DRUG COUNTERFEITING AND THE RIGHT TO HEALTH IN NIGERIA

BY

JADESOLA OYETORO LOKULO-SODIPE

B.A. Hons (UniMaid), LL.B. Hons (Lond.) LL.M. Hons (Lond.), BL, M.Sc. Bioethics (Ibadan)

A Thesis in the Department of Commercial and Industrial Law

Submitted to the Faculty of Law

In Partial Fulfilment of the Requirements for the Degree of

DOCTOR OF PHILOSOPHY

of the

UNIVERSITY OF IBADAN

MARCH, 2019

CERTIFICATION

I certify that this work was carried out by Jadesola O. Lokulo-Sodipe in the Department of Commercial and Industrial Law, University of Ibadan, under my supervision.

_____

Supervisor

Adeniyi I. Olatunbosun

Professor of Law,

Department of Jurisprudence and International Law,

Faculty of Law,

University of Ibadan, Nigeria

ACKNOWLEDGMENTS

For the success of this Ph.D., I am indebted to many people.

Firstly, I would like to express my sincere gratitude to my supervisor, Professor A I Olatunbosun for the continuous support of my Ph.D. and related research, for his patience, motivation and immense knowledge. His guidance helped me in all the time of research and writing of the thesis. I could not have imagined a better supervisor for my Ph.D. study.

I am also grateful to my colleagues at the Faculty of Law, for their insightful comments and encouragement, which were incentives for me throughout the time of research and writing of this thesis.

To my team mates, my husband, Taiwo and my children, Oluwatobiloba, Toluwanimi and Oluwatimilehin, many thanks for your unwavering interest, encouragement and enthusiasm. You are indeed my greatest cheerleaders, always keen to know how I was proceeding and keeping me on my toes, so I didn't get too comfortable with the breaks I took in between the chapters of the work.

I am grateful to my siblings and parents for their moral, emotional and prayer support. I am also grateful to my other family members and friends who have supported me along the way. Ifeoluwa Okunmadewa, you are a gem.

I appreciate all other people, who have helped and encouraged me during the course of writing this thesis.

Finally, all glory to God Almighty, my hiding place, my help in ages past, my hope for years to come.

ABSTRACT

The right to the highest attainable standard of mental and physical health includes availability, accessibility, acceptability and quality of prescription drugs. Counterfeit drugs have been described as the most dangerous goods in the market with harmful consequences to citizens' health. Previous studies have focused largely on prevalence, effects and ways of curbing the menace without addressing the legal issues in drug counterfeiting and the right of victims to remedy. This study was, therefore, designed to examine the legal and institutional framework on drug counterfeiting and the right to health as well as legal issues associated therewith.

The Sociological School of Jurisprudence Theory guided the study, while doctrinal and analytical legal research methodologies were adopted. Primary data included the Constitution of the Federal Republic of Nigeria,1999 (as amended), the National Agency for Food and Drug Administration Act, Counterfeit and Fake Drugs Act, all of the 2004 Laws of the Federation of Nigeria. International instruments included the Universal Declaration of Human Rights and the United Nations Guiding Principles for Business and Human Rights (UNGP). Constitutions and legislation of India and Kenya, with high incidents of counterfeit drugs, were purposively examined and case laws were also used. Secondary data included legal texts, journal articles, online and off-line, newspapers and workshop materials. Two key informant interview sessions each were held with lawyers, doctors and pharmacists and two other focused group discussions with patent medicine vendors and victims. Data were subjected to content and comparative analyses.

Nigeria's legal framework on drug counterfeiting is characterised by provisions of some legislation overlapping thereby resulting in loopholes and confusion, while enforcement machinery is not effective. Penalties of imprisonment of a term of three to 15 months and a maximum fine of Five Hundred Thousand Naira are lenient compared to the harm caused and profits earned. While there is no legislation on compensationof victims of counterfeit drugs, the implementation of the law has also been hindered by corrupt personnel and lack of effective enforcement mechanism. Although the UNGP requires states to protect citizens' right to health, corporations to respect the right, and that victims of violation be entitled to

remedy, there is yet no statutory enactment for remediation in Nigeria. Under the common law principle of negligence in tort and product liability, however, a victim of counterfeit drug may be entitled to compensatory damages where he can establish a breach of duty. Kenya regards drug counterfeiting as an intellectual property rights infringement, while India and Nigeria regard it as both public health and intellectual property rights violations. Though there are technological means of detecting counterfeit drugs in Nigeria, the public awareness is low. The unstructured interviews revealed that counterfeit drugs violate the right to health of citizens. Consequently, victims should be compensated.

Inadequate legal framework for punishing drug counterfeiting offenders has contributed to the violation of the right of Nigerians to health, without effective remediation for the victims. There is a need for improved public awareness of the means for detecting counterfeit drugs in Nigeria.

Keywords: Fake drugs in Nigeria, Nigerians' right to health, Compensation for victims of drug counterfeiting.

Word count: 497

TABLE OF CONTENTS

TABLE OF CASES

TABLE OF STATUTES

LIST OF ABBREVIATIONS

ACA	Anti-Counterfeit Act. (Kenya)
ACHPR	African Charter on Human and Peoples' Right
ACRWC	African Charter on the Rights and Welfare of the Child
ACTA	Alien Claims Tort Act
ADR	Adverse Drug Reaction
ANC	African National Congress
AIDS	Acquired Immunodeficiency Syndrome
ARSO	African Regional Organisation for Standardisation
CA	Certificate of Analysis
CCI	Clean Report of Certification
CDSCO	Central Drugs Standards Control Organisation - India
CESCR	United Nations Committee on Economic, Social and Cultural Rights
CIF	Cost, Insurance and Freight
CPCN	Consumer Protection Council of Nigeria
CR	Certificate of Registration
CRBN	Certificate of Registration of Brand Name
CRF	Clean Report of Findings
CRIA	Clean Report of Inspection and Analysis
DFID	Department for International Development
DRF	Drug Revolving Fund
ECOSOC	Economic and Social Rights

EDL	Essential Drug List
FAO	Food and Agriculture Organisation
FMOH	Federal Ministry of Health
GATT	General Agreement on Tariffs and Trade
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
ICC	International Chamber of Commerce
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Convention on Economic, Social and Cultural Right
IDR	Import Duty Report
IEC	International Electrotechnical Commission
IMPACT	International Products Anti-Counterfeiting Taskforce
IPR	Intellectual Property Rights
IRACM	International Institute for Research Against Counterfeit Medicines
IS	Industrial Standards
ISO	International Organisation for Standardisation
ITU	International Telecommunication Union
KAPI	Kenya Association of Pharmaceutical Industries.
KEBS	Kenya Bureau of Standards
LFN	Laws of the Federation of Nigeria
MAS	Mobile Authentication Service
MDDCs	Mega Drug Distribution Centres
MHFW	Ministry of Health and Family Welfare
MIS	Mandatory Industrial Standards

MPA	Mobile Product Authentication
NAFDAC	National Agency for Food and Drug Administration
NAPPMED	National Association of Patent Proprietary Medicine Dealers
NDDG	National Drug Distribution Guideline
NDLEA	National Drug Law Enforcement Agency
NDP	National Drug Policy
NHP	National Health Policy
NIC	National Industrial Court
NIS	Nigerian Industrial Standards,
NNRF	Non-Negotiable Report of Findings
OECD	Organisation for Economic Co-operation and Development
OIML	International Organisation of Legal Metrology
PBN	Pharmacists Board of Nigeria
PCN	Pharmacists Council of Nigeria
PHCCs	Primary Health Care Centres
PMD	Patent Medicine Dealer(s)
PPMV	Patent and Proprietary Medicine Vendor
PPMVL	Patent and Proprietary Medicine Vendor Licence
PRC	Premises Retention Certificate
PSI	Pre-shipment Inspection
PSN	Pharmaceutical Society of Nigeria
SAP	Structural Adjustment Programme
SDDCs	State Drug Distribution Centres
SMOH	State Ministry of Health

SMS	Short Message Services
SON	Standards Organisation of Nigeria
TRIPS	Agreement on Trade and Related Aspect of Intellectual Property Rights
UDHR	Universal Declaration of Human Right
UNGP	United Nations Guiding Principles on Business and Human Rights
UNODC	United Nations Office on Drugs and Crime
UNTOC	United Nations Convention on Transnational Organised Crime
USAID	United States Agency for International Development
USP	United States Pharmacopeia Convention
WCO	World Customs Organisation
WHA	World Health Assembly
WHO	World Health Organisation.
WTO	World Trade Organisation

CHAPTER ONE

GENERAL INTRODUCTION

"Nearly all men die of their medicines, not of their diseases"[1]

A counterfeit is a product made in imitation, with the intention to deceive. It is not genuine, it is forged and unreal. Counterfeit goods are sold under a trademark that is identical to, or substantially similar to the brand owner's trademark for the same goods, without the approval of the trademark owner. The global trade in counterfeit goods is booming[2], and it is shifting from relatively innocuous items like shoes and handbags, to things like medicine and pesticides which can carry serious health and safety implications.[3]

Counterfeiting is different from Piracy, in the sense that counterfeit refers to fake goods, whilePiracy is the act of reproducing movies, music books, or other copyrighted works, without permission from the copyright owner. Counterfeiting can be distinguished from traditional trademark infringement or passing off, which involves the use of confusingly similar trademarks or service marks, on or in association with similar (as opposed to fake), products or services.

Drug counterfeiting is more common in countries where regulations and laws governing the production of pharmaceuticals are limited or lacking. According to a World Health Organisation (WHO) report[4], five out of every six-member states lack drug regulatory capacity, with the effect of uncertainty in the composition and quality of medicines.

---

[1]Poquelin J. 1626-1673.*Le Malade Imaginaire* (The Imaginery Invalid). Referred to inAria Ilyad Ahmad. 2012. Addressing Variability in Drug Quality: Finding The Right "Quality" Framework(s). A thesis submitted in conformity with the requirements for the degree of Master of Science. Graduate Department of Pharmaceutical Sciences University of Toronto.

[2] The value of counterfeiting is estimated by the OECD to be in the region of $250 billion per year, while the World Customs Organization has identified counterfeit products destined for 140 countries. See "*Counterfeit goods: A bargain or a Costly Mistake*". Available on www.unodc.org. Retrieved on 9th July, 2013.

[3] Hargreaves S. 2013, "Counterfeit goods becoming more dangerous". Retrieved from www.money.cnn.com on 14th June, 2013.

[4] WHO, 2004. "The World Medicine Situation." World Health Organization: Geneva.

Like other crimes, the counterfeiting of medical products affects all countries, whether as countries of origin, transit or marketplace. It is however impossible to gauge the exact extent of the problem.

The right to health is the right to the enjoyment of the highest attainable standard of physical and mental health.[5]The right to health demands that health care, health products and health systems must be available, accessible, acceptable and qualitative.Counterfeit drugs can amount to a violation of the right to qualitative health care.International Products Anti-Counterfeiting Taskforce (IMPACT) estimates that poor quality medicines in circulation range from 25% - 50% in highly vulnerable, inadequatelyregulated low and middle-income countries.[6]Fraudulent pharmaceuticals can obscure the long-term risks: there are numerous examples of disability and death caused by tainted medication, and such pharmaceuticals contribute to the growth of drug-resistant diseases.

In combating drug counterfeiting, criminal law and intellectual property approaches have been applied. Judging by the increase in the growth of drug counterfeiting globally, it is obvious that both approaches are insufficient. Secondly, the law provides minimal comfort for the victims, who suffer as a result of this menace. Consequently, this study will propose applying the "all embracive approach (The approach)",[7] as propounded by the United Nations Guiding Principles on Business and Human Rights (UNGP).[8]The UNGP proposes the Protect, Respect and Remedy framework. This framework requires that State members do all within its powers to protect the human rights of its citizens, business corporations are to conduct their businesses in a manner that the human rights of the citizens of their places of business are protected, provisions for remedy, in the event of violation of human rights, should be made by the government and the corporations.

---

[5] WHO Constitution of 1946.

[6] *Op. cit.,* fn. 5

[7] This is the framework of "protect", "respect" and "remedy", developed by Prof. John G. Ruggie, known as the UN General Principles for Business and Human Rights. "The approach", will be examined in detail in the latter part of the study.

[8] See the "United Nations Guiding Principles on Business and Human Rights", available on www.ohrch.org. The Principles are standards for preventing and addressing the risk of adverse impact on human rights which result from business activities. There are three elements to the principles, namely, 'Protect' – this recognizes that states have a duty to protect the human rights of their subjects; 'Respect' – corporate bodies have the responsibility to respect human rights; 'Remedy' – there must be accessible remedy for the victims of business-related human rights violation.

The work is divided into six chapters. The first chapter is the introduction.The second chapteraddressed the literature review, conceptual and the theoretical frameworks for the thesis.Chapter three looked into the legal and institutional framework on drug counterfeiting and the right to health in Nigeria. In the fourth chapter, the legal issues and principles involved in drug counterfeiting will be identified and discussed. These are the common law principles such as contract, criminal law, tort, strict liability and product/manufacturer's liability, intellectual property rights, human rights issues. Chapter five present analysis of, and discussedthe findings of the study, and drug counterfeiting in Kenya and India. The concluding chaptercontainsthe summary, conclusionand the recommendations.

1.1 Background to the Study

Drugs play a pivotal role at all levels of healthcare. They are useful for the maintenance of health and for the diagnosis, prevention, treatment, or mitigation of diseases or disorders. However, due to the immense benefits derived from drugs and their global usage, some unscrupulous persons see them as a means of making fast money, therefore, they indulge in producing and circulating counterfeit drugs.[9]According to Phillips[10], as long as people have been in the business of inventing, others have been in the business of faking their inventions. Counterfeiting hasto a considerable extent,contributed to padding business profits, waging wars, defrauding governments and undermining currencies. It has been described as the second oldest profession.[11]

The production and sale of counterfeit goods are global problems that affects all kinds of products. It has been noted that, anything that can be made, can be counterfeited. Counterfeit goods include not only clothing, jewellery, purses, CDs, and DVDs, but also baby formula, medications, cigarettes, electronic equipment and parts, airplane and automobile parts, and toys. Counterfeit goods also have serious economic and health

[9] Akunyili D. 2004. Fake and counterfeit drugs in the health sector: the role of medical doctors. *Annals of Ibadan Postgraduate Medicine*. Vol. 2, No. 2, p. 19

[10] Phillips T. 2005. *Knockoff: The Deadly Trade in Counterfeit Goods*. Kogan Publishers, London, p. 7

[11] Bates R. 2008. *Making a Killing: The Deadly Implications of Counterfeit Drugs.* The AEI Press. Washington, D C p.1. Documents from the second century BC tell the story of a Gallic winemaker who tried to pass off cheap local wine as a much finer Italian vintage.

ramifications for governments, businesses and consumers. Counterfeiting is everywhere and all too often the link between fake goods and transnational organized crime is overlooked in the search for knock-offs at bargain-basement prices. While counterfeiters continue to reap significant profits, millions of consumers are at risk from unsafe and ineffective products.

With regards to counterfeit drugs, there are two situations, namely, where the drug as a whole is fake and where counterfeit raw materials are unknowingly included in materials used in producing branded drugs.[12] The counterfeit ingredients often come from countries like China, which has less stringent laws.[13] This type of counterfeiting is easy to curb. This is because manufacturers can determine their standard and/or decide to purchase raw ingredients from other sources, where possible. Furthermore, given that the brand owner will market their drugs, it will be in their best interest to avoid tortious liability, therefore, they have to do all possible to prevent counterfeit raw materials from infiltrating their products.

1.1.1 History of Drug Counterfeiting[14]

Counterfeit and substandard drugs have long existed for many centuries. As far back as 400BC, there were warningsabout them[15]. In recent years, they have however become an international problem[16] contributing to illness, death, toxicity, and drug resistance.[17] In 1938 in USA, a sulphanilamide elixir formulation error occurred, when a dispensing pharmacist used toxic ethylene glycol solvent instead of the non-toxic propylene glycol

[12] Bogdanich W. 2007. China Prohibits Poisonous Industrial Solvent in Toothpaste. *New York Times*, July 12, 2007. Column 4. This is an instance involving diethylene glycol in toothpaste. Referred to inDavison, M. 2011. Pharmaceutical Anti-Counterfeiting: Combating Real Danger from Fake Drugs. New Jersey. John Wiley & Sons, Inc. p. 414

[13] Davison M. 2011. *Ibid*. p. 414.

[14] One of the most harmful forms of counterfeit goods is fraudulent medicines, with sales from Asia to South-East Asia and Africa alone amounting to some $1.6 billion per year. See "*Counterfeit Goods: A bargain or a Costly Mistake*". Available on www.unodc.org. Retrieved on 9th July, 2013.

[15] WHO. Counterfeit Drugs - Guidelines for the development of measures to combat counterfeit drugs. Geneva, Switzerland: s.n., 1999. Similarly, in 1 A.D. Pedanius Dioscorides, a Greek physician, in his *Materia Medica* commented on the dangers of adulterated drugs.

[16] The spread of counterfeit drugs is generally more pronounced in those countries where the manufacture, importation, distribution, supply and sale of drugs are less regulated and enforcement may be weak and the exact extent of the problem is difficult to measure. See also Akunyili, D. 2006. "Lessons from Nigeria: the fight against counterfeit drugs in Africa". Diabetes Voice. September 2006 Volume 51 Issue 3. Page 41.

[17] Green M D. 2013. *Perspectives: Counterfeit Drugs*. Retrieved from www.nc.cdc.gov on 30/5/2013.

solvent. This error caused the death of about seventy-six (76) patients, mostly children. It was this incident that inspired the 1938 U. S. Food, Drugs and Cosmetics Act, which created a requirement for independent pre-marketing approval of new pharmaceutical products and established the U.S.Food and Drug Administration.[18]

Nigeria, has also experienced what is often referred to as the "Paracetamol syrup disaster of 1990"[19], when about one hundred and nine (109) children residing in two cities in Nigeria (Ibadan and Jos), were killed after ingesting a paracetamol-based cough syrup, produced using the toxic diethylene glycol solvent instead of the non-toxic propylene glycol. In the University of Jos Teaching Hospital and the University College Hospital in Ibadan, some of the children presented symptoms which included fever, diarrhoea, vomiting, anuria, and convulsions. Laboratory findings also showed that some of the children suffered from hyperkalaemia, acidosis, elevated creatinine level and hypoglycemia. All the children died within two (2) weeks of admission.[20]

Similarly, between 2008 and 2009, "My Pikin" a teething powder mixture killed at least eighty-four (84) children[21], as of, 16 February, 2009, in different parts of Nigeria.[22] The children died after taking *My Pikin Baby Teething Mixture*, a batch of which also contained the toxic diethylene glycol solvent instead of the non-toxic propylene glycol.[23]"Diethylene Glycol" is an industrial solvent and an ingredient in antifreeze and brake fluid.

In 2012, the World Health Organisation (WHO) issued a drug safety alert about Primethamine – contaminated Isoserbide 5 mononitrate in Pakistan.[24] One hundred and twenty-five (125) people died of fatal bone marrow suppression after taking the

---

[18] Akunyili D. 2004. Fake and counterfeit drugs in the health sector: the role of medical doctors. *Annals of Ibadan Postgraduate Medicine*. Vol. 2, No. 2, p. 19

[19] Adekeye F. 2002. Death Merchants. *Newswatch*, Vol. 35, No. 21, May 27, 2002

[20] Ibid.

[21] Polgreen L. 2009. 84 Children Are Killed by Medicine in Nigeria. *The New York Times*. February, 6th, 2009. Accessed from www.nytimes.com on 27th February, 2015.

[22] Anon, 2013. My Pikin: A Case for the Review of NAFDAC Law. *The Vanguard Newspaper*. 5th June, 2013.

[23] Anon, 2012. NAFDAC: How My Pikin Tragedy Occurred. *This Day Newspaper*. 12th Feb, 2012.

[24] WHO Drug Safety Alert No.125, 3rd Feb, 2012. Retrieved from http://www.who.int/medicines/DrugSafetyAlert 125.pdfon 25th July, 2013.

contaminated drugs, which were given free to the poor, from a public cardiology pharmacy in Lahore.[25]

There are other examples of counterfeit or mislabelled products having fatal consequences. Toxic cough syrup in Pakistan[26], in Panama[27], and tainted baby formula in China[28], have all led to the death of several children over the past few years.Harms and damages caused by drug counterfeiting in Nigeria cannot be overemphasized. Some have been maimed; many have brain retardation and a large number are disabled as a result of the use of counterfeited drugs.[29] The victims of drug counterfeiting in Nigeria cut across the rank and file of every segment of the society, including patients, the manufacturers and the Government, as it results in loss of revenue for the government. In addition, proceeds of drug counterfeiting are used for terrorism.

1.1.2 Drug Counterfeiting in Nigeria

The era from 1985 to 2000, heralded the regime of quackery, counterfeit drugs, unlicensed drug vendors, illegal pharmacy stores and illegal hospitals, in Nigeria.[30]The said period was characterized by austerity measures, which were adopted through the Economic Stabilization Act of 1982. The programme, rather than achieving economic recovery and growthas intended, increased poverty in the country.[31]Furthermore, the performance of Nigeria's health care system was seriously undermined during this period.Between 1985 and 1993, the per capita investment in health had stagnated at about $1(one US dollar)[32]

---

[25] Nishtar S. 2012. Pakistan's Deadly Cocktail of Substandard Drugs. *The Lancet*. Vol. 379:1084-1085.
[26]Anon, 2012. Retrieved from http://www.telegraph.co.uk/news/worldnews/pakistan/9703065/16-killled-from-toxic-cough-syrup-in-Pakistan.html, on 6th May, 2013.
[27] Posted on 6th May, 2007. Retrieved from www.the newser.com/story/1946/toxic-cough-syrup-cases-deaths-in-panama.html on 6th May, 2013.
[28] Posted on 17th September, 2008 and retrieved from www.theguardian.com on 6th May, 2013.
[29] See footnotes 22-26 on page 5.
[30] Erhum W O, Babalola O O and Erhum M O. 2001. Drug Regulation and Control in Nigeria: The Challenges of Counterfeit Drugs. *Journal of Health and Population in Developing Countries.*4(2)23-24, p. 23
[31] The period was characterized by economic crisis, which was a consequence of the dramatic fall in oil exportation revenue due to the boycott of Nigerian oil in the world market in 1978. At that time, Nigeria's revenue fell from US$10 billion to US$5.161billion, and the GDP fell by 2% in 1982 and 4.4% in 1983. See Folakemi, O. 2012. Austerity and the Challenges of Health for all in Nigeria". *International Journal of Development and Sustainability.* Vol. 1, No. 2: 437-447, pp. 437-438.
[32]$1 is equivalent to ₦361.67

per person, compared to the recommended level of $37 (thirty-seven US dollars).[33] The main effect of the low investment in health was the resulting poor state of the health facilities and products, especially in the primary health care sector.[34] To alleviate drug shortage, especially in public hospitals, the Drug Revolving Fund/Scheme was inaugurated in 1989.[35]This however failed as it was plagued with the "out-of-stock" syndrome[36], which was characterized by erratic supplies and non-availability of basic, essential and specialized drugs and health supplies. All these contributed to the rise and growth of the problem of fake, substandard and spurious drugs in Nigeria. Since that time, Nigeria has struggled to reduce the production and trafficking of counterfeit drugswithout adequate infrastructure or the political will to properly enforce legislation and standards.[37]The high trend of mortalities and morbidities, associated with use of counterfeit drugs, prompted the public and the Pharmaceutical Society of Nigeria (PSN) to put pressure on the government to take incisive steps towards controlling the prevalence of counterfeit and substandard drugs in Nigeria. This led to the promulgation of the Counterfeit and Fake Drug (Miscellaneous Provisions) Act[38], which prohibited the sale and distribution of counterfeit, adulterated, banned, and fake drugs or poisons, in open markets and without a license of registration. Additionally, National Agency for Food and Drug Administration (NAFDAC) was established in 1993 to create a fake-drug-free environment with the intent of ensuring effective registration of good quality drugs.[39]

---

[33] Nigeria Federal Ministry of Health, 2004. Health Sector Reform Programme (HSRP): Strategic Trust and Plan of Action 2004-2007. Abuja Nigeria: FMOH 2004. p. 7. As at 2011, the per capita of governments' health sector spending in sub Saharan Africa is $41 and half of that in South East Africa (see WHO. 2011. WHO Statistics 2011. Geneva Switzerland). This figure is still below the $60 per capita that WHO estimates would require by 2015 (see WHO. 2011. WHO- The World Health Report: Health Systems Financing – The Path to Universal Coverage. Geneva. Switzerland. Available on www.who.int accessed on 11th December, 2015).

[34] Folakemi O. *Op. cit*. p. 442.

[35] *Ibid*. p. 442.

[36] The scheme was phased out in 1999. See, Erhum, W. O. 2000. A Modified Bamako Initiative Drug Revolving Fund Scheme: Lessons from Nigeria. Being Paper delivered at the 11th International Social Pharmacy Workshop, Kuopio, Finland, on June, 13-17, 2000. Referred to in Erhum, et al. p. 24.

[37] Garba H A., Kohler J C, Anna M 2009. Transparency in Nigeria's Public Pharmaceutical Sector: Perceptions from Policy Makers. *Global Health* 5:14.

[38] Cap 73 of the Laws of the Federation of Nigeria, 1990. This has been repealed and replaced by the Counterfeit Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, Cap C34 LFN 2004. See also, Food and Drug Act Cap 150, LFN 1990. Now Cap F32, LFN, 2004.

[39] National Agency For Food and Drug Administration and Control Decree No 15 of 1993, Now Cap N1, LFN 2004.

In addition to these, is the issue of patent medicine stores and dealer. A patent medicine vendor is a person without a formal pharmacy training, who sells orthodox healthcare products on a retail basis for profit.[40] Patent medicine stores are unique and very important in health care and drug distribution. A large portion of medicines used by the public in Nigeria and other African countries are supplied by patent medicine stores.[41]They are a recognized reference point in the supply of health care products. The main purpose of these stores is retail business, consequently, they are avenues for dispensing generic drugs.[42] Similarly, counterfeit drugs are also dispensed in these stores.[43]

1.1.3 The Drug Counterfeiting Situation in Kenya

The extent of counterfeit medicine in Kenya, as in many developing nations, has not been quantified. In August 2010, the International Criminal Police Organization (INTERPOL) reported seizing 9,072 kilograms of counterfeit medicines and arresting 80 people suspected of illegal trafficking in six East African nations of Uganda, Burundi, Kenya, Rwanda, Tanzania and Zanzibar.[44] However, the Pharmacy and Poisons Board of Kenya, estimates that 30% of the drugs sold in Kenya in 2012,were counterfeit. This accounts for an annual loss of revenue of more than 10 billion shillings ($117 million).[45]

Kenya in 2008, enacted an Anti-Counterfeit Act which provides several measures aimed at targeting the general availability of counterfeit goods in the country, including drugs. The Act defines counterfeiting in relation to medicine, as the deliberate and fraudulent mislabelling of medicine with respect to identity or source, whether or not such products

---

[40] Brieger W B, et al. 2004. Interactions between Patent Medicine Vendors and Customers in Urban and Rural Nigeria. Health Policy Plan. Vol. 19, p. 178

[41] *Ibid*. p.177

[42] *Ibid*. p.177

[43] The D-G, NAFDAC, at a seminar organized for members of Delta State Chapter of the National Association of Patent Proprietary Medicine Dealers (NAPPMED) tagged, "Fight Against Fake and Substandard Regulated Products – A Fight for all", was reported to have directed patent medicine dealers to buy drugs from genuine and authentic sources to make the business of fake drugs unattractive. See Ogwuda, A. 2013. NAFDAC To Medicine Dealers: Buy Drugs from Genuine Sources. *Vanguard* Newspaper. 20/10/2013.

[44] "Kenya Pharmacy and Poisons Board seeks Kenya Anti-Corruption Commission (KACC) Partnership to stop Fake Drugs" in Business Daily dated 4th July, 2011. Retrieved from www.businessdaily.com on 12th January, 2015.

[45] Ramah R. 2013. *Counterfeit Drugs Pose Public Health Threat in Kenya*. Retrieved from www.sabahionline.com on 13th July, 2014.

have correct ingredients, wrong ingredients, have sufficient active ingredients, or have fake packaging.[46]

The Act established the Anti-Counterfeit Agency which has the power, through inspectors employed by it, to enter upon and inspect any place, premises or vehicle at, on, or in which goods that are reasonably suspected of being counterfeit goods are to be found, or on reasonable grounds are suspected to be manufactured, produced or made, and search such place, premises or vehicle and any person found in such place, premises or vehicle, for such goods and for any other evidence of the alleged or suspected act of dealing in counterfeit goods, and for purposes of entering, inspecting and searching such a vehicle, an inspector may stop the vehicle, wherever found, including on any public road or at any other public place.[47] The inspector also has the power to take the steps that is deemed necessary to terminate the manufacturing, production or making of counterfeit goods or any other act of dealing in counterfeit goods being performed, at, on, or in such place, premises or vehicle and to prevent the recurrence of any such act in future.[48]

It has however been said that the Act needlessly confuses counterfeiting with violations of non-trademark intellectual property rights, while also weakening existing Kenyan legislation, by allowing parallel imports which will certainly delay generic competition while doing nothing to improve the quality or safety of medicines. Thus on 8th July, 2009, three petitioners filed a case against the government based on the fact that the Act threatens access to medicines and would deny them life-saving medicines at the expense of their health and right to life guaranteed by Section 43(1)(a) and 26 of the Kenya Constitution respectively.[49]The court found that Sections 2, (32) and (34) of the Anti-Counterfeit Act of 2008, threaten to violate the right to life of the petitioners as protected by Article 26 (1),

[46] Section 2, Anti-Counterfeit Act No. 13 of 2008.
[47] Section 23(1)(a), Anti-Counterfeit Act No. 13 of 2008.
[48] Section 23(1)(b), Anti-Counterfeit Act No. 13 of 2008.
[49]Anti-Counterfeit Act in Kenya is commenced, despite Human Rights petition filed in court - http://www.haiafrica.org/index.php?option=com_content&view=article&id=87:anti-counterfeit-act-in-kenya-is-commenced-despite-human-rights-petition-filed-in-court&catid=93:latest-news

the right to human dignity guaranteed under Article 28 and the right to the highest attainable standard of health guaranteed under Article 43 (1) of the Kenya Constitution.[50]

Consequently, in April of 2012, the Kenyan High Court accordingly ruled against the Anti-Counterfeiting Act, stating that it was too vague and could undermine access to affordable generic medicines since the Act had failed to clearly distinguish between counterfeit and generic medicines[51].Some of the reasons for the prevalence of drug counterfeiting in Kenya has been said to be the inadequacy of Standards Agencies to excellently perform their duty and the lack of demonstrated political goodwill of the government to invest in intensive consumer information, education and communication to curb further use of counterfeit goods[52]. It is for this reason that Kenya integrated mobile telephony-based consumer verification into their safety regulations[53].

1.1.4 Drug Counterfeiting in India

Counterfeiting has been described as the major problem to India's economy.[54] This has been attributed to globalization and low-cost manufacturing which opened up India for not only commerce and direct foreign investment, but also counterfeit trade.[55] The World Health Organization (WHO) estimates that one in five drugs made in India are counterfeit and that counterfeit pharmaceuticals are a seventy-five ($75) billion-dollar global industry[56]. India has been declared as one of the countries at the forefront of the problem, selling fake drugs locally and online to unsuspecting consumers worldwide.[57]

---

[50]Patricia Asero Ochieng and 2 Ors v.The Attorney General.Petition No. 409 of 2009.

[51] A. I. Ahmad. 2012. Addressing Variability in Drug Quality: Finding the Right "Quality" Framework(s). A thesis submitted in conformity with the requirements for the degree of Master of Science. Graduate Department of Pharmaceutical Sciences University of Toronto.

[52]Kennedy Kangethe. Accessed last on 26th June, 2014 fromhttp://allafrica.com/stories/201307290128.html

[53]Counterfeit drugs raise Africa's temperature. Accessed last on June 26th 2014 from http://www.sierraexpressmedia.com/archives/58458

[54] A. Singh and H. Kane. 2011. Report on Anti-Counterfeiting in India. Being paper delivered at the Asian Patent Attorneys Association, India's 59th Council Meeting, Manila, Philippines on 12th-15th November, 2011. p. 2. Retrieved from www.apaaonline.org on 19th September, 2015.

[55] Ibid, p. 2.

[56] Fake Drugs from India Present a Public Health Threat, 24 Feb. 2014. Retrieved from www.safemedicinesonline.org on 19th September, 2015.

[57]Ullekh N P. 2013. Fake and Sub-Standard Drugs: India and China may be Worst Offenders. The Economic Times, 16th July, 2016. Retrieved from https://economictimes.indiatimes.com on 19th September, 2015.

As at 2011, the counterfeit trade in India was estimated at $5 billion.[58] A 2012 report puts India's pharmaceutical industry as one of the top five in the world[59], with sixty-four per cent (64%) of the companies operating in India, servicing the domestic market. Be that as it may, seventy-five per cent (75%) of counterfeit drugs supplied worldwide originate from India.[60,61]. India has therefore been described as the perfect example of a developing country with a strong pharmaceutical industry.[62]

India, the world's largest manufacturer of generic drugs, has become a busy centre for counterfeit and substandard medicines. Stuffed in slick packaging and often labelled with the names of such legitimate companies as GlaxoSmithKline, Pfizer and Novartis, the fake drugs are passed off to Indian consumers and sold in developing nations around the world[63].However, according to the Indian government, 0.4 percent of the country's drugs are counterfeit and substandard drugs account for about eight per cent (8%). Independent estimates however, range from twelve to twenty five percent (12-25%).[64]It can be assumed that the Indian Government, like many other governments, is oblivious of this problem and unwilling to admit its intensity or there is government collusion to hide the true state of things.

It has been noted by Indian officials, that the illicit trade has affected negatively, India's booming pharmaceutical industry and its exports, worth $8.5 billion a year, mostly to African and Latin American countries. To clamp down on the illegal trade, India's Ministry of Health, in 2010, launched a reward programme offering fifty-five thousand dollars ($55,000) to those who provide information about fake-drug syndicates. Similarly,

---

[58] Ibid, p.2.
[59] Dun and Bradstreet. 2012. Industry Overview. Retrieved 6 25, 2013, from Dun and Bradstreet: http://www.dnb.co.in/SME_cluster_series2012_Indore/PDF/IndustryOverview.pdf
[60] www.outsourcing-pharma.com/Contract-Manufacturing/New-counterfeit-report-highlights-worrying-trends
[61] Raufu A. 2003. India Agrees to Help Nigeria Tackle the Importation of Fake Drugs. *British Medical Journal*. 2003; 326:1234. See also, Verma, S., Kumar, R. and Phillips, P. J. 2014. The Business of Counterfeit Drugs in India: A Critical Evaluation. *International Journal of Management and International Business Studies*. Vol. 4, No. 2, pp. 141-148 at p. 141.
[62] Verma, et al., *ibid.* p.144
[63] Lakshmi R. 2010. 'India's Market in Generic Drugs also leads to Counterfeiting'. Washington Post Foreign Service. Retrieved from www.washingtonpost.com on 21st September, 2015.
[64] Lakshmi R, *ibid*

in 2009, the Ministry strengthened its drug law to speed up court trials. Suspects found guilty of manufacturing and selling fake drugs can be sentenced to life imprisonment.

The reasons for the growth of drug counterfeiting trade in India are not different from those of other countries in the world.These include, growing pharmaceutical industry, poor pharmaceutical regulation, high drug prices, value added tax, prescription of drugs without registration, lack of public awareness, weak enforcement of legislation and flexibility in the current legal framework. Drug Counterfeiting in India is a very lucrative business. India's status as a low-cost manufacturing base has opened up its gates for counterfeiters. Counterfeiters share none of the heavy research and development costs incurred by genuine manufacturers yet are able to earn high profits.

It is worthy of note that India has no specific legislation to address counterfeiting and piracy on its own. This is so even though various other statutory remedies – civil, criminal and administrative – can be found in various statutes, including the Consumer Protection Act 1986, the Copyright Act 1957, the Customs Act 1962, the Designs Act 2000, the Drug and Cosmetics Act 1940, Food Safety and Standards Act 2006, the Geographical Indications Act 1999, Information Technology Act 2000, Patent Act 1970, Penal Code, Prevention of Food Adulteration Act 1954 and the Trademarks Act 1999.[65]

1.1.5 Human Rights and Drug Counterfeiting in Nigeria, Kenya and India[66]

Human rights are rights that are inherent to all human beings, regardless of their nationality, place of residence, sex, ethnic origin, colour, religion, language, or any other status.[67] Human rights are the freedoms, immunities, and benefits that, according to modern values (especially at an international level), all human beings should be able to claim as a matter of right in the society in which they live. They can also be said to be fundamental rights which means constitutional rights. That is, a significant component of

[65] Narula R. 2014. Taking Issues with Counterfeits in India. *World Trademark Review*. August/September, 2014, p 108

[66] These rights are also protected by other legislative documents such as, the Universal Declaration of Human Rights (UNDHR) 1948; The International Covenant on Civil and Political Rights (ICCPR) 1966; the African Charter on Human and Peoples' Right 1981.

[67] Art. 2, UNDHR. These rights are however all interrelated, interdependent and indivisible.

liberty, infringements of which are challenged in courts to ascertain the propriety or otherwise of such interventions.[68]

Human rights are based on the principle of respect for the individual. Their fundamental assumption is that each person is a moral and rational being who deserves to be treated with dignity. They are called human rights because they are universal. Whereas nations or specialized groups enjoy specific rights that apply only to them, human rights are the rights to which everyone is entitled - no matter who they are or where they live - simply because they are alive.Thus, a right is seen as an entitlement, which the beneficiary has under a legal code; a benefit or privilege that is recognized and enforced by the law. Human rights, therefore, are the basic standards without which people cannot live in dignity. Consequently, to violate someone's human right is to treat that person as though he or she is not a human being.

The Nigerian 1999 Constitution recognizes and seeks to protect these rights. They include the right to life. This right is conferred on man by God. Consequently, it is inviolable, inalienable and indivisible. Section 33 guarantees the right to life.[69] It can be said to be a natural right (that is, a right that a person has, by virtue of the fact that he is a human being. It provides that,

> every person has the right to life, and no one shall be deprived of his life, except in execution of the sentence of a court in respect of a criminal offence of which he has been found guilty in Nigeria.

By virtue of Section 34 the right to human dignity is guaranteed. Section 34(1)(a) states that,

> every individual is entitled to respect of the dignity of his person and accordingly no person shall be subjected to torture or to inhuman or degrading treatment.

The right to personal liberty is guaranteed by section 35 of the 1999 CFRN. It provides *inter alia* that, every person shall be entitled to his personal liberty and no one shall be

[68] Bryan A G (ed.) *op. cit*. 697

[69] See also Art.3 United Nations Declaration of Human Rights (UNDHR) 1948; Art. 6(1) International Covenant on Civil and Political Rights 1966; Art 4 African Charter on Human and Peoples' Rights 1981, which have all been ratified by Nigeria.

deprived of such liberty except in some cases and in accordance with a procedure permitted by law. The Constitution by the above provision vests in individuals, the right to their personal liberty, and they must not be deprived of this right.By way of exception, persons may be deprived of their liberty in the case of persons suffering from infectious or contagiousdisease[70], person of unsound mind, person addicted to drugs or alcohol or vagrants, for the purpose of their care and treatment or protection of the community.[71]

Also entrenched in the 1999 Constitution, are the rights to privacy and family life; and freedom of thought,conscience and religion. All these are preserved in sections 37 and 38 of the 1999 Constitution. The right to privacy implies a right to protect one's thought, conscience or religious belief and practice from coercive and unjustified intrusion; and, one's body from unauthorized invasion.

The right to freedom of thought, conscience and religion implies a right not to be prevented, without lawful justification, from choosing the course of one's life, fashioned on what one believes in, and a right not to be coerced into acting contrary to one's life, religious belief. The limits of these freedoms, as in all cases, are where they impinge on the rights of others or where they put the welfare of the society or public health in jeopardy.The sum total of the rights of privacy and of freedom of thought, conscience or religion which an individual has, put in a nutshell, is that an individual should be left alone to choose a course for his life, unless a clear and compelling overriding state interest justifies the contrary.[72]

Section 42 makes provision for the right to freedom from discrimination, on the grounds of ethnicity, place of origin, sex, religion, or political opinion.

---

[70] In a United States of America, in *Jacobson v. Massachusetts* [(1905) 197 U.S. 11 at 29], the court opined that an individual who did not carry disease may yet, in some circumstances, be held in quarantine against his will until it be ascertained by inspection, conducted with due diligence, that the danger of the spread of the disease among the community at large has disappeared. Also in *United States ex rel. Siegel v. Shinnick*, 219 F. Supp. 789, 790-91 (E.D.N.Y. 1963), the plaintiff's mother was quarantined in United States upon her return from Stockholm, a place considered to be infected with small pox at that time. The district court concluded that the quarantine had been done in good faith and the detention permissible.

[71] See section 35(1)(e) of the Constitution. See also section. 45 1999 Constitution of the Federal Republic of Nigeria.

[72] Per Ayoola, JSC in *Medical and Dental Practitioners Disciplinary Tribunal v Dr John E. N. Okonkwo.* (2001) 2 MJSC 67 at pp. 103-104.

According to International instruments on the right to health[73], every human being has a right to health. Article 12 of the International Covenant on Economic, Social, and Cultural Right (ICESCR) affirms the right of everyone to the highest standard of physical and mental health.

Similarly, Comment No 14 of the UN Committee on Economic, Social, and Cultural Rights (CESCR) makes health a fundamental human right, indispensable for the exercise of other human rights. Every human being is therefore entitled to the enjoyment of the highest standard of health conducive for living a life in dignity. Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.[74] Consequently, the right to health guarantees the right to life, on which other social, economic and political rights are hinged.

