

ROUNDTABLE ON FOOD AND DRUG LAW

8th March, 2012

The Food and drug industry is a multi- billion dollar industry which makes food and drug administration one of the most vital sectors of the social system of most countries. The sector accounts for a significant share of the gross national product of many countries. This cannot be divorced from the fact that the combined socio-economic importance of food and drug as the essential and the most indispensable commodities of human consumption accounts for over 25% of consumer spending. The food and drug industry is a globalised one and the cause of millions of shipments from many facilities across the world. Growth of the food and drug industry has been attributed to globalization in various segments of economy including production, trade, technology and regulation.

The sheer size of the industry and transactions that take place within it force global regulatory standards for making the products available worldwide necessary. As large as the sector is, it is not without its challenges, which touch on social, economic and health sphere of human endeavors, and occur on both the supply and consumption side of the chain. The problem is more glaring and destructive in developing countries such as Nigeria. They include the production and sale of fake and counterfeit drugs, tampering with sealed drugs, unwholesome food production, unlicensed and unqualified sale of drugs, sale of vaccines in the open market, lack of proper storage and transportation facilities for food and drugs, unavailability of drugs in the pharmacies of hospitals and illicit drug sale. The menace caused by drug related problems are compounded by poverty, ignorance, lack of options and access to genuine drugs, availability of fake or counterfeited drugs among others. This has led to deaths, injuries, incapacity, psychological trauma and more for consumers.

The legal regime responsible for tackling this menace in Nigeria has its own challenges to grapple with. These include lack of coordination among food and drug related regulatory bodies, multiplicity of regulators, multiple legislations and regulations, lack of coherence in action by regulatory agencies, lack of capacity to discharge mandate as well as lack of equipment to carry out functions.

It is for the reasons mentioned above, the need to develop Food and Drug Law jurisprudence in Nigeria as well as the compulsion to address the lack of coherence and coordination in the Nigerian Food and Drug Administration with the aim of mapping out strategy for a vibrant and more effective/ efficient regime that can reduce the menace caused by fake and counterfeit drugs and unwholesome food production, that the Nigerian Institute of Advanced legal Studies Held a Roundtable on Food and Drug Law on the 8th March 2012.

OBSERVATIONS

Some of the observations made at the roundtable include the following:

- 1 The menace of fake drugs has eroded the public's confidence in the nation's health care delivery system.
- 2 Fake drugs have led to a proliferation of treatment failures, organ dysfunctions or damages, worsening of chronic disease conditions, and death of many Nigerians.
- 3 Out of the 130 existing pharmaceutical manufacturers with installed capacity to produce between 50% and 75% of the nation's drug needs, only 60 are in active manufacturing.
- 4 Capacity utilization in pharmaceutical manufacturing in Nigeria is below 30%
- 5 A huge percentage of the drugs consumed in Nigeria are imported.
- 6 The legal and regulatory framework of NAFDAC's work should not be punitive based
- 7 Media adverts concerning the dangers of the use of fake and counterfeit drugs are being preached to the converted as the majority of the counterfeit and fake drugs are being sold and used in the rural areas.
- 8 Drugs are still regarded as commercial merchandise hence the large number of unlicensed and unqualified sellers and peddlers.
9. Sellers and peddlers in many cases are the first point of contact by consumers.
- 10 The consumer's inability to judge the quality of medicine they take becomes a huge public health challenge as such drugs can be ineffective and harmful.
- 11 Lack of knowledge of drug quality on the path of the consumer makes them vulnerable to the business interest of drug sellers.
- 12 Patronising peddlers and unlicensed sellers are done for several reasons including convenience, affordability, dependability of supply as well as poverty

13 Lack of access to medicine in government clinics and pharmacies and where it is available, the prohibitive cost is also a factor that leads to patronising unqualified drug peddlers and unlicensed drug sellers.

14 The prohibition of drugs, especially psychoactive substances is premised on the vast number of negative consequences that are thought to arise from their usage as well as the adverse reaction that characterizes the use of some of them.

15 Drug prohibition is also due to the social problems associated with psychoactive drugs. Drugs such as cocaine, heroin, Indian hemp are usually used by persons responsible for some incidences like murder, assault, suicide, drowning, spousal abuse and rape; most of which are against the criminal laws of states, hence the treatment of persons who commit offences in a psychoactive induced state as criminals.

16 The economic dimension to drug prohibition with respect to drug importation is to protect and encourage indigenous drug manufacturing companies in Nigeria.

