World Organisation for Animal Health

Substandard and Falsified Veterinary Products Workshop

4 - 6 March 2025. Dar es Salaam, Tanzania.

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL
NAFDAC

FMAFS
FEDERAL MINISTRY OF AGRICULTURE AND FOOD SECURITY, FEDERAL REPUBLIC OF NIGERIA

The Fleming Fund

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NAFDAC MANDATE

NAFDAC was established by Decree 15 of 1993, as amended by Decree 19 of 1999, now NAFDAC Act CAP N1 LFN 2004 which empowers NAFDAC to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals. These products are known as **NAFDAC regulated products**.

VISION

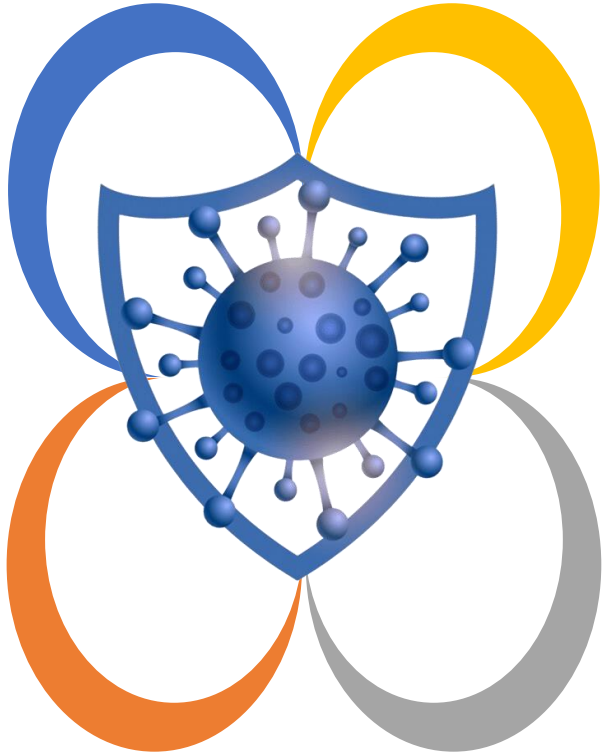
To be a World Class Regulator that ensures availability of quality and safe Food, Drugs, and other Regulated Products.

MISSION

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

Overview of NAFDAC's Role in Veterinary Medicines Regulation

- ❖ Product Registration and Marketing Authorization
- ❖ Quality Control through laboratory analysis.
- ❖ Conduct regulatory inspection of manufacturing facility for compliance with Good Manufacturing Practice (GMP), GWP & GSP
- ❖Advertisement control for products with marketing authorization.



- ❖Issuance of Permit for API bulk importation.
- ❖Port Inspectorate Directorate conducts the inspects all regulated products.
- ❖Issuance of Export certificate by Port Inspection Directorate

Overview of NAFDAC's Role in Veterinary Medicines Regulation contd..

❖Enforcement activities to mop up fake, adulterated and unwholesome pesticides and agrochemicals

❖Developing and promoting standards, regulations and guidelines in consultation with Government Agencies and stakeholders.

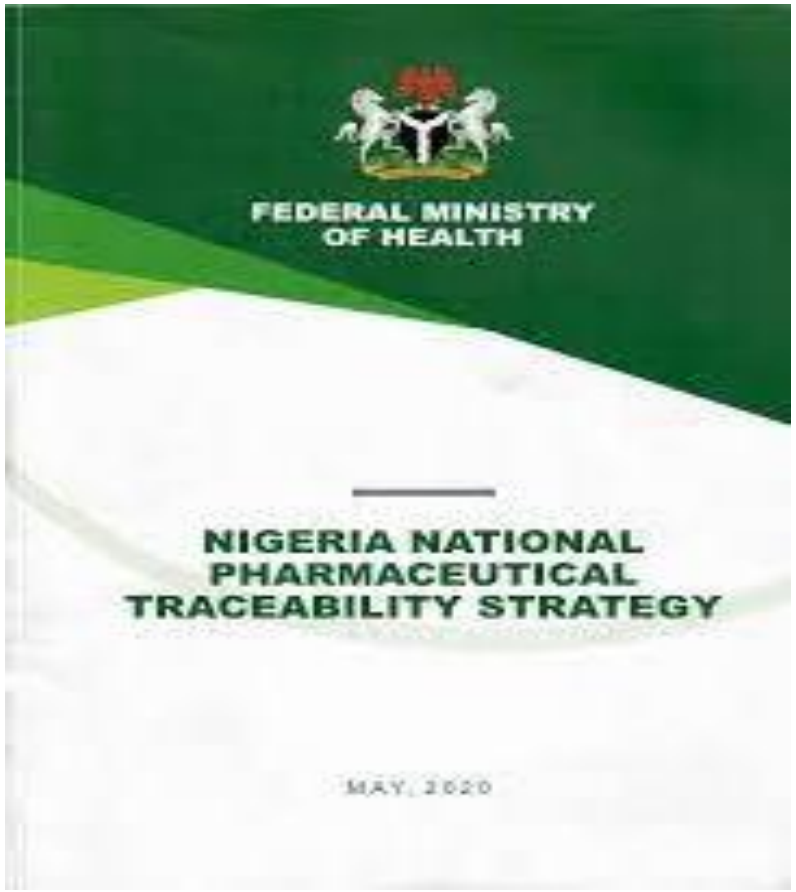
❖Conduct routine Post Marketing Surveillance (PMS) of NAFDAC Regulated products.