The right to health involves availability, accessibility, acceptability, and quality of public health and health care facilities, goods and services.Be that as it may, access to medicine is a public health challenge in low-medium income countries. This is mainly due to the inability of the majority of the population to afford most life-saving medicines. This has contributed to the emergence of informal pharmaceutical supply networks/chains, a breeding ground for counterfeit and substandard drugs. The effects of these poor quality drugs include increased disease burden, resistance to available treatments, unnecessary deaths and suffering with the resulting effect of wastage of limited health resources on poor quality products, loss of confidence in the health professionals, health systems, pharmaceuticals and brands.

Medicine is an essential contribution to the quality of life, human dignity, and self-esteem of people worldwide. The importance of good quality drugs in medical practice can therefore not be over emphasised. With regards to prophylaxis, used for disease prevention and(or) spread, poor quality drugs result in the increase of disease burden. In the same vein, diagnostics, used for diagnosis and investigations must be of acceptable standard, otherwise test results will be incorrect and consequently, the treatment process will be

[73] See footnotes 92-96.
[74]Constitution of the WHO, 1946

affected negatively. Lastly, therapeutics is the branch of medicine specifically concerned with the treatment of disease.[75]Administering substandard, fake or falsified drugs could lead to therapeutic failure, drug resistance and unnecessary deaths.

The availability of counterfeit drugs is a direct infringement on the right to health, which provides that health care must not only be affordable, accessible and acceptable, but must be of good quality. The requirement for quality applies to facilities, goods and services, which must be scientifically and medically appropriate and of good quality. Counterfeit drugs are deadly and can result in death, amongst others. Where death occurs, it constitutes a violation of the right to life. Dealing in counterfeit drugs has been classified as a transnational organized crime[76], *with the bodies of the victims becoming crime scenes*.[77]

1.1.6 The Relationship between Health and Human Rights

Promoting health and upholding the various human rights are interrelated. Human rights violation on health can result in harmful traditional practices, slavery, torture, inhumane and degrading treatment and violence against women and children. In addition, health policies can affect human rights to freedom from discrimination, individual autonomy, participation, privacy and information. For instance, policies and laws on drug counterfeiting can affect the right to affordable, accessible healthcare. All services, goods and facilities must be available, accessible, affordable, acceptable and of good quality.

The vulnerability to ill health can be reduced by taking steps to respect, protect and fulfil human rights such as freedom from discrimination on account of race, sex and gender roles, rights to health, food and nutrition, education and housing.[78]In the same vein, there is a correlation between the right to health and the right to life. The right to life can be said to be a fundamental human right with philosophical, religious, moral and legal foundations.

---

[75]Retrieved from https://www.merriam-webster.com on 14th June, 2014.

[76] "Fraudulent Essential Medicines from South Asia to West Africa" in Focus on the Illicit Trafficking of Counterfeit Goods and Transnational Organised Crime". Retrieved from http://www.unodc.org/documents/counterfeit/FocusSheet/Counterfeit_focussheet_EN_HIRES.pdf on 31st August, 2013.

[77] Ebam K. 2011. *Dangerous Dose: A True Story of Cops, Counterfeiters and the Contamination of America's Drug Supply*. (Kindle Edition). A Harvest Book, Harcourt Inc. New York. Loc. 344 of 822.

[78] See "Health and Human Rights". A publication of the World Health Organisation. Retrieved from www.who.int on 5th May, 2013.

The right is seen as a basic one upon which other social, economic and political rights hinge. Thus, the right to life and other rights are interdependent. That is, all human rights are part of a complementary framework. It can even be said that the right to life cannot be enjoyed while recognition is not being given to the other rights, since there is a crucial correlation between the enjoyment of the right to life and social economic development on which other rights, especially the socio-economic rights, one of which is the right to healthprivileges.[79]

Therefore, looking at the effects of the usage of counterfeit drugs on the health of individuals and the public at large, it will be seen that the right to health is linked with the right to life and that both are intertwined. The effects of using counterfeit drugs are a direct reflection that it infringes on the right to health and eventually the right to life. On that basis, the issue is worth looking into, so as to enable the government adequately safeguard the right to health and the right to life of its citizens.

1.2. Statement of Problem

Counterfeit drugs have been around for a long time.[80]Pedanius Dioscorides in his "*Materia Medica*", written in AD 1, had issued warning on the dangers of adulterated drugs. When it comes to fake products, the sheer size of the industry is staggering. A report,[81] lists counterfeit medicines as the "greatest concern" when it comes to counterfeit goods. This is because not only can they result in the deaths of people using them, but medicines with insufficient doses can lead dangerous pathogens to become resistant to even the legitimate drugs. According to Nayyar, et al., who commenting on the effects of poor-quality anti-malarial drugs, noted,

> Of the many public health consequences of poor quality anti-malarial drugs, drug resistance is of particular concern. Low concentrations of active pharmaceutical ingredients in poor-quality anti- malarial drugs can result in sub-therapeutic concentrations of

[79] Section 1, Paragraph 8 of the Vienna Declaration of 1993.
[80] Counterfeiting generally has been described as the second oldest profession. See Phillips, T. 2005. *Knockoff: the Deadly Trade of Counterfeit Goods*. London. Kogan. p. 7.
[81]

> drug in vivo,which contributes to the selection of resistant parasites.[82]

According to WHO's World Health Statistics[83], more thanUS$5.3 trillion is spent on health services worldwide, each year. Pharmaceuticals are estimated to account for 25% or US$1.3 trillion worldwide. Be that as it may, access to safe and effective medicines remains highly variable globally. High-income countries (representing 15% of the world's population) account for over 78.5% of the global pharmaceutical expenditures, whilst low and medium income countries (representing 85% of the world's population) account for 21.5% of the global pharmaceutical expenditure.[84]

Closely linked with the issue of drug counterfeiting is access to medicine, which in turn is central to the right to the highest attainable health in medical care in the event of sickness, prevention, treatment and control of diseases. State parties are obliged to respect, protect and fulfil the right to health.The right to health encompasses the AAAQ (accessible, available, acceptable and good quality) framework. By this, states have the responsibility of ensuring that medicines are available, accessible, culturally acceptable and of good quality.Counterfeit drugs violate the right to good quality health.

In recent years, there has been a marked increase in the manufacturing, trade and consumption of counterfeit or spurious or substandard drugs - often with harmful, and at times, fatal results. The sale of fraudulent medicines from Asia to South-East Asia and Africa alone amounts to some $1.6 billion per year[85] - a size able amount of money being fed into the illicit economy. The WHO estimates that up to 1 per cent of medicines available in the developed world are likely to be fraudulent. This figure rises to 10 per cent in various developing countries, and in parts of Asia, Africa and Latin America, fraudulent

---

[82] Nayyar G M L., Brenan J G., Newton P N and Herrington J. 2012. Poor Quality Anti-Malarial Drugs in South East Asia and Sub Saharan Africa. *THE LANCET Infectious Diseases*. Vol.12, No. 6 p. 488-496, at p. 488.

[83]Pp 127-135. Retrieved from www.who.int on 7th September, 2013.

[84] Roberts R. 2012. Third of Malaria Drugs are Fake. *BBC News*. 22/5.2012. Accessed from BBC News Online. On 7th September, 2013.

[85] The Globalisation of Crime: A Transnational Organised Crime Threat Assessment. A UN Publication, Sales No. E.10.iv.6.2010. Accessed from www.undoc.org/data-andanalysis/tocta/TOCTA Report2010 on 7th September, 2013.

pharmaceuticals amount to as much as 30 per cent of the market.[86]The Lancet infectious disease research in mid-2012, noted that one third of malaria medicines used in East Asia and sub-Saharan Africa are fake or counterfeit. The above data shows that the problem of counterfeits is even more serious in developing countries, where custom procedures are less stringent, authorities' controls are less effective, and the use of ineffective drugs may result in a substantial loss of public confidence in the health care system.[87]

Combating counterfeit drug trade has been a major concern of many countries. For instance, Nigeria has criminalised drug counterfeiting with penalties ranging from two (2) to five (5) years imprisonment andor fine, ranging from five thousand Naira (₦5,000) to five hundred thousand Naira (₦500,000).[88] However, this penalty has been considered inadequate, as it has not achieved much in the fight against drug counterfeiting, so much so, that NAFDAC is advocating a review of the penalty to life sentence.[89] In the same vein, drug counterfeiting has been handled as an intellectual property (IP) right infringement. This has also not achieved the needed results. The reasons given for this include lack of public awareness and understanding of the IP laws in Nigeria. In addition to this, are the issues of weak and corrupt custom services enforcement, delays in the judicial system, and other barriers to justice delivery.

Over the years, technology has also been deployed in the fight against drug counterfeiting. Methods such as the Mobile Authentication Service (MAS), which allows consumers to verify that products bought are genuine, by simply using a mobile phone and a free SMS message, and TRUSCAN handheld instrument used to identify counterfeit and sub-standard drugs imported and sold in Nigeria. It identifies the slightest differences in drug formulation. This has however not recorded a notable change in the fight against

[86] WHO, 2006. MS: An Update on Estimates. Accessed from www.who.int/medicines/services/counterfeit/impact/TheNewEstimates.counterfeit.pdf on 7th September, 2013.
[87] Baratta F., Germano A and Brusa P. 2012. Diffusion of Counterfeit Drugs and Stability of Galenico. *Croat Med. Journal*, 53: 173-84. p. 174.
[88] See Section 3 of the Counterfeit and Fake Drugs (Miscellaneous Provision) Act, Cap C34 LFN, 2004.
[89] Nnanna M G. 2014. Counterfeit Drugs: NAFDAC Push For Life Sentence. Leadership. September 19. Retrieved from www.leadership.ng on 26th March, 2015.

counterfeiting, as the counterfeit drug manufacturers have also used technology to perfect their 'act'.

NAFDAC has over the years embarked on various enlightenment programmes which involves dialogue, education and persuasion, through print and electronic media, such as the "NAFDAC and Your Health" programme. These programmes are geared towards, enlightening the citizenry on the need to check for tell-tale signs such as, NAFDAC registration numbers and expiry dates. In its fight against counterfeit drugs, NAFDAC has recorded assassination attempts, threats through phone calls and mails to its management and staff, deposition of fetish objects in offices, destruction of its properties and physical attacks on its staff.[90]

Given the rapid growth in the drug counterfeit trade, in spite of global efforts at combating it, its effect on the individual, and nations, and the criminal component of drug counterfeiting, there is need to conduct a study on the effective means of combating the menace, which is a violation of the right to qualitative health care, the right to life, which member states of the WHO have an obligation to protect and uphold. The study willalso look at the plight of the victims of drug counterfeiting, who suffer harm as a result of these activities, and propose how they can be taken care of.Previous studies on drug counterfeiting have addressed the issue of drug counterfeiting from the medical andor public health angle, examining reasons for growth[91] and its effect[92] on public health. Other studies[93] have suggested that curbing the menace may be tackled from either the criminal or the IP perspective. This study, however, examines the legal issues in drug counterfeiting, evaluates the legal mechanism put in place to combat drug counterfeiting, under right to health, criminal, torts and intellectual property law with a view to

[90]Akunyili D N. 2005. Counterfeit Drugs and Pharmacovigilance. Being lecture delivered at the 10th Pharmacovigilance: The Study of Adverse Drug Reaction Training Course, held at Uppsala Monitoring Centre, Sweden, on 20th May, 2005. Retrieved from www.fug.se/ovrigt/akunyili.pdf on 5th January, 2015.
[91] Akunyili. D. 2006. *Loc cit*; Ambrose-Thomas P. 2012. The Tragedy Caused by Fake Anti-Malarial Drugs. *Mediterranean Journal of Haematology and Infectious Diseases*. Vol. 4 (1), p. 1-4; Erhun, W. O., *et al.* (2001*). Loc cit*.
[92] See Gibson L. 2004. Drug Regulators study Global Treaty to Tackle Counterfeit Drugs. *British Medical Journal*. 28:328(7438), p. 486; Newton, P. N., Green, M. D., Fernandez, F. M., Day, J. P. and White, N. J. 2006. Counterfeit Anti-Infective Medicines. The Lancet Infec. Dis. 6:602-613.
[93]Ambroise-Thomas P. 2012. *Loc.cit*; "Combating Counterfeit Drugs". A Concept Paper for Effective International Collaboration. WHO. 2005.

establishing how and to what extent the victims' interests are being protected, if at all, and proposes an alternative approach. The study proposes applying the "all embracive approach" as propounded by the United Nations Guiding Principles on Business and Human Rights[94].

1.3 Research Aim and Objectives

The aim of this study was to examine the effects of drug counterfeiting on the right to health in Nigeria.

The specific objectives of the research were to:

a) examine the legal issues in drug counterfeiting;

b) assess the adequacy of the existing and applicable legal and institutional framework for drug counterfeiting in Nigeria, in protecting the interest of the people affected by counterfeit drugs;

c) determine whether there is a legal relationship between the manufacturers of counterfeit drugs and the end users; and

d) Consider whether the "all embracive approach" of the UN Guiding Principles on Business and Human Rights can be employed to combat the menace of drug counterfeiting in Nigeria.

1.4 Research Questions

Flowing from the objectives of this research work, the research questions are as follows:

1. What are the legal issues in drug counterfeiting?
2. How adequate are the existing legal and institutional framework for combating drug counterfeiting in Nigeria for protecting the interest of the victims of counterfeit drugs?
3. What legal relationship, if any, exists between the manufacturer of counterfeit drugs and the end users?

[94] See footnote 8 on pg.2.

4. Can the "all embracive approach" of the UN Guiding Principles on Business and Human Rights be employed to combat the menace of drug counterfeiting in Nigeria?

1.5. Research Methodology

This study applied doctrinal and qualitative examination of law dealing with counterfeit drugs and the right to health in Nigeria. The study, in addressing the issue of drug counterfeiting and the right to health, adopted the Sociological School of Jurisprudence. The study examined primary and secondary sources of data in conducting this study. The primary sources of data included, case laws, the Constitution of the Federal Republic of Nigeria, 1999, statutory laws and regulations, namely the NAFDAC Act, Counterfeit and Fake Drugs Act and the Criminal Code Act, NAFDAC guidelines, namely the Guidelines for Registration of Drugs and related products in Nigeria, and NAFDAC regulations, namely the Drugs Labelling Regulations; International and Regional Conventions, Policies, and Treaties, such as Universal Declaration of Human Rights (UNDHR), International Convention on Economic, Social and Cultural Rights (ICESCR), Economic and Social Rights (ECOSOC), United Nations Guiding Principles on Business and Human Rights (UNGP).

In achieving its objectives, the study undertook a comparative study of the laws of Kenya – a developing African Nation and India, to determine how and to what extent they have been able to develop a framework to combat Drug Counterfeiting, thereby upholding the right to health, within the ambit prescribed by the WHO. The choice of Kenya is precipitated by the fact that, like Nigeria, the country is fighting a major battle against drug counterfeiting.[95] This is coupled with the fact that it is taking visible steps in fighting against drug counterfeiting and its consequences. India on her part, like Nigeria, operates a federal system of government and a multi-religious, ethnic and heterogeneous society. In addition, it is a hub for producing generic and counterfeit drugs.

[95] The Pharmacy and Poisons Board of Kenya, reported that 30% of the drugs sold in Kenya in 2012 were fake, resulting in a loss of $117million income for the country. See Rammah R., "Kenya: Counterfeit Drugs Pose Public Health Threat in Kenya", published in the 13th June edition of the AllAfrica Magazine. Accessed from www.allafrica.com on 8th August, 2013.

The UNGP framework was examined for the purpose of determining how the laws of Nigeria can be reformed to achieve maximal results in combating drug counterfeiting, thereby upholding the right to health in Nigeria.

The secondary data referred to included journal articles, findings, perspectives, opinions of researchers and jurists, reports of various Commissions, newspapers reports and internet materials.

The study also made use of data collected from wo key informant interview sessions each held with lawyers, doctors and pharmacists and two focused group discussions held with patent medicine vendors and victims.Six (6) participants each were selected for each group. A total of thirty (30) participants were recruited for the study.The participants represented the six (6) geo-political zones in Nigeria. The interviews were conducted by the researcher and an assistant. Each session lasted between 1:30 minutes to 2 hours. The interviews with the doctors, pharmacists and patients were done at the University College Hospital, Ibadan, Oyo State. Those with the patent medicine vendors were done in Egbeda Local Government Area of Oyo State. Lawyers were interviewed at the University of Ibadan. The Social Sciences and Humanities Research Ethics Committee (SSHEC) of the University of Ibadan approved the protocol of the study (Appendix II). Informed Consent forms were administered to all participants, who willing gave their consent. A copy of the Informed Consent for is attached as Appendix III. At the discussion sessions, their knowledge, understanding and assessment of the effects of drug counterfeiting on the right to health was probed. Questions were asked in relation to their views on the existing provisions of the law and how drug counterfeiting could be curbed, if not totally eradicated. A tape recorder was used to record the interview sessions.After the interviews were done, the recordings were transcribed and that qualitatively analysis was done using Atlas Ti Version 7.

1.6 Justification for the Study

Health is an important issue to mankind. It is the foundation of human existence. Healthy living is a *sine qua non* to human growth and development. For a sustainable living, usage of drugs is indispensable by human beings. However, access to drugs for clinical outcomes in patients is most challenging in Nigeria. There are reported instances of adulterated drugs causing grave havoc and serious adverse consequences to the consumers. Invariably counterfeiting drugs leads to poor health conditions of patients or consumers and often leads to death.

This study therefore, provides additional information and further insight into appropriate legal and institutional framework and formulation of policies that will adequately combat the menace of drug counterfeiting in Nigeria. This study is also relevant as a contribution towards addressing the negative effects of drug counterfeiting on the health of the consumers and human well-being.

Lastly, the study examined the subject matter from the consumers' or victims' point of view. Hitherto, there are no provisions in the law for compensating victims of counterfeit drugs for the right to qualitative healthcare. The study will proffer the application of the UNGP which proposes payment of compensation to victims of human rights violation, resulting from the activities of business corporations.

1.7 Scope of the Study

This studyexamined drug counterfeiting and its effect on the right to health in Nigeria. Itdiscussed counterfeiting and human rights generally. It analysed applicable or relevant laws relating to drugs, counterfeiting, health and human rights.The topic, drug counterfeiting has received massive global attention, however, this had been done either from the public health, criminal law and intellectual property perspectives. Consequently, the study discussed other legal issues involved in drug counterfeiting, such as the existence of contractual relationship, between the manufacturers of these counterfeits and the end users of the drug. The law implies a condition that a buyer of a product is entitled to have products which are of merchantable quality and fit for the purpose for which it was purchased. If there is such a relationship, what duty (or duties) and consequentially, civil and criminal liabilities do/does the relationship create? Finally, itexamined the human

rights issues involved in drug counterfeiting and propose the all embracive approach to combat the menace of drug counterfeiting in Nigeria. The foregoing will be discussed in line with the Nigerian and other international legal and institutional frameworks.

1.8. Expected Outcome

Flowing from the objectives of the study, the study made recommendations that may lead to law reform which will include the elements of the all embracive approach. It will also contribute to the wealth of knowledge available. This attempt will assist in combating the menace of drug counterfeiting and its effects on the right to qualitative health care in Nigeria, and how the right of the victims can be protected.

1.9. Structure of Study

This study was structured into six (6) chapters as follows: Chapter one is the general introduction. It gives the background to the study. The statement of problem, research questions, aim and objectives of the study, literature review, research methodology and the expected outcome were discussed here.

Chapter two contained the literature review, conceptual and theoretical framework for the study. The theoretical framework that this study adopted the Sociological School of Jurisprudence as propounded by Roscoe Pound, Jhering and Jeremy Betham, andHart's theory of law, morals and the minimum content of law. Hart postulates that the *teleos* of man is survival. Consequently, laws must contain certain content to ensure that the end is realized.[96]

Chapter three discussed the legal and institutional framework for drug counterfeiting in Nigeria. This chapter examined the various statutory instruments regulating drug production, distribution and counterfeiting in Nigeria. In addition, international and regional treaties and conventions will be analysed. The roles of institutions such as NAFDAC, Pharmaceutical Society of Nigeria (PSN) was reviewed.

[96] Hart H L A. 1961. *The Concept of Law*. Claredon Law Series. Oxford University Press. Oxford, p. 176. Referred to in Starr W C. 1984. Law and Morality in Hart H L A's Legal Philosophy. *Marquette Law Review*, Vol. 67, pp. 673-689.

In Chapter four, legal remedies and redress mechanisms for drug counterfeiting were discusses. In this chapter, the remedies available to victims of counterfeit drugs for the harm suffered and its consequences were analysed. These included, common law principles of contract and tort, civil remedies, criminal issues, human rights issues, consumer protection and intellectual property rights issues.

Chapter fivediscussed the findings of the study, in relation to the research aim and objectives.The chapter also examined the United Nations' Guiding Principles for Business and Human Rights.

In Chapter six, recommendations were made; this is also the concluding chapter.

CHAPTER TWO

LITERATURE REVIEW, CONCEPTUAL AND THEORETICAL FRAMEWORK

2.1 Literature Review

A counterfeit is a product made in imitation with the intention to deceive. It is not genuine, it is forged and unreal. Counterfeiting is the practice of manufacturing goods, often of inferior quality, and selling them under a brand name without the brand owner's authorization. Generally, counterfeit goods are sold under a trademark that is identical to, or substantially indistinguishable from the brand owner's trademark for the same goods, without the approval or oversight of the trademark owner.

Hence, Article 51, footnote 14 of the Trade Related Aspect of Intellectual Property Rights (TRIPS) Agreement[97], defines counterfeit goods as

> Any goods; including packaging, bearing without authorisation, a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country or importation.

Counterfeiting has also been defined as,

> to unlawfully forge, copy, or imitate an item, especially money or a negotiable instrument (such as a security or promissory note) or other officially issued item of value…, or to possess such an item without authorization and with the intent to deceive or defraud by presenting the item as genuine[98].

It is an imitation intended to pass for an original. Hence, it is spurious or false and to counterfeit, is to make false.[99]

---

[97] The TRIPS Agreement sets the minimum standards for forms of Intellectual Property regulation by member states of the World Trade Organization (WTO). It is the outcome of negotiations at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994.

[98] Bryan A G. (ed.) *Black's Law Dictionary*, 9th edition: 376

[99] Perkins R M andBoyce R N. 1982. *Criminal Law* 431 3rd ed. 1982 cited in Bryan A.G. (ed.) *Black's Law Dictionary*, 9th edition. 376

Jean-Baptiste Poquelin (1622-73), also known as Moliére, in his "Le Malade Imaginaire" (the Imaginary Invalid), noted that 'nearly all men die of their medicines, not of their diseases'. One of the themes of the play was quackery in the medical profession. This statement aptly illustrates the danger posed by counterfeit drugs.

2.1.1 Counterfeit Drugs

Product counterfeiting is a form of consumer fraud. It entails a product being sold, purporting to be something that it is not. This is however different from the crime of copyright violation, which involves the unauthorized reproduction of licensed material, such as the sharing of music or video files electronically. It is typically an organised group activity, because the manufacturing of goods involves people and time and the goal is invariably profit.

Having explained the word "counterfeit", it is pertinent at this juncture, to define the word "drug" and eventually explain "counterfeit drugs". A drug is a substance intended for use in the diagnosis, cure, treatment, or prevention of disease.[100] The National Agency for Food and Drug Administration and Control (NAFDAC) Act[101], extends this definition to include any substance of vegetable, animal or mineral origin or any preparation or admixture manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state, or the symptom thereof, in man or animal; or restoring, correcting or modifying organic functions in man or in animal; or disinfection or the control of vermin, insects or pests; or contraception.[102]

The Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous) Act[103]defines fake drugs as,

(a) Any products which is not what it purports to be,

[100] Bryan A G. *op. cit.* 535. See also, the definition section of the work.
[101] Section 31 Cap N1, LFN 2004.
[102] Ibid
[103]Section 12 Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, Cap C34 LFN 2004.

(b) Any drug or drug product which is coloured, coated, powdered, or polished that the damage is concealed or which is made to appear to be better, or of greater therapeutic value than it really is, which is not labelled in the prescribed manner or which labels or containers or anything accompanying the drug bears any statement, design or device which makes a false claim for the drug or which is false or misleading; or

(c) Any drug or drug product whose container is so made, formed or filled as to be misleading; or

(d) Any drug or drug product whose label does not bear adequate direction for use and such adequate direction for use and such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe usage or methods or duration of use; or

(e) Any drug or drug product which is not registered by the agency in accordance with the provisions of the Food, Drugs and Related Products Acts, Cap F33.

The WHO describes a counterfeit medicine as one which is deliberately and fraudulently mislabelled with respect to identity and or source.[104] Their quality is also unpredictable, because they may contain the wrong amount of, or insufficient active ingredients, wrong ingredients, ingredients different from what is stated on the package or the total absence of active ingredients altogether, fakes and copies, orthodox medicines mixed with herbal preparations, and expired drugs which have been relabelled with a fake later expiry date.[105] Counterfeit drugs are also said to include drugs without the full name and address of the manufacturer and drugs not certified and registered by NAFDAC[106]. In some cases, counterfeiters set up fake companies and procure fake certificates and documents for exporting and importing pharmaceutical ingredients as well as machinery.[107]

[104] www.who.int/medicines/services/counterfeit/faqs/03/en.
[105] WHO. Guidelines for the Development of Measures to Combat Counterfeit Drug. Accessed at www.who.int on 23rd June, 2013.
[106] Akunyili D. 2006. Lessons from Nigeria: the fight against counterfeit drugs in Africa. *Diabetes Voice*. Volume 51 Issue 3:42; See also, Akunyili, D. *op. cit.* p.19
[107] Counterfeit Medicines. World Health Organization. Fact sheet No. 275 revised 2006. Accessed at www.who.inton 1st August, 2013.

Green[108], defines counterfeit medicine as a compound that is not made by an unauthorized manufacturer, but is presented to the consumer as though it were. He noted that both the packaging and pill construction of counterfeit drugs are often virtually identical to the authentic medication.

It has been argued that the definition of counterfeit drugs, first devised by WHO in 1992 and revised by the International Products Anti-Counterfeiting Task Force (IMPACT) in 2008, has generated continuing controversy by combining the concept of counterfeiting which has a specific meaning in relation to intellectual property law, with issues related to quality, safety and efficacy of medicines.[109] The WHO definition, it has been claimed, could lead to threats to the legitimate trade in generic drugs of assured quality. This concern has been voiced mainly in the developing countries that the lack of clarity in defining counterfeit drugs and the resulting confusion, will limit access to generic drugs.[110]

This lack of uniformity in the definition of counterfeit drugs across nations is a contributory factor affecting quantifying and combating the menace. According to Forzley[111], there is much confusion between the words counterfeit, fake, illicit and substandard, such that it is often difficult to determine whether a report is referring to an actual or suspected counterfeit or a substandard product that may or may not be counterfeit in the Intellectual Property legal sense.

2.1.2 Nature and Scope of Drug Counterfeiting

Apart from being a public health issue, drug counterfeiting is also an infringement of the intellectual property rights of the manufacturers of genuine drugs. This has a devastating effect on the value of a brand and the reputation of the manufacturers. When customers

---

[108] Green M D. 2013. *Perspectives: Counterfeit Drugs*. p. 1. Retrieved from www.nc.cdc.gov on 20th November, 2013.
[109] Clift C. 2010. Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward. Chatham House Briefing Paper. Retrieved from www.chathamhouse.org.uk on 12th June, 2014.
[110] Machemedze R. 2010. Generics .vs. Counterfeit Drugs: Dynamic Multi-Site Diplomacy. *Journal of Health and Diplomacy.* Vol. 1.3:17.
[111] Forzley W. 2005. Combating counterfeit Drugs: A Concept Paper for Effective International Collaboration. *WHO, Health Technology and Pharmaceuticals*. Accessed from www.who.int on 20th November, 2013.

lose confidence in a product, such a product is likely to suffer from poor patronage even if it is a good product. The result is a loss in goodwill.

In recent years, there has been a marked increase in the manufacturing, trade and consumption of counterfeit drugs, often with harmful results, most of which are fatal. The sale of fraudulent medicines from South Asia and South-East Asia to West Africa alone amounts to some $1.6 billion per year[112], a sizeable amount of money being fed into the illicit economy. The WHO estimates that up to one per cent (1%) of medicines available in the developed world, are likely to be fraudulent. This figure rises to 10 per cent in various developing countries, and in parts of Asia, Africa and Latin America, fraudulent pharmaceuticals amount to as much as 30 per cent of the market.[113] In an article in the medical journal "The Lancet" in mid-2012, Roberts noted that one third of malaria medicines used in East Asia and sub-Saharan Africa are substandard.[114]

A counterfeit medicine is a compound that is not made by an authorized manufacturer but is presented to the consumer as if it were. Both the packaging and pill construction of counterfeit drugs are often virtually identical to the authentic medication. Counterfeit drugs also include random mixtures of harmful toxic substances to inactive, useless preparations and occasionally, there can be "high quality" fakes that do contain the declared active ingredient.[115] In addition, the medicine may contain correct ingredients but fake packaging and may also contain ingredients that are not on the label.[116]

In all cases, counterfeit medicines are manufactured secretly with no possibility of control. One fact that is worthy of note is that counterfeiting occurs with both branded and generic products. It has been found that counterfeiters do not only copy or imitate existing products, but they also manufacture products that are completely new inventions.[117]

---

[112] Fraudulent Essential Medicines from South Asia and South East Asia to West Africa. Accessed from www.undoc.orgon 16th June, 2013.
[113] Counterfeit Drugs Kill! 2006. World Health Organization. [Updated 2008 May; cited 2012 Aug 8]. Accessed on 30th May, 2013 from: http://www.who.int/impact/FinalBrochureWHA2008a.pdf
[114] Roberts M. 2012. Third of Malaria drugs 'are fake'. *BBC News (Health)* 22nd May, 2012. Accessed from www.bbc.co.uk/news/health-18147085on 30th May, 2013.
[115] Counterfeit Drugs Kill. Accessed at www.who.int on 1st August, 2013.
[116] Buowari O Y. 2012. Fake and Counterfeit Drug: A review. *AFRIMEDIC Journal* Volume 3. No. 2 2: 1
[117] Ibid. fn 38

Counterfeits can be found in street vendor stalls as well as in standard stores. In recent years, many stores selling counterfeits have become increasingly well organised and established so as to imitate a store selling legitimate products. Furthermore, counterfeits are now increasingly sold online, creating more opportunities to dupe consumers into thinking they are buying genuine goods at discounted prices. In fact, it has been proven that medicines purchased over the Internet from sites that conceal their physical address are counterfeit in over fifty per cent (50%) of cases.[118]

It should also be noted that any kind of product can be and has been counterfeited ranging from expensive lifestyle and anti-cancer medicines, antibiotics, medicines for hypertension and cholesterol-lowering drugs, contact lenses[119], hormones, steroids and inexpensive generic versions of simple pain killers and antihistamines. It is pertinent to note that, counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of) active ingredient(s), or with fake packaging.[120] In developing countries, the most disturbing issue is the common availability of counterfeited medicines for the treatment of life-threatening conditions such as malaria, tuberculosis and HIV/AIDS[121].

According to Bamitale[122], counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals; medicines manufactured below established standards of quality and therefore dangerous to patients' health and ineffective for the treatment of diseases. The difference is that counterfeits are deliberately and fraudulently mislabelled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but

[118] Counterfeit drugs kill. Accessed at www.who.int on August 1, 2013.
[119] In 2004 in France, counterfeit contact lenses were detected by the regulatory authorities after receiving complaints from patients.
[120] WHO, 1999. "Counterfeit Drugs – Guidelines for the Development of Measures to combat Counterfeit Drugs". Geneva, Switzerland. s.n.1999. Retrieved from www.who.int on 23rd June, 2013.
[121] Brieger W B, et al. 2004. Interactions between Patent Medicine Vendors and Customers in Urban and Rural Nigeria. Health Policy Plan. Vol.19. p.177.
[122]Bamitale K D S. 2007. "Effects of Fake and Expired Drugs on Health". Available on http//:netacad.oauife.edu.ng/faculties/dentistry/Inotes/FAKE%20DRUG%20AND%20HEALTH%20IMPLICATIONS%20Bamitale.doc. Retrieved on 12th June, 2014, p. 3

fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.

Bates[123] noted that there are few distinguishing features between legitimate and fake drugs, and sometimes, the counterfeits are so well done that a consumer has almost no way to tell the difference. So much so that, even the best-versed pharmaceutical security expert, may have difficulty distinguishing between fake and real goods. This is because, they carry identical holograms, batch numbers and expiry dates, blisters and tablets and look absolutely genuine, with the packaging being a perfect copy, making them difficult to detect. For the average consumer in low income countries where information about medicine and disease is sparse, most people will not know what to look for and telling the two apart, will be almost impossible.

Chandra[124], however, noted that people often seem to confuse counterfeit, substandard and generic medicines, using the terms interchangeably, but that they are very separate issues and clearly defining their differences is critical to any discussion.

According to Fenoff, et al.[125] the legitimate drug supply chain, provides opportunities at each stage, for illicit activity. The process relies on a wholesale distribution network which often includes numerous distributors, intermediaries, and secondary and tertiary wholesalers. The process, though multifaceted and appears confusing, makes the delivery of drugs more efficient and economical.[126] It allows the supplier to produce drugs in large quantities and sell them in lots to distributors, who then pass the products along the distribution network where small wholesalers are able to sell them in lots to distributors, who then pass the products along the distribution network where small wholesalers are able to quickly find buyers. This distribution network is however a mix of legitimate and

[123] Bates R. 2008. *Making a Killing: The Deadly Implications of Counterfeit Drugs. The AEI Press*. Washington DC. Kindle ed. Loc. 169 of 1127.
[124] Chandra M. 2012. Strengthening Supply Chain Integrity to Combat Illicit Trade: Counterfeiting Landscape in India being lecture delivered at the *OECD Illicit Trade Workshop* held on 26 October 2012, at the OECD Headquarters, Paris.p.5
[125] Fenoff R S and Wilson J M. 2009. Africa's Counterfeit Pharmaceutical Epidemic: The Road Ahead. *Anti-Counterfeiting and Product Protection Programme (A-CAPP) Paper Series*. P.6.
[126] Eban K. 2005. *Dangerous Doses: A True Story of Cops, Counterfeiters and the Contamination of the American Drug Supply*. Harvest Books. Harcourt Inc. New York. Loc. 344 of 822.

criminal players.[127] Consequently, the wholesale market opens doors for counterfeits and substandard drugs, or the manipulation of the legal distribution chain.[128]The effect of this being that, while authentic products can be sold outside the intended market, opportunities are being created to introduce fakes into the supply chain.[129]

The drug supply process begins with the manufacturer who may be a legitimate pharmaceutical company or an illegitimate high- or low-level producer. The producer may directly put the product into the local licit or illicit market or pass it on to a distributor who would usually be connected to a criminal network.[130] The distributor may then directly enter the product into the local licit or illicit market or sell the counterfeit drugs to wholesalers in the international market. These secondary wholesalers may then pass the product onto the local licit and illicit markets or pass it on to a tertiary wholesaler who continues to forward the drugs along the supply chains and in some cases, they may even sell the drugs directly to patients or health care providers.[131]On the other hand, damaged or expired drugs are returned to the producer for destruction. However, many of these drugs never make it back to the manufacturer but are instead diverted, repackaged or re-labelled, and then inserted back into the supply chain to be resold to consumers.[132]

2.1.3The Growth of Counterfeit Drugs Trade

Various factors have contributed to the growth of the drug counterfeit market. Widespread infectious diseases coupled with passive poverty, make the developing countries of Africa particularly vulnerable to harm from counterfeit drugs.[133] According to Gautaum et al[134], poverty, high cost of medicines, lack of official supply chain, legislative lacunae, easy accessibility to computerised printing technology, ineffective law enforcement machinery,

---

[127] Phillips. 2005. *Knockoff: The Deadly Trade in Counterfeit Goods*. Kogan Publishers. London. p.7.
[128] Daleiden B. 2009. Systematic Security Protection through Pharmaceutical Traceability. Retrieved from http://secprodsline.com.
[129]*Ibid.*
[130] Kontnik, 2004. Pharmaceutical Counterfeiting: Preventing the Perfect Crime. Greenwood Village, Co: Law Kontnik Assocs. Referred to in Fenoff R S, ibid, p. 7
[131] Kontnik. Ibid. note 160.
[132] Yankens W. 2006. Counterfeit Drugs: Coming to a Pharmacy near You. Retrieved from www.acsh.org on 3rd August, 2014.
[133] Fenoff R S. *loc. cit*. p.2
[134]*Op. cit.*

and light penalties all contribute to the growth of the market. Akunyili[135], noted that, drug counterfeiting is prevalent because of the chaotic drug distribution system[136]. For instance, in Nigeria, one can get even prescription drugs from the open markets, patent medicine stores, community pharmacies, private and public hospitals, wholesalers or importers and pharmaceutical manufacturers. As a matter of fact, it is a common sight in Nigeria to see petty traders who sell kola nuts, cigarettes, and oranges, among other items, in market kiosks, motor parks, and road sides, also hawking drugs that range from over the counter items to antibiotics (popularly called "capsules")[137] and these non-professionals are not in a good position to differentiate between genuine and counterfeit drugs.[138]

According to Akunyili,[139] drug counterfeiting is also on the increase because of non-existent or inadequate cross border legislation to control the piracy of medicines. Added to this is impotent or inactive drug regulatory system and authority. Where there are laws against drug counterfeiting, those laws are not effectively and efficiently enforced. For instance, the penalties for offenders are too light,[140] they should be increased, making them equivalent to penalties for manslaughter, if not murder, in order to deter and discourage counterfeiters. The lack of comprehensive documentation on the prosecution of offenders also tends to further suggest (albeit arguably) ineffective enforcement. Thus, it can be said that the implementation and enforcement of the various drug laws in Nigeria are deficient. Offenders should be speedily and adequately prosecuted.[141]

Another reason is that drug availability in the public and private health care delivery system in Nigeria is in a poor state[142]. This has been said to be due to inadequate funding of hospital Pharmacies, the "out of stock syndrome", the involvement of unqualified persons in the procurement and distribution of drugs, inadequate storage facilities,

---

[135] Akunyili D. 2006. *Loc.cit*

[136] Akunyili D, *ibid*. See also, Erhun, W. O., Babalola, O. O. and Erhun, M. O. 2001. Drug Regulations and Control in Nigeria: The Challenges of Counterfeit Drugs. Journal of Health and Population in Developing Countries. Vol.4. No.2:23-24. p.23.

[137] Erhun W O, Babalola O O and Erhun M O. *op cit.*

[138] ibid. See also, Onwuka, C. J. 2010. The Situation of Medicines Counterfeiting in Africa. A Publication of the School of Pharmacy. University of London. Retrieved from www.whpa.org on 25th May, 2014. p.3

[139] Akunyili D.*op cit*.

[140] Penalties range from fines ₦5,000.00 - ₦500,000 to 2-15years imprisonment.

[141] Erhun W O, Babalola O O, Erhun M O. *op cit.*

[142]Ibid.

transportation and distribution.[143] 'Out-of-stock syndrome' or 'stock-outs' is a situation where a pharmacy in a health facility, temporarily has no medicine (either a particular type or all types) on its shelf. The out-of-stock syndrome comes with consequences ranging from the patient seeking medicines at other health facilities, or in the private sector, which may be far away, expensive or choosing to go without the much needed medication, get alternatives, which may or may not be appropriate, or lose confidence in the health care system meeting their needs.[144]

The high cost of drugs has also been said to be another reason for the preponderance of drug counterfeiting. Most genuine drugs are very expensive, as the local input in drugs manufactured in Nigeria is quite small; most of the raw materials are imported and equally attract an unnecessarily high tariff. The devaluation of the Naira (Nigerian currency) has also worsened the situation. The high prices make drugs unaffordable, hence people go for cheaper drugs that are counterfeit in many cases and even patronize quacks with deadly consequences.[145]

Greed, conflict of interest and corruption have also been given as part of the reasons for the growth of the drug counterfeiting market.[146] Some regulatory officials are greedy and they try to enrich themselves by corrupt means, sometimes they collude with foreigners to import substandard drugs. Also, the effectiveness of various regulatory bodies is negatively affected by the high level of official corruption and manipulations in the Nigerian health care system and it is common knowledge that the law enforcement agents, including drug law enforcement officials are paid off to look the other way while the business of counterfeit and fake drugs flourishes.[147]

Buowari[148], cites lack of awareness as a reason for the proliferation of drug counterfeiting. According to him, there is a low level of citizens' literacy in most developing countries and even among those who are literate, there is little knowledge about health issues[149] and

---

[143] Ibid.

[144] Ogundana F. 2012. Austerity and Challenges of Health for All in Nigeria. International Journal of Development and Sustainability. Vol. 1 No. 2. p.444.

[145] Ibid. See also Bates R and Boateng K. 2006. Drug Snares: Africans Fighting Malaria. Available on www.fightingmalaria.org/article.aspX?id=28 . Last accessed 20th July, 2014.

[146] Akunyili D. 2004. *Op. cit.* Page 19

[147] ibid;

[148] Buowari O Y. 2012. Fake and Counterfeit Drug: A review. *AFRIMEDIC Journal* Volume 3, No. 2 2: 1-4

[149] *ibid*

given that drug counterfeiters have become very sophisticated in their activity, it is becoming increasingly difficult to distinguish between a genuine drug product and a counterfeit.

