The Legal Regime for Consumer Protection in Drug Administration and Control in Nigeria

Obumneme-Okafor, N.J
Department of Jurisprudence and International Law, Faculty of Law,
Chukwuemeka Odumegwu Ojukwu University, Anambra State.
Email: nikina4eva@gmail.com

ABSTRACT

The drug industry forms part of the live wire of every society and the state of health of every society largely depends on it. This is because the consumption of drugs by people affects their lives positively or otherwise depending on whether the consumed drug is of the desired quality and consumed in the right quantity and at the right time. A whole lot about the efficacy and effectiveness of drugs depends on their administration. Even if a drug is of good quality, yet if it is not well administered, it will not give the desired result. It is a notorious fact that the enforcement of the available legal framework for drug administration in Nigeria leaves much to be desired in spite of the availability of the legislations on the subject. It is thus either that the legislations are not adequate to deal with the situation or that their implementation by the appropriate authorities or institutions is the problem or both. The place of importance occupied by the state of health of the nation in its development and sustenance can hardly be over emphasized. The statutes in focus are the Poisons and Pharmacy Act, Food and Drugs Act and the National Agency for Food and Drugs Administration and Control Act. An examination of the operation of the related agencies created under or by these laws (if any) in the enforcement of the provisions of these statutes needs to be undertaken. The work will examine the problems associated with the administration of laws and the agencies and attempt proffering solutions to such problems so as to create a consumer friendly environment in drug administration in Nigeria where the consumer will consume the drugs to be healthy and not to die or have his health jeopardized or compromised.

INTRODUCTION

Drugs and their consumption play a major role in the health and well-being of man. They aid in the maintenance of good health and the treatment and management of diseases. Consumption of drugs affects the social life of individuals. This makes the drug industry occupy a prominent position in the welfare of the society as one of the vital sectors of the social system of most countries. In fact, the drug industry constitutes part of the live wire of every society and the state of health of every society largely depends on it. The quantum and manner in which drugs are consumed by the people affect their lives positively where the drug consumed is of the right quality and of the adequate quantity and taken depending on the prescribed time frame. Thus a whole lot about the efficacy and effectiveness of drugs depends on their administration. That a drug is of the desired quality is not enough where it is not well administered as it will not produce the desired result. The consumer will not be cured of the ailment in question neither will the illness be well managed. The consumer of the drug might just have engaged in an exercise in futility where much less than the required quantity is consumed or where the required quantity is consumed at an inappropriate or the wrong right time. Therefore, proper administration goes to the root of the efficaciousness of any drug.

The axiom is that production is propelled by consumption. Consequently, the production of drugs presupposes that there is quest for them by the society. This places consumption as the very essence of production, for the process of production would be worthless if the products of that process are not consumed. The consumer is the toast of every production process for without him the wheel of commerce grinds to a halt. The germane position of the consumer was captured in the latter part of the nineteenth century by Adam Smith in this manner:

> Consumption is the sole end and purpose of all production and the interest of the producers ought to be attended to, only so far as it may be necessary for promoting that of the consumer. The maxim is so perfectly self-evident that it would be absurd to prove it. But in the mercantile system, the interest of the consumer is almost constantly sacrificed to that of the producer and it seems to consider production and not consumption as the ultimate end and object of all industry and commerce (Smith 1880).

This obvious position of the consumer and the socio-economic importance of the drug industry as the producer of one of the most essential and indispensable commodities for human consumption require that the administration and

control of drugs shall be based on legal policies by legally created agencies or institutions. The food and drug industry is so important that it accounts for over 25% of consumer spending in Nigeria (Azinge 2012).
Irrespective of the foregoing, the enforcement of available laws on the administration of drugs in Nigeria is nothing to write home about in spite of the existing legislations on the subject. It is either that the available legislations are not adequate or that their implementation by the appropriate authorities or institutions is the problem or both. The place of importance occupied by the state of health of the nation in its development and sustenance can hardly be over-emphasized. This being the case, there is the need to delve into the laws regulating the administration of drugs in Nigeria and the manner of control measures put in place to ensure that an effective administration system on ground is maintained or that such a system is made to exist and equally sustained.

Due to space, the focus of this discourse will be the Pharmacy Law, Foods and Drugs Act and the National Agency for Food and Drugs Administration and Control Act. The work will examine the activities of the statutorily created agencies or institutions concerned with the subject matter in ensuring that drugs are properly administered to the consumers so that consumers use these drugs for their well-being and not to their detriment. In doing so, the work will examine the challenges encountered in the administration of the laws by the agencies while ensuring that these drugs are administered in the proper manner to the public and solutions will be proffered on how to combat the obstacles and achieve effective administration and control of drugs.

Terms-Their Meanings and Essence in Relationship with the Topic; Meaning and Usage of the key terms/words within the context of the Discourse.
Defining a word or term implies giving explanation to the meaning or purport of the word to be defined. In doing so the major words as they concern the object of the work are the words to be explained. Thus here we set out to use words or sets of words to elaborate the meaning of the key words and in so doing attempt to examine them as put in use within the context of the discourse.

Drug and Drug Administration
The popular definition of a drug is that it refers mainly to chemical or plant derivative substances that affect psychological, behavioural or physical function and lead to varying degrees of dependence or addiction, Forcon, (Fovensic Consulting (2015). This definition brings into focus both the normal drugs taken to treat ailments and hard drugs like cocaine, marijuana, heroine and the like. These affect the behavioral pattern of people that consume them. Although every drug is prone to be addicted to where, due to regular and long usage of a drug one's system becomes accustomed to the drug and functions as if it cannot do without such a drug.