❖ Continuous advocacy and awareness raising through **NAFDAC and Your Health** program and other mass media and stakeholders' engagement.

Current Monitoring and Surveillance Systems for Pharmaceutical in Nigeria

Federal Government of Nigeria , FMOH developed a strategy document – ***"Nigeria National Pharmaceutical Traceability Strategy 2020"***

NAFDAC guided the development of a 5-year traceability implementation plan in line with this strategy Document



National Pharmaceutical Traceability: Strategic Objectives

1 Establish Governance Structure

- Lead strategy
- Advocacy
- Collaboration
- Resource Mobilization
- Oversight of implementation

2 Strengthen Regulatory Environment

- Develop and disseminate Regulation
- Publish guidelines for implementation
- Enforce compliance

3 Create Supply Chain Efficiency

- Standardized Identification
- Automated Data Capture
- Automated Reporting

4 Build and Sustain Technology

- Support interoperability of health systems
- Implement traceability
- Improve data visibility

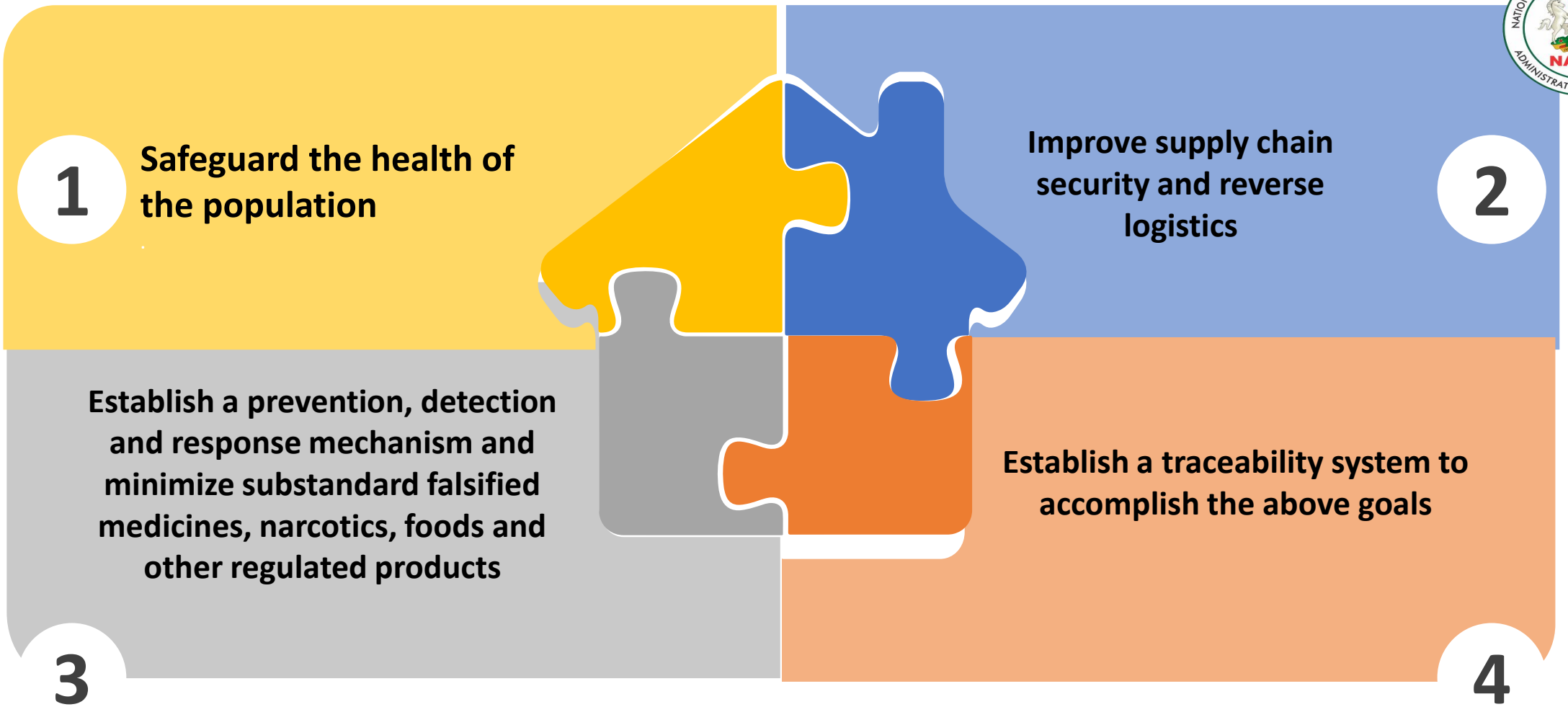
5 Enable use of Standards

- Identification of commodities
- Authentication of commodities at service delivery points in public and private sectors.

Nigeria Pharmaceutical Traceability Strategic Objectives

The Goals of NAFDAC Regulatory Control

The goals of NAFDAC regulatory control on traceability include, but are not limited to the following:



Animal Disease Control Act 2022 (as amended)

- (2) The Federal Department of Veterinary Services shall be responsible for the control of veterinary biologies, veterinary medicinal products. medicaments, infectious agents, veterinary pesticides, and veterinary products of biotechnology within Nigeria, and the CVON shall issue permit authorizing the use of the products before the products may be presented and accepted to undergo the mandatory process of statutory regulatory certification by the appropriate authority or agency as prescribed by law.

Animal Disease Control Act 2022 (as amended)

- (3) Holders of annual veterinary premises license and veterinary practicing license, or veterinary pharmacy certificate issued by the Veterinary Council of Nigeria (VCN) on one hand, and veterinary pharmacy certificate issued by the International College of Veterinary Pharmacy (ICVP) or any O other national or international institutions recognized by the VCN, on the other hand, shall be accepted for trade, import and export in veterinary biologics, veterinary medicinal products, pet foods, feeds, feed additives or medicaments, veterinary medical devices, veterinary products and for operation of veterinary premises or establishments..