17 In a study conducted in 2001, the cause of the preponderance of counterfeit drugs in Nigeria included ineffective enforcement of existing laws, non- professionals in drug business, loose control system, high cost of drugs, greed, ignorance and corruption.

18 Some of the awareness programmes lack impact and thrust and do not reflect or articulate the magnitude of the damage fake drugs can cause.

19 Fake drugs affect the entire community and not just a segment.

20 Some adverts give the wrong message as to the effect of certain drugs which in effect becomes misleading.

21 Law enforcement officers, especially those on the low income scale, are sometimes not convinced about the need to eradicate the menace of substandard drugs

22 The existence and effect of fake drugs may not be completely eradicated, but it can be minimized.

23 The percentage of imported drugs into Nigeria has reduced from the 90% range which it used to be around 2004

24 Herbal drugs consumption in itself is not a bad thing, but the problem lies with the lack of regulation of such drugs, that is not under the jurisdiction of NAFDAC as NAFDAC only regulate the product not the practice.

25 NAFDAC encourages the growth of drugs from alternative medicine. NAFDAC fully supports the National Institute of Pharmaceutical Research which is undergoing third stage test of a drug NIPRISAN, developed using herbs for the cure of Sickle Cell.

26 Illegal drug market structures have reared their heads in populated and busy areas such as Onitsha “Head Bridge”, in Anambra State, Ariaria Market in Abia State. Before these drug markets can be closed down, an alternative option in all the locations such as the Mega Drug Distribution center in Onitsha, must be provided where only trained pharmacists are allowed to operate

27 One of the major challenges faced by all drug agencies worldwide is drug counterfeiting which is a multi- billion dollar business

28 In wealthy economies, counterfeit drug amount to 10% of their sales, whereas about 50 % of such sale occurs online.

29 The most widely counterfeited drugs are anti- malaria, anti-biotics and analgesics.

30 Drug counterfeiting increases loss of human lives and reduces confidence in the health sector

31 The importance of the sector is largely due to the combined socio- economic importance of food and drug as the essential and the most indispensable commodities of human consumption accounting for over 25% of consumer daily spending worldwide

32 The food and drug industry in Nigeria has grown from an unregulated to a regulated industry. There are regulations governing Food and Drug Administration in Nigeria

33 The legal regime governing the conduct of activities in the industry did not come to the fore until the recent national attention on the scourge of fake drugs and adulterated food substances which led to the emergence of a defined and more focused regulatory regime.

34 There is a considerable degree of consensus that regulation has become an indispensable instrument of public governance of a modern economy.

35 The primary theory for regulation of food and drugs is founded on public health with sustained attention now focused on the institution of regulatory models and 'character ' of governance beyond the precincts of private law.

36 Regulatory imperatives, reforms and overlaps are main challenges to food and drug law in Nigeria

37 Food and drug law has gradually developed into a body of law with statutes and regulatory agencies, although it has not been fully developed in our jurisprudence.

38 The food and drug market has become completely riddled with fake, adulterated and counterfeit products that have undermined the state of public health and safety, requiring urgent and more effective regulatory intervention.

39 An important part of the development of the regulatory powers of NAFDAC is the exercise of power of the agency to order the withdrawal from circulation of a regulated product consequent upon suspension or cancellation of registration of the said product

40 The wide ranging powers, functions and activities of NAFDAC has enabled it to be proactive and to launch a holistic campaign against fake and adulterated regulated products thus bringing the entire food and drug market under tight regulatory oversight.

41 The Nigerian regulatory model through NAFDAC appears to have moved from a mere registration system to an effective regulatory system in addressing the menace of fake and counterfeit food and drugs.

42 There is a need to settle the imperative of the Food and drug law regime

43 There is a need to examine the adequacy or otherwise of the existing regulation to meet up with international standard of governance.

44 The Nigerian regime for food and drug law is lying in an awkward position and needs to be repositioned and made more responsive to the nagging problem of drug counterfeiting, faking and unwholesome processed foods..

45 Food and drug administration in Nigeria is multi- statutory regulated based.

46 The statutes were enacted to regulate the various aspects of the problems of drug counterfeiting, fake and unwholesome processed food.

47 The multiplicity of statutes has not proved to be more advantageous in tackling the problems.

48 There are lacunas in the existing statutes and some of such lacunas prevent drug law administration from compelling drug manufacturers and handlers to carry out some vital functions such as Drug Formulary under the NDFA which results in practitioners relying on British National Formulary (BNF) as opposed to Nigerian national Formulary (NNF).

