World Organisation for Animal Health

Training Seminar for National Veterinary Products Focal Points

Veterinary Products: A Vital Tool for Improving Animal Health and Welfare

05 – 07 September 2023 Lilongwe, Malawi

The Fleming Fund

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Quality of Veterinary Medicinal Products in Nigeria

By

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Federal Ministry of Agriculture and Food Security

Outline

- Background on Nigeria
- An overview of VMPs in Nigeria
- Assessment and authorization of veterinary use,
- Surveillance and reporting,
- Pharmacovigilance,
- Residues and Laboratory Control & Quality Assurance)

Background

- Nigeria
- Land mass of 923,768 km²
- Human Population: >200 million
- Livestock population

Cattle	**20,231,592**
Sheep	**45,617,031**
Goats	**79,989,676**
Pigs	**8,267,279**
Poultry	**193,578,483**
Horses	**102,324**
Donkeys	**978,402**
Total	**348,764,787**

Introduction

- Veterinary medicinal products are essential for the treatment of infections in animals and so are *vital tools for animal health and welfare*

- Substandard and falsified drugs have for some time been seen as a major public health challenge, particularly in LIMC countriesr

- These SFPs can exert very harmful effects on the consumer resulting to illness; disability and even death especially in children

- Anyone can be a victim because most times the consumers do not know the quality of what they are buying or taking

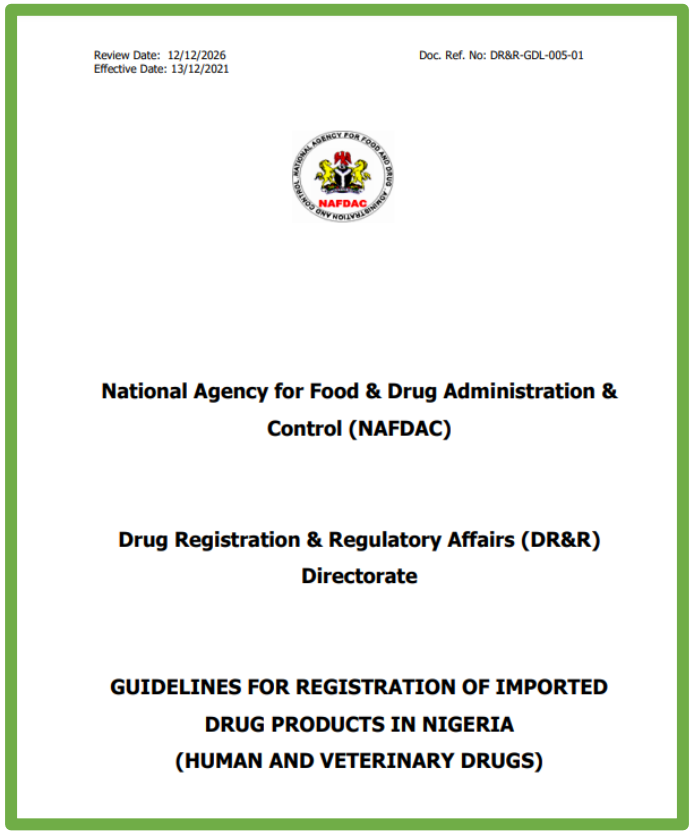
- This challenge can affect the credibility of Healthcare systems

Regulatory authorities for the control of VMPs in Nigeria

- Office of the CVON - Federal Ministry of Agriculture and Food Security
- Veterinary Council of Nigeria (Regulates the practice of vets and vet para professionals)
- National Agency for Food and Drug Administration and Control (NAFDAC - VMAP Directorate)
- Nigeria Veterinary Medical Association
- Nigeria Police Force
- Nigeria Custom Services
- Directors of Veterinary Services

Assessment and authorization process for veterinary medicinal products

Guidelines for assessment and authorization of VMPs (VMAP-NAFDAC)



