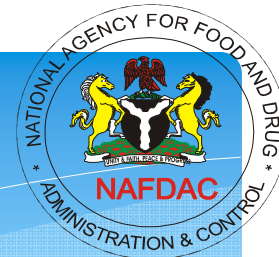


**“CHALLENGES IN ADDRESSING THE PROBLEM
OF ILLICIT PRODUCTION, DISTRIBUTION AND
TRAFFICKING OF FRAUDLENT MEDICINES –
CHALLENGES FROM A REGULATORY AGENCY”**



**BY
HASHIM UBALE YUSUFU**

**CHAIRMAN, FEDERAL TASKFORCE ON FAKE AND
COUNTERFEIT DRUGS AND UNWHOLESOME
PROCESSED FOODS – **NAFDAC** NIGERIA**

AT THE

**TECHNICAL CONFERENCE ON THE TRAFFICKING
IN FRAUDLENT MEDICINES**

**14TH – 15TH FEBRUARY 2013
VIENNA-AUSTRIA**

ORDER OF PRESENTATION

1. INTRODUCTION

2. NAFDAC MANDATE

3. COUNTERFEIT MEDICINES – NATIONAL PICTURE

4. FACTORS THAT ENCOURAGE COUNTERFEITING

**5. STRATEGIES EMPLOYED TO FIGHT
COUNTERFEITING**

6. CHALLENGES

7. CONCLUSIONS

The criminal economy of counterfeit medication is appalling:

•Because it preys on the poorest countries, and within them, on families with no social protection and no financial means;

•Because it involves drugs that are the most vital to individual and public health: treatment for malaria, tuberculosis and AIDS;

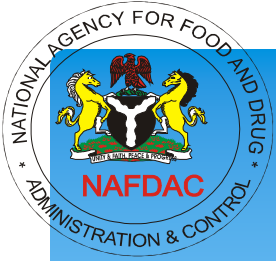
**President Jacques Chirac – Cotonou
Declaration
Monday October 12, 2009.**

INTRODUCTION:

Nigeria : Demographics

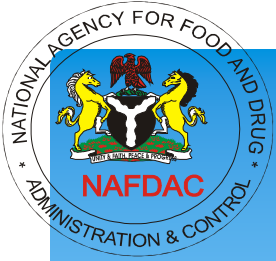
Nigeria is a country in west Africa bordered to the East by Cameroun and Tchad, the West by Benin Republic, and the North by Niger Republic.

- * Area: 923,768 km²**
- * Structure: 36 States + FCT**
- * Capital: Abuja**
- * Other main cities: Lagos, Port Harcourt & Kano**
- * Population: 140million**
- * Adult literacy rate : 111/179- (71.0)**
- * Below poverty line: 34.1%**
- * Development index: 154 (0.499)**
- * GDP Per capita PPP USD: 139 /179-(1,852)**



NAFDAC Mandate:

- * The National Agency for Food and Drug Administration and Control (NAFDAC), was established by the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004.**
- * This Act mandates NAFDAC to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices and packaged water (known as regulated products).**

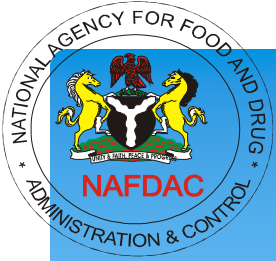


COUNTERFEIT MEDICINES – NATIONAL PICTURE

*** Definition: WHO/IFPMA**

”A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source.”

- ❖ Re-labeled drugs with the intention of extending the shelf life**
- ❖ Drugs not registered by NAFDAC**
- ❖ Herbal preparations fraudulently mixed with orthodox medicine**
- ❖ Drugs without full name and address of the manufacturer**



COUNTERFEITING: NIGERIA PICTURE

◆ **Drug counterfeiters target medicines that are used in high volume for managing diseases of public health interest such as:**

- * **Antimalarials**
- * **Antibiotics**
- * **Antihypertensives.**
- * **Anti-diabetic agents**
- * **Life style drugs**