49 Multiplicity of statutes has engendered uncoordinated enforcement in the regulation of food and drugs in Nigeria.

50 The National Drug Formulary and Essential Drugs List Act (NDFA), a vital statute in the Food and drug Administration in Nigeria is not administered by NAFDAC.

51 With the present state of Food and Drug Laws in Nigeria, the Federal Task Force on the Counterfeit and Fake Drugs Act (CFDA) and the Unwholesome Processed Food Act (UPFA) can enforce the law.

52 NAFDAC is operating in a challenging environment, addressing a problem that has international dimensions with local regime.

53 No statute alludes to the need for international collaboration or grant seeking in our Nigerian Food and Drug legal regime.

54 Appropriate international instruments to help reduce drug counterfeiting or the dumping of counterfeit drugs and unwholesome processed food in Nigeria are yet to be explored.

55 There is no reliable data on the mortality or morbidity arising from the consumption of adulterated food and counterfeit drugs in Nigeria.

56 Apart from drug counterfeiting, fake drugs and unwholesome processed food, another serious problem is tampering with original packages with drugs packed in large pack sizes.

57 NAFDAC is Nigeria's lead food safety Authority responsible for the regulation of the manufacture, importation, exportation, advertisement, distribution, sale and use of all processed packaged food, water and other beverages.

58 NAFDAC was established to control and regulate the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, medical devices and packaged water including all drinks.

59 NAFDAC's mandate is shared by other government Ministries, Departments and Agencies (MDAs) across the different tiers of government.

60 There is over- regulation of the industry due to overlap of functions.

61 There is lack of effective collaboration and co-ordination of the MDAs as well as a lack of system for collection and dissemination of information.

62 There is lack of effective regulation of street food vending.

63 There is a prevalence of inadequate funding of hospitals pharmacies and the “out of stock syndrome” in Nigeria.

64 There are inadequate storage facilities, transportation and distribution of Food and Drugs in Nigeria.

65 One of the major challenges being faced by regulatory agencies especially in developing countries is the counterfeiting of regulated drugs.

66 Counterfeiting has become a global problem that presents an enormous public health challenge

67 Counterfeiting, viewed from public health perspective is a major obstacle preventing access to safe, quality and efficacious medicines.

68 According to WHO, over 270 million people in Africa lack access to the most essential medicines.

69 Counterfeiting can apply to both branded and generic products, and may include products with the correct ingredients, without active ingredients or with fake packaging.

70 The Pharmaceutical Security Institute data shows that most counterfeiters target developing countries of Asia, Africa and Latin America

71 It is also estimated that drug counterfeiting is S 750 billion business annually, while the World Customs Services estimate it as a S 200 billion business annually.

72 In emerging economies, counterfeits are estimated at 10% whilst in some parts of the developing world, counterfeits are put at about 30%.

73 According to a study conducted by NAFDAC in collaboration with WHO and Department for International Development (DFID) in 2006, pharmaceutical counterfeits in Nigeria stood at 16.7% as against 40% in 2001.

74 The WHO estimates that tens of thousands of people may be dying due to counterfeit of HIV/AIDS, diabetes and psychotropic medicines.

75 In an effort to reduce the negative public health impact, the burden on patients and to execute its mandate, NAFDAC has devised several strategies to improve access to safe and efficacious medicines.

RECOMMENDATIONS

The roundtable consequently came up with the following recommendations

1 There is a need to reintroduce health law into the curriculum of Nigerian Universities and other tertiary institutions

2 There is a need to have strong regulatory policy on herbal drugs

3 The government should adequately equip and also have training facilities for laboratory technicians in drug analysis.

4 NAFDAC should ensure the registration of all drug products either manufactured locally or imported.

5 The state task forces on counterfeit and fake drugs that are not in existence should be reconstituted and invigorated.

6 Pharmaceutical industries should have established drug surveillance units to monitor their products in the market to detect faking.

7 There should be stiffer penalties for those who contravene the prohibited drug laws.

8 The various agents of socialization should intensify the socialization process on societal reaction to deviance. The socialization should be extended to law and enforcement

agents who consume drugs illicitly and aid and abet those who are involved in the act of production.

9 There is a need for grass root enlightenment on the dangers of fake drugs.

10 There is a need for sustained public enlightenment on the dangers of fake drugs.

11 There is the need for standard and regulation, to improve the quality of drugs circulating in the society.

12 There is a need to regulate and sensor advertisements in order to check the types and quality of products which circulate in Nigeria.

