products Automated Database (PRD/NARPAD)

iii. Global Listing Office

iv. Technical Services which comprises:

- Regulations
- Quality Management System
- Dossier Review Team

7.2 Highlights of Activities:

- QMS Self- Assessment of divisions within DR&A held January 14th to 17th, 2020
- DR&R Internal Audit Assessment held January 24th to 27th, 2020
- Training on thirteen (13) NAFDAC-QMS SOPs, 28th & 29th January 2020
- DR&R 2020 1st Quarter Quality Meeting, 25th February 2020
- DR&R In-House Training on Concept of Traceability and Global Standards held 10th March 2020.
- Training on NAFDAC SOP on Risk Based Sampling of Regulated Products for Laboratory Analysis held 24th July 2020
- Training on NAFDAC SOP on Risk Management During Emergencies held 28th July 2020
- Training on the Reviewed NAFDAC Quality Manual held 28th July 2020

- Training on Reviewed SOP of FDRC meeting held 13th August 2020
- Training on Guidance for Promotion and Advertisement Practices held 2nd September 2020
- Training on Handling Applications Exceeding Timelines held 24th September 2020
- Training on SOP NAPAMS Management held 24th September 2020
- SOP Processing Abridged/Expedited Registration/Approval Processes During Emergencies 24th September 2020
- Virtual Training for NAFDAC Staff on E-registration and Regulations held 13th October 2020
- NAFDAC-CTFA Technical Partnership Virtual Training on Cosmetics 6th November 2020
- Participation at the GSI Global Healthcare Summit held virtually 17th to 19th November 2020.

A) Drugs Registration Divisions

The Directorate carried out the registration of regulated products which are summarized below:
The total number of products Drugs and other products registered in 2020 was five thousand, two hundred and eight (5,208):

Table 7.1: Comparative Analysis of Registered NAFDAC Regulated Products 2019-2020

NAFDAC regulated products	January - December 2019	January - December 2020
Drugs and related products	5,162	5,208

This represents a 0.89% increase over the figures of the same period in 2019 (Five thousand, one hundred and sixty-two (5,162) products).

(i) Drugs and Related Products Registration Divisions

A total of five thousand, two hundred and eight (5,208) drugs, and related products were registered:

Table 7.2: Summary of the Activities of Drug and Related Products Registration Divisions

Products		Forms purchased	Completed forms received	Products presented for approval	Products approved	Products rejected
Human drugs	Imported	e-reg	2,514	1,978	1978	0
	Local	e-reg	312	386	386	0
Medical devices	Imported	e-reg	534	252	252	0
	Local	e-reg	240	48	48	0
Vaccines / biologicals	Imported	e-reg	109	0	0	0
	Local	e-reg	1	0	0	0
Cosmetics	Imported	e-reg	0	223	217	6
	Local	e-reg	134	1,149	1,149	0
Herbal drugs	Imported	e-reg	311	299	298	1
	Local	e-reg	88	259	258	1

Pesticides	Imported	e-reg	170	189	188	1
	Local	e-reg	88	69	69	0
Veterinary drugs	Imported	e-reg	248	252	252	0
	Local	e-reg	158	113	113	0
Finished Chemical	Imported	e-reg	0	0	0	0
	Local	e-reg	0	0	0	0
Total		∑(e-reg)	**4,907**	**5,217**	**5,208**	**9**

Table 7.3: Comparative Analysis of the Activities of LOD Drug 2018-2019

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

- Two thousand, one hundred and fifty-five (2,155) drugs and related products applications were received and sent to the Legal Unit for perusal.
- Three thousand, one hundred and ninety-seven (3,197) applications of drugs and related products were processed and sent to relevant Divisions.

Activities in LOD Drug	**2019**	**2020**
No. of drugs and related products applications received and sent to the Legal Unit for perusal	4,610	2,155
No. of appli cations of drugs and related products applications processed and sent to relevant Division	5,810	3,197

(v) Global Listing

A total of Forty-eight (48) approvals (Acknowledgment Form) were issued within the year. Also, Eleven (11) Additional Items Approvals were issued within the year.

(vi) Post Registration Documentation / NAFDAC Registered Products Automated Database (PRD)/NARPAD

This Unit is charged with the responsibility of preparing Registration and Listing Certificates of products that have successfully completed the registration process. It is also charged with the responsibility of keying in registered products into NAFDAC Registered Products Automated Database (NARPAD).

- Eight thousand, five hundred and sixty-one (8,561) certificates were prepared in the period under review. Breakdown: Drug (699), Cosmetic products (1,189), packaged water (3,064), Food products (2,092), Medical devices (156), Herbal (308), Veterinary products (430), Pesticides (530) and correction & omissions (93).
- five thousand, seven hundred and thirteen (5,713) products were keyed into the NAFDAC Registered Products Automated Database (NARPAD).
- Two thousand, nine hundred and fifty-seven (2,957) Registration and Listing certificates were issued in the period under review. Breakdown: drug (664), food (495), cosmetics (358), pesticides (111), veterinary drugs (205), medical devices and biological & vaccines (148), herbal (132) and water (733).

Chapter 8

FOOD REGISTRATION AND REGULATORY AFFAIRS DIRECTORATE

Summary of R&R Food Directorate Activities for the Month January - December, 2020

	FOOD	WATER	FEED
Imported	664	0	11
Local	1,971	1,998	38
Total	2,635	1,998	49

A total of 4,682 Food products were registered within the period.

Activities of Food Registration Division (I&II) January - December , 2020

S/No	Process		Food (Local)	Food (Imported)	Feeds (Imported)	Feeds (Local)	Water	Total
1	No of Application Forms brought forward		**9**	**70**	**0**	**0**	0	**79**
2	Number of application Forms received		**0**	**356**	**47**	**125**	**174**	**702**
3	Total Number of application Forms available for processing		**746**	**426**	**47**	**125**	174	**1518**
4		Total Number of application Forms Treated	719	424	**47**	**125**	174	1489
5		No of Application Forms pending as backlog	**27**	**2**	**0**	**0**	0	**29**
6	No of products sent to lab		0	654	**11**	**0**	NIL	665
7	No of laboratory reports received		754	414	**35**	**74**	2,182	3459
a		satisfactory	735	414	**35**	**74**	2,044	3302
b		unsatisfactory*	19	0	**0**	**0**	334	353
8	No of Administrative Approval		58	0	**0**	**0**	2	60
9	No of Fast Track Approval issued		208	0	**0**	**16**	2	226
10	No of Import Permit issued		0	312	**11**	**0**	0	323
11	No of GMP reports received		325	482	**15**	**65**	1,937	2824
a		satisfactory	325	482	**15**	**65**	1,937	2824
b		unsatisfactory*	0	0	**0**	**0**	0	0
12	No of Products Presented for Approval (FDRC		1,971	666	**11**	**38**	1,998	4,684

a		Approved	1,971	664	**11**	**38**	1,998	4682
b		Non-Approved*	0	2	**0**	**0**	0	2
13	Full Registration		521	390	**32**	**102**	326	1371
14	Listing		961	0	**0**	**0**	1,447	2408
15	Renewal		411	160	**12.0**	**23.0**	137	743
16	No of Approved Pack Size Extensions		160	80	**0**	**0**	41	281
17	No of Approved Change in Agencyship		75	1	**1**	**0**	0	77
18	Change in Product Name		10	0	**0**	**0**	13	23
19	Change in label design		65	6	**0**	**0**	4	75
20	Additional Manufacturing Source		4	27	**0**	**0**	3	34
21	Change in Manufacturing Site		28	6	**0**	**0**	0	34
22	No of Compliance Directive		75	2	**0**	**0**	0	77
23	No of change in packaging design		0	1	**0**	**0**	0	1
24	No of additional packaging materials		0	10	**0**	**0**	0	10
25	No of change in formulation		24	16	**0**	**0**	0	40
26	Promotional labels design		67	1	**0**	**0**	0	68
27	Additional Variant		0	81	**0**	**0**	0	81

Advert Control Division for Jan- Dec. 2020

Products/Activities			**Food**		**Water**	
			Local	**Imp.**	**Local**	**Total**
No of Applications brought forward						452
No of Applications received for Advert						0
Total Number of Applications available for processing						0
		Processed				452
		Number Outstanding				0
Products Advert Monitored		Television				111
		Out-Of-Home				182
		Press				5
		Radio				135
		Medical Journal				0
		On-Line				44
No. of Adverts Presented for FDRC						234
		Approved				234
		Not Approved				0
Breakdown of Approved Advert		New Application				400
		Re-validations				52
Miscellaneous Service		Approval				0
		Amendment				0
		Payment Advice				460
		Unauthorised/Admin Charge				10
		Consultative Meeting				0
		Admin Charges				0

Activities Of Food Regulation Division For 2020

Activities		Number	Revenue Generated (□)
No of Regulations Sold		0	
No of drafted/reviewed Regulations	In Process	12	
	Completed	2	
No of Drafted Nigerian Industrial **Standards** (SON)		0	
No of Gazetted Regulations		0	
No of developed SOP's		4	
No of Stakeholders meeting		6	
No of Reg ulations considered by NAFDAC Technical Committee		3	
No. of NAFDAC Technical Committee meetings held		0	
No of Products Vetted	Satisfactory	2	
	unsatisfactory	0	
No of Meetings/Training attended		34	
No of Drafted/Reviewed Guidelines		5	
No of Technical/Regulatory inputs mode		11	
No of Memo treated		24	

Chapter 9

PORTS INSPECTION DIRECTORATE (PID)

9.0 Introduction:

Ports Inspection Directorate, in the year under review was responsible for ensuring that NAFDAC regulated products imported into or exported out of Nigeria met requisite standards of safety and right quality. The mandate of the directorate amongst other things embraced the following statutory functions:

- To regulate and control the importation of drug, food, medical devices, cosmetics, detergents, drinks and bottled water.
- Screening of import documents before the issuance of pre-release stamps.
- To undertake the inspection of imported food, drugs, medical devices, cosmetics, chemicals, detergents, drinks and bottled water at ports of entry before release.
- To control the exportation of regulated products and issue quality certification for such regulated products.

The activities of the Directorate were carried out by the various Divisions, Units, Ports and Outstation offices viz:

- Director's Office
  - ❖ E-Clearance/Statistics Unit
  - ❖ Intelligence and monitoring unit

- Divisional Offices
  - ❖ Export
  - ❖ Port Chemical, Cosmetics and Medical Devices
  - ❖ Port Drug
  - ❖ Port Food
  - ❖ New Technologies/Post Port-Clearance

- Port Offices in Lagos
  - ❖ Seaports –Apapa, Tincan, Kirikiri Lighter Terminal, Lilypond, Ikorodu
  - ❖ Airports:
  - ❖ Lagos – Murtala Mohammed International, Airport,
  - ❖ Kano –Aminu International Airport, Kano,
  - ❖ Abuja – Nnamdi Azikiwe International Airport, Abuja,
  - ❖ Enugu – Akanu Ibiam International Airport, Enugu

- Outstation Offices
  - ❖ Port-Harcourt
  - ❖ Warri
  - ❖ Calabar
  - ❖ Kaduna
  - ❖ Kano

- ❖ Abuja
- ❖ Enugu
- ❖ Onitsha

- Land borders:
  - Idiroko
  - Seme
  - Kamba
  - Jibia
  - Maigatari
  - IllelaThis report is presented under the following major headings:
  - Staff Report
  - Activities Summary
  - Divisional/Outstation Reports
  - Achievements
  - Challenges
  - Way forward

9.2 Activities Summary

9.2.1 Transactions Summary

In 2020, the activities of PID involved the processing of port clearance transactions which generated revenue from inspection charges, analysis, and radiation charges as well as administrative charges imposed on violations as well as administrative approvals. The following are noteworthy:

- A total of Two thousand, one hundred and seven **(2107)** violations were treated accounting for over 11.2% increase to the One thousand, eight Hundred and Ninety-Six **(1896)** cases reported in 2019.
- Statistics of the reports are shown in Table 8.2 below.

Table 9.2: ***Transaction Summary Table for 2020***

PID Office Locations	No. of Transactions
Lagos Ports	21,752
Land Borders	-
Outstations	3992
Director's office	1125
Export office	-
Total	**26,869**

9.2.2 Treated SGDs

- A total of Twenty-one thousand, seven hundred and fifty-two **(21,752)** SGDs were treated from Lagos office, six hundred and Ninety **(3,992)** from Outstation offices and no SGD treated by Land borders due to closure of land borders. A total of Twenty-five thousand, seven hundred and forty-four **(25,744)** treated SGDs in the year under review.

Table 9.3: *SGDs Treated in 2020*

Month	Lagos Office	Land borders	Outstations	Total
January	2,001	-	852	**2853**
February	1,842	-	476	**2318**
March	1,810	-	576	**2386**
April	908	-	444	**1352**
May	1,424	-	333	**1757**
June	1,922	-	149	**2071**
July	2,148	-	127	**2275**
August	2,167	-	151	**2318**
September	2,098	-	175	**2273**
October	1,406	-	241	**1647**
November	2,019	-	262	**2281**
December	2,007	-	206	**2213**
TOTALS	**21,752**	**-**	**3,992**	**25,744**

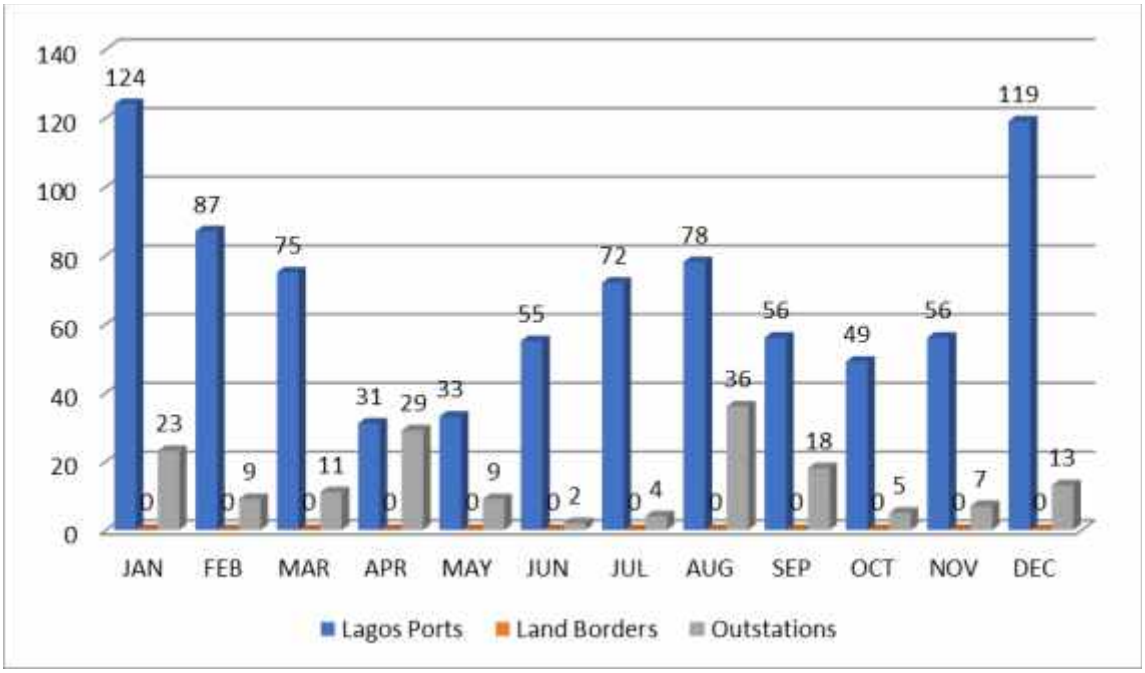
9.2.3 Report on Violations

A total of Two thousand, one hundred and seven **(2107)** violations were treated in the year under review.

Table 9.4: Total Cases of Violation Treated by PID Port Locations

Month	PID Lagos Divisional Offices					PID Office Locations		
	Food	Drug	CCMD	Export	NT/PPC	Lagos Ports	Land Borders	Outstations
January	34	36	81	-	-	124	-	23
February	17	49	40	-	-	87	-	9
March	13	32	52	-	-	75	-	11
April	6	16	22	-	-	31	-	29
May	14	23	25	-	1	33	-	9
June	13	26	35	-	-	55	-	2
July	20	-	50	-	1	72	-	4
August	22	42	62	-	7	78	-	36
September	11	38	31	-	14	56	-	18
October	8	45	30	-	-	49	-	5
November	14	34	45	-	-	56	-	7
December	15	47	35	-	-	119	-	13
Totals	**187**	**388**	**508**	**0**	**23**	**835**	**0**	**166**

Figure 9.1: Cases of Violations by PID Port Locations for the Year 2020



9.3 Divisional/Outstation Reports

9.3.1 Export Activities

- Activities in the Export Division involved Documentation, Inspection, Laboratory Analysis and Certification. These operations were carried out in collaboration with relevant Directorates of the Agency and Other stake holders.
- Applications received were Seventy-seven (**77**) with seventy-one **(71**) Certificates issued and Sixteen **(5)** Export Approval
- The Export Division did not hold any workshop in 2020.
- Details of Export activities are found in Table 7 below.

Table 9.5: **Details of Export activities**

Product Group	Applications Received	Weight (MT)	Certificates Issued for 2020							
			Combined Certificate of Manufacture and Free Sale	Certificate of Free Sale	Health Certificate	Certificate of Pharmaceutical Product	Export Approval	Export Certificates	Compliance Directive	Revenue Generated
FOOD (Finished, processed & semi processed)	35	3,154.9745	24	1	5	-	3	-	**3**	261,500

FOOD COMMODITIES	2	15.9045	-	-	2	-	1	-	-	5,500
DRUGS (Finished Pharmaceutical & Cigarettes)	24	6,233.065	17	1	-	6	1	-	2	198,000
COSMETICS	8	140.134	6	-	-	1	-	-	-	60,500
CHEMICAL	8	1,064.202	8	-	-	-	-	-	-	80,000
TOTALS	**77**	**10,610.28**	***55***	***2***	*7*	*7*	***5***	**-**	***5***	**605,500**
			Total Certificates issued: 71			**Total Export Approvals: 5**				

Figure 9.2: Export Certificates Issued in the Year 2020

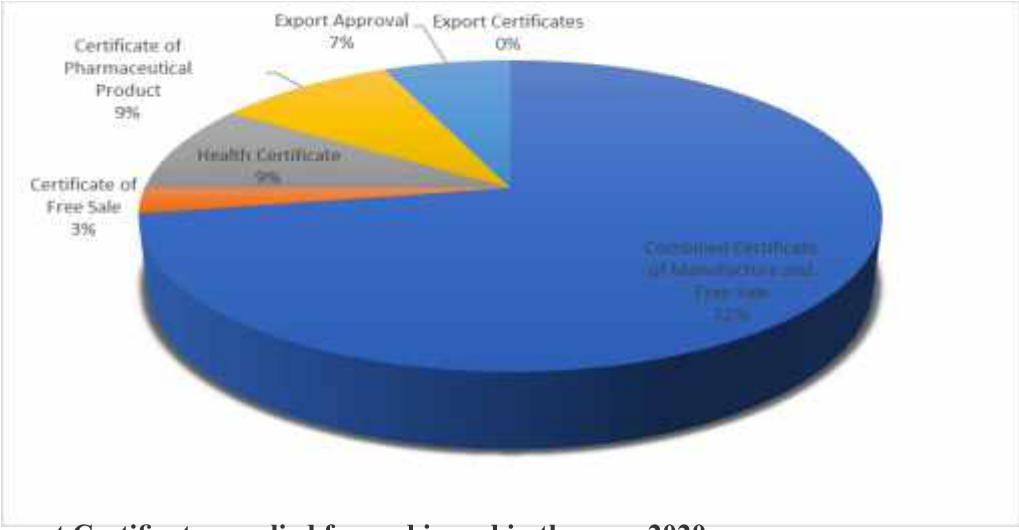
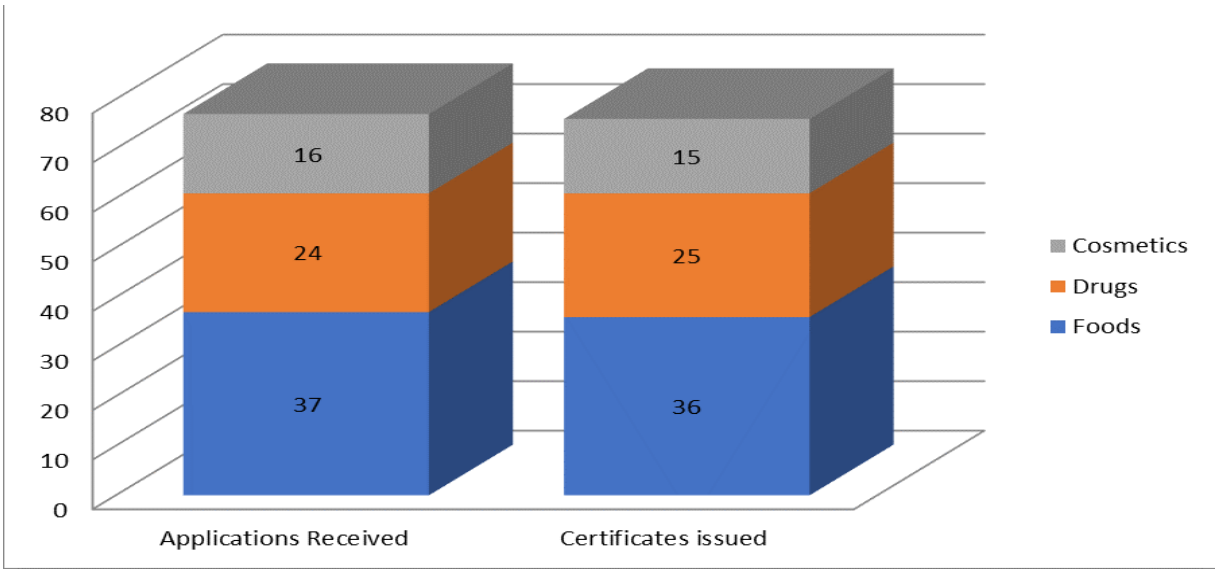


Figure 9.3: Export Certificates applied for and issued in the year 2020



9.3.2 New Technologies/ Post-Port Clearance Division (NT/PPC)

NT/PPC became a full fledge division in 2014. The division has three distinct activities namely: Minilab, Hold assignment and fast track inspection.

3.2.2 Placement/ Removal of Hold Label Report

- A total of Twenty-nine (29) hold assignments were carried out in the year under review.
- Table shown below is the statistic of hold placement and hold removal.

Table 9.6: Hold Assignment Activities

S/NO	Month	Hold Removal	Hold Placement
1	January	0	2
2	February	0	3
3	March	0	4
4	April	0	0
5	May	0	1
6	June	2	1
7	July	2	1
8	August	0	0
9	September	1	1
10	October	0	5
11	November	0	7
12	December	0	4
	Total	**5**	**29**

9.3.3 Violation Reports

8.3.1 Treated Violation by Divisions in PID Lagos

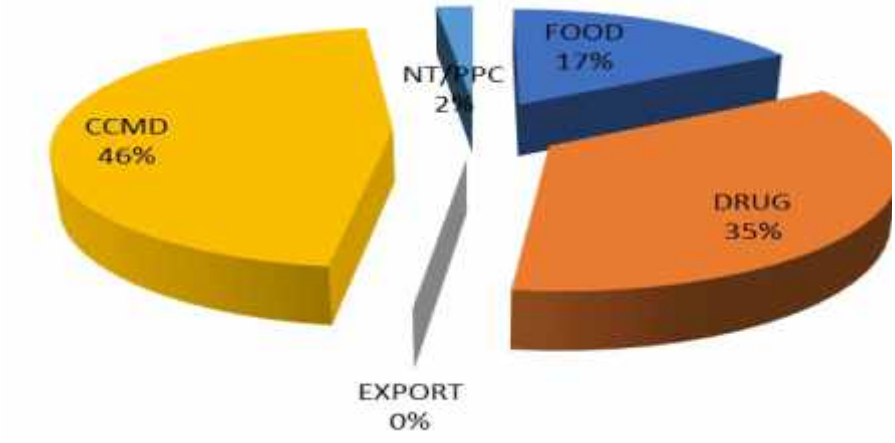
- The table and chart below give the details of violations treated by the divisions
- A total of One thousand, one hundred and six (1106) violations were treated in the divisions. Food Division treated one hundred and eighty-seven (187), Drug Division treated three hundred and eighty-eight (388), Chemical, Cosmetics and Medical Devices Division treated five hundred and eight (508), New technology and post port clearance treated twenty-three (23) cases, while Export Division did not record any violation.
- Chemical, cosmetics and medical devices division had the highest percentage of treated violations which amounted to forty-six percent (46%).
- Food division had seventeen (17%) percent of violations treated.
- Drug division had thirty-five percent (35%) and NT/PPC had just two (2) percent of violation treated as the least percentage among the divisions.

Table 9.7. Total Cases of Violation Treated by Divisions in PID Lagos

PID Office Locations	PID Lagos Divisional Offices				
	Food	**Drug**	**CCMD**	**Export**	**NT/PPC**
January	34	36	81	-	-
February	17	49	40	-	-
March	13	32	52	-	-
April	6	16	22	-	-
May	14	23	25	-	1

June	13	26	35	-	-
July	20	0	50	-	1
August	22	42	62	-	7
September	11	38	31	-	14
October	8	45	30	-	-
November	14	34	45	-	-
December	15	47	35	-	-
Totals	**187**	**388**	**508**	**0**	**23**

Figure 8.4: Percentage of Violations Treated by PID Lagos Divisional Offices in 2020



9.3.2 Types of Violation

- The most reported types of violations in the year under review were Labeling lapses (32%), No permit (21%), Non-Endorsement (9%), Change of source (2%) and others (5%).
- Table 10 below gives the statistics report of types of violations.

Table: 9.8. Cases of violation

Violation Types Reported	Total Cases
Change of Source	37
Concealment	49
Importation above Approved Quantity	70
No CRIA	227
Tampering with or removal of hold	1
Labelling Lapse	547
Expired Certificate	32
No Permit	347
Non-Endorsement	155
Others (Specify in Remark)	81
Unapproved Pictorials	83
Unregistered Pack Size	32
Unregistered Products (Excl. Medicines)	13
Unauthorized parallel importation	6
Mobile Authentication service	20
Total	**1,700**

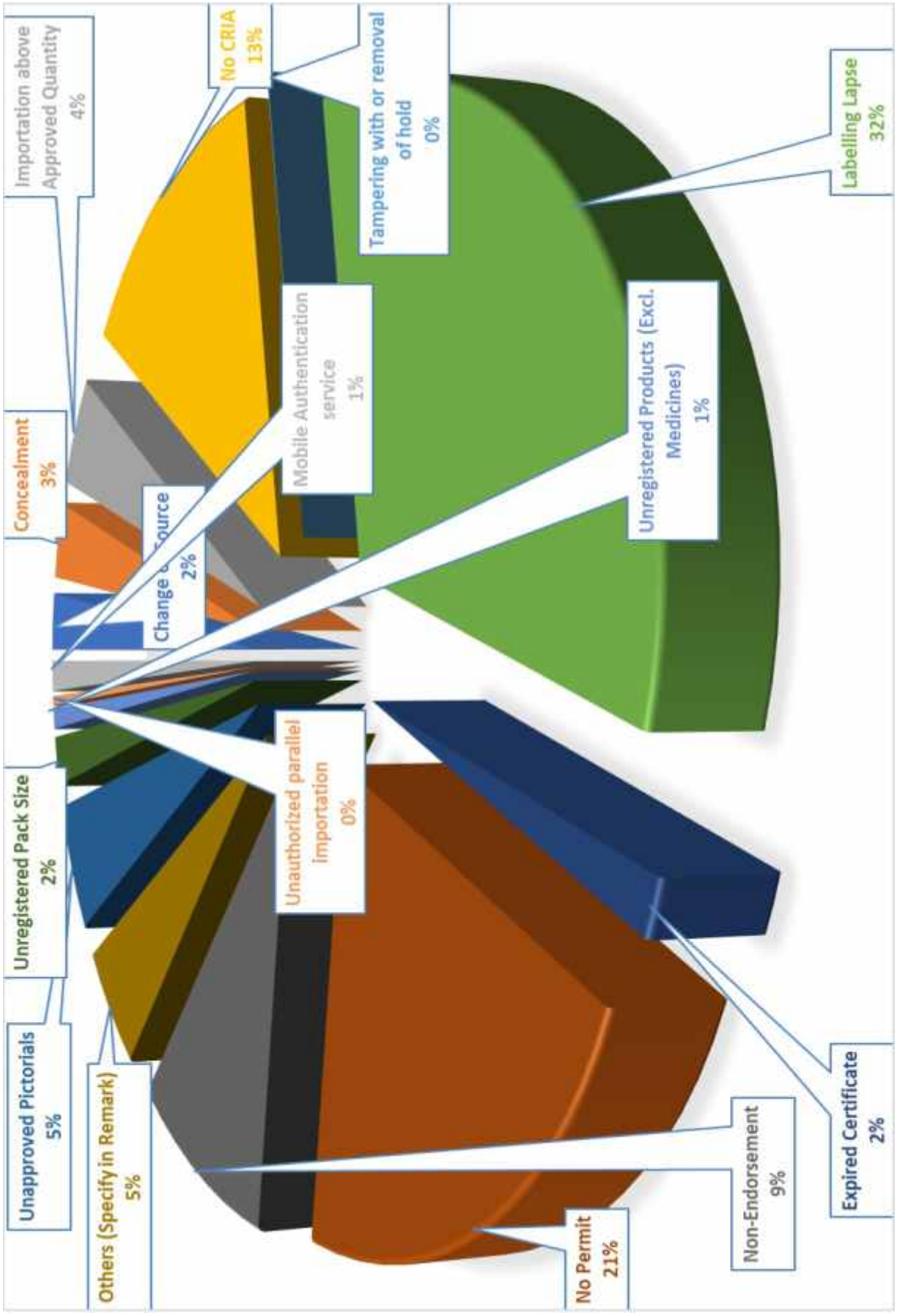


Figure 9.5: Types of Violation Reported in 2020

9.4 Outstation Activities Report

9.4.1

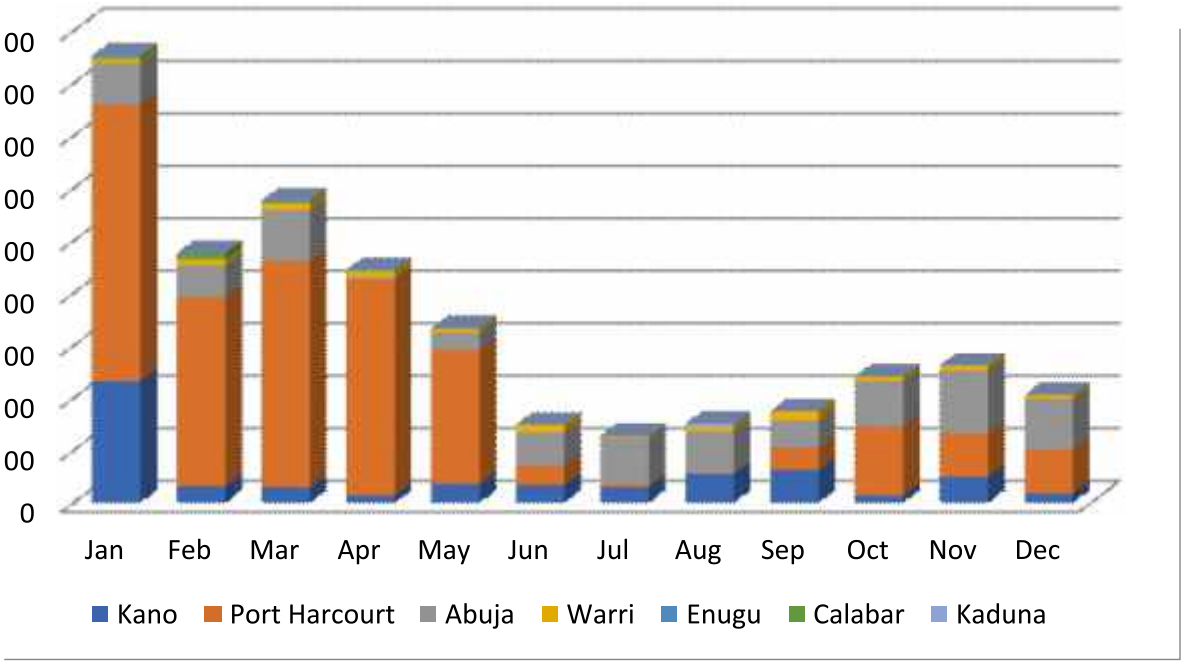
Outstation SGDs Treated

- Outstation offices accounted for a total of three thousand, nine hundred and Ninety-two (3992) SGDs with Port Harcourt accounting for the most treated SGDs and highest revenue generated.
- A total of two thousand, three hundred and sixty-seven (2367) SGDs were treated in Port Harcourt, while Enugu had the least number of SGDs accounting for zero SGDs.