In his book,[150] Davison noted that the logistics of drug counterfeiting business is also responsible for its growth. According to him, the unauthorised supply and distribution of fake pharmaceutical products are easy and cheap. The counterfeiters engage the use of a combination of legitimate business and international organised crime to make their business highly efficient and hard to detect. They usually outsource production to countries, such as India and China, with products expertise, low costs, weak governance and a poor record of IP enforcement. Third party freight forwarders are used. That way, the movement of the products is legitimised. The products travel through convoluted international routes, mainly free trade zones, thereby concealing their origin and enabling them to be easily laundered. The funders would never see nor touch the products.[151]

Ambroise-Thomas[152], notes that the spread of counterfeit drug is due to the widespread use of the internet to market them in an unregulated environment of anonymity. Setting up an online pharmacy is quite easy. Quoting a WHO statement, he stated that at least fifty percent (50%) of the drugs available via the internet are fake. Bates,[153] posits that the internet offers fakers direct access to people seeking too-cheap-to be true therapeutics, or 'too embarrassed to get' prescriptions for lifestyle drugs, such as those for impotence. In 2008, the European Alliance for Access to Safe Medicine conducted a "mystery Shopper" internet pharmacy survey, which revealed that over ninety (90%) per cent of the sampled sites supplied prescription-only drugs without a prescription and sixty-two (62%) per cent of the medicines purchased on line were fake or substandard. They had examined over one hundred (100) online pharmacies and purchased over thirty (30) common prescription only drugs.[154] The internet provides an expanded opportunity for the various groups in the

---

[150] Davison M. 2011. *Pharmaceutical Anti-Counterfeiting: Combating Real Danger from Fake Drugs*. New Jersey. John Wiley & Sons, Inc. p.12.

[151] Davison M. *Ibid*. p.12

[152] Ambroise-Thomas P. 2012. The Tragedy Caused by Fake Anti-Malarial Drugs. *Mediterranean Journal of Haematology and Infectious Diseases*. Vol. 4(1):1. Available on line at www.mjhid.org last accessed on 12th January, 2014.

[153] *Op cit.*

[154] European Alliance for Access to Safe Medicines (EAASM). 2008. The Counterfeiting Superhighway. Retrieved from www.eaasm.eu on 12th January, 2014.

supply chain to connect. With an increasing use of the internet, the number of cybercrimes continues to grow.

To fight drug counterfeiting online, validation schemes such as the Verified Internet Pharmacy Practice Sites (VIPPS) Scheme have been established. This scheme is run by the National Association of Boards of Pharmacy in the US.[155]

Advancement in technology has enabled counterfeiters to produce better copies of products and packaging. Consequently, the global trade in counterfeit goods is booming[156], and is shifting from relatively innocuous items like shoes and handbags to things like medicine and pesticides that can carry serious health and safety implications.[157] Counterfeiting is one of the fastest growing economic crimes worldwide, it threatens the economies of developed and developing countries alike, destroying new investment and increasingly endangers public health and safety[158].

Another contributory factor to the growth of drug counterfeiting is permissive legal environment. Davison posits that the profit accruing from this business is a major reason for its growth.[159] As a result of the profit margin, drug counterfeiting appeals to organized criminals, including terrorists, as a means of income.[160] He noted further, that most countries treat counterfeiting as infringement of IP right and pharmaceutical counterfeiters are prosecuted under the same law as those who sell knock-off shoes and perfumes. Penalties are light compared of its profit margin and impact on health. If allowed to go unchecked, it will amount to a greater risk to society. In the United States, the Food and Drug Administration Globalisation Act which was promulgated in 2009, introduced stiffer penalties for convicted drug counterfeiters. The Act makes provisions for a *minimum of twenty (20) years or a maximum of life imprisonment if the fake drug is a proximate cause*

---

[155] NABP, 2010. Retrieved from www.nabp.net/indexvippos2.asp on 12th January, 2014.

[156] The value of counterfeiting is estimated by the OECD to be in the region of $2 billion per year, while the World Customs Organization has identified counterfeit products destined for 140 countries. See "*Counterfeit goods: A bargain or a Costly Mistake*". Retrieved from www.unodc.org on 9th July, 2013.

[157] Hargreaves S. 2013. Counterfeit Goods Becoming More Dangerous. Retrieved from www.money.cnn.com on 14th June, 2013.

[158] Counterfeiting Intelligence Bureau. A publication of the International Chamber of Commerce. Retrieved from www.icc-ccs.org, on 19th June, 2013.

[159] Davison M. *Loc. cit*.

[160] Liang B. 2006. Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into Public Health. *31 NCJ International Law and Com. Reg. 847* at pp. 869-870. Referred to in Davison, M. p. 417

of death. As a means of combating drug counterfeiting, the European Union (EU) on its part has criminalise it.[161]

2.1.4. Effects of Counterfeit Drugs

Gibson[162], noted that, drug counterfeiting affects both developed and developing countries, although the problem is far more pronounced in developing countries. She stated for instance that, in Nigeria and Pakistan, counterfeit drugs, account for forty to fifty percent (40% - 50%), of the total drug count. On their part, Newton, et al[163], says that the value of the counterfeit drug market has been estimated at US$ 36 billion. This figure, according to them, represents more than fifteen percent (15%) of the world's pharmaceutical market, with this proportion rising to more than 60% in developing countries[164]. In general, Bates[165] opined that, the market for the fake drugs in developing countries tend to have a broader profile than in the industrialised world, with the types of drugs counterfeited not being only lifestyle drugs and pain killers, but also lifesaving medicines, such as retroviral for HIV/AIDS, antibiotics, and treatments for malaria and tuberculosis.

Access to medicine, is a public health challenge in low-medium income countries. This is a direct consequence of the inability of the population to afford most life-saving medicines, leading to the emergence of informal pharmaceutical supply networks or chains, a breeding ground for counterfeit and substandard drugs. IMPACT[166] estimates that poor quality medicines in circulation range from twenty-five percent to fifty percent (25% to 50%) in highly vulnerable and inadequately regulated low and medium income countries.

Given these figures, Onwuka[167] and MacKay and Liang[168], have noted that, like alleged cures, which have not been proven, the full extent of the drug counterfeiting situation is not

[161] Council of Europe. 2010. See www.coe.int/E.DGHL/StandardSetting/PharmaCrime.
[162] Gibson L. 2004. Drug Regulators Study Global Treaty to Tackle Counterfeit Drugs. *British Medical Journal.* 28:328(7438) p.486.
[163] Newton P N., Green M D., Fernandez F M., Day J P and White N J. 2006. Counterfeit Anti-Infective Medicines. *The Lancet Infec. Dis*. 6:602-613.
[164] The estimate given for South East Asia is between 35% and 90%.
[165] Bates, *op cit.* loc. 169
[166] International Medical Products Anti-Counterfeiting Taskforce (IMPACT). 2011 IMPACT *Handbook: Developed by the Assembly and the Working Groups, 2006-2010*. See also, WHO, 2006 "WHO Fact Sheet No: 275: Counterfeit Medicines. Geneva.
[167] Fact Sheet. Protecting Trademarks. Retrieved from www.inta.org on 29th June, 2014.

known. The reasons given are that, figures are underestimated, and the consequences go beyond human boundaries. In addition, is the dearth of information on the extent of medicines counterfeiting in Africa, though documents available show that the problem of poor-quality medicines, particularly medicines counterfeiting are on the increase and that almost half of the medicines in some regions in Africa, may be counterfeits.

According to Wilson[169], an estimated 700,000 (Seven hundred thousand) Africans die annually from consuming fake anti-malarial or tuberculosis drugs, imported mainly from China. This has a detrimental effect on Africa. The effects include, health issues, loss of revenue, which might be used to develop newer and better products, loss of jobs and economic opportunity and additional costs incurred by government to secure supply chains; this makes foreign investments unlikely.

The WHO, in its "Counterfeit Drugs: Guidelines for Development of Measures to Combat Counterfeit"[170], noted that fake drugs are harming health and impeding pharmaceutical innovation. Onwuka[171], opines that medicine counterfeiting undermines the ability of Research and Development companies to invest in future innovations, reduces public trust in healthcare providers and may lead to importation of costlier branded medicines, which may be perceived by the patients as being more potent. It causes wastage of scarce resources, especially in most of the African Countries where patients are forced to pay out of pocket for these ineffective medicines.[172]In addition, Onwuka notes that it results in huge losses for genuine manufacturers who incur expenses on technology to thwart medicine counterfeiting. Medically, the effects of drug counterfeiting range from therapeutic failures, development of adverse drug reactions, increased disease severity, development of complications, development to even death.

---

[168] Mackay T K and Liang B A. 2011. "The Global Counterfeit Drug Trade: Patient Safety and Public Health Risks". *J.Pharm.Sci.* 100:4571-4579. See also, Amon, J. J. 2008. "Dangerous Medicines – Unproven AIDS kvCures and Counterfeit Antiretroviral Drugs". *Globalisation and Health* 4:5.p.10.

[169] Wilson J. 2011. "The Health and Economic Effect of Counterfeit Pharmaceuticals in Africa". A publication of Michigan University, USA. Retrieved from www.a-capp.msu.edu on 21st December, 2014.

[170] Available at http://whqlibdoc.www.who.int.hq/1999/WHO_EDM_QSM_99.1.pdf. Last accessed on 23rd September, 2013.

[171] *Op. cit.*

[172] Op. cit. p. 3, see also, Raufu, A. 2002. Influx of Fake Drugs to Nigeria worries Health Experts. *BMJ.* Vol. 324, p. 698.

Behrens, et al[173], in discussing the effects of counterfeit drugs aptly noted that,

> the effect of either inadequate drug formulation or content, leads to a sub-therapeutic dose or content and the development of drug resistance of infectious agents. The consequences of this are obvious: (1) relatively cheap drugs will become ineffective, (2) the loss of such drugs will require new drugs development, which will be more expensive and will further disadvantage patients in developing countries, (3) selection of drug resistant pathogens will lead to increased morbidity, morality and a significant economic burden on developing regions of the world.

2.1.5 Criminalising Drug Counterfeiting

Counterfeit drugs have had tragic consequences on many victims. According to Ambrose-Thomas[174], drug counterfeiting amounts, at the very least, to manslaughter. Drug counterfeiting has been classified as a transnational, organised crime, whose effect is subtler than that of others.[175] Consequently, their effect is almost impossible to measure. The sick gets sicker and resistant strains evolve, which will not make headlines, until it is too late. With regards to quality of life, these effects are of great importance.

WHO describes drug counterfeiting as a threat to public health and a criminal activity that is hard to reveal and control. Consequently, it should be criminalized.[176] This is because, when counterfeit drugs cause death, either directly (by some toxic reaction) or indirectly (no therapeutic benefit from the drug), a murder has taken place. It has been described as "attempted murder"[177], with the bodies of the victims becoming crime scenes.[178] In addition, Miller[179], noted that there is growing evidence that the sale of counterfeit drugs

---

[173] Behrens R H., Awad A I and Taylor R B. 2002. Substandard and Counterfeit Drugs in Developing Countries. *Tropical Doctor*. 32(1):1-2. p.1.
[174] Ambroise-Thomas P. *ibid*
[175] Fraudulent Essential Medicines from South Asia and East Asia to West Africa, in *Focus on the Illicit Trafficking of Counterfeit Goods and Transnational Organised Crime*. A publication of the United Nations Office on Drug and Crime. Retrieved from www.unodc.org on 12th August, 2014.
[176] Combating Counterfeit Drugs. A Concept Paper for effective International Collaboration. WHO, 2005
[177] Aldhous P. 2005. Murder by Medicine. *Nature*, 434:132-136. See also, Akunyili, D. 2007. Counterfeit Medicines: A Serious Crime against Humanity. *Proceedings of the Director – General of NAFDAC, Nigeria, to the European Union Parliament* in Brussels, on 10th April, 2007.
[178] Eban K. 2005. *Loc. Cit.*
[179] Miller K. 2002. *Financing Terror – Profits from Counterfeited Good Pay for Attacks*. A Publication of the Office of Public Affairs, US Treasury, Customs and Border Patrol Today (formerly known as Custom Today). Accessed from http://www.cbp.gov/xp/Customstoday/2002/nov/interpol.xml

and other products is being used to finance terrorism and may become a vector for terror activity.

It has been noted that the high level producers of counterfeit drugs are the ones who sell the counterfeit drugs to criminal networks; some of these producers have been linked to terrorist groups.[180] Similarly, Interpol has established connections between counterfeit drugs and terrorist financing, the relationship is either direct, when a terrorist group produces and sells the goods, or indirect when a group receives funds from sympathizers.[181]

With regards to drug counterfeiting and the right to good quality health care service. in Nigeria, studies have been carried out on the reasons for the growth of the counterfeit trade and the effects of counterfeit drugs on people. These studies have offered definitions for drug counterfeiting and counterfeit drugs, delineating its scope and recommending that it be criminalised. It has been established that drug counterfeiting is a violation of the right to good quality healthcare service.

It is worthy of note that most of the studies were carried out by scholars in the public health discipline. The studies therefore discussed drug counterfeiting as a public health menace. The studies carried out by legal scholars looked into drug counterfeiting as an IP rights and/or human right issue, sought means of curbing it from that perspective.One can therefore conclude that, there is a dearth of literature on the legal issues in drug counterfeiting, and the right of victims to compensation. This study among other things, has filled this gap.

2.2 Conceptual Framework of Drug Counterfeiting

[180] Bates, 2008. The Deadly World of Fake Drugs. Foreign Policy, September/October. p. 56. See also, International Anti-Counterfeit Coalition. 2005. The Negative Consequences of International Intellectual Property Theft. Retrieved from http://Counterfeiting.unicri.it(whitepaperpdf) on 31st August, 2014.

[181] Interpol, 2009. Intellectual Property Crimes. Retrieved from http://www.interpol.int/public/financialcrime/IP/Default.asp on 15th March, 2015.

The conceptual framework discussed in this workincludes, counterfeiting, drug counterfeiting, human rights and the right to health.

2.2.1 Counterfeiting

Counterfeiting, according to the International Trademark Association is,

> the practice of manufacturing, importing or exporting, distributing, selling, or otherwise dealing in goods, often of inferior quality, under a trademark that is identical to or substantially indistinguishable from a registered trademark owner.[182]

It is different from traditional trademark infringement or passing off, which involves, inter alia, the selling of products under confusingly similar trademarks or service marks. It is also unlike the identical or substantially indistinguishable trademark or service marks.[183]

The International Chamber of Commerce describes counterfeiting as one of the fastest economic crimes of modern times. It presents companies, governments and individuals with a unique set of problems.[184] Counterfeiting has become a highly sophisticated network of organized crime that has the capacity of threatening national economies, endanger safety and frequently kill. It devalues corporate reputations, hinders investments, funds terrorism and costs hundreds of thousands of people's livelihoods.[185]

The OECD noted that counterfeiting encompasses, "any manufacturing of a product which so closely imitates the appearance of the product of another, to mislead a consumer that it is the product of another.[186] It covers trademark and copyright infringements, copying of packaging, labelling and any other significant features of the product. Counterfeiting spreads across the fashion, software, motion picture, music, spare parts, pharmaceutical, etc., industries. These products are usually traded on the grey market, alongside recycled

---

[182] International Trademark Association, 2015. *Factsheet*. Retrieved from www.inta.org on 18th May, 2015.
[183] *Ibid*.
[184] Counterfeiting Intelligence Bureau. *Fighting Crimes*. A Publication of the International Chamber of Commerce. Retrieved from www.iccwbo.org on 18th May, 2016.
[185] *Ibid*.
[186] OECD, 1998. *The Economic Impact of Counterfeiting*. A publication of the OECD. Retrieved from www.oedc.org on 18th May, 2016. p.3.

items, stolen goods and over- runs, making it difficult to control the market and separate the illegal items from the legal.[187]

Article 51, footnote 14 of the Trade Related Aspect of Intellectual Property Rights (TRIPS) Agreement[188], provides thus,

For the purpose of this Agreement:

> a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorisation a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;
>
> b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorised by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

Technically, the term "counterfeiting" only refers to specific cases of trademark infringement. However, in practice, the term is allowed to encompass any making of a product which so closely imitates the appearance of the product of another as to mislead a consumer that it is the product of another.[189] Consequently, it may also include the unauthorised production and distribution of a product that is protected by other intellectual property rights, such as copyright and neighbouring rights. It is an imitation intended to pass for an original. Hence it is spurious or false, and to counterfeit is to make false[190].

---

[187] *Ibid.*

[188] The TRIPS Agreement sets the minimum standards for forms of Intellectual Property regulation by member states of the World Trade Organization (WTO). It is the outcome of negotiations at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994.

[189] OECD. *Op cit*. p.5.

[190] Perkins R M and Boyce R N. 1982. *Criminal Law* 431 3rd ed. 1982 cited in Bryan, A.G. (ed.) *Black's Law Dictionary*, 9th edition. 376

Advancement in technology has enabled counterfeiters to produce better copies of products and packaging. Consequently, the global trade in counterfeit goods is booming[191], and is shifting from relatively innocuous items like shoes and handbags to things like medicine and pesticides that can carry serious health and safety implications.[192] Counterfeiting is one of the fastest growing economic crimes worldwide, it threatens the economies of developed and developing countries alike, destroying new investment and increasingly endangers public health and safety[193].

Product counterfeiting is a form of consumer fraud. It entails a product being sold, purporting to be something that it is not. This is however different from the crime of copyright violation, which involves the unauthorized reproduction of licensed material, such as the sharing of music or video files electronically. It is typically an organized group activity, because the manufacturing of goods involves people and time, and the goal is invariably profit.

2.2.2 Drug Counterfeiting

A drug is a substance intended for use in the diagnosis, cure, treatment, or prevention of disease.[194]The National Agency for Food and Drug Administration and Control (NAFDAC) Act[195], extends this definition to include any substance of vegetable, animal or mineral origin or any preparation or admixture manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or animal; or restoring, correcting or modifying organic functions in man or in animal; or disinfection or the control of vermin, insects or pests; or contraception.[196]

---

[191] The value of counterfeiting is estimated by the OECD to be in the region of $2 billion per year, while the World Customs Organization has identified counterfeit products destined for 140 countries. See "*Counterfeit goods: A bargain or a Costly Mistake*". Retrieved from www.unodc.org on 9th July, 2013.

[192] Hargreaves S. 2013. *Counterfeit Goods Becoming More Dangerous*. Retrieved from www.money.cnn.com on 14th June, 2013.

[193] Counterfeiting Intelligence Bureau. A Publication of the International Chamber of Commerce. Retrieved from www.icc-ccs.org, on 19th June, 2013.

[194] Bryan A G. *op. cit.* 535. See also, the definition section of the work.

[195] Section 31 Cap N1, LFN 2004.

[196] Section 31 of NAFDAC Act

Counterfeit drugs are also said to include drugs without the full name and address of the manufacturer and drugs not certified and registered by NAFDAC[197]. In some cases, counterfeiters set up fake companies and procure fake certificates and documents for exporting and importing pharmaceutical ingredients as well as machinery[198].

A counterfeit medicine is a compound that is not made by an authorized manufacturer, but is presented to the consumer as if it were. Both the packaging and pill construction of counterfeit drugs are often virtually identical to the authentic medication. Counterfeit drugs also include random mixtures of harmful toxic substances to inactive, useless preparations and occasionally, there can be "high quality" fakes that do contain the declared active ingredient[199]. In addition, the medicine may contain correct ingredients but fake packaging and may also contain ingredients that are not on the label.[200]

In all cases, counterfeit medicines are manufactured secretly with no possibility of control. One fact that is worthy of note is that counterfeiting occurs both with branded and generic products. It has been found that counterfeiters not only copy or imitate existing products, but they also manufacture products that are completely new inventions[201]. Counterfeits can be found in street vendor stalls as well as legitimate-looking stores. In recent years, many stores selling counterfeits have become increasingly well organized and established so as to imitate a store selling legitimate products. Furthermore, counterfeits are now increasingly sold online creating more opportunities to dupe consumers into thinking they are buying genuine goods at discounted prices. In fact, it has been proven that medicines purchased over the Internet from sites that conceal their physical address, are counterfeit in over fifty percent (50%) of cases[202].

[197] Akunyili D. 2006. Lessons from Nigeria: the fight against counterfeit drugs in Africa. *Diabetes Voice*. Volume 51 Issue 3:42; See also, Akunyili, D. *op. cit.* p.19
[198] Counterfeit Medicines. World Health Organization. Factsheet No. 275 revised 2006.Accessed at www.who.int on 1st August, 2013.
[199] Counterfeit Drugs Kill. Accessed at www.who.int on 1st August, 2013.
[200] Buowari O Y. 2012. Fake and Counterfeit Drug: A Review. *AFRIMEDIC Journal* Volume 3. No. 2 2: 1
[201] Ibid. fn 38
[202] Counterfeit drugs kill. Accessed at www.who.int on August 1, 2013.

Apart from being a public health issue, drug counterfeiting is also an infringement of the intellectual property rights of the manufacturers of genuine drugs. This has a devastating effect on the value of a brand and the reputation of these manufacturers. When customers lose confidence in a product, such a product is likely to suffer from poor patronage even if it is a good product. The result is a loss in goodwill.

In recent years, there has been a marked increase in the manufacturing, trade and consumption of counterfeit drugs - often with harmful results, most of which are fatal. The sale of counterfeit medicines from South Asia and South-East Asia to West Africa alone amounts to some $1.6 billion per year[203] - a sizeable amount of money being fed into the illicit economy. The WHO estimates that up to one per cent (1%) of medicines available in the developed world are likely to be fraudulent. This figure rises to ten percent (10%) in various developing countries, and in parts of Asia, Africa and Latin America, fraudulent pharmaceuticals amount to as much as 30 percent (30%) of the market.[204]

2.2.3 Human Rights

Human rights are those rights which are inherent in human beings. These rights are enjoyed by all, regardless of their race, sex, and religion, political or social affiliation. According to Dr Justice Durga Das Basu,

> human rights are those minimal rights; every human being must have against the State, or other public authority, by virtue of his being a member of the human family irrespective of any consideration.[205]

Firstly, these rights though not creations of the law, are guaranteed by the law and states have the obligation to uphold these rights. The UDHR defines human rights as "rights derived from the inherent dignity of human persons".[206] They are founded on respect for the dignity and worth of each person, they are universal, inalienable, indivisible,

[203]Fraudulent Essential Medicines from South Asia and South East Asia to West Africa. Accessed from www.undoc.orgon 16th June, 2013.
[204] Counterfeit Drugs Kill! 2006. World Health Organization. [Updated 2008 May; cited 2012 Aug 8]. Accessed on 30th May, 2013 from: http://www.who.int/impact/FinalBrochureWHA2008a.pdf
[205] Human Rights: Nature and Constituent. Retrieved form http://archive.mu.acc.in on 8th June, 2015.
[206] Preamble to the UDHR.

interrelated and interdependent.[207] The implication of this is that, they are conferred on a person by virtue of his or her existence. Secondly, human rights are essential and necessary because they provide material and moral uplifting of people. These rights include the rights to life, dignity, personal liberty, privacy and family life, freedom of thought, conscience and religion, freedom from discrimination on ground of ethnicity, place of origin, sex, religion, or political opinion.

The concept that individuals by virtue of being humans have certain basic rights which are inalienable, has its origin in the doctrines of natural law and natural rights. Plato was the first journalist to recognize Human Rights. He did this by separating good and evil, truth and untruth, as just and unjust. He argued that a just society can be formed by linking human rationality and the nature of the good, found in the soul.[208] His view constitutes a departure from the norm of his time, which believed that justice was always in the interest of a stronger party.

Aquinas, opined that people who were alike be treated alike and that the unalike be treated differently. He noted that,

> that which is correct in the works of justice…...is constituted by a reference to the other person. It is the case therefore, that in our works, what responds to the other, according to the demands of a certain equality, aequalitatem is what is called justum.[209]

By this, Aquinas affirmed universal laws and the equality of humans before God. In line with Hobbes and Locke, natural law evolved into natural rights of the individual, founded on human nature. Hobbes developed the Social Contract theory which argues that man, in his pre-social state, lived in a "state of nature", where he was free to do what he wants, given that there were no laws, a no "notion of right and wrong", justice and injustice.[210] In the social contract, man agreed to surrender his unlimited freedoms to a sovereign to fulfil

[207] *Human Rights: A Basic Handbook for UN staff*. Retrieved from www.un.org on 8th June, 2015. p.3.
[208] Hayden P. 2001. *The Philosophy of Human Rights*. Paragon House. St. Paul, Minnesota. p.13.
[209] Aquinas T. 1988. *St Thomas Aquinas: On Law, Morality and Politics*. Baumgarth, W. and Regan, R. eds. Indianapolis. Hackett Publishing. p. 137
[210] Hobbes. 1958. *Leviathan: Party One and Two*. New York. The Liberal Arts Press. p. 108.

his desire for self- preservation. The implication of this is that, individuals surrender their rights to resistance and on the recognition of a basic right, the individual's right to security.

Locke noted that man was peaceful by nature and his desire for happiness and safety motivates him to form a civil society, to submit to the determination of the majority, and to be concluded by it.[211] His social contract is one of subjection and the exclusion of minority. He argued that individuals possess natural rights, which are independent of the political recognition granted to them by the government. [212] He noted that man had these rights, independent of and prior to the formation of any political community. Natural rights, he stated, derived from natural law which originates from God.[213] For Hobbes and Locke, politics is based not on a 'conception of good', but as a desire to escape evil.[214]

The French Declaration des Droits de L'Homme et du Citoyen (1789) and the American Declaration of Independence (1776), enshrined individual rights. Both documents upheld the inalienable and universal rights, though it set certain limitations or rights to be regulated by laws passed by a democratically elected institution.

2.2.4 The Right to Health

Health and health care are daily concerns in the society. This is mainly because health is a major asset.[215] Consequently, the right to health is a key aspect of human rights and in turn to living a dignified life. The WHO Constitution defines the right to health as 'the right to the enjoyment of the highest attainable standard of physical and mental health. This, it classified as a fundamental human right of all human beings.[216]

The right to health has been described as an inclusive right.[217] This is because, the right encompasses certain determinant of health, which include, access to healthcare, healthcare facilities, safe drinking water, sanitation, safe food, adequate nutrition, housing, healthy

[211] Locke J. 1994. *Two Treatises of Government*. Berman D. Ed. London. Everyman Publishing. Sec.97.
[212] Fagan A. 2015. *Human Rights*. Retrieved from www.iep.utm.edu. On 3rd September, 2015. p. 5.
[213] *Ibid*.
[214] Douzinas C. 2001. *The End of Human Rights*. Oxford. Hart's Publishing. p.84.
[215] There is a popular adage that says, "Health is wealth".
[216] The preamble to the WHO Constitution, 1946. See also, art.25 UDHR and ICESCR, 1966.
[217] WHO Right to Health fact sheet No. 31. p. 3. Retrieved from www.who.int on 16th April, 2014.

working and environmental conditions, health-related education and information, and gender equality. In addition, the right to health guarantees some freedoms, such as the freedom from non-consensual medical treatment, freedom from torture and other cruel, inhuman or degrading treatment or punishment. Furthermore, the right includes entitlements, such as the right to a system of health protection providing equality of opportunity for everyone to enjoy the highest attainable level of health, right to prevention, treatment, control of diseases, access to essential medicines, maternal, child and reproductive health, equal and timely access to basic health services, provision of health-education and information, and the participation of the population in health-related decision making at the national and community levels.

The right guarantees that health services, goods and facilities must be provided to all without discrimination. Similarly, all services, goods and facilities must be available, accessible, acceptable and of good quality.[218]

Nation states have the obligation to make every possible effort, within its resources, to realize this right. They have a duty to respect, protect and fulfil. States must therefore, ensure minimum level of access to the essential material components the right to health.[219] The right to health is however not synonymous with the right to be healthy. This is because the latter is dependent of certain variables such as individual biological composition and socio-economic conditions. The right to health is therefore, the right to the enjoyment of goods, facilities, services and conditions which are essential to it attainment.[220]

The UN Committee on Economic, Social and Cultural Rights developed an analytical framework in respect of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

[218] General Comment No. 14 to the ICESCR.
[219] WHO Factsheet No. 31. p. 5.
[220] *Ibid*. p.5

Included in the analytical framework are:

1. all health services, goods and facilities shall be available, accessible, acceptable and of good quality;
2. States have duties to respect, protect and fulfil the right to the highest attainable standard of health;
3. The right to healthrequires that there are effective, transparent and accessible monitoring and accountability mechanism available at the national and international levels.

State parties must do all that is reasonably possible to ensure that existing medicines are available in sufficient quantities and quality, within their jurisdiction. In accomplishing this, states should effectively promote the development and availability of medicines and medical and commercial incentives, which will influence research. In addition, states, should ensure that good quality existing medicines are available and that new ones are developed and are readily available.

The obligation in respect of supply of good quality affordable medicines involves ensuring, within available resources, that the drug supply chain is reliable, efficient and transparent. It must ensure value for money, by minimising waste and not accommodate corrupt practices. It must meet the needs of all citizens. In addition, states are to ensure safety, efficacy and quality of medicines, available both at public and private sectors of the healthcare delivery system. This duty also covers accuracy and appropriateness of medicine information.

2.3 Theoretical Framework

The theoretical framework adopted for this study is the Sociological school of Jurisprudence as postulated by Roscoe Pound, Jhering and Jeremy Bentham. Also, to be considered is Hart's minimum content of law theory.

2.3.1 Sociological Jurisprudence

The term sociology was invented by Comte (1798-1857). It is the study of behavioural pattern of people in relation to their environment or surroundings. In sociological parlance, law is a social phenomenon which reflects human needs and aspiration. According to Faris, sociology is a branch of science of human behaviour that seeks to discover the causes and effects that arise in social relations among persons and in the intercommunication and interaction among persons and groups.[221]

The Sociological School of Law promotes the study of law as a phenomenon. It attempts to look at law against the background of the people it is meant to govern. It believes that law cannot exist in the absence of the people, that law must be part and parcel of the people in order to command legitimacy. Consequently, Sociological Jurisprudence is the study of law in its social setting or as a social institution. Roscoe Pound noted that sociological jurisprudence is,

> Movement for pragmatism as a philosophy of law, for the adjustment of principles and doctrines to the human conditions they are to govern rather than to assumed first principles; for putting the human factor in the central place and relegation logic to its true position as an instrument .[222]

Sociological jurisprudence has been described as a method which attempts to use the various social sciences to study the role of law as a living force in society and seeks to control this force for the social betterment.[223] Montesquieu, the fore runner of sociological jurisprudence, in his *L'Esprit des Lois*, postulates that a system of law is a living growth and development, which is interrelated with the physical and societal environment.[224]

---

[221] Curzon L B. 1995. *Jurisprudence*. 2nd ed. London. Cavendish Publishing Ltd. p.37.
[222] Pound R. 1908. *Mechanical Jurisprudence*.
[223] Gardner J A. 1960. The Sociological Jurisprudence of Roscoe Pound (Part 1). *Willanova Law Review*. 1 (1961). Available at http://digitalcommons.law.villanova.edu/vlr/vol7/iss1/1 p. 9. Retrieved on 5th May, 2016.
[224] Montesquieu. *L'Esprit des Lois,* referred to in Gardner, J. A. 1960. *Ibid*. p. 3

According to the sociological approach, to Jurisprudence, law is non-unique, but a method of social control.[225] The proponents of this approach reject the 'jurisprudence of concepts', which views law as a closed logical order.[226] They are sceptical about rules as presented in textbooks, but were more concerned with 'the law in action', that is, what really happens.[227] They espouse relativism rather than naturalism which believes that an ultimate theory of values can be found.[228] They believe in the importance of harnessing the techniques of the social sciences, as well as the knowledge from sociological research towards the establishment of a more effective science of law.

According to Roscoe Pound,[229] the role of sociological jurisprudence is ensuring that the making, interpretation and application of laws take social facts into account. To accomplish this, he proposed a comprehensive programme which comprises of:

(a) A factual study of the social effect of legal administration;

(b) Social investigations as preliminaries to legislation;

(c) A constant study, of the means for making laws more effective which involved;

(d) A constant study, both psychological and philosophical, of the judicial method;

(e) A sociological study of legal history;

(f) Allowance for the possibility of a just and reasonable solution individual cases;

(g) A ministry of justice in English speaking countries; and

(h) The achievement of the purposes of the various laws.

The proponents of the sociological approach include, Jhering, Ehrlich, Bentham, the Tubingen School, Roscoe Pound and Duguit. As noted earlier, this study will however confine itself to the theories of Jhering, Pound and Bentham.

---

[225] Parker, 1968. The Limits of the Criminal Sanction; Black, 1976. The Behaviour of Law. Ch. 6. Both were referred in Lloyd and Freeman, M. D. A. 1985. *Lloyd's Introduction to Jurisprudence*. 5th ed. Stevensons & Sons. London. p. 548

[226] *Ibid*. p. 548

[227] *Ibid.* p. 548

[228] Pound R. (1923). *Interpretation of Legal History*. Ch. 7. Referred to in Lloyd's. p. 548

[229] Dias R W M. 1985. *Jurisprudence.* Butterworths. London. p. 430

2.3.1.1 Rudolf Von Jhering or Ihering (1818-1892)

In his *The Spirit of Roman Law*, Jhering noted that the origin of laws lay in sociological factors and that the basis of a 'right' was an interest, which led him to consider more closely, how laws deal with conflicting interests.[230] According to Jhering, the dominant notion in the exercise of human will is purpose.[231] In other words, causality in the natural world is governed by a 'because'. He posited that, 'a stone falls because without its support, it must fall'. He noted that,

> The stone does not fall, because in order to fall, but because it must fall, because its support is taken away; whilst the man who acts does so, not because of anything, but in order to attain to something. This purpose is as indispensable for the will as cause is for the stone. As there can be no motion of the stone without a cause, so can there be no movement of the will without a purpose.[232]

Law, in Jhering's opinion, is a part of human conduct and its purpose is as an instrument for serving the needs of society by furthering and protecting the interests of the society.[233] The essence of law is for the protection of societal and individual interests. However, these interests often clash. In such instance, law co-ordinates and resolves the competing interests. According to him, the conflicting interests are mutual, because the essence of the society is to secure and guarantee the satisfaction of human wants.

Jhering opined that, law, in a social setting, exists for a special purpose. This, for instance can be seen in the preamble of the 1999 Constitution of the Federal Republic of Nigeria, which provides that the Constitution exists,

> for the purpose of promoting the good government and welfare of all persons in our country and the principles of freedom, equality and justice, and for the purpose of consolidation the unity of our people.

Law, to him, aims at the good of the society and permits individuals to realize their purposes. It is a mediator, the balancer and the harmoniser. Legal institution enables man

[230] Dias R W M. *op. cit*. p. 423
[231] Law as a means to an End (Zweck im Recht/ purpose of law).
[232] Jheirng. 1913. *Law as a Means to an End*. Boston. The Boston Book Company. p.2.
[233] Dias. *Op cit*. p.424.

to add to the quality of his being. He noted further that, societal purpose and standards will change in time and space. According to him, the existence of immutable natural law as an absolute guide to social and legal activities is unrealistic. Consequently, Jhering rejects a universal law that will minister to the needs of all, at all times.

To Jhering, reconciling selfish purpose with unselfish purpose and suppressing the former when they clash with the latter, is the problem of the society. The law according to Jhering, does not exist for the individual as an end in himself, but it serves his interest with the good of society in view.[234]

Jhering clarified his point by using property as an example. Property is both a social and an individual institution and it justifies expropriation and limitation of the individual's rights.[235] To reconcile the individual with the society, it is necessary to balance various interests. These, he grouped into three (3) categories, namely, individual, state and social.[236] Consequently, the social activities of the people need to be encouraged and this can be done through the principle of the levers of social motion.[237] These social motions, according to him are four (4), namely, reward and coercion, duty and love.

With regards to reward and coercion, Jhering posited that they seek to identify the selfish interest of the individual with some larger social interest. Dias[238] illustrated the notion of reward for instance, that since the economic wants of man need satisfaction, trade was instituted to meet this need. Consequently, its purpose is to pander to the selfish motive of profit. Coercion, in its part, is a feature of legal administration, a part of social machinery; it is coercion organized in a set form by the state. Also available are unorganized coercion in the form of social conventions and etiquette. Law is however a form of coercion which is organized by the state. While acknowledging the existence of altruistic impulses, he

[234] Jhering, *op. cit*. pp. 63-68, referred to in Dias. *Op cit*. p.424.
[235] Jhering. *Ibid*. p.391.
[236] Dias. *Op. cit*. p.424.
[237] *Ibid*.
[238] *Ibid*. p.424

recognised that these would not suffice without the coercive form of social control provided by law.[239]

On the second part, are what Jhering called duty and love, which also direct men towards social ends. Jhering further noted that law is only a type of means of achieving an end, which is social control,[240] it being a feature of the state. It is the sum of the conditions of social life in the widest sense of the term, as secured by the power of the state through the means of external compulsion.[241] He noted that there is a need to reconcile competing social and individual interests. Consequently, the success of the legal process was to be measured by the degree to which it achieved a proper balance between competing social and individual interests. He however did not provide a scale of values with which to strike this balance.[242]

Jhering described law as the *reconciliator* of conflicting interests.[243] It is therefore, a tool of social engineering, which brings reforms by modifying existing ones, whilst taking into cognizance the varied interests in society and to avoid any conflict that the interests may create. The law must aim at protecting, respecting and fulfilling the right to enjoy the highest attainable standard of healthcare, which includes good quality medicines and medical products, without conflict between the different actors. Consequently, in the bid to curb drug counterfeiting, the law can be reformed so as to serve the interest of the society as a whole, balancing the economic interest of the individual (counterfeit drug producers) against that of the society.

2.3.1.2 Jeremy Bentham (1748-1832)

Bentham was an individualist. He therefore approached societal problems on this basis. His moral philosophy, social sense and juristic insight cannot be separated and his

[239] Lloyd. *Loc cit*. p.553
[240] *Ibid*. p.424.
[241] Jhering. *Loc cit*. p.380
[242] Lloyd. *Op. cit*. p.553
[243] *Ibid.* p.566

utilitarianoutlook ran through his work. According to Bentham, man is governed by pleasure and pain.[244]

Bentham posited that the function of laws ought to be the promotion of the greatest happiness of the greatest number of people.[245] This theory is an application of the principle of utility, which approves or disapproves of action according as it increases or diminishes happiness.[246]

Bentham concluded by noting that the task of laws should be to bring about the maximum happiness of each individual. Since the happiness of each will result in the happiness of all.[247] This however raises the issue of reconciling the interests of individuals with that of the community. According to Dias, harnessing a selfish pursuit of pleasure and avoidance of pain to the unselfish service of the common wealth is a contradiction.[248] To avoid this conflict therefore, one can assume that individual pleasure and pain motivations by and large would not run counter to those of the community.

In Bentham's view, legislation on a drastic scale was essential to remedy the evils which he saw around him, but once these had been eradicated, legislation should aim at providing subsistence, abundance, equality of opportunity and security for all.[249] In summing up, Bentham believes that the happiness of the individual leads to the happiness of the community. Where the right to qualitative health care of an individual is guaranteed, it contributes to the happiness of the individual and this result in the happiness of all. Where everyone has sound health, the community will thrive.

Bentham also noted that, there are times when individual interests clash with community interests. For instance, the interest of the counterfeit drug manufacturers is to make money.

---

[244] Bentham, 1907. *An Introduction to the Principles of Morals and Legislation I*. Eds. Burns and Hart. Para1. Referred to in Dais. *Loc. cit*. p.427.
[245] Bentham. 1988. *A Fragment on Government*. Eds. Harrison. Referred to in Dias. *Ibid*.p.427.
[246] Bentham. *Op. cit*. para 2-3.
[247] Bentham. *Ibid*. para 6
[248] Dias. *Loc cit*. p. 427
[249] Dias. *Ibid*. p. 428.

This conflicts with the interest of the society at large, which is to enjoy good quality health care.

Bentham's theory supports the need for law reform. Consequently, in line with Bentham's prescription for the role of law, that where there is such conflict, there is need for drastic legislation to remedy the evil perpetrated by these selfish interests. The law must be such that will prevent further violation of the right to health. This can be done by enacting stricter, enforceable laws,to curb drug counterfeiting, thereby protecting the citizens' right to health. Once the first legislation has achieved this, subsequent legislations should strive to provide subsistence, abundance, equality of opportunity and security for all.

2.3.1.3 Roscoe Pound (1870-1964)

According to Roscoe Pound, Jurisprudence is not so much a social science, but a technology.[250]He gave an analogy of applying engineering to social problems. Social engineering according to Pound, is not a mechanism for producing rapid or radical social departures.[251] He opined that the aim of social engineering is to build as efficient a structure of society as possible. This according to him requires the satisfaction of the maximum of wants with the minimum of friction and waste.[252] Lawyers and legislators, consequently have the responsibility for social engineering. They are saddled with the responsibility of assisting the courts by classifying and expatiating on the interests protected by law.

He went on to define "interest" as,

> "claims" or "demands" or "desires" which human beings either individually or in groups of associations or relations, seek to satisfy, of which therefore, the adjustment of relations and ordering of human behaviour through the force of a politically organized society must take account.[253]

[250] Lloyd. *Op. cit*. p. 565
[251] Lloyd. *Ibid*. p. 565
[252] Pound. *Interpretations of Legal History*, p. 156. Referred to in Dias. *Op. cit*. p. 437
[253] Pound. (1943-44). A Survey of Social Interests. 57 Harvard Law Review 1.

For an interest to qualify for protection, it must be upgraded to the status of a right. The right to health is a legal right which should be protected. To accomplish this fully, Nigeria should make the right justiciable.

Pound categorized interests into three (3), namely, individual interests, public interests and social interests.[254] They are discussed below.

(a) Individual Interests: These are claims, demands or desires which relate to the individual life. These include:

i. Personality:Comprises interests in the physical person, freedom of will, honour and reputation, privacy and belief and opinion.

ii. Domestic relations: Distinguish between the interest of individuals in domestic relationship and that of society in such institutions as family and marriage. Individual interests include those of parents, children, promised advantages, advantageous relations with others, freedom of association and community employment.

iii. Interest of substance:This includes property, freedom of industry and contract, promised advantages, advantageous relations with others, freedom of association and continuity.

