# THE CHALLENGES FACED BY NAFDAC IN THE NATIONAL REGULATORY PROCESS AS IT RELATES TO ESSENTIAL DRUGS FOR PREVENTION OF MATERNAL AND NEWBORN DEATHS IN NIGERIA

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## INTRODUCTION

This dialogue has come at a very good time as a step towards achieving the target of the Millennium Development Goals (MDGs), which affects child mortality and maternal health by 2015. To achieve this, we need Public Private Partnership and all hands must be on deck; government, private sector, researchers, policy makers, NGOs, Religious Organizations and the society at large. Nigeria has been reported to have the worst under 5 mortality rate in Africa, ranging from 235 to 198 per 1000 live births in 1990 to 2003, respectively and high neonatal mortality rate of 48 per 1000 live births.

Some causes of neonatal mortality can be attributed to malaria, infections, acute respiratory tract infections, vaccine preventable diseases, etc. Malaria is a known cause of morbidity in-utero resulting in low birth weights with attendant lowered survival rates. Malaria also causes Preterm births. Also an estimated 50,000 Nigerian women die each year from complications in pregnancy and child birth, accounting for 10% of global estimates of maternal deaths. Some causes of these deaths are as a result of Malaria (11%), Anaemia (11%), Haemorrhage (23%), Eclampsia (11%), Sepsis (17%).

The Federal Government has made several efforts to reduce maternal and infant mortality and morbidity in Nigeria through various policies and establishment of various Agencies. In line with this, the National Agency For Food and Drug Administration and Control (NAFDAC), established by Decree No. 15 of 1993 (as amended by Decree 19 of 1999), regulates and controls the manufacture, importation, exportation, distribution, advertisement sale and use of food, drugs, medical devices, chemicals, cosmetics, and packaged water (referred to as NAFDAC regulated products).

The effective discharge of this mandate by NAFDAC, ensures essential drugs and other regulated products of good quality, efficacy and safety are available and easily accessible for mothers, children and the society at large.

## BRIEF OVERVIEW OF THE REGULATORY PROCESS

Regulation of drugs and other regulated products entails public policies that control private behaviour for public good. Effective regulation ensures that only safe, efficacious and right quality products are used in Nigeria. Without aggressive strengthening of our regulatory activities, fake and substandard product eradication will not be sustained.

This is what we experienced prior to April 2001 when I assumed office as Chief Executive Officer (CEO) of NAFDAC. We were faced with the arduous task of reactivating a failed food and drug regulatory environment of over three decades, which resulted in a crises situation characterized by massive copying of original brands of most regulated products. Various forms of fake drugs, unwholesome food, substandard cosmetics, chemicals and related products were dumped in Nigeria. The most worrisome was the case of tins of baby milk filled with a mixture of cassava flour and sugar.

The consequences of fake and counterfeit drugs were of greater dimension for obvious reasons and Nigeria became rated as one of the countries with the highest incidence of fake drugs.

The average incidence of counterfeit medicines in Nigeria was over 41% from various studies done before 2001. NAFDAC baseline study also showed that during the same period, about 68% of drugs in circulation were unregistered. Almost all drugs have been counterfeited, and counterfeiters target cost and volume.

Fake drugs embarrassed our health care providers and eroded the confidence of the public in our healthcare system. It led to treatment failures, development of drug resistance and death.

As people were dying, legitimate businesses were collapsing. Many multinational companies left

Nigeria or divested out of frustration due to unfair competition with the counterfeiters. Made-in-Nigeria drugs were banned by other West African countries.

## CHALLENGES OF DRUG REGUALTION IN NIGERIA

The challenges of drug regulation encompass the totality of effective control and regulation of drugs, their production processes, all the personnel involved with them, as well as the consumers and general public.