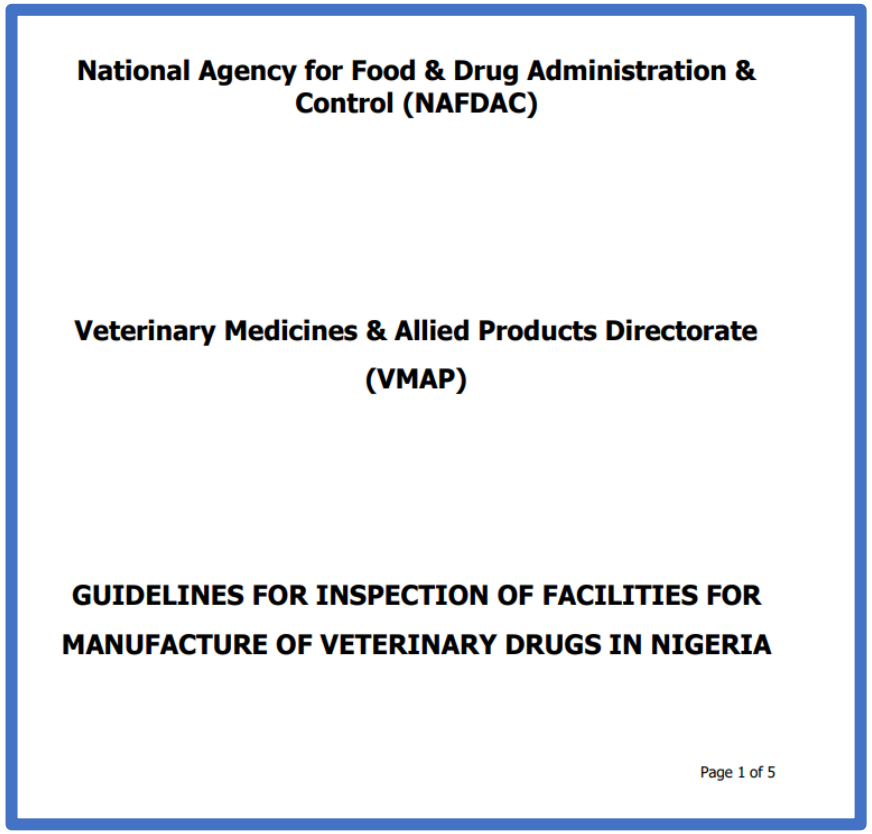
Review Date: 12/12/2026
Effective Date: 13/12/2021

Doc. Ref. No: DR&R-GDL-005-01

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

Drug Registration & Regulatory Affairs (DR&R) Directorate

GUIDELINES FOR REGISTRATION OF IMPORTED DRUG PRODUCTS IN NIGERIA (HUMAN AND VETERINARY DRUGS)

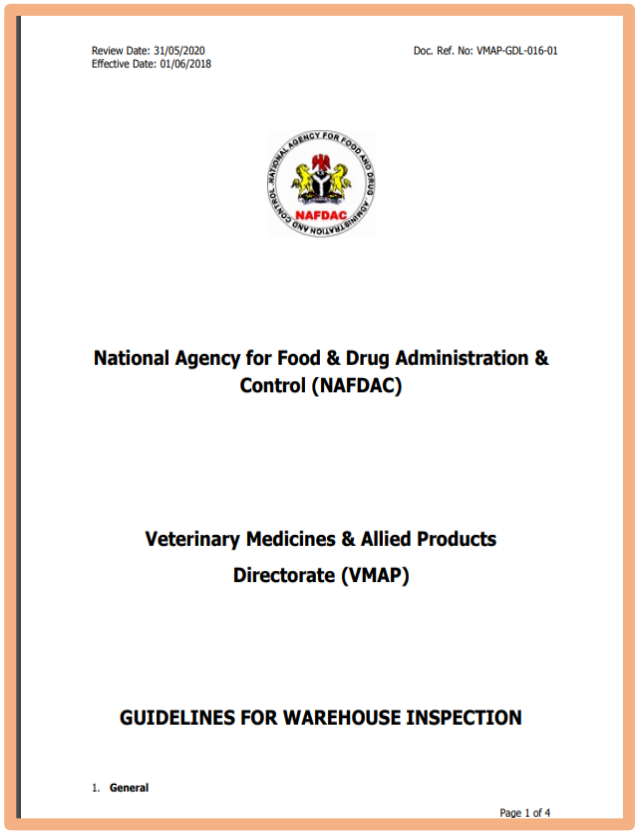


National Agency for Food & Drug Administration & Control (NAFDAC)

Veterinary Medicines & Allied Products Directorate (VMAP)

GUIDELINES FOR INSPECTION OF FACILITIES FOR MANUFACTURE OF VETERINARY DRUGS IN NIGERIA

Page 1 of 5



Review Date: 31/05/2020
Effective Date: 01/06/2018

Doc. Ref. No: VMAP-GDL-016-01

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

Veterinary Medicines & Allied Products Directorate (VMAP)

GUIDELINES FOR WAREHOUSE INSPECTION

1. General

Page 1 of 4

Assessment and authorization process for veterinary medicinal products

The assessment process begins with the registration of products intended for import or manufacture through an online application portal

(Via NAFDAC Automated Products Administration And Monitoring System (Www.napams.org)/Nigerian Single Window (https://trade.gov.ng)

Registration requirement for imported products

- A Completed NAFDAC Application form
- Notarized power of Attorney
- GMP Certificate
- Certificate of manufacture and free sale
- Certificate of Pharmaceutical Products
- Clinical trial documents and or documentary evidence/studies to determine the safety and efficacy of the product
- Evidence of product registration from country of origin

Product dossier

Certificate of incorporation of the Nigerian company Registering the products.

Veterinary Annual License to Practice

Veterinary Premises

Evidence of trademark registration and Notarized declaration by applicant.

