Food and Drug Administration Reforms

The Problem

Prior to the reforms in 2001, Nigeria was a haven for substandard and counterfeit drugs. In 2003, the National Institute of Pharmaceutical Research reported that 80% of drugs on sale in Lagos were fake. Generally, the incidence of fake drugs in Nigeria was reported to be at least 41% of all drugs in the market. Counterfeit drugs were freely sold in commercial buses and there was even a specialist fake drugs market in Onitsha, Anambra State. West African countries had banned the importation of all pharmaceutical drugs from Nigeria. The Food and Drug Administration and Control regime had failed for over three decades, and every facet of the operation was dysfunctional – from the staff, to the laws, to the facilities. The National Agency for Food and Drug Administration and Control (NAFDAC) did not have a single functional laboratory, their offices were dilapidated, and their personnel were completely unmotivated. The situation was completely out of control. As examples:

a. In 1990, 200 children died after taking Paracetamol syrup produced with toxic diethylene glycol solvent

b. In 2003, two children who had benefitted from heart surgery sponsored by the Kanu Nwankwo Heart Foundation died as a result of fake cardiac stimulants administered on them during the surgery process

c. In 2008, 70 children died from contaminated teething powder mixture (My Pikin Teething Mixture)

Although there were numerous other cases, such as contaminated intravenous infusions, contaminated water for injections, fake anti-diabetic, antibiotic, and anti-arthritis drugs, the incidences that caused the most severe public outrage were those that resulted in the death of children.

Reform Actions

NAFDAC undertook a whole-system review of all its operations. Its reform was based on four main strategies:

1. Restructuring and reorganising NAFDAC, including staff reorientation, reorganisation and motivation, restructuring the organisation, improving laboratory capacity, and improving physical infrastructure.
2. Improving the operations of NAFDAC, including introducing new regulations, controlling clinical trials, targeting the sources of counterfeit medicines, strengthening surveillance at all ports of entry, destroying fake drugs already in circulation, and quality assurance of locally manufactured products.
3. Engaging stakeholders, including the use of public enlightenment campaigns, workshops and seminars, engaging with manufacturers, engaging with all relevant stakeholders including the media, the courts, the Standards Organisation of Nigeria and the Nigeria Customs Service.

4. Enforcing discipline, including naming and shaming offenders, blacklisting offending companies, seizure and destruction of fake and substandard drugs and jailing of offenders.

Additionally, NAFDAC has ensured that its recruitment is open and transparent, that there is a robust performance management system in place, that there is zero tolerance for corruption, that there are clear incentives and sanctions, that the technical capacity of officers is enhanced and that there is public support for NAFDAC activities.

Main Achievements

1. The incidence of counterfeit and substandard drugs in Nigeria has reduced to less than 10% from about 41% ten years ago. Truscan survey carried out in 2012 indicated that the level of counterfeit and substandard medicines has dropped to 6.4%.
2. NAFDAC was rated by NOI Polls as the most effective government agency in Nigeria for three years in a row, 2007, 2008, and 2009.
3. The United Nations Office on Drugs and Crime has rated Nigeria as West Africa's most effective drug control country and commended the work of NAFDAC.
4. Successful completionof a multi-million Naira ultra-modern state-of-theart regional laboratory complex in Agulu, Anambra State in 2010.
5. Successful re-certification of all registered packaged water and training of the producers in 2012.
6. Successful registration of over 18,010 water products from 2009 to 2013.
7. In 2013, Nigeria received commendation and congratulatory messages over Dr Orhii's selection as Chair of the WHO's Member State Mechanism (MSM) for the international fight against substandard, spurious, falsely- labelled, falsified and counterfeit medical products (SSFFC Medical Products). This was in recognition of NAFDAC's consistent and successful fight against drug counterfeiting.
8. There has been an introduction of cutting -edge technologies in the fight against counterfeit drugs. i.e. Truscan, Mobile Authentication Service (MAS), Radio Frequency Identification (RFID), Mini Lab, Black Eye amongst others.
9. In 2013, Nigeria obtained the ISO 17025 accreditation conducted by the American Association of Laboratory Accreditation (sponsored by the United Nations Industrial Development (UNIDO)) for two Lagos-based NAFDAC's laboratories (Pesticide and Mycotoxin Labs). Consequently launching the two laboratories into the league of internationally recognized and respected laboratories.
10. SWIPHA pharmaceutical company has obtained World Health Organisation (WHO) pre - qualification with support from NAFDAC, WHO, DFID etc. CHI pharmaceuticals, May & Baker Pharmaceuticals and Evans Pharmaceuticals are at the verge of obtaining theirs, while many more are still in the process.
11. Creation of an electronic platform for the management of registration process and a database to capture information on all NAFDAC-regulated products.
12. Provision of guidance through training, laboratory analysis, advisory inspections, and consultative meetings with producers in the water sector.
13. Review of safe and responsible use of agrochemicals, guidelines and standard operating procedure for chemical regulation and control to address emerging trends.