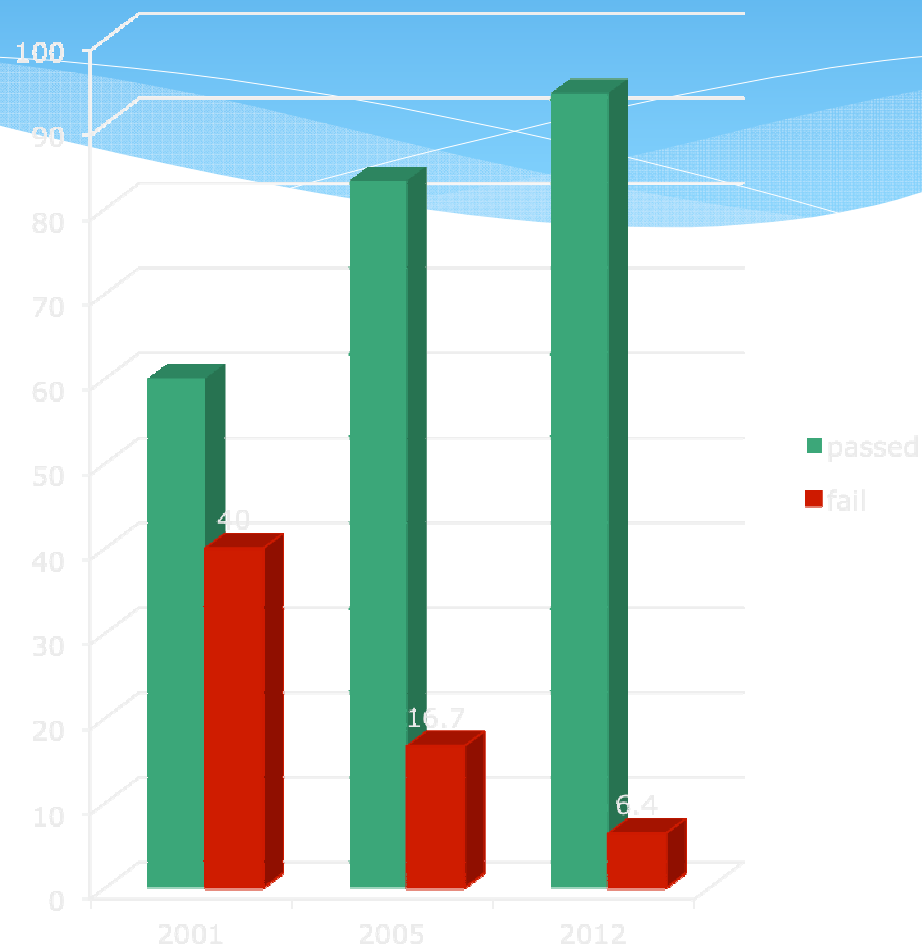
COUNTERFEITING: NIGERIA PICTURE

According to studies conducted by NAFDAC from 2001 – 2012 there is a positive trend which shows a progressive decrease in the incidence of counterfeit medicines in Nigeria:

NAFDAC/WHO/DFID Study shows that:

In 2001 counterfeit stood at 40% as against 16.7% in 2005.

National Survey on Quality of Medicines using Truscan shows that counterfeits stood at 6.4% in 2012





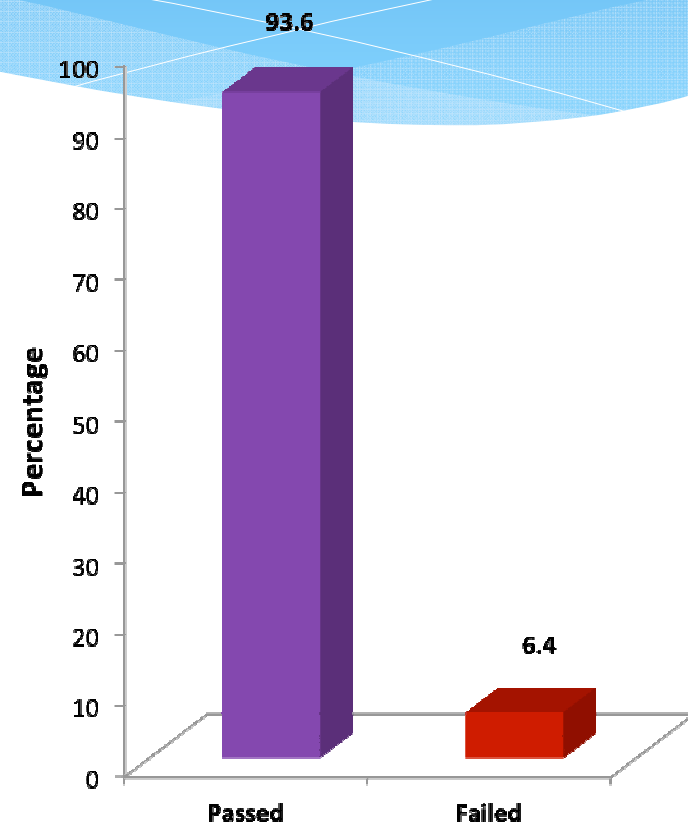
COUNTERFEITING: NIGERIA PICTURE

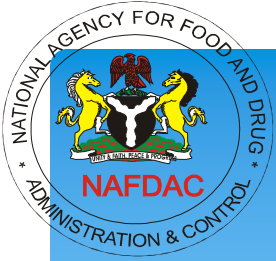
National Survey on Quality of Medicines

The National Survey on Quality of medicines using Truscan device was conducted by NAFDAC across 29 States including FCT, Abuja from January, 2010 to April, 2012.