Letter of invitation from Manufacturer for the Agency's GMP visit

Automated online systems (NAFDAC)

Majority of NAFDACs processes are now automated and online:

PIDCARMS: aimed at automating the Ports Inspection Directorate operations:

To ensure effective and efficient control of channels through which regulated products are imported and exported

To safeguard public health by ensuring that only the right quality and safe drugs, food and other regulated products are imported and exported

NAPAMS: An online portal for registration

LIMS: Lab information management system

NARPAD: A portal to the list of registered imported and locally manufactured products including VMPs

Labelling requirement

- Name of medicine (brand name) where applicable and generic name.
- Name and full location address of the manufacturer.
- Provision for NAFDAC Registration Number on product label.
- Batch No., Manufacturing date and Expiry date.
- Dosage form & strength on the package.
- Indications for use, frequency, route and conditions of administration
- Dosage regiment on the package (OTC).
- Leaflet insert, if prescription only medicine.
- Quantitative listing of all the active ingredients per unit dose.
- Adequate warnings where necessary.
- Net content of products
- For Veterinary use only.
- Withdrawal Period.

Packaging requiment

- The package must not be a look alike or pass off for an already registered product.
- It must be tamper proof where applicable.
- Must be suitable for the product to be packaged.
- The packaging material used must be able to protect the integrity of the material which is to be packaged.

Marketing authorization

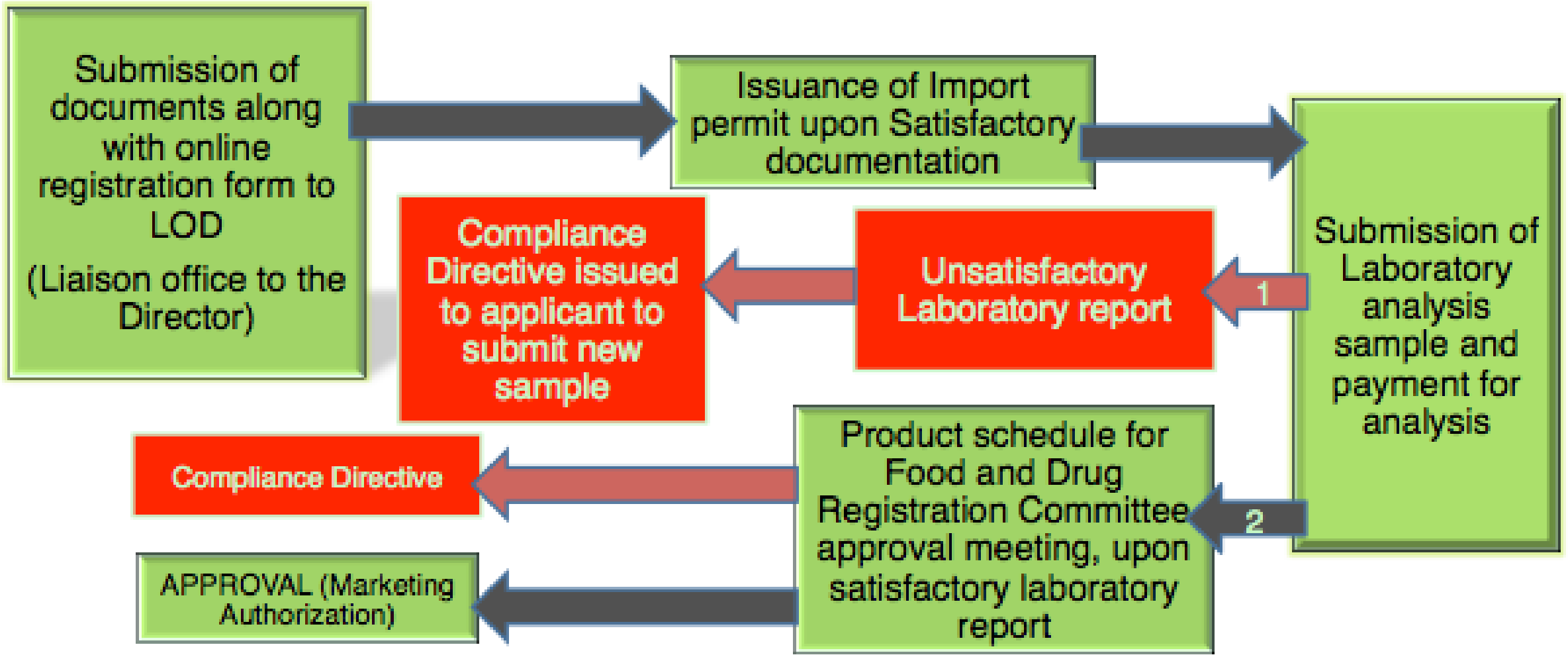
- Upon successful registration, **NAFDAC registration number** (**marketing authorization**) is issued

- Marketing Authorization issued for a product is renewable after every (5) five years.

- The marketing authorization can however be withdrawn before the five years if the condition under which the approval was given has changed before the end of five years.