Surveillance of Imported VMPs

- 5. (1) A veterinary officer, police officer or any authorized officer who has reason to believe that there is in any premises, animal, animal products or commodities, pet foods, feeds, feed additives, biologies, veterinary medicinal products, pesticides, infectious agents or products of veterinary biotechnology which have been imported into Nigeria in contravention of the provisions of this Act shall—

- (a) immediately enter, inspect the premises and examine any suspected animal, animal products or commodities, pet foods, feeds, feed additives. veterinary biologies, veterinary medicinal products, pesticides, infectious agents or products of veterinary biotechnology therein;

Surveillance of Imported VMPs Cont'd

- (b) demand, from the owner or person in charge or in possession, for the evidence of import permit issued by the CVON to import such animals. animal products or commodities, pet foods, feeds, feed additives, veterinary medicinal products, pesticides, biologies or samples or specimen, infectious agents or products of veterinary biotechnology found on the premises ; and

- (c) where he has reasonable grounds to believe that such animals, animal products or commodities, pet foods, feeds, feed additives, biologies, veterinary medicinal products, pesticides, infectious agents or products of veterinary

Surveillance of Imported VMPs... Cont'd

- (9) A veterinary officer, or authorized officer receiving a notification under subsection (1) or otherwise becoming aware that any animal, animal products or commodities, biologics, veterinary medicinal products, pesticides, infectious agents, pet foods or medicated feeds, products of veterinary biotechnology within the limits of his jurisdiction is infected with disease, contaminated or adulterated in the case of animal products or commodities, medicated animal feeds, feed additives, pet foods, products of veterinary biotechnology, fake or counterfeit in the case of biologics or veterinary products, pesticides, shall take measures to enforce the provisions of this section with regard to isolation and quarantine or non-movement of the animal, determination of the identity and quality of the seized items and shall immediately notify the nearest Magistrate or police officer.