Clinically a drug is a therapeutic agent, any substance other then food, used in the prevention, diagnosis, alleviation, treatment or cure of disease in man (Forensic Consulting 2015). This definition imputes to a drug the generally acclaimed notion of using it to treat or cure sicknesses. But setting out the meaning of a drug statutorily the Pharmacy Law Cap.122 Revised Laws of Enugu State 2004 (hereinafter referred to as the Pharmacy Law) gave the meaning of drug to include any substance of vegetable, animal or mineral origin, or any preparation or admixture thereof, which is used for internal or external application to the human body in the treatment of disease. The National Agency for Food and Drug Administration and Control Act (2004) (hereinafter referred to as the NAFDAC Act (2004) defines a drug as any substance of vegetable, animal or mineral origin or any preparation or admixture thereof manufactured, sold or advertised for use in;

(a) the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or animal,
(b) restoring, correcting or modifying organic functions in man or in animal,
(c) disinfection or the control of vermin, insects or pests or
(d) contraception.

The Food and Drugs Act (2004) hereinafter referred to as the F&D Act in giving the meaning of drug described it in exactly the same way and manner that the NAFDAC Act did. The same meaning has been ascribed to it by the National Drug Policy of 2003. Moreover, a drug is seen as any substance, other than food, used for the prevention, diagnosis, alleviation, treatment or cure of diseases. It is also used to refer to substances of abuse while a medicine is a term used to describe a therapeutic drug in order to distinguish it from narcotics and other addictive drugs that are used illegally for non-medical purposes, Pharmacists Council of Nigeria (2005). The definition of drug and meaning of medicine here are in tandem with the ones given above except that in both, the stress is on the narcotics to distinguish them from the normal drugs. From these definitions or meanings (apart from the popular definition by

forcon) there is one general notion regarding all these definitions, that is that a drug is preventive, curative and therapeutic in nature. That

is the drug in focus here. That is, a medicine as defined above. Not the narcotics as in the addictive drugs which though are used for therapeutic purposes yet are also consumed illegally with their attendant negative effects. A drug can only perform any of these functions when it is well administered to the consumer, that is where it is of the desired quality and is consumed in the right quantity and at the right time where the diagnosis is right. The use of the drug should be checked to avoid the negative effect of addiction where the consumption is not controlled. This informs why the discourse is to foray into the laws on ground to guarantee that the drugs consumed are well administered within the required parameters.

Consumer and Consumer Protection

Consumer:

Legally, a consumer has two meanings: the broad and the narrow meanings (Ajai 1992/93). The broad meaning regards as consumers all persons whether legal or physical human beings, who purchase and consume goods and services as consumers provided that person is the final or end user of such goods and services (Grady 1982). Elaborating this further, (Schiffman and Kanut 1984) posit that there are the personal and the organizational consumers. A personal consumer to them is one who buys goods and services for his own use, for the use of his household or for just one member of the household or even as a gift for a friend while an organizational consumer comprises private business, government agencies and institutions all of which must buy products, equipment and services in order to run their organizations whether for profit or not.

The narrow meaning describes a consumer as one who purchases goods for general or household use as different from the acquisition of capital goods; that is, consumption of capital goods. Viewing it from this angle (Lowe and Woodroffe, 1991) see a consumer as a customer who buys for personal use and not for business purposes. Furthermore, the consumer is seen as a person who buys goods and services for personal, family or household use, with no intention for resale, a natural person who buys products for personal use rather than for business purpose (Garner, 2007).

Statutorily, a consumer is an individual who purchases, uses, maintains or disposes of products or services (Consumer Protection Council Act, 2004). Though inferring from the above, a consumer is an individual whether natural or artificial who constitutes the final or the end-user of a product or service. But for the purpose of this work, a consumer is taken as an individual, a natural person as against a juristic or artificial person because it is a natural physical person who can consume a drug and not a juristic person like a corporation. Therefore, for this purpose, we take the meaning of a consumer to be that of the narrow approach as this best fits the person to whom drugs can be administered and for whom such drugs can be controlled.

Consumer Protection

The purpose of consumer protection is to avoid exploitation and check various business malpractices. Bird (1983) described the phrase as legislation which protects the interests of consumers. Consumer protection consists of laws and organizations designed to ensure that the rights of consumers are not trampled upon as well as maintain fair trade competition and free flow of truthful information in the market place, Consumer Protection (2013). To Monye (2003) the phrase means the act of safeguarding the interest of the consumer in matters relating to the supply of goods and services, fraudulent and hazardous practices as well as environmental degradation. It has been explained to mean concrete efforts made by individuals or organistions to protect the consumer against defective and often unsatisfactory goods and services frequently provided by manufacturers and sellers, it refers to the use of laws and legislations to keep these manufacturers in check with the sole aim of protecting the rights of the consumers. The phrase to us is the prevention of injuries, losses or wrongs from occurring to the users of goods and services and the provision of remedy to the consumer in a situation where there had been such an occurrence through the instrumentalities of the law, governmental and non-governmental organizations and individuals.

Following in tow, the consumer of drugs is to be protected from hazardous and harmful practices that dispensers and handlers of drugs get involved in and where inadvertently such practices are perpetrated and the consumer is injured or harmed, there are measures in place via the instrumentality of the law and statutorily created agencies and other organizations to ensure that the injured consumer is well assuaged.