Factors which militate against effective drug regulation in Nigeria include;

**Corruption and Conflict of Interest/Insecure and Unfriendly Environment**

The drug counterfeiters came in different guises to negotiate with us so as to compromise us and continue to do their business as usual. When this failed they fought back with intimidation, harassment, blackmail and threats. On several occasions they deposited fetish objects in my office. **When all of these failed, they resorted to physical attacks and arson against NAFDAC staff and facilities.** These attacks culminated in a shooting attack on my person on December 26, 2003. During this near-death encounter, bullets shattered the back windscreen of my car, pierced through my head scarf and burnt my scalp. A bus driver was killed on the spot. **Three months later, between 7th and 11th March 2004, there was a synchronized burning of NAFDAC's facilities across the country. We also recorded twenty three other attacks against NAFDAC staff and destruction of over eight cars in the last seven years.**

**Discriminatory Regulation by Exporting Countries**

**Some countries have strong regulations for drugs and other products consumed internally and little or no regulation for those meant for export, and this encourages exportation of fake products. This is critical since about 60% of drugs in Nigeria are imported. Most of the fake drugs in Nigeria are imported from India and China. Consequently, from 2001 till date, we have banned 30 Indian and Chinese companies and 1 Pakistani company, confirmed to be fake drug producers, from exporting drugs to Nigeria.**

**Sophistication in Copying Technology**

**Sophistication in product faking has made it difficult for even brand owners to tell the difference between their brands and counterfeits.**

**False Declaration By Importers**

Some counterfeit product importers make false declarations about the contents of their containers. They stash drugs in the inner parts of containers of other items like clothes, motor spare parts and household items. We have made seizures of drugs concealed inside children's wears, men's clothes, duvets, shoes and DVD player cartoons.

**Inadequate Legislation**

**In most countries, laws against drug counterfeiting are very weak. Consequently, criminals are shifting from gun running and cocaine pushing to drug counterfeiting because it is financially as lucrative but of relatively lower risk.** The penalties for producing, importing or distributing fake drugs or other fake regulated products in Nigeria range from imprisonment of 3 months to 5 years, or option of fine of N10,000 to N500,000. In order to stem this tide, the Agency reviewed the laws and forwarded to the National Assembly in 2001, and we have resubmitted the reviewed laws several times on the legislators' request. We are still praying and waiting. The weak laws are further hampered by Abuse of Judicial Process, granting of inordinate injunctions to counterfeiters, long delays of trials and other handicaps.

i. Some cases get so protracted that the judges are either transferred or die in the process, and the cases are started all over again.
ii. On one occasion, a lawyer contracted by NAFDAC to prosecute a high profile case claimed that he lost all documents used in prosecuting the case.
iii. On another occasion, our lawyer (a Senior Advocate of Nigeria) signed to settle out of court with the defendant's lawyer without our permission.

**Lack of Awareness**

Drugs counterfeiters succeeded for about three decades in Nigeria largely because of lack of awareness which was worsened by the culture of silence that enshrouds the issue of drug and other regulated products counterfeiting. People died inexplicably after the right diagnosis and

correct medication were given without being able to link the deaths to fake drugs.

**Chaotic Drug Distribution System**

Drug distribution in Nigeria is very chaotic, with drugs sold in open markets, in buses and ferries, and hawked in the streets.

**Lack of Cooperation Among Regulatory Agencies**

Lack of cooperation among government regulatory and enforcement agencies (Food and Drug Agency, Customs, police, clearing agents, etc) at the ports creates a fertile ground for counterfeiting to thrive.

**Poor Database on Health Related Activities**

Another factor that encourages faking of drugs and other regulated products in Nigeria is the generally poor or total lack of record keeping, of health related activities in our various health establishments. There is actually no documentation or database on drugs used previously and experiences gained from using them.

**Irrational Use of Drugs**

Equally critical is the issue of rational use of drugs, which concerns every member of the health care delivery team as well as the consumer. The effect of dispensing doctors, prescribing nurses and some other health professionals becomes worrisome from this WHO report, "Many prescribers, as well as drug retailers, earn their living by selling medicines and not by charging consultation fees. It has been shown in many countries that prescribers who earn money from dispensing medicines consistently prescribed more drugs than those who do not make money from dispensing. In a study in Zimbabwe, dispensing doctors prescribed antibiotics to 58% of their patients compared to non-dispensing doctors who prescribed antibiotics to 48% of their patients". You can imagine the consequence on pregnant mothers and neonates.

## NAFDAC STRATEGIES TO ENSURE EFFECTIVE REGULATION OF DRUGS IN NIGERIA

**Staff Re-orientation, Reorganization and Motivation.**

**The following measures were taken to reposition NAFDAC staff for better effectiveness:**

Corrupt, redundant and incorrigible staff were retrenched.