Surveillance of Imported VMPs... Cont'd

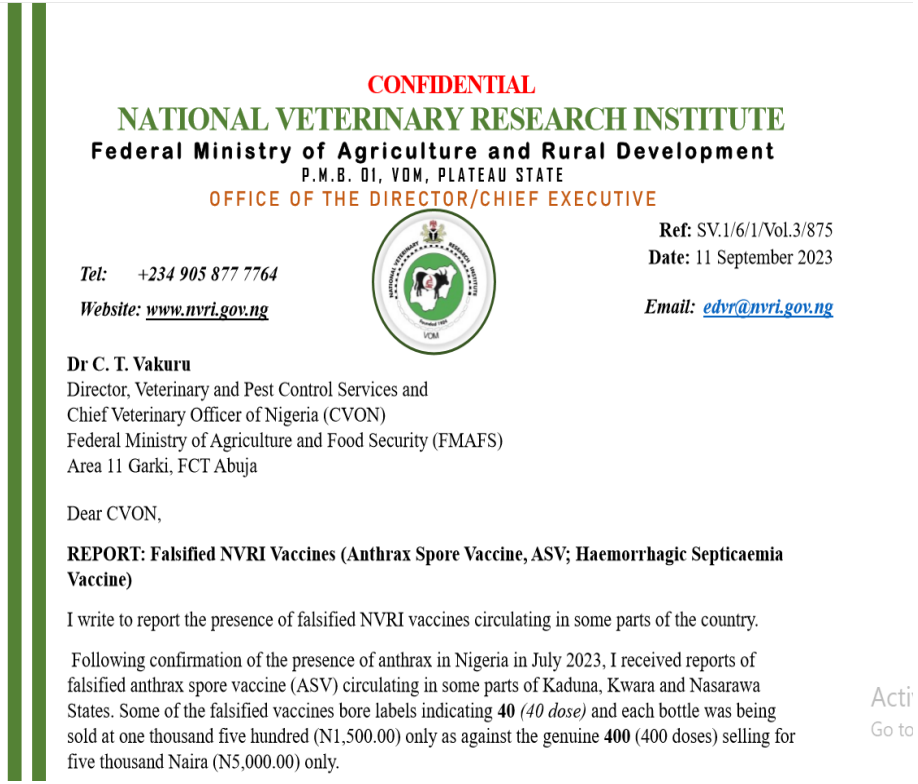
- (11) All veterinary biologics, veterinary medicinal products, veterinary pesticides and veterinary medical devices shall be handled, sold or administered only by a veterinary surgeon, or any authorized officer under his supervision, with up-to-date annual practicing license issued by the VCN.

Accessing the VSAFE Platform

- Nigeria joined the VSAFE reporting Platform in 2023 following the interest indicated by the Delegate of Nigeria
- Nigeria has since been reporting on the platform
- The reporting template is user friendly and allows for ease of reporting
- The country has been consistent in reporting since then.
- The reminders from the VSAFE Team is a very useful reminder.

Declaration

- In 2023, Nigeria reported an outbreak of Anthrax and in a bit to control the outbreak, nation wide vaccination was carried out.
- The National Veterinary Research Institute produces animal vaccines including anthrax.
- During that period, there was a report on falsified anthrax vaccine which was reported.
- Additionally, there was a report of falsified Haemorrhagic Septicaemia Vaccine during the same period.



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Chief Veterinary Officer of Nigeria (CVON)
Federal Ministry of Agriculture and Food Security (FMAFS)
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Dear CVON,

REPORT: Falsified NVRI Vaccines (Anthrax Spore Vaccine, ASV; Haemorrhagic Septicaemia Vaccine)

I write to report the presence of falsified NVRI vaccines circulating in some parts of the country.

Following confirmation of the presence of anthrax in Nigeria in July 2023, I received reports of falsified anthrax spore vaccine (ASV) circulating in some parts of Kaduna, Kwara and Nasarawa States. Some of the falsified vaccines bore labels indicating **40** *(40 dose)* and each bottle was being sold at one thousand five hundred (N1,500.00) only as against the genuine **400** (400 doses) selling for five thousand Naira (N5,000.00) only.

Actions taken

- Samples were taken to the lab for analysis and both products did not meet the product quality check
- Also packaging and labelling did were inconsistent with that of the NVRI
- Investigation was carried out
- The state security services were approached to support the investigation, but on return to the market, the products were no longer in the market
- Surveillance was then intensified to ensure that the products were not sold anywhere in the country.