Legal Regime

The Free Dictionary (2013) described a regime as a system of government or a particular administration, a system of rule or government while the Findlawdictionary (2013) explained it as a system of principles, rules or regulations for administration. Also a legal regime is seen as a system of principles and rules governing something and which is created by law. It is a framework of legal rules (US Legal Definitions Home 2013). Deducing from the foregoing, a legal regime is made up of the law and set of rules and regulations that form a system for the administration of any aspect of government. Therefore, the legal regime for protecting the consumer in drug administration entails the laws related to the administration and management of drug dispensing in Nigeria. It embodies the laid down system through which drugs reach the consumers and the rules set down to enforce it.

More often legal regime is used interchangeably with legal and institutional framework, but here legal regime is as set out above encompassing the obtainable rules and regulations involved in drug administration. Legal regime usually incorporates both the laws and regulations and the agencies/bodies/authorities set up to ensure that these laws are obeyed. But for the purpose of this work we shall not go into detailed discussion of the agencies since our focus is on the legal framework. Nevertheless, there would be a cursory foray into some of the agencies (the NAFDAC and the PCN to be precise) to examine the way these bodies oversee the administration and control of drugs in the country.

The Requisite Legal Structures

In Nigeria there are a lot of laws dealing with drugs whether medicines or the narcotics. Since focus is on the administration and control of drugs from the therapeutic angle, the narcotics are not within the purview of this discourse. Various laws regulate and control the manufacture, sale and distribution of drugs in Nigeria (Akinyandenu 2013). But the laws of our interest are the Pharmacy Law, Food and Drugs Act and the National Agency for Food and Drug Administration and Control Act. These laws will be discussed in conjunction with their institutional framework as created by the statutes to ensure that the provisions of these laws are effectively implimented though the institutions will be discussed cursorily as indicated above.

The discussion of the legal regime is anchored on two premises;

- Only drugs are to be discussed as narcotics are not within contemplation.
- The discourse is not concerned with the production or manufacture of goods, rather with the sale of drugs and its attendant and collateral correlatives.

The Food and Drugs Act (F & D Act)

This Act was enacted in Lagos on 28th October 1974 as Decree No 35 of that year. But it had a prospective commencement date of 10th February 1976 as evidenced by the Legal Notice No 5 of 1976. It made provisions for the regulation of the manufacture, sale and advertisement of food, drugs, cosmetics and devices and also for the prohibition of sale, advertisement, importation, exportation and distribution, etc of certain and specified drugs, food and cosmetics as contained in the schedule to the Act. The Act was later amended and re-enacted as Food and Drug Act, Cap 150 Laws of the Federation of Nigeria, (LFN) 1990 and now is known as Food and Drugs Act, Cap F32, LFN, 2004. This Act provides for food, drugs, cosmetics and devices. Our discussion pertains only to the provisions on drugs. The Act provides that no person shall sell any drug which is adulterated, or was manufactured, prepared, preserved, packaged or stored under unsanitary conditions (F & D Act, 2004). It also provides that no person shall sell or advertise any drug to the general public as a treatment, preventive or cure for any of the diseases, disorders or abnormal physical states specified in the first schedule to the Act nor should any person sell or advertise any drug in a manner that is false or misleading or is likely to create a wrong impression as to its quality, character, value, composition, merit or safety (F & D Act 2004).

Under sections 9 and 10 of the Act, it makes provisions for Drug Analyst and Drug Inspecting Officer, of people who possess the requisite qualifications. These, when on duty shall have the authority to enter any premises where any drug to which the provisions of the Act apply is manufactured, prepared, preserved, packaged, stored or sold and carry out any examination on any article, container, package, any books or documents or other records or take samples or specimens of any article or seize and detain any article for such time as may be necessary, where they believe that the provisions of the Act or its regulations have been contravened. These persons shall not be obstructed in the course of their duties (Section 12 F & D Act). Either as a Drug Analyst or Inspecting Officer the person shall be a graduate in Chemistry for food and drug and must be a Pharmacist when he is a Drug Analyst. Such a person as an inspector has the powers to take samples of any article for analysis to ascertain whether such a drug is adulterated, or fake or counterfeit.

The Food and Drug Advisory Council

Under section 15 of the F & D Act, the Minister (that is Minister of Health) is empowered to set up a Council known as Food and Drugs Advisory Council. This Council is the regulatory body or institution that sees to it that the objectives for enacting the Act are attained and maintained. The Council has the duty to assist and advise the Minister in the

preparation and review of the regulations required for the execution of the provisions of the Act and any other matter which is connected with the Act.

The Council shall be composed of such persons as the Minister may appoint, who to him are suitable for such appointment.

(i) by reason of their knowledge or experience in subjects to which the Act relates
(ii) as representing the manufacturer's or distributor's interests in subjects to which the Act relates,
(iii) as representing the interests of the consumers or users of articles to which the Act relates (S15 (2) F & D Act 2004).

The Act recognizes the fact that drugs or food when produced need to be consumed to make the effort of production worth the while. Thus it provides for the appointment of people who represent the interests of the consumers, that is, the consuming public. This is necessary and cogent and a nice piece of legislation as it is the consumer that determines the wholesomeness or fitness of a drug. The representative of the consumer in the Council shall pursue policies that will bring safe drugs to the stable of the public, the process that will enable such drugs to be dispensed in the proper manner and in the same vein the consumption. Actually not only the representative of the consumers but everybody in the Council since every human being is a consumer.

