Your Excellencies, Very distinguished Ladies and Gentlemen,

I appreciate the opportunity given to me by the European Parliament to share my experiences as the Director General of the National Agency For Food And Drug Administration And Control (NAFDAC), Nigeria.

Fake drugs were first noticed in Nigeria in 1968, when Crown Agents divested as sole distributors of pharmaceuticals.

Estimates of the extent of counterfeit medicines in Nigeria were over 41% from various studies done before 2001.

NAFDAC’s study in 2002 showed that 68% of drugs in Nigeria were unregistered.

Drug counterfeiters target cost and volume. Almost all drugs are counterfeited, but antimalarials, antibiotics and multivitamins are most affected because they are among the most used drugs in Nigeria.

WHAT IS COUNTERFEIT MEDICINE?

Despite the global nature of fake drugs, the international community has not given it the attention it deserves, as evidenced by not having a harmonized definition of counterfeit drugs.

NAFDAC has however identified the following forms of fake drugs:

• Drugs with no active ingredient(s)
• Drugs with insufficient active ingredients
• Expired drugs or drugs without expiry date, or re-labelled with the intention of extending the shelf-life.
• Clones of fast moving drugs – which are drugs with the same quantity of active ingredients as the original brand.
• Drugs with active ingredient(s) different from what is stated on the label.
• Herbal Preparations fraudulently mixed with orthodox medicine.
• Drugs without full name and address of manufacturer.
• Drugs not registered by NAFDAC
IMPLICATIONS OF COUNTERFEIT DRUGS

- Fake drug is bad news.
- Counterfeiting of medicines is one of the greatest atrocities of our time.
- It is also a form of terrorism against public health, as well as an act of economic sabotage.
- It is mass murder.
- Counterfeit drugs violate the right to life of innocent victims.
- The evil of fake drugs is worse than the combined scourge of malaria, HIV/AIDS, armed robbery and illicit drugs. Malaria can be prevented or treated, HIV/AIDS can be avoided, armed robbers may or may not kill, cocaine and similar drugs are taken out of choice and by those who can afford them, but fake drugs are taken by all, and anybody can be a victim.
- Fake drugs have led to death of many people, treatment failures and development of drug resistance.
- The human cost of counterfeit drugs can be high. In 2003, three children died after open-heart surgery in Nigeria. NAFDAC’s investigations revealed that the adrenaline and suxamethonium used were fake, while some of the infusions used were contaminated.
- As people were dying, legitimate businesses were collapsing.
  - Due to unfair competition, local drug manufacturers were running out of business, and many multinational companies left Nigeria or divested out of frustration.
  - Made-in-Nigeria drugs were banned by other West African countries.

The new management of NAFDAC was compelled to declare a “war”, against drug counterfeiters.

**To execute this “WAR” we developed some strategies and administrative guidelines which include:**

- Re-orientation, re-organization and motivation of NAFDAC staff to reposition them for better effectiveness.
- Restructuring & Modernization of our regulatory processes.
Public enlightenment campaign.

- This is our most effective strategy involving dialogue, education and persuasion.
- It is sustained by using:
  - Print and electronic media such as jingles, alert notices, billboards, publication of the differences between identified fake and genuine products in the national dailies.
  - We have also produced many other publications in English and Vernacular languages.
  - Workshops, seminars and meetings have been conducted for all stakeholders.
  - Mobilization campaign for rural dwellers is 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 and televisions 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 culture of quality consciousness in Nigeria.

Stopping the importation of fake drugs to Nigeria at source was tackled through the following measures:

- NAFDAC officials must inspect factories anywhere in the world before we register their drugs, cosmetics, food and other regulated products to ensure Good Manufacturing Practice (GMP) compliance.
- NAFDAC appointed analysts in India, China and Egypt who re-certify drugs 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 documents for drug importers.
- Before an imported drug is registered in Nigeria, we ensure that it is being used in the country of production by insisting on Certificate of Free Sale signed by a Minister of Trade or Industry in that country and authenticated by Nigerian embassy or any commonwealth mission in a country without a Nigerian embassy.
Beefing up of surveillance at all ports of entry
- NAFDAC also stepped up surveillance at both land and sea borders, which led to the counterfeiters resorting to the use of airlines. As a result, NAFDAC can now ground any aircraft that carries drugs to Nigeria without proper authorization.