Challenges in Controlling SFVPs in Nigeria

NAFDAC related challenges

- Disorganized distribution systems, especially in large drug markets
- Delayed detection of substandard and falsified medical products

INDUSTRY related challenges

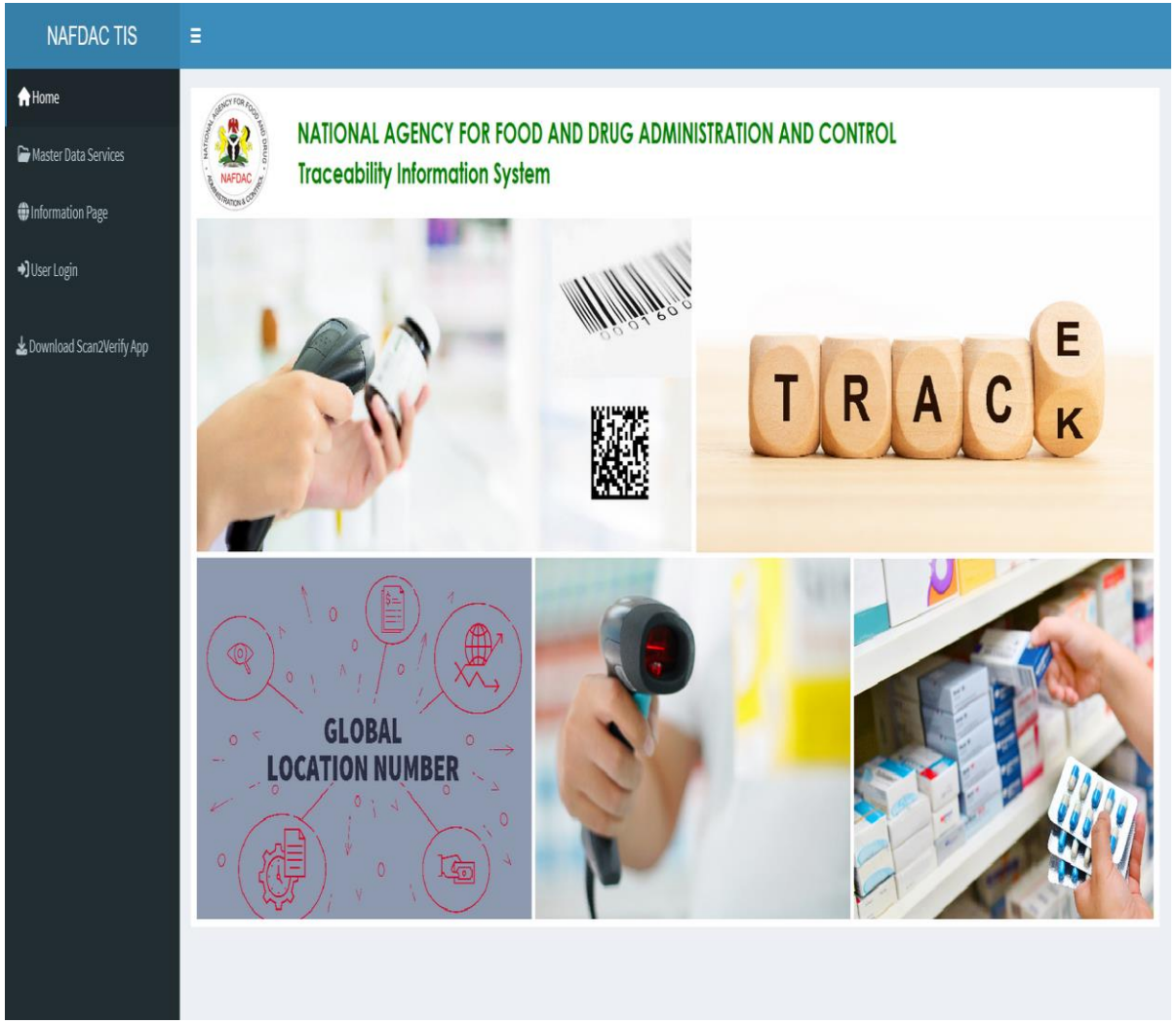
- Expired medications
- Frequent disruptions in the supply chain
- Improper storage
- Unavailability of medicines when required
- Inefficient inventory management
- Persistent challenges with **Substandard and Falsified medicines (SFs)**

CONCLUSION

NAFDAC remains committed to strengthening the regulation of Substandard and Falsified Veterinary Products (SFVPs) through enhanced surveillance, enforcement, and collaboration.

By leveraging the VSAFE initiative and WOAH's technical support, we aim to improve reporting, traceability, and supply chain integrity.

Together, we will safeguard animal health, ensure food safety, and protect public health in Nigeria



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NAFDAC Traceability Regulation –
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NAFDAC Recall, Handling and Disposal of Sub- Standard and Falsified Medicinal Products Regulations, 2021

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Nigeria National Pharmaceutical traceability Strategy
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NAFDAC Website
www.nafdac.gov.ng