The Act provides for penalties for failure to comply with any requirement of the Act or for the contravention of the provisions of the Act. The penalty for an individual on conviction is a fine not exceeding one thousand naira (N1,000.00) or imprisonment term of two years or both where the offender is a body corporate with the connivance of any officer of managerial cadre in the company, such a person with the company are deemed guilty of the offence and they shall be liable to be proceeded against and punished accordingly. Proceedings for the prosecution of the alleged offender shall be commenced within six months of the commission of the offence, else, such a victim will be statutorily barred from commencing the legal action (S17(1-3) F & D Act 2004).

The National Agency for Food and Drug Administration and Control Act (NAFDAC Act).

The safety of human lives remains the paramount responsibility of the government of every nation. The need to ensure the regulation and control of the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs, cosmetics, medical services, chemical and packaged water is what led to the creation of NAFDAC by the Federal Government of Nigeria with the inspiration from a 1988 World Health Assembly resolution requesting the help of countries in combating the global threat posed by counterfeit drugs. (National Bureau of Statistics, 2015).

In 1992, the first Governing Council of NAFDAC was formed and chaired by Tamiun Saulawa, but it had no legal backing. In January 1993, the NAFDAC was legally created by Decree No. 15 of that year with a retrospective commencement date of 1st October 1992. Later, during the revision of the Laws of the Federation, it became known as NAFDAC Act, Cap N1, Laws of the Federation of Nigeria 2004. The aim of the establishment of NAFDAC is to regulate and control among others the advertisement, distribution, sale and use of drugs, compile standard specifications and guidelines for the sale and distribution of drugs, undertake the registration of drugs, pronounce on the quality and safety of drugs, advise the Federal, State and Local Governments, the private sector and other interested bodies regarding the quality, safety and regulatory provisions on drugs, issue guidelines on, approve and monitor the advertisement of drugs, establish the relevant guidelines and measures for quality control of drugs, establish appropriate programmes for the safety and national use of drugs, encourage and promote activities related to the process, standard specifications, guidelines on sale and distribution of drugs,….. (Sections 5a,e,f,i,m, and b(e,f and g NAFDAC Act).

The above comprise the functions of the Agency and the Council created thereunder. A perusal of these functions-cum-duties reveals that a lot depends on the agency on the issue of drug administration and control. It lies squarely on its shoulders to oversee how safe drugs are sold, and or dispensed and the advertisements which the manufacturers and sellers of these drugs post for the public on their drugs. The body is run by a Director-General who is the Chief Executive of the agency and who is in charge of its day-to- day running. The agency is structured to be run by directorates some of which have been mentioned in the Act and while also providing for the further creation of directorates assuming the existing ones would not suffice (Sections 8 and 9 NAFDAC Act). It is assured that the body as empowered by its functions enumerated ante has an arm of its directorates charged with the responsibility of monitoring the sale, distribution, use and advertisement of drugs.

Generally, the presence of NAFDAC has been felt during the tenure of late Prof Dora Akunyili as the Director-General of the organization. In fact, she, it was who brought the existence and functions of the body to the public domain and the same became appreciated by all and sundry. She did a good job of show-casing the activities of the organization and ensuring to a large extent the effective control of sale and distribution of drugs. The existence of the Agency is being felt these days, though minimally, under Mr. Paule Bortwesv Orhii as the Director-General.
The Composition of the membership of the governing council of the agency cuts across. However, it does not include any consumer body or organization as mentioned, nor did it make any provision to such effect. All that the Act provides is for these other persons to represent public interest to be appointed by the Minister (Section) 2 (a-j). This is quite unlike the Food and Drugs Act which specifically mentioned as part of those suitable for appointment, people representing the interest of consumers. (S 15(c) food & Drugs Act).

Like the Food and Drugs Act, the agency can designate and empower an officer of the agency in the course of his duty and where such duty requires, to enter into any premises where drugs are manufactured, packaged, stored or sold to examine any article in use or to be used for manufacture, packaging, storage or sale, take a sample or specimen of any article which he is empowered by the Act to examine, open and examine any container that will help his work or investigation, examine books or documents for other records containing relevant information, seize and detain for necessary time any article by means of which the provisions of the Act have been contravened. (Section 24 NAFDAC Act.).

In the course of carrying out the functions of the Act it constitutes an offence where an officer of the agency is obstructed while performing his duties. Such an act is prosecutable. Such a person if found guilty is liable on conviction to a fine of N5,000.00 or an imprisonment term not exceeding two years or both of them (Section 25 NAFDAC Act). Where the contravention is on the provision of the regulations made under the Act, the person is guilty and is liable on conviction to the specified penalties in the regulations. Where no penalty has been specified, the person shall be liable to a fine of N50, 000.00 or imprisonment term of one year or both. For a corporate body and any of the officers who connived with the body to so commit offence. Both the officer and the corporate body shall be guilty and liable on conviction to a fine of N100, 000.00 (S25 NAFDAC Act).

The NAFDAC comes under the institutional framework established for food and drug related matters. There is no outside law it exists to oversee the implementation of its provisions. Rather as an independent body it has power to regulate food and drugs matters as contained in its enabling statute.