- Products approved are sampled from time to time from the market and from each consignment imported to ensure compliance

Summary


Submission of documents along with online registration form to LOD
(Liaison office to the Director)
Issuance of Import permit upon Satisfactory documentation
Submission of Laboratory analysis sample and payment for analysis
1
Unsatisfactory Laboratory report
Compliance Directive issued to applicant to submit new sample
2
Product schedule for Food and Drug Registration Committee approval meeting, upon satisfactory laboratory report
Compliance Directive
APPROVAL (Marketing Authorization)

Legal Instruments for authorization, distribution and use of VMPs

NAFDAC Act CAPN1 LFN 2004

Regulates and control the importation, exportation, manufacture, advertisement, distribution, sale and use of veterinary medicinal products, biologics and vaccines through the

- Regulation of veterinary medicinal products, biologics and vaccines in NAFDAC began in 2013 when the Directorate of veterinary medicines and allied products was created.

Drugs and Related Products (Registration) Regulations, 2021 (NAFDAC)

makes provision for the registration of drugs manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

Regulation :

1. Scope of application.
2. Prohibition.
3. Application for registration.
4. Disclosure of information supplied by applicant.
5. Post-registration changes.
6. Changes requiring new application.
7. Suspension or cancellation of Certificate of Registration.
8. Clinical trials.
9. Service Drug Scheme.
10. Combination Drug Products.
11. Over-The-Counter drug products (OTC).
12. Multi-branding.
13. Additional Manufacturing site.
14. Stability testing, shelf life, expiration dating and storage statement.
15. Power to seal.
16. Offences and Penalties.
17. Forfeiture after conviction.
18. Enforcement of the Regulations.
19. Interpretation.
20. Citation.

Good Distribution Practice for Pharmaceutical Products Regulations, 2021 (NAFDAC)

provides for *authorization to distribute the products; inspection; documentation and record keeping; storage and transport conditions; shipment containers and container labelling; quarantine conditions; offences and penalties; interpretation of relevant terms.*

Regulation :

1. Scope.
2. Prohibition.
3. Distribution authorisation.
4. Inspection.
5. Organisation and personnel.
6. Location, design and construction of building facilities.
7. Documentation or Record keeping.
8. Written policies and procedure.
9. Storage condition.
10. Examination of shipments.
11. Returned, damaged and expired pharmaceutical products.
12. Vehicles and equipment.
13. Shipment containers and container labelling.
14. Recalls.
15. Offences and Penalties.
16. Forfeiture after conviction.
17. Enforcement of these Regulations.
18. Interpretation.
19. Citation.

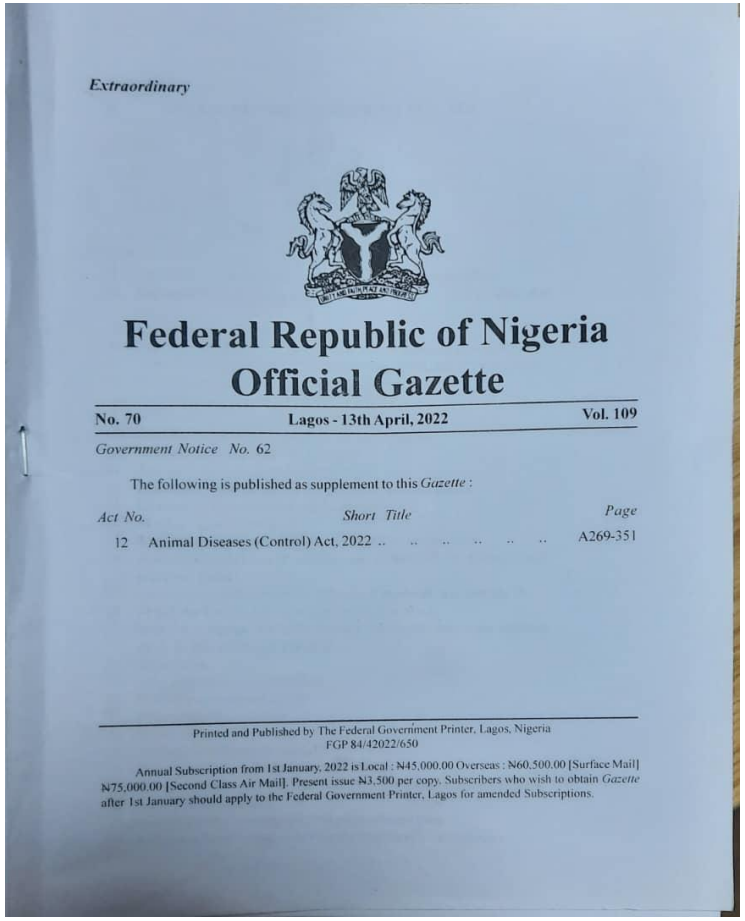
Counterfiet and fake drugs and unwholesome processed foods (miscellaneous provisions) ACT Cap C34 LFN 204

COUNTERFEIT AND FAKE DRUGS AND UNWHOLESOME PROCESSED FOODS (MISCELLANEOUS PROVISIONS) ACT Cap C.34 LFN 2004

ARRANGEMENT OF SECTIONS

COUNTERFEIT AND FAKE DRUGS AND UNWHOLESOME PROCESSED FOODS (MISCELLANEOUS PROVISIONS) ACT

An Act to provide for the prohibition of sale and distribution of counterfeit, adulterated, banned or fake, substandard or expired drug or unwholesome processed food; and of sale, etc., of drugs or poisons in certain premises or places.