Table 9.9: SGDs Treated in PID Outstations for the Year 2020

Month	Outstations							*Total SGDs*
	Kano	Port Harcourt	Abuja	Warri	Enugu	Calabar	Kaduna	
January	232	527	79	7	-	5	2	852
February	32	360	61	11	-	12	-	476
March	30	431	97	13	-	4	1	576
April	14	412	3	12	-	2	1	444
May	36	256	33	7	-	1	-	333
June	34	37	64	14	-	-	-	149
July	30	5	89	3	-	-	-	127
August	55	1	80	8	-	-	7	151
September	63	42	52	18	-	-	-	175
October	14	131	87	9	-	-	-	241
November	50	83	119	10	-	-	-	262
December	18	84	97	7	-	-	-	206
Sub-Total	**608**	**2369**	**861**	**119**	**0**	**24**	**11**	**3992**

Figure 9.6: SGDs Treated in PID outstations in 2020



9.5. Land Borders Activities Report

Due to border closure, land border activities were grounded, hence no return.

9.6 Report of Samples for Laboratory Analysis

- A total of seven thousand, nine hundred and one (7,901) samples were sent to the Laboratory for analysis while four thousand, six hundred and four (4,604) samples were received in the year under review.
- A total of four thousand, five hundred and ninety-nine (4,599) samples had satisfactory laboratory evaluation while five (5) were unsatisfactory.

Table 9.10: ***Samples sent for Laboratory Analysis in 2020***

Months	FOOD	DRUG	CCMD
January	336	321	68
February	335	351	39
March	340	528	11
April	-	-	15
May	170	130	-
June	175	460	45
July	306	0	29
August	396	766	52
September	292	414	142
October	393	350	49
November	303	328	48
December	496	156	57
Total Samples Sent	**3542**	**3804**	**555**

Figure 9.7: Samples sent for Laboratory Analysis in the year 2020

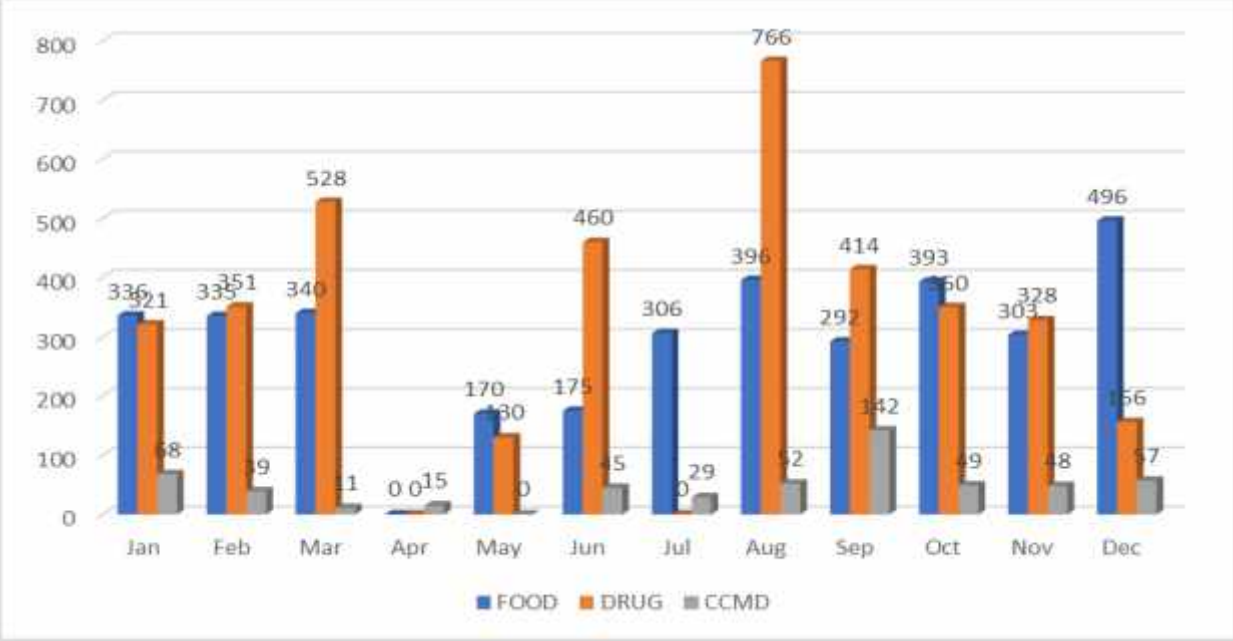


Table 9.11: Analysis report of samples received from the Laboratory in 2020

Month	FOOD		DRUG		CCMD	
	Passed	Failed	Passed	Failed	Passed	Failed
January	104	0	50	0	9	0
February	435	0	69	0	0	0
March	163	0	165	0	0	0
April	-	0	0	0	2	0
May	-	0	0	0	0	2
June	-	0	0	0	2	2
July	-	0	0	0	0	0
August	-	0	214	0	51	0
September	256	1	171	0	0	0
October	289	0	2	0	22	0
November	83	0	941	0	112	0
December	40	0	787	0	41	0
Total Samples	**1370**	**1**	**2990**	**0**	**239**	**4**

9.7 Product Details Statistics

In the year under review, the various divisional and port offices carried out-activities as follows:

- A total of 25,744 SGD forms, 21,999,644.22 weight in metric tonnes, and 2,107 violations were carried out at the ports

- Table 8.12 below shows a comprehensive detail of activities carried out.

Table 9.12: Breakdown of Activities and revenue generated by Month.

Month	Approval of letter of non-objection	Authorization to open form M	Materials for machine trials & Research purposes	Approval to import donated items by NGO'S	Approval to import pr oducts by Government agencies, multinational organizations, and international bodies
January	44	75	17	4	3
February	66	120	14	2	3
March	26	67	11	2	5
April	10	18	2	2	5
May	12	21	1	2	4
June	13	29	9	1	1
July	24	33	6	3	3
August	15	90	11	5	6

September	8	69	6	6	3
October	10	66	6	6	4
November	15	69	6	7	4
December	5	42	4	4	1
Total	**248**	**699**	**93**	**44**	**41**

TABLE 9.13: Import Statistics by Exporting Country in the Year 2020

ITEMS/COUNTRY OF ORIGIN	WEIGHT (MT) CIF VALUE	CHINA	INDIA	INDONESIA	MALAYSIA	SOUTH AFRICA	UNITED KINGDOM	UNITED STATES OF AMERICA	OTHERS
CHEMICALS	WEIGHT (MT)	158,823.77	102,877.14	4,104.61	2,593.81	60,854.58	63,539.94	32,946.38	869,591.36
	CIF VALUE	978,529,304,722,987.00	1,227,660,087,750,490.00	1,025,255,815.03	679,828,682.00	1,869,396,144.60	5,891,360,500.22	19,184,353,213.10	1,074,422,148,044,320.00
FOODS	WEIGHT (MT)	46,954.69	62,638.47	10,916.37	676.55	966,456.65	110,239.04	211,541.00	20,943,900.81
	CIF VALUE	32,872,780,986,796.90	33,450,576,278,722.30	2,541,381,124.43	300,507,276.00	650,787,982,471,211.00	4,757,013,047,471,900.00	468,186,339,876,027.00	2,001,554,887,447,970.00
DRUG	WEIGHT (MT)	22,103.80	2,047,856.80	121.19	19.95	813.96	926.22	270.04	6,227.18
	CIF VALUE	29,022,852,362,097.80	2,935,320,710,830,990.00	137,054,707.00	38,345,867.00	23,797,311,466.00	6,252,951,521,275.54	2,558,778,805.00	10,076,081,411,846.50
PHARM RAW MATERIAL	WEIGHT (MT)	2,665.46	38,567.39	24.53	-	1.00	3.89	-	2,218.94
	CIF VALUE	4,648,844,504.00	68,077,663,262,729.90	46,820,299.00	-	436,840.00	23,930,879.00	-	56,040,298,137,403.00
PACKAGING MATERIALS	WEIGHT (MT)	8,095.77	55,378.53	31.46	9.66	178.28	1,287.44	828.86	15,337.49
	CIF VALUE	3,115,738,218,275.00	346,109,135,157,755.00	8,158,623.00	10,086,010.00	234,233,599.00	70,690,318.00	291,142,262.49	21,634,561,485,549.80
MEDICAL DEVICES	WEIGHT (MT)	147,599,768.39	5,586.61	-	139.11	276.79	1.23	6,797.55	88,058.52
	CIF VALUE	79,087,996,732.93	899,675,410,674,485.00	-	117,456,700.90	333,441,908.00	28,471,658.00	5,678,582,451,462.00	1,342,950,540,945.57
COSMETICS/ HOUSE HOLD PROCT	WEIGHT (MT)	6,490.29	802.70	23.90	23.37	142.05	93.90	99.08	12,171.68
	CIF VALUE	569,118,043,153,747.00	223,438,602.00	8,613,621.00	18,952,472.00	101,815,986.00	114,128,783.00	58,441,054.00	13,045,462,888,726.90
AGROCHEMICAL	WEIGHT (MT)	354,112.11	60,563.79	215.45	-	16.84	-	107.10	9,538.16
	CIF VALUE	272,925,983,872,232.00	16,463,151,525,250.10	133,908,723.22	-	19,375,151.00	-	-	23,582,840,948,843.00
AUTOCARE PRODT	WEIGHT (MT)	24.49	194.94	-	-	-	42.23	215.35	1,435.28
	CIF VALUE	10,681,912.00	107,507,601.92	-	-	-	45,468,982.64	249,583,031.55	1,414,534,060.83
PACKAGING MATERIAL	WEIGHT (MT)	812.22	359.36	-	-	-	21.00	-	332.54
	CIF VALUE	211,108,817.00	115,165,053.00	-	-	-	-	-	264,993,265.00
INSECTICIDES	WEIGHT (MT)	772.90	227.00	-	-	-	42.49	-	272.51
	CIF VALUE	94,689,019.00	328,993,722.10	-	-	-	44,618,651.00	-	189,676,991.00

ANTISEPTICS	WEIGHT (MT)	-	-	-	-	43.36	-	-	135.14
	CIF VALUE	-	-	-	-	28,009,463.60	-	-	55,682,091.88
CONTROLLED CHEMICALS	WEIGHT (MT)	1,908.40	2,663.63	124.56	754.21	816.94	159.89	257.28	48,140.10
	CIF VALUE	502,439,218.00	848,391,124.68	29,499,414.00	33,744,912.00	256,935,934.00	196,105,106.01	223,471,785.30	5,075,844,715.54
	CIF VALUE	502,439,218.00	848,391,124.68	29,499,414.00	33,744,912.00	256,935,934.00	196,105,106.01	223,471,785.30	5,075,844,715.54
VETERINARY PRODUCTS	WEIGHT (MT)	1,217.67	177.79	3.45	-	16.18	17.36	-	1,722.61
	CIF VALUE	775,307,270.00	147,832,493.00	13,355,909.00	-	14,490,763.00	3,732,161.00	-	912,343,043.31
VACCINES/BIOLOGICALS	WEIGHT (MT)	3.03	49.91	-	-	-	0.08	4.06	64.67
	CIF VALUE	57,543,173.00	177,852,219.00	-	-	-	555,940.00	99,692,331.00	1,481,884,949.00
REAGENTS	WEIGHT (MT)	76.96	128.94	-	-	0.50	0.12	114.81	497.24
	CIF VALUE	97,652,447.00	316,058,089.53	-	-	14,744,335.00	1,978,656.00	22,610,360.00	737,723,895.10
TOTAL	WEIGHT (MT)	148,203,829.96	2,378,072.99	15,565.51	4,216.66	1,029,617.15	176,374.84	253,181.51	21,999,644.22
	CIF VALUE	1,885,670,189,579,230.00	5,526,759,000,719,320.00	3,944,048,235.68	1,198,921,919.90	650,814,652,662,801.00	4,763,272,420,034,810.00	473,887,610,400,331.00	3,201,709,363,588,620.00

9.8 Achievements

1. Deployment of the Ports Inspection Data Capture and Risk Management System (PIDCARMS) Online System as a web-based, online, fully automated business process application used across all PID formations Nationwide and enables importers conduct documentation and clearance processes from the comfort of the homes and officers, within and outside Nigeria.
2. Development, deployment, and implementation of electronic invoicing and receipting of all payments at the Ports Inspection Directorate.
3. Improved collaboration between NAFDAC and Nigeria Customs Service which has led to the joint seizure of over 200 containers of fake pharmaceuticals.
4. Expanded PID activities to various bonded terminals and land borders such that NAFDAC commenced operations in Kaduna and Onitsha.
5. Stakeholders and sectoral groups engagement that has led to improvement in compliance to NAFDAC regulatory requirements and processes.
6. Continuous In-House monthly lectures for all Regulatory and Non-Regulatory staff.
7. Strengthening of the Clean Report of Inspection and Analysis Scheme (CRIA) scheme and the unraveling of sharp practices by importers on imported products.
8. Continued increase in revenue for the Agency from year to year and overwhelming appreciation by stakeholders on the robust improvement of transparency and integrity in the business processes of the Directorate.

9.9 Challenges

- Shortage of computer systems for use by officers because of loss of computers from Lightening attack on NAFDAC equipment.
- Poor power supply at offices in PID offices outside Lagos which has become very glaring because of the automation of NAFDAC Ports Clearance processes.

- Poor internet connectivity at the locations outside PID, Yaba office which leads to increase in the turnaround time for clearance of NAFDAC regulated products due to poor processing speed of transactions.
- Poor rainstorm prevention at the PID Building which leads to the adverse effects of rainstorm and flooding of the PID corridors and premises although this is currently being handled.
- Shortage of staff has been an issue as some locations are not properly manned because of this.
- Shortage of serviceable operational vehicles for some of the PID locations. This has led to high cost of servicing the very old and disruptive vehicles being used and the use of personal vehicles for official assignments.

9.10 Way Forward

- Purchase and supply of laptops and computers for officers as some of them do not have personal computers and those who have are using them for official purposes.
- Provision of Power generators for locations that do not have good running ones so that there would be uninterrupted service provision to clients after the lockdown and Covid-19 pandemic.
- Provision of operational vehicles as replacement for unserviceable ones and for locations that do not have operational vehicles.
- Recruitment of personnel for effective coverage of port terminals that are currently not covered or under covered.

Chapter 10

NARCOTICS AND CONTROL SUBSTANCES (NCS) DIRECTORATE

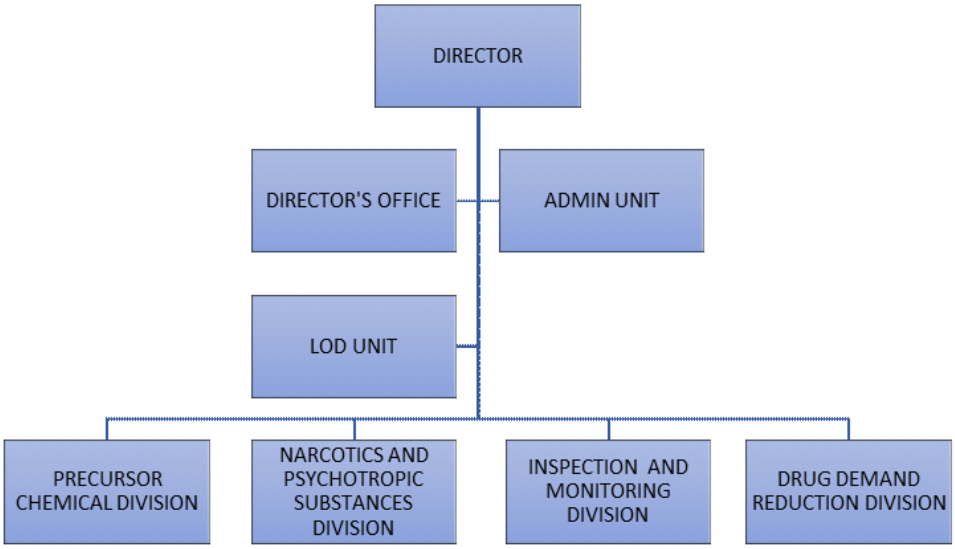
10.0. Introduction

The Directorate is empowered by the NAFDAC Act 2004 to ensure availability of narcotics and other controlled substances for medical and scientific purposes while minimizing the diversion to illicit channels and abuse.

The Directorate has the following core 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 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.
- Coordinate Drug Demand Reduction Activities.
- Grants authorization to health facilities to purchase finished narcotics from central and zonal narcotics stores.
- Audits Warehouses to ensure proper storage, handling and distribution practices.
- Submission of statutory information to the International Narcotics Control Board and ensures Nigeria fulfils 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)

Figure 10.1 Structure of the Directorate



10.2 Programs, Projects and Initiatives

10.3.1. Launch of INCB report

The Agency hosted the annual launch of INCB world report 2019 on the 27th February 2020. In the Report, the International Narcotics Control Board (INCB) highlighted the following:

- Connection between the use of alcohol and tobacco and the use of psychoactive substances like cannabis, opiates and cocaine by children and adolescents.
- Focus on the physical, emotional and social impact that psychoactive drugs have on young people between the ages of 15-24;
- Urges governments to improve services using evidence-based prevention and treatment interventions for young people.
- Expresses concern about the fast-changing global landscape of illegally manufactured designer-precursors tailored to a diverse and online market;
- Addresses injustices related to the availability of controlled medicines from over-prescription in some countries to limited access in other countries;
- Reminds governments to respect human rights in the implementation of drug policies and in compliance with the three international drug control conventions.

10.3.2 Development of National Drug Control Master Plan (NDCMP)

The Directorate in collaboration with other relevant stakeholders continued to promote the development and implementation of strategic instruments to respond to the evolving drug situation. The first National Drug Control Master Plan (NDCMP) was developed in 1999; the second one covered the period 2008 – 2011 (extended to 2013) and the third five-year NDCMP was from 2015-2019. The NDCMP 2015-2019 provided the critically needed focus to drug control activities in Nigeria by setting out measurable targets for the various agencies of the government involved in drug control.

The current NDCMP 2021-25 followed the same framework, while its development was similarly supported by the European Union funded UNODC project **"Response to drugs and related organized crime in Nigeria"**. The NDCMP 2021-25 aims to contribute to the enhanced health and security of all Nigerians and it contains four thematic pillars:

- Supply reduction
- Drug demand reduction
- Access to drugs for medical purposes
- The governance and coordination pillar.

The Masterplan will support the achievement of Sustainable Development Goal 3 to "ensure healthy lives and promote well-being for all ages" and target 3.5 "to strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol".

The directorate participated at two (2) levels – the core writing team that developed the plan, as well as the high-level participation for finalization of the plan. The National Drug Control Master Plan (NDCMP 2021-2025) is ready for endorsement.

10.3.3 Commission on Narcotic Drugs

The Directorate participated in the 63rd Session of the United Nations Commission on Narcotic Drugs which took place in Vienna from 2nd to 6th March, 2020. Mrs. Asomugha A. Unoma (DD) made presentation on "**STRENGTHENING THE EVIDENCE BASE ON QUANTIFICATION OF CONTROLLED MEDICINES AND ESTIMATION OF PSYCHOTROPIC SUBSTANCES AND PRECURSORS FOR MEDICAL AND SCIENTIFIC PURPOSES IN NIGERIA"** at a side event during the meeting. The paper which was co-presented with the desk officer, Narcotics programme of the Federal Ministry of Health, x-rayed

the 2019 National Quantification/Estimation exercise; an evidence-based determination of the country's need for controlled medicines (Picture 1)

The Directorate also participated in the CND Follow-up Thematic Sessions on the Implementation of All International Drugs Policies Commitment, which held from 19th - 21stNovember, 2020. The Director was one of the expert panelists at the session and spoke on "**Availability of Internationally Controlled Substances for Medical and Scientific Purposes, Including for The Relief of Pain and Palliative Care**". The presentation provided insight on the challenges of regulating controlled medicines and substances and the measures put in place to ensure balance between access and control.

10.3. Internal Capacity Building

In order to strengthen regulatory activities, knowledge acquired from workshops and other training activities were cascaded down to other staff. Current regulatory issues and new processes were the regular topics for the capacity building exercises. A total of ten (10) internal capacity building were carried out in 2020.

10.4. Drug Demand Reduction

10.4.1. The Directorate's drug demand reduction activities focused on preventing initial drug use by carrying out education and awareness campaigns in relevant settings such as the family, the community and the work places. The Directorate conducted seventeen (17) campaigns with full compliance to Covid-19 safety protocols (Picture 2).

Figure 10.2 Summary of the Activities of NCS Directorate in 2020

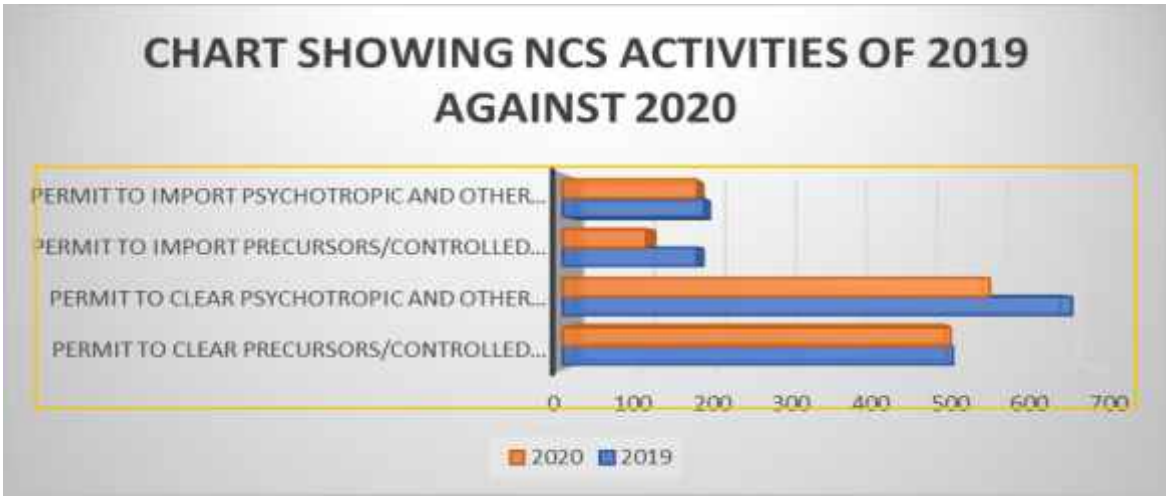


Figure 10.3 Chart Showing NCS Activities of 2019 against 2020

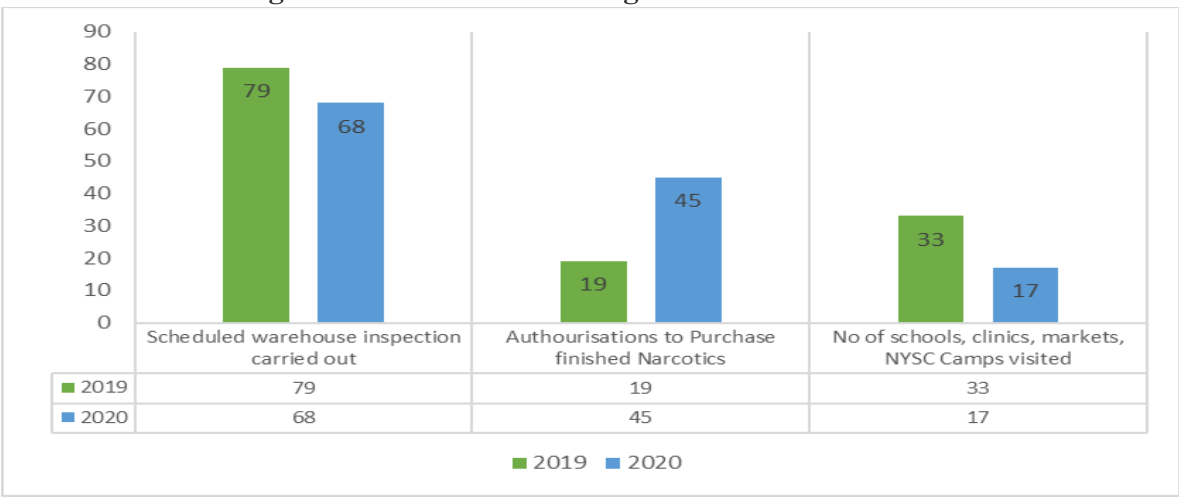


Table 10.1 Summary of Activities for the Year 2020

S/N	Activities	Inspection and Monitoring	Narcotics and Psychotropic Substances	Precursor Chemical
	No. of Applications Received	193	194	94
1	Permit to import Controlled/Precursor Chemical	-	-	75
2	Permit to clear Controlled/Precursor Chemical	-	-	506
3	Permits to Import Psychotropic/other controlled drugs	-	175	-
4	Permits to Clear Psychotropic/ other controlled drugs	-	557	-
5	Authorisations to Import Narcotics (Bulk and Finished Schedule 1 Narcotics)	-	-	-
6	Authorisations to Clear Narcotics (Bulk and Finished Schedule 1 Narcotics)	-	-	-
7	Authorisations to Purchase finished Narcotics	-	44	-
	No. of Inspections	-	-	-
8	Schedule Warehouse Inspections	68	-	-
	I. Satisfactory	65	-	-
	II. Unsatisfactory	2	-	-
	II. Inspection not held	1	-	-
9	Routine Warehouse Inspections	33	-	-
	I. Satisfactory	30	-	-
	II. Unsatisfactory	-	-	-
	II. Inspection not held	3	-	-
10	No of outstation inspection Reports Received	24	-	-
	I. Satisfactory	24	-	-
	II. Unsatisfactory	-	-	-
11	Sales Verification	36	-	-
	I. Satisfactory	10	-	-
	II. Unsatisfactory	11	-	-
	II. Verification not held	15	-	-
12	LPO Verification	-	-	-
	I. Satisfactory	-	-	-
	II. Unsatisfactory	-	-	-
13	Hospital Inspections	2	-	-

	I. Satisfactory	1	-	-
	II. Unsatisfactory	-	-	-
	II. Inspection not held	1	-	-
14	Surveillance	-	-	-
15	No of investigations conducted	-	-	-
16	No of inves tigations conducted (Outstation)	-	-	-
17	Outstation verification report received	-	-	-
18	Total Permits/Author isations Issued	-	-	-
19	Permit to Import Controlled/Precursor Chemical	-	-	109
20	Permit to Clear Controlled/Precursor Chemical	-	-	506
21	Permit to Import Psy chotropic/ other controlled drugs	-	175	-
22	Permit to Clear Psychotropic/ other controlled drugs	-	557	-
23	Authorizations to Import Narcotics (Bulk and Finished Schedule I Narcotics)	-	-	-
24	Authorizations to Clear Narcotics (Bulk and Finished Schedule I Narcotics)	-	-	-
25	Authorizations to Purchase finished Narcotics	-	45	-
26	Pre-export Notification	-	77	32

CONCLUSION

The year 2020 was challenging due to the Covid-19 pandemic. Nonetheless, to minimize the impact of the Covid-19 pandemic, process such as issuance of permit to clear were modified and carried out electronically. This ensures the availability of controlled substances for medical, scientific and industrial purposes all through the year.

Legend: Pharm. Clara Anyanwu , Head Drug Demand Reduction Division at a sensitization campaign

Legend: Nigeria being represented at the 63rd CND by Pharm. Unoma Asomugha

Chapter 11

INVESTIGATION AND ENFORCEMENT DIRECTORATE.