5790 samples tested
5419 samples passed
371 samples failed.

The percentage of the samples that passed is 93.6% while the percentage failure is 6.4%.





National Survey on Quality of Medicines (Antimalarials)

5790 samples

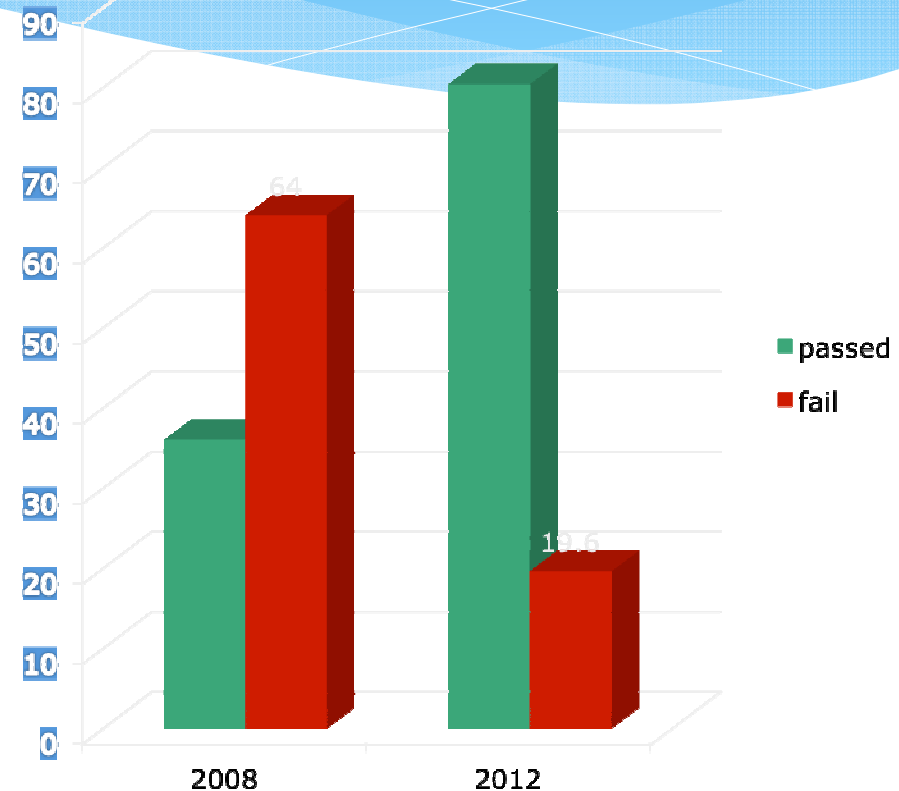
910 of these were antimalarials.

732 of these samples passed

178 of these samples failed.

The percentage of the antimalarial samples that passed was 80.4%, while the percentage failure was 19.6%. This is an improvement on the figures obtained from the study on the Quality of Anti-Malarials in Sub-Saharan Africa (QAMSA).

*** The QAMSA Study of 2008 had a failure rate of 64% whilst 36% passed.**



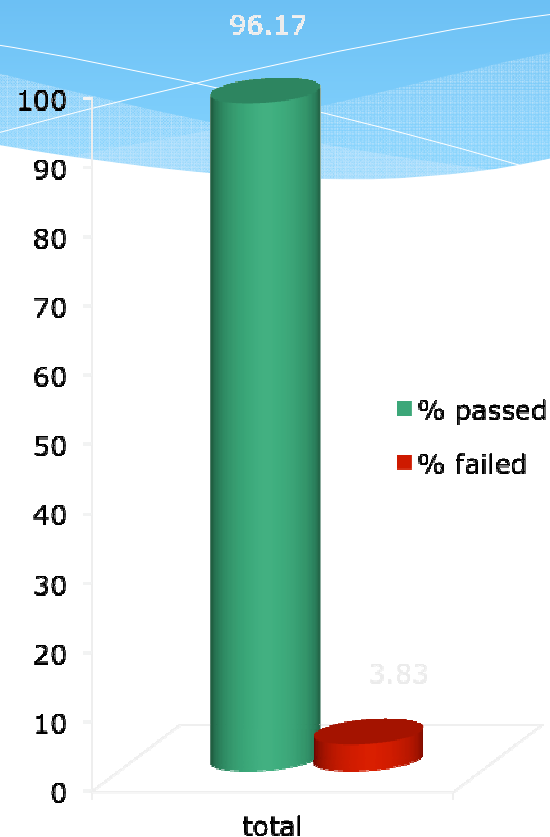


Samples of Medicines Tested Using Truscan Device

Another survey on the quality of medicines was conducted in Lagos State in May, 2012 using the Truscan device.