Pharmacy Law

Initially the Pharmacy Law we have today in various states of the federation started as the Pharmacy Ordinance No.8 of 1902 and later as Poisons and Pharmacy Ordinances of 1923, 1927, 1936 and later Poisons and Pharmacy Act 1960 as Cap 152 of 1960. In 1964 the Act was re-enacted to repeal certain sections of the Act by Act No. 26 of 1964. Then it was named Poisons and Pharmacy Act. At that time, it was a Federal legislation applicable to only Lagos as a Federal Capital Territory. During the revision of the laws in 1990 it was renamed Poisons and Pharmacy Act, Cap 535, Laws of the Federation of Nigeria 1990, thus elevating it to the level of a Federal legislation, though inadvertently so as it was not supposed to be. This explains why it was omitted from the 2004 codification of Federal statutes because it was not a federal law *per se*. Its federal character was borne out of the former position of Lagos as the federal capital. The law was but a state/regional law. Consequently, various states have their Pharmacy Laws. In Enugu State it is the Pharmacy Law, Cap 122, Revised Laws of Enugu State of Nigeria, 2004 with its counterpart in Anambra as Pharmacy Law, Cap 104, Revised Laws of Anambra State 1991. Both Laws have identical provisions.

The Pharmacy Law of Enugu State besides the provisions on the restriction of sale of poisons which is not within the scope of this paper, provides for the control of sale of patent and proprietary medicines. It provides that no person shall sell or deliver any patent or proprietary medicine unless he is either a selling dispenser or chemist and druggist or the holder of a patent and proprietary medicines vendors licence. The contravention of the provision attracts a fine of N20.00 Patent or Proprietary medicines are to be sold intact in the original container under which it was imported, or if imported unpacked in bulk in box, bottle, vessel or parcel under which it is packed and made ready for sale in Nigeria and such container shall be properly sealed and bear the name or trade mark of the proprietor or manufacturer except where the medicine is prepared by the selling dispenser or chemist and druggist or where the dispenser or chemist and druggist is complying with a prescription given by a registered or licensed-medical practitioner, dentist, medical or qualified veterinary surgeon. No person other than a selling dispenser or a chemist shall import in bulk and

subsequently repack any patent or proprietary medicine on the road, at motor parks or at marked squares except in a shop licensed for such purpose (Sections 27 and 28 Enugu State Pharmacy Law, 2004).

Except where otherwise provided, any person found guilty of an offence under this law shall be liable to a fine of N200.00 or to an imprisonment term of 12 months or both. (Section 37 Enugu State Pharmacy Law 2004). Gleaning from the foregoing, drugs/medicines are to be sold by authorised persons-dispenser or chemist and druggist or a licensed patent and proprietary medicine vendor. They should be sold in their original containers except where otherwise permitted while complying with the prescription of a licensed medical practitioner, neither should drugs be hawked, sold or displayed for sale at any other place except in a licensed shop or store.

Pharmacists Council of Nigeria and the Patent and Proprietary Medicines Vendors

The Pharmacists Council of Nigeria hereinafter referred to as the PCN is a parastatal of the Federal Government. It is statutorily, created. (Pharmacists Council of Nigeria Act 2004 section 1) It is charged with the responsibility, among others, of regulating and controlling the practice of the pharmacy profession in all its respects and ramifications in Nigeria. It has a Governing Council which is the decision and policy making body of the PCN and the registry which is the implementation organ with the responsibility of implementing the decisions of the Council as well as enforcing the regulations for the effective functioning of the council. (Pharmacist Council of Nigeria 2008).

Our interest in the PCN is, the body regulates and controls the practice of pharmacy in Nigeria which means that it supervises the administration and control of drugs by registered pharmacists and non-pharmacists alike. It is of general knowledge that the prescribed drugs are advisedly to be bought from pharmacy shops while the over-the-counter drugs (OTC drugs) could be bought from both the pharmacy shops and from the patent and proprietary medicines vendors. Moreover, the PCN is the body authorized to oversee the activities of the patent and proprietary medicines vendors by the Federal Ministry of Health (PCN 2008).

The Patent and Proprietary Medicines Vendors

The government recognized the dearth of qualified health personnel in the country and the need to allow non-professionals to handle the very basic needs of the populace albeit under strict control. The licensing of non-pharmacists to stock and sell simple medicines became a necessity. This represents an attempt to redress the insufficient number of pharmacists operating in Nigeria. This led to the creation of the patent and proprietency medicines vendors (hereinafter referred to as PPMV). It has a long history of existence which is not within the scope of this paper. The issuance of the patent and proprietary medicine vendors' lisences (hereinafter referred to as PPMVLs) was suspended in 1963, and later resumed in 1964. Since then there has been a dispute as to which body to superintend its activities with a lot legal tussles that ensued. Eventually it ended in 2003 with the intervention of the Minister of Health and leaders in the pharmacy profession and the management of the body was reverted to the PCN.

The PCN, thus issued the guidelines on the issuance of the PPMVLS in 2003. These guidelines provide for the licensing authority, eligibility, mode of application, orientation and continuing education for the license holders and monitoring and inspection of the holders among others (PCN 2003). The requirements are as provided for in the Pharmacy Law of Enugu State under Section 27 and the third schedule of the Law. The PPMV is the body that brings the common drugs used in the treatment of simple ailments, for example malaria to the door steps of the consumers. They come in contact with the largest number of consumers because they are found in the nooks and

cranies of the country, even in the remotest parts, where the sophisticated and bourgeois pharmacists cannot, or rather, would not like to get into and live in. This informs our interest in prying into how other activities of the PPMVs are managed and coordinated.