(b). Public Interests: these claims, demands, or desires, though asserted by individuals are involved in or looked at from the standpoint of political life. Pound identified two (2).

i. Interests of the state as a juristic person:These include the integrity, freedom of action and honour of the state's personality, and claims of the politically organized society as a corporation to property acquired and held for corporate purposes.

ii. (ii) Interests of the state as guardian of social interests.[255]

[254] Dias. *Op. cit.* p. 431.
[255] Social interests are discussed under the third head.

(c). Social Interest: these are thought of in terms of social life and generalized as claims of the social group. Social interests include,

i. Social interests in the general security:This according to Pound, are claims or wants or demands, asserted in title of social life in civilized society and through the social group, to be secure against those forms of actions and courses of conduct which threaten its existence.[256] Within this category, are those branches of the law which relate to general safety, general health, peace and order, security of acquisitions, and security of transactions. Others in this class include, social interest in the security of social institutions – a fundamental institution of the civilised society being secured from actions and conducts that threaten their existence or impair their efficient functions.

ii. Social institution in general morals:Claims, wants or demands to be secured against actions or conducts which are offensive to morals of the general body of individuals therein for the time being. This covers laws dealing with prostitution, drunkenness and gambling.

iii. Social interest in the conservation of social resources:This involves the claims, wants or demands involved in a civilized society that the goods of existence shall not be wasted. This category sometimes clashes with individual interests in dealing with one's own property as one pleases. Within this category, are laws governing conservation of natural resources, protection and training of dependents and defectives, that is conservation of human resources.

iv. Social interest in the general progress:The claim, wants or demand involved in social life in civilized society, that the development of human powers and human control over nature for the satisfaction of human wants go forward. This category includes, economic progress, such as freedom of use and sale of property, free trade, free industry, encouragement of invention by grant of patent; political progress, such as free speech, free association and cultural progress, which

[256] Dias. *Op. cit.* p.432

includes, free science, free letters, free arts, promotion of education and learning and aesthetics.

v. Social interests in individual life:These are claims, wants or demands involved in social life in civilized society that each individual be able to live a human life therein, according to the standards of the society. It involves self-assertion, opportunity and conditions of life.

Roscoe Pound noted that in law making, the various interests of stakeholders should be considered and evaluated. The existing Nigerian laws on combating drug counterfeiting do not take care of all interests. The interests of the manufacturers of branded drugs are to a considerable extent, protected under the intellectual property laws. Similarly, it partially takes care of the interest of society, having been criminalized. However, with regards to counterfeiting, the interests of the victims, as it relates to have not been adequately addressed. If the law is a tool for social engineering, the law should be all-embracive. The need and workability for an all-embracive law is one the objectives of this study. In addition, the law ought to protect, respect and fulfil the rights of the citizens to the highest attainable health.

2.3.2 Herbert Lionel Aldophus Hart's Minimum Content of Law

In his *The Concept of Law*,[257] Hart (1902-1992), argues that certain fundamental principles of justice are required for a legal system. He takes the relationship between law and morality seriously, and finds that there is much in natural law theory which any philosophically defensible theory of law must include. He has been described as a critical, moral philosopher as well as an analytical legal philosopher.[258]

According to Hart, there are two types of rules that make up the essence of law, primary (duty imposing) rules and secondary (power conferring) rules. He opined that 'law may be most illuminatingly characterized as a union of primary rules of obligation with such secondary rules.'[259] These are duty imposing rules of a state, failing which they may be subject to certain legal sanctions. They are basic rules. Examples of these will include laws

[257] Hart H L A. 1961. *The Concept of Law*. Claredon Law Series. 2nd ed. Oxford University Press. Oxford.
[258] Starr W. 1984. Law and Morality in Hart's Legal Philosophy. *Marquette Law Review*. Vol. 67:673. p. 675
[259] Hart. *Op. cit*. p. 93. referred to in Starr. *Ibid*. p.675.

which prohibit trespass. The primary rules are therefore rules that an ordinary citizen will refer to as "the law".

Hart noted that,

> under rules of the one type, which may well be considered the basic or primary type, human beings are required to do or abstain from certain actions, whether they wish to or not. Rules of the other type are in a sense parasitic upon or secondary to the first; for they provide that human beings may by doing or saying certain things introduce new rules of the primary type, extinguish or modify old ones, or in various ways, determine their incidence or control their operations. Rules of the first type impose duties; rules of the second type confer powers, public or private.[260]

The secondary rules on their part, do not impose duties. Hart describes them as being power-conferring. These rules state the manner in which primary rules may be recognised, changed and adjudicated. It gives the legislature the power to legislate and the citizens the right to vote.[261] According to Hart, secondary rules are "rules about primary rules".[262] He noted that,

> [secondary rules] may all be said to be on a different level from the primary rules, for they are all about such rules; in the sense that, while primary rules are concerned with primary rules themselves, they specify the ways in which the primary rules may be conclusively ascertained, introduced, eliminated, varied and the fact of their violation conclusively determined.[263]

Secondary rules, in Hart's opinion, are necessary in any reasonably complex society. This is due to the fact that, it is pertinent to have laid down procedures on what the primary rules are, how they can be challenged, altered or reformed. The secondary rules make provisions for these. The combination of the primary and secondary rules, according to Hart, is the essence of a legal system.

Hart's secondary rules can further be categorised into three, namely,[264]

---

[260] Starr. *Ibid*. p. 676.
[261] Starr. *Ibid*. p. 676.
[262] *Ibid.*
[263] Hart. *Loc. cit*. p.92.
[264] *Ibid.* p. 94.

a. rules of recognition, which are authoritative texts or standards for properly identifying the primary rules that have thus far been established;

b. rules of change, these specify how primary rules may be changed;

c. rules of adjudication, which are necessary to remedy the inefficiency of a legal system with just primary rules. The rules within this category, set out the criteria for determining when a primary violation has been established. By these set of rules, judges, commissions and regulatory agencies are given authority to apply them when the occasion is appropriate. These provide the centralized official sanctions of the system.

Hart further noted that, law and morality though not related, are very close. Law, in his opinion should continually be subjected to moral scrutiny. Impartiality, according to him, is a moral standard which is necessary in a legal system. Consequently, any judge applying a particular legal rule is expected to do so uninfluenced by prejudice, interest or caprice.[265]

Law, according to Hart, is an instrument of social control. Consequently, rules of law must satisfy certain conditions if they are to properly achieve this goal.[266] Hart's concept of law comprises of formal justice, principle of impartiality and the principle of fairness. This according to Starr, is a moral beginning.[267]

Hart propounded two perspectives of viewing legal order, namely,

i. external point of view, that is observing how members of a different society, act with respect to its legal system.[268] In this instance, the observer is outside the legal system. The observer here can note that the citizens obey the law but he cannot say whether the citizen believes that he or she has any moral obligation to do so.[269]

[265] *Ibid*. p. 202
[266] Starr. *Op. cit*. p. 682
[267] *Ibid*. p. 682.
[268] *Ibid*. p. 682.
[269] Hart. *Op. cit*. p. 86-88

ii. To ascertain the citizens' reason for obeying the law, Hart prescribed that the legal system be viewed from an internal point of view.[270] This observation will be done by someone who is not only a member of a legal system but also accepts its legitimacy. The internal point of view offers the added advantage of the opportunity of knowing why the citizens obey the rules.

Hart postulates that the *teleos* of man is survival. Consequently, laws must contain certain content to ensure that that end is realised.[271] This is the minimum content of the law.

The sociological school of jurisprudence which see law as a tool of social engineering postulates that sometimes interests of citizens, which if upgraded, becomes rights, clash. In such instances, as it with instances where there are gaps in the law, there should be law reform to correct the wrongs in the society. In addition, the legal system must contain rules for protecting persons, property and promises, for it to be viable. Consequently, it must have a minimum content. Where this standard is not met, the law fails to ensure the survival of man, and should be reformed.

The laws put in place to combat drug counterfeiting, appear to be failing, seeing that the menace has not been controlled. Applying the sociological theory to the situation, there is need for a reform, so that the society will be what it ought to be. The law must be free of loopholes which make violation of the right to health possible.

An analysis of the theoretical framework is hereby attached as Table 1.

[270] Falk R. 1969. *The Role of Domestic Courts in the International Legal Order*. pp. 23-24. Referred to in Starr. *Op. cit*. p. 683.
[271] Hart H L A. 1961. *The Concept of Law*. Claredon Law Series. Oxford University Press. Oxford. p. 176. Referred to in Starr, W. C. 1984. Law and Morality in Hart's Legal Philosophy. *Marquette Law Review*, Vol. 67, pp. 673-689.

THEORETICAL FRAMEWORK
SOCIOLOGICAL JURISPRUDENCE
LAW AS A TOOL OF SOCIAL ENGINEERING

THEORIST	THEORY
Jhering/Ihering	- The origin of law is found in sociological factors. - Law is an instrument for serving the needs of society- protecting societal and individual interests. - The basis of rights is interest. Where interests clash, law co-ordinates and resolves the competing interests. - It not realistic to have an immutable natural law as an absolute guide to social and legal activities. Law should be progressive. - The success of a legal process should be measured by the degree to which it achieves a proper balance between competing social and individual interests. - Law is a reconciliator, harmoniser and balancer of conflicting interests. It is therefore a tool of social engineering - it brings reforms by modifying existing laws, while taking cognisance of the varied interests in the society, thereby

	avoiding any conflict that the interests may create. - The law must aim at protecting, respecting and fulfilling the right to enjoy the highest attainable standard of healthcare, which includes good quality medicines and medical products, without conflicts with the different stakeholders.
Bentham	- Man is governed by pleasure and pain. - Law ought to promote the greatest happiness of the greatest number. - Law ought to bring about the maximum happiness of each individual. - It reconciles the interests of the individual with that of the society. - Legislation is necessary to remedy the evils in the society. Once this has been accomplished, legislation is to provide subsistence, abundance, equality of opportunity and security for all. - Such law must be such that will prevent further violation of the right

	to health, and enforceable. - Happiness of the individual leads to the happiness of all. - Individual interests sometimes clash with that of the community. - Where everyone has sound health, the community thrives.
Roscoe Pound	- Social engineering is building an efficient structure in the society. - To accomplish this, there has to be the satisfaction of the maximum wants with minimum friction and waste. - Lawyers and legislators have the responsibility for social engineering. - They are responsible for assisting the courts by clarifying and expatiating on the interests protected by law. - Interests are claims or demands or desires which human beings, either as individuals or a group seek to satisfy. - An interest should be legally protected by giving it the status of a legal right.

	- In law making, interests of various stakeholders should be considered and evaluated. - The law in force, should protect, respect, and fulfil the rights of the citizens to the highest attainable health.
Hart – Minimum content of law	- The *teleos* of man is survival. Law must therefore contain certain content to ensure that that end is realised. - Without the minimum content, laws and morals could not accomplish the minimum purpose of survival which men have in associating with one another. - Legal system must contain rules for protecting persons, property and promises, for it to be viable. - Law must provide a system of mutual forbearances enforced by sanctions. - The minimal protections and benefits of the system need not be extended to all members of the society. - There must be no loopholes in the law, which will result in violation of

	the right to health.

Table 1.

CHAPTER THREE

LEGAL AND INSTITUTIONAL FRAMEWORK FOR DRUG COUNTERFEITING IN NIGERIA

There are both national and international legislation, that point to drug counterfeiting and the human right to health either directly or indirectly. These legislations define, protect and preserve the human right to health. The right to health is so vast and wide, having so many aspects and issues under it. One of the issues under the right to health is drug counterfeiting. Drug counterfeiting has been established to be one of the major ways through which the human right to health is being negatively affected.

In this chapter, the legal and institutional framework for drug counterfeiting in Nigeria will be discussed. In doing this, legislative instrument in force in Nigeria at the relevant time, will be treated. In addition, relevant international conventions and institutions saddled with oversight responsibilities in respect of drug counterfeiting and consumer protection will be discussed.

3.1 Statutory Laws on Production, Supply and Marketing of Counterfeit Drugs

This section examines the Constitution,[272]the Child's Right Act,[273]Consumer Protection Council Act,[274] the Counterfeit and Fake Drugs and Unwholesome Processed Foods

[272]Constitution of the Federal Republic of Nigeria, 1999.
[273]Child's Right Act, 2004.
[274] CAP C25, Laws of the Federation (LFN) 2004.

(Miscellaneous Provisions) Act,[275] the Criminal Code Act,[276] the Food, Drugs and Related Products (Registration) Act,[277] the NAFDAC Act,[278] among other legislations.

3.1.1. The Constitution of the Federal Republic of Nigeria, 1999

The Constitution is the supreme law of the country. Section 17 makes provisions for the social objectives. These are sections of the Constitution, which prescribe the ultimate social, environmental, educational, and economic cum cultural goals of the government. These are identified aims, goals or objectives a state hopes to achieve in order to uplift the living standard of its citizens.

These objectives are anchored on a social order based on the idea of freedom, unity and justice. The objectives recognize the sanctity of human person and his dignity. Consequently, the government is expected to conduct its business in [279]a humane manner, which exploit human and natural resources for the good of the citizens as fundamental objectives and directives principles of state policy.

Section 17 states that the social order of the State is founded on ideals of freedom, equality and justice. The citizens have equal rights, obligations and opportunities before the law.[280]The government is expected to safeguard the health, safety and welfare of all persons in employment,[281] andprovide adequate medical and health facilities for all citizens.[282]

These provisions are directed at protecting the right to health of the citizens. The provisions of the section are however not justiciable. Be that as it may, other justiciable legislations have been promulgated, to protect the right to the highest attainable standard of health. These are justiciable. These include the Labour Act,[283]and the Child's Right Act.[284]

3.1.2. Child's Right Act

[275] CAP C34, Laws of the Federation (LFN) 2004.
[276] CAP C38, Laws of the Federation (LFN) 2004.
[277] CAP F33, Laws of the Federation (LFN) 2004.
[278] CAP N1, Laws of the Federation (LFN) 2004.
[279]Section 17(1) 1999 CFRN
[280]Section 17(2)(a) 1999 CFRN
[281]Section 17(3)(c) 1999 CFRN
[282]Section 17(3)(d) 1999 CFRN
[283]Cap L1, LFN 2004
[284]No. 26 of 2003.

Section 1, provides that, in every action concerning a child, whether undertaken by an individual,public or private body, institutions or service, court of law, or administrative or legislative authority, the best interest of the child is the primary consideration.It is expected that every child shall be given such protection and care that is necessary for his/her well-being, considering the rights and duties of the child's parents, legal guardians, or other individuals, institutions, services, agencies, organisations, or bodies legally responsible for that child.[285]

In addition, by virtue of Section 2(2), every person, institution, service, agency, organisation and body responsible for the care or protection of children should conform with the standards established by the appropriate authorities, particularly in the areas of safety, health, welfare, number and suitability of their staff and competent supervision.

By virtue of Section 13, every child is entitled to enjoy the best attainable state of physical, mental and spiritual health, and it is the responsibility of every Government, parent, guardian, institution, service, agency, organisation, or body responsible for the care of a child to endeavour to provide for the child the best attainable health.

The above provisions are geared towards fulfilling Nigeria's obligation under the Convention on the Rights of the Child.The provisions guarantee the child's right to good quality healthcare, consequently, right to be protected from counterfeit drugs.

3.1.3. National Health Act, 2014

This is an Act to provide a framework for the regulation, development and management of a National Health System and set standards for rendering health services in Nigeria. Section 1 provides for the establishment of a National Health Establishment System, responsible for defining and providing a framework for standards and for regulating health services. This system includes public and private health service providers and promotes cooperation and shared responsibilities among all providers of health services.

The section further provides that the system will provide for Nigerians, the best possible health services within the limits of available resources, set out the rights and obligations of health care providers, health workers, health establishment and users and protect, promote and fulfil the right of the people of Nigeria to have access to health care services.

[285]Section 2(1) Child's Right Act, 2003.

3.1.4The National Agency for Food and Drug Administration and Control Act

The National Agency for Food and Drug Administration and Control is established under Section 1 of the Act and the objective of the Act is to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals.[286]

The Agency is responsible for the safeguard of public health and the life of every Nigerian and its functions are as stated in Section 5 of the Act. These will be discussed in subsequent parts of this chapter. To carry out its functions effectively, the Agency has the power to enter and search premises, take samples and seize offending products, and detain offenders.

Section 25 makes provision for offences under the Act and the liability of offenders. A person that obstructs an officer of the agency in the performance of his duties will be liable on conviction, to a fine of five thousand Naira (₦5,000.00), or imprisonment for a term not exceeding two years or both fine and imprisonment. Where no penalty is specified, the offender, on conviction, will be liable to a fine of fifty thousand Naira (₦50,000), or to imprisonment for a term of one year or to both fine and imprisonment.

In a bid to effectively discharge its duties, the Agency made regulations pursuant to the NAFDAC Act.[287]The Agency has regulations on the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals pursuant to Section 5 (especially Section 5(o) and 30 of the Act).[288]

The powers granted to the Agency under the Act is all encompassing, wide enough for it to function adequately. This is evident in the activities of Agency. However, the penalty for obstructing an officer in carrying out his or her duties, of Five Thousand Naira (₦5,000) and or two (2) years imprisonment is very inadequate as a deterrent for an offender. This

[286] Preamble to the NAFDAC Act, CAP N1, LFN 2004
[287] Section 30 NAFDAC Act, Cap N1, LFN 2004.
[288]The Drug Products Advertisement RegulationsS.1.15 of 1995 and Bottled Water (Advertisement) Regulations S.1.17 of 1995

is because, given the value of the counterfeit drugs and the expected profit, an offender would rather pay the fine than lose the proceeds of the sale. Secondly, the effect of the counterfeit drugs getting into the licit supply chain and the consequence on the victims, is unquantifiable, as it may lead to the death of the victim.

3.1.5 Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act

The Counterfeit and Fake Drugs and Unwholesome Processed Foods Act[289] was promulgated to provide for the prohibition of sale and distribution of counterfeit, adulterated, banned or fake, substandard or expired drugs or unwholesome processed foods; and of sale, manufacture and display of drugs or poisons in certain premises or places.

According to the Act, it is an offence to produce, import, manufacture, sell or display for the purpose of sale, distribute, or be in possession of any counterfeit, adulterated, banned or fake, substandard or expired drug, or unwholesome processed food, in any whatever form. It is also an offence to aid or abet the doing of any of these acts.[290] The Act further prohibits the sale of drugs or poisons in places which have not been duly licensed by the appropriate authority.[291] The penalty is the payment of a fine not exceeding five hundred thousand Naira (₦500,000), or imprisonment for a term not less than five (5) years or more than fifteen (15) years, or both such fine and imprisonment, for an offence under Section1.[292] For a Section 2 offence, the penalty is a fine of five hundred thousand Naira (₦500,000), or 2 (two) years imprisonment, or both.[293]

[289] Cap C34, LFN 2004.
[290] Section 1, Counterfeit and Fake Drugs and Unwholesome Processed Foods Act
[291] Section 2, Counterfeit and Fake Drugs and Unwholesome Processed Foods Act.
[292] Section 3(1)(a) Counterfeit and Fake Drugs and Unwholesome Processed Foods Act
[293] Section 3(1)(b) Counterfeit and Fake Drugs and Unwholesome Processed Foods Act.

If the offence is committed by a body corporate, every person who at the time of the commission of the offence was proprietor, director, general manager, secretary or other similar officer, servant or agent of the body corporate (or a person purporting to act in any such capacity), he, as well as the body corporate shall be deemed to be guilty of the offence and may be proceeded against and punished accordingly.[294]

By virtue of Section 4, the Federal High Court has exclusive jurisdiction over matters arising from the provisions of this Act. Section 5 provides for the establishment and composition of a Federal Task force. Section 6, in its part, provides for the functions of the Federal Task Force, which functions includes enforcing the provisions of the Act and overseeing the activities of the State Task Forces.[295]The Task Forces have powers to enter and where necessary, seal premises where suspected violating products are kept and seize such.[296]

Section 9 establishes the Nigerian Police Force Squad to assist the Federal Task Force in enforcing the provisions of the Act. Under Section 10, goods seized will be forfeited to the Federal Government. By virtue of Section 11, whoever obstructs the task force in performing its duties, will be liable to a fine of FiftyThousand Naira (₦50,000), or 5 (five) years, or both.

The Act empowers NAFDAC, in conjunction with the Police, to ensure that fake, counterfeit and unwholesome products are restricted from entering the legitimate drug and processed food circulation chain.

The provisions of the Act cover all necessary issues in line with its subject matter. It makes provision for its enforcement which is adequate. Be that as it may, the penalty for obstructing the task force is inadequate, when compared to the value of possible proceeds of the business and the harm that may come upon the victim. If the accused is able to hide

[294] Section 3(2) Counterfeit and Fake Drugs and Unwholesome Processed Foods Act
[295] See Sections 7 and 8 for the Establishment, Composition and Functions of the State Task Forces.
[296] See Sections 6 and 8.

the magnitude of his business, things will go on as usual, even though he is in prison. He will possibly come out to an expanded business.

3.1.6 Food, Drugs and Related Products (Registration, etc.) Act

This Act[297] was enacted to regulate the manufacture, importation, exportation, advertisement, sale or distribution of processed food, drugs and related products and registration thereof. The Act, prohibits the manufacture, importation, exportation, advertisement, sale or distribution of processed food, drugs, drug products, cosmetics, medical devices or water in Nigeria, unless it has been registered in accordance with the provisions of the Act or regulations made under it.[298] The Agency (NAFDAC), may however permit the manufacture or importation, exportation of a sample of drugs, drug product, cosmetics, or medical device for the purpose of registration or clinical trial. In this instance, the manufacture or importation would be in accordance with the conditions specified in the permit.[299] The procedure for registration is contained in Section 2. Section 3 prescribes the way in which information supplied by the applicant may be disclosed, whilst Section 4 makes provisions for the conditions under which a certificate of registration may be suspended or cancelled.

Only a holder of a valid clinical trial certificate may import, supply, or procure the manufacture, or assembly of a drug, drug product, cosmetics or medical device. The clinical trial must be conducted in accordance with the terms of the certificate and the provisions of any regulation in force at the relevant time.[300] Application for a clinical trial certificate shall be made to the Agency in the prescribed form.[301]

The penalty for an offence committed under this Act is a fine not exceeding fifty thousand Naira (₦50,000), or imprisonment for a term not exceeding two years or both such fine and imprisonment for private individuals, and a fine not exceeding one hundred thousand Naira

[297] Cap F33 LFN 2004
[298] Section 1(1) Food, Drugs and Related Products (Registration, etc.) Act
[299] Section 1(2) Food, Drugs and Related Products (Registration, etc.) Act.
[300] Section 5(1) Food, Drugs and Related Products (Registration, etc.) Act.
[301] Section 5(2) Food, Drugs and Related Products (Registration, etc.) Act.

(₦100,000), for corporate bodies.[302] Where a corporate body commits the offence, all its directors, managers, secretaries, or other similar officers or all partners or officers of the firm or all trustees of the body concerned or every person who purports to act in any aforementioned capacity shall be severally guilty of the offence, and proceeded against and punished accordingly, except he or she can prove that the act or omission was carried out without his knowledge, consent or connivance.[303]

In addition, any processed food, drug, drug product, cosmetic, medical device or water seized by the Agency shall be forfeited to the Federal Government and shall be dealt with in such manner as the Minister of Health may, from time to time, determine.[304] Assets and properties used in the commission of an offence under the Act, or procured with the proceeds of the offence shall also be forfeited to the Federal Government.[305]

Section 11 establishes the Food and Drug Registration Committee to assist the Agency to achieve the smooth application of the Act. By virtue of Section 12, the Governing Council of the Agency is empowered to, subject to the approval of the Minister, make regulations which will give effect to the provisions of the Act. As noted earlier, the Act is to regulate manufacturing, importation, exportation, advertisement, sale or distribution of processed food, drugs and related products and their regulation. It also regulates the conduct of clinical trials.

With regards, to liability for violation of its provisions, the Act makes provisions for corporate criminal liability. Prescribed penalties do not exceed fine of Fifty Thousand Naira (₦50,000) and or two years (2) imprisonment for individuals and one hundred thousand Naira (₦100,000), for corporate bodies.

The penalties prescribed by this legislation, though adequate as at the time of promulgation, have over the years become mild. This is due to rate of currency exchange and inflation, which have affected pricing of products. In addition, the extent of

[302] Section 6(1), Food, Drugs and Related Products (Registration, etc.) Act
[303] Section 7 Food, Drugs and Related Products (Registration, etc.) Act.
[304] Section 10, Food, Drugs and Related Products (Registration, etc.) Act
[305] Section 8, Food, Drugs and Related Products (Registration, etc.) Act

consequences of the crime on the society, coupled with its magnitude have watered down the effect of the penalty on offenders. These penalties therefore are not positive deterrent.

3.1.7 Food and Drug Act

This is an Act[306]to make provision for the regulation of the manufacture, sale and advertisement of food, drugs, cosmetics and devices and the repeal of existing state laws, on those matters. Section 1(2) prohibits the sale, importation, manufacture or storage of any article of food or drug which is adulterated. The sale, importation, manufacture of any article of food or drug which is manufactured, preserved, packaged or stored under insanitary conditions, is also prohibited by virtue of section 1(3). Section 3 prohibits the importation, exportation, manufacture, sale and distribution of the drugs specified in the 2nd Schedule to the Act, without authorisation.

Section 5(a) prohibits labelling, packaging, treatment, processing, selling or advertising food, drugs, cosmetics or device in a false or misleading manner or in a manner which could create a wrong impression as to its quality, character, value, composition, merit or safety. By virtue of section 5(c), where there is contained in a publication, the standard for a drug specified in the 3rd Schedule to the Act, the labelling, packaging, sale or advertisement of any substance which is not of the published standard, in a manner which could cause it to be mistaken for a drug of the published standard, is prohibited.

Where the drug is a drug for which no standard has been prescribed, either under a regulation or any publication specified in the 3rd Schedule, no one can sell that drug in any manner which is likely to deceive or mislead a purchaser, as to its quality or character.[307] The sub section further prohibits the sale of such drug as one which complies with some other standard, unless it actually complies with such standards.

[306] Cap F32 LFN 2004.
[307] Section 5(d) Food and Drug Act.

By virtue of Section 7(1), no person shall, manufacture for sale, any drug specified in 4th Schedule[308] without first obtaining a certificate of the Minister to the effect that the premises in which the drug is intended to be manufactured and the process and conditions by and under which the manufacture is to be carried on, are in the opinion of the Minister, suitable for ensuring that the drug is safe for use. In the same vein, under Section 7(2), no person shall sell any drug specified in the 5th Schedule to this Act[309], without first obtaining, in accordance with the regulations, a certificate of the Minister that the batch from which the drug was taken is safe for use. In addition, except as provided in the regulations made pursuant to the Act, no person shall distribute or cause to be used as samples, any of the drugs listed in the 4th or 5th Schedule to this Act.[310]

Section 8(1) empowers the Minister or his representative to order a manufacturer of any article of food, drug, cosmetics or device to provide a declaration that the article was manufactured in accordance with the provisions of the Act or any other regulation. Food, drugs, cosmetics or devices imported to Nigeria must be accompanied with a certificate from the manufacturer that it was manufactured in accordance with existing standards or code of practice pertaining to such products where such standard or code of practice does not exist for the particular product, in accordance with any international standard laid down, in the case of food, under the directive of the Codex Alimentarius Commission.[311] Such imported goods shall also be accompanied by a certificate issued by, or on behalf of the government of the country of manufacture, that its sale in that country would not be illegal.[312]

---

[308] The drugs listed in the 4th schedule include, Liver extract in all forms, Insulin in all forms, Anterior pituitary extracts, Radioactive isotopes, Living vaccines for oral or parenteral use, Drugs prepared from micro-organisms or viruses, for parenteral use Sera and drugs analogous thereto, for parenteral use, Antibiotics for parenteral use.

[309] Drugs listed in the 5th Schedule include, Arsphenamine, Dipchlorophenarsine hydrochloride, Neoarsphenamine Oxophenarshine hydrochloride, Sensitivity discs and tablets, and Sulpharsphenamine

[310] Section 7(3) Food and Drug Act.

[311] Section 8(2)(a) Food and Drug Act. The Codex Alimentarius (Food Code) was established by Food and Agriculture Organisation (FAO) and WHO as a means of harmonising international food standards, which protects consumers' health and promote fair practice in food trade. Retrieved from www.fao.org/fao-who-codexalimentarius on 16th December, 2016.

[312] Section 8(2)(b) Food and Drug Act.

By virtue of Section 9, the Minister, on recommendation of the Food and Drug Advisory Council, may appoint a Food and Drug analyst or a food inspector.Section 10 makes provisions for the powers of inspecting officers which ranges from power to enter premises where he or she reasonably believes that any article to which the Act or other regulations apply, to power to seize and detain such articles.Making or inserting a false statement in any certificate or document required by the Act or regulations made thereunder, is an offence.[313]

Section 13(1) empowers an inspection officer to examine customs entries and for purposes of analysis or examination, take samples of any food, drug or cosmetics imported in Nigeria and which are still in customs shed or government warehouse. Subsection 2 provides that, where samples have been taken of food, drug and cosmetics, such shall not be released to the importer unless on production of an analyst's certificate or report to the effect that the food, drug or cosmetics comply with the requirements of the Act and regulations. Subsection 3 provides that, where samples are taken, it will be done in triplicates – for the importer, owner or the person in apparent control, the analyst and the inspecting officer.

Subject to the consent of the owners, goods seized under the Act, will be forfeited to the Minister.[314]Subsection 2 provides that, the articles which formed the subject matter of a conviction shall be forfeited to the Minister. Given that subsection 2 specifically deals with a convict, it is safer to assume that sub section 1 applies to an accused, who for whatever reason, does not mind forfeiting his/her goods. Such goods may be ordered forfeited by a judge or magistrate before whom the case is brought, under subsection 3. Goods forfeited to the Minister shall be held by him, free from encumbrances. The Minister may, by virtue of subsection 4, retain it, destroy it or otherwise dispose of it.

Section 15 empowers the Minister to set up a Food and Drug Advisory Council to assist and advise him in the preparation and review of regulations for carrying out the purposes and provisions of the Act. Lastly, section 16 provides that the Minister may make

[313] Section 11 Food and Drug Act.
[314] Section 14(1) Food and Drug Act

regulation for carrying out the purposes and provisions of the Act, and in relation to any other matter connected to the Act.

This Act makes provisions for the regulation of the manufacture, sale and advertisement of food, drugs, cosmetics and devices and the repeal of existing state laws. It makes provision in respect of manufacture of goods to be imported. Inspectors may be appointed by the Minister on the recommendation of the Food and Drug Advisory Council. These have powers of entry, inspection, taking samples, examine records and seize goods. Prima facie, the provisions of this Act is adequate.

3.1.8 Poisons and Pharmacists Act

This Act[315] was promulgated to regulate the sale and distribution of drugs and poisons. Section 3(1) provides that all selling dispensers and chemists should register all premises used for their business. By virtue of subsection 2, the Registrar has a duty to maintain a register of all registered dispensers and chemists. A selling dispenser or chemist is expected under section 4(1), to furnish a list of all premises where his business of sale of drugs is being carried out, to the Registrar, in the month of January in each year.

For the purposes of securing compliance with the provisions of the Act, a government medical officer, police officer, not below the rank of superintendent, or inspector authorised by the Pharmacists Board of Nigeria, has the power at all reasonable times, to enter any premises in which it is suspected that a breach of law has been committed in relation to sale of poisons or drugs.[316]The power entitles him to also make examination and inquiry as necessary, and to do other things, including taking samples.

Section 6(1) provides that any officer mentioned in section 5(1) has powers to enter any premises where he has reasonable grounds to suspect that drugs, poisons or wares therein are unwholesome, deteriorated, impure or adulterated. He may seize samples of the said drugs, poison or wares and send them to a qualified analyst for examination. Where such drugs, poisons or wares are proved to be unwholesome, deteriorated, impure or adulterated,

[315] Cap 535 LFN 1990
[316] Section 5 Poisons and Pharmacist Act.

such selling dispenser, or chemist is guilty of an offence.[317] By virtue of section 6(3), an offender shall be liable on conviction, to a fine of ten Naira (₦10) for a first offence and to a fine of twenty Naira (₦ 20), for subsequent offences. The article in respect of which the conviction shall be made, shall be given up to a medical officer, police officer or inspector, for the purpose of being destroyed.[318]

The Act was promulgated to regulate the sale and distribution of drugs and poisons. It requires that all premises where drugs and poisons are sold be registered. Such registration is to be done annually. An inspector, authorised by the Pharmacists Board of Nigeria (PBN), who is a government medical officer or a police officer, not below the rank of superintendent, has the powers to enter any premises, where there is reasonable suspicion of violation of the provisions of the Act. For offences relating to sale of unwholesome, deteriorated, impure, or adulterated drugs or poisons, the dispenser or chemist will be guilty of an offence and liable, on conviction to a fine of Ten Naira (₦10) for first offender and Twenty Naira (₦20) for subsequent offences.

This provision, as with others, had fines that were adequate at the times of their promulgation. However, at today's value of the Naira, this amount is ridiculously low and cannot be an effective deterrent. The provision, in the researcher's opinion is overdue for reform.

3.1.9. Trade Malpractice (Miscellaneous Offences) Act

This is an Act[319] which creates certain offences relating to trade malpractice, despite the existence of the Weights and Measures Act.[320] The Act listed eight (8) offences which would incur liability and on conviction, a fine of not less than fifty thousand naira (₦50,000). By virtue of Section 1(1)(h), anyone who does any of the eight acts listed therein, commits an offence under the Act and will be liable on conviction, to a fine of not less than fifty thousand naira (₦50,000).

[317] Section 6(2) Poisons and Pharmacist Act.
[318] Section 6(3) Poisons and Pharmacist Act
[319] Cap T12, LFN 2004.
[320] Cap W3, LFN 2004.

Actions prohibited under Section 1(1) include; sale of a product using false and misleading labels, packages or advertisement, or using any weight, measure, weighing instrument, or measuring instrument which is false. Also included are acts such as misrepresentation, omission to do an act, matter, or thing calculated, or likely to mislead, as to the number to be sold or offered for sale.

The Act sets up the Special Trade Malpractice Investigation Panel (the Panel), under the Federal Ministry of Commerce, to investigate whether an offence has been or is being committed under the Act.[321] The Panel, on completion of an investigation, makes a report to the Attorney General of the Federation.[322]Where based on a report submitted under section 3, the Attorney-General of the Federation is of the opinion that an offence has been committed, may by himself or through a person he designates, institute an action in the tribunal established under the Miscellaneous Offences Act, in line with the procedure set out in the said Act.

The Act is meant to be read in conjunction with the Weights and Measures Act, for the purposes of prosecuting offences. In the event of conflict however, the provisions of the Trade Malpractices (Miscellaneous Offences) Act prevails.[323]

The prescribed penalty in the Act can be said to be reasonable.

3.1.10 Criminal Code Act

The Criminal Code Act[324] does not have specific provisions against drug counterfeiting. However, Chapter 23, Sections 243 to 248 of the Criminal Code Act, makes provision (generally) for offences against public health.

The Act makes it an offence to sell food or drink, or to intend to sell food or drink, when same is unfit for consumption,[325] and prescribes one-year imprisonment as sanction. Also,

[321] Section 2 Trade Malpractice (Miscellaneous Offences) Act.
[322] Section 3 Trade Malpractice (Miscellaneous Offences) Act.
[323] Section 6 Trade Malpractice (Miscellaneous Offences) Act
[324] Cap C38, LFN 2004.
[325] Section 243 (1), Criminal Code Act

food or drink adulteration when same is to be sold, is made an offence under the Act[326] and the same punishment is prescribed.

Dealing in diseased meat[327]; fouling water or corrupting water,[328] are also offences under the Act and the punishment is two years and six months imprisonment. The provisions of this Act are not applicable to drugs, but food.

3.1.11 Penal Code Act

The Penal Code[329] in Section 184, makes it an offence to adulterate food or drinks intended for sale. Similarly, Section 185 penalises the sale of food and drink which do not correspond with the description. Sections 186 and 187 penalises the offences in sections 184 and 185 and the sale of adulterated food or drink. Section 188 makes provision in respect of sale of noxious food or drink; adulteration of drugs or medical preparations, is dealt with under section 188. The sale of drugs as different drugs or preparation is punishable under section 189.

In addition to creating criminal liability for selling adulterated food and drinks, it creates criminal liability for selling adulterated drugs and medical preparations. The penalty for this is an imprisonment for a term of six (6) months and or a fine of One Hundred Naira (₦100). This is inadequate, given the consequences of using adulterated drugs or medical preparations.

3.1.12 Trade Marks Act

Section 1(1) of the Trade Marks Act[330] creates the office of the Registrar of Trade Marks. The Register of Trade Marks shall be kept, controlled and maintained by the Registrar at

[326] Section 243 (2), Criminal Code Act
[327] Section 244, Criminal Code Act
[328] Section 245, Criminal Code Act
[329] Cap P3, LFN 2004.
[330] Cap T13, LFN 2004.

the Registrar's office.[331] The Register shall be in two parts (A & B) and be opened to the public and subject to such rules as may be prescribed from time to time.[332]

By virtue of section 3, where a trade mark is not registered, the owner may only bring a court action, where it has to do with passing off. With regards to certain goods, the trade mark must be registered.[333] The register determines issues that relate to class of goods.

Section 5 provides that registration gives the person registered as the proprietor of the trade marks, the exclusive right to the use of that trade mark in relation to those goods. This right is deemed to have been infringed where any person who is not the proprietor of the mark or a registered user, uses a mark identical with the trademark or nearly resembling it as to be likely to deceive or cause confusion, in the course of trade in relation to any goods in respect of which it is registered and in such manner as to render the use of the mark likely to be taken either as being used as a trade mark[334], or it is being used on goods or in physical relation thereto, or in an advertising circular or other advertisement issued to the public, as importing a reference to some persons having the right either as proprietor or as registered user to use the trademark, or to goods with which such a person as aforesaid is connected in the course of trade.[335]Section 5(3) provides that the right to use a trade mark is subject to any conditions or limitations that may from time to time be entered on the register.

Where the registration of a person in Part B of the register as proprietor of a trade mark is valid, it gives or is deemed to have given that person the same right as if it was a Part A registration. The provisions of section 5(2) to section 5(4) of the Trade Marks Act apply in respect to a trade mark registered in Part B accordingly.[336]

In the case of an alleged infringement, where the Defendant is able to prove that the use complained of is not likely to deceive or cause confusion, or to lead to the belief in a

[331] Section 2(1)&(2).
[332] Section 2(4) Trade Marks Act.
[333] Section 4 Trade Marks Act.
[334] Section 5(2)(a) Trade Marks Act.
[335] Section 5(2)(b) Trade Marks Act
[336] Section 6(1) Trade Marks Act.

connection in the course of trade between the goods and some persons entitled either as proprietor or as a registered user to the trade mark, no injunction or any other relief would be granted.[337]

By virtue of section 14, with regards to all legal proceedings relating to a trade mark registered in Part A of the register (including applications under section 38 of the Act), the original registration shall, after the expiration of seven (7) years from the date of that registration be taken to be valid in all respects, unless it was obtained fraudulently,[338] or it offends against the provisions of section 11.[339,340]

3.1.13 Pre-Shipment Inspection Imports Act

Section 1 of the Pre-Shipment Inspection Imports Act[341] makes provision for mandatory pre-shipment inspection for all imported goods. All such goods are to be accompanied by a Clean Report of Findings (CRF) and an Import Duty Report (IDR).[342]This inspection shall be with respect to quality and quantity, and price comparison, and shall be carried out for all goods except explosives, pyrotechnic products, arms and ammunitions, weapons and implements of war, supplied to diplomatic consular missions and international organisations for their own needs and such other goods as may be prescribed by Federal Government of Nigeria from time to time.[343]

By virtue of Section 2(1), where the inspecting agent is satisfied that all requirements, as to quality, quantity and price have been complied with, he issues a CRF and IDR. Where on the other hand, he is not satisfied, he issues a Non-Negotiable Report of Findings (NNRF). A seller who gets the aforementioned report may make all necessary adjustment. In such

[337] Section 6(2) Trade Marks Act
[338] Section 14 (1)(a) Trade Marks Act
[339] Section 14(1)(b) Trade Marks Act.
[340] Section 11 makes it unlawful to register as a trade mark or a part of a trade mark, any matter, the use of which would, by reason of its being likely to deceive or cause confusion or otherwise, be disentitled to protection in a court of justice or be contrary to law or morality or any scandalous design.
[341] Cap P26 LFN 2004.
[342] Section 1(1)(b) Pre-Shipment Inspection Imports Act.
[343] Section 1(5) Pre-Shipment Inspection Imports Act.

instance, the inspecting agent may subsequently issue a CRF and IDR in respect of the goods concerned.[344]

Imports not accompanied with the relevant IDR will be liable for confiscation on arrival in Nigeria and the shipper(s) responsible for transporting the goods into Nigeria will on conviction by a court of competent jurisdiction, be liable to payment of fines not exceeding the value of the impounded goods.[345] Section 7(1) provides that anyone who imports goods into Nigeria, on which pre-shipment inspection had not been done, is guilty of an offence. Liability for the offence is, for an individual, a fine of ₦50,000 (fifty thousand Naira) or the value of the goods, whichever is higher, or to imprisonment for a term of not more than twelve (12) months or both fine and imprisonment. Where the offence was committed by a corporate body, it will be liable to a fine of One Hundred Thousand Naira (₦100,000), or twice the value of the goods, whichever is higher.[346] In addition to the foregoing, the goods concerned will be forfeited to the Federal Government of Nigeria.[347]

This Act makes provisions for mandatory pre-shipment inspection for all imported goods. By virtue of its provisions, all imported goods must be accompanied by a CRF and an IDR, failing which there will be liability for confiscation on arrival in Nigeria. The shipper, on conviction will be liable to the payment of fines not exceeding the value of the imported goods. The importer on his part, will be liable for a fine of Fifty Thousand Naira (₦50,000), or if an individual, the value of the goods, whichever is higher, or to imprisonment for a term of not more than twelve (12) months, or both fine and imprisonment.