A total of 235 samples of medicines comprising antimalarials, antibiotics, antidiabetics and anti-inflammatory agents were tested.

**235 total samples
226 samples passed – 96.2%
9 samples failed – 3.8%**



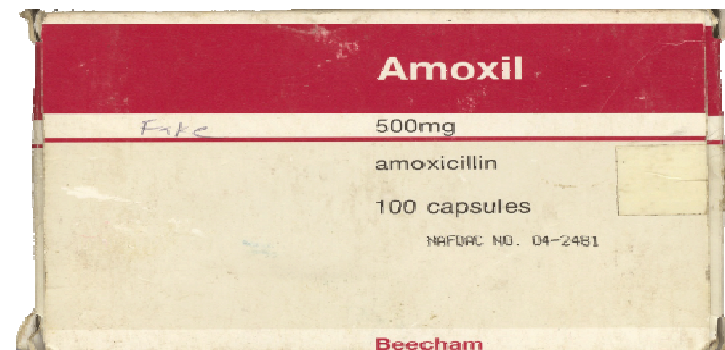
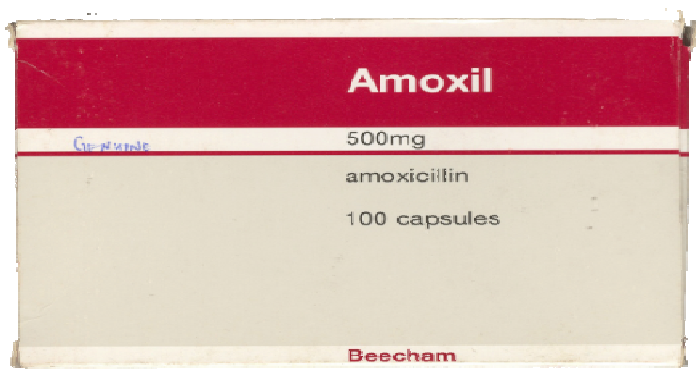


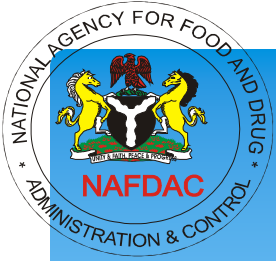
The advent of sophisticated printing technologies makes visual detection with the naked eye almost impossible.



GENUINE

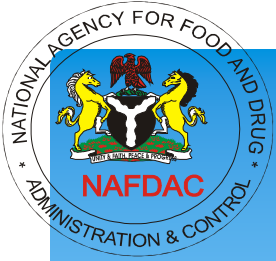
FAKE





COUNTERFEITING: NIGERIA PICTURE...

- * In 2009, NAFDAC officers intercepted a huge consignment of almost 700,000 doses of fake clones of a popular Indian anti-malarial labelled as made in India.**
- * The Chinese State Food and Drug Administration and the Chinese Chamber of Commerce worked with us on this landmark case and six Chinese citizens were arrested and sentenced to death.**
- * At that time, the Chinese authorities were fixed in their position that it was the responsibility of the importing country to ensure the quality of pharmaceuticals coming into its territory.**

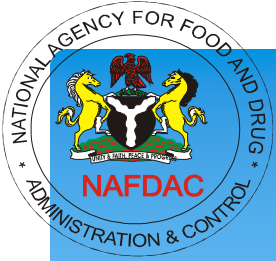


Factors that Encourage Counterfeiting

*** In Nigeria:**

- * A developing country**
- * Large population – 167 Million**
- * Good market size**
- * Low local production capacity/over 60% Importation**
- * Good buying power as oil producer**
- * Vast and porous borders - 924,000km²**

All these make Nigeria the choice destination on the African continent.



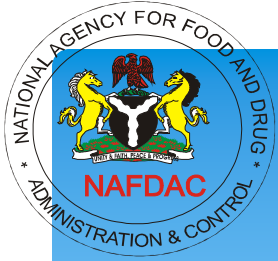
PUBLIC HEALTH IMPLICATIONS:

Patients are denied access to quality medicines leading to:

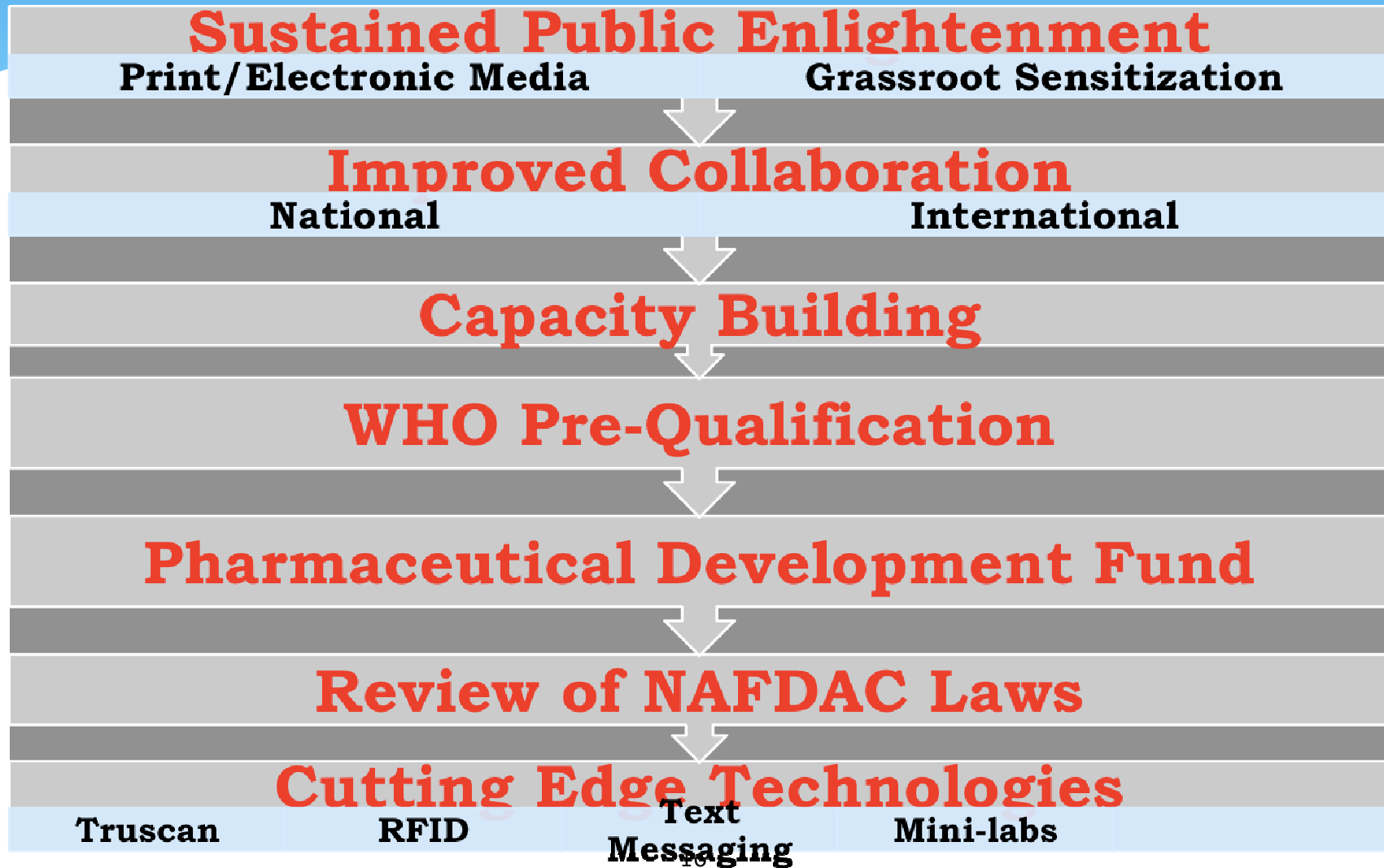
- **Treatment failures and death**
- **Increased hospital admissions**
- **Prolonged hospital admissions**
- **Development of resistance:**
 - **drug resistance**
 - **multi-drug resistance**
 - **cross resistance**

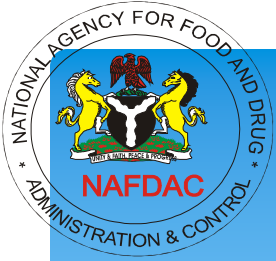
All these lead to:

- **Increased cost of controlling disease**
- **Increased out of pocket expenses**
- **Increased human suffering**
- **Loss of confidence in the healthcare system**
- **Increased burden on the healthcare system**



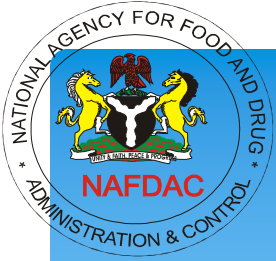
NAFDAC STRATEGIES





SUSTAINED PUBLIC ENLIGHTENMENT

- **Increased public enlightenment programs**
- **NAFDAC and your Health aired on NTA, Channels TV, AIT and Ben TV in the UK..**
- **NAFDAC Number and NAFDAC Half Hour aired on Radio stations in Yola, Lagos, Yenegoa, Ibadan, Awka, Kano, Calabar and Makurdi.**
- **NAFDAC Consumer Safety Club**
- **Consultative fora with stakeholders.**
- **Sensitization programmes**
- **Advocacy visits**