Extraordinary

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Official Gazette

No. 70 | **Lagos - 13th April, 2022** | **Vol. 109**

Government Notice No. 62

The following is published as supplement to this *Gazette* :

Act No.	*Short Title*	*Page*
12	Animal Diseases (Control) Act, 2022	A269-351

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FGP 84/42022/650

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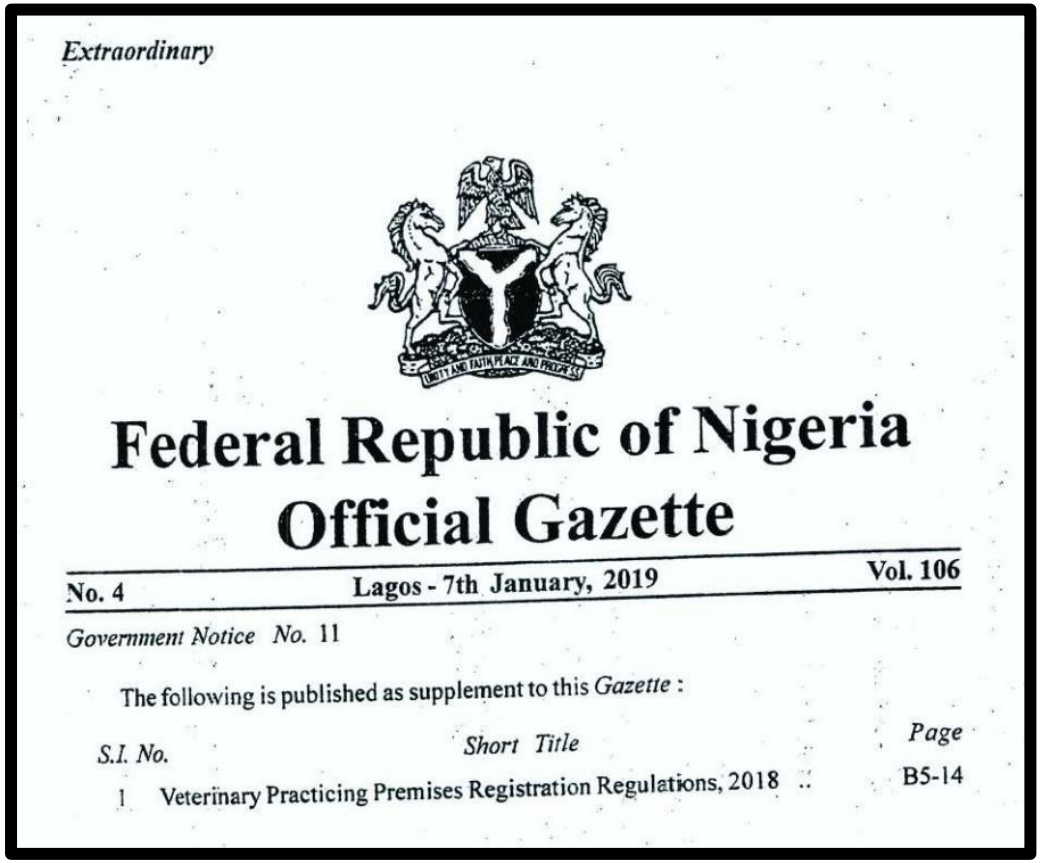
Animal Disease Control Act 2022 as amended - *provides for the control and prevention of animal diseases, with the objective of preventing the introduction and spread of infectious and contagious diseases among animals, hatcheries and poultries in Nigeria. It has a section (35) on veterinary medicinal products and AMR*

Veterinary Surgeons Act, 2004 (as amended)

provides for the control of the practice of veterinarians; Registration of veterinary surgeons and vet para professionals



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No. 4 **Lagos - 7th January, 2019** **Vol. 106**

Government Notice No. 11

The following is published as supplement to this *Gazette* :

S.I. No.	*Short Title*	*Page*
1	Veterinary Practicing Premises Registration Regulations, 2018 ..	B5-14

Surveillance of VMPs and reporting

NAFDAC enforces the laws and regulations of the Agency by performing the following activities;

a. Collection of Information on registered products
b. Surveillance
c. Intelligence gathering & Analysis
d. Inspections of premises
e. Interrogation of suspects
f. Sampling and packaging samples for analysis

Surveillance and reporting cont'd

Surveillance activities are carried out for:

- unregistered veterinary drugs/vaccines/biologics
- Banned veterinary drugs in food producing animals
- Improperly labeled veterinary drugs/vaccines/biologics
- Expired veterinary drugs/vaccines/biologics
- Labeling lapses e.g. Product without full address of manufacturers

All these are violations and appropriate regulatory measures are taken when encountered