Where the offender is a corporate body, it will be liable to a fine of One Hundred Thousand Naira (₦100,000) or twice the value of goods, whichever is higher. The goods will in addition, be forfeited. The provisions of the Act are adequate for achieving its purposes, if enforced properly.

[344] Section 2(2) Pre-Shipment Inspection Imports Act.
[345] Section 6(2) Pre-Shipment Inspection Imports Act. See also Section 7(2) of the same Act.
[346] Section 7(3)(b) Pre-Shipment Inspection Imports Act.
[347] Section 7(4) Pre-Shipment Inspection Imports Act.

3.1.14 Pre-Shipment Inspection of Exports Act

This Act[348] makes provisions for the inspection of goods in Nigeria prior to their shipment to a place outside Nigeria. Section 1 provides that no exportation of goods should be undertaken outside Nigeria except an inspecting agent has issued in respect of the goods, a Clean Certificate of Inspection (CCI) to the overseas buyers of the goods. Section 2 states that, subject to section 3, all oil and non-oil goods are liable to pre-shipment inspection, with respect to their quality, quantity and price comparison. Section 3 contains a list of goods exempted from pre-shipment inspection. These include, goods listed in the Export Prohibition List, set out in the 6th Schedule to the Customs, Excise Tariff, etc. (Consolidation) Act.[349] Objects of art, explosives, pyrotechnic products, arms, ammunition, weapons, implements of war, animals, household or other non-commercial products, such as gifts, personal effects, trade samples, printed business matters, machinery and equipment being shipped out of Nigeria for repairs and return, the return of empty containers, transhipment, supplies to diplomatic consular missions and international organisations for their own needs and such other goods as may be prescribed from time to time.

Section 6 makes provisions for inspection of Pharmaceutical products. With regards to inspection of pharmaceutical products, the inspecting agent shall, restrict the pre-shipment inspection to the inspection of the expiry date, cost of the products to be exported, and ensuring that the products conform with the active ingredients and chemical requirements specified by overseas buyers.

By virtue of section 8, once inspection has been done, the inspecting officer shall, if satisfied, issue a CCI. If not satisfied, he will issue a NNCI for all purported goods, and where the seller makes necessary adjustments, the inspecting officer subsequently issues a CCI.

[348] Cap P25 LFN 2004.
[349] Cap C49 LFN 2004.

Section 18 states that anyone who exports goods outside Nigeria without carrying out the mandatory inspection is guilty of an offence.[350] Such a person will be liable on conviction, to a fine of Fifty Thousand Naira (₦50,000) or the value of the goods, whichever is higher, or to imprisonment for a term of not more than 12 months or to both such fine and imprisonment.[351] Where a corporate body is the offender, it will be liable to a fine of one hundred thousand naira (₦100,000) or twice the value of the goods, whichever is higher. Where the offence is attributable to any officer of the corporate body, such officer(s) shall be deemed guilty of the offence and may be proceeded against and punished in the same manner as an individual.

The provisions of this Act recommend inspection, before goods leave Nigeria. Its provision are a kin to that of its counterpart, The Pre-Shipment Inspection of Imports Act. The inspecting agent will, on inspecting the goods, issue a CCI to the overseas buyers of the goods. With regards to pharmaceuticals, the inspecting officer is expected to look out for expiry dates, cost of the products to exported, and ensure that the products conform to the active ingredients and chemical requirements specified by overseas buyers.

Exporting goods outside Nigeria without first obtaining a CCI, creates a criminal liability, which on conviction, is subject to a fine of fifty thousand-naira (₦50,000), for an individual or the value of the goods, whichever is higher and or, to an imprisonment for a term of not more than twelve (12) months. Where the offender is a corporate body, the liability on conviction is, One Hundred Thousand Naira (₦100,000) or twice the value of the goods, whichever is higher. However, where the offence can be attributed to an officer of the corporate body, he or she shall be deemed guilty of the offence and proceeded against in the same manner as an individual. If properly enforced, the provisions of this legislation are adequate for achieving its intended purposes.

An analysis of the laws relating to drug counterfeiting and the right to health is hereby attached as Table 2.

[350] Section 18(2)(a) Pre-Shipment Inspection of Exports Act.
[351] Section 18(2)(b) Pre-Shipment Inspection of Exports Act

3.1.15 Standards Organisation of Nigeria (SON) Act 2015

This is an amendment to the SON Act, Cap S9 LFN 2004. The 2015 Act, whilst retaining most of the provisions of the 2004 Act, the 2015 Act provided for additional functions for the organisation, increasing penalty for violation, amongst others. Sections 1-22 make provisions relating to the establishment, composition and functions of the SON and the Standards Council of Nigeria. These will be discussed in a latter part of this chapter. Sections 23-52 deal with prescribed Nigerian Industrial Standard (NIS), offences and miscellaneous and supplementary provisions.

Section 23 sets out the procedure for the establishment of industrial standards (IS). The Council, in establishing new IS, shall consult all stakeholders in the industry concerned, [352] set up a committee to look into the issues and make a report.[353]The Council, after considering the report, may establish the IS, if it deems it fit to do so.[354]In making that decision, the Council shall consider its significance to the national economy. Such IS shall be subject to review from time to time, at least not less than once in every three (5) years.[355]The Council may revise or revoke any IS established under the section.[356] By virtue of section 24, IS made under section 23 are to be known as Nigerian Industrial Standards, to the exclusion of others.

The Council on receipt of a satisfactory report from the committee set up in accordance with section 23(2), in respect of a product which is deemed important or significant to the national economy, may permit a manufacturer (permitted manufacturer) to affix a special certification mark to show that the item of manufacture falls under the Nigerian Industrial Standards.[357] Such permit may however be revised, reallocated or revoked. The revocation, reallocation or revision must be notified in the Federal Gazette.[358]Section 25(5)

[352] Section 23(2)(a) SON Act.
[353] Section 23(2)(b) SON Act.
[354] Section 23(3) SON Act.
[355] Section 23(4) SON Act.
[356] Section 23(5) SON Act.
[357] Section 25(1) SON Act.
[358] Section 25(3) SON Act.

provides that the standardisation mark shall not be identical or nearly so resemble any mark registered under the Trade Marks Act,[359] and vice versa.

Section 26 provides that where any person, other than the permitted manufacturer, makes or sells, exposes for sale, or uses for the purpose of advertising any material or document on which it is portrayed, an IS in a way resembling or purporting to be any of the NIS established under the Act or a certification mark issued pursuant to section 25 of the Act, is guilty of an offence and on conviction, is liable to a fine of not less than one million naira (₦1,000,000), or to imprisonment for a period not exceeding two (2) years or to both such fine and imprisonment.[360]

Where an item of manufacture does not comply with any mandatory industrial standard, it constitutes an offence for it to be sold or delivered to any one in Nigeria, for consumption and or for sale to the public.[361] The person who violates the above sub section, shall on conviction be liable, if a manufacturer, to a fine of not less than twenty percent (20%) of the value of the product, or two million naira (₦2, 000,000), whichever is greater, or to a term of not less than 3 years, or to both such fine and imprisonment.[362]Where the offender is a seller, he or she shall be liable to a fine of not less than fifteen percent (15%) of the value of the product, or one million naira (₦1,000,000), whichever is higher or imprisonment for a term not less than two (2) years, or to both such fine and imprisonment.[363]Where an importer violates the provisions of the section, he or she will be liable to a fine of not less than twenty percent (20%) of the Cost, Insurance and Freight (CIF) per shipment or Two Million Naira (₦2,000,000), whichever is higher, or to both such fine and imprisonment.[364]

In addition, the court may order that the subject matter of the offence be forfeited to the state and may, summarily inquire into and assess the monetary value of any advantage gained, or likely to be gained by such person in consequence of that offence and impose on

[359] Cap T13, LFN 2004.
[360] Section 26(1) SON Act.
[361] Section 26(2) SON Act.
[362] Section 26(2)(b)(1) SON Act.
[363] Section 26(2)(b)(ii) SON Act.
[364] Section 26(2)(b)(iii) SON Act.

that person, a fine to a maximum equal to the amount so assessed. Where there is a default in payment of the amount, a further imprisonment term for a period, not exceeding one (1) year may be added.[365]

The Minister may on the recommendation of the Council, declare that an IS established under section 12 of the Act is binding through an order published in a Federal Gazette publication in two (2) national dailies, or a notice served on a manufacturer. Such IS shall be known as a Mandatory Industrial Standard (MIS).[366]The manufacturer concerned shall ensure that the item for which the MIS was declared complies with such standards.[367]

Section 29(1) empowers the Director-General(DG), where he or she is satisfied that the quality, purity or potency of any product is detrimental or hazardous to life, property and the economy, to seize, detain, prohibit selling or offering for sale, apply to court for an order of forfeiture, or seal up the premises where the product is being manufactured or stored or direct the person to rectify the deficiency, in the case of a substandard, mis-described or hazardous product. The court may order that the hazardous or injurious products be seized, destroyed or disposed of in any manner it deems fit.[368]

The Organisation may order the destruction of goods detained under Section 29(1), if it is satisfied that testing indicates that the goods do not meet the relevant NIS and that it is reasonably necessary to destroy the goods, because the goods are in a dangerous state or injurious to the health of human beings, animals, or plants.[369]The owner of the product, under section 29(3)(c), may be required to pay the cost of the destruction of the goods, including costs of transportation and storing of the goods before destruction. The owner of the goods is however entitled to a 14-day notice, of the impending destruction, either in writing or by publication in the Gazette.

[365] Section 26(3) SON Act.
[366] Section 27(2) SON Act.
[367] Section 27(3) SON Act.
[368] Section 29(2) SON Act.
[369] Section 29 (3)(a) and (b) SON Act.

Section 30 provides that the DG, other officers, employees or any other person, authorised by the DG, in writing, have the powers to enter any premises, including seaports, airports, land borders or vehicles where an industrial or commercial undertaking is being carried out and may use reasonable force where necessary with regards to products which violate the Act.

Evasion and attempt to evade fees or levies payable or chargeable under the Act is an offence which upon conviction, attracts a fine of not less than one million naira (₦1,000,000), or a term of imprisonment of not less than nine (9) months or to both fine and imprisonment.[370] Neglect or refusal or failure to comply with the provisions of the Act is an offence. Any article or products seized, will be liable to be forfeited. The offender shall on conviction, be liable to a fine of not less than one million naira (₦1,000,000), or imprisonment and where it is a continuing offender, to a further fine of not less than two hundred and fifty thousand naira (₦250,000) for everyday during which the offence continues.[371]

Any person who commits an offence under the Act for which there is no specific prescribed penalty, shall on conviction, be liable to a fine of not less than five hundred thousand naira (₦500,000), or to imprisonment for a term of not less than nine (9) months or both.[372]

The 2015 Act has expanded the powers of the SON.

3.1.16 Consumer Protection Council Act (CPCA)[373]

The CPCA has been described as an Act which seeks to preserve the consumer's civil rights of action for compensation and prevent the circulation of any product which

[370] Section 31(1) SON Act.
[371] Section 31(2) SONAct.
[372] Section 32(4) SON Act.
[373] Cap C25 LFN 2004

constitutes public hazard.[374] In protecting the consumer, the Act upholds certain rights of the consumer. These are:

a. Right to Safety:The consumer has a right not to be exposed to undue risk of physical harm, injury, or death, resulting from the use of a product. Section 2(j) provides that the Council is to ensure that products are safe for the purpose for which they are intended. It is to notify the public of health hazards inherent in any products,[375] prohibit the sale, distribution, advertisement of products that fall short of safety and health regulations.[376]

b. Right to Information and Advice:Information is essential to enable the consumer compare quality, cost, safety, content, ingredients and expiry date of products or service, in order to make informed choices. Consequently, Section 2(c) mandates the Council to publish a list of banned, withdrawn, and restricted, or those products not approved for consumption, to organise campaigns and other sensitization programmes for improved public awareness.[377]

c. Right to be heard:By virtue of Section 2(a), the Council is to provide "speedy redress" to consumers using alternative dispute resolution. Section 2(d) makes provision for compensation for an injured consumer.

Other salient provisions of the Act, include the duty imposed on a manufacturer, who having put his product in the market, becomes aware of an unforeseen hazard, to notify the public of the impending hazard and where necessary, withdraw the product from the market. Failure to comply with this provision, gives rise to criminal liability, and on conviction, to a fine of fifty thousand naira (₦50,000) or five (5) years imprisonment or both such fine and imprisonment.[378]

[374] *Nigerian Breweries Plc. vs. David Audu* (2009) LPELR 8863 CA
[375] Section 3(e) CPCA.
[376] Section 3(f) CPCA
[377] Section 2(e and h) CPCA
[378] Section 9 CPCA

In addition, the Attorney-General of the Federation has powers to institute actions against persons, who the Council or State Committee have asked to give written "assurance" where they have persistently carried on their business in a manner detrimental to consumers, but have either refused to give the assurance or have breached the assurance. In such a situation, the court may make a prohibitive order refraining them from continuing in that course of conduct.[379]

Where a person contravenes the provisions of the Act by selling or offering for sale products which are unsafe or hazardous; or causes injury or loss to a consumer by providing service, information or advertisement contrary to the spirit and letter of the Act, he is guilty of an offence and liable on conviction, to a fine of fifty thousand naira (₦50,000), or a term of imprisonment for five (5) years or both.[380]

3.2 Policies, Guidelines and Regulations

There are various policies, guidelines and regulations, which have been put in place by the different agencies responsible for upholding the right to health. These policies, guidelines and regulations were made pursuant to the enabling legislations of these ministries. This section examines these. Some relate directly to drug counterfeiting, while the others by implication, can be applied to drug counterfeiting issues. In examining these documents, only the salient portions will be discussed.

3.2.1 National Policies on Drugs

3.2.1.1 National Drug Policy (NDP) 2005[381]

The NDP was formulated to, amongst others, ensure efficient and effective drug management in the public and private sectors, ensure safe, effective, affordable and good quality drugs at all levels of health care on the basis of health needs, ensure that all drugs in the National drug distribution system are safe, efficacious, effective and good quality,

[379] Section 10 CPCA
[380] Section 12 CPCA
[381] Published by the Federal Ministry of Health

strengthen administrative, legislative and regulatory controls of the importation, manufacture, procurement, storage, distribution, supply, sale and use of drugs.[382]

To implement the NDP, the government adopted certain strategies, such as focusing on effective drug management processes, such as rational drug selection, proper quantification of drug needs at all levels of healthcare delivery, and effective procurement practices, assurance of quality of drugs at all levels, appropriate storage, proper costing and effective distribution of drugs, promotion of local drug manufacturing, appropriate legislation, proper accountability and rational use of the drugs by health workers and consumers, product registration, research and development, human resources development, mentoring and evaluation.[383].

Rational drug distribution channels are to be promoted at all sectors.[384]To achieve this, the Federal Government of Nigeria will ensure that the following measures would be enforced, namely:

a. Drug distribution, supply, sale and dispensing at all levels are to be under the control and supervision of pharmacists.
b. Drug manufacturing, wholesaling and retailing activities are to be registered as distinct enterprises.
c. The channel for private sector drug distribution shall flow from manufacturer or importer to wholesalers and retailers.
d. With regards public health facilities, drug supplies will be based on expressed need and whether purchased or donated, shall be channelled through the Central Medical Stores.

Paragraph 6.12 provides that importation and exportation of drugs shall be restricted to designated ports, equipped with adequate storage facilities and on-the-spot testing facilities

[382] Paragraph 4.0 NDP 2005
[383] Paragraph 6.0 NDP 2005.
[384] Paragraph 6.6. NDP 2005.

to ensure quality. It further provides that, regular training of regulatory authority personnel is to be carried out to ensure effective inspectorate activities. In addition, it provides for the encouragement of inter-sectoral collaboration between the drug regulatory authorities and other government agencies, such as Customs, Police, National Drug Law Enforcement Agency (NDLEA) and others, at the ports.

Drug registration is a means for ensuring government control over drugs distribution and usage in Nigeria. It ensures that drugs distributed in the country have been produced under Good Manufacturing Practices (GMP) and have passed the tests of need, efficacy, safety and good quality. It is an effective means for limiting the number and types of drugs and drug products brought into or manufactured in the country.Drug registration which is the responsibility of NAFDAC shall be upheld, the list is to be published periodically and any violation of the laws, regulations and guidelines on drug registration shall bear appropriate sanctions.[385]

Paragraph 6.15 makes provision with respect to quality assurance. It states that, in order to ensure that drugs provided for use are safe, efficacious and of good quality, regulatory authorities will be strengthened and empowered to monitor and enforce effective compliance with quality assurance provisions by manufacturers of imported and locally produced drugs, to ensure that end users receive only safe, efficacious and good quality drugs. Drugs imported and purchased at all levels in public and private health facilities shall meet the standards of good quality and safety before such drugs are distributed to dispensing units. GMP shall continue to be monitored and enforced in all drug manufacturing outfits in the country. Duly qualified individuals and organisations will be licensed to set up quality control laboratories for assessing the quality of drugs in the National Drug Distribution System. Pharmacy Departments in universities, with appropriate personnel and equipment are encouraged to complement the functions of the laboratories of the regulatory authorities in assessing drug quality. Similarly, adequately equipped and staffed drug quality control laboratories are to be established in strategic locations within the various geo-political zones of the country and manufacturers will be

[385] Paragraph 6.13 NDP 2005

required to package their products in appropriate containers in order to ensure quality and stability of such products.

Paragraph 6.17 makes provision in respect of Pharmacovigilance. It provides that, all drugs are to be regularly monitored with respect to their efficacy, safety, quality as well as adverse reactions, so as to determine whether there is a need to change the conditions of their continuing registration or withdrawal from the market. The paragraph further provides that any drug withdrawn or banned in many countries, due to unacceptable health risks, will be automatically withdrawn from distribution in Nigeria.

Information about drugs is provided by manufacturers as package inserts, labels, promotional literature and advertisement. This should comply with the requirements of the national health policy and relevant national regulations. They must therefore be reliable, accurate, informative, balanced, up-to-date, capable of substantiation, not misleading and in good taste.[386]

The policy acknowledges the importance of co-operation between importing and exporting countries, especially in combating the influx of substandard and counterfeit drugs into importing countries, resulting in considerable reduction of the illicit drug trafficking. It therefore sets out steps through which this can be achieved. These include the establishment and maintenance of appropriate channels of communication and exchange of information between drug regulatory and law enforcement authorities, use of diplomatic channels in exchanging information on substandard and counterfeit drugs, using the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce or such similar schemes for all drug imports and exports.[387]

3.2.2 Guidelines

3.2.2.1 National Drug Distribution Guidelines (NDDG) 2012

These guidelines were drawn up to establish a well ordered drug distribution system for Nigeria by ensuring efficient and effective drug supply management in both public and

[386] Paragraph 6.18 NDP 2005
[387] Paragraph 6.24 NDP 2005

private sectors, ensuring that all drugs in the National Drug Distribution System are safe, efficacious, effective affordable and of good quality and ensuring access to good quality and affordable drugs at all levels.[388]

The NDDG provides that drugs will move from the manufacturer or importer, to either the Mega Drug Distribution Centres (MDDCs), for the private sector or the State Drug Distribution Centres (SDDCs). For the public sector or the National Health Programme (NHP), from the MDDCs, and sometimes the SDDCs or the NHP, drugs will move to the wholesalers, and through them to community pharmacies and Public[389] or Primary health care and sometimes, directly to private health institutions[390] and the Patent and Proprietary Medicine Vendors (PPMVs). Community pharmacists may also supply the private health institutions and the PPMVs. The consumers get drugs from either the community pharmacies, private health institutions, PPMVs, or the public or primary health care.

The Guidelines further provide that the manufacturers and importers shall be registered by the PCN, whilst their products shall be registered by NAFDAC. Approval shall be obtained from NAFDAC for the importation of orphan drugs. The manufacturers are to sell to only the SDDCs and the MDDCS, comply with good storage practices stipulated by NAFDAC and the PCN, and ensure proper documentation of all transactions for tracking of all products and easy monitoring.[391]

SDDCs are owned by state governments and are to be under the direct supervision of the Pharmaceutical Services Department of the State Ministry of Health (SMOH).[392]They are to be registered by the PCN.[393]It is expected that they will have adequate number of registered pharmacists[394] and distribution vans.[395]

[388] NDDG 2012. p. 13
[389] Public health facilities include tertiary, secondary and primary health care facilities.
[390] These include corporate organisations.
[391] Art. 1 NDDG 2012
[392] Art. 2(1) NDDG 2012
[393] Art.2(ii) NDDG 2012
[394] Art. 2(vi) NDDG 2012
[395] Art. 2(vii) NDDG 2012

They are expected to follow the drug distribution supply chain as stipulated by the NDP, namely, selection, procurement, storage, distribution, transportation, documentation, tracking and recall.[396]They are to sell to public health institutions and wholesalers[397] who are registered and currently licensed by the PCN.[398]

Art. 2 (E) provides that drugs shall be selected by the SDDCs, based on the Essential Drugs List (EDL) and registered by NAFDAC for quality assessment.[399]Their stores are to be of sufficient capacity to allow for orderly storage of various categories of materials and products.[400] They shall be kept clean and dry always at acceptable temperature limits, using air-conditioners of appropriate capacities and temperature and humidity log recording equipment,[401] and shall comply with the provisions of PCN and NAFDAC.[402]

The MDDCs are private sector initiatives.[403]They are to be registered as such and established in each state or at least in each geo-political zone. MDDC premises are to be manned by superintendent pharmacists with ten (10) years cognate experience. Drugs are to be received and issued by registered pharmacists.[404]Distribution and quality assurance managers are to be pharmacists. All MDDC premises must be registered by PCN[405] and must comply with all regulations on Good Distribution Practices as stipulated by PCN and NAFDAC.[406]

With regards to the MDDCs, drug selection shall be based on the prevalent disease pattern in the respective state and all selected medicines shall be registered by NAFDAC[407] and procured directly from registered drug manufacturers/importers.[408] They are expected to

[396] Art. 2 (viii) NDDG 2012
[397] Art. 2(ix) NDDG 2012
[398] Art. 2 (I)(iii) NDDG 2012
[399] Art. 2 (E)(v) NDDG 2012
[400] Art. 2 (H)(ii) NDDG 2012
[401] Art. 2 (E)(vi) NDDG 2012
[402] Art. 2 (E)(xiv) NDDG 2012
[403] Art. 3 (i) NDDG 2012
[404] Art. 3 (v) NDDG 2012
[405] Art. 3 (vii) NDDG 2012
[406] Art. 3 (viii) NDDG 2012
[407] Art. 3 (1)(B)(i)&(ii) NDDG 2012
[408] Art. 3(1)(C)(i) NDDG 2012

have facilities for quality assessment,[409] provisions in relation to storage facilities, distribution and logistics, documentation, tracking and recall as those made in respect to SDDCs.

Wholesalers are corporate bodies duly registered by the PCN[410] and are to procure their medicines from MDDCs and under peculiar conditions, from the SDDCs. They shall be involved in the distribution of pharmaceutical products to community pharmacies, public health care facilities, including primary health care centres and distribution of limited products (PPMVL approved drug lists) to licensed PPMVL holders.[411] Their products are not to be openly displayed[412] and they are not authorised to sell directly to consumers.[413]

The Guideline further provides that, one of the members of the Board of Directors of the wholesale company must be a registered Pharmacist, with at least ten (10) years cognate experience.[414]Their premises must be registered by the PCN and under the direct supervision and management of a superintendent Pharmacist, with at least ten (10) years cognate experience.[415] Art 4(B) makes provision for storage of drugs by the wholesaler and Art 4(C) deals with documentation by the wholesaler.

With regards to retailing outfits or community pharmacies, the Guideline provides that the premises must be registered by the PCN and owned by a registered pharmacist.[416]These shall be involved in selling drugs to consumers.[417]They shall not be located in market places, motor parks, petrol stations, or in clustered areas.[418]If in a supermarket, it shall have a patient counselling area and a poisons and drug sales register.[419] There shall also be

[409] Art. 3(1)(C)(iv) NDDG 2012
[410] Art. 4(1)NDDG 2012
[411] Art. 4(iii) NDDG 2012
[412] Art. 4(iv) NDDG 2012
[413] Art. 4(v)NDDG 2012
[414] Art. 4(A)(i) NDDG 2012
[415] Art. 4(A)(ii) NDDG 2012
[416] Art. 5(i) NDDG 2012
[417] Art. 5(ii) NDDG 2012
[418] Art. 5 (v) NDDG 2012
[419] Art. 5 (vi)&(viii) NDDG 2012

on the premises, a consumer suggestions or complaints box.[420]Drugs in retail shops are to be stored in accordance with PCN and NAFDAC regulatory provisions.[421]

The National Health Programme obtains medicines from the manufacturer, importer, or SDDCs.[422]These medicines are to be selected based on the EDL and registered by NAFDAC.[423] Procurement of medicines by the NHPs shall be under the direct supervision and management of the Food and Drug Services Department of the Federal Ministry of Health (National Products Supply Chain Management Programme).[424]It shall comply with the drug supply chain as stipulated by the National Drug Policy. The drugs shall be received and stored at the Federal Central Medical Stores by a pharmacist, under storage conditions as provided in the NDP.[425] Public Health Care Facilities (tertiary and secondary) shall have Pharmacy Departments which shall be registered by the PCN[426] and manned by a Pharmacist.[427] Drug selection shall be based on EDL[428] and drugs must have been registered by NAFDAC.[429] Drugs shall be procured from wholesalers, under the supervision and advice of the Pharmacy Department and follow the supply chain as stipulated by the NDP.[430] The Guideline also made provisions for storage and documentation as with others in the drug distribution chain.[431]

Primary Health Care Centres (PHCCs) are to have Pharmacy Departments which are registered by PCN and shall be manned by a pharmacist, who, due to inadequate availability of pharmacists, at that level may supervise up to four (4) PHCCs pharmacies.[432] Medicines for these centres shall be selected based on the EDL and selected medicines shall be registered by NAFDAC. They are to procure drugs from SDDCs or the

[420] Art. 5 (x) NDDG 2012
[421] Art. 5 (A)(1) NDDG 2012
[422] Art. 6 (B)(ii) NDDG 2012
[423] Art. 6 (A)(i)&(ii) NDDG 2012
[424] Art. 6 (A)(i)&(ii) NDDG 2012.
[425] Art. 6 (C)(i) NDDG 2012.
[426] Art. 7 (i)NDDG 2012
[427] Art. 7(ii) NDDG 2012
[428] Art. 7 (A)(i)NDDG 2012
[429] Art. 7(A)(ii) NDDG 2012
[430] Art. 7(B)(i-iii) NDDG 2012
[431] Art. 7 (C)&(D) NDDG 2012
[432] Art. 8(iii) NDDG 2012

wholesalers and are to be under the supervision and advice of the Pharmaceutical Services Department of the State Ministry of Health.[433]

Drug procurement shall follow the drug supply chain as prescribed by the NDP.[434]Storage of drugs shall be in a defined drug store and supervised by a registered pharmacist.[435]PHCCs must establish and maintain inventories and records of all transactions regarding receipts and sale of drugs and other health commodities to patients.[436]

Private Health Facilities must meet PCN requirements with regards personnel and infrastructure.[437]Their Pharmacy Departments are to be registered with PCN and manned by pharmacists. Drug selection by this category shall be in line with the provisions of the NDP and selected medicines must be registered by NAFDAC.[438] They shall procure drugs from wholesalers or community pharmacists and sell only to consumers or patients.[439] They are to have a defined drug store manned by a pharmacist.[440] In addition, they shall establish and maintain inventories and records of all transactions and have Adverse Drug Reaction (ADR) reporting.[441]

PPMV shops shall procure drugs from wholesale or retail pharmacies and only sell drugs on the approved list of the FMOH.[442] They shall be registered with the PCN.[443] They shall sell only to consumers, or end users, or patients.[444] They shall establish and maintain

[433] Art. 8(B)(i-ii) NDDG 2012
[434] Art. 8 (B)(iii) NDDG 2012
[435] Art. 8 (C)(i) NDDG 2012
[436] Art. 8 (D) NDDG 2012
[437] Art. 9 (1) NDDG 2012
[438] Art. 9 (A)(i-ii) NDDG 2012
[439] Art. 9(B)(1) NDDG 2012
[440] Art. 9(C)(i) NDDG 2012
[441] Art. 9 (D)(i-ii) NDDG 2012
[442] Art. 10 (A)(i-ii) NDDG 2012
[443] Art. 10(i) NDDG 2012
[444] Art. 10 (A)(iii) NDDG 2012

inventories and records of all transactions regarding receipt and sales of drugs and other health commodities to consumers.[445]

The NDDG is to be monitored by the Department of Food and Drug Services of the FMOH in collaboration with other stakeholders.[446]It prohibits the operation of hawkers in the motor parks, markets, bus stops, kiosks, and so on.[447]Lastly, it provides that non-compliance will attract professional disciplinary measures as prescribed by NAFDAC and PCN.[448]

3.2.2.2 Guidelines for Registration of Drugs and Related Products Manufactured in Nigeria (NAFDAC/RR/003/00)[449]

These guidelines were made for the particular interest of Pharmaceutical, Herbal and Cosmetics industries in Nigeria. It reiterates the registration requirement as provided in the Food, Drugs and Related Products (Registration, etc.) Act.Art. A(3) provides that a manufacturer who intends to register a drug or related product in Nigeria should first have its factory inspected by the Establishment Inspection Directorate of NAFDAC and be assigned a Certificate of Recognition as a manufacturer before an application to register the product can be made.

Art. B deals with the procedure for application, while Art. C lists documents to be submitted with the application. Art. D provides that all labelling must be informative, clear and accurate. It further provides that, where a brand name is used, the generic name must also be provided. The name of a drug must not bear close resemblance with the name of another drug or product which has been registered. Where a drug or product contains a label written in a foreign language, it will not be considered, unless an English translation is included in the label and package insert.

[445] Art. 10 (C)(i) NDDG 2012
[446] Art. 11(i) NDDG 2012
[447] Art. 11(ii) NDDG 2012
[448] Art. 12 NDDG 2012
[449] NAFDAC/RR/003/00

Registration is however not an automatic advertising permit.[450]NAFDAC, however reserves the right to revoke, suspend or vary the Certificate of Registration during its validity period.

3.2.2.3 Guidelines for Registration of Imported Drug Products in Nigeria[451]

The guidelines were made for the particular interest of Pharmaceutical Industries in Nigeria. It also reiterates the registration requirements prescribed by the Food, Drugs and Related Products (Registration, etc.) Act.[452]

Application for registration shall be made by the manufacturer. Where the manufacturer is outside Nigeria, he shall appoint a duly registered pharmaceutical company in Nigeria as his representative, by Power of Attorney.[453]It is the responsibility of the representative to inform competent authority of any serious hazard newly associated with the imported product, or any criminal abuse of the certificate in particular to the importation of falsely labelled, spurious, counterfeit or sub-standard medicinal products.[454]

With regards to drug products imported from India and China, evidence that the manufacturer is licensed to manufacture drugs for sale in the country of origin (Manufacturer's Certificate), issued by the competent Health Authority, must be filed with the application.[455] Also to be filed, is the evidence, issued by a competent health authority, that the sale of the product does not constitute a contravention of the drug laws of that country. This is known as certificate of pharmaceutical products (COPP). It must conform to the WHO format.[456] In addition, evidence that the drug product was manufactured

[450] Art. F(i) NAFDAC/RR/003/00
[451] NAFDAC/RR/002/00
[452] Art. A(1)(2) NAFDAC/RR/002/00
[453] Art. B(1)(a&b) NAFDAC/RR/002/00
[454] Art. B(1)(c) NAFDAC/RR/002/00
[455] Art. C(1) NAFDAC/RR/002/00
[456] Art. C(3) NAFDAC/RR/002/00

according to Good Manufacturing Practice (GMP), must be filed alongside other documents.[457]

These three (3) documents must be authenticated by the Nigerian Diplomatic Mission in the country of origin. If none, any High Commission or Embassy of any Commonwealth or West African country existing there can authenticate them.[458]

A drug product shall not be manufactured in Nigeria unless the factory is inspected and a Certificate of Recognition is issued by NAFDAC. Evidence of locally conducted clinical trials and registration in country of origin and at least two (2) or more developed countries must be submitted.[459]Products which are found to be of doubtful, little, or no therapeutic value shall not be considered for registration.[460]Labelling shall be informative, clear and accurate.[461]The product name shall not closely resemble that of an already registered product and labels must be in English Language or bear an English translation in the insert of the packaging.[462]

3.2.2.4 Guidelines for Clearance of Imported Drugs (Human and Veterinary) and Related Products in Nigeria[463]

This Guideline was made in respect of clearing imported drugs and related products. Part A makes general provisions such as the reason for the guidelines, which is for the interest of the general public and importers of registered pharmaceutical and related products in Nigeria. It further provides that importation of drugs and related products must be done by the pharmaceutical company who registered the products. Art. A(4) provides that drugs and related products should not be manufactured, imported, exported, advertised, sold or distributed in Nigeria, unless it is registered in accordance with the provisions of the Food, Drugs and Related Products (Registration, etc.) Act, and the guidelines made pursuant to it.

[457] Art. C(2) NAFDAC/RR/002/00
[458] Art. C(3) NAFDAC/RR/002/00
[459] Art. D(1-2) NAFDAC/RR/002/00
[460] Art. D(5) NAFDAC/RR/002/00
[461] Art. E(1) NAFDAC/RR/002/00
[462] Art. E(5) NAFDAC/RR/002/00
[463] NAFDAC/PID/001/00

Where the imported drugs are either not registered, or registered, but imported by persons other than those that registered the product, it will amount to a violation.[464]

Art. A(6) provides that vaccines and biologicals must be accompanied by functional cold chain monitoring devices at the ports of entry and must be maintained according to stipulated conditions at company's warehouse.

Part B is concerned with the process for application to import drugs and related products. While Part C lists the NAFDAC appointed analysts to inspect drugs and related products which are imported from India, China and Egypt. The documents required to accompany an application include, a 'Clean Report of Inspection and Analysis' (CRIA), issued before shipment into Nigeria, the importer's current Pharmacist's Annual Licence to practice as a pharmaceutical chemist issued by the PCN, current Premises Retention Certificate issued by the PCN, shipping documents, photocopy of Narcotics Permit to import and permit to clear (where applicable), evidence of valid product registration certificate with NAFDAC, and Certificate of Analysis issued by the manufacturer.

By virtue of Part E, the importer is expected to provide an undertaking that the product(s) will be forfeited if found to be unsatisfactory, and the address of the warehouse where the product will be stored.

Part F in its part, makes provision for the procedure for physical examination of each consignment. The products will be released to the importer's warehouse, pending satisfactory laboratory analysis which is to be carried out within ten (10) working days from the date of sample collection. The products, can however only be marketed after satisfactory laboratory analysis by NAFDAC.[465]

[464] Art. A(5) NAFDAC/PID/001/00
[465] Part G NAFDAC/PID/001/00

3.2.2.5 Guidelines for Packaging Bulk Semi-Finished Drug Products in Nigeria[466]

The guidelines were made in the interest of industries that may wish to import bulk semi-finished drug products and other regulated products, such as Nutra chemicals, food supplements in drums or sacks for the purpose of packaging them in Nigeria.[467]The document reiterates that drugs manufactured, imported, exported, advertised, sold or distributed in Nigeria must have been registered in accordance with the provisions of the Food, Drugs and Related Products Act.

The Guidelines is also applicable to manufacturers of an already registered drug product who may choose to import the semi-finished bulk product to package in Nigeria.[468]

The procedure for application is set out in Part B of the Guidelines. Part C enumerates the documentation to be submitted with application. These include the current Good Manufacturing Practice (GMP) certification of the manufacturing facility, for manufacturers from Asian Countries.[469]Applicants are expected to submit Certificate of Registration of Brand Name (CRBN) with the Trademarks Registry.[470]

Part F provides detailed requirements for labelling, noting that product label should be clear, informative and accurate.[471]

3.2.3 National Regulations on Drugs

3.2.3.1 Drug Labelling Regulations (DLR) 2005

The Regulation is applicable to all labelling of drugs and related products.[472] It prohibits the manufacture, importation, exportation, distribution, advertisement, and display for sale or sale of any drug without adequate labelling.[473] Information on labels shall be prominent, legible and distinct. It must be in English Language, though it may include other

[466] NAFDAC/RR/009/00
[467] Art. A(2) NAFDAC/RR/009/00
[468] Art. A(4) NAFDAC/RR/009/00
[469] Art. C(2)(c) NAFDAC/RR/009/00
[470] Art. C(3) NAFDAC/RR/009/00
[471] Art. F(1) NAFDAC/RR/009/00
[472] Reg. 1 DLR 2005
[473] Reg. 2 DLR 2005.

languages. It must be informative and accurate and shall not be false or misleading.[474] The label shall specify the name and location address of the manufacturer and that of the packer or distributor, where applicable.[475]

The packaging components shall contain the name, active ingredients, strength, and dosage form of the drug. The generic name and strength shall be displayed on the outer and inner labels. If a branded drug, its generic and brand names are to be reflected on the outer and inner labels. The ingredient(s), location address of the manufacturer shall be complete on the outer label, unless the container of drug contains five (5) ml or equivalent, or less.[476]

The net content of the drug shall also be displayed on the outer label.[477] Reg. 8(a) provides that, where the drug has a trademark displayed on the label, the trademark shall not give a wrong impression of the nature, quality or substance of the drug product. The outer and inner labels shall also bear the registration number assigned by the Agency (NAFDAC number).[478]

Drugs are also to bear their identification marks which are traceable to the manufacturer or the holder of a Certificate of Registration (CR). Exempted from these requirements are drug products intended for clinical trials or bio equivalent studies, radiopharmaceutical drug products, drugs with shape, size or physical appearance which make it difficult to imprint the identification marks on them and drugs administered solely in controlled health care settings. Exemptions are to be obtained on application to the Agency, stating reasons for waiver.[479]

By virtue of Reg.12, prescription drugs shall contain package insert with all relevant information, in accordance with the Regulations, except drugs in five (5) cm or less

[474] Reg. 4(1-4) DLR 2005
[475] Reg. 5(1) DLR 2005
[476] Reg. 6(2-7) DLR 2005
[477] Reg. 7 DLR 2005
[478] Reg. 9 DLR 2005
[479] Reg. 10 DLR 2005

containers.[480] Injectable drug products shall contain adequate information to ensure safe and proper use.[481]

A person who contravenes any provision of the Regulation, is guilty of an offence and liable on conviction, if an individual, to a fine not exceeding Fifty Thousand Naira (₦50,000), or imprisonment for a term not exceeding two (2) years or to both fine and imprisonment, and if a corporate body, to a fine not exceeding one hundred thousand Naira (₦100,000).[482]

Reg. 20 provides that, in addition to the penalties of Reg. 19, a person convicted of an offence under the Regulations shall forfeit the drug products and whatever is used in connection with the commission of the offence to NAFDAC.

3.2.3.2 The Drug Products Advertisement Regulations[483]

The Drug Products Advertisement Regulations was made to regulate the nature and content of drug advertisement. On the nature of advert, the regulation provides that advertisement of drugs shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health care practitioners. Thus, statements or illustrations shall not mislead either directly or by implication.[484]

The regulation frowns at referential advert and provides that no advert of a drug product shall imitate the general layout, text, slogan or visual presentation of another drug product in a way likely to mislead or confuse the consumer; or be framed in such a manner as to exploit any superstitions or be calculated to induce fear among consumers causing them to purchase the product being advertised.[485]

Regulation 13 provides for restrictions on advert. According to the regulation, no advert for any drug product shall contain:

[480] Reg. 13 DLR 2005
[481] Reg. 14 DLR 2005
[482] Reg. 19(1)(a-b) DLR 2005
[483] Regulations S.1.15 Of 1995 (Pursuant To Sections 5 And 29 of NAFDAC Act)
[484] Drug Products Advertisement Regulations, Regulation 3
[485] Drug Products Advertisement Regulations, Regulation 4a and 4b

(a) any false or misleading information;

(b) half-truths, inadequate qualification and limitations regarding safety or effectiveness of the drug;

(c) vague, unsubstantiated statements, or suggestions of superiority over other competing drugs; or

(d) any false impression that the advertised drug is for universal cure or should be regarded as a more effective and safer alternative to other related drugs.

3.2.3.3 The Consumer Protection (Products and Services Monitoring and Registration) Regulations [CP (P&SM&R) R] 2005

This was promulgated pursuant to the powers of the Consumer Protection Council under section 31 Consumer Protection Council Act. The Regulation provides that, products manufactured, imported, advertised, sold, distributed in Nigeria are to be registered by the Council.[486]

If the Council is satisfied with the information supplied by the applicant, it will issue a Certificate of Registration which is valid for five (5) years or for such period prescribed by the Council.[487] Where the Council is not satisfied, it will inform the applicant, stating reasons and the applicant can re-apply.[488]

The Council reserves the right to suspend, withdraw or cancel the certificate at any time, if the information upon which the product or service was registered was incomplete or false, or the circumstances on which the product was registered no longer exists, or the conditions for registration has been contravened, or the standard of quality for registration of the products are not complied with.[489]

Where a person contravenes the provisions of the Regulation, he may be prohibited from carrying on manufacturing, distribution, sale, advertisement and importation of the product

[486] Reg. 1CP(P&SM&R)R 2005
[487] Reg. 6&8 CP(P&SM&R)R 2005
[488] Reg. 7 CP(P&SM&R)R 2005
[489] Reg. 9 CP(P&SM&R)R 2005

completely or for such period as the Council may determine. In addition, the Council may impose a fine of fifty thousand naira (₦50,000).[490]

3.3 International and Regional Conventions, Protocols and Guidelines

Nigeria is a signatory to quite a number of regional and international conventions, protocols and guidelines. Although, these documents by implication, affect the right to health and drug counterfeiting, there is no convention on drug counterfeiting per se. Relevant instruments are discussed hereunder.