11.0. Introduction

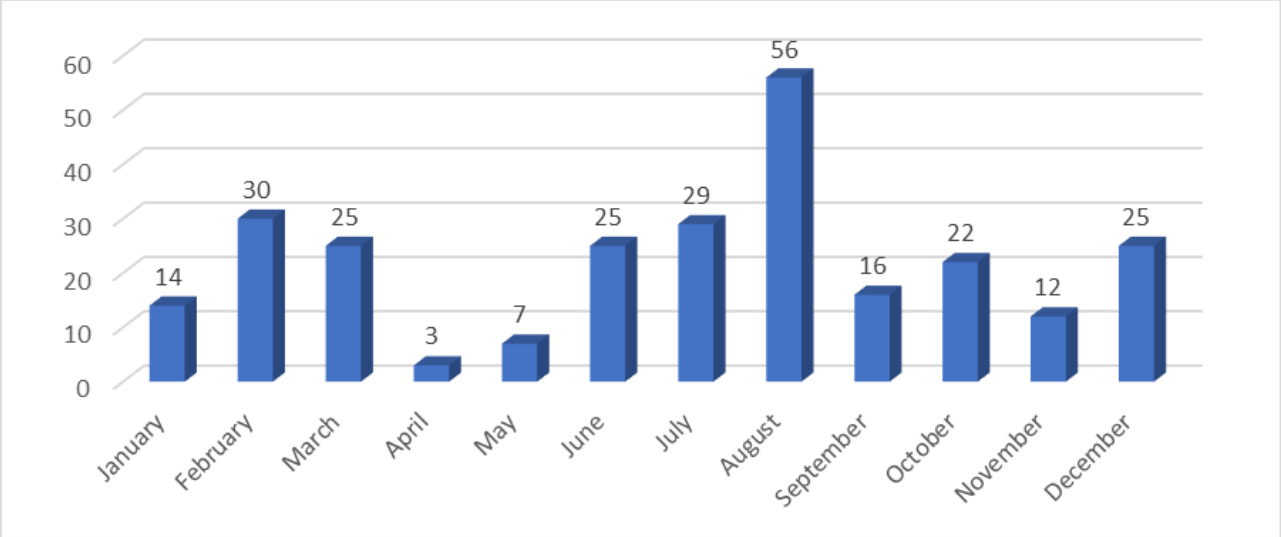
The Investigation & Enforcement Directorate is the arm of NAFDAC, principally responsible for ensuring compliance with the Agency's mandate on regulatory activities related to Food, Drugs, Cosmetic, and Medical Device etc. It coordinates the enforcement activities of all the other Directorates, zonal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

In 2020, the Directorate continued its enforcement activities with more vigor despite a number of challenges, principally the Covid-19 Pandemic and End SARS National Protest. The activities are summarized under the following headings:

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

11.1. Surveillance The Directorate carries out surveillance in order to recognize or monitor threats and prevent/investigate criminal activities. A total of 264 surveillance activities were carried out in 2020, details of which are as follows:

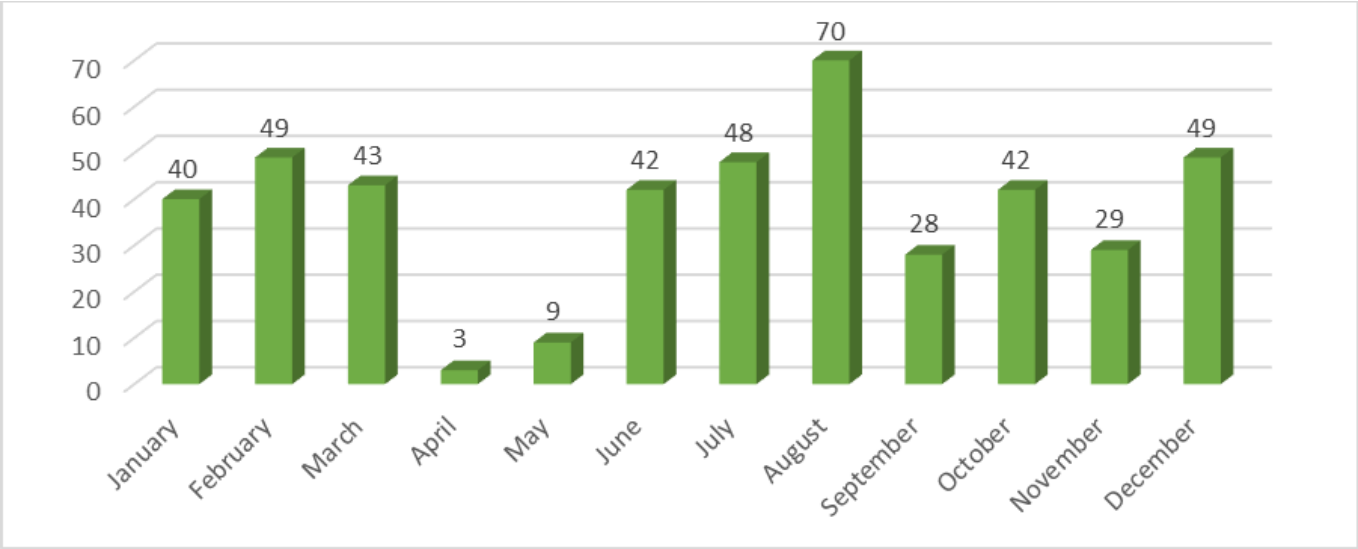
Figure 10.1: No of Surveillance Carried Out



11.2. Investigations

To ascertain the veracity of Cases under investigation, the Directorate examines all materials and available facts before reaching a conclusion; a total of 452 investigations were carried out, details of which are as follows:

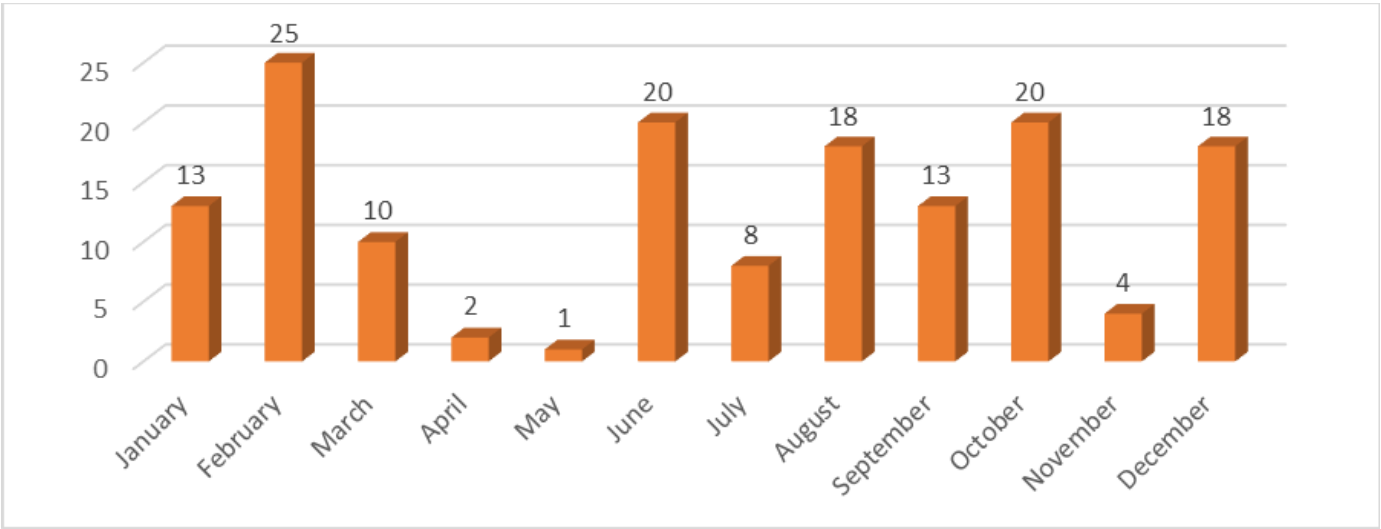
Figure 11.2: No of Investigations Carried Out



11.3. Interrogations

The Directorate interrogated suspects interviewed victims and witnesses of crimes related to NAFDAC Enactments. 152 Interrogations and interviews were conducted, the breakdown is as follows:

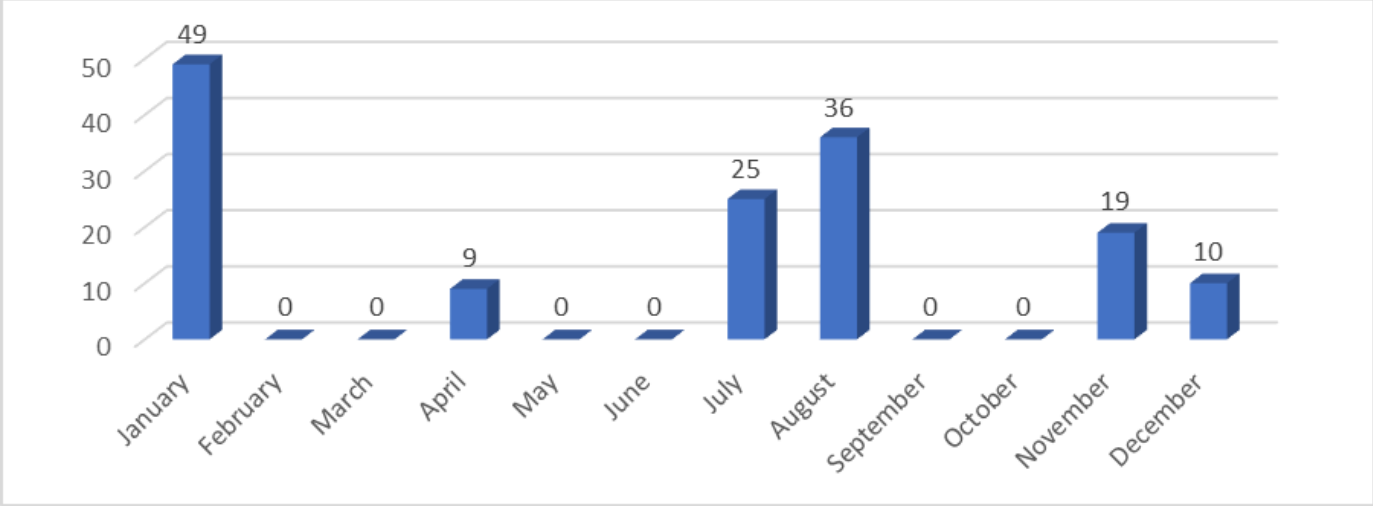
Figure 11.3: No of Interrogations Carried Out



11.4. Sampling

During the process of investigation, all violative NAFDAC Regulated Products were sampled and forwarded to the laboratory for appropriate analysis and pronouncement. A total of 148 investigative samples were forwarded, with the breakdown as follows:

Figure 11.4: No of Samples Sent to the Laboratory



11.5. Raid on Hawkers of Pharmaceutical Products

Raids are routinely carried out on hawkers of drugs in markets, streets and moving vehicles. The Directorate carried out a total of 11 raids and arrested 1 hawker in the year under review.

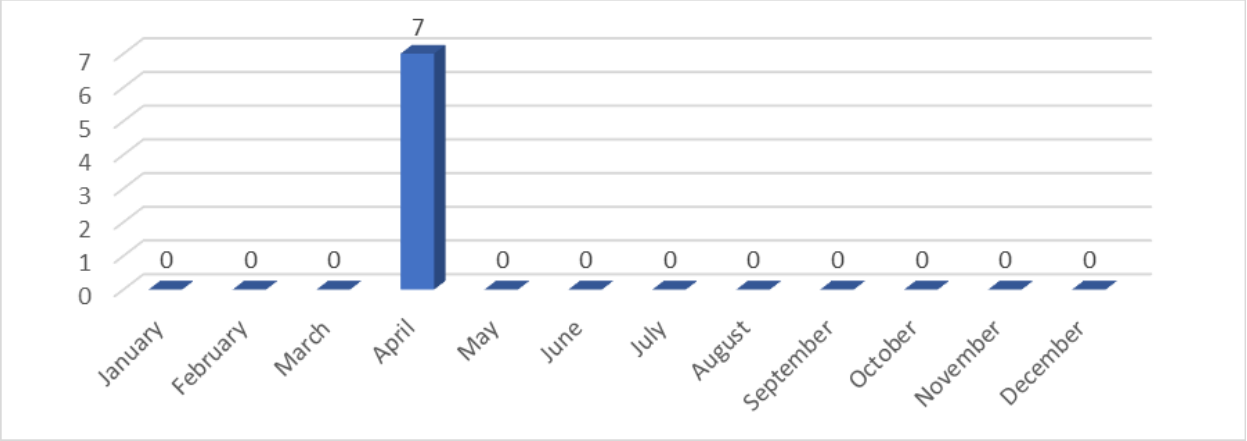
Table 11.1: No of Hawkers Arrested

Month	Raid	Hawkers Arrested	No of Wares Seized
January	7	1	0
February	1	0	0
March	3	0	0
April	0	0	0
May	0	0	0
June	0	0	0
July	0	0	0
August	0	0	0
September	0	0	0
October	0	0	0
November	0	0	0
December	0	0	0
Total	**11**	**1**	**0**

11.6. Compilation of Case Files

The Directorate compiled and forwarded 7 Cases to the Legal Unit of the Directorate and the Legal Services Directorate for advice. The breakdown is as follows:

Figure 11.5: No of Cases Sent to Legal Unit



11.7. Other Activities

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

Table 11.2: Summary of Enforcement Activities 2017 - 2020

Month	Raid	Hawkers Arrested	No of Wares Seized
January	7	1	0
February	1	0	0
March	3	0	0
April	0	0	0
May	0	0	0
June	0	0	0
July	0	0	0
August	0	0	0
September	0	0	0
October	0	0	0
November	0	0	0
December	0	0	0
Total	**11**	**1**	**0**

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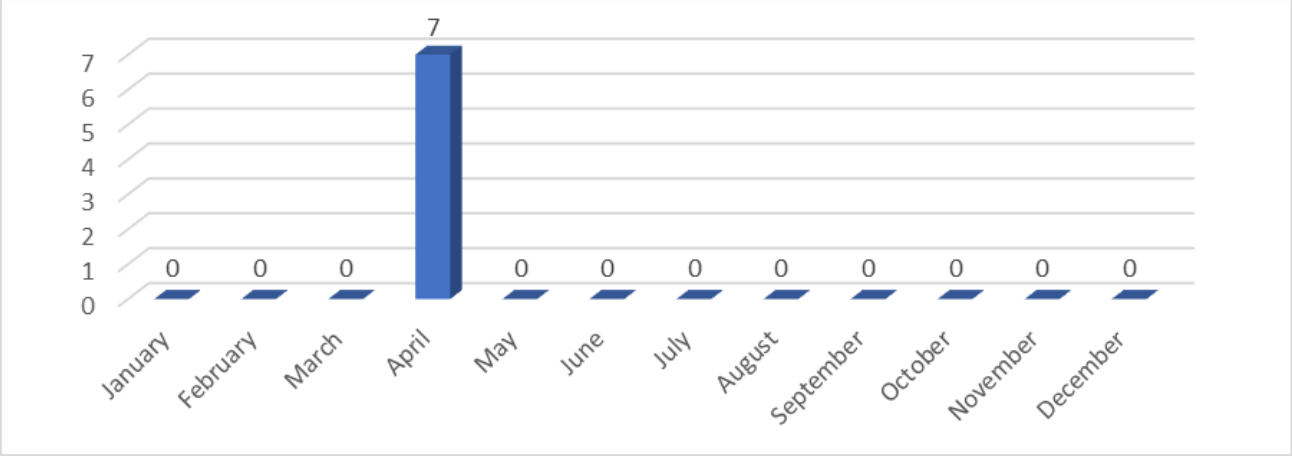

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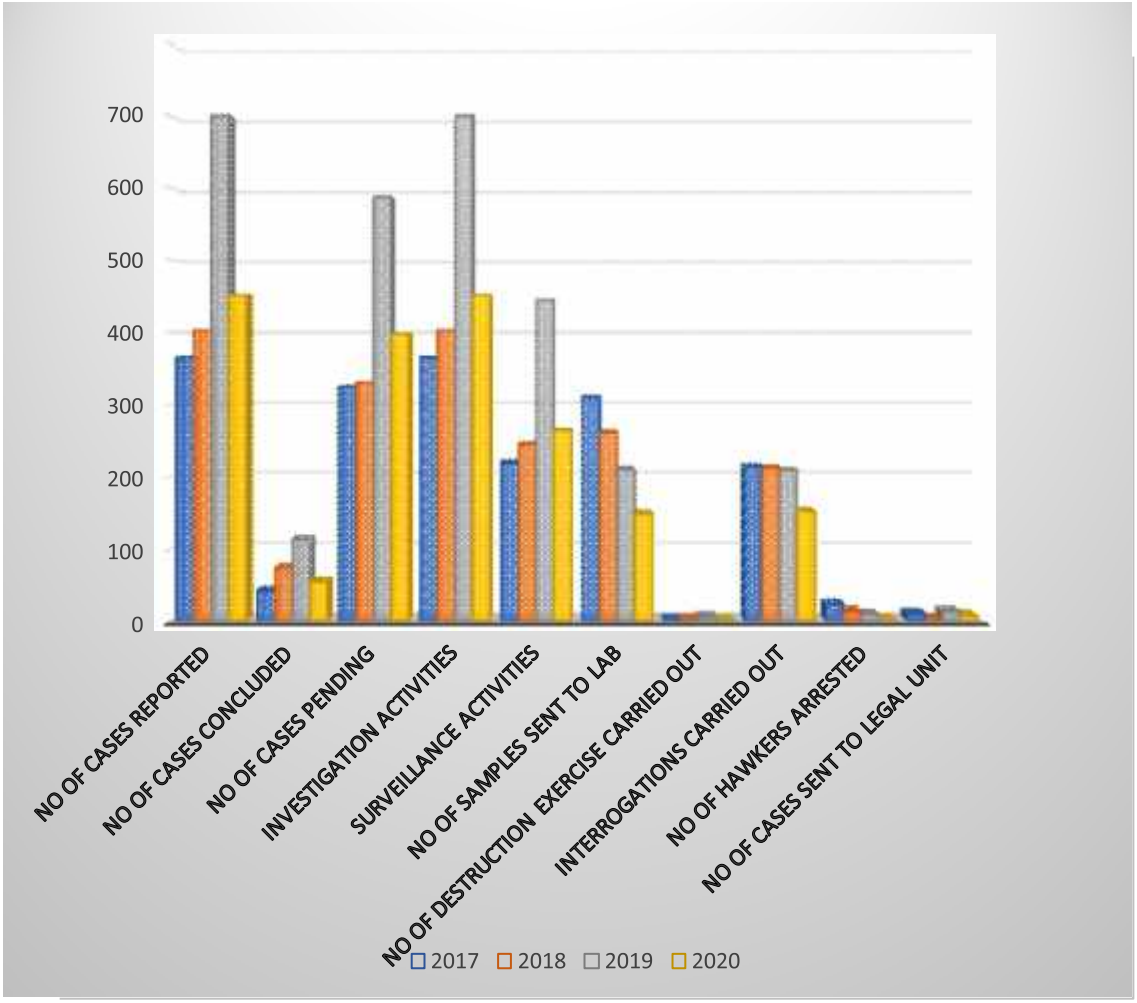
There was appreciable improvement in compliance by stakeholders with relevant Laws and Regulations particularly in registration, due to enforcement activities.

Table 11.2: Summary of Enforcement Activities 2017 - 2020

	2017	2018	2019	2020
No of Cases Reported	365	403	701	452
No of cases Concluded	41	73	113	54
No of Cases Pending	324	330	588	398
Investigation Activities	365	403	701	452
Surveillance Activities	219	245	445	264
No of Samples Sent to Lab	310	261	210	148
No of Destruction Exercise Carried out	1	1	5	0
Interrogations Carried out	214	212	209	152
No of Hawkers Arrested	23	13	9	1
No of cases sent to legal unit	10	2	13	7
Total	**1,843**	**1,852**	**1,951**	**1,928**

Figure 11.6: Chart Showing Major Enforcement Activities for Year 2017, 2018, 2019 and 2020



Chapter 12

CHEMICAL EVALUATION AND RESEARCH DIRECTORATE (CER)

12.0. Introduction

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

12.1. Structure of CER

The Directorate is structured into 4 Divisions. These are:

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

12.2. 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 of 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

12.3. Summary of Activities

In 2020, a total of **Thirteen Thousand, Four Hundred and Fifty (13,450)** regulatory activities were carried out by CER directorate nationwide. **Ten Thousand, Seven Hundred and Seventy-Nine (10,779)** of these regulatory activities were carried out in Lagos state while **Two Thousand, Six Hundred and Seventy-One (2,671)** CER regulatory activities were recorded in NAFDAC offices in the other states.
A total of **Six Thousand, Five Hundred and Ninety (6,590)** applications were received for issuance of permits to import general and restricted chemicals, permits to clear, Listing Certificate and Warehouse inspection.
Two Thousand, Seven Hundred and Twenty-five (2,725) permits to import were approved for both general and restricted Chemicals while **Seven Hundred and Ninety-One (791)** permits to clear were issued for restricted chemicals. **Seven Hundred and Thirty-Six (736)** companies were approved as chemical marketers and issued Listing Notifications. A total of **One Thousand, Five Hundred and Seventy-One** inspection activities were carried out of which **One Thousand, One Hundred and Seventy-Two (1,172)** were satisfactory.
Two Hundred and Six (206) routine monitoring inspections were carried out in Lagos. **Seven Hundred and Eighty-eight (788)** Compliance Directives were issued for various inadequacies and incomplete documentations.

S/N	TYPE OF ACTIVITIES	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
1	No of applications received for Permit to Import	273	284	344	74	163	160	227	233	212	348	373	320	**3011**
2	No of applications received for Permit to Clear	64	75	50	35	58	69	88	93	78	43	74	78	**805**
3	No of applications received for Warehouse inspection	252	173	63	0	23	39	73	74	74	61	148	176	**1156**
4	No of applications received for Listing Certificate	94	44	46	0	25	32	63	74	74	56	89	89	**686**
5	No of applications received for LPO verification	49	40	47	3	21	22	26	34	19	20	9	26	**316**
6	No of applications received from outstation for permits to import/clear, warehouse inspection, LPO verification and Listing certificates	123	12	85	11	20	27	30	39	50	42	65	112	**616**
7	No of E-permits to Import issued (General Chemicals)	493	289	247	43	119	91	164	154	129	137	188	398	**2452**
8	No of E-permits to Import issued (Restricted Chemicals)	63	53	49	20	15	15	15	21	14	2	3	3	**273**
9	No of approved permits to Clear	76	68	53	37	61	50	86	95	80	43	72	70	**791**
10	No. of Listing Notifications issued to Chemical Marketers	80	92	51	0	15	58	63	78	73	55	100	71	**736**
11	No of Listing Notifications issued to Chemical Manufacturers	0	0	1	0	0	0	0	0	0	0	0	0	**1**
12	No of inspections conducted (Satisfactory reports)	165	163	141	2	0	0	55	84	73	75	150	264	**1172**
13	No. of follow- up inspections	1	14	3	0	0	0	0	0	5	4	4	4	**35**
14	No. of routine monitoring inspections	30	54	80	4	1	0	1	0	1	0	11	24	**206**
15	No of surveillance inspections	38	44	19	3	1	2	0	4	9	9	13	16	**158**
16	No. of LPO verification treated	26	34	28	2	0	4	0	31	14	18	6	12	**175**
17	No. of Queries/CDs issued	94	114	65	9	48	27	39	39	68	65	110	110	**788**
18	No. of consultative meetings/seminar and workshop held	2	5	1	0	0	2	0	0	13	5	6	0	**34**
19	No. of Violations	1	3	0	0	3	8	0	0	2	1	3	0	**21**
20	No. of Warehouses/Products/Consignments put on Hold	0	0	0	0	0	0	0	0	0	0	0	18	**18**
21	TOTAL	**1924**	**1561**	**1373**	**243**	**573**	**606**	**930**	**1053**	**988**	**984**	**1424**	**1791**	**13450**

Comparative Analysis of Key CER Regulatory Activities 2019-2020

S/N	ACTIVITIES	2019	2020
1	Number of Regulatory activities recorded	13,309	13,450
2	Number of Applications received	5,198	6,590
3	Number of Permits to Import issued for General and Restricted Chemicals	2,476	2,725
4	Number of Permits to Clear issued for Restricted chemicals	701	791
5	Number of Inspections Conducted	1,368	1,571
6	Number of Listing notifications issued to Chemical Marketers	642	736
7	Number of Queries/CDs issued	906	788

The Chemical Evaluation and Research Directorate recorded considerable level of success in 2020 despite the SARS-CoV-2 (COVID 19) pandemic and lockdown that hampered activities across the world.
A significant higher number of applications for import permits and warehouse inspections were received in 2020 as compared to 2019. The number of Permits to Import issued were also higher whilst also recording a significant low number of queries and compliance directives. This may be attributed to the full transition and adoption of the e-permit system by applicants and various sensitization programs the Directorate organized to guide applicants on the proper use of the e-permit system.
The directorate also ensured that timelines for all its processes were adhered to while also making the processes easy and seamless for the clientele.
The number of inspections conducted in 2020 increased significantly, as the directorate adopted a virtual mode of inspection in compliance to COVID 19 protocols.

12.4.CER Outstation Activities 2020

S/N	Outstation	Number Of Activities
1	South West	358
2	South East	556
3	South South	656
4	North West	444
5	North East	47
6	North Central	182
7	FCT Abuja	428
	Total	**2,671**

12.5.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.

12.1. Collaborations

The Directorate participated in various inter-ministerial meetings and committees:

- The Inter-Ministerial Committee (IMC) meeting on Chemical and Biological Weapon Conventions hosted by the Office of the Secretary to Government of the Federation on the 26th-27th February, 2020
- The inauguration of the Project Committee on the study of available sustainable alternative materials to plastics, and innovative packaging and recycling technologies coordinated by the Federal Ministry of Environment and membership of the National Project Committee on the start of the plastics assessment (24-25th February, 2020)
- The first Coordination Meeting of the Project Steering Committee on strengthening of the Legal and institutional infrastructures for sound management of Chemicals in Nigeria at the Federal Ministry of Environment, Abuja
- The deliberation of Draft Standard for anatomical models for educational purposes and agenda of the virtual working group with SON on the 10th November, 2020.
- The stakeholders' inception workshop on improving energy efficiency in the refrigeration and air conditioning cooling sector and commitment to address illegal/unwanted trade in Ozone Depleting and fluorinated global warming substances controlled under the Montreal Protocol and its Kigali Amendment organized by the Federal Ministry of Environment on the 27th February 2020.
- At the event NAFDAC was given the Global Montreal Protocol Award for Customs and Enforcement Officers in recognition of the strong commitment to address illegal/unwanted trade in Ozone-Depleting and Fluorinated Global Warming Substances controlled under the Montreal Protocol and its Kigali Amendment.

12.2. Major Activities of CER in 2020

1. The draft regulations on chemical were finalized and forwarded to Regulatory Affairs for their further action.
2. Chemicals of security concern such as Hexamine, Nitric acid, Hydrogen peroxide, Nitrocellulose and Caustic Soda were re-classified as severely restricted chemicals to enhance their regulatory oversight.
3. An online sensitization workshop was held for all stakeholders on the re-classified chemicals.
4. An in-house Human Capacity Building Program on key components of Chemical Monitoring was organized for CER Regulatory Officers.
5. Chemical Manufacturing sites and plants in Lagos and outstation offices were visited and inspected for compliance in activities.

12.3. Surveillance

Three Hundred and Sixty-Four (364) surveillance inspection activities were carried out in the year under review by outstation.

Local Purchase Order Verifications

One Hundred and Seventy-five (175) Local Purchase Orders were verified for chemicals of safety and security concerns.

12.4. Challenges

1. Operational Vehicles
2. Robust Internet Facility
3. Computer Systems
4. Human Capital and Man-power development

12.5. Way Forward

1. Deployment of the electronic processing for Listing Notification for Chemical Marketers.
2. Initiation of the electronic processing of Permits to clear for restricted Chemicals and Listing Certificates to manufacturers.
3. Enhanced collaboration with International Chemical Control Organizations such as Organization for the Prohibition of Chemical Weapon, Montreal Protocol, Stockholm Convention etc.
4. Strengthening the regulatory control of chemicals through development, review and harmonization of regulations, guidelines, checklists and Standard Operating Procedures (SOPs).
5. Regular compilation of standard specifications and guidelines for the production, importation, exportation, sale and distribution of chemicals.
6. Continuous sustenance of Quality Management System achievements through Monitoring and Evaluation to ensure continuous improvements.
7. 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.
8. Establishment of a Laboratory in collaboration with the Laboratory Services Directorate for Chemicals.
9. Regular engagement with industries and other relevant stakeholders to ensure sound management of chemicals in Nigeria.
10. 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.
11. Continuous monitoring (through enhanced routine inspections) of chemicals in Industries to check utilization and stock levels and possible diversion for unauthorized purpose; and monitor disposal practices.

Chapter 13

LABORATORY SERVICES DIRECTORATE (FOOD)

13.0. Introduction

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

- Central Laboratory, Oshodi, Lagos State
- Area Laboratory, Port Harcourt, Rivers State

13.1. Goals

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

- To generate quality and timely test results that meet international standards
- To provide excellent customer service
- To be the best reference laboratory in the West African sub region

13.2 Analytical Performance

The Laboratory Services Directorate (Food) received fifteen thousand two hundred and seventy (**15,270**) samples in 2020. One thousand one hundred and fifty (**1,150**) samples were carried over from 2020 bringing it to a total of sixteen thousand four hundred and twenty samples (**16,420**) handles in 2020. Out of these, fourteen thousand three hundred and thirteen (**14,313**) samples were analysed which represents **87.2%** output in 2020.

Table 13.1 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 13.1: Summary of Analytical Performance in the Year 2020

	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	1108	13288	14396	12469	12152	317	1927	86.6%
P/Harcourt	42	1982	2024	1844	1724	120	180	91.1%
Total	**1150**	**15270**	**16420**	**14313**	**13876**	**437**	**2107**	87.2%

Overall Performance = 87.2%

Figure 13.1: Profile of Samples Handled in the Year 2020

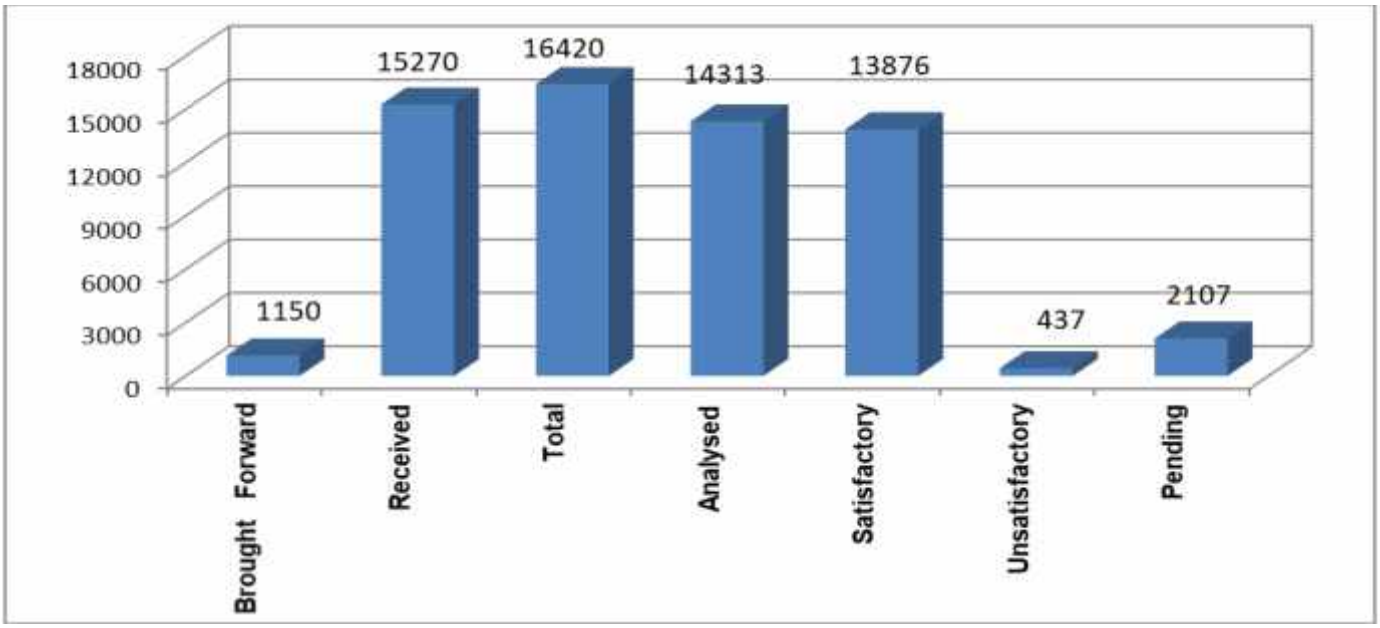


Figure 13.2: Percentage of Samples Analyzed in 2020

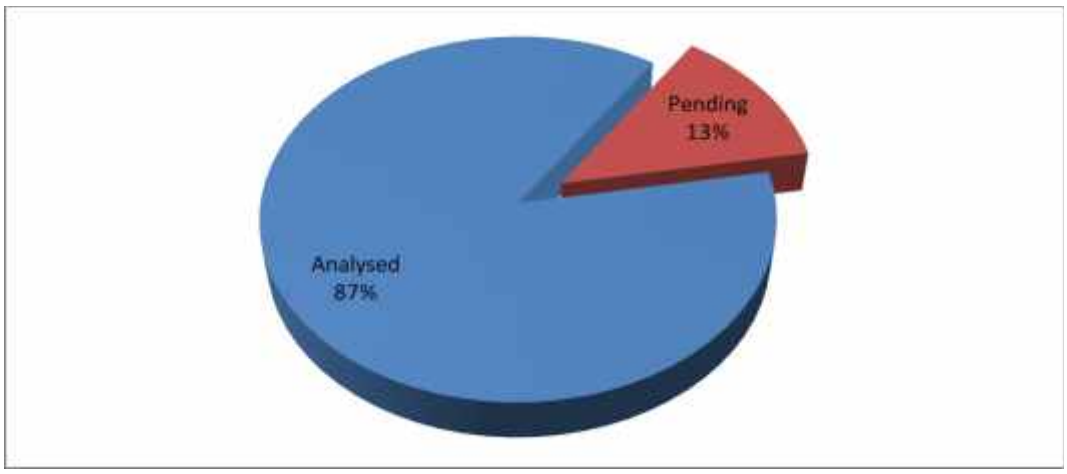


Figure 13.3: Percentage of Satisfactory/Unsatisfactory Samples

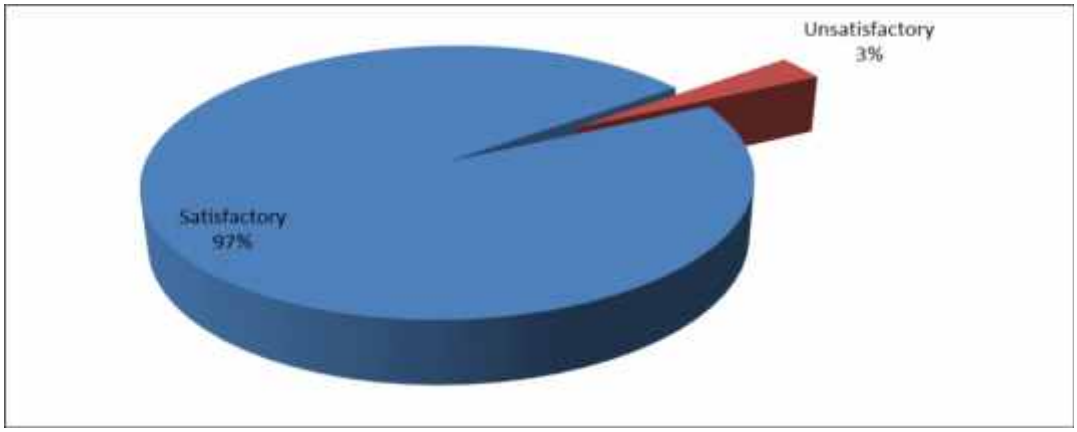


Figure 13.4: Individual Laboratory Performance

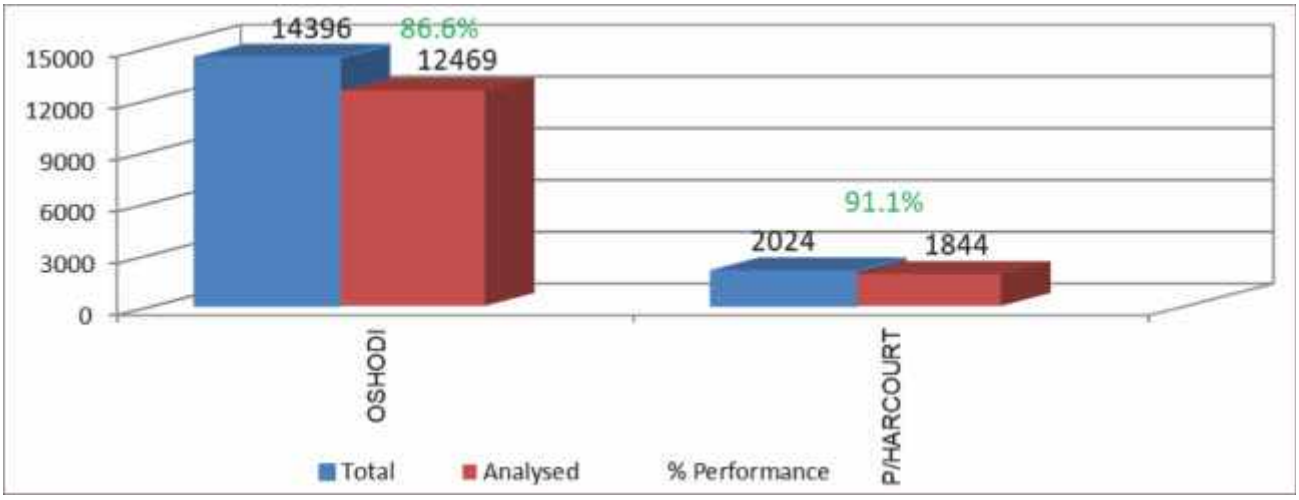


Table 13.2: Sample Received According to Categories in (2020) Figure 5:

	January- December					
	Registration	Compliance	Investigation	Enforcement	Others	
Food	8,144	4,097	361	18	1	
Dairy and Milk Product	414	373	11	-	-	
Baby and Infants Foods	102	120	32	-	-	
Fat and Oils	219	205	39	4	-	
Cereal and Cereals Product	457	272	111	-	-	
Bread	1,445	33	7	-	-	
Tea, Coffee and Cocoa Product	141	166	11	1	-	
Fruits and Fruits Products	143	28	19	-	-	
Carbonated Drinks	200	138	14	-	-	
Meat and Meat Products	95	16	1	-	-	
Fish and Fish Products	195	390	1	-	-	
Salt	13	37	-	-	-	
Seasoning and Flavouring Products	386	216	11	1	-	
Sugar and Sugar Products	202	139	6	5	-	
Nut and nut products	155	23	2	-	1	
Legume and legume products	123	14	-	-	-	
Egg and egg products	14	2	-	-	-	
vegetable and vegetable products	6	9	-	-	-	
root and tuber products	301	17	2	-	-	
Alcoholic Beverages	773	219	74	7	-	
Flavoured Drinks	186	16	-	-	-	
Food Additives	20	181	5	-	-	

Food Supplements	26	20	-	-	-
Ready to Eat	85	35	13	-	-
Miscellaneous (Food Samples)	2,443	1,428	2	-	-
Water	1,815	26	18	4	-
Pesticides F.	338	341	10	-	-
Animal feeds	61	35	1	-	-
Fertilizer	-	-	-	-	-
Chemicals	-	-	-	-	-
TOTAL	10,358	4,499	390	22	1

Figure 13.5: Categories of Samples Received In 2020

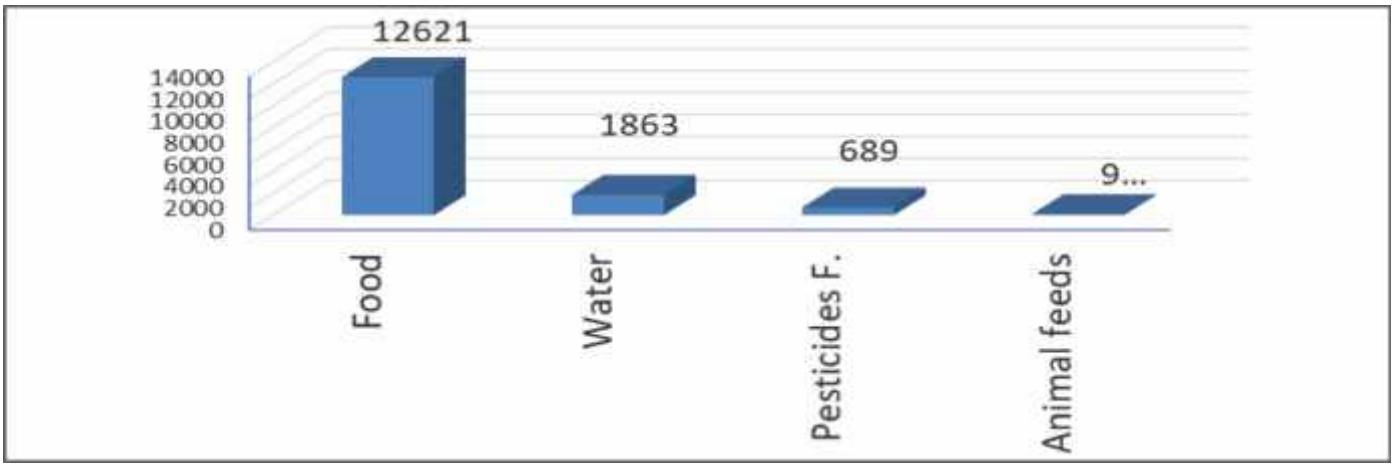
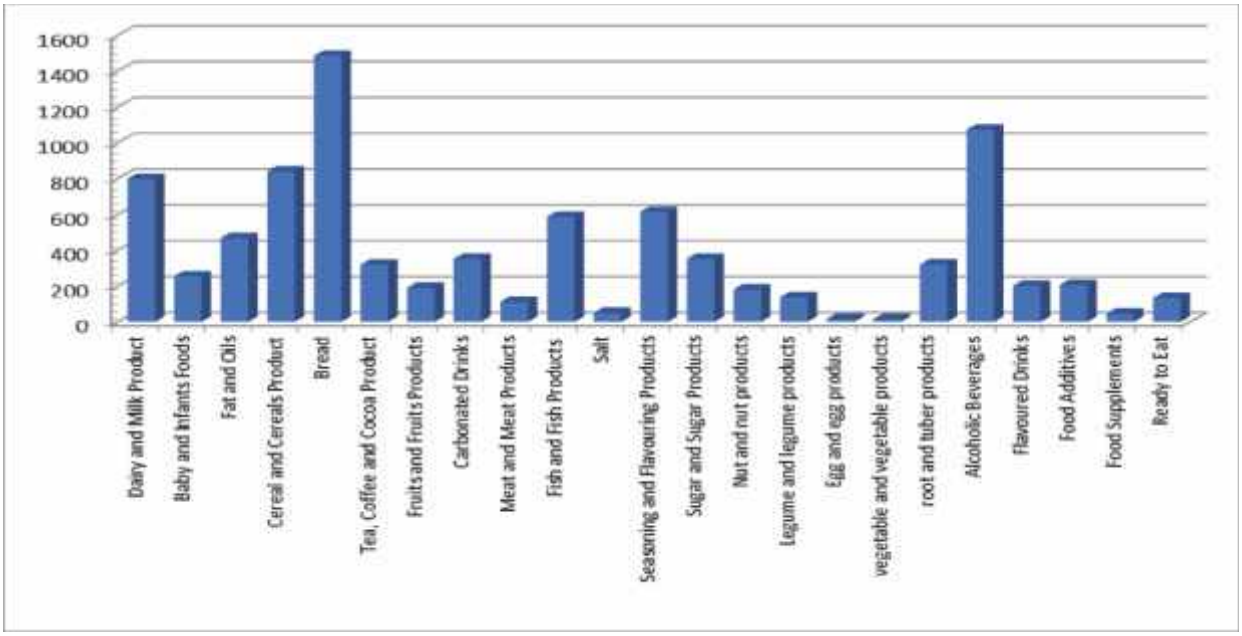


Figure 13.6: Summary of Food Samples Received According to Categories



13.3 Trend in Assessment of Regulated Products

Table 13.1: Trend of samples received based on purpose of analysis

Purpose of analysis	Number of samples 2020	Percentage 2020
Registration	10,358	67.83%
Compliance	4,499	29.46%
Investigation	390	2.55%
Enforcement	22	0.14%
Others	1	0.01%
Total	**15,270**	100%

Table 13.1 shows that 67.83% of samples received for analysis in the Laboratory Services Directorate (Food) were for registration purposes while the compliance samples account for 29.46% of the samples received.

The volume of samples received for Investigation and enforcement purpose were quite low.

13.4 Trend in the Categories of Regulated Products Received in the Directorate

- Food samples constituted the highest number (12,621; 82.72%) of samples received in the Directorate followed by Water samples (1,863; 12.22%)
- Of the Food samples received, Bread samples constituted the highest (1,485; 11.8%) and then alcoholic beverages (1,073; 8.5%)
- Of the 1,863 water samples received, 97.4% (1815) were for registration purpose
- Of the 390 samples received for investigation purposes, Cereal and Cereal Products samples constituted the highest percentage (28.5%;111) followed by Alcoholic beverages (19.0%;74)
- Only twenty-two (22) samples were received for enforcement purposes

13.5. ISO 17025 Laboratory Accreditation

13.5.1 Central Laboratory Oshodi

- The Laboratory was re-assessed virtually on the 11 and 12 November 2020 by ANAB for ISO 17025:2017 Laboratory accreditation of the previously accredited scopes and extended its accreditation scopes. The Laboratory currently have thirty-nine (39) scopes accredited and received its Certificate of recognition of Accreditation from ANSI-ASQ National Accreditation Body (ANAB) in December, 2020.
- The Laboratory scopes of ISO 17025:2017 Laboratory accreditation by NINAS in 2019 is also still running.

13.6. Partnership With Governments and Organisations

13.6.1. International Atomic Energy Agency (IAEA)

- The Laboratory formations is participating in a new IAEA/AFRA Project; RAF 5084 (Strengthening Food Contaminant Monitoring and Control Systems and Enhancing Competitiveness of Agricultural Export Using Nuclear and Isotopic Techniques). The Project is scheduled to last for four (4) Years; 2020- 2024.
- NAFDAC was represented at the "National Workshop for IAEA Project Counterparts in Nigeria" at Abuja by the project coordinator; Dr. C. U. Nwachukwu in November 2020

- IAEA supported Mycotoxin, Veterinary Drug Residues and Metal Laboratory Units with NMISA and Progetto Trieste Proficiency Testing Materials under the RAF 5084 Project

13.6.2. Global Alliance for Improved Nutrition (GAIN)

- GAIN is still supporting the Central Laboratory Oshodi on testing of micronutrients, Food safety parameters and food fortificants.
- Following the mentorship program under the GAIN-ENABLE Project on Food safety in 2018/2109, a follow-up exercise on development of a joint Laboratory Quality and Capacity Building Plan is ongoing

13.6.3. Organisation for Prohibition of Chemical Weapons (OPCW)

- The OPCW sponsored Laboratory unit in Central Laboratory Oshodi dedicated for testing of Chemical Weapons is now well equipped and functional. There have been series of internal training on the use of the new equipment by the installing Engineers.
- Three (3) staff of the Agency (one from Laboratory Services Food and two from Laboratory Services Kaduna) attended an OPCW training on analysis of chemical weapon in Netherlands in February 2020 duly sponsored by OPCW
- The OPCW Laboratory, Oshodi participated in the CCACT 11 Proficiency Test

13.7. Special Activities

13.7.1. Micronutrient Monitoring Survey

13.7.2. Central Laboratory Oshodi

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

Food Vehicle	Quantity
Vegetable Oil	2,160
Flour	2,160
Sugar	1,440
Salt	1,440
Total	**7,200**

13.5.1. Activities of Central Laboratory Oshodi Health Safety and Environment (HSE) for 2020

The Health Safety and Environment (HSE) was initiated in the Agency by the Director General, Prof. Mojisola Adeyeye in December 2018. The Central Laboratory Oshodi HSE safety committee was inaugurated by the Director LS (Food) on 14th January 2019 comprising of ten (10) members.

The committee is working assiduously to ensure good work health safety & environmental control. The committee is ensuring that the non-pharmaceutical interventions are abide with by the staff and visiting public.

13.5.2. Overview of HSE Activities

✓ **Covid 19 Preventive Measures**

The committee ensured that Hand Sanitizers are available at strategic position within the complex. Also, strict adherence to use of nose mask by every staff and visitor to the complex was maintained as well as temperature check with Infrared thermometer at the entrance.

✓ **Change in Management**
On the 18th of December 2020, the position of the HSE Committee Chairperson of the Central Laboratory Oshodi was re-assigned to Mrs. Hadiza Yunusa due to posting of the previous Chairperson.

✓ All safety signages are strictly complied with was observed in 2020

13.6. Proficiency Testing

All Laboratory Units in Central Laboratory Oshodi with accredited scopes successfully participated in Proficiency Testing Schemes and inter-Laboratory testing.

13.9. Constraints

The major constraints that hampered the efficiency of the Laboratories in 2020 included the following:

- COVID-19 lockdown
- Insufficient staff in the Directorate
- Lack of adequate computers.
- EndSARS Protest

13.7. Way Forward in 2021

For continuous improvement in efficiency and services of the Directorate, it is recommended thus;

Laboratory Equipment and Consumables

- Procurement of more Laboratory equipment, chemicals and consumables

Staff

- The Laboratory is grossly short staffed and in need of the following disciplines; Biochemists, Chemists, Food Technologists, Laboratory technologists, Instrument Engineers and Laboratory Assistants.

Infrastructure

- Renovation of Central Laboratory, Oshodi
- Relocation of Area Laboratory, Port Harcourt, Rivers State to Calabar, Cross River State.

Accreditation

- The Directorate would ensure it sustain the accredited scopes and hope to extend the scopes further.

13.8. Conclusion

The Laboratory Services Directorate (Food) achieved much in terms of analyses of samples despite the COVID-19 lockdown and other pertinent challenges. The Directorate successfully sustained the previously accredited analytical scopes in the Central Laboratory Oshodi and extended its scopes.

Chapter 14

LABORATORY SERVICES (DRUG AND BIOLOGICS) DIRECTORATE

14.0. Introduction

The Drug and Biologics Laboratory Services (LS) Directorate was established by the new Director General to enable the Drug and Biologics Laboratory to be more prudent and more productive in achieving its mandate and that of the Agency.

The Drug and Biologics Directorate has three functional laboratories viz:

- Central Drug Control Laboratory, Yaba, Lagos.
- Vaccine Control Laboratory, Yaba, Lagos
- Area Laboratory, Maiduguri

Goal

The goals of the Laboratory Services are:

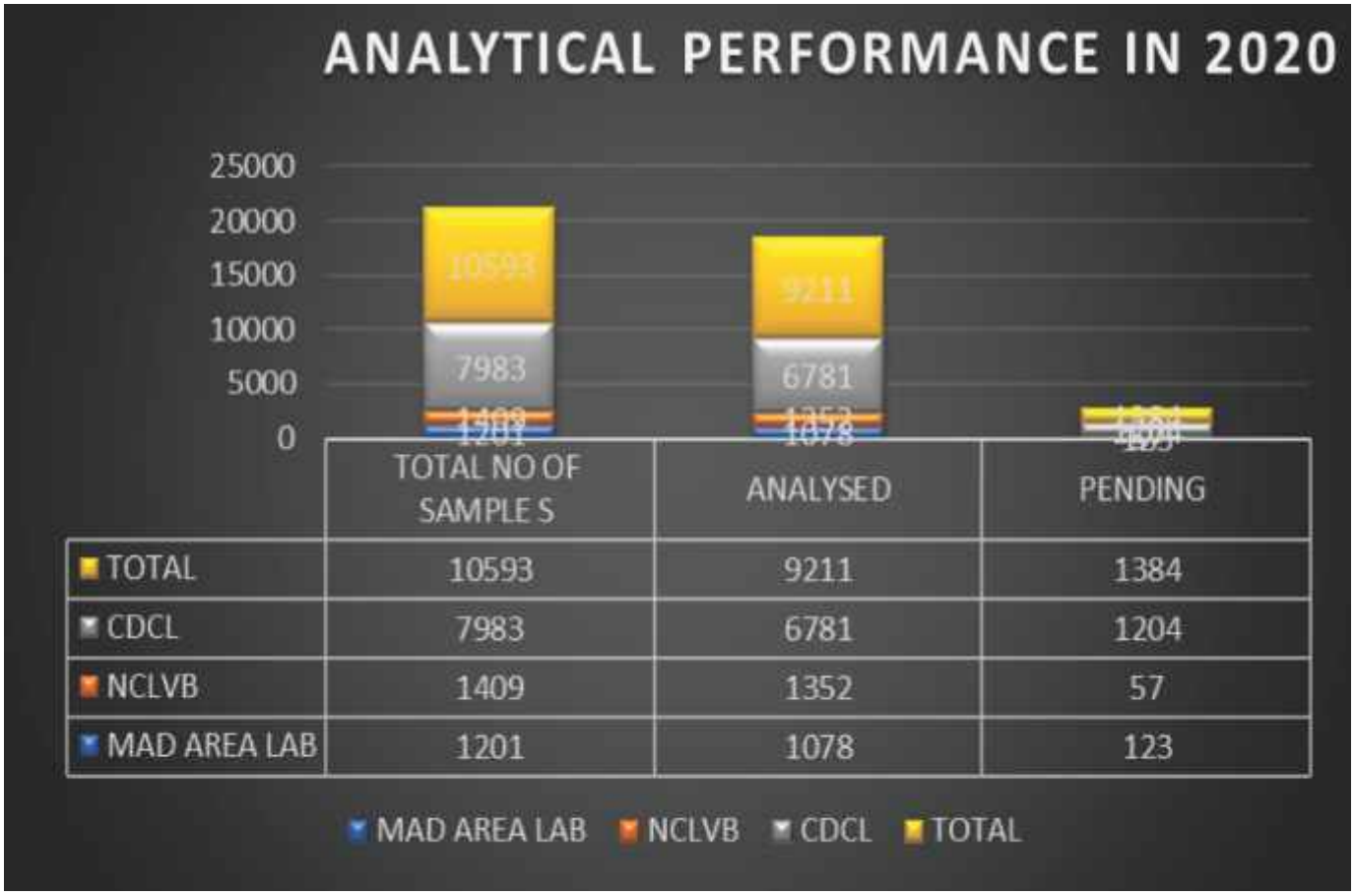
- To generate quality and timely test results that meet international standards
- To provide excellent customer service
- To be the best reference laboratory in the West African sub region

14.1. Analytical Performance

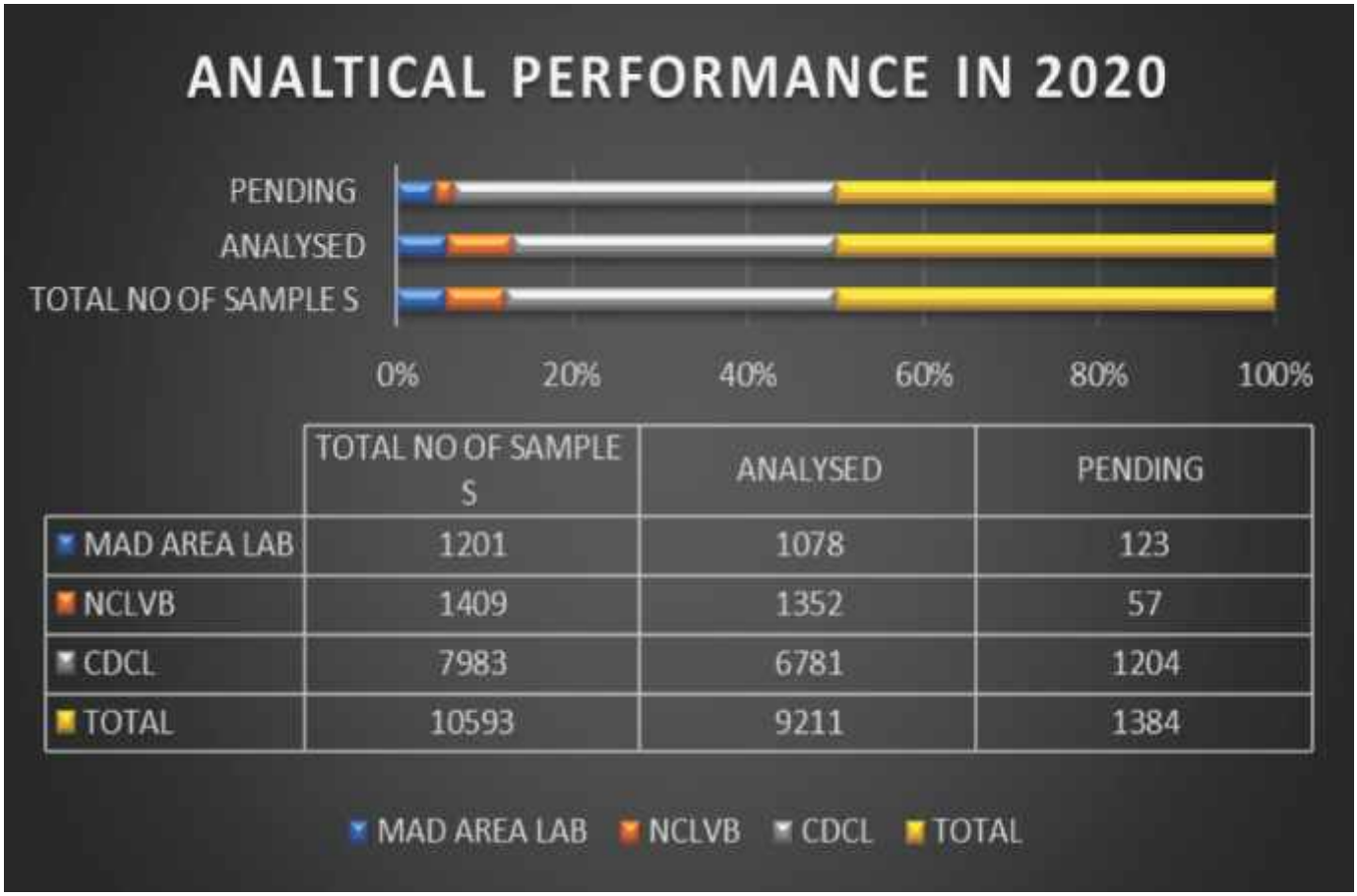
In the year 2020 being period under review, the Laboratory Services Directorate (Drugs& Biologics Laboratory) received a total of **1,0190** samples. The number of samples brought forward (carried over) from December 2019 was **403.** This implies that a total of **1,0593** samples were available for analysis in the year 2020. **However, from this number (1,0593), 9,211 samples were analyzed representing 87.10 %.** Table X below shows the summary of activities for the period under review.

Table 14.1: Summary of Analytical Performance for the Year, 2020

Labs	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
Maiduguri	9	1192	1201	1078	814	264	123
Yaba Biologics	123	1286	1409	1352	1352	-	58
Yaba Drugs	271	7712	7983	6781	6374	407	1204
Total	403	10190	10593	9211	8540	671	1385



	TOTAL NO OF SAMPLE S	ANALYSED	PENDING
TOTAL	10593	9211	1384
CDCL	7983	6781	1204
NCLVB	1409	1352	57
MAD AREA LAB	1201	1078	123



	TOTAL NO OF SAMPLE S	ANALYSED	PENDING
MAD AREA LAB	1201	1078	123
NCLVB	1409	1352	57
CDCL	7983	6781	1204
TOTAL	10593	9211	1384

14.2. Highlights

- The Directorate participated on the virtual audit surveillance for ISO 9001:2015 which was carried out in October as it is one of the locations covered in the ISO certification of the Agency.
- A virtual surveillance for ISO 17025:2017 was also conducted for various NAFDAC laboratories with Central Drug Control LAB(CDCL) as the Parent Laboratory while others are Satellite sites. The audit lasted for Two weeks which was between November 2nd to November 13th,2020. All the various laboratories concerned retained their accreditation status in their different scopes.
- The Directorate had a one-day Management Review Meeting (MRM) which is mandatory for an
    - ✓ ISO: 17025:2017 accredited laboratory. The meeting was done collectively with that of Oshodi Central Laboratory.
- In the month of November, the National Control Laboratory for Vaccines & Biologics (NCLVB) had to move out of the May & Baker building they were occupying following request from their landlord (M&B). They are currently "squeezed in a one office apartment" that used to be CDCL's staff workstation. The office accommodation is not just grossly inadequate but highly inconvenient for both the staff of CDCL and the Vaccine and Biologics staff most especially in this Covid-19 pandemic period.

14.3. Constraints

General constraints that affected the efficiency of the Laboratories for the period under review are as follows:

- Inadequate/Lack of some reference standards, HPLC Columns, chemicals and other laboratory consumables.
- Low staff strength.
- Laboratory/Office Space constraints

14.4 Conclusion

There is need to be urgently address both the staff offices and laboratory space deficit as highlighted and there is also need to prioritise for immediate supply of laboratory consumables and improve upon the number of laboratory equipment so as to facilitate analysis of the samples and prevent delay in release of reports. There is also urgent need to address staff deficit particularly those of lower cadre between level 8 to 10 and swapping of the Higher level 14 as discussed during the management review meeting in October. The lockdown earlier imposed because of covid-19 has greatly affected staff movement and laboratories output.

Chapter 15

LABORATORY SERVICES, AGULU

15.0 Introduction

Laboratory Services, Agulu was created as a full-fledged Directorate in January, 2020 by the Director-General. The Laboratory serves the South-East and South-South Zones of the country where analysis of Food, Drugs, Cosmetics, Medical Devices and Herbal products are carried out.

15.1. Analytical Performance

15.1.1. No. of Samples Received

In 2020, the Laboratory received three thousand and four (3, 0004) samples. One hundred and sixty-four (164) samples were brought forward from the previous year 2019 bringing to a total of three thousand, one hundred and sixty eight (3,168) samples for analysis within the year under review.

15.1.2. No of Samples Analysed

Two thousand, nine hundred and nine (2,909) samples were analyzed within the year under review. This represents 91.82% productivity.

15.1.3. No of Pending Samples

Two hundred and fifty-nine (259) samples were pending within the year under review.

15.1.4. No of Satisfactory and Unsatisfactory Samples

Two thousand, seven hundred and (2,701) samples were satisfactory while two hundred and eight (208) were unsatisfactory within the year under review.
Tables 15.1 & 15.2, Figures 15.1 & 15.2 shows the statistics of the activities within the year under review.

Table 15.1. **Summary of Analytical Performance for the Year 2020**

Product	No. Samples Brought Forward	No. of Samples Received	Total Number of Samples	No. of Samples Analysed	No. of Satisfactory Samples	No. Unsatisfactory sample	No. o f Samples Pending
Food	7	780	787	758	694	64	29
Drug	149	1.095	1,244	1014	926	88	230
Water	0	617	617	617	579	38	0
Cosmetics	8	257	265	265	257	8	0
Medical Devices	0	76	76	76	68	8	0

Pesticide Formulations	0	32	32	32	32	0	0
Herbal Preparation	0	147	147	147	145	2	0
Total	**164**	**3004**	**3168**	**2,909**	**2,701**	**208**	**259**

Figure 15.1: Graphical Representation of Activities for the Year 2020

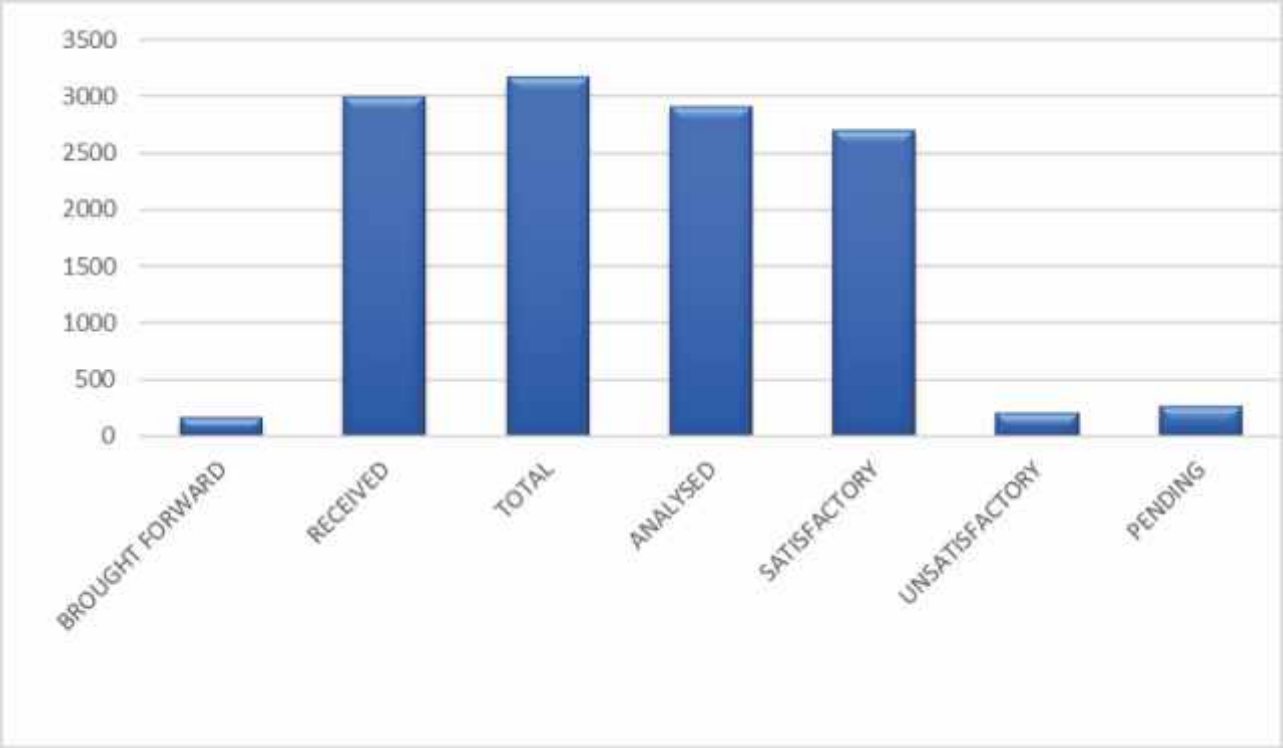
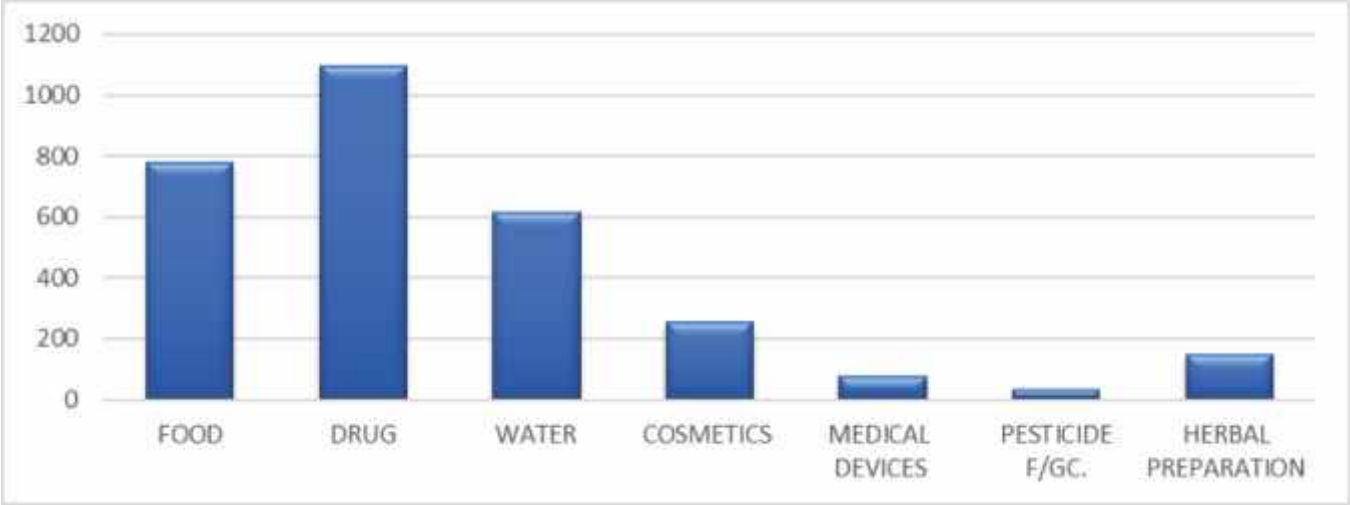


Table 15.2: Sources of Samples Received in the Year 2020

Sources	Food	Drug	Water	Cosmetics	Med. Device	Herbal Prep	Pesticide Form.	Total	Total Analysed	Total Pending
Registration	756	423	591	225	38	144	0	2,177	2,148	29
Enforcement	1	10	0	0	0	0	0	11	7	4
Compliance	8	632	1	29	37	3	32	742	518	224
Investigation	15	30	24	3	1	0	0	73	71	2
Consultancy	0	0	1	0	0	0	0	1	1	0
Others	0	0	0	0	0	0	0	0	0	0
Total	**780**	**1,095**	**617**	**257**	**76**	**147**	**32**	**3,004**	**2,745**	**259**

Figure 15. 2: Categorized Quantity of Samples Received In 2020



15.2 Installation of New Equipment/Instrument

New Ultra-Violet-Visible Spectrophotometer (UV-Vis) was installed in the laboratory within the year under review.