Herbal Medicine

Herbal medicines are widely used in the country. They have thus become a common choice therapy for self-care among individuals who are now playing more active roles in their health care. Many of the drugs used in modern medicine originate from plants and there is no doubt that new drugs can still be discovered from plants including those plants indigenous to Nigeria (National Drug Policy 2005)**.** According to the World Health Organization (WHO), herbal medicines are medications prepared from one or more herbs or plant park (roots, stem bark, seeds and/or fruits) (Pharmacy Practice 2013). Many patients use a wide range of herbal medicines in addition to their conventional medicines. In addition, the irrational claims or advertisements by manufacturers, through different mass media, have enhanced the widespread use of herbal medicines among the general populace. The NAFDAC Act of 2004 as amended in 2005 prohibits the manufacture, importation, exportation, distribution, advertisement or sale of any herbal medicine or related product unless it is appropriately labeled and registered by the agency. The regulation stipulates that herbal medicines and related products labeling should be informative and accurate, not promotional in tone, not misleading or provide a false claim. (Pharmacy Practice 2013).

The National Drug Policy 2005 write-up postulates that there is the need for Government to provide funds in institutions and universities to promote research in drug development especially herbal medicine. It gave a list of possible areas of research and interventions which include **inter alia**, the rational use of herbal medicines, standardization of products to ensure efficacy, regulation and control of advertisements of traditional medicine and practice by Government.

Advertisement of Drugs

Naturally when a new product is manufactured there is the need to market the product to create awareness in the minds of the public on the arrival of the product so as to sensitize the people and cause them to go for it when the need arises. It is the same thing with drugs and in fact any article of trade at all. Herbal medicines are not left out. Deductbly there are statutory provisions relating to the advertisement of drugs. The Enugu State Pharmacy Law, the NAFDAC and the Food and Drugs Acts all provide regulations for the advertisement of drugs.

The Enugu State Pharmacy Law under Part VI and section 32 states that, there should be no publication of any advertisement by any method whatsoever of any drug that is effective for the cure and prevention of certain ailments like veneral diseases such as gonorrhea, syphilis or other genitor-urinary diseases, cancer, diabetes, heart diseases, goitre, promotion of sexual virility etc. the NAFDAC Act has drug products advertisement regulations with 28 regulations with regulation 22 stating that no person shall advertise a drug as a treatment, prevention or cure for any disease, disorder or abnormal physical state as specified in the schedule which schedule contains the similar ailments as found in the Pharmacy Law of Enugu State. Same goes for section 2 of the Food and Drugs Act and the First Schedule. The only difference between both Acts is that the FDACT in addition has the Acquired Immune Deficiency Syndrome as one of such diseases.

Setbacks and Solutions

An original and fresh research exercise is like a foray into the unknown, an adventure into a wild forest and naturally the adventurer cannot come out unscathed. In the same vein, an academic work of this nature is bound to throw up a lot of challenges for which ways of combating such difficulties must be suggested so as to enable the related industry be the better for it. Hence in this work on the drug industry we discovered certain problems as militating against the consumers in the drug industry. Some of these problems and the recommendations for them include among others-;

(1) **Advertisement:**

The laws discussed above all provide for how manufacturers should advertise their drugs relaying the process and procedure to be followed in carrying out the advertisements. The NAFDAC Act under its regulation for advertisement provides that no advertisement shall state in absolute terms that any pharmaceutical product is safe or has guaranteed efficacy and that any advertisement shall not carry any false or misleading information. The three laws stated that no drug shall be advertised as a treatment, prevention or cure for any disease as specified above. These provisions are as regards the orthodox drugs.

The herbal drugs are by implication inclusive where they have been registered by NAFADC as legally required.

But it is a known fact that the producers of certain herbal medicines particularly the bitter cleansers (eg Dr. Iguedo Goko Cleansers) have constantly violated and insulted our sensibilities with their advertisements laddened with their bogous and phoney claims of their drugs being capable of healing or curing every ailment under the sun not minding the requirements and regulations on advertisement as given by NAFDAC etc, especially non-claiming of a drug guaranteeing efficacy or safe. Even in spite of the list of ailments as shown ante, one still hears such proclamations or statements as ***"O na-agwo diabetes o na kpamkpam, ona agwo pile, all types of infection, ogwu anyi enwerokwa side effect"*** etc. This goes on unabated and continuously uninterrupted. The question is where are the PCN and the NAFDAC officials who are supposed to confront these marketers and put a stop to the violation of the provisions of the law? And these people carry on with this with all impunity and recklessness:

The body responsible for the control of advertisement of drugs (whether herbal or orthodox) should rise to the occasion and stop the deceit of the public so as to market and sell their products. Advertising a drug saying it has no side effect is exhibiting callousness which nobody should condone no not even the authority charged with such responsibility.

