

The background of the slide features a collection of medical supplies on a reflective surface. In the foreground, a single red and yellow capsule lies horizontally, with its reflection visible below. To its right, a white syringe with a needle is positioned diagonally. Further right, a clear glass vial with a white cap is partially visible. In the background, several other capsules in red and yellow colors are scattered, and a blurred glass vial containing an orange liquid is visible in the upper left corner. The overall lighting is warm and soft, creating a professional and clinical atmosphere.

# **THE CHALLENGES OF ILLEGAL USE OF MEDICINES/ DRUGS** (The Tramadol Menace)

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# NAFDAC a Statutory Body

The National Agency for Food and Drug Administration and Control (NAFDAC) was established by Decree No. 15 of 1993 as amended by Decree No. 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

**Mandate:** To regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of Food, Drugs, Cosmetics, Medical Devices, Packaged Water, Chemicals and Detergents (collectively known as regulated products).

# NAFDAC a Statutory Body

## Vision:

- The Vision of NAFDAC is “to be a world class regulator that ensures availability of quality and safe Food, Drugs and other regulated products.”

## Mission:

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

## Core Values:

The **PRIDE** core values of the Agency are:

- Professionalism
- Resilience
- Integrity
- Dedication & Commitment
- Excellence



# Structure of the Agency

The organization consists of the Director General's Office and fourteen (14) directorates overseeing the functions of the agency:

Directorates: Examples

- Regulatory & Registration
- Narcotics & Controlled Substances
- Investigation & Enforcement
- Legal Services
- Laboratory Services
- Port Inspection
- Drug Evaluation & Research
- Veterinary Medicine and Allied Products
- Pharmacovigilance and Post-marketing Surveillance
- Chemical Evaluation and Research
- Four non-technical Directorates
- Zonal and State Offices

# Pharmaceutical Legislations Enforced by NAFDAC

- NAFDAC Act CAP. N.1 LFN 2004 – The Enabling Act
- Food, Drug and Related Products (Registration) Act CAP F.33 LFN 2002
- Food and Drugs Act CAP F32 LFN 2004
- Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provision) Act CAP C34 LFN 2004
- Relevant Regulations

# Investigation & Enforcement Directorate/ Federal Task Force on Counterfeit Drugs and Unwholesome Processed Foods

Investigation & Enforcement Directorate is the arm of NAFDAC, principally responsible for enforcing compliance with the Agency's mandate on regulatory activities.

It also coordinates enforcement activities of all other Directorates, Zonal and States offices of NAFDAC Nationwide.

The Federal Taskforce on Counterfeit and Fake Drugs and Unwholesome Processed Foods

- Domiciled in the Directorate

# Strategies for Ensuring Effective Regulation and Control

- Product Registration and Regulation
- Inspection of production facilities
- Inspection of imported/exported Regulated products
- Laboratory evaluation
- Post Marketing Surveillance/Pharmacovigilance
- Investigation, enforcement and prosecution
- Information Communication Technology



# Regulatory Activities

## – what are we doing?

- Nationally controlled to reduce supply and track distribution.
- Routine inspection and monitoring of facilities where medicines are stored, manufactured and distributed.
- Restrict importation of tramadol to 50mg and 100mg dosage strength.
- Estimation of licit needs 2017 and 2019.



# Pharmacological Actions

– What are the dangers to the individual?

- Respiratory depression (shallow breath and irregular breathing)
- Central depression/ severe drowsiness
- Muscle rigidity
- Unconsciousness/ Coma

# Socio-economic Consequences

## - Danger to the society

- Crime
- Terrorism
- Loss of Economic Productivity
- Pressure on the healthcare system.

# Initiatives

- International collaborators
  - WHO
  - Interpol
  - WAHO
  - UNODC
  - National Drug Regulatory Authorities
- National collaborators
  - Nigeria Police Force
  - PCN
  - NDLEA
  - Nigeria Customs Service
  - SON and FC&CPC
  - Relevant Professional Bodies and stakeholders

# Enforcement-Related Successes Recorded

(from Nov. 2017 till date)

- Return of NAFDAC to the ports
- Three persons involved in the distribution of banned Tramadol have been arraigned at the Federal High Court, Lagos. The Agency secured the conviction of one of the distributors and the court ordered the destruction of the seized consignment.
- Destruction of Tramadol with estimated street value of one trillion, seven hundred and two billion, six hundred and ninety-two million, two hundred and fifty thousand naira (N1,702,692,250,000.00)
- Continuous seizures and destruction of substandard and falsified medicines, unwholesome foods and beverages



# Enforcement-Related Successes Recorded

(from Nov. 2017 till date)

- Upgrading of NAFDAC laboratories
- Enthronement of Quality Management Systems and ISO 9001 certification
- Global Benchmarking Audit ISO 90004
- Digitalisation of NAFDAC processes

# Recommendations

- Sustenance of inter-agency collaborations – NAFDAC, Nigeria Customs Service, NDLEA, Police etc
- Sustained Enforcement of existing regulations regarding the following;
  - Prohibition of importation of unregistered medicines
  - Adherence to approved dosage strength
  - Adherence to importation guidelines, and Procedures
    - permits to import and clear and inventory control.

# Challenges of Anti-Counterfeiting

- Weak penalty – One Ezeanwu Ifeanyi was sentenced to 5 years imprisonment or an option of fine of N300,000.00 for being in possession of Tramadol by the Federal High Court, Lagos.
- Weak drug distribution system
- Porous borders
- Inadequate resources (systems and manpower) for proper monitoring
- Lack of synergy for sharing information (intelligence) in real time between relevant MDAs
- Limited knowledge of consequences of the 2005 Strategic Action Against Piracy ("**STRAP**") initiative in counterfeiting of Intellectual Properties (Trademarks, Patents) related to regulated products.

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A teal-tinted background image featuring a hand holding a pen over a notebook. The notebook has a spiral binding on the right side. Scattered around the notebook are several white, oval-shaped pills. The word "THANKS" is written in a white, hand-drawn font across the center of the image.

THANKS