List of registered veterinary products can be found on NAFDAC website; www.nafdac.gov.ng

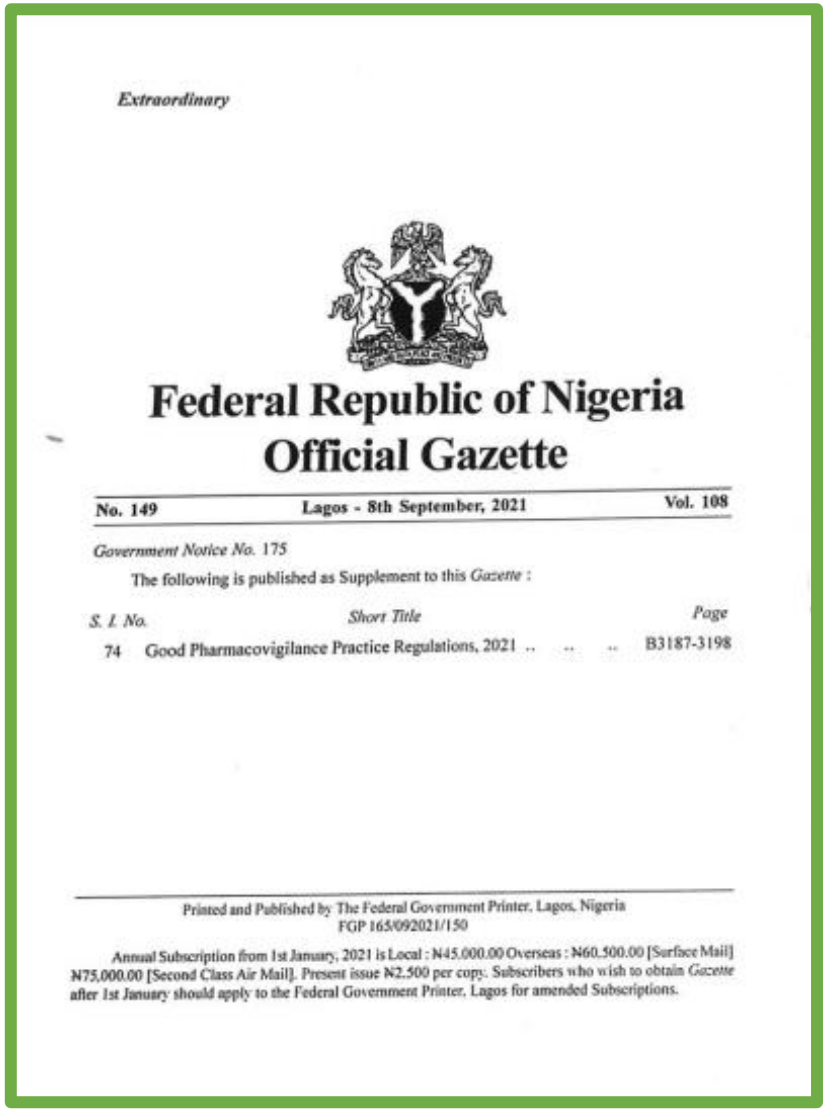
Surveillance and reporting

- Surveillance and monitoring are carried out to ensure compliance with NAFDAC regulations and guideline by importers, manufacturers, distributors and marketers of veterinary medicinal products

Tools of enforcement against violators include:

- Issuing compliance directives and warning letters to offenders
- Seizure of violating products
- Placing offending products/premises on hold
- Sanctioning non-compliant adverts/marketing of products
- Revocation of market authorizations or import permits
- Destruction of violating products
- Prosecution of offenders
- Administrative fines

Pharmacovigillance



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No. 149 **Lagos - 8th September, 2021** **Vol. 108**

Government Notice No. 175

The following is published as Supplement to this *Gazette* :