(2) **Sell of Adulterated Drugs**

Section 1 (2) of the F and D Act provides that no person shall sell any drug which is adulterated. A good piece of legislation no doubt. But how does a seller know that the drug he purchases to sell to the consuming public is adulterated if he is not the producer or as a chemist he examined samples of it in the laboratory. It should be remembered that most of the pharmacists and the PPMVs purchase drugs to sell. The pharmacists only certify the chemical contents as per the leaf let or by what is written on the packet. There is no way to verify whether it is adulterated on the surface either by the pharmacists or the PPMVs. Therefore, adulterated drugs are being sold every day in the markets and are equally consumed by the public. The only way to minimise that is by the inspectorate directorates of both the PCN and the NAFDAC stepping up the monitoring aspect of their duties to make sure that the drugs brought into the market for retailers to buy and sell to the consumers are of at least the minimum required standard, else adulterated drugs will find their way into the hands of the consumers. They should monitor what happens with the manufacturers at the factories, in the warehouses where these drugs are stored and packaged and at the markets where they are sold. Even the imported ones, what do the importers order to be brought into the country? For instance, why should an imported drug from China or India be cheaper than its counterpart produced in the country in spite of the importation cost which should normally raise the price of the imported drug. A lot needs to be done in our drug administration and control in this wise. It is of common knowledge that part of what incensed the passion of late Prof Dora Akunyili (of blessed memory) for the onslaught against the Onitsha headbridge drug marketers on their sale of fake and or adulterated drugs was that she had lost a sister or close relation due to a fake drug or a contaminated device bought from that market that was used in the treatment of her relation, who eventually died in consequence. Even the Analysts and Inspectors that the F and D Act makes provision for under sections 9,10 and 12 should be involved too. In fact, all hands should be on deck to stamp out or minimise the sale of adulterated drugs in the market. They should carry out the inspection and make the seizures if need be.

(3) **Sale of Drugs in their Original Containers**

Section 23(1) of the Pharmacy Law of Enugu State provides that patent or proprietary drugs should be sold in their original containers properly secured, yet our medical doctors dispense drugs in their private hospitals for which their patients pay without their packets or containers and even most often hiding the names of the drugs apparently to prevent the patients from finding out the names of the drugs. This goes on with the pharmacists that work in such hospitals being in the know without them winking an eye. Medical practitioners should be monitored too, particularly in their medical outfits/ hospitals as a lot goes on at such places all in the bid to make money.

(4) **Hawking of Drugs**

The law prohibits hawking patent or proprietary medicines (Section 28(3) Enugu State Pharmacy Law 2004). Yet the hawking of drugs goes on everywhere within the country. Luxurious buses are besieged by drug hawkers when on long distance journey e.g from Enugu to Lagos. There are no arrests effected at any time. In short nobody cares, it is a normal phenomenon.

The public should be sensitized to stand up against this anywhere and in that way the consumer is helping in protecting himself. This is because at the end of the day if such drugs are consumed and there is a problem, it is the consumer that bears the brunt.

(5) **Dormant Consumers and Lack of Enlightenment**

Generally Nigerian consumers are dormant. They sleep on their rights. They neither complain when unwholesome or fake drugs are sold to them neither do they opt for litigation, they just swallow the bitter pills and keep quiet. No follow up course of action when an injury has occurred. They are indolent forgetting that equity and aids the vigilant and not the indolent. They should not sleep on their rights rather should arise on every occasion that presents itself where their rights are violated and stand up to the violator.

Moreover, there is the need for public enlightenment to awaken the crave to protect their rights within the consumers. This should come from the government via their parastatals, the consumer organizations and even the individuals who know should educate the ones that do not know. Consumer education should constitute a major tool in this regard, because no one can react beyond his knowledge in every situation.

(6) **No Representative of Consumers in the Councils of NAFDAC and the PCN**

The laws setting up these two agencies of government did not include representatives of consumers in the membership of their governing councils (Sections 3 and 3 PCN and NAFDAC Acts), yet both of them are involved in activities that directly affect the interests of the consumers and their responsibilities are consumer oriented and consumer based. Without the consumers, these agencies would not be in existence, underscoring the importance of the consumer to them. This omission should be redressed so that the policy making bodies of these agencies should have consumers' representatives as members so as to carry the consumers along in formulating their polices. They should borrow a leaf from the F & D Act that has such a provision (Section 15 (2) C(Act).

(7) **Penal Sections**

The penal sanctions in the laws are laughable. A situation where an offender who has been found guilty is to pay a fine of One thousand-naira (N1,000.00) as contained in Section 17(1) F & D Act or twenty naira N20.00, or two hundred naira (N200.00) as in Sections 27(2) and 37 Pharmacy Law of Enugu State respectively or a fine of five thousand naira (N5,000.00) as in section 25 (1) NAFDAC Act. Apart from the provision for a fine of N50,000.00 as in section 25(3) NAFDAC Act, all other amounts charged as fines are not of any consequence. They cannot ward off or deter any offender because the fines cannot prick their pockets at all, not even a pin-prick. We are calling for a total overhauling of the penal sections of these laws to impose heavier fines to discourage them. The amendment to these laws is urgent. Maybe this partly answers why the affected consumers do not bother because the punishment is not worth the litigation or the stress of the redressal action he/she will be involved in. Moreover, there is no form of compensation that accrues to the injured consumers. This is discouraging enough. The aim of the penal aspect of the law should not be just to punish the offender only. There should be a recompense to the consumer so as to assuage him for the injury suffered. It should not wait until he goes through the whole hog of civil litigation. The law has made provision for compensation even when the matter is before the court in a criminal trial (Section 13 Consumer Protection Council Act 2004).

(8) **Time for Institution of Action under the F & D Act**

Section 17 (3) of the Act provides for a 6 month duration within which to institute an action where someone has been injured or the action will be statute barred. This is for a legal mind to appreciate or for a consumer who has the wherewithal to employ a lawyer to prosecute his case. Otherwise, an illiterate consumer who has been injured may as well dilly-dally, loose time and it becomes impossible for him to prosecute his case. This requires the creation of awareness among the consumers to know that where an injury has occurred they should approach the relevant person or body immediately so as not to be time-barred.