New staff were employed based on merit.

We embarked on staff training and re-training, locally and internationally.

There was effective delegation of duties and staff empowerment at all levels.

There was constant staff performance evaluation to ensure commitment and effectiveness.

Various welfare packages including thirteenth month salary was initiated and is being sustained.

Hard work is rewarded. Reward is in the form of recognition, commendation letter, promotion, oversea inspection or training.

Staff members who catch defaulting companies or report any staff that compromises with defaulting companies are similarly rewarded.

Corruption is severely sanctioned. Staff members involved in aiding or abetting defaulting companies are out rightly dismissed.

Heroic activities are adequately rewarded.

Leadership by example is highly emphasized.

**Restructuring and Modernizing the Regulatory Processes**

NAFDAC was reorganized into eight functional Directorates as against the previous six. New directorates of Enforcement and Ports Inspection were established. We also established new state offices to cover the 36 states of Nigeria and the Federal Capital Territory Abuja. Six Zonal Offices and four special inspectorate offices were also established in towns with big drug markets. Five old laboratories were upgraded, three new ones are almost completed while warehouses and land border offices were also constructed. New Standard Operating Procedures and guidelines were developed so as to institutionalize our processes. All our regulatory processes are continuously upgraded and automated.

**Public Enlightenment Campaigns**

Enlightenment campaign remains one of our most effective strategies in combating product counterfeiting and creating effective regulation. Our enlightenment programme involves dialogue,

education and persuasion because this addresses the fundamental issue at stake, which is **BEHAVIOURAL CHANGE.**

These campaigns are sustained by using:

Print and electronic media, jingles, alert notices, billboards and p**ublications on the differences between identified fake and genuine products.**

**We also produced many other publications** in English and Vernacular.

Workshops, seminars and meetings have been conducted for most stakeholders.

Mobilization campaigns for rural dwellers are on-going.

In 2002, NAFDAC instituted an annual essay competition for Nigerian High School children for which cash prizes are given to the winners and computers, television sets, microscopes and encyclopedia are given to their schools at State, Zonal and National levels. We also established Consumer Safety Clubs in these schools as a platform for interacting with and educating the students for the establishment of a culture of quality consciousness in Nigeria.

In May 2007, **NAFDAC Green Pages,** a comprehensive multi-media publication that contains particulars of all NAFDAC registered products was launched. This publication includes names of products, NAFDAC registration numbers, names and addresses of manufacturers, importers and local agents.

NAFDAC is currently working in collaboration with NYSC members posted to the Agency in all States of the federation to carry and disseminate information on NAFDAC activities to all the villages and local government areas in the country. We have successfully completed this in Abuja, Lagos, Port Harcourt and Ibadan and other states will follow.

**Stopping the Importation of Fake Drugs and Other Substandard Regulated Products to Nigeria at Source i.e. Countries of Production**

NAFDAC officials must inspect factories anywhere in the world before we register their drugs, food and other NAFDAC regulated products, to ensure compliance with current Good Manufacturing Practice (cGMP).

NAFDAC appointed independent analysts in India, China and Egypt who re-certify drugs and other regulated products before they can be exported to Nigeria.

NAFDAC requires mandatory pre-shipment information to be provided by all importers before the arrival of their drugs.

NAFDAC's clearance permit is a requirement for Nigerian Banks to process any financial document for drug importers.

Before an imported drug, food or cosmetic is registered in Nigeria, we ensure that it is being used in the country of production by insisting on the provision of the Certificate of Free Sale, signed by the Minister of Trade or Industry in that country, and authenticated by the Nigerian Embassy, or any Commonwealth Mission if there is no Nigerian Embassy in that country.

**Beefing Up of Surveillance at All Ports of Entry**

NAFDAC has re-enforced the Directorates of Ports Inspection and Enforcement, for more effective surveillance at all ports of entry and better enforcement activities.

NAFDAC also stepped up surveillance at both land and sea borders, which led to the counterfeiters resorting to the use of airlines. **Consequently, NAFDAC issued a guideline that any aircraft that lifts drugs to Nigeria without obtaining NAFDAC's authorization from their clients would be grounded.**

**Mopping Up Fake Drugs and Other Substandard Regulated Products already in Circulation**

Cognizant of our many porous borders, NAFDAC embarked on planned, continuous and sustained surveillance at all markets and retail outlets for drugs and other regulated products.