15.3. Special Activities

The Laboratory participated in the production of Hand Sanitizer and Liquid Soap for staff of the Agency within the South-East and South-South Zones and other NAFDAC formations within the axis in the wake of Covid-19 Pandemic.

15.4. Audit

The Laboratory successfully underwent the annual assessment for ISO 17025:2017 re-accreditation. It was conducted virtually. All accredited scopes were monitored and implementation of QMS in all the laboratory units continued within the year under review.

15.5 Health, Safety and Environment (HSE)

Lecture on Health, Safety and Environment was organized at the beginning of the year for all laboratory staff to be abreast with the safety precautions in the laboratory workplace.
Certified training on First Aid at workplace was organized for the HSE First-Aid officers in March at Abuja and Lagos offices by the Nigerian Red Cross Society as approved by the Director-General through the SMO-DGO, Miss Mariam Bubakari.
Public Area Notices and Stickers on COVID-19 guidelines were installed at strategic locations of the Laboratory for staff and visitors to see as reminders.
Social Distancing was enforced, and Virtual meetings became the new normal.
Temperature probes, Hand Sanitizers and Liquid Soap were placed at Entrance gates and the reception hall respectively.

15.6. Conclusion

Agulu Laboratory Services achieved much despite the challenges of the COVID-19 pandemic when we had to work with a reduced number of staff. The Directorate successfully sustained the previously accredited analytical scopes in the laboratory. The directorate is committed to sustaining and exceeding her achievements there by meeting the NAFDAC mandate. We also hope that most of the constraints facing the laboratory will be resolved as soon as possible.

Chapter 16

LABORATORY SERVICES, KADUNA

16.1. Sample Analysis

The Laboratory received a total of eight thousand six hundred and sixty-three (8,663*) samples*; seven thousand, two hundred and seventeen (7,217) samples were locally produced while one thousand four hundred and forty-six (1,446) samples are imported products. Eight hundred and fifty-seven (857) samples were brought forward from 2019 making a total of nine thousand five hundred and twenty (9,520) samples.

Of these samples, eight thousand eight hundred and thirteen (8,813) were analysed out of which seven thousand six hundred and sixty-nine (7,669) were satisfactory and one thousand one hundred and forty-four (1,144) failed analyses. The remaining seven hundred and seven (707*)* samples were carried over into 2021. The summary of activities is indicated in Table 1 below.

Table 16. 1: Summary of Activities for 2020.

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	134	4164	4298	3876	3543	333	422
Chemistry	158	453	611	592	533	59	19
Water	153	2040	2193	2059	1480	579	134
Cosmetics	40	453	493	406	283	123	87
Pesticides	40	110	150	146	128	18	04
Mycotoxins	14(01)	517(62)	531(63)	531(63)	530(63)	01(0)	0(0)
Microbiology	19(0)	6131(04)	6150(04)	6098(04)	5460(04)	638(0)	52(0)
Compliance	331	1377	1708	1667	1635	32	41
TOTAL	**857**	**8663**	**9520**	**8813**	**7669**	**1144**	**707**

NOTE: Performance activity is 92.57%

16.2. Chemistry Unit

Chemistry unit received four hundred and fifty-three (453) samples and brought forward one hundred and fifty-eight (158) samples making a total of six hundred and eleven (611) samples. Five hundred and ninety-two (592) samples were analysed, and five hundred and thirty-three (533) were satisfactory while fifty-nine (59) were unsatisfactory. Nineteen (19) samples were carried over into 2021.

16.3. Food Unit

The Food Unit received four thousand one hundred and sixty-four (4164) samples and brought forward one hundred and thirty-four (134) making a total of four thousand two hundred and ninety-nine (4298*) samples.* Of this number, three thousand eight hundred and seventy-six (3876) samples were analysed; three thousand five

hundred forty-three (3543) were satisfactory and three hundred and thirty-three (333) were unsatisfactory. The remaining four hundred and twenty-two (422) samples were carried over into 2021.

16.4 Water Unit

The Water Unit received two thousand and forty (2040*)* samples, brought forward one hundred and fifty-three *(153)* samples making two thousand one hundred and ninety-three (2193) samples. Two thousand and fifty-nine (2059) samples were analysed, one thousand four hundred and eighty *(1480) samples* were satisfactory while five hundred and seventy-nine *(579)* were unsatisfactory. The remaining one hundred and thirty-four (134) samples were carried over into 2021.

16.5. Cosmetics Unit

The Cosmetics Unit received four hundred and fifty-three (453) samples, brought forward forty (40) making a total of four hundred and ninety-three (493). Four hundred and six (406) samples were analysed, two hundred and eighty-three (283) samples were satisfactory while one hundred and twenty-three (123) samples were unsatisfactory. Eighty-seven (87) samples were carried over into 2021.

16.6. Drug Compliance Unit

This unit received one thousand three hundred and seventy-seven (1377) samples and brought forward three hundred and thirty-one (331) samples making a total of one thousand seven hundred and eight (1708). One thousand six hundred and sixty-seven (1667) samples were analysed and one thousand one hundred and thirty-five (1635) were satisfactory and thirty-two (32) were unsatisfactory. The remaining forty-one (41) samples were carried over to 2021.

16.7. Pesticides Unit

The pesticide unit received one hundred and ten (110) samples this year, brought forward forty (40) samples making one hundred and fifty (150). One hundred and forty-six (146) samples were analysed, one hundred and twenty-eight (128) samples were satisfactory while eighteen (18) were unsatisfactory. Four (04) samples were carried over to 2021.

16.8 Mycotoxin Unit

This unit received five hundred and seventeen (517) samples and brought forward fourteen (14) sample making a total of five hundred and thirty-one (531). Five hundred and thirty-one (531) samples were analysed, five hundred and thirty (530) were satisfactory while one was unsatisfactory. No sample was carried over to 2021.

16.9 Microbiology Unit

The Microbiology Unit received six thousand one hundred and thirty-one (6131*)* samples, brought forward nineteen *(19)* samples making six thousand one hundred and fifty (6150) samples. Six thousand and ninety-eight (6098) samples were analysed, five thousand four hundred and sixty *(5460) samples* were satisfactory while six hundred and thirty-eight *(638)* were unsatisfactory. The remaining fifty-two (52) samples were carried over into 2021.

16.10. Total Sample Received in 2020

Table 16.2.Number of Sample Received in 2020

SN	Product Type	Quantity
1.	Chemistry	453
2.	Food	4164
3.	Cosmetics	453
4.	Water	2040
5.	Pesticides	110
6.	Compliance	1377
7.	Mycotoxins	62
8.	Microbiology	04
	Total	**8663**

Fig 16.1: Number of samples received in 2020

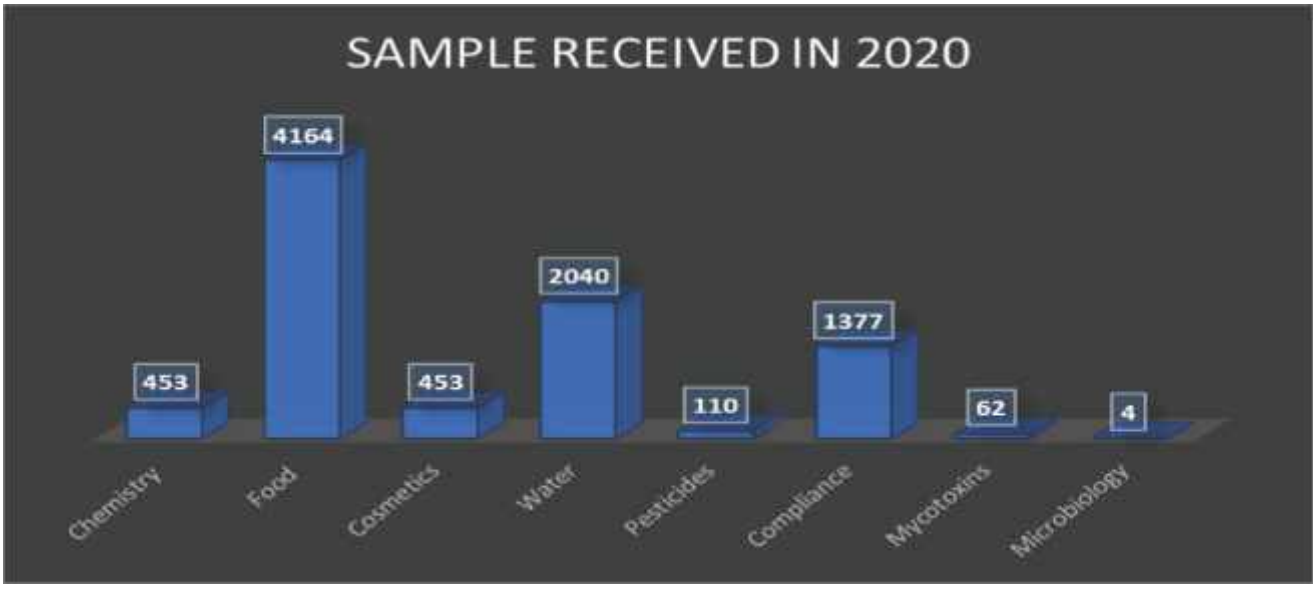


Table 16. 3: Profiles of Samples Received in 2020

S\N	Product type	Samples received	
		Local	**Imported**
1..	Drugs	496	1334
2.	Food	4067	97
3	Cosmetics	445	08
4.	Water	2040	0
5.	Pesticides	103	07
6.	Mycotoxins	62	0
7.	Microbiology	04	0
	Subtotal	7217	1446
	Total	8663	

Figure 16.2: Local Samples Received

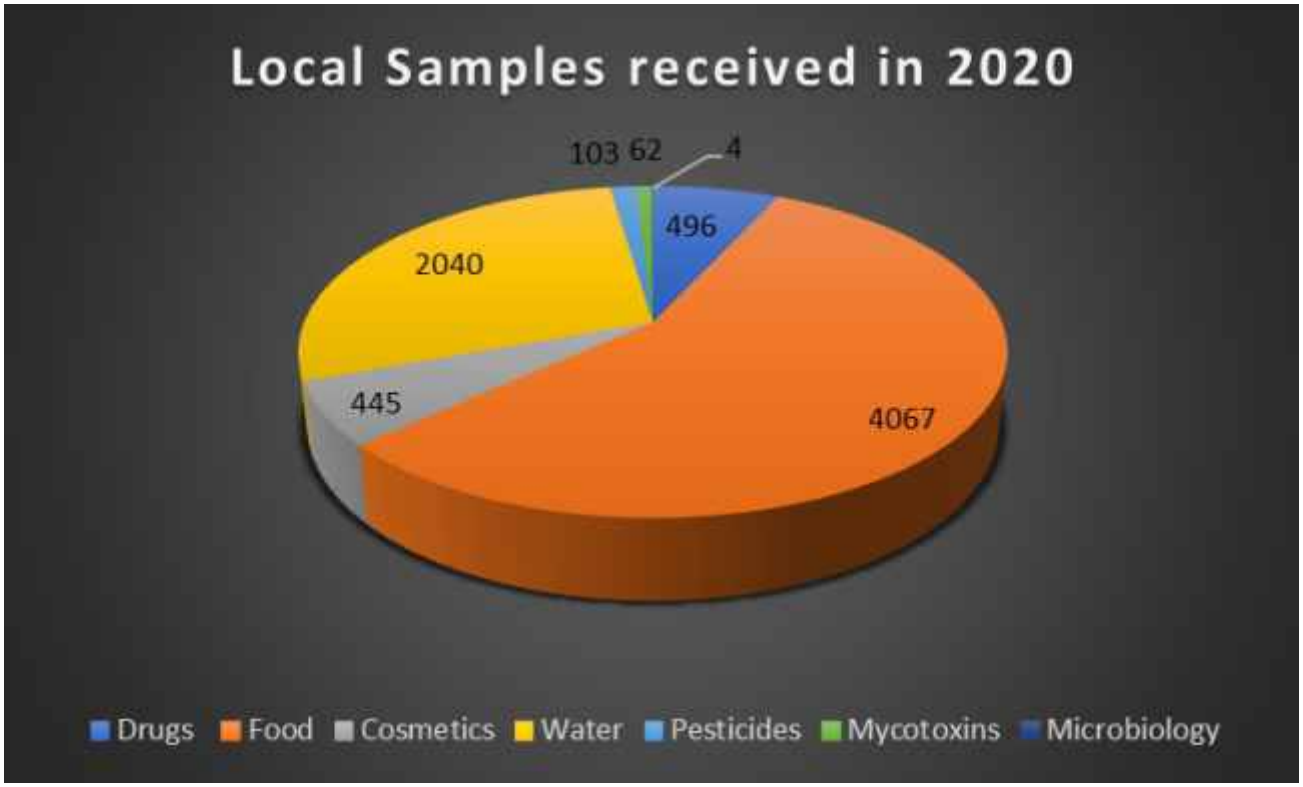


Figure 16.3: Foreign Samples Received

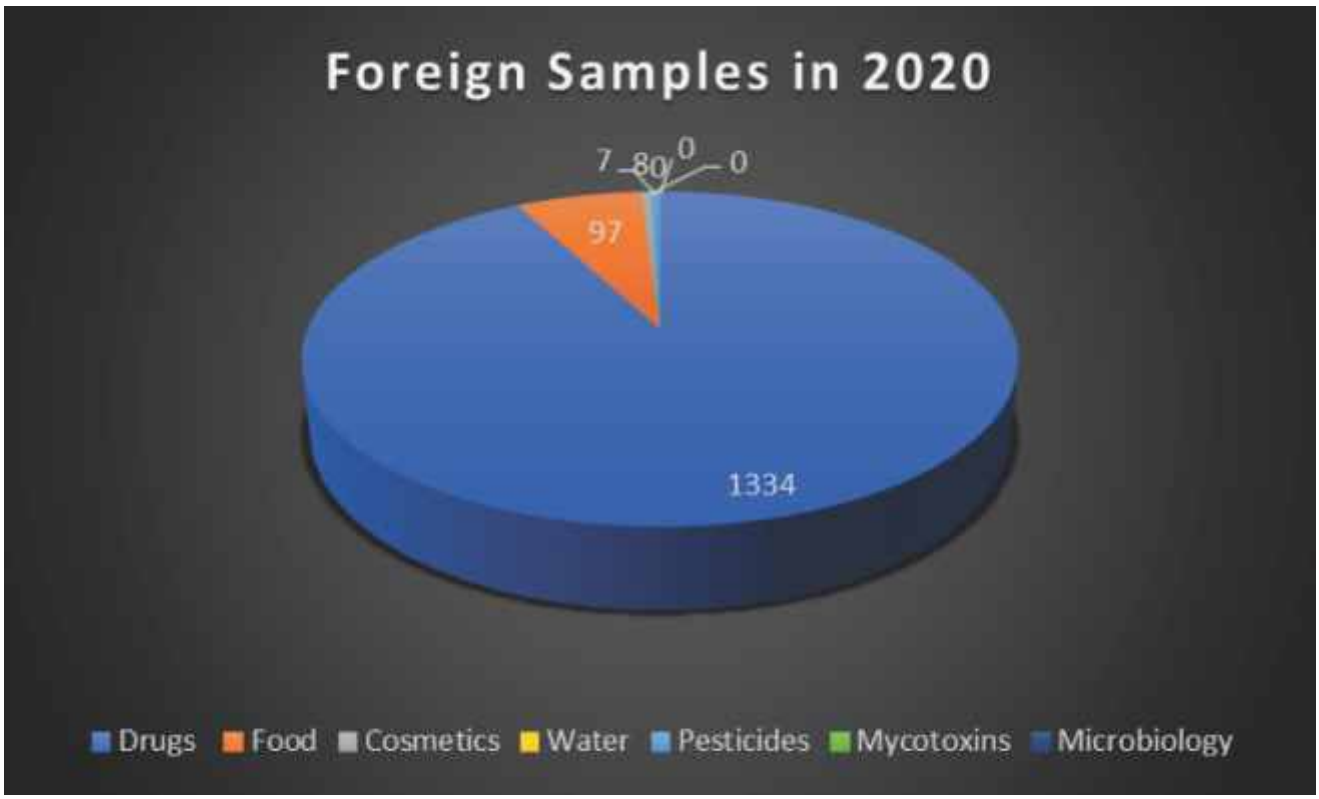


Table 16.4: Sample Classification Based on Purpose of Analysis For 2020.

Type of Sample	Water	Food	Drugs	Cosmetics	Pesticide	Mycotoxins	Microbiology	Total
Registration	950	3380	396	370	66	50	04	5216
Renewal	1070	592	103	71	09	12	-	1857
Compliance	-	09	1266	06	11	-	-	1292
Investigation	20	183	65	06	24	-	-	298
Factory Extension	-	-	-	-	-	-	-	-
Pack Size Extension	-	-	-	-	-	-	-	-
Total Samples	**2040**	**4164**	**1830**	**453**	**110**	**62**	**04**	**8663**

Figure 16.4: Classification of Sample For 2020

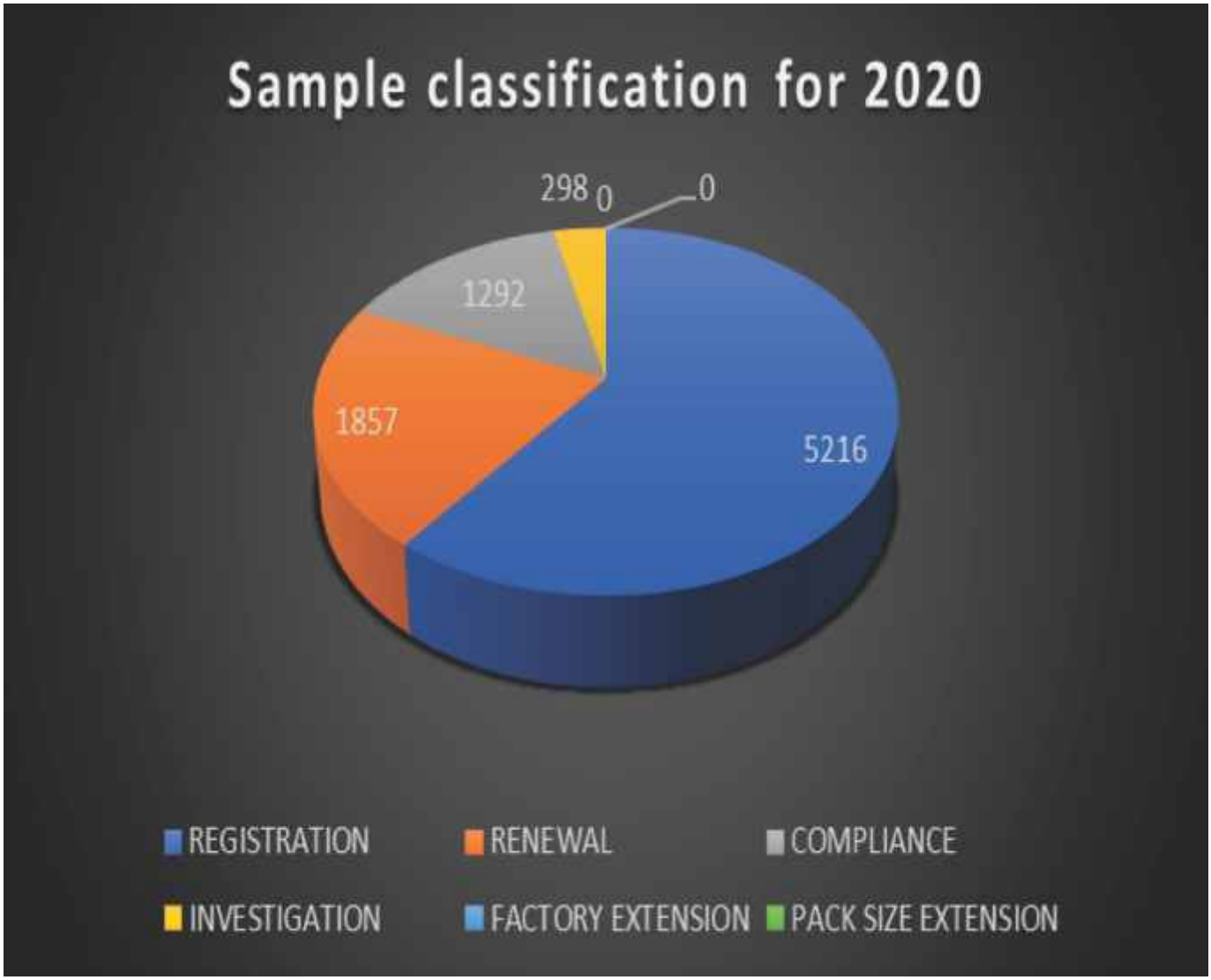


Table 16.5: Profile of Samples For 2020

S/N	Product Type	Sample Received	
		Local	Imported (Foreign)
1.	Dairy and Milk Product	199	2
2.	Baby and Infants Foods	-	-
3.	Fat and Oils	212	7
4.	Cereal and Cereals Product	982	76
5.	Bread	1143	-
6. -	Tea, Coffee and Cocoa Product	82	1
7.	Fruits and fruits products	39	-
8.	Carbonated Drinks	1	-
9.	Meat and Meat Products	42	-
10.	Fish and Fish Products	30	-
11.	Salt	02	-
12.	Seasoning and Flavouring Products	521	05
13.	Sugar and Sugar Products	135	03
14.	Alcoholic beverage	15	-
15.	Water	2040	-
16.	Pesticides	103	07
17.	Analgesic	14	89
18.	Anesthetic	10	06
19.	Antibiotics	17	287
20.	Antimalarial	15	120
21.	Antifungal	04	101
22.	Antihypertensive	03	157
23.	Antacid	04	-
24.	Antihelmantic	-	02
25.	Antiviral	-	86
26.	Respiratory	07	35
27.	Haematinic	06	12
28.	Diabetics	07	15
29.	Diuretic	-	48
30.	Minerals and Vitamins	10	112
31.	Ophthalmic	-	22
32.	Veterinary	17	46
33.	Med Devices	148	09
34.	Cosmetics	445	08
35.	Herbal prep	88	-
36.	Drug Others	146	187
37.	Food others	663	03
38.	Animal feed	67	-
Sub Total		**7217**	**1446**
Total		**8663**	

Table 16. 6: Source of Samples for 2020

Product type	Registration	Compliance	Investigation	Enforcement	Others	Total
Dairy and Milk Product	199	01	01	-	-	201
Baby and Infants Foods	-	-	-	-	-	-
Fat and Oils	212	04	03		-	219
Cereal and Cereals Product	982	76	-	-	-	1058
Bread	1143	-	-	-	-	1143
Tea, Coffee and Cocoa Product	82	1	-	-	-	83
Fruits and Fruits Products	39	-	-	-	-	39
Carbonated Drinks	1	-	-	-	-	01
Meat and Meat Products	42	-	-	-	-	42
Fish and Fish Products	30	-	-	-	-	30
Salt	02	-	-	-	-	02
Seasoning and Flavouri ng Products	521	05	-	-	-	526
Sugar and Sugar Products	135	03	-	-	-	138
Alcoholic beverages	15	-	-	-	-	15
Water	2038	-	02	-	-	2040
Pesticides	103	07	-	-	-	110
Analgesic	14	89	-	-	-	103
Anesthetics	10	06	-	-	-	16
Antibiotics	17	287	-	-	-	287
Antimalarial	15	120	-	-	-	135
Antifungal	04	101	--	-	-	105
Antihypertensive	03	157	-	-	-	160
Anti ulcer	04	-	-	-	-	04
Antihelmantic	-	02	-	-	-	02
Antiviral	-	86	-	-	-	86
Respiratory	07	35	-	-	--	42
Haematinic	06	12	-	-	-	18
Diabetics	07	15				23
Diuretic	-	48				48
Minerals and Vitamins	10	112	-	-	-	122
Ophthalmic	-	22	-	-	-	22
Veterinary	17	46		--	-	63
Med Devices	147	09	01	-	-	157
Cosmetics	445	08	-	-	-	453
Herbal Prep	88	-	-	-	-	88
Drug others	146	187				333
Food (others)	656	03	07	-	-	666
Animal feed	67	-				67
Total	7203	1446	14	-	-	8663

Table 16.7: Pending Samples for 2020.

S/N	Laboratory Unit	Number of Samples Pending	Reasons for Pending Samples
1.	Food	422	Most of the Samples were receiv ed at the end of December and are undergoing analysis.
2.	Chemistry	19	The pending samples were allocated to the analysts towards the end of the month and are still undergoing analysis
3.	Water	134	Most samples came at the end of December
4.	Pesticides	04	Samples came at the end of December
5.	Cosmetics	87	Samples came at the end of December and are still undergoing analysis
6.	Microbiology	52	Samples came at the end of December and are still undergoing analysis
7.	Compliance	41	Samples still undergoing analysis and most samples came at the end of December
8.	Mycotoxin	0	
	Total	**707**	

Table 16.8. Laboratory Constraints In 2020

	Laboratory Unit	Constraints
1	Food	• Need Reagents, apparatus and some equipment's
2	Chemistry	• Unavailability of consumables and reference standards • Reagents unavailable • Faulty instruments
3	Water	Lack of adequate test kits
4	Mycotoxin	Need more test kits

16.11. Recommendation

The reagents Kits and equipment's need urgent attention.

Chapter 17

VETERINARY MEDICINES AND ALLIED PRODUCTS (VMAP) DIRECTORATE

17.0 Introduction

The Directorate embraced the year 2020 with well fine-tuned strategies to effectively regulate the agricultural inputs within the Veterinary Medicine and Allied Products (VMAP) directorate's mandate as articulated in 2020 workplan. However, barely into the first quarter activities the global challenges upon the advent of COVID-19 in early March 2020 dismantled the strategies. In response to the unexpected challenge the directorate re-strategized to ensure that the effect of the pandemic on the directorate activities was minimal. Being one of the technical directorates of the Agency, the directorate reviewed the modalities earlier put in place to ensure that the directorate mandated to regulate and control Veterinary Medicines, Veterinary products, Pesticides and Agro-chemicals, Animal Feeds, Feed additives and Pet food, was effectively carried out. The Directorate activities commenced with the review of guidelines, and development of regulations, issuance of annual import permit (renewal and fresh) for Bulk Pesticides and Agrochemicals, Animal Feed Concentrates, Supplements, Additives, Premixes and Fish Meals and collation of data on the 2020 activities. The Directorate also conducts the inspection of facilities (both warehouses and production facilities) using virtual platform, carried out Industrial Outreaches along with stakeholder's engagement on virtual platform too, and monitoring of field trial research in line with COVID-19 published protocols.

17.1 Functions of VMAP

The statutory functions of the directorate as deduced from the NAFDAC Act Cap N1 LFN Section 5 (a) and 5 (s) and other enabling laws are as follows:

- Providing Science-based advice and information on the quality, safety and efficacy of veterinary medicines, veterinary products, pesticides, and agro-chemicals.
- Developing and promoting standards, regulations, and guidelines in consultation with other Government Agencies and stakeholders on veterinary medicines, veterinary products, pesticides and agro- chemicals.
- Regulating the manufacture and distribution of animal feeds, feed ingredients, feed additives and drugs for animals.
- Regulating foods, feed ingredients and feed additives and drugs for pets and companion animals.
- Monitoring the safety of foods and medications for animals.
- Regulating and controlling the use of pesticides and agro chemicals.
- Conduct inspection and monitoring of production premises of veterinary and allied products facilities.
- Conduct Scientific Research into various areas of Veterinary and Allied Products.
- Conduct Industrial outreach.

17.2 Structure of VMAP

The Directorate is structured into the following four (4) Divisions with the respective units:

1. Veterinary Medicines Division (VMD)

- Veterinary Drugs and Veterinary Medical Devices Unit
- Veterinary Vaccines and Biologics Unit
- Clinical Evaluation and Research Unit

2. Animal Feed and Premix Division (AFPD)

- Animal Feeds, Pet Food and Feed ingredients Unit
- Premix and Feeds additives Unit

3. Pesticide and Agrochemical Division (PAD)

- Pesticides Unit
- Agrochemical Unit

4. Inspection, Regulations and Stakeholders Relations Division (IRSD)

- Inspection and Monitoring Unit
- Regulations and Stakeholders Relations Unit

17.3. Highlights of 2020 Activities

The Directorate activities ranged from the statutory mandates to ad hoc assignments and other functions as directed by the management. The role of the directorate in securing the food chain and ensuring the "farm to fork" concept of food safety made the directorate to work more closely with Food Safety and Applied Nutrition (FSAN) and Food Registration and Regulation (FR&R) directorates during the year under review. The directorate ensures the safety of farm inputs through effective training of officers, stakeholders, and implementation of regulatory policies.