(9) **Multiple Laws on Drug Administration and Control.**

There are various laws that regulate and control the distribution and sale of drugs in Nigeria. This constitutes the weakest point in the drug industry in the implementation and enforcement of these laws. There are a lot of over-lapping functions among the agencies that oversee the implementation of these laws.

There is multiplicity of regulatory bodies, multiplicity of regulators and multiplicity of legislations and regulations. Each body minding its own business without proper coordination among the regulatory bodies.

There is need for a merger of some of these regulatory agencies and even the laws to have a consolidated and formidable legal framework that can properly monitor the happenings in the drug industry, to make for better and more effective coordination and monitoring.

CONCLUSION

In conclusion, the drug industry in Nigeria has come a long way in the protection of the consumer in relation to the administration and control of drugs. The setbacks experienced in the industry are not extraordinary. It is envisaged that the implementation of the foregoing recommendations will go a long way in according the consumer in the drug industry the desired protection and ensure a more secure future for the health of the nation which invariably translates to the wealth of the nation.

REFERENCES

Ajai O, (1992-93) "Caveat Venditor! Consumer Protection Decree No 66 of 1992 Arrives the Nigerian Market Place". (1992/93) Nigerian Current Law Review, 23.

Akinyanedu O. (2013) Counterfeit Drugs in Nigeria: A Threat to Public Health, Academic Journals, www.academicjournals Org/AJPP.Accessed, Tursday 30/07/2015, 5:15pm

Azinge, E. (2012), Roundtable on Food and Drug Law, NIALS, Lagos.

Bird R, (1983) Osborn's Concise Dictionary, 7th edn. Sweat and Maxwell, London, 90.

Consumer Protection Council Act, Cap C25, Laws of the Federation of Nigeria 2004, Section 32.

Consumer Protection (2013) en.www.wikipedia.org. Accessed 27/07/2015, Monday 1:05pm

Consumer Protection Council Act (2004) Cap C25, Laws of the Federation of Nigeria.

Enemo I. P (2002) Adequacy of the Tort of Negligence for Consumer Protection, "*ESUT Law Journal*, 1(1), 107.

Food and Drugs Act, cap F32 Laws of the Federation of Nigeria, 2004.1 (2 &3) 2 (a & b) and 5(a) 12, 15 and 17(13)

Findlawdictionary (2013) dictionary findlaw.com/definition Accessed 27/07/2015, Monday 1:15pm

Forcon (2015), What is a drug, www.forcon.ca/learning/drugs.html

Grady O. (1983) "Consumer Remedies, "60 Canadian Bar Review No 4, 549.

Legal Regime Law and Legal Definitions. US Legal Sites (2015) definitions. USlegal.com/1/legal-regime. Accessed 28/07/2015, Tuesday 9:20pm.

Monye F. N (2003) Law of Consumer Protection, Spectrum Books Ltd, Ibadan, 20.

National Agency for Food and Drug Administration and Control Act (2004). Cap N1 Laws of the Federation of Nigeria 2004. Sections 5 and 6, 8 and 9, 2(a-j) ,24 and 25

National Bureau of Statistics (2015). Summary Report of Food and Drug Administration and Control in Nigeria 2012-2014.

National Drug Policy (2005). Federal Ministry of Health in Collaboration with World Health Organization, 29

Pharmacists Council of Nigeria (PCN) (2005). Four-part Compendium of Minimum Standards for the Assurance of Pharmaceutical Care in Nigeria, Pharmacists Council of Nigeria (PCN), Abuja, 5.

Pharmacists Council of Nigeria (2008). The PCN Sourcebook on Pharmacy Regulation in Nigeria 2nd edn, Bliss International Limited, 29 – 30. Pharmacists Council of Nigeria (2008) The PCN Sourcebook on Pharmacy Regulation in Nigeria, Ibid, 16 – 17 (provides the history of body).

Pharmacy Practice (2013). Herbal Medicines Supplied by Community Pharmacies in Lagos, Nigeria: *Pharmacists' knowledge*, www. Ncbi.n/m.nih.gov/pmc/articles/pmc3869638. Accessed on Friday 07/08/15, 10:47am

PCN (2003). Guidelines on the Issuance of Patent and Proprietary Medicines Vendors' Licence, with the Approval of the Honourable Minister of Health, Federal Ministry of Health, Abuja.

Pharmacy Law Cap 122 Revised Laws of Enugu State 2004.

Pharmacists Council of Nigeria Act (2004) Cap p17 Laws of the Federation of Nigeria. Section 1

Smith A (1880), An Enquiry into the Nature and Causes of the Wealth of Nations (ed) Liberty Classic, Indianapolis, 660.

Schiffman L. G. and Kanut L. L, (1978). *Consumer Behaviour*, Prentice – Hall Inc, Engle wood – Cliff 4 – 5.

Sections 5 & 6 National Agency for Food and Drugs Administration and Control Act, Cap N 1, Laws of the Federation of Nigeria, 2004.Sections 8 and 9**, 2** (a-j), 24, 25 Sections 27, 28 and 37 Pharmacy Law, Cap 122 Revised Laws of Enugu State 2004.

BIO-DATA

Dr. Mrs. N.J Obumneme-Okafor Nkiru Justina, L.L.B (Hons), LL.M, PhD BL, Reader in Law, Department of Jurisprudence and International Law, Faculty of Law, Chukwuemeka Odumegwu Ojukwu University, Uli, Igbariam Campus, Anambra State.