13 Sensitising the members of the public to the danger of fake drugs to health should be emphasized by NAFDAC, as opposed to the punishment for drug consumption.

14 There is a need to adopt the encouragement of attitudinal change by Nigerians to be able to tackle the menace of fake drugs

15 All drug regulatory agencies should also get involved in dealing with the challenges posed by fake drugs.

16 NAFDAC should create special zones in counterfeit prone areas for proper and continuous surveillance to reduce to the barest minimum, if not eradicate the menace of the sale of counterfeit, adulterated, expired and improperly stored drugs.

17 Children should be encouraged to imbibe the culture of respect for the proper use of drugs as well as the right way to handle food from childhood

18 There should be collaboration with the appropriate international agencies for a more effective food and drug administration.

19 There should be an increase in capacity building and training of personnel involved in food and drug administration.

20 Compensation for victims of fake drugs by the sellers, should be encouraged

21 Cutting edge technology such as Truscan and use of infrared which gets the details of the drugs which can be used as evidence for prosecution should be encouraged and invested in.

22 The provisions of the Nigerian law must be distinguished from that of the US, particularly in the area of prevention based regulation

23 The regulatory regime proceeding upon specified regulatory policy or goal should define the regulatory practices and protocols that address the emergent nuances and mischief of the industry that the traditional legal regime or a mere regulatory coverage can no longer tackle.

24 The retention of NAFDAC among the remaining agencies at the ports of inspection will help in consolidating the gains of the current regulatory practice.

25 An effective regulatory regime beyond a mere legal regime or regulatory coverage is crucial to effective governance which constitutes the established and the primary legal regime for food and drug administration.

26 There should be an avenue by which foreign manufacturers of counterfeit drugs and unwholesome processed food who conspire with Nigerians will be made liable even where such foreigners do not come into the Nigerian territory.

27 Express provisions are needed in the FDA, NDFA and CFDA to vest the power of enforcement of Food and Drug laws on NAFDAC.

28 There is a need to domesticate appropriate international instruments with which to string the regime on Food and Drug Administration for better efficiency and effective tackling of the international dimension of drug counterfeiting and unwholesome processed food.

29 The Palermo Convention under which counterfeiting, manufacture and sale of unwholesome processed food should be domesticated and applied to individuals.

30 Bilateral treaties should be used to clearly and in detail define the rights and obligations of parties under each subject.

31 There should be a provision in the NDFA mandating the NAFDAC to annually publish NNF for guidance of medical practitioners, pharmacists and other users of the information specified in the Second Schedule to the Act.

32 The power of NAFDAC to appoint inspection officers and their powers under the FDA and the powers of its officers under the NAFDAC Act, being essentially the same should be streamlined to avoid the unnecessary repetition in our statutes.

33 The provision of the FDA, CFDA and the NAFDAC Act vesting jurisdiction to Federal High Court (FHC) should be amended to give concurrent jurisdiction as in other criminal matters granted to the Court under the Constitution of the Federal republic of Nigeria 1999.

34 The provision of the NAFDAC ACT on the conduct of proceedings which makes the Criminal Procedure Code applicable, being in conflict with the provision of the FHC Act should be amended.

35 Upon the proper identification of foreign manufacturers as major actors in dumping counterfeit drugs and unwholesome processed food in Nigeria, the offence of conspiracy should be included in the statutes governing Food and Drug Administration.

36 The FDRA provides for the conduct of clinical trials in accordance with the provisions of regulation in force. In the absence of any, there is a need to make regulations for clinical trials.

37 There is a need for overhaul and consolidation of the legislations that make up the legal regime for Food and Drug administration in Nigeria to enable NAFDAC discharge its mandate effectively and efficiently.

38 Government subsidized drugs should be made available to the public and private health care delivery system.

39 There should be well developed distribution network of food and drugs in Nigeria.

40 There is a need to consolidate drug related laws in Nigeria.

41 There is a need to create a National Policy on E- Medicine and licensing online pharmacies.

42 There is a need for improved cooperation and collaboration of MDAs with roles in Food Safety or create a Food Safety Authority.

43 Enhanced regional co-operation, collaboration and information sharing on food and drug safety issues should be encouraged.

44 Patient protection and affordable care to provide for the protection of sick persons and to make sure consumers have access to accurate, science- based information about the products they need and rely on every day to improve their health and well- being.

45 There should be Increase in the nation's preparedness to address threats as a result of bioterrorism pandemic and emerging infectious diseases to ensure organisational excellence, transparency and accountability.

Professor Epiphany Azinge, SAN

Director General