14. Introduction of risk assessment and field trials of fertiliser for effective control and management of agrochemicals.
15. Creation of an e-clearance portal for online electronic clearance of goods at the ports.
16. Creation of a laboratory information management system to support quality laboratory procedures and data processes.
17. Procurement and refurbishing of ultra-modern operational office complexes in Isolo, Lagos and Port Harcourt.
18. Land allocations for stand alone prototype NAFDAC offices in Abuja, Makurdi among others.
19. Rebuilding of burnt NAFDAC Kaduna Area Laboratory Complex which is now ready for commissioning.
20. Establishment of additional Directorates for greater effectiveness along product lines regulated by NAFDAC to entrench professionalism in the system.
21. Gender Reforms- Developed and distributed the Agency's Gender Policy.
22. Increased human capacity building to constantly keep abreast of developments in the international community and scientific world to improve productivity.

Key Challenges

1. Out-dated laws as well as deficiency in the implementation of laws.
2. Existence of 'open drug markets' in the production and distribution of drugs. This has made it possible for many young persons, particularly in Northern Nigeria, to abuse off-the-shelf drugs such as Benylin and codeine.
3. Alcoholic herbal concoctions known as 'paraga' and 'sepe' are very popular among young persons, and NAFDAC seem to be unable to control or regulate their sale. They are hawked freely on the streets.
4. There is continued consumption of non-vitamin-fortified food products.
5. There is still a stronger-than-desirable influx of counterfeit and substandard drugs into the Nigerian market.
6. The inspection regime, particularly the unannounced raids on pharmacy stores and markets seem to have slowed in the last few years.

Assessment of the Reforms

Judged against the 10 assessment criteria, the food and drugs administration reforms made significant impact in bringing sanity in the Nigerian pharmaceutical industry.

S/No.	Assessment Criteria	Result of Assessment
1.	Have the reforms improved the quality and quantity of public services?	Yes. Only less than 10% (6.4% as at 2012) of pharmaceutical drugs in the country are substandard or counterfeit.
2.	Do more people now have access to services, including	Yes. Citizens can now send a text to NAFDAC, free of charge, to ascertain whether a drug is

S/No.	Assessment Criteria	Result of Assessment
	disadvantaged groups such as women, young persons, and people with disabilities?	genuine or counterfeit. Using MAS technique - Scratch a card and send the pin by text to the code 38353 to ascertain if it is genuine.
3.	Have reform reduced the cost of governance?	The reduction in cases of treatment failure from counterfeit drugs has reduced the cost of public healthcare.
4.	Have the reforms made the service more affordable for citizens?	Citizens now get better value for money as they are now spending money on genuine pharmaceuticals and other NAFDAC regulated products.
5.	Have the reforms reduced corruption?	Yes. The reforms have reduced the corruption inherent in the drug administration and control regime in Nigeria.
6.	Have the reforms reduced unnecessary bureaucracy and red tape?	Yes. It is now much easier and faster (upon submission of all required documents) to get licences for pharmaceuticals and other NAFDAC regulated products, without paying a bribe or going through unnecessary bureaucracy.
7.	Are the reforms likely to lead to improved development outcomes?	Yes. A better regulated food and drug regime will lead to better development outcomes for citizens in terms of improved health and safety.
8.	Are things improving, staying the same, or getting worse?	Things are improving and the reforms in NAFDAC are worthy of emulation by other agencies.
9.	Where things are improving, will those improvements endure?	The menace of fake drugs is a vicious and unrelenting one. Improvements will only endure with constant vigilance, surveillance and enforcement activities, review of processes and policies, continuous awareness-raising and stringent action against counterfeiters.
10.	Where things are not improving, what should be done?	Not Applicable.

Proposed Next Steps

1. Strengthen collaboration with the Nigeria Customs Service, the Standards Organisation of Nigeria, and others to ensure that the gains made on the reduction of the incidence of counterfeit and substandard drugs are not lost.
2. Strengthen the enforcement of regulation around herb-infused alcoholic drinks.
3. Instruct pharmacies to limit quantities of off-the-shelf drugs sold, without causing undue hardship to citizens.

4. Strengthen routine, unannounced inspections of pharmacies, surveillance and enforcement
5. Continue efforts to secure WHO support to get more pharmaceutical companies obtain World Health Organisation (WHO) pre-qualification.
6. Sustain and increase public awareness about the dangers of herbal preparations and the abuse of off-prescription drugs.