We carry out routine sampling, checking and testing of all NAFDAC registered products in circulation.

We also trace fake drug and other regulated product dealers through reports from victims, health professionals and constant tip-off from the public.

Reports made by individuals have enabled us to trace the source of large consignments of fake drugs and other substandard regulated products.

**In 2003, Nigerian journalists reported the death of three children after an open-heart surgery. NAFDAC's investigations confirmed that fake drugs were used during the surgery.**

**In 2004, following reports from doctors about**

**adverse reactions of some infusions on their patients, infusions were sampled from all over the country, and our results confirmed that some batches of infusions produced by 4 indicted companies were contaminated with microorganisms.**

**In the same year, 147 of the 149 brands of water for injection screened on routine sampling were found to be non- sterile.**

Raids are regularly carried out on drug hawkers, and their drugs are confiscated and destroyed.

This continuous surveillance has led to the sealing off of drug shops, supermarkets and eateries, and the closure of 3 major drug markets: Aba for 6 months in 2002, Kano for 3 months in 2004 and Onitsha for almost 4 months in 2007.

To achieve a high level of success with our mopping up exercise, NAFDAC has put in place the following guidelines:

- **We confiscate and subsequently destroy all drugs from sellers who fail to provide proper invoices of purchase with full names and addresses.** This is to enable us trace the big time importers, producers and distributors of fake drugs.
- Faced with the frustrations of evacuating many lorry loads of fake drugs from warehouses on tip off without anybody accepting ownership, NAFDAC notified the public that whenever the importer of fake drugs cannot be traced, **the landlord of the premises used for the storage of such products would be arrested, with a view to tracing the importer.** On one occasion in Lagos, it was only after the landlord of the warehouse was arrested that the fake drug owner surfaced.

**Regular GMP Monitoring of Local Manufacturers**

NAFDAC monitors local manufacturers of drugs and other regulated products routinely to ensure compliance with Good Manufacturing Practice.

Compliance Directives are issued and enforced to the letter when lapses are observed.

Prosecution is carried out as a last resort.

**Streamlining and Strict Enforcement of our Registration Guidelines**

NAFDAC has strengthened its registration processes with some administrative guidelines which include the following:

All products must comply with inspection requirements and laboratory standards before they are registered.

Renewal of registration of drugs and other regulated products is every 5 years, while renewal of herbal medicine listing is done every 2 years until the product gets full registration. For herbal medicine we test only for quality and safety as is done all over the world with this caveat on the label, "These claims have not been evaluated by NAFDAC".

NAFDAC insists on fixing of **NAFDAC REGISTRATION NUMBER** on the label of all products to enable the public identify registered products.

**NAFDAC will soon commence the use of serialized holographic labels to safeguard NAFDAC registration numbers on registered products to prevent counterfeiters from copying and faking NAFDAC numbers.**

Drugs can be imported for a maximum of ten years, after which the importer must start local production.

**Regulation and Control of Clinical Trials**

Clinical trial is a requirement for NAFDAC registration of new drug molecules in Nigeria. NAFDAC ensures that clinical trials are conducted in compliance with regulatory requirements. In this regards, we have established a Clinical Trial Unit in the Registration and Regulatory Affairs Directorate and developed all necessary regulations and guidelines for clinical trials of drugs.

**OTHER INTERVENTIONS:**

**Pharmacovigilance:** NAFDAC established a National Pharmacovigilance Centre (NPC) in September 2004 and we got admitted as the 74th member of the WHO Drug Safety Monitoring Program. Till date, we have received over 649 reports of adverse drug reactions. These reports have enabled us to ban or restrict the use of some drugs.

**Regulatory control of prescription medicines:** It is common practice in Nigeria for ethical drugs to be purchased without prescription. This fuels irrational drug use which sustains drug counterfeiting. **NAFDAC has started enforcing the requirement that ethical drugs are obtained strictly on**

**prescription. In agreement with other stakeholders, we started with all injectables in addition to sedatives that are already being enforced. Others will follow in phases.**

**International Collaboration: NAFDAC initiated and is currently heading the West African Drug Regulatory Authorities Network (WADRAN) which is a forum where heads of drug regulatory authorities in West Africa can share strategies and experiences and carry one another along in the fight against drug counterfeiters.**
This was necessitated by the fact that when drug counterfeiters were chased out of Nigeria, they relocated to other West African countries and became a big problem for them. It therefore became necessary for us to work in concert so as to ensure that drug counterfeiters do not find a safe haven anywhere in the sub-region. We are also extending this collaboration to other countries in Africa.