3.3.1 Regional Instruments

3.3.1.1 The African Charter on Human and Peoples' Rights (ACHPR) 1986[491]

The ACHPR is an international human rights instrument aimed at promoting and protecting human rights and basic freedom in Africa. By Art. 1, member States who are parties to the Charter are to recognise the rights, duties and freedoms enshrined in the Charter and should undertake to adopt legislative or other measures to give effect to them. The Charter recognises that human beings are inviolable. Every human being shall be entitled to respect for his life and the integrity of his person. It provides further that no one may be arbitrarily denied of his rights.[492]

Art. 16 upholds the right to the best attainable state of physical and mental health and goes on to prescribe that state parties are to take necessary steps to protect the health of their people and ensure that they receive medical attention when they are sick.

3.3.1.2 The African Charter on the Rights and Welfare of the Child (ACRWC)

[490] Reg. 11 CP(P&SM&R)R 2005
[491] The Banjul Charter
[492] Art. 4 ACHPR

This instrument was adopted in 1990 but came into force in 1999. It sets out the rights and defines the universal principles and norms regarding the status of the child. It detailed the civil, political, economic, social and cultural rights of children.

Art. 5 upholds children's right to life, whilst Art. 14 upholds the right of the child to enjoy the best attainable state of physical, mental and spiritual health. This includes the provision of nutritious food and safe drinking water, as well as adequate healthcare.

3.3.2 International Instruments

International instruments that relate to drug counterfeiting and combating it, can be classified into three (3). The first category relates with fundamental human rights, the second category is trade specific and the last category is concerned with transnational crimes. They will be examined under these heads. In addition, the WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs will be discussed.

3.3.2.1 Human Rights Documents

These include the Universal Declaration of Human Rights (UDHR) 1948. This is the first document to set out the fundamental human rights which are to be universally protected. It recognises that the inherent dignity of all members of the human family is the foundation of freedom, justice and peace in the world.[493]The UDHR, among others, guarantees the right to life,[494] and health. Art. 25(1) guarantees the right to a standard of living adequate for health and wellbeing of every person and of his family, including food, clothing, housing, medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age, or other lack of livelihood in circumstances beyond his control.

[493] See the Preamble to the UDHR.
[494] Art. 3 UDHR

The International Covenant on Civil and Political Rights (ICCPR) 1960 in its part, preserves the right to life for all human beings. The right is to be protected by law and there shall be no arbitrary deprivation of life.[495]

The International Covenant on Economic, Social and Cultural Rights (ICESCR) was adopted in 1966, but came into force in 1976. Art. 12 preserves the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. All state parties are enjoined to take steps towards realising this right.

3.3.2.2Trade Related Instruments

3.3.2.2.1Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

This is an agreement between all the member nations of the World Trade Organisation (WTO). It covers copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits and undisclosed information such as trade secrets and test data.[496] It has three (3) main features.

3.3.2.2.1.1Features of TRIPS Agreement

a. Standards – it sets out minimum standards of protection to be provided by each member nation. The elements of protection are; the subject matter to be protected, the rights to be conferred, the permissible exceptions of those rights, and the minimum duration of protection.

   The standards set by TRIPS requires that the substantive obligations of the main conventions of World Intellectual Property Organisation (WIPO), the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) in their recent versions, be complied with.[497]

[495] Art. 6(1) Part III, ICCPR
[496] Overview: The TRIPS Agreement. Retrieved from www.wto.org. on 13th February, 2017.
[497] See Art 2.1 and 9.1 TRIPS

The standards further imposed additional obligations on matters on which pre-existing conventions are silent or are seen to be inadequate. Consequently, the TRIPS Agreement is referred to as the Berne and Paris Plus Agreement.[498]

b. Enforcement – the Agreement lays down certain principles applicable to all Intellectual Property Rights (IPR) enforcement procedures. It also makes provisions on civil and administrative procedures and remedies, provisional measures, special requirements related to border measures and criminal procedures, which specify, to an extent, the procedures and remedies that must be available so that rights holders can effectively enforce their rights.

c. Dispute Settlement – disputes between WTO member states in respect of TRIPS obligations are subject to the WTO dispute settlement procedures.

Other provisions in the Agreement include national and most-favoured nation treatment, and general rules for ensuring that procedural difficulties in acquiring or maintaining IPRs do not nullify the substantive benefits that should flow from the Agreement.

Whilst the provisions of the Agreement are applicable to all member states, member states that belong to the developing group had a longer period within which to comply. Where a developing country does not have patent protection for pharmaceuticals, a special transition arrangement would apply.

Member States are obliged to accord the treatment in regard to the protection of IP provided for under the Agreement to nationals of other member states.[499] The criteria for determining those, to whom the Agreement would apply, would be as prescribed in the WIPO Conventions, whether or not they are party to those conventions.

These Conventions include the Berne Convention, the Paris Convention, the International Convention for the Protection of Performers', Producers of Phonograms and Broadcasting

[498] See n.222 above.
[499] Art. 1.3 defines nationals as persons, natural or legal, who have close attachment to other members without necessarily being members.

Organisations (Rome Convention) and the Treaty on IP in respect of Integrated Circuit (IPIC Treaty).

Arts. 3, 4, and 5 address treatment of foreign nationals by national and most-favoured nations. The obligations provided in these articles relate to matters affecting availability, acquisition scope, maintenance and enforcement of IPRs as well as those matters affecting the use of IPRs specifically addressed in the Agreement. The national treatment clause in its part forbids discrimination between member states' own nationals and the nationals of other member states. The most-favoured nation treatment clause prohibits discrimination between the nationals of other members.

With regards to the national treatment obligation, the exceptions allowed under the pre-existing IP conventions of WIPO are allowed under TRIPS. Where material reciprocity is allowed by the exception, consequential exception to the most-favoured nation treatment is permitted. Provisions for other limited exceptions to the most-favoured nation obligations were also made.

3.3.2.2.1.2Objectives of the TRIPS Agreement

The objectives of the TRIPS Agreement are the reduction of distortions and impediments to international trade, promotion of effective and adequate protection of IPRs, ensuring that measures and procedures for IPRs enforcement do not become barriers to legitimate trade. The protection and enforcement of IPRs should contribute to the promotion of technology innovation, to the transfer and dissemination of technology, to the mutual advantage of producers of technological knowledge in a manner conducive to social and economic welfare and to a balance of rights and obligations.

By virtue of Art. 8, member states may adopt measures for public health and other public interest reasons and to prevent the abuse of IPRs, provided that such measures are consistent with the provisions of TRIPS Agreement.

With regards to trademarks, Art. 15 provides that any sign or combination of signs which are capable of distinguishing the goods and services of one undertaking from those of other

undertakings must be eligible for registration as a trademark. The sign must however be visually perceptible. Members may require additional condition(s) for eligibility for registration as trademark, where the signs are not inherently capable of being distinguishing. In addition, members may allow registration of signs that are not visually perceptible such as sound or smell marks. Registration in member states may be dependent on use.Actual use would however not be a condition for filing an application for registration, at least three (3) years must have passed after the filing date before failure to realise an intent to use is permitted as the ground for refusing the application.[500]

Where an identical sign for identical goods or services is used, the likelihood of confusion must be presumed.[501]

TRIPS Agreement sets out minimum standards regarding the grant of rights to the IPRs holder, the requirements for the enforcement in the municipal legal enactments, and the remedies for infringements and dispute settlement. The agreement gives member states, rights to enact laws which are suited to their peculiar circumstances.

3.3.2.2.2 Agreement on Pre-Shipment Inspection (PSI)[502]

The PSI was negotiated in Uruguay Round of Multilateral Trade Negotiations (1986) and it applies to all pre-shipment inspection activities carried out on the territory of members, whether contracted or mandated by the government, or any government body, that is, in the country of export, prior to exportation.[503] Pre-shipment activities include all activities relating to the verification of the quality, quantity, price, including currency exchange rate and financial terms, and or the customs classification of goods to be exported to the territory of the user member state.[504]

[500] Art. 14.3 TRIPS Agreement
[501] Art. 16(1) TRIPS Agreement.
[502] Retrieved from www.wto.org on 11th February, 2017.
[503] Art. 1(2) PSI Agreement. See also WTO Analytical Index: PSI (para.2). Retrieved from www.wto.org on 11th February, 2017.
[504] Art. 1(3) PSI Agreement.

It did not create any administrative body. However, since 1999, it has been monitored by the Committee on Customs Valuation.[505]

It is a service provided to developing countries to monitor the quantity and quality of their imports. It is provided to these countries by specialised private corporations to check shipment details such as price, quality and quantity of goods ordered overseas. It was established as part of the Uruguay Round of Negotiations of the General Agreement on Tariffs and Trade (GATT).[506]

The obligations of the PSI user are listed in Art 2. The PSI user has the responsibility of ensuring that the inspection is carried out in a non-discriminatory manner.[507]The PSI user is also to ensure that all the provisions of paragraph 4 of Article III of GATT 1994, are respected to the extent[508]of their relevance to the provisions of all relevant local laws, regulations and requirements. In addition, he or she is to ensure that all pre-shipment inspection activities, including the issuance of a Clean Report of Findings or a note of non-issuance, are done in the custom territory from which the goods are exported. Where there is no adequate inspection mechanism and or both parties agree, the PSI will be undertaken in the custom territory in which the goods were manufactured.[509]The PSI user is further responsible for ensuring that quality and quantity inspections are performed in accordance with the standards defined by the seller and buyer in the purchase agreement and that, in the absence of such standards, relevant international standards will apply.[510]

[505]*Ibid*, para. 3
[506] E. Rome. 1998. The Background, Requirements and Future of GATT/WTO PSI Agreement. *Minnesota Journal of Global Trade*. p.469.
[507] Art. 2(1) PSI Agreement
[508] Art. 2 (2) PSI Agreement
[509] Art. 2(3) PSI Agreement.
[510] Art. 2(4) PSI Agreement

3.3.2.3 United Nations Convention on Transnational Organised Crime and its Protocols on Trafficking in Persons; Smuggling of Immigrants and Trafficking in Firearms (UNTOC)

Trafficking in counterfeit medicines has been described as one of the emerging forms of transnational organised crimes (TOC), which threaten peace and security. At the 20th session of the Commission on Crime Prevention and Criminal Justice (CCPCJ) adopted resolution 20/6 on fraudulent medicine (counterfeit drugs). The resolution further noted the potential usefulness of the UNTOC, which the United Nations Office on Drugs and Crime oversees, in improving international cooperation in the fight against trafficking, through mutual assistance, extradition and the seizing, freezing and forfeiture of the instrumentalities and proceeds of crime.[511]

The UNTOC has been described as a general flexible and practical legal instrument which aims at promoting co-operation in preventing and combating transnational organised crime more effectively.[512]It was adopted by the General Assembly Resolution 55/25 of 15th November 2000, but came into force in 2003.

It covers four (4) key areas, namely, criminalisation, in this regard, it created four (4) offences; participation in an organised crime group,[513] laundering proceeds of crime,[514] corruption,[515] and obstruction of justice.[516]Secondly, it made provisions for domestic measures as it relates to combat offences, facilitating investigation and prosecution, and established liability of legal persons. It further provided guidelines for domestic

[511] An illustration is the "Operation Singapore" which involved the importation of counterfeit medicines into the UK's legitimate supply chain. The ensuing investigation involved twelve (12) countries and led to the discovery of a vast network of criminals trafficking fraudulent medicines and laundering the proceeds. It was a breach of the UK's regulated supply of medicines with over £4.5 million worth of counterfeit medicines imported. 72,000 packs were seized, 32,000 had reached pharmacies and patients, 25,000 remained unaccounted for, even after recall. The counterfeits were shipped from China via Hong Kong, Singapore and Belgium, packaged as French medicines and taken to UK as parallel imports. See R .v. Gillespie and Others (Operation Singapore). UNODC Case Law Database. UNODC No. GBRx001. Retrieved from www.unodc.org/cld/caselaw/criminalgroupcrimetype/gbr/r_v_gillespie_and_ors_operation_singapore.html on 22nd March, 2017.
[512] Art. 1 UNTOC
[513] Art. 5 UNTOC
[514] Art. 6 UNTOC
[515] Art. 8 UNTOC
[516] Art. 23 UNTOC

obligations such as co-operation, information gathering or sharing and prevention, and international cooperation, which is necessary for criminal investigations and prosecutions.

Art. 3(1) sets the scope of the UNTOC as being applicable to the prevention, investigation and prosecution of offences established by Arts. 5, 6, 8 and 23 of the Convention, which must be serious crimes as defined in Art. 2,[517] are transnational in nature[518], and involve an organised criminal group.[519]

The UNTOC recommends the engagement of the following tools for international cooperation, namely, tracing, freezing, confiscation, mutual legal assistance (MLA)[520] and extradition.[521] "Operation Singapore" is an illustration of the use of the provision for mutual legal assistance in gathering evidence internationally and in extraditing the defendants in the resulting case. It further established the legal frameworks and legal obligations with regards to international cooperation for the purpose of confiscation.[522] Capable of being confiscated are proceeds of the crime and instrumentalities.

Art. 27 on law enforcement cooperation, makes provision for measures to enhance communication and collaboration. Furthermore, it permits case-by-case cooperation for joint investigations,[523] by the creation of international teams and special investigative techniques both at domestic and international levels.[524]

The UNTOC forms the legal basis for international cooperation against serious crime.

[517] A serious crime is one which is punishable by a maximum deprivation of liberty of at least four (4) years or more. See Art. 2(b) UNTOC.
[518] For an offence to be transnational, it must have been committed in more than one state, or a substantial part of the preparation, planning, direction or control takes place in another state or, it involved an organized criminal group engaging in criminal activities in more than one state or has substantial effects in another state. See Art. 3(2) UNTOC.
[519] An organized criminal group is a structured group of three (3) or more persons which had existed over a period of time and acting in concert, having the aim of committing one or more serious crimes in order to obtain a direct or indirect financial or other material benefit. See Art. 2(a) UNTOC.
[520] Art. 18 UNTOC
[521] Art. 16 UNTOC.
[522] Art. 13 UNTOC
[523] Art. 19 UNTOC
[524] Art. 20 UNTOC

3.3.2.4 WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs (1996)[525]

These guidelines were developed in response to the World Health Assembly's request. They are aimed at providing guidance to member states on developing their national measures for combating counterfeiting of drugs. An overview of the problem and factors contributing to the drug counterfeiting was given in the Guidelines.[526] Steps to be followed in developing national strategies and specific measure to be considered in combating drug counterfeiting were also enumerated.[527] Sections 7-10 provided for other supplementary guidance on the specific measures mentioned in sections 5 and 6.

As seen from the foregoing, various legislative instruments regulate the manufacture, sale and distribution of drugs in Nigeria. These instruments overlap and conflict, creating civil and/or criminal liabilities for the same events, and having different, but sometimes same penalties. Most are old and in need of overhauling to meet present day realities. The effect is a legal framework that leaves room for offenders to manoeuvre, thereby creating difficulties in prosecuting offenders. Secondly, the prescribed penalties are inconsequential compared to the magnitude of harm perpetrated.

3.4 Institutional Regulatory Framework

This section looks at the various institutions whose functions, in one way or the other, regulate drug production and distribution, thereby regulating, directly or indirectly, the production and distribution of counterfeit and substandard drugs. These institutions are, NAFDAC, Pharmacist Council of Nigeria (PSN), Standards Organisation of Nigeria (SON) and Consumer Protection Council of Nigeria (CPCN). Also examined in this section are international institutions, namely the UNODC and the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

3.4.1 Composition and Nature of the National Agency for Food and Drug Administration (NAFDAC)

[525] Retrieved from www.who.int/medicines/regulation/ssffc/en on 11th February, 2017.
[526] Sections 2 and 3 Guidelines for the development of measures to combat counterfeit drugs.
[527] *Ibid,* Sections 5 and 6

NAFDAC is a federal government agency and a parastatal under the Federal Ministry of Health.

The period 1985-1993 was characterized by poor state of health facilities and products, growth of the problem of fake, substandard and spurious drugs in Nigeria. This led to the promulgation of the Counterfeit and Fake Drug (Miscellaneous Provisions) Act,[528] and the establishment of NAFDAC in 1993,[529] to amongst others, carry out the control functions of the defunct Department of Food and Drugs Administration and Control (FDAC). A governing council was inaugurated as an oversight for the agency, by virtue of S.2 NAFDAC Act.

3.4.1.1 Composition, Tenure and Removal from Office of Members of the Governing Council

The Governing Council (Council) of NAFDAC was inaugurated, pursuant to S. 2 of the NAFDAC Act as an oversight over the agency. The Council is headed by a Chairman, who is appointed by the President on the recommendation of the Minister. Other members include the Permanent Secretary of the Federal Ministry of Health or his representative, the Director and Chief Executive of the National Institute for Pharmaceutical Research and Development or his representative, the Director-General of the Standards Organisation of Nigeria or his representative, the chairman of the National Drug Law Enforcement Agency or his representative, the chairman of the Pharmacists Board of Nigeria or his representative, one person to represent the Pharmaceutical Group of the Manufacturers Association of Nigeria, one person to represent the Food Beverages Group of the Manufacturers Association of Nigeria, the Director-General of the Agency and three other persons to represent public interest to be appointed by the Minister.[530] The Minister, may also appoint any other member, aside the Chairman, who has been recommended by the body he is representing.[531] Section 2 (3) provides that, the members are to receive

[528] Cap 73 Laws of Federation, 1990. This has been repealed and replaced by the Counterfeit Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act Cap C34 Laws of the Federation 2004.
[529] Decree No. 15 of 1993. See also S.1 NAFDAC Act, Cap N1 Laws of the Federation, 2004.
[530] See S. 2 (1) NAFDAC Act.
[531] See S.2 (2) NAFDAC Act.

remuneration as approved by the Federal Government from time to time. The order of proceedings of the Council is as provided for in the 1st Schedule to the Act.[532]

The tenure of office for a member who was not appointed by virtue of his office, is four years. He or she may, subject to the provisions of S.3 (2), however be eligible for a further term of four years.[533]By the provisions of S.3 (2) the office of a member of the Council will become vacant if, he resigns as a member of the Council by notice in writing under his hand addressed to the Minister, or the Minister is satisfied that it is not in the interest of the Agency for the person appointed to continue in office and notifies the member in writing to that effect.

Where it appears to the Council that a member of the Council, other than an ex-officio member, should be removed from office on the grounds of misconduct or inability to perform the functions of his office, the Council will make a recommendation to the President.[534] On receipt of such recommendation, the President will make enquiries as he considers necessary. Where he approves the recommendation, the Minister will, in writing, declare such office vacant.[535] The President, however has powers to remove any member of the Council, where he is satisfied that it will be in the interest of the public to do so.[536]

3.4.1.2 Functions of the Council

The Council is responsible for advising the Federal Government generally on the national policies on the control and quality specifications of food, drugs, cosmetics, medical devices, bottled water and chemicals.[537] It designates, establishes and approves quality specifications in respect of food, drugs, cosmetics, medical devices, bottled water and chemicals, necessary for their certification. In addition, it establishes the relevant guidelines and measures for quality control of food, drugs, cosmetics, medical devices, bottled water and chemicals in conformity with the Agency's standard specification. It appoints, promotes and disciplines employees necessary for the proper discharge of the

[532] See S.2 (4) NAFDAC Act.
[533] See S.3 (1) NAFDAC Act.
[534] See S.4 (1) NAFDAC Act.
[535] See S.4 (2) NAFDAC Act.
[536] See S.4 (3) NAFDAC Act.
[537] See S.6 (a) – (j) NAFDAC Act.

functions of the Agency. The Council may from to time, establish committees as may be expedient which shall be charged with specific functions delegated by the Council. It may establish appropriate programmes for the quality, safety and rational use of the food, drugs, cosmetics, medical devices, bottled water and chemicals. It encourages and promotes activities related to this process, standard specifications, and guidelines on importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water and chemicals. The Council is responsible for utilising and promoting the expansion of research, experiments, surveys and studies by public or private agencies, institutions and organisations concerning the quality, safety and use of food, drug, cosmetics, medical devices, bottled water and chemicals and such other matters related to the Act as the Agency may, from time to time, determine as necessary or useful.Furthermore, the Council may establish, encourage and promote training programmes for the employees of the Agency and other appropriate persons from public or private organisations and may carry out such other activities which are connected with its other functions.

3.4.1.3 Powers of the Council

The Council is empowered to open and operate ordinary and domiciliary accounts for the Agency in recognised banking institutions in Nigeria.[538] Secondly, subject to Section 8 of the Act, to specify the management system of the Agency, including financial approval ceilings for officers of the agency. It may also, enter into agreement with public or private organisations and individuals to develop, utilise, co-ordinate and share such information as it considers to be appropriate for the performance of its functions under the Act; and to do such other things as are necessary for the successful performance of its functions under the Act.

3.4.1.4 Functions of NAFDAC

[538] S.7 (a) – (c) NAFDAC Act.

The functions[539] of the Agency are, to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals. It conducts appropriate tests and ensures compliance with standard specifications designated and approved by the Council for the effective control of the quality of food, drugs, cosmetics, medical devices, bottled water and chemicals and their raw materials as well as their production processes in factories and other establishments. In addition, it undertakes appropriate investigations into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water and chemicals and establishes relevant quality assurance systems, including certificates of the production sites and of the regulated products. NAFDAC undertakes inspection of imported food, drugs, cosmetics, medical devices, bottled water and chemicals and establish relevant quality assurance systems, including certification of the production sites and of the regulated products. It compiles standard specifications and guidelines for the production, importation, exportation, sale and distribution of food, drug, cosmetics, medical devices, bottled water and chemicals. It undertakes the registration of food, drugs, cosmetics, medical devices, bottled water and chemicals. Furthermore, it controls the exportation and issue quality certification of food, drugs, cosmetics, medical devices, bottled water and chemicals intended for export. It establishes and maintains relevant laboratories or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions under the Act.[540]

It also has powers to make pronouncements on the quality and safety of food, drugs, cosmetics, medical devices, bottled water and chemicals after appropriate analysis. It undertakes measureto ensure that the use of narcotic drugs and psychotropic substances are limited to medical andscientific purposes. It is empowered to grant authorisation for the import and export of narcoticdrugs and psychotropic substances as well as other controlled substances. In carrying out itsduties, it collaborates with the National Drug Law Enforcement Agency (NDLEA) in eradicatingdrug abuse in Nigeria. It advises Federal, State and local governments, the private sector andother interested bodies regarding the quality, safety, and regulatory provisions on food, drugs,cosmetics, medical devices,

[539] Section 5 NAFDAC Act, Cap N1 LFN 2004.
[540] Section 5(a-h) NAFDAC Act

bottled water and chemicals; undertake and co-ordinate researchprogrammes on the storage, adulteration, distribution and rational use of food, drugs, cosmetics,medical devices, bottled water and chemicals.[541]

In addition, it has powers to issue guidelines on, approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals; compile and publish relevant data resulting from the performance of the functions of the Agency under this Act or from other sources; sponsor such national and international conferences as it may consider appropriate; liaise with relevant establishments within and outside Nigeria in pursuance of the functions of the Agency; determine the suitability or otherwise of medicines, drugs, food products, cosmetics, medical devices or chemicals for human and animal use; and carry out such activities as are necessary or expedient for the performance of its functions under this Act.[542]

In performing its duty, NAFDAC from time to time releases lists of banned, restricted or controlled foods, drugs, cosmetics and chemicals. In addition, the Agency destroys seized fake drugs.[543]

The unstructured interviews carried out during this study revealed that the government in Nigeria realizes that it is its responsibility toprovide protection for its citizens. As a result, it has not only promulgated laws and decrees but also, has regulatory agencies like NAFDAC in place to ensure compliance. In addition, consumers are made aware of the existence of these agencies and their functions, so they could patronize them. The respondents know what functions NAFDAC exists to fulfill. NAFDAC in it part has succeeded in their strategy of creating consumer awareness of their existence through awareness campaigns on various media, particularly the Radio and Television.[544] Most of those interviewed were of the

[541] Section 5(i-n) NAFDAC Act
[542] Section 5(m-t) NAFDAC Act
[543] It was reported recently that over a period of three (3) years, NAFDAC destroyed counterfeit drugs worth Twenty-nine Billion Naira (₦ 29b) and seven (7) convictions in two (2) years. See "70% Drugs in Nigeria Not Fake - NAFDAC". Vanguard News. Retrieved from www.vanguard.com on 20th November, 2017.
[544]The interview carried out during this study amongst stakeholders revealed this.

opinion that NAFDAC is efficiently fulfilling all its objectives. From all the above, it is concluded that NAFDAC as a government regulatory agency is efficiently fulfilling the purpose of its existence, to a large extent. There is however a need for the government to still look into areas where they are deficient, to make room for improvement.
NAFDAC as an institution, will further be evaluated in Chapter 5.

3.4.2 Composition, Nature and Functions of the Pharmacists Council of Nigeria (the Council)

The Pharmacists Council of Nigeria was established by the Pharmacists Council of Nigeria (PCN) Act.[545]

3.4.2.1 Composition and Nature of the Council

The composition of the Council is provided for by Section 3 of the Act. All its members shall be citizens of Nigeria and registered pharmacists. There shall be a chairman, a registered pharmacist of not less than fifteen (15) years post-registration experience. He shall be appointed by the President. Other members are, a representative of the Federal Ministry of Health (FMH), who is the Director of the Food and Drugs Services in the FMH, the president of the Pharmaceutical Society of Nigeria (PSN), the Director of Pharmaceutical Services of each State, including the Federal Capital Territory (FCT), the Deans of recognized Faculties or Schools of Pharmacy in Nigerian Universities, eight (8) members from such states as may be appointed by the Minister on the recommendation of the PSN, one (1) representative of the Armed Forces, who is also a registered pharmacist and the Executive Director of the National Institute of Pharmaceutical Research and Development. The Chairman holds office for a term of three (3) years and will be eligible for re-appointment for one (1) more term.[546]

Section 8 provides that the Council shall appoint a fit and proper person as the Registrar,[547] who will be the Secretary to the Council and the Disciplinary Tribunal.[548] The duties of the

[545] Cap P17 LFN 2004. See Section 1.
[546] Section 4 PCN Act.
[547] Section 8(1) PCN Act.
[548] Section 8(2) PCN Act.

Registrar includes preparing and maintaining a register of the names, addresses, approved qualification and of such other qualifications and particulars as may be specified in the rules, of all persons who are entitled to be enrolled as associates and members, and who apply to be so registered.[549] He or she shall also keep a register of premises where members of the profession engage in the manufacture, distribution, sale and dispensing of drugs and medicines.[550]

In addition, the Registrar's duties include, correcting any entry that was incorrectly made and which the Council directs him to do, making necessary alteration to the registered particulars of registered persons and premises, removing from the register, the names of dead registered persons, persons who are in default for more than six months in the payment of annual subscriptions and to take such other actions relating to this, as the Council may direct or require.[551]

By virtue of Section 9, the Registrar shall print and publish the register and any correction for sale. Section 10 makes registration a pre-requisite for the appointment or practice as a pharmacist in Nigeria. The conditions for registration as a pharmacist in Nigeria are stated in Section 11. These include, good character, a fit and proper person, attended a course of training approved by the Council or a course conducted at an institution approved by the Council, and holds a qualification approved by the Council, amongst others.

Where the person is a Nigerian citizen who qualifies in an approved institution outside Nigeria, he or she shall satisfy the Council, amongst others that, in the country of qualification, he or she is under no legal disability in the practice of pharmacy; he holds an acceptable certificate of registration, and any other condition as may be prescribed by the Council, including passing an examination in forensic pharmacy.[552]

By virtue of Section 12, a non-Nigerian may be registered as a pharmacist under the Act, if amongst others, his country of origin grants reciprocal registration and facilities to

[549] Section 8(3)(a) PCN Act.
[550] Section 8(3)(b) PCN Act.
[551] Section 8(5)(a-d) PCN Act.
[552] Section 11(2) PCN Act.

Nigerians, if he has passed the Council's examination in law and ethics, governing the practice of pharmacy in Nigeria and such other examinations as the Council may prescribe, he has attained the age of twenty one (21) years and has not been convicted in Nigeria or elsewhere of any offence involving fraud or dishonesty.

The Act further provides for the establishment of the Pharmacists Council of Nigeria Disciplinary Tribunal, which shall consider and determine cases referred to it by the Investigating Panel and any other cases of which the Tribunal is aware of under the Act.[553]

By virtue of Section 23, any person, where for the purpose of procuring registration of a name or qualification, or other matter, makes a statement which he believes to be false, or recklessly makes a false statement, he shall be guilty of an offence.[554] Similarly, any person who, not being registered practices or holds himself out as a pharmacist shall be guilty of an offence.[555]

A Registrar or any other employee of the Council who wilfully makes any falsification in any matter relating to the register is guilty of an offence.[556] A person, who is guilty of an offence, shall on summary conviction, be liable to a fine not exceeding one thousand naira (₦1,000), or on indictment, to a fine not exceeding one thousand naira (₦1,000) or imprisonment for a term not exceeding two years (2), or to both such fine and imprisonment.[557] Where an offence has been committed by a body corporate and it is proved to have been committed with the consent and knowledge of any of its major officers, such persons, shall as well as the corporate body, be guilty of the offence and shall be liable to be prosecuted and punished accordingly.

3.4.2.2 Functions of the Council

[553] Section 17 PCN Act.
[554] Section 23 (1) PCN Act.
[555] Section 23 (2) PCN Act.
[556] Section 23 (4) PCN Act.
[557] Section 23 (5) PCN Act.

The Council is responsible for determining the standard of knowledge and skill to be attained by persons seeking to become registered members of the Pharmacy profession, to review and prepare a code of conduct which it considers desirable for the practice of the pharmacy profession, to regulate and control the practice of the profession in all its aspects and ramifications, promote legislation for the enhancement of the image and the interest of the Pharmacy Profession and the Practitioners in Nigeria, collate and disseminate statistical, scientific and other information relating to Pharmacy and publish such in an official journal, advice on labour conditions relating to Pharmacists and to perform all other functions as may be required of the Council under the Act.[558] This includes, inspecting, approving and licensing premises where pharmaceutical activities take place, such as Pharmaceutical manufacturing, Importation, Mega or State Drug Distribution centres, Distribution, Wholesale and Retail premises, Hospital Pharmacies and Patent and proprietary Medicines Vendors Licenses. The PCN also registers and issues annual permits to Pharmacy Technicians.

The PCN in carrying out its duties have sealed off numerous unregistered pharmacies. This has to an extend regulated the drug distribution outlets. For instance, in 2018, itsealed 378 drug outlets in Osun State, amongst others, for alleged non-compliance with its directives.[559]

3.4.3 Composition, Nature and Functions of the Standards Organisation of Nigeria (SON)

The Standards Organisation of Nigeria was established pursuant to Section 1 of the Standards Organisation of Nigeria Act 2015. The SON receives directives and reports to the Minister of Industries.[560]By virtue of Section 3, the Standards Council of Nigeria (The Council) was established.

3.4.3.1 Composition and Nature of the Standards Council of Nigeria

[558] Section 1(1)(a-e) PCN Act
[559]Adeniyi A. 2018. Pharmacists Council seals 378 drug outlets in Osun. *The Nation Newspaper,* 1st July, 2019. Retrieved from www.http://thenationonlineng.net on 23rd March, 2019.
[560] Section 2 SON Act 2015.

The Council is made up of a Chairman; a representative each from the Federal Ministries of Agriculture and Rural Development, Defence, Trade and Investment, Finance, Works, Health, Science and Technology; a representative each from any university education and research, Chambers of Commerce, industry and mines, engineering and engineering consultancy services, processing and manufacturing, construction industry, manufacturers' association and consumers' association; a person of unquestionable integrity, not employed in the public service, and in the opinion of the Minister, represents the interest or fields of activity not already listed and the Director-General.[561]The President, on recommendation of the Minister, appoints the Chairman and all other members of The Council.[562] Each member is to serve for a term of four (4) years and may be eligible for re-appointment for a further term of four (4) years.[563]

3.4.3.2 Functions of the Council

The functions of the Council include, advising the Federal Government generally on the National Policy on standards, standards specification, quality control and metrology; designating, establishing, and approving standards in respect of metrology, materials, commodities, structures and processes for the certification of products in commerce and industry throughout Nigeria; providing the necessary measures for quality control of raw materials and products in conformity with the standard specification; authorizing the recognition and registration of quality certification bodies, inspection bodies, testing laboratories, calibration laboratories and qualified personnel related to these activity areas operating legally, and carrying out other functions imposed on it under this Act or any other enactment.[564]

3.4.3.3 Functions and Duties of the SON

In a bid to position and equip the SON to function optimally, the 2015 Act increased its functions. The SON is saddled with the responsibility of organizing tests and all that is necessary to ensure compliance with standards designated and approved by the Council; undertaking investigation as necessary into the quality of facilities, systems, services,

[561] Section 3(1) SON Act 2015
[562] Section 3(3) SON Act 2015
[563] Section 3(4) SON Act 2015
[564] Section 4 SON Act 2015.

materials and product, whether imported or manufactured in Nigeria; evaluating quality assurance activities, including certification of systems, products and laboratories throughout Nigeria; ensuring that all products imported and exported are up to the expected standard. In doing this, the SON is to establish an Import and Export Product Surveillance, Certification and Conformity Assessment Scheme.[565]

Section 14 SON Act 2015, mandates the agency to be present at all the Nation's entry points to prevent the influx of substandard and life endangering products into the country. In fulfilling this obligation, the SON collaborates with the Nigerian Customs and the Nigerian Ports Authority.[566]

In addition, the SON is to establish a mandatory conformity assessment programme for locally manufactured goods; impose fees and fines or penalties on a person who contravenes any import or export surveillance, certification or conformity assessment scheme. Towards accomplishing this, SON prepares standards related to product measurements, material, processes and services, their promotion at national, regional and international levels, the certification of products, assistance in the production of quality goods and services, improvement of measurement accuracy and the circulation of information.

The SON has the responsibility of undertaking the registration of all manufactured products distributed, marketed and consumed throughout Nigeria;[567] carry out training and undertake the accreditation of training institutions and organisations for purposes of international standards, such as International Telecom Union (ITU), International Electrotechnical Commission (IEC), International Organisation for Standardisation (ISO),

[565] Section 5(1) (a),(b),(c) and (h) SON Act 2015.
[566] Retrieved from www.son.gov.ng on 21st October, 2017.
[567] Section 5(1)(l) SON Act 2015

International Organisation for Legal Metrology (OIML), CODEX standards,[568] or system certification throughout Nigeria.[569]

The SON also has powers to establish a register for national standards, standard marks, certification systems and licenses and for making entries of all matters relating to standards referred to under the Act.[570] In addition, it may undertake appropriate investigations into the production premises and systems, including certificates of production sites for regulated products,[571] and administer and enforce the provisions of the Act.[572]

In exercising this power, SON recently seized and destroyed various substandard, and life-threatening products in Lagos and other parts of the country, ranging from tyres to breakfast cereal. Some importers have been arraigned to court in relation to the seizure.[573]

By virtue of Section 5(2) SON Act, all other regulatory agencies who are concerned with matters pertaining to or related to standards will collaborate with the SON.

The major challenge of the SON has been identified as funding. Poor funding has undermined the implementation of its mandate on product standardization in Nigeria. Improved funding is advisable to cover for recruitment of staff, establishing more laboratories, and procure more utility vehicles for carrying out these duties.[574]

SON is a member of the African Regional Organisation for Standardisation (ARSO), member of Codex Alementarius Commission which is the Food Standardisation

[568] CODEX Alimentarius or 'Food Code' was established by the FAO and WHO in 1963 to develop harmonised international food standards, which protect consumer health and promote fair practices in food trade.
[569] Section 5(1)(q) SON Act 2015.
[570] Section 5(1)(s) SON Act 2015
[571] Section 5(1)(t) SON 2015
[572] Section 5(1)(v) SON Act 2015
[573] www.son.gov.ng on 12th October, 2017
[574] Okorie A and Humphrey A. 2016. Funding Challenges to Quality Control. *Mediterranean Journal of Social Science*.

Organisation of the UN's Food and Agriculture Organisation (FAO) and a member of the International Organisation for Standardisation.[575]

The SON's mandate is to ensure elaboration of industrial standards for goods made in Nigeria and products imported into the country, to monitor compliance of these products to the standards, it has been noted that the major challenge facing SON is false declaration of goods.[576] Importers declare one thing at the point of Pre-Arrival Assessment Report (PAAR) and a different thing at the process where the cargo is going to be released. In 2016, it launched SONCAP (SON Conformity Assessment Programme). This is a pre-shipment verification of conformity to Standards process used to verify that products to be imported into Nigeria are in conformity with the applicable NIS or approved equivalents, and technical regulations before shipment. SONCAP has enhanced SON's performance. Be that as it may, a major challenge of the SON, as with other government agencies, is funding.

3.4.4 Composition, Nature and Functions of the Consumers Protection Council of Nigeria (CPC)

The CPC was established by virtue of section 1(1) of the CPC Act, to protect consumers from harmful products and to provide protection and redress for the consumer.

3.4.4.1 Composition and Nature of the CPC

The CPC[577] is headed by a Chairman who is appointed by the President on recommendation of the Minister for Commerce and Tourism. Other members of the CPC are a representative of each state on the recommendation of the Governor of the state, four (4) persons representing related Ministries, namely, Commerce and Tourism, Industries and Technology, Health and Petroleum Resources.

---

[575]See Member States. Retrieved from www.arso-oran.org on 23rd March, 2019. See also Members of Codex Alimentarius. Retrieved from www.fao.org. on 23rd March, 2019.
[576]Clement U. 2017. Our Problem with Fake Imported Products- SON. *The Vanguard*. 30th April, 2017. Retrieved from https://www.vanguardngr.com on 23rd March, 2019.
[577] Section 1(2) CPC Act

The Chairman and members, who are not ex officio members, will hold office for a period of three (3) years and will be eligible for re-appointment for an additional term only.[578]A member may resign at any time that he or she so desires, by writing a resignation letter to the President.[579] Similarly, where the President is of the opinion that, it is not in the interest of the nation or the CPC for a member to continue in office, he may remove such member. The CPC may recommend to the President, the removal of any member, where in its opinion, the continuance of such person in the office is not in the national or the CPC's interest.[580]

3.4.4.2 Functions of the CPC

The Consumer Protection Council Act established the Consumer Protection Council[581] which has the responsibility to seek speedy redress for consumers' complaints through negotiation and conciliations. It seeks ways and means of removing or eliminating from the market, hazardous products causing offenders to replace such products with safer and more appropriate alternatives. It encourages manufacturers to adopt more appropriate measures for future production to ensure safe products for consumers' use. In addition, it ensures publication at intervals, of list of banned products by both Nigerian and foreign government, thereby ensuring that an offending company, firm, trade, association or individual protects, compensates, provides relief and safeguards to injured consumers or communities from the adverse effects of any technologies that are inherently harmful, injurious, violent or highly hazardous, organise and undertake campaigns and other forms of activities as will lead to increased public consumer awareness.

The CPC is also to encourage trade, industry and professional associations to develop and enforce in their various fields quality standards designed to safeguard the interest of consumers, issue guidelines to manufacturers, importers, dealers and wholesalers, in relation to their obligation under the CPC Act and finally, to encourage the formation of voluntary consumer groups or associations for consumers' wellbeing.

[578] Section 1(3) CPC Act
[579] Section 1(4) CPC Act
[580] Section 1(6) CPC Act
[581] Section 2 CPC Act

3.4.4.3 Powers of the CPC

In order to carry out its functions effectively, the Council[582] is empowered to:

(a) apply to court to prevent the circulation of any product which constitutes an imminent public hazard;

(b) compel a manufacturer to certify that all safety standards are met in their products;

(c) cause, as it deems necessary, quality tests to be conducted on a consumer product;

(d) demand production of labels showing date and place of manufacture of a commodity as well as certification of compliance;

(e) compel manufacturers, dealers and service companies, where appropriate, to give public notice of any health hazards inherent in their products;

(f) ban the sale, distribution, advertisement of products which do not comply with safety or health regulations.

The Act also provides for the payment of compensation to anyone who is injured by the failure of another to comply with regulations as to the safety of products[583] (drugs inclusive) and prescribes penalty for anyone who contravenes enactments protecting consumers.[584]

The CPC, in carrying out its duties, collaborates with other organisations such as the Nigerian Medical Association, the Nigerian Tobacco Alliance and the Association of Food, Beverage and Tobacco Employers.[585]

The CPC has identified certain challenges in carrying out its duties. These include, the ignorance of many consumers of their rights, difficulty experienced by the Council in

[582] Section 3 CPC Act
[583] Sections 8 and 13, Consumer Protection Council Act.
[584] Sections 11 and 12, Consumer Protection Council Act
[585] The CPC is collaborating with the Nigerian Civil Aviation to seek redress for students of Glisten International College, Abuja from Turkish Airline over the consequences of their delayed flight from

suspending the business activities of big multinationals such as MTN and DSTV in proven cases of abuse of consumers' rights, as well as Federal Government agencies.[586]

3.4.5 United Nations Office on Drugs and Crime (UNODC)

The UNODC was established in 1997, through a merger between the UN Drug Control Programme (UNDCP) and the Centre for International Crime Prevention (CICP). The UNODC is very active on the fight against illicit drugs and international crime. It is also responsible for implementing the UN lead programme on terrorism.

In addition, it works to improve crime prevention and assists with criminal justice reform in order to strengthen the rule of law, promote stable and viable criminal justice system and combat the growing threats of transnational organized crime and corruption.[587]

In fulfilling its purpose, the UNODC has three (3) core programmes, namely, research and analytical work, normative work to assist member states in the implementation of drug conventions and field-based technical cooperation projects. It mobilises and promotes regional and transnational cooperation to confront the growing threat to security posed by the convergence of organized crime, drug trafficking, corruption and terrorism.