S. I. No.	*Short Title*	*Page*
74	Good Pharmacovigilance Practice Regulations, 2021	B3187-3198

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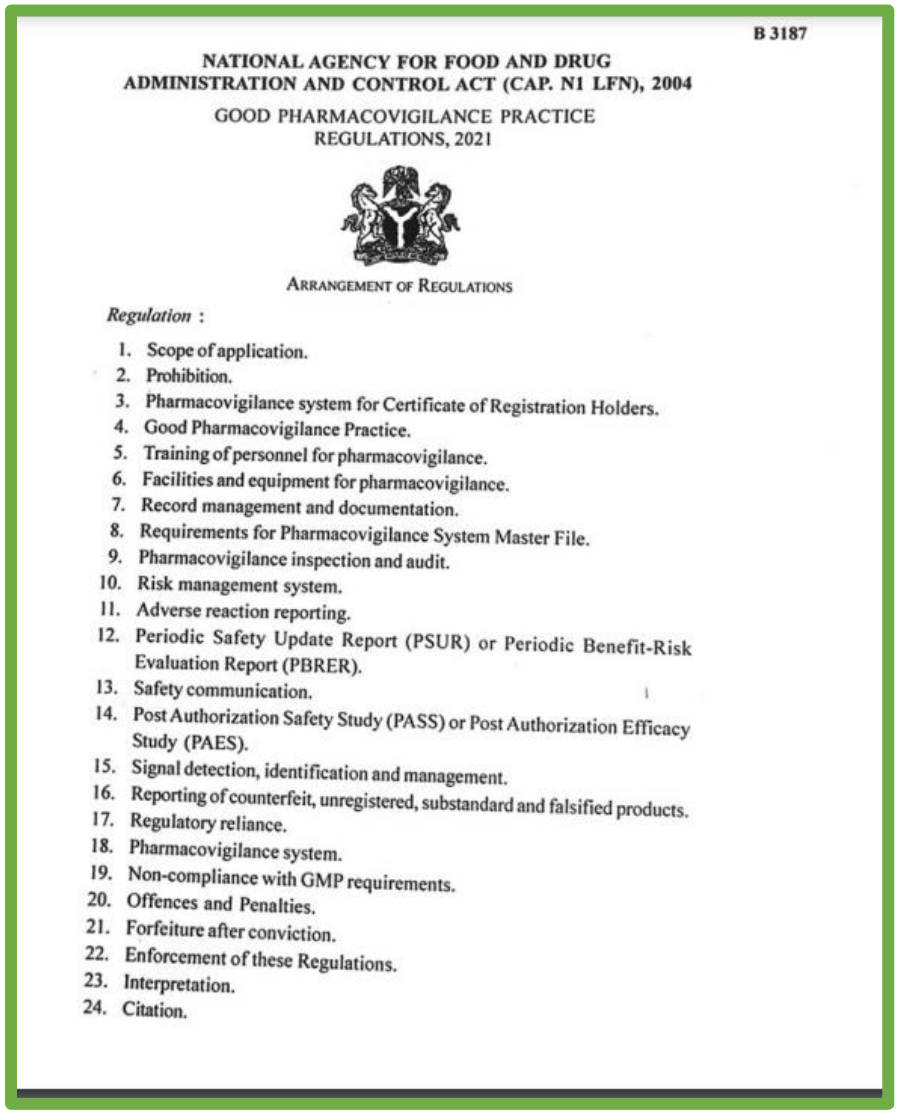


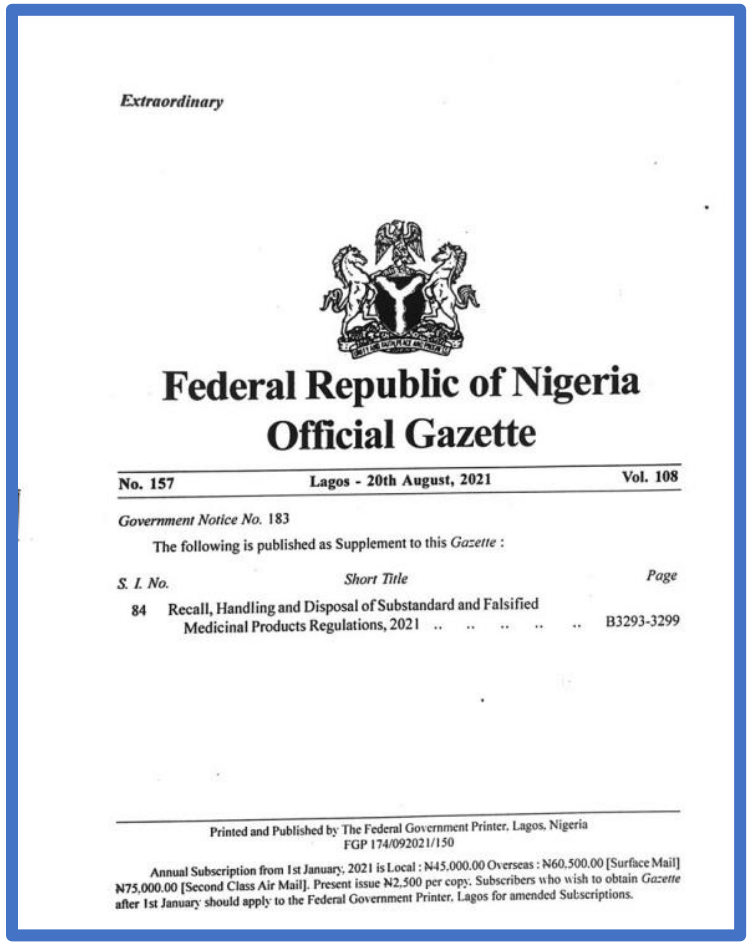
NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

GOOD PHARMACOVIGILANCE PRACTICE REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

Pharmacovigillance



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S. I. No.	*Short Title*	*Page*
84	Recall, Handling and Disposal of Substandard and Falsified Medicinal Products Regulations, 2021	B3293-3299