17.4. Collaborations

The Directorate participated technical meetings with stakeholders and relevant statutory international meetings on regulatory functions. Such meetings include:

- VMAP Directorate and the Management of Hi-nutrients held a meeting with respect to year 2020 import permit on 15th January 2020.
- Consultative Meeting with Saro Agro sciences Limited representatives on the seizure of Sniper-100ml pack size held at NAFDAC Abuja Office on 13th of January, 2020.
- Consultative Meeting with Representative of Harvest Field Ltd on the Importation of Bulk Agrochemical Raw Materials held at the VMAP office in Lagos on 13th of January, 2020.
- Consultative Meeting with Representative of Sole Options Company Limited on Field Trial Evaluation and Registration of their Product held at the VMAP office in Lagos on 15th of January, 2020.
- Consultative Meeting with Representative of D-links Divine World Investment PLC on the Importation of Bulk Dehydrated Sludge for the purpose of Producing Organic Fertilizer in Nigeria held at the VMAP office in Lagos on 16th of January, 2020.
- Consultative Meeting with Jubaili Agrotech Limited held at the VMAP office in Lagos on 16 of th January, 2020.
- Consultative Meeting with Representative of Sumo Agro-science Ltd on the prospective of Production of Pesticides held at the VMAP office in Lagos on 24th of January, 2020.
- Attended CropLife/NAIDA Meeting on proposed Training of Agro Input Dealers at the Travel Inn Hotel, Ikeja Lagos on 28th of January, 2020.
- Info-session on Common Technical Documents with Technical Officers of Pharmaceutical Dealers at NAFDAC Auditorium Isolo-Lagos on 29th of January, 2020.

17.5. Import Permits Prepared

The directorate issued a total number of Four Hundred and Eighty-Nine (489) Import Permit in the year 2020. These various permits were issued for the importation of animal feed additives, pesticides and agrochemicals and novel veterinary drugs. The highest number of permits (393) was issued for animal feed additives with over 80% (489).. Kindly find the summary in table below:

Table 17.1: Import Permit Distribution

Type of Import Permit	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Total (Annual)
Import permits for Animal feeds, Concentrates, Additives, Premixes, and Fish meals.	140	19	70	162	**393**
Import permits for Pesticides	9	0	3	2	**14**
Import Permit for Agrochemicals	2	2	3	7	**14**
Import Permit for Animal Feeds	0	9	0	0	**09**
Import Permit for Vet. Drugs	1	1	0	0	**02**
Import Permit for Vet. Vaccines	1	0	0	0	**01**
Import Permit for Pet Food	0	36	9	13	**58**
Total	**153**	**67**	**85**	**184**	**489**

Table 17. 2: Summary of Inspections Conducted in 2020

	Veterinary Drug	Veterinary Vaccine	Veterinary Devices	Veterinary cosmetics	Pesticides	Agrochemical	Animal feed	Pet/ Companion Food	Feed additive/concentrate /supplement and premixes	Total
VMAP LAGOS										
Warehouse	15	1	0	0	14	6	14	30	2	82
Production	2	0	0	0	3	3	5	9	2	24
Cold Chain	0	22	0	3	2	2	2	0	4	33
Surveillance	23	7	0	0	14	107	30	10	5	196
Advisory/Special.	3	0	0	3	3	4	1	0	0	14
Routine	7	0	0	3	3	5	25	0	0	43
Renewal	0	0	0	3	3	5	0	1	0	12
Follow-up	0	0	0	3	3	2	2	0	0	10
GMP Inspection	5	0	0	3	0	0	0	0	0	8
Pre-Registration	0	0	0	3	3	5	0	0	0	11
Over Sea GMP	0	0	0	0	0	0	0	0	0	0
								TOTAL		**433**
N/W Zone										
Surveillance inspection	140	10	5	3	2	30	23	1	6	238
Pre-Registration	0	0	0	0	0	0	0	0	0	0
Advisory	0	0	0	0	0	1	1	0	0	2
Routine	0	6	0	0	0	0	0	0	0	6
GMP Inspection	4	0	0	0	0	0	0	0	0	4
Warehouse	0	0	0	0	0	2	0	0	0	2
								TOTAL		**252**
VMAP, FCT										
Routine	9	7	6	8	14	3	4	3	11	75
Warehouse	0	0	0	0	0	0	0	0	0	0
Advisory	0	0	0	5	5	0	0	0	0	10
Follow-up	0	0	0	0	0	0	0	0	0	0
Production	0	0	0	0	0	0	0	0	0	0
Investigation	5	2	0	3	4	0	0	0	0	14
									TOTAL	**99**
Grand Total Number of Inspections										**760**

17.6. Risk Assessment/Categorization for Overseas GMP Inspection

The Directorate through her Lagos Office evaluated Two Hundred and Twenty-Five (**225**) overseas facility based on risk assessment /categorization policy of the agency. The summary of the assessment vis-à-vis the products category is presented in table 3 below:

Table 17.3: Summary of Risk Assessment of Overseas GMP Inspection

	Vet Drugs	Vet Vaccines	Vet Devices	Vet cosmetics	Pesticides	Agrochemicals	Animal Feeds/Pet Foods	Fed Additive/premixes	Total
Risk Assessment for Overseas GMP Inspection	79	6	1	1	31	84	16	7	**225**

17.7. Sanctions

The Directorate carried out One Hundred and Forty-Nine (**149**) sanction activities across the country during the period under review. 87% of the activities was seizure and 84% of the seizure was carried out at the Federal Capital Territory followed by the North-West zone. The summary of the activities is presented in table 4 below:

Table 17.4: Summary of Sanctions Carried out in 2020

S/N	LOCATION	Sanction Activity								TOTAL
		Invitation Letter	Warning Letter	CD	Admin Fine	Seizure	Product Place on Hold	Removal of Hold Label	Destruction.	
1	**VMAP** Lagos	0	0	0	0	1	5	0	0	**6**
2	**VMAP**- FCT Abuja	0	0	0	0	109	0	0	0	**109**
5	**N/W** Zone Kaduna	0	0		0	20	9	0	5	**34**
Total no of Sanctions		**0**	**0**	**0**	**0**	**130**	**14**	**0**	**5**	**149**

NAFDAC-CROPLIFE Sensitization Workshop for Agro-Input Dealers On Safe And Responsible Use Of Dichlorvos Products In The North-West In Kano (6th -7th August 2019).

NAFDAC Officers at the North West Workshop for Stakeholders

VMAP Officers monitoring field trial Exercise for Agrochemical products

NAFDAC-CROPLIFE sensitization workshop for Agro-input Dealers on safe and responsible use of Dichlorvos products in the North-West in Kano (6th -7th August 2019).

NAFDAC-CROPLIFE sensitization workshop on the "Safe and Responsible use of Crop Protection Products for Agricultural Commodity Storage" which was flagged off on 5th February, 2019 in Kaduna State by the DG (NAFDAC).

NAFDAC-CROPLIFE sensitization workshop for Agro-input Dealers on safe and responsible use of Dichlorvos products in the South-West Region, Ibadan (2nd -3rd December 2019).

Chapter 18

PHARMACOVIGILANCE/POST MARKETING SURVEILLANCE DIRECTORATE

18.0 Introduction:

Pharmacovigilance/Post Marketing Surveillance Directorate is one of the eighteen Directorates of the Agency. It was established in November 2012 alongside three (3) others. The Directorate operates from the NAFDAC Corporate Headquarters Abuja and PV/PMS Liaison office Lagos. PV/PMS activities are carried out in zonal offices and 36 States and FCT, Abuja.

18.1 Structure:

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

1. Office of the Director headed by the Deputy Director in charge
2. PV/PMS Liaison office Lagos headed by a Deputy Director
3. Pharmacovigilance Division headed by a Deputy Director
4. Advocacy and Public Health Collaborations headed by a Chief Regulatory Officer
5. Post Marketing Surveillance Division headed by an Assistant Director
6. Food and Drug Information Center (FDIC) headed by a Deputy Director
7. Zonal and state Offices

In addition to the various Divisions within the PV/PMS 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/PMS Directorate is saddled with the following responsibilities.

- ✓ Implementation of National Policy on Pharmacovigilance and provision of science-based advice and information on safe use of medicines.
- ✓ Post Marketing Surveillance of all Regulated Products in collaboration with Marketing Authorization Holders (MAHs).
- ✓ Coordination of Pharmacovigilance activities Nationwide
- ✓ Implementation of Risk Management Plans (RMP) in collaboration with the Pharmaceutical Industry and MAHs as appropriate
- ✓ Pharmacovigilance Inspections
- ✓ Supporting the establishment of active Pharmacovigilance Centers in healthcare institutions in the country
- ✓ Creation of awareness on Pharmacovigilance among health professionals, healthcare providers, Marketing Authorization Holders and the general public
- ✓ Promoting rational and safe use of medicines in Nigeria
- ✓ Medicine safety communication
- ✓ Coordinating the activities of the National Drug Safety Advisory Committee (NDSAC)
- ✓ Sourcing, collating, preserving, storing, retrieving and dissemination of information on food, drugs,

cosmetics, chemicals, and other NAFDAC regulated products
- ✓ Establishing and maintaining a functional national database on ADRs and other medicine related problems
- ✓ Conducting regular survey on regulated products for required regulatory action.
- ✓ Coordinating the activities of NAFDAC Consumer Safety Club NCSC in Secondary Schools and NAFDAC Consumer Safety Publications NCSP

The PV/PMS Directorate engaged in several activities in 2018 with the following achievements

18.3 Achievements:

A. **Launch of Med Safety App**

The WHO Med Safety week was held from 2nd to 8th November, 2020. The mobile App for reporting of adverse drug reactions was launched on 4th November, 2020 in the Director-General's Conference room, Abuja. The Benefits of the Med Safety App include the following:

- it is convenient for ADR reporting
- it promotes awareness & increased ADR reporting
- it gives instant access to stakeholders via NAFDAC social media platforms
- it is free to download & use on Android and iOS devices
- it gives NRAs news feed
- Summaries of ADR data are available in graphical form and
- It can be used in 3 languages: English, Russian or Armenian.

Records available to the office show that over 600 smart phone users have downloaded the app by 30th November, 2020.

B. PV Assessment of Facilities

NAFDAC in collaboration with the Management Sciences for Health (MSH) is implementing a number of activities approved under the Global Fund Resilient and Sustainable Systems for Health (GF-RSSH) grant 2020. One of the activities to be implemented under this current grant is quarterly assessment of pharmacovigilance systems in selected health facilities towards future active safety monitoring of new medicines used for HIV-AIDS, Tuberculosis and Malaria (ATM) interventions across the country. The main objective of this exercise is to evaluate the level of participation of healthcare institutions across the country in the Pharmacovigilance system preparatory to monitoring drug safety problems of new molecules used in HIV-AIDS, Tuberculosis and Malaria in patients using the modified Indicator-Based PV Assessment Tools (I-PAT).

In the period under review, there was a PV Assessment of Facilities in Eighteen states of the federation and in each state, Ten (10) healthcare facilities were visited.

PV Assessment at Kogi State

PV Assessment Visit at Adamawa State

C. Other Activities:

- The Head of PV Division is representing NAFDAC at the African Union Smart Safety Surveillance (AU 3S) Programme which is taking place in four African Countries namely Nigeria, Ghana, Ethiopia and South Africa. The programme which is being coordinated by AUDA-NEPAD is focused on conducting safety surveillance for the proposed COVID-19 Vaccine introduction so that all safety concerns related to the use of the vaccine in country can be monitored, tracked and documented.
- The Head of PV Division is also representing the Agency at the Nigeria COVID-19 Technical Working Group (NICOTeG) which is being coordinated by NPHCDA in preparation for the introduction of COVID-19 Vaccine.
- The Directorate is participating in the NAFDAC Traceability and Pharmacovigilance Technical Working Group to develop plans for tracking the COVID-19 Vaccines when deployed in-country and also monitor and report all identifies AEFIs.
- The Directorate is collaborating with NCDC to see ways of getting real time AEFI and ADR data from their already existing SORMARS data platform. Several meetings have been held to see how their data platform can be interphased with vigiflow.
- The Directorate drafted a Guideline for Safety Monitoring of COVID-19 Vaccines.

D. Sensitization Campaign

A Sensitization Campaign on "Illegal Food Practices at Mbodo Aluu Boundary Market on 12th March, 2020 by NAFDAC Rivers State and NAFDAC NYSC CDS Group, Ikwerre, Rivers State. Food vendors and the general public were sensitized on the dangers associated with the use of paracetamol to soften meat, this makes food toxic, unwholesome and unfit for human consumption. The use of unapproved food colourants and also Calcium carbide to ripen fruits is also a dangerous practice and the marketers were educated about these.

E. Quality Management System

An SOP on Safety Surveillance on Covid-19 vaccine was drafted and finalized.

Quality Management Systems (QMS) Trainings held during the period under review are listed below:

Table 18.1: QMS Trainings

S/N	Training Topic	Date Conducted
1	Reviewed Agency wide Quality Management System SOPs	24/6/2020
2	Training on Risk Based PMS	3/7/2020
3	Training on Risk Based Sampling of Regulated Produc ts for Laboratory Analysis	17/07/2020
4	Training on NAFDAC Quality Manual	17/07/2020
5	Step down Training on NAFDAC Quality Manual	5/8/2020
6	Step down Trai ning on Risk Based Sampling of Regulated Products for Laboratory Analysis	5/8/2020
7	Step down Training on NAFDAC Quality Objectives	5/8/2020
8	Training on SOP Monitoring and Measuring of Resources	5/8/2020
9	SOP on Risk Management During Emergencies	5/8/2020
10	Training on SOP on Organizational Knowledge	5/8/2020
11	SOP on Staff Retention Policy	6/08/2020
12	Smart Safety Surveillance	12/08/2020
13	Reviewed NAFDAC Quality Policy and New Procedure on Internal Convergence of NAFDAC Activities	04/09/2020
14	Pharmacovigilance SOP trainings for PV focal persons	13/10/2020

F. WHO-GBT Assessment

In preparation for WHO virtual follow up assessment of GBT program, a Mock Virtual Assessment of all Regulatory Functions was held by the Agency. The Directorate participated in assessment of 4 key areas as follows: Regulatory systems, Market Surveillance & control, Regulatory Inspection and Vigilance.

G. Report on Adverse Drug Reaction Case Reports received in 2020

The National Pharmacovigilance Centre (NPC) received Adverse Drug Reactions (ADR) reports from various stakeholders including patients, health care professionals, health institutions and Marketing Authorization Holders (MAHs) across the country. One thousand, two hundred and thirty-seven (**1,237**) ADR reports were received within the period under review [ICSRs accounting for seven hundred and eighty-one (781) and CIOMS amounting to four hundred and fifty-six (456)], this brings the Cumulative total number of ICSRs received to **25,446** from inception. The reports are being analyzed for causal relationships using the WHO causality assessment guidelines.

Table 18. 2: Record of ICSR Reports Uploaded and Committed into VigiFlow and VigiBase in 2020 and Since Inception (2004)

Total No of ICSR reports uploaded i nto Vigiflow from January –December, 2020	Total No of ICSR reports committed into VigiBase f rom January-December, 2020	Cumulative total no of ICSRs repo rt uploaded into VigiFlow from 2004 - 2020	Cumulative total no of ICSR reports committed into VigiBase from 2004 - 2020
1,264	710	15,588	12,473

One thousand, three hundred and eighty-six (1386) ICSRs including reports received from 2019 were uploaded to VigiFlow, and nine hundred and sixty (960) were committed to VigiBase as represented visually below.

Figure 18.1: Reports of ICSR Received According in 2020 Monthly

MONTHLY	No of ICSR received monthly
JAN	13
FEB	92
MARCH	155
APRIL	0
MAY	3
JUNE	2
JULY	194
AUGUST	5
SEPTEMBER	0
OCTOBER	0
NOVEMBER	317
DECEMBER	0
TOTAL	781

Figure 18. 2: Total Number of ICSR Reports Received In 2020 According to States

STATES	NO OF ICSRs RECEIVED
ABIA	26
ADAMAWA	10
ANAMBRA	4
BENUE	3
EDO	329
FEDERAL CAPITAL TERRITORY	3
IMO	3
KADUNA	119
KEBBI	5
KWARA	13
LAGOS	58
NIGER	55
OYO	94
PLATEAU	2
RIVERS	57
OTHERS	0
TOTAL	**781**

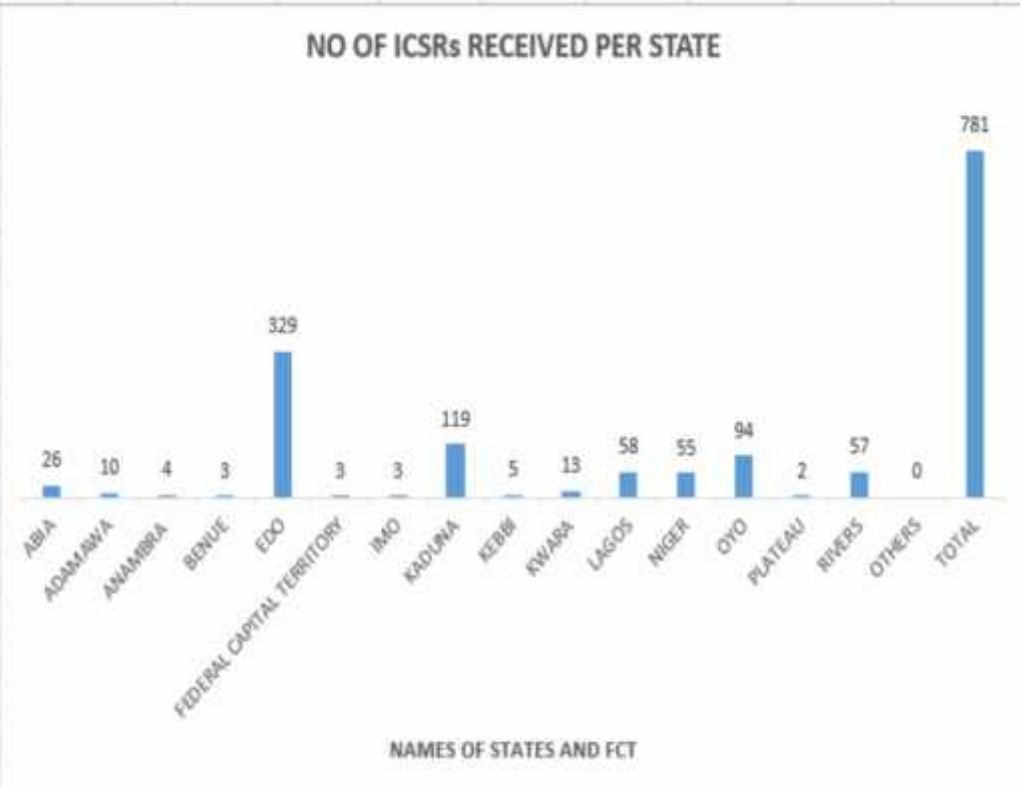


Figure 18.3: ICSRs received by Gender

NIGERIA NPC 2020 VIGILYZE VISUALIZATION

Patient sex	Count	Percentage
Female	455	47.4%
Male	423	44.1%
Unknown	82	8.5%

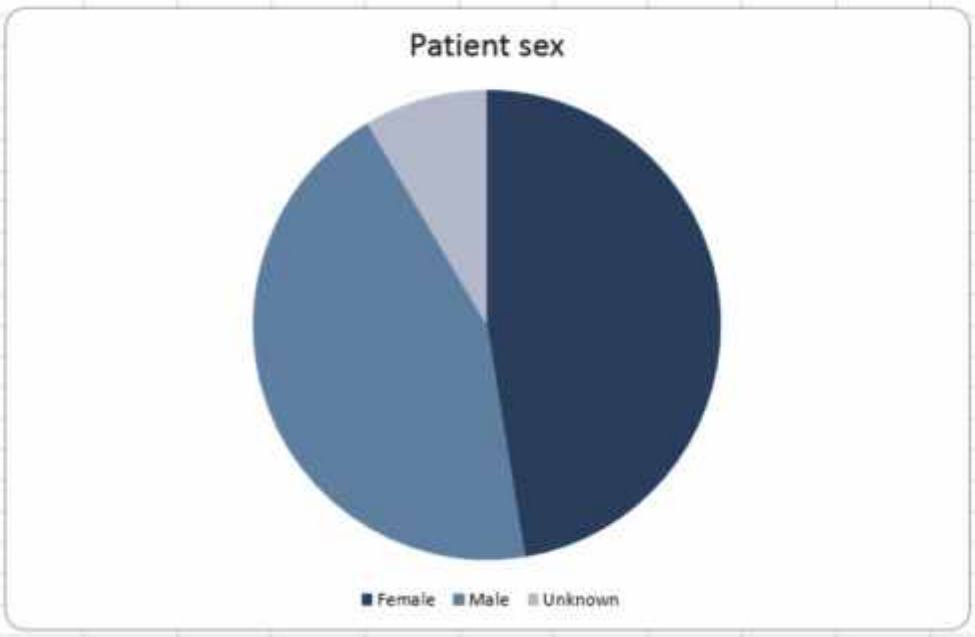


Figure 4: System Organ Classification of received ICSRs

NIGERIA NPC 2020 VIGILYZE VISUALIZATION

Reaction (MedDRA)	Count	Percentage
SOC: Blood and lymphatic system disorders	14	1.5%
SOC: Cardiac disorders	19	2.0%
SOC: Congenital, familial and genetic disorders	2	0.2%
SOC: Ear and labyrinth disorders	53	5.5%
SOC: Endocrine disorders	5	0.5%
SOC: Eye disorders	35	3.6%
SOC: Gastrointestinal disorders	196	20.4%
SOC: General disorders and administration site conditions	276	28.8%
SOC: Hepatobiliary disorders	12	1.3%
SOC: Immune system disorders	3	0.3%
SOC: Infections and infestations	18	1.9%
SOC: Injury, poisoning and procedural complications	53	5.5%
SOC: Investigations	56	5.8%
SOC: Metabolism and nutrition disorders	75	7.8%
SOC: Musculoskeletal and connective tissue disorders	65	6.8%
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyp	6	0.6%
SOC: Nervous system disorders	202	21.0%
SOC: Pregnancy, puerperium and perinatal conditions	13	1.4%
SOC: Product issues	4	0.4%
SOC: Psychiatric disorders	90	9.4%
SOC: Renal and urinary disorders	23	2.4%
SOC: Reproductive system and breast disorders	21	2.2%
SOC: Respiratory, thoracic and mediastinal disorders	44	4.6%
SOC: Skin and subcutaneous tissue disorders	132	13.8%
SOC: Social circumstances	3	0.3%
SOC: Surgical and medical procedures	1	0.1%
SOC: Vascular disorders	17	1.8%

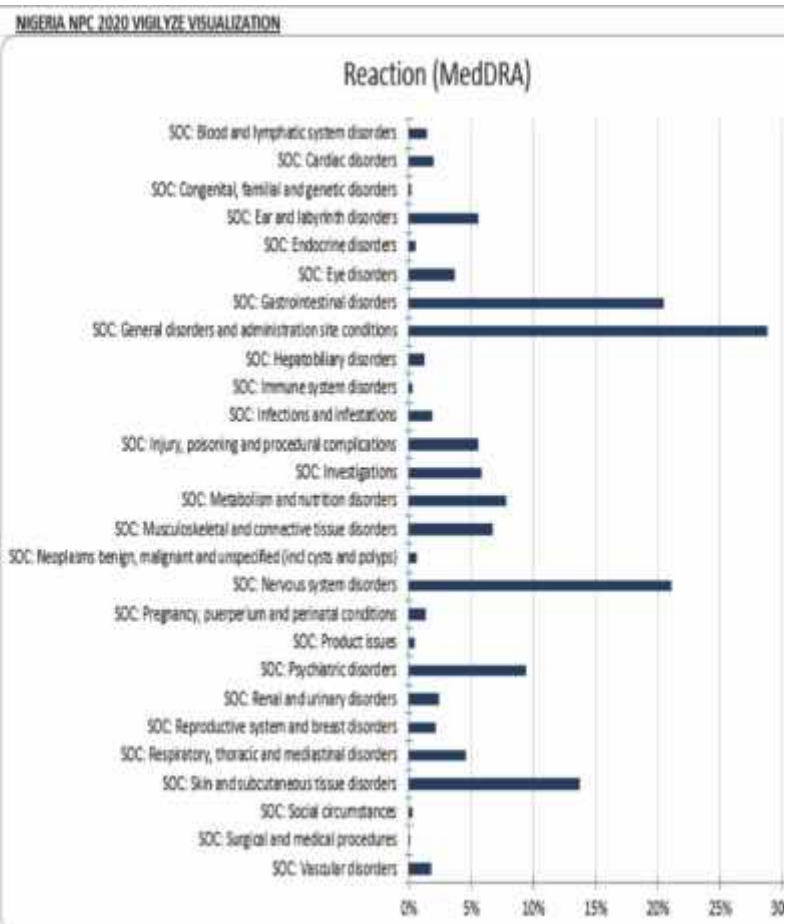


Figure18.5: Classification of Reporters of received ICSRs

H. Recalls and Alert Notifications

The PV/PMS Directorate received alert notifications on recalled products and safety communications from relevant Food and Drug Authorities. The information from notifications were disseminated to the Nigerian public in Alert Notice and /or Dear Healthcare Provider Letter (DHCPL). Seventy (70) Zonal Notifications, 42 Public Alerts and 52 DHCPLs were prepared and disseminated from January to December 2020.

I. Consumer Complaints

Thirty-two (32) consumer complaint investigations were carried out within the period under review.

Table 4: Number of Consumer Complaints Received

S/N	Products	No. of Complaints
1	Cosmetics	1
2	Food	15
3	Drug	7
4	Water	5
5	Medical Devices	0
6	Chemicals	2
7	Herbals	0
8	Others	2
	Total	**32**

J. Rapid Alert System for food and Feeds (RASFF)

RASFF is Rapid Alert system for Food and feeds. 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 European Commission Authentication Service and notifications are disseminated to the Nigeria Custom 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 18. 5: Border rejections received from the European Commission Authentication Service in 2020

Date	Ref. No.	Reason for Rejects	Comments
09/01/2020	2020.0132	Attempt to illegally export grounded crayfish from Nigeria to United Kingdom.	Alert disseminated to relevant M DAs for necessary action.
22/01/2020	2020.0307	Withdrawal of live bivalve molluscs harvested in France because of possible contamination with norovirus.	Alert disseminated to relevant MDAs for necessary action.
11/02/2020	2020.0663	Aflatoxins B1-9-1 T ot-13.74 in organic roasted groundnuts from Nigeria.	Alert disseminated to relevant MDAs for necessary action.
13/02/2020	2020.0743	Attempt to illegally export dried beans to UK.	Alert disseminated to relevant MDAs for necessary action.
12/03/2020	2020.4450	Migration of aluminium (1.9mg/kg - ppm) from metal baking pan exported to Belgium from Nigeria	Alert dissemi nated to relevant MDAs for necessary action.
13/03/2020	2020.1178	Attempt to illegally export dried beans to UK	Alert disseminated to relevant MDAs for necessary action.
31/03/2020	2020.1465	Salmonella enterica ser Menston (in 1 out 5 samples) in Sesame seed exported to Greece from Nigeria.	Alert disseminated to relevant MDAs for necessary action.
15/04/2020	2020.1654	Salmonella spp in Sesame seed exported to Poland	Alert disseminated to relevant MDAs for necessary action.
21/04/2020	2020.1732	Petrol smell and taste in brown beans from Nigeria via Netherland to Germany	Alert disseminated to relevant MD As for necessary action.
21/04/2020	2020.2164	Too high content of lead(163.84mg/kg) in Manganese sulphate monohydrate exported to Austria.	Alert dissemina ted to relevant MDAs for necessary action.
27/05/2020	2020.2226	Aflatoxin (6.7µg/kg) in unpeeled Sesame seed exported to UK	Alert disse minated to relevant MDAs for necessary action.
3/06/2020	2020.2285	Illegal export of Smoked fish to UK	Alert disseminated to relevant MDAs for necessary action.
5/06/2020	2020.2322	Illegal export of Dried Beans to Germany	Alert disseminated to relevant M DAs for necessary action.
16/06/2020	2020.2388	Zinc Oxide with Dioxin exported to Belgium from Germany.	Alert dissemina ted to relevant MDAs for necessary action.
14/07/2020	2020.2859	Border rejection Attempt to illegall y import various food items smoked fish, beans, dairy chicken, melon and	Alert disseminated to relevant MDAs for necessary action.

17/07/2020	2020.2933	Alert for follow up on Unauthorised Colour Sudan 1 (>50mg/kg-ppm) and Orange colour ii (>50mg /kg-ppm) in cayenne pepper powder from Nigeria to Belgium	Alert disseminated to relevant MDAs for necessary action.
20/07/2020	2020.2953	Salmonella spp in 1 out of 5 samples /25g of Sesame seed from Nigeria to Spain	Alert disseminated to relevant MDAs for necessary action.
23/07/2020	2020.3005	Information for attention on Aflatoxin B1:44,4 µg/kg -ppb) in kuli kuli from Nigeria to United Kingdom.	Alert disseminated to relevant MDAs for necessary action.
21/08/2020	2020.3357	Salmonella present/25g) in hulled Sesame seed exported to Greece	Alert disseminated to relevant MDAs for necessary action.
26/08/2020	2020.3416	Aflatoxins (B1=8.6µg/kg) total 10.16µg/kg in hulled Sesame seed.	Alert disseminated to relevant MDAs for necessary action.
28/08/2020	2020.3479	Aflatoxins (B1=14.7µg/kg) total 20.1µg/kg in black pepper.	Alert disseminated to relevant MDAs for necessary action.
4/09/2020	2020.3587	Aflatoxins in ground ginger from Hungary (31 µg/kg – ppb). Raw material from Nigeria	Alert disseminated to relevant MDAs for necessary action.
10/09/2020	2020.3686	Attempt to illegally export a prohibited product into the UK.	Alert disseminated to relevant MDAs for necessary action.
15/10/2020	2020.4331	Unauthorised orange II col our in grind dried pepper from Nigeria exported to Belgium.	Alert disseminated to relevant MDAs for necessary action.
3/11/2020	2020.4689	High content of Cyanide acid (57.1mg/kg-ppm) in Cassava flour exported to Ireland.	Alert disseminated to relevant MDAs for necessary action.
20/11/2020	2020.	Cypermethrin 0.79mg/kg ppm and unauthorised substance methamidophos (0.06mg/kg-ppm) and acephate (0.057mg/kg-ppm) in Chilli peppers from Nigeria to Ireland.	Alert disseminated to relevant MDAs for necessary action.
26/11/2020	2020.5337	Aflatoxin (B I =27.33µ g/kg-ppm) in KuliKuli Peanut Snack exported to UK.	Alert disseminated to relevant MDAs for necessary action.
27/11/2020	2020.5357	Aflatoxins B1=5.3µg/kg -ppm in Groundnut exported to UK.	Alert disseminated to relevant MDAs for necessary action.
1/12/2020	2020.5445	Salmonella Widemarsh and Salmonella Hull in sesame seeds exported to Lithuania from Nigeria via Ukraine.	Alert disseminated to relevant MDAs for necessary action.

3/12/2020	2020.5519	Aflatoxin (BI =µg/kg -ppm) in groundnuts from Nigeria exported to Poland.	Alert disseminated to relevant MDAs for necessary action.
14/12/2020	2020.5780	unauthorised substanceet hylene oxide in unhulled sesame seeds from Nigeria exported to Germany	Alert disseminated to relevant MDAs for necessary action.