In paragraph 8 of its nine point action, Resolution 20/6 of the CCPCJ,[588] requested the UNODC, in accordance with its mandate and in close cooperation with other Nations' bodies and international organisations, such as the International Narcotics Control Board (INCB), the World Health Organisation (WHO), the World Customs Organisation (WCO), and the International Criminal Police Organisation (INTERPOL), as well as relevant regional organisations and mechanisms, national agencies that regulate medicines and, where appropriate, the private sector, civil society organisations and professional associations. To assist Member States in capacity building, to break the organized criminal networks engaged in all stages of the illicit supply chain, especially distribution and trafficking, to put to more coordinated use, the experiences, technical expertise and

[586] Retrieved from www.cpc.gov.ng on 4th November, 2017.
[587] "UNODC" A publication of the United Nations Office in Vienna. Retrieved from www.unov.org on 15th March, 2017.Houston, USA to Abuja.
[588] *Ibid.*

resources of each organization, to create synergies with interested partners, and request Member States and other donors to provide extra-budgetary contributions for the relevant provisions of Resolution 20/6, in accordance with the rules and procedures of the UN.

3.4.6 World Health Organisation (WHO)

WHO came into existence in 1948,its primary role is to direct and coordinate international health within the UN system. Its main areas of work are health systems, promoting health through the life-course, non-communicable diseases, communicable diseases, corporate services and preparedness, surveillance and response. It was established to protect public health and promote access to affordable, safe, efficacies and quality medical products, through effective collaboration among member states and WHO, to prevent and control counterfeit medical products.

The WHO is concerned with providing leadership on matters critical to health and engaging in partnerships where joint action is needed, shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge, setting norms and standards and promoting and monitoring their implementation; articulating ethical and evidence-based policy options, providing technical support, catalysing change, building sustainable institutional capacity; and monitoring health situation and assessing health trends.[589]

It supports member states in coordinating efforts of governments and partners such as bi-laterals and multi-laterals, funds and foundations, civil society organisations and private sector, in attaining their health objectives and national health policies and strategies.

The quality of pharmaceuticals has been a concern for WHO, since its inception in 1948. Art. 2 of the WHO Constitution states that the WHO is obliged to set standards to be implemented with regards to drugs by the Quality Assurance Programme. It is also responsible for setting norms, developing Guidelines and advising WHO member states on

[589] WHO: About. Retrieved from www.who.int on 11th March, 2017.

issues relating to quality assurance of pharmaceutical preparations in national and international markets, with particular emphasis on generic products.[590]

In carrying out its responsibility of quality assurance of pharmaceutical products by combating counterfeit drugs, the WHO established its WHO Member States Mechanism, which is a global forum, for countries to convene, coordinate, decide and organize activities to address counterfeit drugs.[591]The WHO Surveillance and Monitoring System was launched in 2013, to provide technical support in emergencies, link incidents between countries and regions, to issue WHO medical product alerts, and accumulate a validated body of evidence to more accurately demonstrate the scope, scale, harm caused by counterfeit medical products and identify the vulnerabilities, weaknesses and trends.[592]

Other WHO initiatives in respect of counterfeit drugs include, programmes initiated in 1988, in response to WHA Resolution 14.16, for the prevention and detection of the import, export and smuggling of counterfeit drugs; developing a working definition of counterfeit drugs in conjunction with the International Federation of Pharmaceutical Manufacturers'Association (IFPMA) in 1992,[593] the creation of the WHO project on counterfeit drugs in 1994. The project staff conducted several field studies on the occurrence of counterfeit drugs and oversaw the drafting of the WHO Guidelines for the Development of Measures to Combat Counterfeit drugs, published in 1999. In its bid to assist member states in ensuring the quality of drug supply, the International Medical Product Anti-Counterfeiting Taskforce (IMPACT) was inaugurated in 2006.[594]

The WHO is proposing and working on an international convention on combating drug counterfeiting.

3.4.7 International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

[590] Forzley M. 2005. *Combating Counterfeit Drugs: A Concept Paper for Effective International Collaboration*. Retrieved from www.who.int on 12th November, 2015.
[591] "Substandard, Spurious. Falsely Labelled, Falsified and Counterfeit (SSFFC) Medical Products. WHO Factsheet. January, 2016. Retrieved from www.who.int on 13th December, 2016.
[592] *Ibid*.
[593] Forzley M=. *ibid*. p.9
[594] IMPACT: Facts|Activities|Documents. Developed by the Assembly and the Working Groups of IMPACT, 2006-2010. p. 18. Retrieved from www.who.int on 11th February, 2017.

IMPACT was borne out of the need for greater international cooperation in combating counterfeit medical products. The need was noted by the World Health Assembly (WHA) in its Resolution 41.16 of 1988 and reiterated in Resolutions WHA 47.13 of 1994, WHA 52.19 of 1999 and WHA 57.14 of 2004. Consequently, at the WHO conference held in Rome in 2006, IMPACT was set up.[595]

It is a coalition of stakeholders that co-ordinate international activities aimed at combating counterfeit medical products for the purpose of protecting public health.[596] IMPACT is open to intergovernmental organisations and institutions, such as WHO, European Commission, the Commonwealth secretariats, ASEAN secretariat, governmental institutions and agencies, WHO collaborating centres that are competent in combating counterfeit medical products, international non-governmental organisations which are actively involved in combating counterfeit medical products, international association or umbrella organisations representing health professionals such as physicians, pharmacists, nurses, dentists, international associations, or umbrella organisations representing manufacturers, the medical product supply chain, other stakeholders and concerned parties (including technology and service providers) of medical products.[597]The goals of IMPACT are, improving collaboration among governments, organisations, institutions, agencies and associations which are engaged in combating counterfeit medical products at the national, regional and or international levels; raising awareness among national and regional authorities and decision makers with a view to calling for effective legislative measures in order to combat counterfeit medical products; establishing mechanisms for the exchange of information and to provide assistance on specific issues pertaining to combating counterfeit medical products; developing technical and administrative tools to support the establishment or strengthening of international, regional and national strategies and encouraging and facilitating co-ordination among different anti-counterfeiting initiatives.[598]

[595] IMPACT: Facts|Activities|Documents. Developed by the Assembly and the Working Groups of IMPACT, 2006-2010. Retrieved from www.who.int on 11th February, 2017.
[596]*Ibid*. p. 19
[597]*Ibid*. para. 1.3.5. p. 20
[598]*Ibid*. para. 1.1.2. pp. 9-10

IMPACT is administered by WHO. It provides participants with the platform for discussing matters which fall within its terms of reference. In addition, it formulates proposals and recommendations to be adopted through a consensus-based approach, and published. These constitute a reference for guidelines, official policy, other actions, as appropriate under the responsibility and according to the prerogative, mandate and internal rules and procedures of each such participating governments, organisations, institutions, agencies and associations.[599]

It is however not a legal entity. It therefore cannot take any action, unless it is agreed to in writing, by all participants. In the same vein, all participants must also consent to its representation at any fora, by an individual participant.

In this chapter, the international, regional and national legal and institutional frameworks for drug counterfeiting in Nigeria were examined. With regards to the regional and international legal instruments, they can be grouped into soft laws and hard laws. Soft laws refer to rules that are neither strictly binding in nature nor completely lacking legal significance. It encompassed non-binding or voluntary resolutions, recommendations, code of conduct and standards. Hard laws on its part, are the actual binding legal instruments and laws. They give parties binding responsibilities as well as rights.

As noted earlier, Nigeria has a dualist approach in receiving international law. Treaties and convention have to be domesticated before they can be applicable.[600] With the exception of the African Charter which has been domesticated, no other UN instrument, having direct bearing on the right to health, is enforceable.

The General Comment states that, the right to health has a "core content" which prescribes the minimum essential level of the right. Attaining this level is however a national task and the key elements are set out to guide the priority setting process. The core content include, essential primary health careminimum essential and nutritious food, sanitation, safe and potable water and essential drugs.

[599] *Ibid*. para. 1.1.4. p.10
[600] See fn.103.

States are also expected to adopt and implement national public health strategy and plan of action. This must address the health concerns of the whole population; be devised, and periodically reviewed, on the basis of a participatory and transparent process; contain indicators and benchmarks by which progress can be closely monitored; and give particular attention to all vulnerable or marginalized groups.

It is expected that State Parties move forward in line with the *principle of progressive realization.*[601]Consequently, State Parties should take deliberate, concrete and targeted steps forward, using the maximum available resources. These resources include those within a State as well as resources available through international assistance and co-operation. In this context, it is important to distinguish the inability from the unwillingness of a State Party to comply with its right to health obligations.

From the foregoing, it can be said that Nigeria has made efforts in fulfilling its obligation relating to the right to health, in line with the General Comment No. 14. Legislation, policies, guidelines, institutions and health systems are in place. There is also evidence of international collaboration.

With regards the obligation to respect, protect and fulfil the right to health, vis-à-vis drug counterfeiting, it appears that Nigeria has done a lot. One can conclude that the machinery for ensuring that citizens enjoy the right to the highest attainable health is in place. The failure to accomplish this, which is evident in the availability of counterfeit drugs, can be safely attributed to enforcement challenges.

TABLE OF LEGISLATION ON RIGHT TO HEALTH AND DRUG COUNTERFEITING

[601]General Comment No. 14 to ICESCR– The Right to the Highest Attainable Standard of Health.

Laws/policies	Relevant Sections
National Health Act, 2014	All Nigerians are entitled to a basic minimum package of health services.[602]
Constitution of Federal Republic of Nigeria,1999	The right to health is guaranteed by section 17(c) & (d) of the Nigerian 1999 Constitution (as amended) which states: The State shall direct its policy towards ensuring that: (c) the health, safety and welfare of all persons in employment are safeguarded and not endangered or abused; (d) (d) there are adequate medical and health facilities for all persons.
Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act	Prohibits sale and distribution of counterfeit, adulterated, banned or fake, substandard or expired drugs or unwholesome processed foods; and of sale, manufacture and display of drugs or poisons in certain premises or places.
The Nigerian Health Policy, 2014	It provides for a protective health and access to quality and affordable health care which is a human right. It also provides for equity in health care and in health for all Nigerians.[603]
Child rights Act, 2004	Section 13 of the Childs Rights Act provides for the

[602] Part III, Section 20 of the National Health Act 2014
[603] National health policy, 2004

	right to health and health services. Section (1) Every child is entitled to enjoy the best attainable state of physical, mental and spiritual health. (2) Every Government, parent, guardian, institution, service, agency, organization or body responsible for the care of a child shall endeavor to provide for the child the best attainable state of health. (3) Every Government in Nigeria shall- (a) endeavor to reduce infant and child mortality rate; (b) ensure the provision of necessary medical assistance and health care services to all children with emphasis on the development of primary health care; (c) ensure the provision of adequate nutrition and safe drinking water; (d) ensure the provision of good hygiene and environmental sanitation; (e) combat disease and malnutrition within the framework of primary health care through the application of appropriate technology; (f) ensure appropriate health care for expectant and nursing mothers; and (g) support, through technical and financial means, the mobilization of national and local community resources in the development of primary health care for children; (4) Every parent guardian or person having the care and custody of a child under the age of two years shall ensure that the child is provided with full

	immunization. (5) Every parent, guardian or person having the care of a child who fails in the duty imposed on him under subsection (4) of this section commits an offence and is liable on conviction for- (a) a first offence, to a fine not exceeding five thousand naira; and (b) second or any subsequent offence, whether in respect of that child or any other child, to imprisonment for a term not exceeding one month. (6) The Court may make, in substitution for or addition to any penalty stipulated under subsection (5) of this section, an order compelling the parent or guardian of a child to get the child immunized.
Food, Drugs and Related Products (Registration, etc.) Act	Prohibits the manufacture, importation, exportation, advertisement, sale or distribution of processed food, drugs, drug products, cosmetics, medical devices or water in Nigeria, unless it has been registered in accordance with the provisions of the Act or regulations made under it
Food and Drug Act	Prohibits the sale, importation, manufacture or storage of any article of food or drug which is adulterated, and the sale, importation, manufacture of any article of food or drug which is manufactured, preserved, packaged or stored under insanitary conditions,
Criminal Code Act	Makes it an offence to sell food or drink, or to intend to sell food or drink, when same is unfit for consumption

Penal Code Act	Section 188 makes provision in respect of sale of noxious food or drink; adulteration of drugs or medical preparations.
Pre-Shipment Inspection Imports Act	Makes provision for mandatory pre-shipment inspection for all imported goods.
Pre-Shipment Inspection of Exports Act	makes provisions for the inspection of goods in Nigeria prior to their shipment to a place outside Nigeria. Section 6 makes provisions for inspection of Pharmaceutical products. With regards to inspection of pharmaceutical products, the inspecting agent shall, restrict the pre-shipment inspection to the inspection of the expiry date, cost of the products to be exported, and ensuring that the products conform with the active ingredients and chemical requirements specified by overseas buyers.

Table 2. Laws to protect the right to health.

CHAPTER FOUR

LEGAL REMEDIES AND REDRESS MECHANISM FOR DRUG COUNTERFEITING

Drug Counterfeiting is a global problem which has wide ranging consequences for global health.[604]However, the production of counterfeit drugs is still very much under reported, despite its menace. Drug counterfeiting is an important cause of unnecessary and unavoidable morbidity, mortality and loss of public confidence in medicines and health structures.[605]It is also a violation of the right to health of citizens. This raises the need for remedies which may or may not accrue to its victims. These remedies are available in different areas of the law, both under common law principles and statutory law. These form the subject matter of thischapter.

4.1 Common Law Principles

Where a person buys a product, and it is either defective or does not comply with specification or description, or it is unsuitable for the purpose for which it was bought, the question arises as to whether he/she can recover all his money or in part or whether they are entitled to any remedy, such as damages. This scenario raises issues in contract, consumer protection, and product/manufacturer's liability.

This question arises, regardless of who purchased or where they bought the products from. This section examines issues which can be classified under the law of contract, tort and criminal law. Issues such as privity of contract, misrepresentation, tort of deceit, negligence, corporate criminal liability, product liability will be discussed.

[604] Mackey T K and Liang B A. 2011. The Global Counterfeit Drug Trade: Patient Safety and Public Health Risks. *Journal of Pharmaceutical Sciences*. Vol. 100, Issue 11, pp. 4571-4579

[605] Cockburn R, Newton P N, Agyarko E K., Akinyuili D and White N J. 2005. The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers. *Plos Med*. 2940:e100. (vol. 2. Issue 4, e100).

4.1.1 Contract

A contract is a promise or a set of promises that is/are legally binding. For an agreement to be legally binding, it must have been given in exchange for something in return. According to Treitel, a contract is an agreement giving rise to obligations which are enforced or recognised by law. What distinguishes contractual obligations from others is that the former are based on the agreement of the contracting parties.[606]

With regards contractual issues in the type of transaction highlighted above, certain contractual principles are involved. These are the doctrine of privity of contract, caveat emptor, freedom of contract and misrepresentation. These will be discussed below.

4.1.1.1 Privity of Contract

This doctrine states that only parties to a contract can take a right or assume an obligation under it. A person who is not a party to a contract cannot sue on the contract, even though the contract was made for his benefit. In the same vein, a contract, as a general rule cannot confer enforceable rights or impose obligations arising under it on any person except those who are parties to it.

The principle of privity of contract is based on the fact that only parties[607] to a contract may sue and be sued on it. In *Dunlop Pneumatic Tyre Co. Ltd.v. Selfridges Ltd,*[608] where the Plaintiffs had sold tyres to Dew & Co, on terms that Dews would not resell them at less than the P's list prices and that, if they resold them to trade buyers, they would extract a similar undertaking from the trade buyers. Dew resold the tyres to Selfridges who agreed to observe the restrictions and to pay to Dunlop five pounds (£5) for each tyre sold in breach of the agreement. Selfridge supplied tyres to two customers at below list price, and Dunlop sought to recover two sums of five pounds (£5) each as liquidated damages.The court held that one of the fundamental principles of law is that of privity of contract. It

[606] Treitel G H. 1983. *The Law of Contract*. 6th Edition. London. Stevens & Sons. p.1.
[607] The parties to a contract are those whose communication with each other brings an agreement into existence. See Yerokun, O. 2015. *Casebook on Law of Contract*. Lagos. Princeton & Associates Publishing Co. Ltd. p. 382.
[608] (1915) AC 847 at 853.

noted further that the principle of *jus quaestium tertio,*[609] do not arise under contract law. This right may however be conferred by way of property, for instance, under a trust, but not on a stranger to a contract as a right *in personam*[610] to enforce a contract. It can thus be observed that the law of contract recognises the equal bargaining power of the parties, as they are free to vary or discharge their obligations as they deem fit. Introducing third party rights to a contract situation will impede the freedom of the contracting parties.

In *Mercantile Bank of Nigeria Ltd .v. Abusamwan*,[611] the Plantiff/Respondent claimed One Million Two Hundred and Twenty Four Hundred Thousand, Seven Hundred and Twenty Nine Naira, Forty Kobo (₦1,224,729.40) against the Defendant/Appellant, as damages for loss of profit which he incurred as a result of the negligence of the Defendant/Appellant to ensure that a contract entered into between him and some other persons for the supply of cement from overseas was strictly performed. The respondent entered into a contract for the importation of cement with a group of persons. One Mr Tucker was a member of the supply group. The Defendant/Appellant bank gave a guarantee that all shipping documents relating to the cement consignment would be handed over to the Plaintiff/Respondent. The Consignment of five thousand (5,000) bags of Portland cement was actually shipped to Sapele Port which was the port of discharge. The Plaintiff/Respondent did not get all the Plaintiff/Respondent of the receipt of the shipping documents in respect of the cement shipment. Mr Tucker had taken delivery without the shipping documents. The court held that, only a party to a contract can sue or be sued for a breach of contract and that a person who is not a party to a contract, although the contract was made for his benefit, cannot sue on the contract.

Similarly, it was held in *Alfotrin Ltd.v. Attorney-General, Federation and Anor*[612], that an individual cannot make a claim in the contract thereof, unless he is privy thereto or has acquired some legal interest, say, by way of assignment of any rights thereunder. The

[609] 'Rights on account of a third party'
[610] 'against a person for the purpose of imposing a liability or obligation'. See Webster Dictionary. Retrieved from www.merriam-webster.com/dictionary/inpersonam on 30th June, 2017.
[611] (1986) 2NWLR 270; see also, *UBA PLC and anor .v. Alh. Babangida Jargaba*(2007) 5SCNJ 127; *Oshevire Ltd .v. Tripoli Motors* (1997) 5 NWLR 1 and *Chief S. O. Agbareh and Anor .v. Dr Anthony Mimra and 2 Ors* (2008)1 SCNJ 409.
[612] (1996) 9 NWLR 634.

doctrine of privity of contract is that a contract cannot confer rights or impose obligations on a stranger to it. In the same vein, a contract affects only the parties to it and cannot be enforced by or against a person who is not party thereto, even if the contract was made for his benefit and purports to give him the right to sue to make him liable on it. In the instant case, the appellants being total strangers to the contract may not establish a case in contract against the respondent.

In the same vein, a person who is not a party to a contract, cannot be made liable under that contract. In *Ilesha Local Planning Authority (LPA) .v. Olayide,*[613] the respondent was appointed by the Governor of Oyo State under an enabling law as the Chairman of the appellant authority. Under the relevant law, the authority could not appoint or dismiss its Chairman. This power was vested in the governor, acting on behalf of the state. When subsequently the governor relieved the respondent of his appointment, he turned round to sue the authority for breach of contract and arrears of salaries unpaid after his removal. The action was declared invalid by the Court of Appeal. The court held that even though the Respondent was party to a contract of employment, the other party to it was the government of Oyo State, and not the appellant authority. The latter not being privy to the contract of employment between the respondent and the Oyo State government, it could not be sued and made liable for its breach.

Consequently, a purchaser of a counterfeit or substandard drug will only have a course of action against the seller. This doctrine eliminates such a buyer/consumer from having a claim in respect of counterfeit/ substandard drugs, bought or used by him, if he was not a party to the original contract for the supply of goods. This is so, even if by extension one can argue that the contract between the seller and the manufacturer was entered into for the benefit of the end user.

There are however exceptions to this rule. These are in the area of agency, novation, contracts running with land, charter parties and special application of trust concept in

[613] (1994) 5NWLR (Pt 342) 91.

equity. In *UBA PLC .v. Ogundokun,*[614] where the Respondent's friend had sent her a sum of Four Thousand and Two Hundred Dollars ($4200) through Western Union to be delivered to her by UBA in Ilorin. The Appellant through her negligence released the amount to another person who pretended to the Appellant to be Mrs Funmilayo Ogundokun, at their Surulere Branch in Lagos on 15th November, 2005. The Respondent however turned up at the Ilorin Branch of the Respondent to claim the same money on 16th November, 2005. The amount was on that date, to her surprise and chagrin, no longer available.

The Appellant argued that it had followed all the routine and procedure for transfer of money through Western Union before releasing to the beneficiary. The tests applied before releasing such money are amongst others getting the correct name of the beneficiary using the National Driver's Licence to identify her; asking her the test questions; relying on the correct transfer code supplied by the paid beneficiary. The Appellant alleged that the beneficiary passed these tests before the said money was released to her.

Consequently, the Respondent filed an action against the Appellant. The trial court granted the Respondent's claim as prayed, together with general damages of Seven Hundred and Fifty Thousand Naira (₦750,000). Aggrieved, the appellant appealed and contended that the respondent was a stranger to the contract and therefore could not maintain an action either in contract or in tort.

The court on appeal held on the doctrine of privity of contract and exception thereto that, as a general rule, a contract affects only parties thereto and cannot be enforced by or against a person who is not a party to it. The rule admits of a number of exceptions,[615] which includes a case of undisclosed principal who is entitled to sue or is liable to be sued on such a contract. In addition, facts which constitute a breach of contract between two persons may in some cases give rise to a claim in tort in respect of injury or damage suffered, if the breach also constituted a breach of a duty of care owed apart from the contract.

[614] (2009) 6 NWLR 450.
[615] In view of the fact that the exceptions do not apply to the topic under discussion, they will only be mentioned and not discussed here.

Given that drug counterfeiting may give rise to a claim in tort, it will, as noted in the case above, fall within the category of exceptions to the rule, giving the victim, though not a party to the contract, a right of action (a claim in tort) against the manufacturer.

The doctrine of privity of contract has been said, and the writer quite agree, to be a severe limitation on the efficacy of consumer rights given that only an individual who obtains goods directly from the supplier has a right of action against the latter, where the goods are found to be unsatisfactory. In this instance, the victim of a counterfeit drug is left with no redress from the manufacturer. The situation may however be different, where the manufacturer gives an express guarantee/warranty to the consumer. In such situation, the consumer will have a right of action against the person who gives the guarantee, namely, the manufacturer/producer and not the person, through whom the latter might have given the guarantee.[616]

4.1.1.2 The Doctrine of Caveat Emptor

This doctrine enjoins a buyer to "shine his/her eyes",[617] when conducting any transaction. It is expected that a buyer would have examined, tested, measured, weighed or done all that is necessary before making a purchase, as he would not be entitled to reject the goods, nor will he be entitled to any remedy should he find them defective subsequently.

With regards to buying drugs in Nigeria, there is the Mobile Authentication Service (MAS), which allows consumers to verify a product by simply sending a free text message (SMS) to a phone number. The drug comes with a code which is forwarded through a text message to a verification centre and the consumer gets a report on its authenticity. This technology has been seen as a help to the consumer. However, given that the networks of mobile telephone services are not always functional, what happens where a consumer intends to buy a drug, scratches the packaging, sends the SMS, but the reply does not come as expected. Will he be liable to pay for the drug or will the seller be expected to be

[616] See *Carllil .v. Carbolic Smoke Ball Co*. (1893) 1 QB 256. The effect of the decision in the *Carllil* case was to construe the existence of a collateral contract to the original sale contract, between the consumer and the manufacturer, where there was no privity of contract.

[617] This is NAFDAC's catch phrase for its pharmacovigilance programme. It means "be on guard/alert/watchful".

magnanimous enough to accept the product. Knowing our environment, more often than not, the seller will insist on his money seeing that he will not be able to sell the product, which has not been ascertained as a counterfeit.This problem will be more obvious where the manufacturer fails to change the medicine or refund the seller due to the fact that the medicine has been proved to be an original.

Exceptions to the caveat emptor principle would include situation of fraud, mistake and express guarantee/warranty. In such situations, the purchaser may have a right of action.

In *Wells Ltd .v. Buckland S S Ltd,*[618] it was held that a seller is not obliged to disclose to the buyer any defect that there may be on the goods and that no warranties would be implied as an incident of such contract. In this specific case the plaintiffs were chrysanthemum growers and bought sand from a third party that was produced by the defendants. This sand was purchased on the undertaking from the defendants over its iron oxide content. This undertaking proved to be incorrect and the plaintiffs sued on the basis of the loss suffered. It was held that they could claim damages, even though no main contract was in existence, due to the fact that one was in contemplation.

However, in *Jones .v. Bright,*[619] the court noted that there was a necessity for laws to be put in place to protect persons who are ignorant of qualities of a commodity from fraud, and to make it the interest of the manufacturers and those who sell to furnish the best article that can be supplied. This decision led to the development of the doctrine of implied terms which came to be codified in the Sales of Goods Act.

4.1.1.3Freedom of Contract

The doctrine was developed in the 19th Century, when judges were of the opinion that persons of full capacity could make contracts as they liked. The law could only interfere on grounds such as misrepresentation, undue influence or illegality.[620]It allows the parties to provide for the terms and conditions that will govern the relationship. This doctrine is

[618] (1965) 2 QB 170 at 180
[619] (1892) 5 Bing. 535
[620] Treitel G H. 1983. *The Law of Contract*. 6th edition. Stevens & Sons. London. p.2.

hinged on two (2) principles, that contracts are based on mutual agreement and that the creation of a contract was the result of a free choice, made exclusively without external influences, which includes government and legislature.[621]

In reality, however, it can be said of a customer who contracts on standard terms, that he/she had the terms imposed on them, rather than agreeing to them, especially where the seller has monopoly, or where all the suppliers in a particular field use the same standard form. In such circumstance, the customer either accepts the terms, or does without the subject matter of the contract.

The doctrine of freedom of contract was endorsed in *Mercantile Bank of Nigeria Ltd .v. Adalma Tanker, & Bunkering Services Ltd*[622]where the court held that the parties are bound by their agreement and the court will not rewrite the contract for the parties.

However, according to Sagay,[623] in a developing country like Nigeria,

> in which standards of production of goods and other conditions for the protection of the consumer have either not been established or if established remain unimplemented or unenforced, the rejection of any right to be protected against consequences of a fundamental breach of contract is surely to be welcomed. …an unrestricted principle of freedom of contract would be dangerous and contrary to the public interest at the present stage of Nigeria's industrial and commercial development and culture.

In the opinion of the writer, it is rare for parties to a contract to have equal bargaining power. Can it be said that an ailing consumer, who is desperate to get well have equal bargaining power with a pharmaceutical company? Consequently, freedom of contract is workable only if the parties to a potential contract have equal bargaining power, otherwise, the concept is a myth.

---

[621] "Freedom of Contract: Law and Legal Definition". Retrieved from https://definitions.uslegal.com on 16th June, 2017.
[622] (1990) 5 NWLR (Pt. 153) 747. CA
[623] Sagay I E. 2000. *Nigerian Law of Contract*. Spectrum Books Ltd. Ibadan. p. 195

4.1.1.4 Misrepresentation

Misrepresentation is untrue statement made by one party to another before or at the time of contracting with regard to some existing fact or to some past event which is one of the causes that induced the contract.[624] It is an amalgam of common law and equity.[625] Equity fills the gap created by the narrow common law defence of fraud and supplements the inadequate common law remedies for misrepresentation.[626]

Misrepresentation can be found in tort and in contract. Most times, the fields intercept one another[627]. Under the law of contract, misrepresentation usually associates with terms of a contract and mistake, forming part of rules that affect the nature and extent of contractual undertakings.

Misrepresentation is usually raised in relation to the effect of pre-contractual statement on the contract. For instance, a manufacturer of a drug which he declares to meet the approved standard for curing malaria. B buys the drug, only to find the statement to be untrue as the drug is substandard. What remedies, if any, are available?

Initially at common law, under the principle of promissory statement, misrepresentation will be ineffective unless it forms parts of the contract. This had not been satisfactory, as it had not always been easy determining when a statement is to be treated as forming part of the contract. Secondly, the courts have been reluctant to hold apparently serious undertakings to be terms of the contract.[628]As a result of the foregoing, the concept of "mere representation", a statement of fact which had induced the representee to enter into the contract but which did not form part of the contract, was developed.[629] Consequently, at common law, the remedy for fraudulent misrepresentation was rescission, while damages was granted in tortious action of deceit.

---

[624]*Ibid*. See also *Abba .v. Mandillas & Karaberis Ltd* (1964) 2 ALR Comm. 337
[625] Furmston M P (ed.) 1986. Chesire, Fifoot and Furmston. (1986). *Law of Contract*. (11 ed.) London. Butterworth
[626]*Ibid.* p. 256
[627]*Ibid*. p. 256
[628] See *Oscar Chess v. Williams* [1957] 1 All ER 325 and *Beale v. Taylor* [1967] 3 All ER 253.
[629]*Ibid*.

By the 19th Century equity developed a general remedy of rescission for all misrepresentations that induced contract.[630] The right to rescind however has its limitations. In the same vein, equity can only grant indemnity as opposed to other financial compensation and this is in circumstances.

Pre- 1963, a fundamental principle of law was that, there could be "no damages for innocent misrepresentation".[631] In this instance, "innocent" was interpreted to simply mean "non-fraudulent". Before the decision in *Hedley Byrne & Co. Ltd. V. Heller & Partner Ltd*[632], actions for damages based on a pre-contractual statement must show either that the statement was fraudulent or that it was a term of the contract.[633]

Misrepresentation could take the form of mistake. In *Couturier v. Hastie*[634]where the defendant's assertion of having a cargo of corn, at the relevant time, but unknown to him the corn had been sold, was construed as an innocent misrepresentation. Similarly, in*Cooper v. Phibbs*[635] the defendant assumed that he had the right to sell a fishery to the defendant. Unknown to him, the fishery belonged to the Plaintiff. In the same vein, in,*Leaf v. International Galleries*[636]where the defendant sold a painting, which he believed was the original of a famous painter, to Plaintiff. The painting had actually been, though unknown to him, a cheap limitation.The above amounted to misrepresentation by the defendant, even though they constituted mistakes in the law of contract.

In Nigeria, misrepresentation is governed by a combination of common law and equity rules. An illustration of this can be found in the area of remedies where victims of innocent misrepresentation have no remedy under common law but are entitled to rescission in equity and victims of fraudulent or negligent misrepresentation are however entitled damages and rescission at common law.[637] Equity, however also grants the remedy

[630]*Ibid*.
[631] per Lord Moulton in *Heilbut, Symons & Co .v. Buckleton* (1913) AC 30 at 49.
[632] (1964) AC 465
[633]*Ibid*. p. 257
[634] (1856) 5HLC673
[635] (1867) LR 2 HL 149
[636] (1950) 2KB 86
[637]Sagay I E. *Ibid*. p.296

of indemnity which is in no way equivalent to damages, uncertain and generally inadequate and unsatisfactory.[638]

In the UK however, with the promulgation of the Misrepresentation Act of 1967, damages may be granted in lieu of rescission, however, the onus is on the representor to prove that he was not negligent in making the statement with regards to innocent misrepresentation. The representee has the right to rescind the misrepresentation even though a contract has been performed.[639]

One may ask, what is misrepresentation?

A representation is a statement of fact made by one party (Representor) to the other (Representee) which though not a term of the contract, induces the representee to enter into the contract. A misrepresentation is therefore an untrue statement of fact/representation. The representor's state of mind and degree of carefulness are only relevant in determining the type of misrepresentation. A representation is not a statement of opinion, intention or law but a statement of fact. It relates to an existing fact or a past event, *a factum*[640], as opposed to *a faciendum*.[641]

A person, who alters his position based on a misrepresentation, would be entitled to certain remedies. On the other hand, where a person institutes an action based on what in truth is a promise, he must show that the promise forms part of a valid contract.[642] In *Maddsion.v. Alderson*, the Plaintiff, who was prevented by the statement of frauds from enforcing an oral promise to devise a house, contended that the promise to make a will in her favour should be treated as a representation which would operate by way of estoppel. The court in dismissing the argument, noting that,

---

[638] Sagay. *Ibid*. p. 296.
[639] See also the 1989 edition of the contract edit of 1989 of Kaduna State provides that the court can refuse the remedy of recession and instead award damages, if it will be equitable to do so.
[640] A statement fact of a case.
[641] Something that must be done. See Spencer, Bower and Turner. *Actionable Misrepresentation* (3rd edition) p. 42 referred to in Furmton, et al. *ibid*. p. 258
[642] Ibid. p. 258. see also (1883) 8 App Cas. 467

> the doctrine of estoppel by representation is applicable only to representations as to some state of facts alleged to be at the time actually in existence, and not to promises *de futuro* which if binding at all, must be binding as contract[643].

While a statement of intention is not regarded as a representation/statement of fact, the state of an individual's mind, if ascertained is a statement of fact. Bowen LJ in *Edgington v. Fitzmaurice*[644]noted that,

> The state of a man's mind is as much a fact as the state of his digestion. It is true that it is very difficult to prove what the state of a man's mind at a particular time is but if it can be ascertained it is as much a fact as anything else. A misrepresentation as to the state of a man's mind is, therefore, a misstatement of fact.

In the Fitzmaurice case, a company had issued a prospectus which invited a loan from the public or stated that the money would be employed in the improvement of the business premises and expansion of the business.

Their intention however was to use the money to discharge certain existing liabilities. It was held that the prospectus was a fraudulent misrepresentation of a fact and that the company had not made a promise which they might or might not fulfil; they had simply told a lie. One cannot misrepresent one's state of mind except dishonestly.

An expression of an opinion which is a statement based on grounds incapable of actual proof, is not a representation of fact, and in the absence of fraud, its falsity does not entitle the injured party to relief.[645] In *Bisset v. Wilkinson,*[646] the vendor of a holding in New Zealand, which had not previously been used as a sheep farm, told a prospective purchaser that in his judgement, the carrying capacity of the land was 2,000 sheep.

It was held that this was an honest statement of opinion of the capacity of the farm, is not a representation of its actual capacity. However, where it has been proved that the opinion was not actually held, or that it was expressed upon a matter on which the speaker was

[643]Supra at p. 473
[644] (1885) 29 Ch D 459 at 483
[645]*Ibid* . p. 259
[646] (1927) AC 177.

entirely ignorant, an expression may constitute a representation of fact. Similarly, in *Teriba .v. Adeyemo*,[647]where the Plaintiff/Appellant instituted an action against the Defendant/Respondent, seeking a declaration of title over a piece of land situated at Jokodo, Akufor Road, Ibadan, general damages for trespass and injunctive orders restraining the latter from further trespassing on the land. The trial court granted the appellant's claims and awarded Two Hundred and Fifty Naira (₦250), being damages for trespass by the Respondent on the land in dispute. The Respondent's counter claim was dismissed. On appeal it was held that, a statement of fact honestly made by a party cannot be held to be a misrepresentation, simply because it turns out not to be quite correct. To constitute a misrepresentation, the misrepresentor and the misrepresentee must be distinct from one another. Thus, where a person who claims to have been deceived by a misrepresentation is in effect the same person who is alleged to have made it, then there is no misrepresentation in law.

In *Smith .v. Land and House Property Corporation*,[648] Bowen L J noted as follows;

> It is often fallaciously assumed that a statement of opinion cannot involve the statement of fact. In a case where the facts are equally well known to both parties, what one of them says to the other is frequently nothing but an expression of opinion… But if the facts are not only well known to both sides, then a statement of opinion by the one who knows the facts best involves very often a statement of a material fact, for he impliedly states that he known facts which justify his opinion.

Consequently, if it can be proved that the speaker in making the representation, did not hold the opinion or that a reasonable man possessing his knowledge could not honestly have held it, or that he alone was in a position to know the facts on which the opinion must have been based, then there is a misrepresentation of fact for which a remedy is available.[649] Similarly, where an opinion is stated as a fact, for instance, where a

[647](2010) All NWLR (Pt. 533) 1868 at 1872
[648] (1884) 28 Ch D 7 at 15.
[649]*Brown v. Raphael* (1958) Ch. 636; [1958] 2 All ER 79.

company's promoters published a forecasts of experts as positive facts in their bid to magnify the future earning capacity of a mine, there will be a misrepresentation of facts.[650]

A representation does not render a contract voidable unless it was intended to cause and has indeed caused the representee to enter into the contract. Consequently, a misrepresentation would not have caused harm, if the Plaintiff;[651]

(a) never knew of its existence;

(b) did not allow it to affect his judgement; or

(c) was aware of its untruth.

From the foregoing, for the misrepresentation to be actionable, it must have an effect on the Plaintiff's mind. It will not have an effect on the plaintiff's mind if he was not aware of it. In *Northumberland and Durham District Banking Company, exp. Bigge,*[652]a shareholder had pleaded that he had been induced to acquire shares by a misrepresentation. His action failed on the ground that he was not able to prove that, even though there was a false report in respect of the company's finance, he had read it or that he was aware of its content. Where the representee's judgement was not affected by the misrepresentation, even though it was intended to have affected his judgement, it cannot become a ground for relief. In *Smith v. Chadwick,*[653]the representee regarded the alleged misrepresentation as unimportant. On the other hand, he might have opted to rely on his own business sense or an independent report which he specially obtained.

Knowledge of the untrue and fraudulent statement will prevent the aggrieved party from successfully claiming the relief.[654]For relief to be withheld, it must be proved that the

[650]*Reese River Silver Mining Company Ltd .v. Smith*(1869) LR 4HL 64.
[651]*Locit* p. 262 – 263
[652] (1858) 28 LJ Ch. 50; See also*Horsfall v. Thomas*(1862)1 H& C 90
[653] (1884) 9 App Cas. 187 at 194. See*Attwood v. Small*(1838) 6 CI & F.232, where a buyer of a mine had employed independent investigators to look into the vendor's statement in respect of the earning capacity of a mine and it was held that the buyer could not rescind the contract on the basis of misrepresentation.
[654]*Domingo v. Boughton*(1854) 5 De GM & G. 126

Plaintiff possessed actual and complete knowledge of the true facts.[655]The Defendant, on his/her part, must show that the Plaintiff had unequivocal notice of the truth.

The mere fact that the aggrieved party has been afforded an opportunity to investigate and verify a representation does not deny him of his right to resist specific performance or to sue for rescission.[656]Similarly, Lord Dunedinin *Nocton v. Lord Ashburton,*[657]observed that,

> No one is entitled to make a statement which on the face of it conveys a false impression than excuse himself on the ground that the person to whom he made it had available the means of correction.

There is a duty to disclose between persons who are in a fiduciary relationship. This is because the law assumes that one person is in a superior position to the other and the trust and confidence of that other is reposed in him. Where there is a contract, it is possible for the person that is in superior position to take advantage of the other party. Consequently, the court will declare a contract based on misrepresentation, voidable and susceptible to rescission by the other party. It is not essential for absence of honesty to be present. All that is essential is in the failure to disclose a material fact to the second party. In *Tate v. Williamson,*[658] an undergraduate in financial difficulty, followed his tutor's advice and sold some of his land to the latter. The tutor had known, but had failed to disclose to the student, that there were mineral deposits on the land and bought the land for half of its market value. Following his death, his executors brought an action, challenging the validity of the agreement. It was held that the tutor was guilty of constructive fraud, and that the agreement was voidable at the instance of the infant's executors.

Other types of fiduciary relationships include, parent and child, doctor and patient, a clergyman and members of his congregate, solicitor and client, trustee and cestui que trust (beneficiary), principal and agent, partners, a company and its promoters.

---

[655] Actual not constructive, complete not fragmentary.
[656]*Redgrave v. Hurd*(1881) 20 Ch. D 1
[657] (1914) AC 932 at 962
[658] (1886) LR 2 Ch. App. 55.

For an action in misrepresentation to succeed therefore, the misrepresentation must consist of facts, past or present not a statement of opinion, intention or law. In *Udogwu v. Oki,*[659] the Appellants granted fishing rights in their pond to the respondent for a period of ten (10) years. The fish pond, unknown to them was jointly owned by the appellants and another family, who had also granted fishing rights to another party for ten (10) years. Both parties had to share the use of the fish pond for the period.

The respondent instituted an action claiming that the appellants' non-disclosure of the fact that the pond was jointly owned and amounted to fraudulent misrepresentation. They also argued that they had 'orally' negotiated for another ten (10) years with the appellants who brought an action for re-possession of the ponds and mesne profits for the period when the respondents were in wrongful possession. The trial court held in favour of the respondent. On appeal, the court in explaining what amounted to fraudulent misrepresentation, noted that where two (2) people are in the course of entering into a contract, and one of the parties makes an untrue representation in point of fact, knowing it to be untrue, at the time, and the other party is induced by the untrue representation, then, the latter has a right of action at law for damages on the deceit and a relief in equity, is available to the latter to rescind the contract. The court held that the respondent had failed to seek the proper remedy which was damages and rescission. Varying or amending the contract was not an appropriate remedy. Consequently, the appeal succeeded.

In *Nidogas Co. Ltd .v. Augusco Nig. Ltd*,[660] where there was implicit in the nature of the contract the duty of care to disclose full particulars considering the nature of the assignment of the respondent. The respondent's pleadings brought out most succinctly the whole facts as to how he was misled by the appellant, whose false representation induced the respondent to undertake the contract in the manner it was done and which caused considerable damages. It was held that where there is a contract and there is implicit in the nature of the contract an obligation to tell the truth or represent the true facts of the case,

[659] (1990) 5 NWLR (Pt 153) P. 271. See also *Dantata .v. Mohammed* (2013) All FWLR (Pt. 675) 279, where the court held that a misrepresentation must be an unambiguous false statement of existing fact. A statement of intention is not a statement of fact, nor is a promise a statement of fact. A person who fails to carry out his stated intention does not thereby make a misrepresentation.
[660](2001) 16 NWLR 268.

there is implicit in the nature of the contract the duty of care to disclose full particulars.And the question whether a representation was made or not should be decided on the civil standard of preponderance of evidence.