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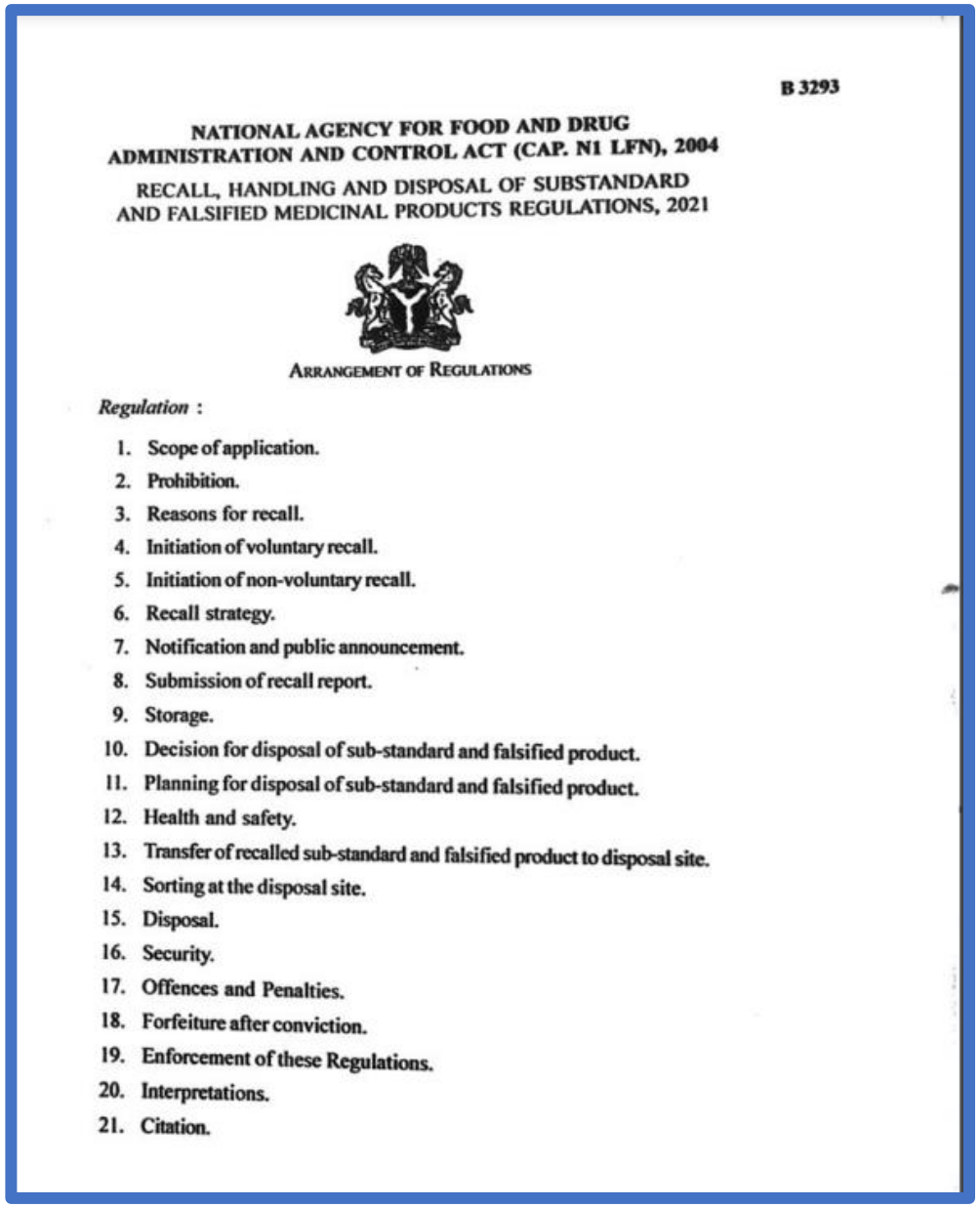

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

RECALL, HANDLING AND DISPOSAL OF SUBSTANDARD AND FALSIFIED MEDICINAL PRODUCTS REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

Reasons for recall

- Incorrect labelling of products
- Incorrect formulation of product
- Result of ongoing stability study (unfavourable) showing negative trends
- Poor storage and handling
- Physical, chemical or microbiological defects

Actions to be taken

The certificate owner shall notify the agency or the agency shall initiate a non voluntary recall of SFP

- The agency shall determine the disposal of SFP

Challenges

- Importation of fake and substandard products into Nigeria through porous land borders

- Unmonitored, unlicensed, unregulated chaotic open drug market that forms major drug distribution centre where many drug outlets patronize

Conclusion

- Veterinary medicinal products remain essential in animal health and welfare
- When VMPs are used it must not only be effective but safe for both animals and humans

Hence:

- The need to form a joint task force for the enforcement of regulations to address the issues of:
- Illegal importation of VMPs
- Unregulated sale of antimicrobials in the open market
- The need to ensure continuous surveillance and reporting of falsified and substandard veterinary medicines

Acknowledgement

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NAFDAC

NIGERIAN VETERINARY MEDICAL ASSOCIATION

World Organisation for Animal Health
Founded as OIE

UKaid
from the British people

The Fleming Fund

MOTT MACDONALD