K. PV/PMS Newsletter:

The FDIC prepares quarterly newsletters to inform stakeholders on current trends in pharmacovigilance. Three (3) pharmacovigilance newsletters were prepared and disseminated to stakeholders within the period under review. The newsletters disseminated are as follows:

1. Fluoroquinolones and the risk of disabling and potentially irreversible side effects
2. Regulation and Control of Medical Products in Response to COVID 19 and
3. Pharmacovigilance: a view on medical devices.

L. National Drug Safety Advisory Committee (NDSAC)

The NDSAC was reconstituted with new members based on the recommendation of the Director-General (NAFDAC) and the approval of the honourable Minister of Health**.** Due to the pandemic, no NDSAC meeting was convened during the period under review.

M. NAFDAC Consumer Safety Club (NCSC)

The NAFDAC Consumer Safety Club (NCSC) is a public enlightenment and sensitization platform used by the Agency in its fight against substandard and falsified products. In order to achieve the aims and the objectives of NCSC, competitions are held at state, zonal and national levels, and a grand ceremony is held at the national level to honour winners of the National Quiz Competition conducted for both the senior and junior cadres. Participants of the quiz competition are drawn from the six (6) geo-political zones of the country. The National Quiz Competition was conducted on 19th February, 2020 at Silverbird Galleria, Central Business District, Abuja and the related 13th NCSC Award Ceremony was held on 20th February, 2020 to recognize and honour winners of the National Quiz Competition.

Table 18.6: Winners of the NCSC Competition (Junior and senior categories)

Junior Secondary Category				
S/No.	**Name**	**School**	**Score**	**Position**
1	Clement Favour	Logos Intl Secondary School Owerri Imo State (SE Zone)	14	1ST
2	Orru Oritsetimiyin	Federal Government College Warri Delta State (SS Zone)	12+4 at Tie Break	2ND
3	Eze Joseph	St Francis Catholic School, Idimu, Lagos State (SW Zone)	12+2 at Tie Break	3RD
Senior Secondary Category				
1	Gabriel Emmanuel	Federal Government College, Ikot-Ekpene, Akwa Ibom State (SS Zone)	8	1ST
2	Taiwo Favour	St. James Anglican College, Birnin Kebbi, Kebbi State (NW Zone)	4	2ND

N. Review of Safety Documents (PSUR & RMP)

One hundred and seventeen (117) Periodic Safety Update Reports (PSUR) and Seven (7) RMP were received and all were reviewed within the periods. Below is a breakdown of these products:

Table 7: Number of PSURs and RMP Received and Reviewed in 2020

SN.	PMS Tools	Received	Reviewed	Undergoing Review
1.	PSURs	117	117	Nil
2.	RMPs	7	7	Nil

O. Global Listing

A total of nine (9) approved inventories of products for global listing of supermarket items were received and communicated to the respective states for monitoring and compliance within the year under review.

P. Updated International Package Leaflet

A total of nine (6) Updated international package leaflets of registered products were received and reviewed within period under review.

Q. Surveillance and Mop-up of unregistered and substandard Alcohol- based Hand Sanitizers in the thirty- six states of the Federation and the Federal Capital Territory, Abuja.

The Surveillance and Mop up exercises were carried out on 16th March 2020, 26th March 2020, 1st April 2020, 7th April 2020, 8th April 2020, 15th April 2020 and 16th April 2020. The samples were procured on 26th March 2020 and the laboratory analysis was concluded on 6th May 2020. Enforcement actions against illegal manufacturers and distributors of unregistered and substandard Alcohol-based Hand Sanitizers were implemented on 16th March 2020, 26th March 2020, 1st April 2020, 7th April 2020, 8th April 2020, 15th April 2020 and 16th April 2020 to serve as deterrent.

R. GDP Inspection/ Risk Based Annual PMS Plan for 2021

Letters were sent out to fifty (50) selected local drug manufacturing company requesting for List of their Distributors for Good Distribution Practices (GDP) inspection in October, 2020. The annual PMS plan for 2021 has been developed using the WHO/USP Medicine Risk Based (Med RS) tool.

S. Meetings and Advocacy Visits

i. Meeting with Pharmaceutical Wholesalers and Distributors Association of Nigeria

A team of PV/PMS officers led by the Deputy Director, attended a meeting of the Pharmaceutical Wholesalers and Distributors Association of Nigeria (Lagos State Chapter) to discuss ways of improvement in the drug distribution system in line with NAFDAC Good Distribution Practice Guidelines. The meeting was held on 11th March, 2020 at Business School of Netherlands (BSN), No. 8, Adekunle Fajuyi way, Lagos.

ii. Annual Scientific Conference of Association of General and Private Medical Practitioners of Nigeria (AGPMPN)

The Deputy Director (PV/PMS) and one staff represented the DG (NAFDAC) at the Annual Scientific Conference of Association of General and Private Medical Practitioners of Nigeria (AGPMPN) which held at Golden Tulip Hotel, Amuwo Odofin, Festac, Lagos on 19th March, 2020. The meeting was cut short due to the pandemic.

iii. Other Meetings

The Directorate participated in the following periodical meetings during the period under review:

- Meetings of the National Advisory Committee on Vaccine and Biologics (NACVB)
- National Codex Committee General Purposes Technical Sub-Committee (NCC-GPTC) Meeting
- Regulation Meetings (Regulation review, Regulation drafting etc).
- Lagos State Office Final Food and Cosmetics Approval Meeting (LSO FFCAM) and
- Meeting of Global Listing of Supermarket Items (GLSI) Taskforce.

viii. PAVIA Annual Consortium

Within the period under review, PAVIA Annual Consortium meeting was held on 19 October 2020. The PAVIA project aims to strengthen Pharmacovigilance (PV) in four African countries. The countries are Ethiopia, Nigeria, Swaziland and Tanzania.

It is funded by the European-Developing Countries Clinical Trials Platform (EDCTP), a funding mechanism under the EU's Horizon 2020 research program that aims to evaluate, primarily through clinical trials, new products for poverty-related infectious diseases (PRDs) in sub-Saharan Africa and to build local capacity for such trials.

ix. Advocacy to National Tuberculosis & Leprosy Control Programme (NTBLCP), Mabushi

An Advocacy visit was organized to strengthen collaboration between NAFDAC and NTBLCP to improve detection and reporting of ADRs as well as to solicit support and assistance toward improving ADR reporting and sending reported ADR forms to the National Pharmacovigilance Centre (NPC). NTBLCP is prepared to intensify their collaborative efforts with NAFDAC to improve ADR reporting.

x. Collaborative Meeting on AEFI Reporting with Nigerian Center for Disease Control (NCDC)

National Center for Disease Control (NCDC) and National Agency for Food and Drug Administration and Control (NAFDAC) organized had several meetings to find a way to Integrate SORMAS (Surveillance Outbreak Response Management and Analysis System) and ADR reporting platform on a seamless reporting of AEFI's (Adverse Event Following Immunization) and also ADRs (Adverse Drug Reactions). The meetings were held both virtually and also at the NCDC Headquarters, Jabi, Abuja.

xi. Draft of National Vaccine Policy

A staff of PV/PMS represented the Agency at the National Vaccine Policy Drafting with FMOH on the 9th of December 2020.

xii. ECOWAS Risk based Post Marketing Surveillance

A zoom meeting titled 'ECOWAS Risk based Post Marketing Surveillance was held on the 9th of December 2020.

xiii. Joint stakeholder meeting through Zoom virtual for the Supermarket operators in Abuja and other States

A stakeholder's meeting was held on the 14th of December, 2020 with the National association of Supermarket owners alongside Staff of PV/PMS, FCT and R&R.

xiv. Visit to Lagos State Health Service Commission

A team of PV/PMS officers visited the Lagos State Health Service Commission for Pharmacovigilance Advocacy to be able to adequately coordinate & encourage adequate reporting of ADRs by the hospitals under them. The meeting was successful and a letter of request was to be forwarded to the Permanent Secretary, Lagos State Health Service Commission (LSHSC) to schedule a meeting with other key stakeholders of the commission.

xv. PV Presentation at St. Nicholas Hospital, Lagos Island

PV/PMS Lagos made a presentation during the hospital's clinical meeting. The presentation was centered on Pharmacovigilance in Nigeria; background and relevant laws and Act that established and empowers NAFDAC to regulate drug safety and Pharmacovigilance. More emphasis was laid on adequate reporting of ADRs.

Table 8: Nationwide Surveillance in 2020

Month/ Product	Food	Drugs & Medical Devices	Cosmetics
March	61	182	22
April	73	31	54
May	41	82	19
June	29	2	1
July	29	16	1
August	191	160	25
September	130	64	45
October	60	175	57
November	15	54	41
December	33	36	25

Table 9: Report of Field Activities per Zones, Abuja and Lagos

Zones/Offices	No Of PMS Activities	No Of Investigations Carried Out	No Of Establishment Visited for M op-Up	No Of Products Moppe d-Up	No Of Consumer Complaints Received	No Of Institutions Visited for PV Advocacy	No Of ADR Reports Received & Sent to PV Center	No Of Sanctions Issued
Lagos PV/PMS	245	43	17	1614	36	111	31	20
Northeast Zone	1591	247	150	54	14	275	0	8
Northwest Zone	4408	181	1353	335	15	97	99	331
North Central	812	121	38	556	7	16	6	202
Southeast Zone	568	3	173	373	1	210	0	17
Southwest Zone	234	5	0	35	0	5	0	7
South S Z	614	93	246	548	14	20	0	4
Abuja	351	19	127	1180	30	0	1242	5
Total	**8823**	**712**	**2104**	**4695**	**117**	**734**	**1378**	**594**

18.5. Recommendations for Improved Performance

To boost the activities and overall performance of the PV/PMS Directorate, the following have been recommended:

- Increase in the number of personnel to process ADRs and carry out all the PMS activities, to cover PMS monitoring in Abuja and its environs.
- Increase in imprest allocation to cover all the activities and also for carrying out PMS Surveillance in Abuja and Lagos (fuelling, maintenance of operational vehicle and other logistics).
- There is need for procurement of up-to-date Pharmacovigilance Reference materials as the most recent version currently available is BNF 2016

Chapter 19

LEGAL SERVICES DIRECTORATE

19.1. Our Goals

1. To render effective legal service to the Agency.
2. To reduce litigation cost by handling at least 90% of the Agency's cases.
3. To vigorously pursue training and retraining of legal officers

19.2. Functions of the Legal Services Directorate

The Legal Services Directorate of the Agency is charged with the following responsibilities.

- Prosecution and defense of criminal and civil cases before the various courts all over the Federation.
- Monitoring criminal and civil cases involving NAFDAC.
- Rendering legal opinion to all formations of the Agency.
- Drafting and vetting of agreements and other legal instruments involving the Agency.
- Conducting searches and investigation of transactions involving the Agency and the preparation of title deeds thereof.
- Vetting of documents forwarded by Regulatory and Registration Directorate of the Agency for the purpose of registration of products.
- Vetting, drafting and preparation of Regulations and Guidelines for smooth operation of the Agency.
- Representation of NAFDAC in arbitration and negotiations relating to the interest of the Agency in e.g. real estate, statutory functions and other issues.
- Preparation and presentation of the Agency's position at public hearings before the National Assembly, State Houses of Assembly and other bodies duly constituted by law.
- Handling of probate matters relating to deceased staff and other staff matters referred to it by the Administration and Human Resources Directorate.
- Liaison with Legal Advisers of the Federal Ministry of Health, Secretary to Government of the Federation, State House, Honourable Attorney General of the Federation and Minister of Justice, Honourable Attorneys-General of the States and Commissioners of Justice, the Judiciary, the National Assembly, State Houses of Assembly, the Police, EFCC, Patent and Trademark Office, Corporate Affairs Commission and other relevant government and non-governmental bodies.
- Involvement in the training of members of staff on request by Planning, Research and Statistics Directorate and other bodies.
- Attendance of consultative meetings to settle or resolve Regulatory and Registration disputes.

19.3. Activities Cases (On-going and Concluded)

A. The Directorate instituted and filed charges against offenders of NAFDAC Laws and also filed processes in the defence of the Agency in the civil cases instituted against her.

a) **IBABATU HAFISA UMAR V DG NAFDAC& 3 OTHERS**: The plaintiff instituted action against NAFDAC in the FHC Bauchi seeking a restraining order against the Agency and is claiming N10, 000,000.00 damages on the grounds that the Agency has no power to demand for investigative charges.

b) **VEN NDUBUEZE, HUMPHREY UCHECHUKWU Vs NAFDAC-** NICN PH/147/2019- The plaintiff instituted action at the National Industrial Court for unlawful dismissal from service. The plaintiff is seeking for the Court to order the Agency to pay him arrears of salaries and allowances from 2012 to date, to resume payment of his salary and allowances and to order that he is a bona fide staff of the Agency.

All cases earlier reported are still ongoing.

19.4. Other Activities

B. The Directorate has vetted over one thousand, three hundred and twenty-seven (1,327) registration documents from January to December 2020.

a) Drugs (medicines, medical devices & cosmetics) - 983
b) Food - 344

C. The Directorate drafted the following which were also executed:

I. Sixteen (16) Contract Agreements
II. One (1) Memorandum of Understanding

D. The Directorate's officers served and are still serving on the following committees:

- Food and Drugs Registration Committee
- NAFDAC Benchmarking Committee
- African Regional Pharm Crime Working Group Roundtable
- NAFDAC Traceability Committee

19.5. Challenges/ Gaps

- Failure of the Police to produce accused persons for arraignment.
- Transfer of Police IPO and their failure to attend Court proceedings.
- Failure to refund/payment of touring advance on time to IPO's, NAFDAC staff and retired staff who serve as witnesses.
- Reluctance of NAFDAC staff to serve as witnesses in the Agency's cases.
- Inconclusive investigation by the Police.
- Delay in payment of External Solicitors fees.

Chapter 20

PLANNING RESEARCH AND STATISTICS (PR&S) DIRECTORATE

20.0. Introduction

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

20.1. Activities of Planning, Research and Statistics (PR&S) Directorate in 2020

Trainings

PR&S Directorate collated staff training needs and successfully coordinated the participation of staff and stakeholders in various trainings/staff development programmes. A total of Four Thousand, One Hundred and Eighty-eight (4,188) staff of the Agency participated in Seventy-seven (77) training programmes/meetings including in-house trainings. (i.e. Four Thousand, One Hundred and Sixteen (4,116) staff attended Sixty-one (61) Local Programmes while Seventy-two (72) staff attended Sixteen (16) various International programmes).

NB: Please note that most of these training programmes/meetings were held virtually due to COVID-19 pandemic.

The breakdown is as shown in the tables below:

Table: Breakdown of staff participation at Local & Foreign Training Programmes in 2020.

Programme	Foreign		Local		Total	
	No of Programs	Staff participation	No of Programs	Staff participation	No of Programs	Staff participation
Trainings/Workshops	13	68	52	4,081	65	4,149
Meetings	3	4	9	35	12	39
Total	16	72	61	4,116	77	4,188

The Directorate also coordinated the hosting of three (3) Virtual TMC Meetings in year 2020.

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 the services of students on Industrial attachment, with courses relevant to the operation of NAFDAC to our various laboratories in Lagos, Port-Harcourt, Agula, Maiduguri and Kaduna. The successful IT students are exposed to the use of state-of-the-Art Laboratory equipment to enhance the practical experience.

During the year under review, a total of Seven hundred and thirty-five (735) application letters were received out of which three hundred and sixty-two (362) applications were processed, ninety-six (96) Assumption letters were received from the various laboratory and two hundred and sixty-three certificates were issued at the end of 2020.

Excursion

During the year 2020, PRS coordinate/implemented Seven (7) excursion visits to the Agency by students of nursery/primary, secondary, and tertiary institutions considered in FCT, Nassarawa, Niger, Kaduna and Akwa Ibom states respectively, with a total of Two hundred and thirty-five **(235)** students being enlightened/ sensitized.

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 program in the agency.
vi. Providing technical guidance to Directorates of the Agency by incorporating appropriate M&E systems into their program.

The following are some of the achievements of the M&E Division of PR&S Directorate in the year 2020:

1.0 The Division reviewed the 2020 Annual reports received from all the Directorates of the Agency. These reports were validated for detailed statistical analysis and finalization of the agency's 2020 Annual report.

2.0 The M&E Division was expected to collect and analyze two hundred and sixteen (216) monthly reports from the eighteen (18) directorates of the agency in the year under review, however, due to the challenges associated with the Covid-19 pandemic, only Ninety-five (95) monthly reports were submitted by Directorates. Of the Ninety-five (95) monthly reports submitted, only 36% of such reports submitted by the Directorates met the specified timeline of 15th of the preceding month. These reports were validated and analyzed by the M&E division to produce periodic performance evaluation reports for management review and evidence-based decision making.

3.0 The M&E Division prepared the 2020 mid-year Performance Evaluation of Directorates activities from January to June Reports of 2018, 2019 and 2020. The activities of the various directorates in the agency witness a notable decrease in the mid-year of 2020 when compared with corresponding period in 2018 and 2019. This may be related to low activities in some months due to COVID 19 pandemic.

4.0 The M&E division in collaboration with Quality Management System (QMS) team streamlined the agency's key performance indicators and subsequently developed data collection templates for the Directorates for ease of data collection, collation and analysis.

5.0 Under the Pharmacists Council of Nigeria (PCN) Decree 91 of 1992, Pharmacy graduates are statutorily required to undergo a compulsory one-year continuous internship training programme in a registered Pharmacist Council approved internship center. NAFDAC is one of the approved centers for training of Intern Pharmacists. The M&E division of PR&S coordinates this training for the agency. In the year under review, a total of Four hundred and twenty-eight (428) Internship Application were processed, the agency however did not engage new intern pharmacists in the year 2020 to ensure compliance with the COVID-19 protocol at workplace.

Ninety-four (94) Intern pharmacists already in the system were Discharge out of which Eighty-six (86) were issued Internship certificate of completion on request.

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 findings to management for evidence-based regulatory decision making. The Division also provides Library Services to staff of the Agency.

During the period under review, the Division carried out the following activities:

- The following research activities were conducted in collaboration with other Directorates:

- ✓ NAFDAC COVID-19 Protocol Awareness Survey
- ✓ Chloroquine Use in Nigeria.

- The Library Unit carried out user education and Selective Dissemination of Information (SDI) so as to encourage the use of library. The Unit attended to Five Hundred and Forty-Four (544) users during the year under review.
- The Directorate collated submissions from relevant Directorates on security related issues. The information was used to produce the Agency 's Eight (8) reports to the Joint Intelligence Board (JIB) during the year under review.
- During the year 2020, PR&S Directorate through R&S Division received and reviewed total of Seventeen (17) foreign GMP Inspections Reports.

S/No.	Summary of Research and Statistics (R&S) Division Activities for the Year, 2020	Total
1	Number of Overseas GMP Inspections Letters Processed	0
2	Number of Overseas GMP Complaints Received	0
3	Number of GMP Inspection Reports Reviewed	17
4	Number of Surveys Designed	3
5	Number of Surveys Concluded	1
6	Number of Surveys Ongoing	1
7	Other Statistical Analysis Carried Out	2
8	JIB Report Prepared	8
9	No. of Library Users	544

Technical Services (TS) Division

Technical Services Division is charged with the responsibilities of coordinating the collaboration with development partners, developing as well as reviewing technical presentations, speeches and talking points for the Director General.

During the period under review the Division participated in the following collaborative engagements among others:

- The meeting of National Trade Facilitation Committee
- The meeting of National Approval Committee (NAC) on ECOWAS Trade Liberalization Scheme (ETLS) Organized by The Ministry of Foreign Affairs, Abuja.
- The meeting of Mapping and Analysis of Nigeria's E-Commerce Ecosystem.
- Inspection of companies that applied for ECOWAS Trade Liberalization Scheme (ETLS) Certificate organized by Federal Ministry of Foreign Affairs, on 4th to 15March, 2020.
- Review of Mid-Term of Nigerian Industrial Revolution Plan (NIRP)
- The meetings of ECOWAS Harmonized Standards for face masks and hand sanitizer.
- The implementation of the National Enterprise Development Programme (NEDEP).
- The Enlarged Stakeholders Meeting of the UK-Nigeria Economic Development Forum (EDF)
- Coordination of the meeting of NAFDAC with World Bank Group on COVID-19 measures.

Chapter 21

HUMAN RESOURCE MANAGEMENT DIRECTORATE

21.0 Introduction:

The Directorate is one of the three Service Directorates and 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 five (5) Divisions namely:

1. Appointment Promotion & Discipline
2. Staff Welfare and Training
3. Admin & Corporate matters
4. Maintenance & Engineering.
5. Records & Registry

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 recommends proper disciplinary actions to be taken by the Agency against erring staff.
- Documentation of new staff, prepares staff nominal roll and issues of identify cards.
- Custody of records of all 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.

21.1 Appointment, Promotion & Discipline Division

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

The 2020 promotion Interview was conducted successfully in November 2020. A Total of 586 staff members were invited, only 561 staff members participated in the exercise. 369 Senior staff members were promoted, 2 Senior staff members were also promoted to the rank of Directors based on Council recommendations and Special promotion was also given to 2 senior staff members who were outstanding based on Social promotion grounds. Therefore, a total number of 371 Senior staff were promoted.

26 junior staff members were promoted and the appointment of 26 staff were upgraded and converted to different cadres.

21.2 Discipline

During the year under review, Disciplinary committee meetings were held and different types of disciplinary measures were meted out to erring staff. These include termination of appointment of officers who were on study leave and absconded eventually.

21.3 Records & Registry

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

Staff Position

- Staff strength - 2 ,157
- Females - 925
- Males - 1, 232
- Senior Staff - 1, 884
- Junior Staff - 273

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

21.4 Leave Matters

During the year, all staff of the Agency enjoyed various types of leave, such as the normal Annual leave, sick leave or casual leave.
The Agency however encourages staff development and training which enabled 5 staff to proceed on study leave to enhance their productivity on the job after the training.

21.5 Staff Welfare and Training

The Division is responsible for staff training and general staff welfare

a. **Welfare**
   During the year under review, a total of 69 staff members benefitted from the staff welfare package of N50, 000 each, for wedding ceremonies or loss of close family members.
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.

22.6 Admin & Corporate 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.

22.7 Maintenance & Engineering Unit-

- Office Accommodation/Development Projects
- Development of prototype office accommodation for some selected states.
- Purchase of furniture for some state offices.
- Renovation of some state offices.

22.8 Insurance Matters

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

22.9 Council Matters

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

22.10 Transport & Maintenance

Activities of the Division are:

- The Agency currently has 198 functional vehicles and 28 non-functional vehicles.
- The Agency also purchased ten (7) Toyota Hilux vans.

22.11 Challenges

- Inadequate funding
- Lack of adequate office accommodation
- Excessive political interference in recruitment.

22.12 Way Forward

- Improved funding
- Continuous training and retraining
- Adherence to work plan and standard operating procedures.
- Constant monitoring and evaluation of programs and activities.

Chapter 22

FINANCE AND ACCOUNTS DIRECTORATE

23.0 Preamble

The Finance & Accounts Directorate is essentially a service Directorate responsible for the day-to-day administration of financial and accounting (sources and use of funds, recording and reporting) functions of the Agency.

The ISO 9001:2015 Standard is the fulcrum on which the established objective of the Directorate is hinged. The audacity to carry out all the Finance and Accounts functions was drawn from financial authorities such as the Financial Regulations, Treasury Circulars and other extant rules.

23.2 Highlights of Activities

The following are the highlights of activities recorded in the Directorate during the year under review:

- Revenue generation compilation and analysis
- Processing and payment of all approved expenditures for staff members, contractors and other government Agencies.
- Updating of all relevant fixed assets registers and schedules.
- Preparation, Submission, and defence of the Agency's 2020 Budget Proposal to the Federal Ministry of Health, Federal Ministry of Finance, Budget and National Planning and the National Assembly.
- Presentation and defence of 2019 Budget performance of the Agency at Federal Ministry of Health, Federal Ministry of Finance, Budget and National Planning and the National Assembly.
- Attending to and make clarifications on all enquiries from the supervisory Agencies and committees of relevant government bodies.

The activities of the Finance and Accounts Directorate in 2020 shall be reported in two parts namely:

I. Finance (receipts and payments)
II. Accounts (record and reporting).

23.3. Finance (Receipts and Payments)

Revenue Generation

In the year under review, the sum of N13,799,805,510.32 (Thirteen Billion, Seven Hundred and Ninety-Nine Million, Eight Hundred and Five Thousand, Five Hundred and Ten Naira Thirty-Two Kobo) only was generated. This amount represents an increase of 17.57% higher than the year 2019 amount of N11,375,711,923.89 (Eleven Billion, Three Hundred and Seventy-Five Million, Seven Hundred and Eleven Thousand Nine Hundred and Twenty-Three Naira Eighty-Nine Kobo) only.
The breakdown of Revenue Generation for year 2020 is given below:

S/NO	Revenue Item	2020 N	2019 N	Remark
1	IGR	2,490,160,810.70	2,648,682,977.78	
2	User Fee	10,577,761,400.32	8,315,716,705.62	
3	VAT	731,883,299.31	411,312,240.49	
	Total	**13,799,805,510.32**	**11,375,711,923.89**	**Up by 17.57%**

23.4 Salary and Wages:

In the year under review, staff salaries and allowances were prepared and paid by Accountant General's office through IPPIS promptly. However, payment of Corps Members and Intern Pharmacists allowances were paid by the Agency from the Internally Generated Revenue.

A total of N141,664,545.78 only was paid as allowances for Corps Members and Intern Pharmacists. The breakdown is as follows:

S/NO	Item	2020 (₦)	2019 (₦)
1	NYSC Members	44,385,871.87	49,942,931.49
2	Intern Pharmacists	88,600,161.45	122,204,899.08
	Total	**132,986,033.32**	**172,147,830.57**

Other activities carried out include:

- Adjustment in staff salaries which includes implementation of cooperative deduction e.g NASMA, FODAL etc including loan deductions from various banks.
- Attending to various complaints by staff in the areas of NHF and Pensions, salary shortfalls and the general review and check of monthly payroll reports for correctness, accuracy, and completeness.
- Preparation/ computation of arrears of promotion for payment to all promoted staff members.

23.5. Treasury Management

During the year under review, the Treasury Management Unit ensured the prompt payment of all approved staff members and third-party claims. All payments were made to their respective beneficiaries at when due, thereby, achieving the Directorate's established target.

In year 2020, a total of N5,894,595,947.53 (Five Billion, Eight Hundred and Ninety-Four Million, Five Hundred and Ninety-Five Thousand and Nine Hundred and Forty- Seven Naira Fifty-Three Kobo) only was paid to both staff members and third party.

The breakdown is as follows:

S/NO	DESCRIPTION	AMOUNT
1	Capital Dev. Fund	42,328,901.18
2	Capital Contingency	734,495,539.30
3	Recurrent	4,607,677,195.59
4	Overhead (GIFMIS)	6,302,966.58
5	Recurrent (Donor Fund)	3,827,263.57
6	CBN Intervention Fund	499,964,081.31
		5,894,595,947.53

23.6. Budget Allocation

To run our Directorates, Zonal and State offices smoothly, a total of N404,648,880.00 **(Four Hundred and Four Million, Six Hundred and Forty-Eight Thousand, Eight Hundred and Eighty Naira)** only was disbursed as Budget Allocation to all the Directorates, Zonal and State Offices in 2020.

23.7. Accounts (Recording and Reporting)

The Directorate continued in the preparation and finalization of the management account for years 2018 and 2019, responding to audit enquiries, engagement with our external auditors as well as receiving/attending to Federal auditors on routine statutory visit.
In the year under review, the Directorate maintained an excellent working relationship with all our supervisory/regulatory bodies.
Enquiries from the Federal Ministry of Health, the Senate and House of Representatives of the National Assembly were promptly attended to. Similarly, statutory inspectors/auditors from the offices of the Accountant General of the Federation, Auditor General for the Federation were also received and attended to accordingly.
Also, inspectors from the Federal Inland Revenue Service (FIRS), were received at various times to examine our books for their oversight duties.

Also, the Directorate undertook inventory of stock in all the stores and laboratories of NAFDAC. Similarly, all the various fixed assets schedules and registers were updated. Assets' verification exercise was conducted and assets in bad conditions were transferred to the appropriate stores.

23.8. Budget:

Year 2020 Budget implementation was not fully implemented. It was affected by Covid-19 Pandemic. Nevertheless, the Budget Performance for 2020 could be seen at a glance as detailed below:

Table 23. 3. Government Based Budget

	Overhead Allocation (₦)	Capital Allocation (₦)
Appropriations	7,568,033.00	129,364,056.00
Releases	5,576,024.74	42,775,248.62
Utilization	5,408,404.95	42,328,901.18
Performance %	97%	99%

23.9. Directorates Budget

In the year 2020, the Directorate carried out the preparation and submission of 2021 Budget Proposal to National Assembly and followed up with defence of same at the Federal Ministry of Health, Senate Committee on Health, House of Representatives Committee on Health Care Services as well as the Budget Office of the Federation. Other duties performed included the following:

- Attending to invitation from Federal of Ministry of Health in respect of 2020 Budget Retreat.
- Preparation and submission of Budget Performance Report for both capital and overhead year 2019 to the Budget Office of the Federation, the Senate and the House of Representatives.
- Attending to Request by Federal Ministry of Health for Information on Capital Projects for 2018 and 2019.
- Presentation and defence of 2019 Budget performance of the Agency at Federal Ministry of Health, Federal Ministry of Finance, Budget and National Planning and the National Assembly.

- Submission of Schedules and Evidence of Remittances to the Consolidated Revenue Fund (CRF) from 2014 to 2019 to House of Representatives Committee on Finance.

23.9. Conclusion

The Finance and Accounts Directorate is basically the live blood upon which he operation of the entire Agency rests. It is in appreciation of this pivotal role that the Directorate will continue to make funds available in a timely manner for the smooth operation of the activities and programmes of the Agency.

Chapter 23

NAFDAC ZONAL OFFICES

24.1. North Central Zone

The North Central consist of six (6) States namely, Benue, Nasarawa, Niger, Kogi, Kwara and Plateau States.