Mopping up of fake drugs already in circulation.
- To mop up fake drugs already in circulation, NAFDAC has the power to confiscate and destroy drugs if sellers fail to provide a proper invoice of purchase. NAFDAC also has the power to arrest the landlord of any premises where fake drugs are warehoused if nobody accepts ownership.

Regular monitoring of GMP of local manufacturers/Streamlining and strict enforcement of our registration guidelines.
- NAFDAC also strictly monitors local manufacturers of drugs, and has strengthened its registration processes.
- All drugs must comply with laboratory standards and inspection requirements before they are registered.
- NAFDAC registration number must be affixed on the label of all products to enable the public identify registered drugs.
- Drug registration renewal is done every five years except for herbal medicines that is done yearly.
- Drugs can be imported for 10 years, after which the importer must start local production.

Other Interventions
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 each other 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 problem for them. It therefore became necessary for us to work in concert so as to ensure that these criminals do not find a safe haven anywhere in the sub region.

CHALLENGES
In this fight for life we have encountered many challenges:
- Corruption and Conflict of Interest/Insecure and Unfriendly Environment
  - The first line of action by drug counterfeiters is to compromise regulators.
• When this fails, they fight back with intimidation, harassment, blackmail and threats. Part of this intimidation was to deposit fetish objects in my office, which included blood stained feathers, African beads and a tortoise.

• In August 2001, 6 armed men invaded my residence at Abuja from 8 to 10pm, searched for me and did not steal a pin. Fortunately, I was out of town.

• In August 2002, NAFDAC laboratory in Lagos was vandalized and most of our sensitive equipment were destroyed.

• When all of that failed, they resorted to physical attacks and arson against NAFDAC staff and facilities which culminated in a shooting attack on my person on 26th December 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 (Fig 1-3).

• Three months after, between 7th and 11th March 2004, there was a synchronized burning of NAFDAC’s facilities across the country (Fig 4-7).

• In 2004, irate drug hawkers beat up our officers in Gombe State and destroyed our car.

• In June 2006, NAFDAC officers were physically attacked and driven out of a drug market along with the 12 policemen that accompanied them for the inspection. Their 6 operational vehicles were also destroyed.

• My family members and some NAFDAC staff still remain constantly under threat.

❖ Discriminatory Regulation by Exporting Countries

- Some countries have strong regulations for drugs consumed internally and little or no regulation for drugs meant for export, and this encourages exportation of fake drugs. This is critical since about 60% of the drugs in Nigeria are imported.

- Most of the fake drugs in Nigeria are imported from India and China.

- From 2001 till date, we have banned 30 Indian and Chinese companies and 1 Pakistani company found to be exporting fake drugs to Nigeria.

❖ Sophistication In Drug Manufacture

Sophistication in drug production has made it difficult for even brand owners to tell the difference between their brands and counterfeits (Fig 8-9).
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 in Nigeria range from imprisonment of 3 months to 5 years, or option of fine of 70 to 3600 USD.

False Declaration By Importers
Some counterfeit drug importers make false declarations about the contents of their containers. They stack 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 clothes, duvets and shoes (Fig 10-15).

SUCCESES RECORDED
Fortunately, with the support of our government, and the good people of Nigeria, NAFDAC is winning the war.
- 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 boosted our economy by encouraging local industries and genuine investors.
- Immense public awareness 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 drugs.
- Counterfeit drugs in circulation have dropped from an average of over 41% in 2001 to 16.7% in 2006.
- Drugs unregistered by NAFDAC stand at 19% 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 6 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 due to improved regulatory environment.
- Ban on ‘made-in-Nigeria’ drugs has been lifted by other West African countries.
In the last 6 years, NAFDAC has carried out 110 destruction exercises of counterfeit and substandard products valued at about 150 million USD.

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

CONCLUSION

- Even though drug counterfeiting is a global problem, developing countries are more affected, and the poor bear most of the brunt, because they are more predisposed to be sick for obvious reasons.
- The negative impact of counterfeit drugs knows no boundaries. Resistant strains of micro-organisms induced by substandard antibiotics do not need visa to travel from country to country.
- We need an international convention on counterfeiting of pharmaceuticals, just as we have for narcotics and psychotropic substances. This will ensure a harmonized regulation of pharmaceutical products moving in international commerce. International co-operation is important if trans-national criminal networks are to be dismantled.
- We must constantly share our experiences and strategies and build on what we have, so as to constantly be a step ahead of these merchants of death. Counterfeiters can be beaten as evidenced by our success in Nigeria.

Thank you for your attention.