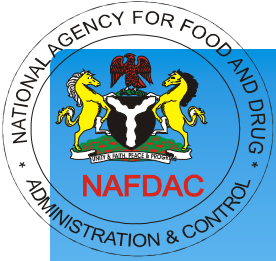


National Collaboration:



Establishment of the Federal Taskforce on Fake and Counterfeit Drugs and Unwholesome Processed Foods (Miscellaneous) Act C34 LFN 2004. The Collaboration draws its membership from:

- 1. NAFDAC**
- 2. Nigeria Police Force.**
- 3. Nigeria Customs Service.**
- 4. Pharmacists Council of Nigeria**
- 5. Nigeria Ports Authority.**
- 6. Consumer Protection Council**



National Collaboration...

We are also working with:

- * Professional bodies – PSN, NANM, PPMVL**
- * Private sector – PMG-MAN, APIN, NIROPHARM, IPMIN**
- * Civil Society Organisations**
- * Religious bodies**
- * Traditional Rulers**



International Collaboration:

- India
- China
- USA
- Ghana

- WHO
- UNICEF
- DFID
- CHIRAC FOUNDATION
- GAIN MI

**BILATERAL
COLLABORATIONS**

**INTERNATIONAL
ORGANIZATIONS**

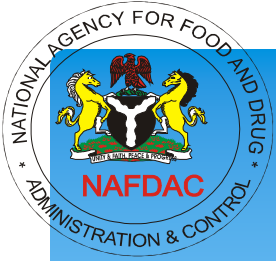
NAFDAC

**IMPACT
MSM ON
SSFFC**

**EMACCOM/
WADRAN**

- INTERPOL
- MRAs
- WCO, WTO, OECD, WIPO, etc.

- ECOWAS member states
- AFDNAN



CAPACITY BUILDING

- * This has been made a top priority through human resource capacity development, upgrade of our laboratories and continuous training of officers to strengthen our regulatory capacity.**
- * Support of the local pharmaceutical sector and working to build appropriate capacity to produce drugs locally that meet international standards and reduce the dependence on imports.**

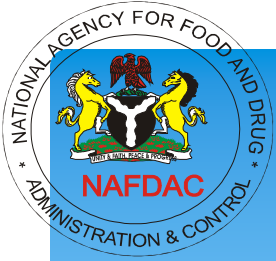


Upgrading of NAFDAC Laboratories:

On 15th October 2010, His Excellency, the President and Commander in Chief of the Federal Republic of Nigeria, Dr. Goodluck Ebele Jonathan, GCFR commissioned the upgraded NAFDAC Ultra Modern Area Laboratory in Agulu, Anambra State.

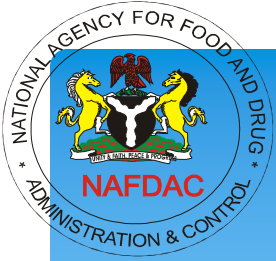
The laboratory was upgraded to international standards to further facilitate international and NAFDAC laboratories.





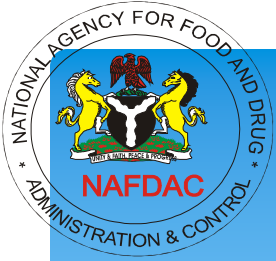
WHO Prequalification

- ◆ **We have actively encouraged the local pharmaceutical industry to work towards attaining WHO prequalification.**
- ◆ **WHO prequalification will facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis.**
- ◆ **This will afford Nigerian pharmaceutical companies the opportunity to participate in international bidding of drugs and other pharmaceutical products.**
- ◆ **This will in turn generate revenue for Nigeria and employment opportunities**



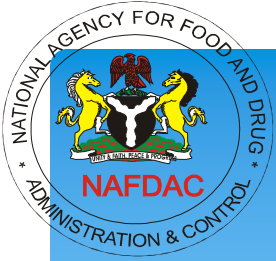
WHO Prequalification...