24.1.1. Highlights of Activities

1. **Routine Inspection**
   Five Hundred and Eighty-Eight (588) routine inspections were carried out during the year under review
2. **Sanctions**
   Nine Hundred and Fifty-Nine (959) sanctions were imposed on various establishments in the zone during the year under review
3. **Surveillance**
   Two Thousand Two Hundred and Fifty-One (2,251) surveillance activities were carried out during the year under review

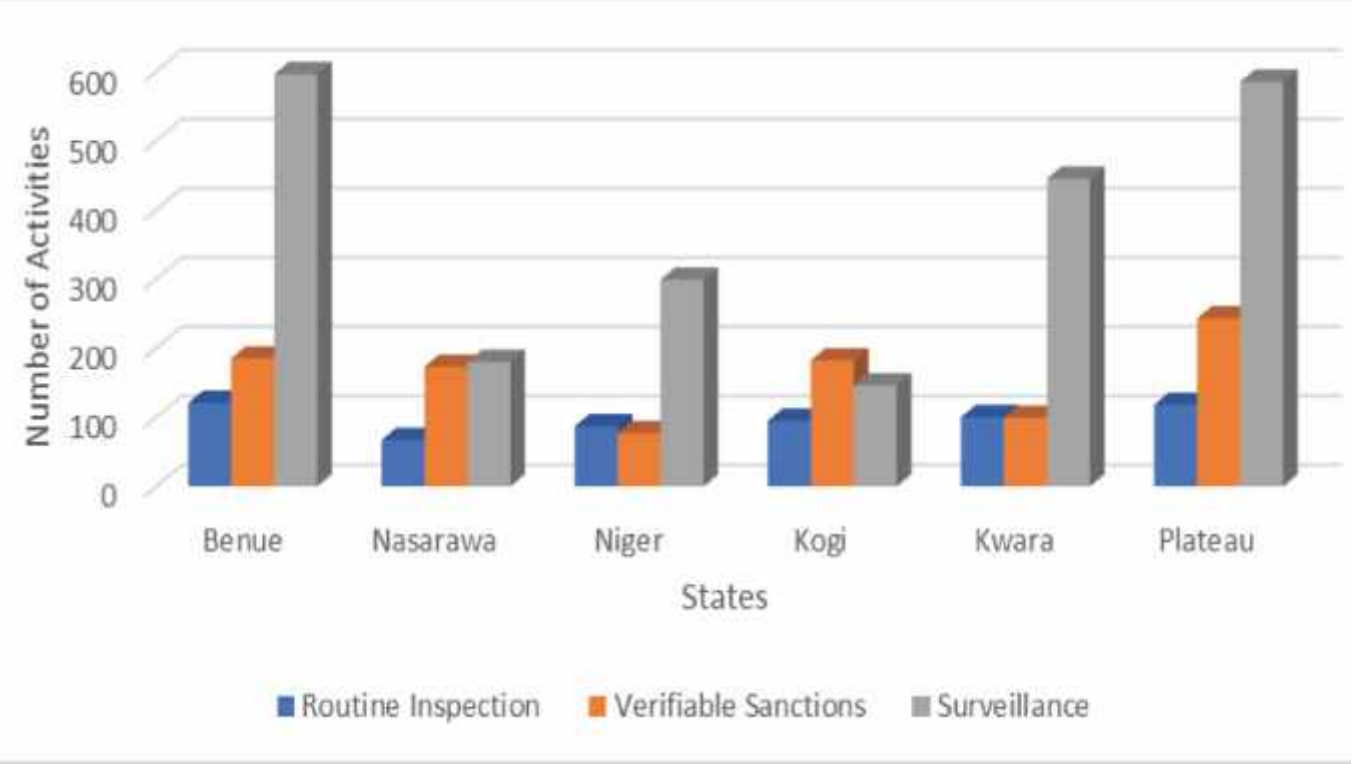
Table 24.1.1:Activities of States in the North Central by Directorates Zone January – December 2020

Directorates	Routine Inspection	Verifiable Sanctions	Surveillance
DER	15	12	0
CER	9	10	13
R&R	0	116	0
PV/PMS	0	542	1,970
VMAP	31	25	15
FSAN	533	254	253
NCS	0	0	0
I & ENF	0	0	0
Total	**588**	**959**	**2,251**

Table 24.1.2: Activities of States in the North Central Zone January – December 2020

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Total
1.	Benue	121	185	596	
2.	Nasarawa	67	173	180	420
3.	Niger	87	77	299	463
4.	Kogi	95	182	146	423
5.	Kwara	100	99	445	644
6.	Plateau	118	243	585	946
	Total	**588**	**959**	**2,251**	**3,798**

Figure 24.1.1:Activities in the North Central Zone January – December 2020



24.2. Northwest Zone

Routine Inspection: A total number of Two Thousand Five Hundred and Forty-Five (2,545) routine activities were carried out within the zone in the year under review.
Verifiable Sanction: A total number of One Thousand, Two Hundred and Fifty-Five (1,255) verifiable sanctions were meted out within the zone in the year under review.

Surveillance: A total number of Thirteen Thousand, Six Hundred and Sixteen (6,951) Surveillance activities were carried out within the zone in the year under review

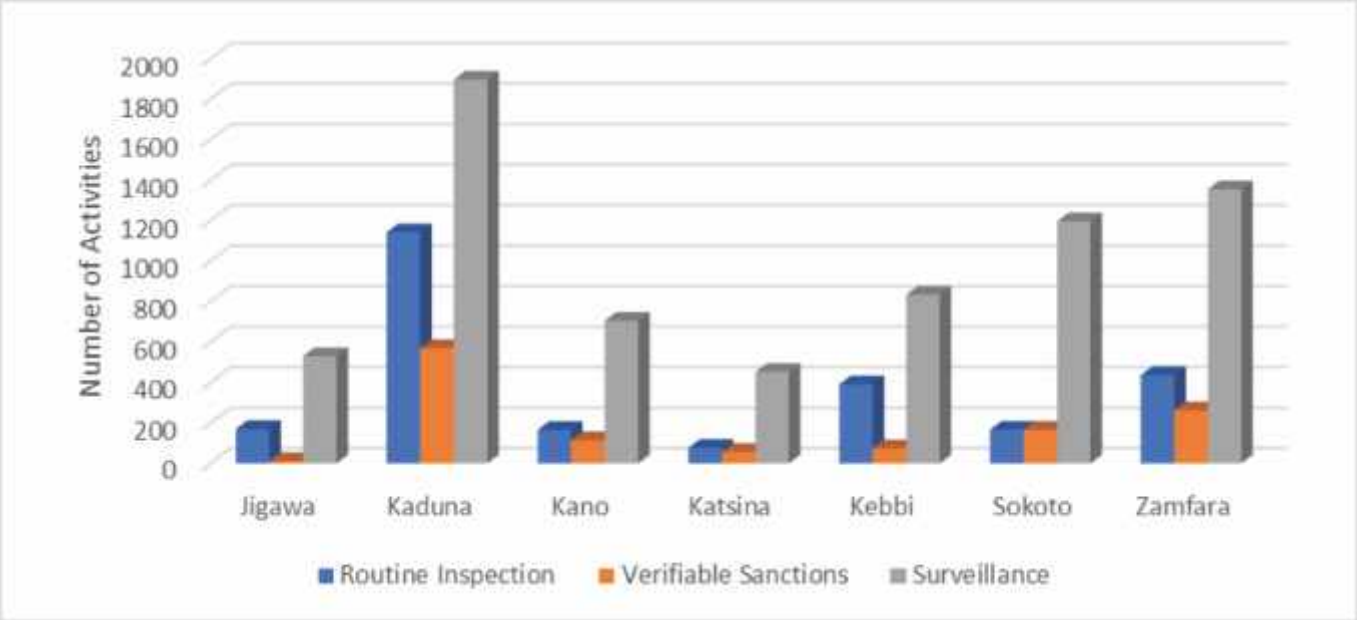
Table 24.2.1:Activities of States in the Northwest Zone by Directorates January – December 2020

Directorates	Routine Inspection	Verifiable Sanctions	Surveillance
DER	272	89	1,069
CER	8	3	156
R&R	152	0	60
PV/PMS	653	471	4,596
VMAP	35	41	407
FSAN	1,343	649	643
NCS	37	1	1
Others	45	1	19
Total	**2,545**	**1,255**	**6,951**

Table 24.2.2:Activities of States in the Northwest Zone January – December 2020

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	**Total**
1.	Jigawa	170	11	529	**710**
2.	Kaduna	1,141	569	1,885	**3,595**
3.	Kano	165	115	704	**984**
4.	Katsina	77	57	452	**586**
5.	Kebbi	390	75	833	**1298**
6.	Sokoto	166	166	1,195	**1,527**
7.	Zamfara	436	262	1,353	**2,051**
	Total	**2,545**	**1,255**	**6,951**	**10,751**

Figure 24.2.1:Activities of States in the North West Zone January – December 2020



24.3. Northeast Zone

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

For the past Eleven (11) years, the Zone has been bedeviled by security challenges.

Still many local government areas particularly in Borno, Yobe and Adamawa are no go areas.

During the period under reviewed the zone carried out Three Thousand Five Hundred and Ninety (3,590) regulatory activities i.e., Routine, Sanction and Surveillance.

Routine Inspections One Thousand and Ninety-Five (1,095) Routine inspections were carried out in the Zone during the period under review.

Sanctions Five Hundred and Eighteen (518) sanctions were imposed on various establishments in the Zone during the year under review.

Surveillance One Thousand Nine Hundred and Seventy-Seven (1,977) Surveillance were carried out in the Zone during the year under review.

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

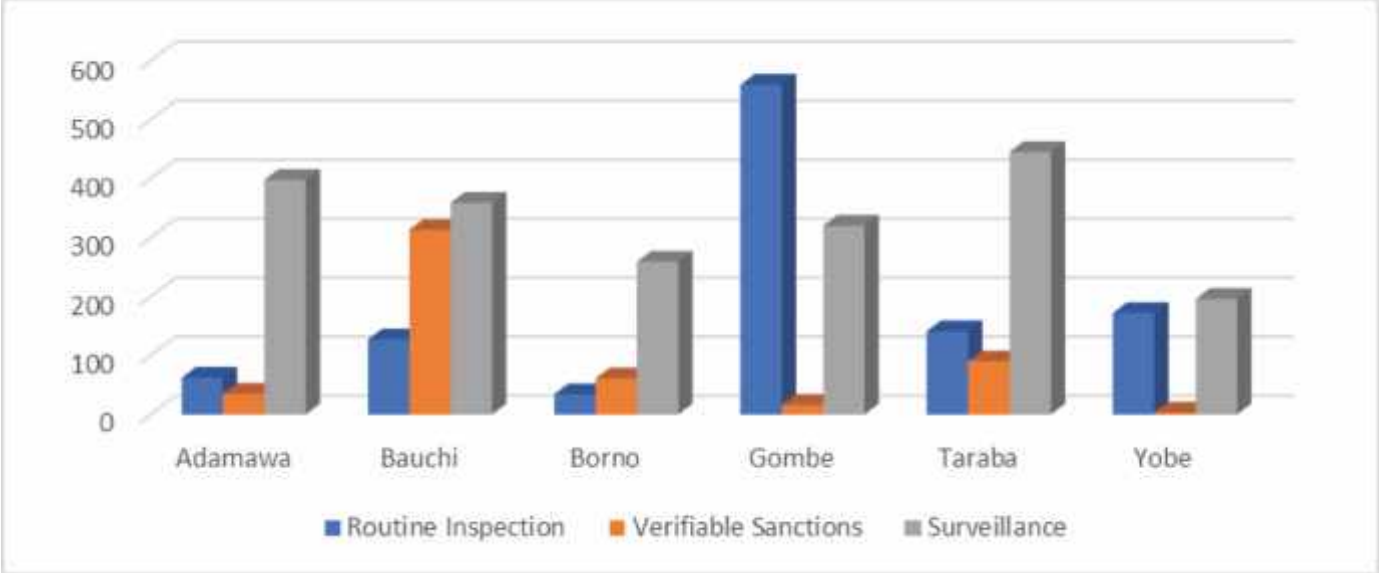
Table 24.3.1:Activities in the Northeast Zone by Directorates January – December 2020

Directorates	Routine Inspection	Verifiable Sanctions	Surveillance	TOTAL
DER	129	96	417	642
CER	26	0	3	29
R&R	0	0	0	0
PV/PMS	59	160	909	1128
VMAP	35	4	18	57
FSAN	845	182	616	1643
NCS	1	0	10	11
I & ENF	0	76	4	80
Total	1,095	518	1,977	3,590

Table 24.3.1:Activities in the Northeast Zone January – December 2020

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Total
1.	Adamawa	62	35	398	495
2.	Bauchi	127	313	359	799
3.	Borno	34	61	259	354
4.	Gombe	559	16	320	895
5.	Taraba	141	90	445	676
6.	Yobe	172	3	196	371
	Total	**1,095**	**518**	**1,977**	**3,590**

Figure 24.3.1:Activities of States in the North East Zone January - December 2020



24.3.2. Decentralization of Product Registration

This has reduced registration processing time for MSME's and all product renewals.
The Zonal Office issued One Hundred and Seventy-Nine (179) product licenses in the year under review.

24.3.3. Public Enlightenment

The Agency has carried out numerous public enlightenment campaigns in all the states within the zone, thus creating awareness on NAFDAC regulatory activities.

24.3.4. Adherence to QMS

In house/Step-down training were conducted for staff by states in the zone.

24.3.5. Surveillance/Mop-Up of Unregistered Hand Sanitizers

Following the directive to mop-up all unregistered hand sanitizers, multiple brands of unregistered hand sanitizers worth 1.5 million were mopped-up in the zone from the unset of COVID-19 pandemic.

24.4. Southwest Zone

The Southwest Zone (SWZ) comprises Five (5) states namely Ekiti, Ogun, Ondo, Osun and Oyo States.

24.4.1. Highlights of activities

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

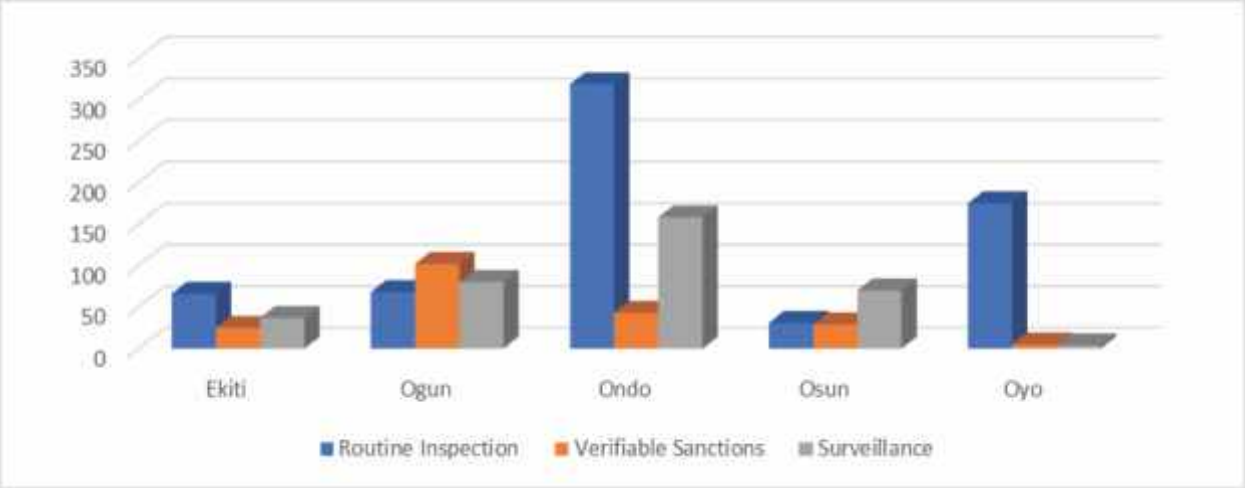
- **Routine inspection**: Two Thousand One Hundred and Twenty-Eight (2,128) routine inspections were carried out.
- **Surveillance:** Eight Hundred and Fifty (850) surveillance activities were carried out
- **Sanctions:** Seven Hundred and Twenty-Three (723) sanction activities were carried out.

Directorate	Routine Inspection	Verifiable Sanction	Surveillance
DER	57	11	42
CER	7	0	6
R&R	0	2	0
PV/PMS	284	30	161
VMAP	7	0	2
FSAN	303	110	136
NCS	0	51	0
I&ENF	0	0	2
PID	0	0	0
Total	658	204	349

Table 24.4.1:Activities of States in the Southwest Zone January – December 2020

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Total
1.	Ekiti	66	25	37	128
2.	Ogun	68	102	80	250
3.	Ondo	318	43	158	519
4.	Osun	31	29	70	130
5.	Oyo	175	5	4	184
	Total	**658**	**204**	**349**	**1,211**

Figure 24.4.1:Activities of States in the South West Zone January – December 2020



- Ondo State carried out the highest number of Routine Inspections while Osun State had the lowest.
- Ogun State had the highest number of verifiable sanctions and Oyo State had the least.
- Ogun State also conducted the most surveillance while Oyo State had the least.

Other Activities by the Zone

In 2020 six (6) approval meetings were held in the zone for production of MSME products and renewal of water.

24.5. Southeast Zone

The Southeast Zone (SEZ) comprises Five (5) states namely, Abia, Anambra, Ebonyi, Enugu and Imo States.

24.5.1. Highlights of activities

The states carried out various activities during the year under review as highlighted below:

- Routine inspection: A total of Six hundred and Fifteen (615) routine inspections were carried out within the period under review.
- Surveillance: One thousand Three Hundred and Twenty-One (1,321) surveillance activities were carried out within the year under review.
- Sanctions: A total of One Hundred and Thirteen (113) verifiable sanctions were carried out in the year 2020.

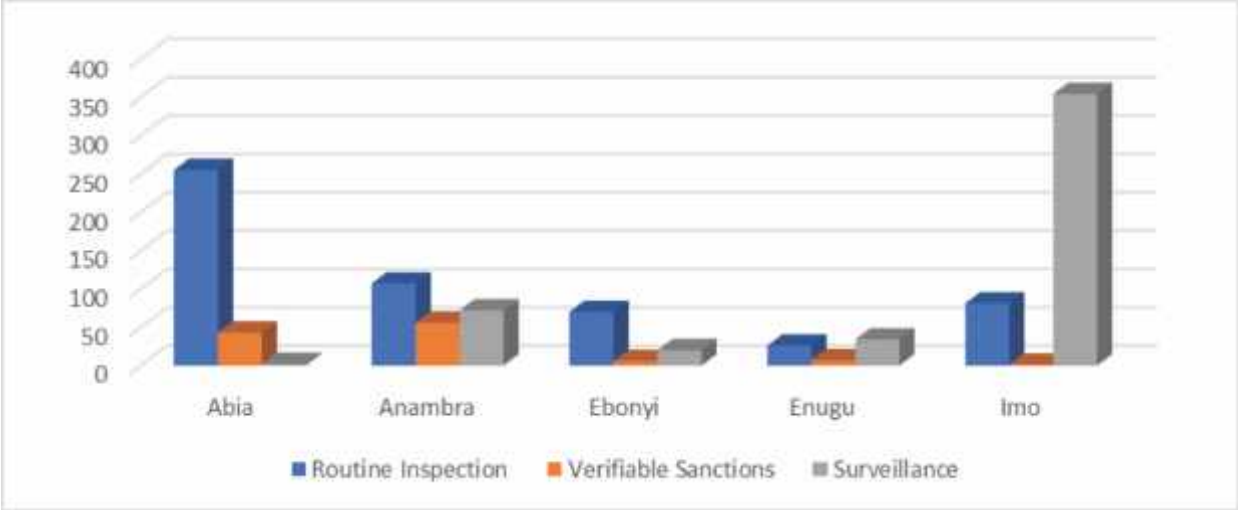
Table 24.5.1: Activities of States in the Southeast by Directorates Zone January – December 2020

Directorate	Routine Inspection	Verifiable Sanction	Surveillance
DER	130	63	362
CER	76	0	0
R&R	0	0	0
PV/PMS	0	0	839
VMAP	0	0	0
FSAN	404	50	119
NCS	5	0	1
Total	615	113	1,321

Table 24.5.2:Activities of States in the South East Zone January – December 2020

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Total
1.	Abia	255	43	2	300
2.	Anambra	107	56	72	235
3.	Ebonyi	70	6	20	96
4.	Enugu	26	7	34	67
5.	Imo	81	1	354	436
	Total	**539**	**113**	**482**	**1,134**

Figure 24.5.1:Activities of States in the South East Zone January – December 2020



24.5.2. Other activities

Approval Meetings

The Zone held South East Zonal approval meetings in January, February, June, July, September, November and December, 2020 by virtual means in accordance with covid-19 protocols at the Zonal office, Enugu State.

All States in the Southeast Zone participated in the meetings.

24.6. South South Zone

The South-South Zone (SSZ) comprises Five (6) states namely Akwa Ibom, Bayelsa, Cross River, Delta, Edo and Rivers States.

24.6.1. Regulatory Activities

A total of 9,635 regulatory activities were carried out during the year under review;

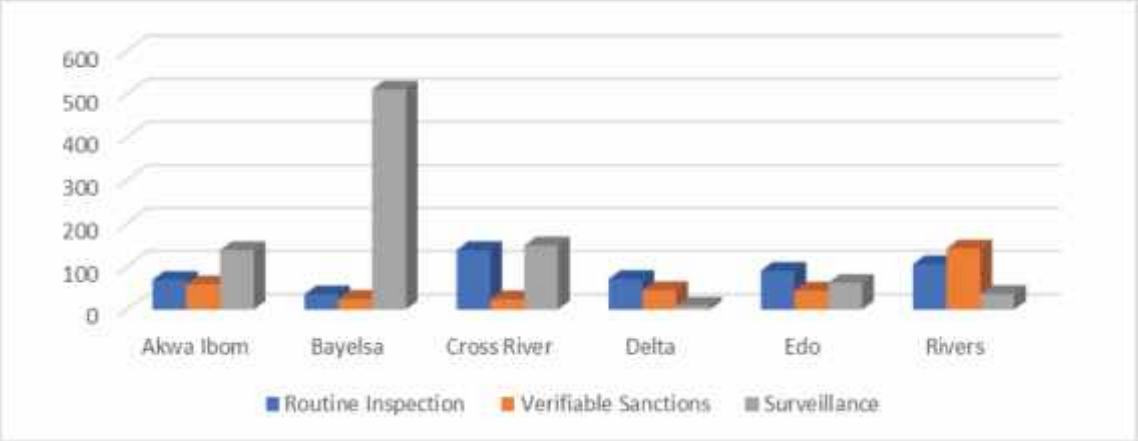
- Rivers State had the highest number of activities of 2,834 followed by Delta State with 1,525 and Bayelsa State with 1,438.
- Generally, the highest number of activities was carried out in January, followed by March with the lowest in June; activities picked up gradually from July to December
- For some selected activities, there was a total of:
  - 508 **routine inspections** were carried out on relevant establishments during the year under review.
  - 1,775 **sanctions including products mopped up** were imposed on relevant establishments

during the year under review.

- 1,222 **surveillances and mop-up** activities were carried out during the year under review.
- 481 **pharmacovigillance and post market surveillance** were carried out during the year under review.
- Of these, **sanctions and number of products mopped-up** was the highest followed by **surveillance and mop-up activities**
- Cross River State carried out the highest routine activities, followed by Rivers State, then Edo State, Delta State, and Akwa Ibom State -
- Rivers State had the highest sanctions and number of products mopped-up, followed by Bayelsa State, then Cross River State
- Edo State carried out the highest surveillances and mop-up activities, followed by Bayelsa State, then, Cross River State and Akwa Ibom State -
- Edo State carried out the highest pharmacovigillance and post market surveillance activities, followed by Cross River State, then, Akwa Ibom State and Delta State

Figure 24.6.1:Activities of States in the South South Zone January – December 2020

SN	States	Routine Inspection	Verifiable Sanctions	Surveillance	Total
1.	Akwa Ibom	69	59	138	266
2.	Bayelsa	35	25	511	571
3.	Cross River	138	24	149	311
4.	Delta	71	45	9	125
5.	Edo	90	44	62	196
6.	Rivers	105	142	36	283
	Total	**508**	**339**	**905**	**1,752**



24.6.3. SSZ Zonal FDRC Approvals of Products for Registration

Registration **of MSME (Categories Permitted for Zonal Registration):**

a. Total Approved for Registration and Renewal:
A total of Four Hundred and Seventy-Nine (479) Products were registered and renewed from the different States in the Zone for MSME Products at State level (Bread) and Zonal level.

b. Renewal:
A total of One Hundred and Twenty-One (121) Water Registration Licenses were renewed from the different States in the Zone at the Zonal Level.

c. New Registration:

A total of One Hundred and Ninety-Four (194) **Food and Cosmetics** Products were registered from the different States in the Zone at the Zonal Level

d. **Bread:**
A total of One Hundred & Ninety-Four (164) **Bread** Products were registered, and Licenses renewed from the different States in the Zone at the State Level

e. Generally, Rivers State had the highest number of products registered/renewed in three of the four categories, followed by Delta State, Edo State and Akwa Ibom State – Table 2a and Figures 2a & 2b.

f. Food products was the highest categories of products registered/renewed

Breakdowns are as follows:

Table 24.6.3.2: Table Showing Registration of Products Per State in South-South Zone for the Year 2020

Number of Products Approved by the Zonal FDRC for South-South Zone in 2020					
State	Renewal	Registration			Total
	Water	Food	Bread	Cosmetics	
Akwa-Ibom	26	24	19	0	69
Bayelsa	2	12	2	4	20
Cross River	10	7	10	0	27
Delta	33	31	45	7	116
Edo	27	20	28	10	85
Rivers	23	68	60	11	162
Zonal Total	**121**	**162**	**164**	**32**	**479**

24.6.4. Achievements

Notable achievements in the Zone during the period under review are as follows:

- Inspection of Cross River Garment Factory, Calabar for Registration of Barrier Mask
- The D(SSZ) represented the DG at the National Training Workshop by the Institute for Health, Safety and & Environment Studies (IHSSES) University of Uyo, Uyo on 16th to 18th March, 2020
- Inspection of Nigeria Air Force Factory, Port Harcourt for Registration of Barrier Mask
- Special Inspection of Cross River Garment Factory, Calabar for intended registration of Medical PPE
- The Zone successfully carried out many activities virtually, physically for surveillance & investigation and hybrid inspections for poor network reception areas as well as collaborative activities with various stake holders despite the many challenges of the global pandemic, civil protests and inadequate Regulatory Officers and facilities;

24.7. Federal Capital Territory Office, Abuja

Table 24.7.1:Activities in the FCT January – December 2020

S/N	Month	Nos. of Routine Inspection	No of other inspections	Verifiable Nos. of Sanctions	No of other Activities	Total No of Activities
1	CER	33	35	0	286	354
2	DER	7	38	6	294	345
3	FSAN	7	450	27	594	1078
4	VMAP	16	185	40	21	
5	R&R	0	0	0	3,011	3,011
6	NCS	0	6	0	1	7
	Total	**63**	**714**	**73**	**4,207**	**5,057**

Figure 24.7.1:Activities in the FCT January – December 2020

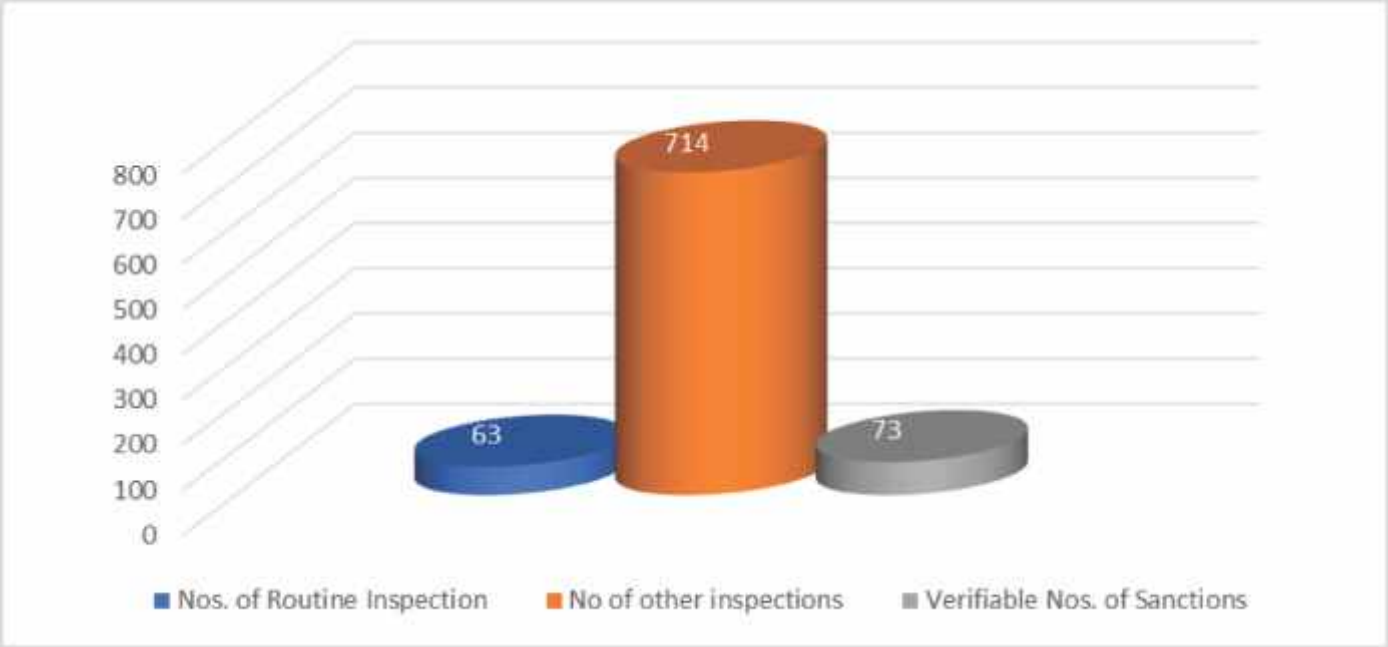


Table 24.7.2: Number of Products approved during FCT Zonal Approval meetings from January – December 2020.

S/N	Category of Products	Type of Registration	No. of Products Registered
1	MSME Food Products	New Registration	114
2	MSME Food Products & Packaged Water	Pack Size Extension	3
3	Bread Products	New Registration	147
4	Cosmetics Products	New Registration	18
5	Bread Products Registered	Pack Size Extension	22
6	MSME Bread Products	Renewal	33

7	MSME Food Products	Renewal	7
8	MSME Water Products	Renewal	41
9	MSME Water	Factory Extension	4
10	MSME Food & Water	Factory Relocation	4
11	MSME Food	Change of Package/Label Design	2
	Total Number of Products Registered		**395**

24.6. Lagos State Office (LSO)

Lagos State Office (LSO) has consolidated in the modest achievements made in the areas of sensitization, awareness campaigns, issuance of Listing Notification, inspections, monitoring, sectorial meetings, seminars and other events via radio, televisions stations and social media Apps to make further remarkable progress.
A major highlight of the LSO activities for the year under review was the introduction of the palliative / e-registration (NAPAMS) launched by the DG. NAFDAC on 15th May, 2020 to reduce most of the delays and difficulties that hindered actualization of timeline and the seamless registration of MSME regulated products.

The outcome of the palliative program contributed impressively to Job creation as several applicants are now self-employed or are entrepreneurs.
It also helped to bring in a lot of NAFDAC regulated businesses (micro & small) from the informal sector to the formal sector of the economy making it easy for NAFDAC regulatory control.
Thirdly, It brought a major boost in the number of applications for product registration currently on the increase at Lagos State Office.

The activities for the year under review started with the monthly in–house meetings, development and review of guidelines, and SOPs. Other activities include Sub / Final Approval meetings, production, Renewal, Follow-up, Advisory, and GHP inspections, to mention but a few, table of summary of activities is attached.

24.8.1. Highlights of Activities

During the period under review, we achieve the following:

Routine Inspections.
Seventy-nine (79) routine inspections.

Production Inspections.
One Thousand Six Hundred and Thirty-Nine (1,639) inspections were conducted.

Good Hygienic Practice (GHP);
Twelve (12) GHP notifications were issued.

Renewal Inspection:
Fifty-Two (52) renewal inspections were conducted.

A full glance details of our activities is summarised in the table below.

Table 24.8.1 Activities Lagos State Office (LSO) January – December 2020

Month	Routine Insp.	Verifiable Sanctions Imposed	Surveillance	GHP Insp. Conducted	Cold Chain Monitoring	Production Inspections	Renewal Inspection
Jan.	14	0	0	0	0	15	2
Feb.	42	0	0	6	0	33	2
March	16	0	0	3	0	34	5
April	0	0	0	0	0	0	0
May	0	0	0	0	0	0	0
June	0	0	0	0	0	7	0
July	0	0	0	3	0	75	3
Aug.	0	0	0	0	0	268	8
Sept.	0	0	0	0	0	348	4
Oct.	0	0	0	0	0	233	12
Nov	0	0	0	0	0	353	0
Dec	7	0	0	0	0	273	16
Total	**79**	**0**	**0**	**12**	**0**	**1,639**	**52**

Figure 24.8.1: Total Number of Inspections Conducted per month

The graph showed that the highest was at month of November 2020. This was because of the continuous sensitization /awareness campaign program carried out at LSO through different media outlets.
There were no activities at the month of April and May. This was because of the pandemic disease that hindered most of the activities at LSO.