**In 2002, we proposed and have continued to advocate for the establishment of an international convention on counterfeit drugs, just as we have for narcotics and psychotropic substances. In 2006, WHO proposed the international Medicine Products Anti-counterfeiting Taskforce (IMPACT), which was subsequently established to formulate and execute strategies for international collaboration. NAFDAC is also playing a leading role in IMPACT by virtue of my being the Vice Chair.**

## CELEBRATING SHORT TERM MILESTONES

Although we have not reached our final destination, we can celebrate the following milestones:

We have sanitized the food and drug industry, and created a reasonably well regulated environment that have saved the lives of millions of Nigerians, and indeed millions of Africans and boosted our economy by encouraging local industries and foreign investors.

Immense public awareness has resulted in the participation of all stakeholders in the regulatory processes, and this has awakened international consciousness that Nigeria is no longer a dumping ground for fake products.

Counterfeit drugs in circulation have dropped from an average of over 41% in 2001 to 16.7% in 2006.

Drugs unregistered by NAFDAC stood at 19% in 2006 as against 68% recorded in 2001.

The production capacities of our local pharmaceutical industries have increased tremendously, and their number has risen from 70 to 150 in the last 7 years.

By 2001 our local pharmaceutical industries were producing less than 25% of our drug need, but now they produce over 40%.

There is a continuous upward movement in the share prices of the pharmaceutical companies quoted in the Nigerian Stock Exchange.

Many multinational pharmaceutical companies are coming back to Nigeria as a result of the improved regulatory environment.

Ban on 'made-in-Nigeria' drugs has been lifted by other West African countries. In fact there is so much confidence in 'made-in-Nigeria' drugs that our drugs are now marketed in many African countries. At the ports, we have even intercepted drugs made in India but labeled 'made-in-Nigeria'.

In the last 7 years, NAFDAC has carried out 121 destruction exercises of counterfeit and substandard products valued at over **22.8 Billion Naira.**

45 convictions have been secured in respect of counterfeit drug related cases, while 60 cases are pending in courts.

Old food and cosmetics industries are expanding their production capacities while new ones are springing up.

Sanitization of bottled and sachet water production has greatly reduced cholera and other water-borne disease outbreaks, which used to be rampant in the country.

NAFDAC monitors salt iodization, and UNICEF has rated **Nigeria as the first country in Africa to achieve Universal Salt Iodization (USI).** We are currently working to achieve the same feat with Vitamin A fortification.

The use of bromate by Nigerian bakers has dropped from over 95% in 2001 to less than 0.001% in 2007.

These 'Short-term-wins' have become great morale boosters for the NAFDAC team. They have earned us the respect of consumers and regulated industries, as well as the trust, support and political

will of Government. They also, to a large extent, helped to promote and sustain the change process.

## CONCLUSION

Although drug regulation is basically a government function, effective food and drugs regulation requires the support and participation of all stakeholders including the consumers.

The regulated industry must take advantage of the established linkages and collaborations within the industry to encourage self-regulation.

The reduction of maternal and infant deaths in Nigeria to the barest minimum requires the following strategies as regards drug regulation and control:

- Full support to the eradication of fake drugs and other unwholesome regulated products and creation of a well-regulated environment.
- Encouragement of local capacity building in the drug manufacturing industry.
- Introduction of overt and covert security measures by regulated product manufacturers right from product design to secure their products from counterfeiting.
- Teaching and practice of rational use of drugs and proper storage conditions should be given some focus in the medical and pharmacy schools as well as in the professional practice environment. Drug storage and cold chain maintenance of vaccines are critical to drug integrity and subsequent efficacy or toxicity.
- Ensuring that source of drugs for the Teaching Hospital, Health Centres and Private Clinics are from certified manufacturers or their accredited distributors. Increased patronage of locally manufactured drugs is strongly recommended.

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