- * Seven (7) prospective companies identified by a team of WHO inspectors will be provided with technical assistance and expert advice as they work towards obtaining WHO Prequalification.**
- * In a similar vein, First Medicals, manufacturers of auto-disable syringes in Port Harcourt, Rivers State, recently obtained WHO prequalification for their products.**
- * This means the products have attained international standards and will promote access to quality products in the industry.**



Pharmaceutical Development Fund

- **NAFDAC in collaboration with the Bank of Industry (BOI) facilitated a Pharmaceutical Development Fund in a bid to provide support to the pharmaceutical sector and ensure an enabling environment for the growth and development of the local pharmaceutical industry.**
- ◆ **This was done in consultation with members of Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG – MAN) which seeks to put aside a fund of Two Hundred Billion Naira (₦ 200,000,000,000) structured at low interest rate to allow for the upgrading of the pharmaceutical industry and the entire value chain.**

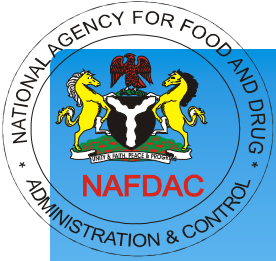


Pharmaceutical Development Fund...

*** These initiatives will:**

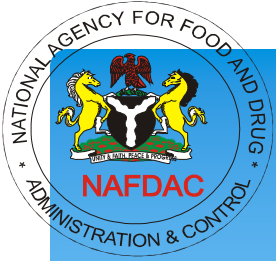
- **Play a significant role towards the growth of the Pharmaceutical Industry in Nigeria.**
- **Generate employment opportunities.**
- **Enable the Industry engage in research activities and provide research grants to academia.**
- **Improve the nation's economy.**

*** His Excellency, President Goodluck Ebele Jonathan (GCFR), is fully supportive of this initiative.**



LAW REVIEW

- **The Agency is reviewing NAFDAC laws, with a view to making them more of a deterrent.**
- **The current law stipulates a fine of N500, 000 or 15 year jail term upon conviction.**
- **The new law seeks life term jail and confiscation of assets upon conviction, compensation for victims where the counterfeit product is found to be the proximate cause of severe bodily injury, as well as to make counterfeiting a non-bailable offence.**
- **A whistle – blower clause is also proposed**



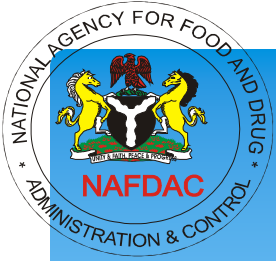
Cutting-Edge Technologies.

NAFDAC is currently spearheading global efforts and has gained international recognition in the use of cutting-edge technologies to fight counterfeit drugs and other regulated products.

These include:

- ✓ **TruScan (Raman Spectroscopy)**
- ✓ **Black Eye (Infra Red)**
- ✓ **Radio Frequency Identification (RFID)**
- ✓ **Minilab**
- ✓ **Mobile Authentication Service (SMS TEXT Messaging)**

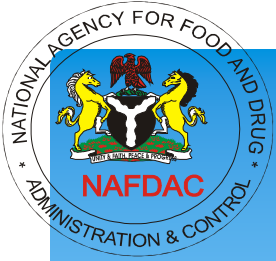
We are the first Medicines Regulatory Authority to deploy and use Truscan[®], a hand held device with resounding success at borders and within the country to detect counterfeit medicines on the spot.



TRUSCAN

- * **The Truscan is a hand-held device used for on - the -spot detection of counterfeit medicines.**
- * **It allows regulators and law enforcement agents to conduct field based screening of pharmaceutical samples to quickly and accurately identify counterfeits.**
- * **Celebrated investigative journalist, Dan Rather, formerly of CBS, was in Nigeria to see this device in use first hand.**





TRUSCAN

Concept of Operations

◆ NAFDAC Central Lab in Lagos

- * Develops and maintains library of medicines
- * Sends updates to field units
- * Collects and analyzes data from field

◆ Field Inspectors

- * Perform random and targeted inspections
- * Generate and sends reports from Truscans to central lab





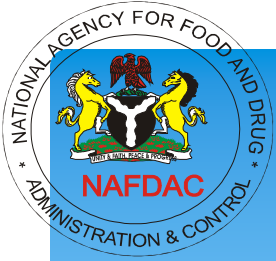
GPHF Minilab Test Kits:

We are utilizing the Global Pharma Health Fund Minilab Test Kits for speedy evaluation of medicines.

The test kit is also useful in detecting counterfeit medicines.

It is a reliable, simple and inexpensive method for detecting counterfeit medicines.





Mobile Authentication Service (MAS)

NAFDAC has launched the Mobile Authentication Service (MAS) using Short Message Service (SMS). This technology has put the power of detecting counterfeit regulated products in the hands of more than 80 million Nigerian cell phone users, thereby enrolling them in the fight against counterfeiting.





NAFDAC's Partner Telecom Operators

Now



Coming



etisalat

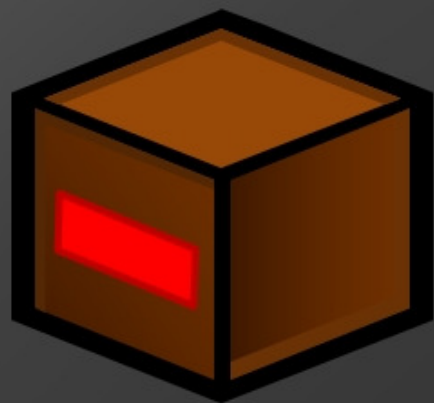




**NAFDAC Raising awareness with
Nigerian celebrities (2Face)**



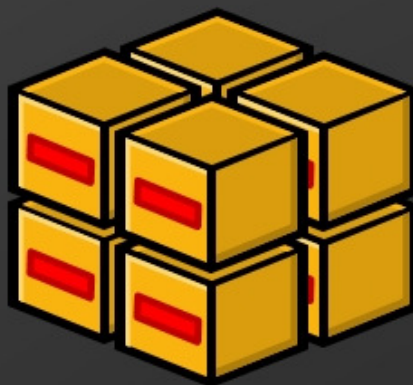
Everyone can check for fakes



Distributor



Genuine



Wholesaler



Genuine



Retailer



Genuine



Consumer



Genuine

SPROXIL.



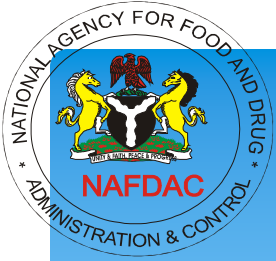
**Stakeholders authenticating using
MAS**



NAFDAC Launch: Stakeholder Reaction

Key members of industry express their views





NAFDAC Launch: Stakeholder Reaction



**International manufacturers
and importers express their
views**



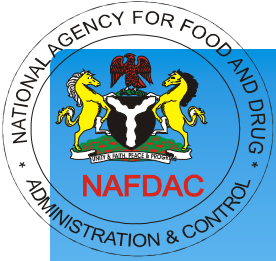
NAFDAC Launch: Stakeholder Reaction



Head of NIROPHARM (Trade Group for Multinational Pharmas in Nigeria)



Head of APIN (Trade Group for Pharma Importers in Nigeria)



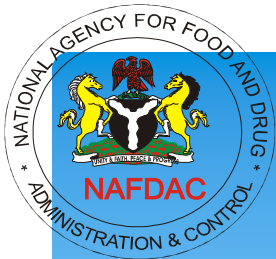
INNOVATIONS

- ◆ **We at NAFDAC are fully aware of the importance of Information Technology and the benefits that accrue from its application. We have deployed various IT tools and solutions to drive our processes. These include:**
 - * **An established Web presence where activities and Information on the Agency are available on the website**
 - * **A Corporate Portal which allows for in house sharing of information.**
 - * **A Laboratory Information Management System (LIMS) to support quality laboratory procedure and data processes.**



INNOVATIONS ...

- * An E-Clearance Portal which allows for online electronic clearance of goods at the ports.**
- * The NAFDAC Automated Product Administration and Monitoring Solution (NAPAMS). This is a web portal that is internet enabled providing an electronic platform for the management of the registration process/E-Registration and a database to capture information on all NAFDAC regulated products.**
- * This makes the process more transparent and support towards the attainment of the 90 days timeline.**



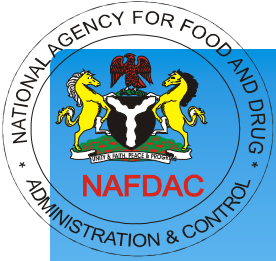
CHALLENGES

Inadequate budgetary allocation

- * **N15.5 million Overhead**
- * **N75 Million Capital expenditure**
- * **High operational Cost**
- * **Shortage of manpower**

	Nigeria	USA
* Population	167,000,000	300,000,000
* Staff	2,198	12,000
* Budget	N90.5 Million	\$2.4 Billion
* Offices	37	223

- * **TGA Australia 16,000 (Population 21 Million)**
- * **SFDA China 70,000 (Population 1.3 Billion)**
- * **Shortage of operational vehicles**
 - * **Large coverage area**
- * **Aged infrastructure – over 10 years.**
- * **Withdrawal of NAFDAC from the Nigerian Ports.**



CONCLUSION:

- **NAFDAC has adopted a holistic, multifaceted, diverse and well coordinated anti-counterfeiting strategy that transcends local, national and international boundaries.**
- **Effective regulation is key to ensuring quality and safety of regulated products.**
- **NAFDAC is relentlessly working with all relevant stakeholders to ensure that all NAFDAC registered products, irrespective of their origin are of good quality, wholesome, safe and efficacious.**