With regards misrepresentation and counterfeit drugs, the manufacturer of a counterfeit or substandard drug can be said to have made a misrepresentation of fact. This can be deduced from the fact that both on the packaging and instruction leaflet, he/she would have made claims relating to the ingredients and the efficacy of the drug, knowing the claims to be false. The claims would likely have induced the buyer to buy the drugs. Consequently, the buyer would be entitled to rescind the contract or bring an action for damages.

4.1.2 Common Law and Statutory Template for the Prosecution of Drug Counterfeiting in Nigeria

Criminal Law as a means of protecting the consumer against counterfeit and substandard drugs, concerns the safety and health of the consumer. In achieving this, numerous legislations have created liability in relation to certain activities provisions for safety standards and procedures, providing for penalties for violation.

These can be said to have made provisions for safety standards and procedures, providing for penalties for violation. In this section of this chapter, the relevant statutory provisions will be examined, and the common law issues discussed. Certain offences in relation to drug counterfeiting are strict liability offences.

4.1.2.1 Statutory Provision

4.1.2.1.1 The National Agency for Food and Drug Administration and Control Act

This Act[661] established the National Agency for Food and Drug Administration and Control to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals.[662]

[661] *Ibid*, fn. 1

[662] Preamble to the NAFDAC Act, CAP N1, LFN 2004

Section 25 makes provision for offences under the Act and the liability of offenders. A person that obstructs an officer of the agency in the performance of his duties will be liable on conviction to a fine of ₦5,000.00 or imprisonment for a term not exceeding two years or both fine and imprisonment. Where no penalty is specified, the offender, on conviction, will be liable to a fine of ₦50,000 or to imprisonment for a term of one year or to both fine and imprisonment.

4.1.2.1.2Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act

The Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act[663] makes provisions for the prohibition of sale and distribution of counterfeit, adulterated, banned or fake, substandard or expired drug or unwholesome processed food; and of sale, and distribution., of drugs or poisons in certain premises or places.

The Act makes it an offence to produce, import, manufacture, sell or display for the purpose of sale, distribute or be in possession of any counterfeit, adulterated, banned or fake, substandard or expired drug or unwholesome processed food, in any whatever form. Aiding or abetting the doing of any of these acts is also an offence[664]The Act creates a criminal liability for selling drugs or poisons in places which have not been duly licensed by the appropriate authority.[665]The penalty is the payment of a fine not exceeding ₦500,000 or imprisonment for a term not less than 5(five) years or more than 15 (fifteen) years or both such fine and imprisonment, for an offence under S. 1.[666] For a S.2 offence, the penalty is a fine of ₦500,000 or 2 (two) years imprisonment or both.[667]

Where the offence is committed by a body corporate, every person who at the time of the commission of the offence was proprietor, director, general manager, secretary or other similar officer, servant or agent of the body corporate (or a person purporting to act in any

[663] Cap C34 LFN 2004
[664] Section 1, Counterfeit and Fake Drugs and Unwholesome Processed Foods Act
[665] Section 2, Counterfeit and Fake Drugs and Unwholesome Processed Foods Act.
[666] Section 3(1)(a) Counterfeit and Fake Drugs and Unwholesome Processed Foods Act
[667] Section 3(1)(b) Counterfeit and Fake Drugs and Unwholesome Processed Foods Act.

such capacity), as well as the body corporate shall be deemed to be guilty of the offence and may be proceeded against and punished accordingly.[668]

By virtue of Section 5 provides a Federal Task force was established. Section 9 provides that the Nigerian Police Force Squad is to assist the Federal Task Force in enforcing the provisions of the Act. By virtue of Section 11, whoever obstruct the task force in performing its duties, will be liable to a fine of ₦50,000 (fifty thousand naira) or 5 (five) years or both.

4.1.2.1.3 Food, Drugs and Related Products (Registration, etc.) Act

This Act[669] regulates the manufacture, importation, exportation, advertisement, sale or distribution of processed food, drugs and related products and registration. It makes it an offence to manufacture, import, export, advertise, sell or distribute processed food, drugs, drug products, cosmetics, medical devices or water in Nigeria, unless it has been registered in accordance with the provisions of the Act or regulations made under it.

The penalty for an offence committed under this Act is a fine not exceeding ₦50,000 or imprisonment for a term not exceeding two years or both such fine and imprisonment for private individuals, and a fine not exceeding ₦100,000 for corporate bodies.[670]Where a corporate body commits the offence, all its directors, managers, secretaries, or other similar officers or all partners or officers of the firm or all trustees of the body concerned or every person who purports to act in any aforementioned capacity shall be severally guilty of the offence, and proceeded against and punished accordingly, except he/she can prove that the act or omission was carried out without his knowledge, consent or connivance.[671]

In addition, any processed food, drug, drug product, cosmetic, medical device or water seized by the Agency shall be forfeited to the Federal Government and shall be dealt with in such manner as the Minister of Health may, from time to time, determine.[672] Assets and

[668] Section 3(2) Counterfeit and Fake Drugs and Unwholesome Processed Foods Act
[669] Cap F33 LFN 2004
[670] Section 6(1), Food, Drugs and Related Products (Registration, etc.) Act
[671] Section 7 Food, Drugs and Related Products (Registration, etc.) Act.
[672] Section 10, Food, Drugs and Related Products (Registration, etc.) Act

properties used in the commission of an offence under the Act, or procured with the proceeds of the offence shall also be forfeited to the Federal Government.[673]

4.1.2.1.4Food and Drugs Act

The Food and Drugs Act[674] makes provision for the regulation of the manufacture, sale and advertisement of food, drugs, cosmetics and devices and the repeal of existing state laws, on those matters. Section 1(2) makes it an offence to sell, import, manufacture or store any article of food or drug which is adulterated. The sale, importation, manufacture of any article of food or drug which is manufactured, preserved, packaged or stored under unsanitary conditions, is also prohibited by virtue of section 1(3). The importation, exportation, manufacture, sale and distribution of the drugs specified in the 2nd Schedule to the Act, without authorisation are prohibited under Section 3.

Section 5(a) makes it an offence to label, package, treat, process, sell or advertise food, drugs, cosmetics or device in a false or misleading manner or in a manner which could create a wrong impression as to its quality, character, value, composition, merit or safety. By virtue of section 5(c), where there is contained in a publication, the standard for a drug specified in the 3rd Schedule to the Act, the labelling, packaging, sale or advertisement of any substance which is not of the published standard, in a manner which could cause it to be mistaken for a drug of the published standard, is prohibited.

Where the drug is a drug for which no standard has been prescribed, either under a regulation or any publication specified in the 3rd Schedule, it is an offence to sell such drug in any manner which is likely to deceive or mislead a purchaser, as to its quality or character.[675] The sub section further prohibits the sale of such drug as one which complies with some other standard, unless it actually complies with such standards.

[673] Section 8, Food, Drugs and Related Products (Registration, etc.) Act
[674] Cap F32 LFN 2004
[675] Section 5(d) Food and Drug Act.

Section 7(1) provides that, no person shall, manufacture for sale, any drug specified in 4th Schedule[676] without first obtaining a certificate of the Minister to the effect that the premises in which the drug is intended to be manufactured and the process and conditions by and under which the manufacture is to be carried on are in the opinion of the Minister is suitable for ensuring that the drug is safe for use. In the same vein, under Section 7(2), no person shall sell any drug specified in the 5th Schedule to this Act[677] without first obtaining, in accordance with the regulations, a certificate of the Minister that the batch from which the drug was taken is safe for use. In addition, except as provided in the regulations made pursuant to the Act, no person shall distribute or cause to be used as samples any of the drugs listed in the 4th or 5th Schedule to this Act.[678]

4.1.2.1.5 Trade Malpractice (Miscellaneous Offences) Act

This Act[679] creates certain offences relating to trade malpractice.[680]By virtue of Section 1(1)(h), anyone who does any of the eight acts listed therein, commits an offence under the Act will be liable, on conviction to a fine of not less than fifty thousand (₦50,000). Section 1 (1) prohibits the sale of any product using false and misleading labels, packages or advertisement, or using any weight, measure, weighing instrument measuring instrument which is false or unjust. Also prohibited are acts such as misrepresentation, omission to do an act, matter or thing calculated or likely to mislead, as to the number to be sold or offered for sale.

The Attorney – General of the Federation, based on report submitted, is of the opinion that an offence has been or is being committed under the Act, may by himself or through a

[676] The drugs listed in the 4th schedule include, Liver extract in all forms, Insulin in all forms, Anterior pituitary extracts, Radioactive isotopes, Living vaccines for oral or parenteral use, Drugs prepared from micro-organisms or viruses, for parenteral use Sera and drugs analogous thereto, for parenteral use, Antibiotics for parenteral use.
[677] Drugs listed in the 5th Schedule include, Arsphenamine, Dipchlorophenarsine hydrochloride, Neoarsphenamine Oxophenarshine hydrochloride, Sensitivity discs and tablets, and Sulpharsphenamine
[678] Section 7(3) Food and Drug Act.
[679] Cap T12, LFN 2004
[680] Cap W3, LFN 2004.

person he designates, institutes an action in the tribunal established under the Miscellaneous Offences Act in line with the procedure set out in the said Act.[681]

4.1.2.1.6Penal Code Act[682]

Section 188 makes provision in respect of sale of noxious food or drink, adulteration of drugs or medical preparations is dealt with under Section 188. The Section provides thus:

> Whoever adulterates a drug or medical preparation in such a manner as to lessen the efficacy or change the operation of a drug or medical preparation or to make it noxious, intending that it shall be sold or used or knowing it to be likely that it will be sold or used for a medicinal purpose as if it had not undergone that adulteration, shall be punished with imprisonment for a term which may extend to six (6) months or with fine which may extend to One Hundred Naira (₦100) or both.

Section 189 creates criminal liability for the sale of drugs as different drugs or its preparation. It provides thus,

> Whoever knowing a drug or medical preparation to have been adulterated in such a manner as to lessen its efficacy or change its operation or render it noxious, sells the same or offers or expresses it for sale or issues it from a dispensary for medicinal purposes as unadulterated or causes it to be used for medicinal purposes by a person not knowing of the adulteration shall be punished with imprisonment for a term which may extend to One Hundred Naira (₦100) or both.

From the foregoing, it is obvious that, statutory provisions criminalising drug counterfeiting are available in Nigeria. For an activity with such grievous consequences, it is saddled with problems which negatively affect efforts at curbing it. The laws are not effectively and efficiently enforced,enforcement and implementation machineries are ineffective, while in comparison with present day economy, the penalties are ridiculously light.[683] All these and the fact that compared to the profit made from the illicit trade contribute to the lack of success in combating the growth of the menace.

[681] Section 3, Trade Malpractice (Miscellaneous Offences) Act
[682] Cap P3, LFN 2004.
[683] For instance, the Penal Code Act sets fine at One Hundred Naira only.

4.1.2.2 Corporate Criminal Liability

Corporate criminal liability is the liability imposed upon a corporation for any criminal act done by any natural person.[684] The liability is imposed in order to regulate the acts of a corporation. The principle of corporate criminal liability is based on the doctrine of "respondent superior" which is known as the theory of vicarious liability, which makes a master liable for the acts of his servant.

It was developed, because it has been felt that awarding damages in civil cases fail to recognise the severity of wrong that the company as a whole did towards their victims.[685] There are however difficulties in explaining how a corporate body can be guilty of an offence, more so when *mens rea* cannot be imputed. In some instances, corporate criminal liability is provided for by laws. However, where no such laws are available, the courts will establish such liability by stretching the interpretation of *actus reus* and *mens rea*.

A corporation is a person, distinct from its members.[686] Consequently, it can enter contracts and commits a tort. It is an artificial person, which has no physical existence. A company has been said,

> …..in many ways may be likened to a human body. It has a brain and nerve centre which controls what it does. It also has hands which hold the tools act in accordance with directions from the centre. Some of the people in the company are mere servants and agents who are nothing more than hands to do the work and cannot be said to represent the mind or will. Others are directors and managers who represent the directing mind and will of the company, and control what it does. The state of mind of these managers is the state of mind of the company and is treated by the laws as such. [687]

It can therefore be criminally liable[688] on any of the following basis, namely, personal liability through express statutory provisions for a strict liability offence, vicarious

[684] US Legal. Retrieved from https://definitions.uslegal.com on 7th September, 2017.
[685] Herring J. 2016. *Criminal Law: Text, Cases and Materials*. Oxford University Press. Online Ed. Chapter 13. P.2. Retrieved from www.oxfordlawtrove.com on 222nd January, 2018.
[686] See section 28 (1) Companies and Allied Matters Act. Cap C20 LFN 2004. See also *Salomon .v. Salomon & Company Ltd* (1897) AC 22.
[687] Per Denning LJ in *H L Bolton (Engineering) Co. Ltd .v. T J Graham & Sons Ltd* (1957) 1 QB 159 at 172
[688] See *George Will .v. Grace Ekine* (1998) 8 NWLR (pt 562) 456, where Aloysius Katsina-Alu, JCA noted that, *given that companies are regarded as having separate identity and personality, once duly incorporated,*

liability,[689] personal liability for an 'operational offence', personal liability for breach of statutory duty,[690] or personal liability on the basis of attribution to the corporation, the conduct and state of mind of an individual.[691]

A company may be liable on the basis of attributing the conduct and state of mind of an individual to the corporation. In Nigeria, what obtains is to identify a natural person who can bind the company that has committed the offence, in the ordinary course of business and guilt will be imputed on him/her, whilst holding the company vicariously liable for his criminal conduct.[692] In such circumstances, regardless of the requirement for *mens rea* if the conduct and state of mind of an individual can be attributed to it. Such attribution will depend on the 'identification principle', also known as the 'directing mind and will' rule.

With regards statutory offences however, attribution would usually depend on the interpretation of statute, where the application of the directing 'mind and will' rule would defeat the purpose of the statute. Whether a person, in doing or failing to do a thing, is to be regarded as part of the corporation's directing mind and will or merely as a corporation's agent, is a question of law. This test is whether, the acts or omissions and the state of mind of the person are those of the corporation.

A corporation will be criminally liable only where the individual whose acts and state of mind are sought to be attributed to its acts within the scope of his authority.[693] Where a corporation has been found to be liable, it usually does not apply to a natural person. However, where a natural person can be identified as having committed the crime, he/she may be convicted as a joint perpetrator with the company or an accomplice, where he

---

it follows therefore, that in furtherance of their objects, companies like natural persons commit crimes. Due to the fact that some are multi-national, such crimes may have international implications.

[689] See *Great North of England Railway Co*. (1846) 2 Cox CC 70.

[690] An example is a duty imposed on an occupier of a factory to fence its machinery or on an employer to ensure the safety and health of its employees See *Birmingham and Gloucester Railway Co*. (1842) 2 QB 227.

[691] Card R and Molloy J. 2016. *Card, Cross and Jones Criminal Law*. (22nd ed.) Oxford University Press. Oxford. Online Ed. p. 7. Retrieved from www.oxfordlawtrove.com on 22nd January, 2018.

[692] Iyidiobi C N. 2015. Rethinking the Basis of Corporate Criminal Liability in Nigeria. *The Nigerian Judicial Review.* Vol.13. pp. 103-130 at p. 106.

[693] See *DPP .v. Kent and Sussex Contractors Ltd* (1944) KB 146 at 198

aided, abetted, counselled or procured its commission.[694] Some legislations however make provisions for the guilt of controlling officers of the corporation by having an officers' liability clause. This makes it easier to get at those who are really responsible for the corporation's offence(s).

Exceptions to corporate criminal liability includes, cases in which, from its nature, the offence cannot be committed by a corporation, such as perjury, bigamy and sexual offences; where the court will not stultify itself by embarking on a trial in which, if a verdict of guilty is returned, no effective order, by way of sentencing can be made.

With regards drug counterfeiting, the following legislations make provisions for corporate criminal liability, Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, Food, Drugs and Related Products Registration Act, Pre-Shipment Inspection of Imports Act, and Pre-Shipment Inspection of Export Act. The following have officers' liability clause, Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act,[695] Food, Drugs and Related Products Registration Act,[696] Pre-Shipment Inspection of Imports Act,[697] and Pre-Shipment Inspection of Export Act.[698]

4.1.2.3 Recklessness

Recklessness is the state of mind which is short of intention, but distinguishable from mere inadvertent negligence because the accused foresaw the consequences of his conduct and risked them.[699]

The consequences of recklessness, may include reasonably likely, likely, probable, or very probable[700]. "Likely" is frequently used in the criminal code. In *R .v. Okoni*,[701] a case that concerns *Section 316 (3) Criminal Code*, "likely" was taken to mean "reasonably

[694] Herring J. *ibid*. p. 19.
[695] Section 3(2)
[696] Section 7.
[697] Section 7(3)
[698] Section 18(3).
[699] Okonkwo and Nash. 1990. *Criminal Law in Nigeria*. Spectrum Books Ltd. Ibadan. p. 57
[700] *Ibid*. p. 57
[701] (1938) 4 WACA 19

probable". In *Idiong .v. R*,[702] on the other hand, a consequence was said not to be likely if a reasonable man would not expect it.

The Penal Code in its Section.19, for instance, draws a clear distinction between a likely consequence, that is, one which would cause no surprise to a reasonable man and a probable consequence, which is a natural and normal consequence.[703]

Okonkwo and Nash are of the opinion that the test of foresight in recklessness ought to be subjective, as it is in intention with the question being, "did the accused foresee the consequences as likely?" The reasonable man test would however be used as a guide in determining what would amount to foresight.[704]Applying this to a counterfeit drug situation, the question would be, "did the counterfeiter foresee that the results of a person using his product have be disastrous?" if yes, then it can be said that he was reckless in going on to produce the counterfeit drugs. In determining the issue of what amounts to 'foresight' one may then ask, "would a reasonable man have foreseen the actual result as a consequence of the usage of the counterfeit or substandard drug.

With regards to the Section.243 (2) of the Criminal Code, the offence, adulteration of food intended for sale, the accused will however not be guilty unless the criminal consequence is likely, to his knowledge. This is a subjective test.

There are no specific provisions in the Criminal Code Act relating to drugs and medicinal products. However, Chapter 23 (Sections 243 to 248) of the Criminal Code Act makes provision (generally) for offences against public health. The Act makes it an offence to sell food or drink or intend to sell food or drink when same is unfit for consumption,[705] and prescribes one (1) year imprisonment as sanction. Similarly, selling adulterated food and drinks is an offence under the Act[706] and the same punishment is prescribed. This

[702](1950) 13 WACA 30.
[703] See *Lamba Kumbin v. Bauchi Native Authority*(1963) NRNLR 49.
[704] Okwonko and Nash. pp. 57 – 58
[705] Section 243 (1), Criminal Code Act
[706] Section 243 (2), Criminal Code Act

legislation will however be applicable to those drugs and medicinal products that can be classified as 'food and drinks'.

4.1.3 Public Health and Law of Torts

A tort, derived from the Latin *torquere*, "to twist", is a civil, non-contractual wrong for which an injured person or group of persons seek remedy in the form of monetary damages. According to Salmon, a Tort is a civil wrong for which the remedy is a common law action for unliquidated damages and which is not exclusively the breach of contract or the breach of trust or other merely equitable obligation.[707]Kodinliye defines Tort as a civil wrong involving a breach of duty fixed by the law, such duty being owed to persons generally and its breach being redressable primarily by an action for damages.[708]Tortious liability therefore arises from the breach of a duty primarily fixed by law.[709]

Tort is therefore a breach of civil duty imposed by law and owed to all person, the breach of which is usually redressed by an award of unliquidated damages, injunction or other appropriate civil remedy. It is a civil wrong and not exclusively a breach of contract. It implies an unjustifiable interference with the right of another person. The essence of torts is therefore to compensate others. It enforces rights and liabilities providing remedies in the areas of law that it covers, such as trespass to person which covers assault, battery and false/wrongful imprisonment, malicious prosecution, trespass to chattel, which includes conversion and detinue, trespass to land, negligence, strict liability, liability for animals, vicarious liability, occupier's liability, defamation, deceit, passing off and economic torts which includes falsehood and passing off.

Tort law, then, characteristically is a private, rather than public, right of action, and a civil, rather than a criminal, proceeding. It is composed of a series of related doctrines that impose civil liability upon persons or businesses whose (usually) substandard conduct causes injury or disease. The functions, or goals, of tort law – although highly controversial and imperfectly achieved are - the: assignment of responsibility to

[707] Salmon J W and Heuston. *Law of Tort.* 18th edition. p.11.
[708] Kodinliye. *The Nigerian Law of Torts*. p.1
[709] Winfield (ed.) 1998 Rogers. *Winfield and Jolowicz on Tort*. (15th ed.) Sweet & Maxwell. London.

individuals or businesses that impose unreasonable risks causing injury or disease; compensation of persons for loss caused by the conduct of individuals or businesses; deterrence of unreasonably hazardous conduct; and, encouragement of innovation in product design, packaging, labelling and advertising to reduce the risk of injury or disease.

In thinking about tort law as a tool of public health, it is important to emphasize the role of litigation in preventing risk behaviour and providing incentives for safer product design. Tort litigation has been identified as a potentially effective tool to reduce the burden of injury and disease. People have resorted to civil litigation to redress many different kinds of public health harms, including: environmental damage, exposure to toxic substances, unsafe pharmaceuticals, vaccines or medical devices, *inter alia*.

As noted earlier, counterfeit drugs pose a public hazard, as a result of their not being of equivalent quality, safety and efficacy to their genuine counterparts. Their productions are not in the purview of their country's Drug Regulatory Authority (DRA). Consequently, associated defects and adverse reactions cannot be easily recognised nor monitored, neither will products recall be possible, where necessary. Counterfeit drugs have been found to be rarely efficacious, positively dangerous and detrimental to the public in terms of human suffering and burden on the health services. Treatment with counterfeit drugs have deleterious effects on wide sections of the population.

Counterfeit drugs have been termed disease mechanism.[710] The types of injuries commonly recognise by public health information systems are the same or similar to those caused by counterfeit drugs. They are therefore mechanisms of unintentional injury and are associated with other diseases and therefore contribute to the global disease burden.

Consequently, tort litigation, being a useful tool in preventing risk behaviour and providing incentives for safer product designs, may be a useful tool in curbing the growth of counterfeit drugs.

[710] Forzley M. 2003. Counterfeit Goods and the Public's Health and Safety. A publication of the International Intellectual Property Institute. Washington DC. Retrieved from www.iipi.org on 27th September, 2016

The tort system is composed of a series of related doctrines that impose liability on persons, businesses, or governments, whose conduct causes injury or disease.[711] These will be discussed in the following paragraphs.

4.1.3.1 Negligence

The tort of negligence can trace its roots to action on the case, that is, those forms of action in respect of injuries indirectly inflicted upon the plaintiff. It has been identified as the important and most dynamic of all torts.[712] Not every act of carelessness or negligence is actionable under the tort of negligence. According to Lord Wright in *Lochgelly Iron & Coal Co. v Mc Mullan*,[713]

> In strict legal analysis, negligence means more than heedless or careless conduct, whether in omission or commission: it properly connotes the complex concept of duty, breach and damage thereby suffered by the person to whom the duty was owing.

The tort of negligence has three essential ingredients namely:

(a) The existence of a legal duty to take care;

(b) A breach of that duty; and

(c) Some damage to the plaintiff as a result of the breach.

4.1.3.1.1. Duty of Care

The duty of care is very important because it is the core of any action in negligence. Success in an action in negligence is dependent on whether or not the plaintiff is able to show that the defendant owes him a legal duty to take care and that the defendant is in breach of that duty. This was stated by Lord Pearce in *Hedley Byrne & Co. Ltd. v Heller & Partners*,[714] where he said

> …there can be no actionable negligence *in vacuo* without the existence of some duty to the plaintiff. For, it would be impracticable to grant relief to everybody who suffers damage through the carelessness of another.

[711] Gostin L O. (Ed.) 2002. *Public Health Law and Ethics.* London, England: University of California Press Ltd.
[712] Kodilinye G and Aluko O. 1999. *The Nigerian Law of Torts.* Ibadan: Spectrum Books Limited.
[713] (1934) A.C. 1 at p. 25
[714] (1964) A.C. 465 at 534.

The court, in *Heaven v Pender,*[715] described the duty of care as:

> Whenever one person is by circumstances placed in such a position with regard to another that everyone of ordinary sense who did think would at once recognize that if he did not use ordinary care and skill in his own conduct with regard to those circumstances he would cause danger or injury to the person or property of the other, a duty arises to use ordinary care and skill.

Usually, to resolve the question as to whether or not there exists a duty of care, the court embarks on two enquiries: first, the court looks to see whether as between the alleged wrongdoer and the person who has suffered damage, there is sufficient proximity or neighbourhood such that, in the reasonable contemplation of the wrongdoer, carelessness on his part may likely cause damage to the person injured. If there is such close relationship or proximity then a duty of care arises *prima facie*. Secondly, if the question is answered affirmatively, then the court will consider whether there are any considerations which it is owed or the damages which a breach of it may occasion. This test is called the "Anns Test" as it was developed by Lord Wilberforce in *Anns v Merton LBC.*[716]

The Common Law duty of care is based on two elements: reasonable foreseeability and proximity or neighbourhood. The duty spoken of here must be a legal rather than a moral duty. Legal duty in this context means an obligation which the law will recognize and uphold as binding in a given set of circumstances. The nature of the duty was described by Lord Atkin in *Donoghue v Stevenson*,[717] where he said "the rule that you are to love your neighbour becomes, in law, you must not injure your neighbour. The rule on proximity and neighbourhood was expanded in the instant case to the effect that where a person is injured from a transaction arising from the contract of two persons, the third party is not precluded from bringing action on the grounds that he was not a part to the contract, the mis-performance or not performance of which has resulted in the damage. The duty imposed here is not because there was a contract but because the defendant had impliedly

[715] (1883) 11 QBD 503 at 507
[716] (1978) AC 728 at 751-2
[717] (1932) A.C. 562

undertaken not to injure the plaintiff. The rationale, in truth, is that, even though not so expressed, the obligations towards the contracting party extended to all such persons who were likely to be injured by the acts or omissions of the defendant. They are the neighbours in contemplation or ought to be in contemplation of the defendant. In the case in point, Mrs Donoghue went to a café with a friend. The friend brought her a bottle of ginger beer and an ice cream. The ginger beer came in an opaque bottle so that the contents could not be seen. Mrs Donoghue poured half the contents of the bottle over her ice cream and also drank some from the bottle. After eating part of the ice cream, she then poured the remaining contents of the bottle over the ice cream and a decomposed snail emerged from the bottle. Mrs Donoghue suffered personal injury as a result. She commenced a claim against the manufacturer of the ginger beer. Her claim was successful and this case established the modern law of negligence and established the neighbour test.

However, in determining whether a duty of care exists, the following have also been taken into consideration:

1. Capacity of the parties to bear the loss;
2. The gravity of the defendant's fault;
3. The need to prevent future occurrence;
4. Administrative convenience;
5. Assumption of responsibility;
6. Applicable statutory provisions; and
7. Existence of a fiduciary relationship.

Notwithstanding the above, based on the words of Brennan J, in the High Court of Australia, in *Sutherland ShireCouncil v Heyman,*[718]a claimant in an action for negligence will not fail simply because the duty-situation he relies on has never previously been recognized. Rather, a claimant seeking recognition of a novel duty of care will now have to

[718] (1985) 50 ALR 1, at 43-4

argue his case in the context of existing authority and to persuade the court that to extend liability into this new situation is a sound development of the law.[719]

4.1.3.1.2. Breach of Duty

Breach of duty in negligence is a question of fact. Once a duty of care has been established, it is for the courts to determine whether the defendant's conduct was or was not reasonable in the circumstances. In assessing the defendant's conduct, the courts try to compare his conduct with that of a reasonable man. He is negligent if his conduct falls short of what is required of the fictitious reasonable man in the circumstances.[720]

4.1.3.1.3. Causation

Liability for negligence requires a reasonably close causal connection between the unreasonably risky conduct and the resulting injury. Causality is often examined in terms of "proximate" (or legal) cause, including "causation in fact". Philosophically, causal relationships can be traced to innumerable antecedent events, but legal responsibility is limited to actions that actually cause harm and to sequences of events that are forseeable. Courts usually adopt a "but for" rule to explain causation in fact – that is, the harm would not have occurred but for the defendant's conduct: or conversely, the harm would still have occurred without the defendant's conduct. A clear definition of proximate cause is difficult to enunciate, because the term is meant to convey the circumstances when, as a matter of law, it is fair to impose liability. Some courts hold that a defendant is liable if his conduct is the direct, rather than a remote, cause of the injury; others say that the harm must be a natural and probable consequence of the act. Most definitions of proximate cause, however, turn on whether the injury was a foreseeable consequence of the defendant's behaviour, that is, whether the defendant reasonably could have anticipated the harm at the time he engaged in the risk behaviour.[721]

[719] Christian Writing. 2015. Street on Torts. 14th Ed. New York: Oxford University Press.
[720] Ezeani A O N and Ezeani R U. 2014. *Law of Torts (With Cases and Materials)*. Lagos: Odade Publishers.
[721] Op. Cit., Gostin, Lawrence O. p. 274.

4.1.3.1.4. Damage Caused by the Breach

Having established that the defendant owed a duty of care to him and that the defendant was in breach of that duty, the plaintiff must then prove that he has suffered damage for which the defendant is liable in law. [722] Liability for negligence requires actual loss or damage and not a mere insult to dignity. [723]

Thus, negligence is a measure of legally acceptable risk; a person must exercise due care to avoid unreasonable risks of harm to others. The law of negligence does not require avoidance of all possibilities of harm, only unreasonable risks are deemed to be negligent.[724]

As it relates to drug counterfeiting, the manufacturer owes the consumer a duty of care, as the latter will rely on the expertise of the former in producing a drug which is fit for consumption. By producing a counterfeit drug, the manufacturer is in breach of that duty. Considering the consequences of counterfeit

4.1.3.2. False Representations[725]

4.1.3.2.1. Deceit

Tort of deceit is concerned with the loss sustained through reliance upon misstatements.[726] It is however not sufficient to show that the Defendant's statement either known it to be false or being indifferent to its truth or falsity.[727]

Deliberate false representations on which the claimant is induced to, and does rely to his detriment are actionable under the tort of deceit. The decision that influenced this position was the one in *Pasley v Freeman,*[728]where the defendant falsely misrepresented to the claimant that X was a person to whom the claimant might safely sell goods on credit. The claimant suffered loss by relying on this representation and was held to have an action on

[722] Op. Cit. Kodilinye and Aluko, p. 54
[723] Op. Cit. Gostin, Lawrence O. p. 274
[724] Ibid.
[725] Op. Cit., Christian Writing. p.
[726] *Derry .v. Peek* (1889)14 App. Cas. 337
[727] Supra
[728] (1789) 3 Term Rep 5F

the case for deceit. Subsequently, in *Derry v Peek*,[729] the tort of deceit was defined in terms of its key elements, namely: as false representation made:

1. Knowingly, or
2. Without belief in its truth, or
3. Recklessly, carelessly whether it be true or false, with the intention that the claimant should act in reliance upon the representation, which causes damage to him in consequence of his reliance upon it.

The core of deceit concerns representations which are misleading as to facts or states of affairs. Usually, the representation will consist of written or spoken words, but any conduct calculated to mislead would suffice. A misrepresentation due to an incomplete statement will also be actionable.[730] In the same vein, where a statement by the defendant was accurate when made, but owing to a change in circumstances of which the defendant was aware, ceases to be true, there is an actionable misrepresentation if the defendant, by remaining silent, induces the claimant to act to his detriment on the basis of the original statement.[731]

4.1.3.2.1.1.Knowledge of Falsity

In order for the defendant to be liable, he must have made the statement knowingly, or without belief in its truth, or recklessly, careless, whether it be true or false. In short, the claimant must prove that the defendant did not honestly believe the statement to be true. In *Derry v Peek,*[732]a company was empowered by private Act to run trams by animal power. The directors, believing that the Board of Trade would give this consent as a matter of course issued a prospectus saying that the company had the ability to run trams by steam power. Relying on this prospectus, the respondent bought shares in the company. The Board of Trade eventually refused its consent, and the company was later wound up. The House of Lords held that an action in deceit against the directors failed because of want of honest belief on the part of any director was established by the director was established by

[729] (1889) 14 App Cas 337, at 374
[730] *Peek v Gurney* (1873) LR 6 HL at 403
[731] *Incledon v Watson* (1862) 2 F & F 841.
[732] supra

the respondent, and it has since been stated that the absence of any injurious intent may nonetheless constitute good evidence of an honest belief in the truth of a statement.

4.1.3.2.1.2.Intention to Deceive

In deceit cases, the claimant must prove that the statement was 'made with the intention that it should be acted upon by the claimant, or by a class of persons which will include the claimant. Lord Cairns in *Peek v Gurney,*[733] said in essence that the defendant must have 'intended' in the sense that he desired or had the purpose that the claimant should act on the statement. Essentially, the statement must have been calculated to induce the claimant. A misrepresentation need not be communicated directly to the claimant by the defendant, so long as the defendant intended that it should be communicated to him and that he should rely on it.

4.1.3.2.1.3. Reliance of the Claimant

The claimant must prove that the misrepresentation of the defendant both influenced him and caused him to act to his own prejudice as he did. The action lies even if the misrepresentation was only one of several factors impinging on the mind of the claimant. And, if the court is satisfied that the false statement was 'actively present to his mind' when the claimant acted, it matters not what the claimant would have done if told the truth. Thus, it is unimportant to enquire whether the claimant knowing the facts would have entered into the same transaction.

4.1.3.2.1.4.Loss

Since it is an action on the case, there is no cause of action in deceit unless the claimant proves that he sustained loss or damage. Although ordinarily, damages will be for financial loss, damages for personal injuries are recoverable in principle. The claimant is entitled to recover for all the actual damage directly flowing from the fraud, even if not all of the damage was foreseeable.

[733] supra

For an action in the tort of deceit to succeed, the defendant must have knowingly, recklessly or carelessly, with the intention to deceive made the statement which influenced the plaintiff to act the way he/she did. In so doing, the plaintiff must have incurred a loss. This entitles the plaintiff to recover for all damages suffered. Applying this to counterfeit drugs, all three conditions are present to qualify the act as a deceit. The victim, by using the drug can be said to have been influenced by the manufacturer's statement to take the medicines, and has suffered a damage resulting from the counterfeit drug. The manufacturer will be liable, whilst the victim will be entitled to damages for whatever loss incurred.

4.1.3.3. Strict Liability

Strict liability is liability that is imposed on a person apart from either, an intent to interfere with a legally protected interest without a legal justification for doing so, or a breach of a duty to exercise reasonable care, that is actionable negligence.[734]The strict liability offences are offences which require no proof of the *mens rea*. They are also known as absolute offences.[735] The court holds a person liable for his acts independently of wrongful intention or negligence.[736] The strict liability offences cover acts that endanger the public welfare or action which are cruel, as they affect or endanger the environment or vegetation of Nigeria.

It is also referred to as "liability without fault".[737]This is a situation where a Defendant is liable for damage caused by his act.

It is a "situation" where a man acts at his peril and is responsible for accidental harm, independently of the existence of either wrongful intent or negligence.[738]The Rule was

[734]Prosser and Keeton on Torts. 1984. (5th edition). Hornbook Series Students edition. West Publishing Company. MN. USA. p. 534.
[735]Bamgbose O and Akinbiyi S. 2015. Criminal Law in Nigeria. Evans Brothers (Nigeria Publishers) Ltd. Ibadan. p 27.
[736] see Section.6 Criminal Code.
[737]*Ibid*.
[738] Salmon. 1977. *Torts*. 17th ed.

developed in *Rylands v. Fletcher,*[739] where the Defendant employed independent contractors to build a reservoir on their land. The contractor carelessly omitted to block up some disused shafts on the site, which communicated with the plaintiff's coal mine beneath the reservoir, so that when the reservoir was filled, water escaped down the shaft and flooded the plaintiff's mine. The Defendants' conduct did not appear to come within the scope of any existing tort; they were not liable for trespass, because the damage was not direct and immediate; nor for nuisance, because the damage was not due to any recurrent condition or state of affairs on their land; nor for negligence, because they had not been careless, and they were not liable for the negligence of their independent contractors. They were however strictly liable for the damage on the basis of the following rule propounded by Blackburn J.[740]

> The person who for his own purposes [and in the course of non-natural user of his land, bring on his land and collects and keeps there anything likely to do mischief if it escapes and must keep it at his peril and if he does not do so, is prima facie answerable for all the damage which is the natural consequent of its escape.

In tort, the principle is applied to cases of product liability in order to hold a seller liable for defective or hazardous products that threaten consumers' personal safety. This is founded on the principles that when a manufacturer presents his goods for sale to the public, he represents that they are suitable for their intended use.[741]

Torts based on negligence can be difficult to prove due to lack of evidence of substandard care. For certain risk-taking behaviours, however, the judiciary affixes liability without regard to culpability such as for unduly hazardous activities and for the sale of defective products. The law holds that even if the defendant exercises reasonable (or even extreme) care, he has to carry the cost of injuries. Strict, or no-fault liability may be thought of as mandatory insurance against designated risks for reasons of social policy; it remains a highly controversial legal doctrine.[742]

---

[739] (1866) LR 1 Exch. 265; [1868] IR 3 HL 330
[740] Supra at pp. 279 – 280.
[741] *Ibid*. p.28
[742] Op. Cit., Public health law. p. 277

For such action to succeed, it must be proved that the product was defective when it was placed in the market.Consequently, where one sells a defective product which is unreasonably dangerous to the user or consumer or his property,he will be subject to liability for physical harm thereby caused to the user/consumer or to his property.

For an action in strict liability to subsist, the following conditions must be met:

i. The seller is engaged in the business selling such types product.

ii. It is expected to, and actually reaches the user or consumer without substantial change in the condition in which it was sold, that is not altered.

iii. The rule applies in Tort, even though the seller has exercised all possible care in the preparation and sale of his product; and

iv. The user or consumer has not bought the product from or entered into any contractual relation with the seller.

The liability is strict in those cases where the defendant is liable for damage caused by his act, irrespective of any fault on his part; or as it has been expressed *where a man acts at his peril and is responsible for accidental harm, independently of the existence of either wrongful intent or negligence*.[743] Strict liability means liability that is imposed on an actor apart from either (1) an intent to interfere with a legally protected interest without a legal justification for doing so, or (2) a breach of duty to exercise reasonable care, that is, actionable negligence. It is usually referred to as liability without fault.[744] In strict liability, the plaintiff is not required to impugn the conduct of the maker or other seller, but he is required to impugn the product. The product must be in a "defective condition unreasonably dangerous" This simply means that the product must be defective in the kind of way that subjects, persons or tangible property are exposed to an unreasonable risk of harm. A product is defective as marketed in the kind of way that makes it unreasonably dangerous for any of the following reasons:

[743] Op. Cit., Kodilinye and Aluko p. 115
[744] Keeton W P., Dobbs D D., Keeton R E and Owen D G. 2004. *Prosser and Keeton on Torts.* 5th Ed. St. Paul, MN: Keeton, Dobbs, Keeton and Owen West Publishing Co.

(1) A flaw in the product that was present in the product at the time the defendant sold it;

(2) A failure by the producer or assembler of a product adequately to warn of a risk or hazard related to the way the product was designed; or

(3) A defective design.[745]

Strict liability does not impose absolute liability, but has the following limits: *intention* – the defendant must knowingly engage in the activity; *proximate cause* – liability is confined to the consequences caused by the activity and to persons foreseeably harmed; *public duty privilege* – liability is not imposed when the law expressly authorizes or imposes a duty to conduct the activity; and the Federal Torts Claims Act of the U.S.A. waives sovereign immunity for claims of governments negligence, but not strict liability.

Under Criminal Law, strict liability removes the usual requirement of establishing knowledge and intention. In addition, there are no applicable defences to this crime. The rationale for this is "public welfare" and "public good" requirement.[746]

4.1.3.4 Products Liability

The emerging market in consumer products at the turn of the twentieth century had enormous benefits for the population, but individuals injured by those products faced insuperable obstacles in gaining compensation. The extant law permitted actions for negligence only against the party with whom an injured person had a contractual relation, that is, privity. Contractual privity was abandoned in the famous 1916 decision in *MacPherson v Buick Motor Company*, where consumers were permitted to sue automobile manufacturers. Although *MacPherson* was a negligence action, no-fault products liability soon followed. Notably, consumers could sue under "implied warranty of merchantability", a contractual theory that did not require negligence. Sellers, however, began to undermine implied warranty litigation by using safety disclaimers in consumer contracts. In response, strict liability for defective products emerged in the middle part of

[745] Ibid.
[746] Ibid. p. 28

the century, and by the 1970s, most states in the U.S. adopted the theory. The two most important concepts in products liability are the meaning of "products" and "defects".[747] Product liability is the name currently given to the area of the law involving the liability of those who supply goods or products for the use of others to purchasers, users and bystanders for losses of various kinds resulting from so-called defects in those products.[748]

A product is broadly understood to be tangible goods. Products liability applies to virtually all goods capable of causing injury, ranging from motor vehicles, household appliances, and work and recreational equipment, to pharmaceuticals, vaccines, and medical devices.

Nigerian Consumers on a regular basis have to deal with the issue of fake, substandard, defective and adulterated goods and their challenges. These have placed the consumers in an unsafe position, exposing them to numerous dangers.Product liability relates to the responsibility of manufacturers, distributors, supplies and retailers for any injury/loss caused by their products.

To meet these societal needs, various legal and institutional frameworks have been put in place to regulate the activities of manufacturers and supplies of goods and providers of services. The courts have developed varied tests of a product "defect" and no single standard is universally accepted. A common standard is whether the product "performed as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner". The reasonable expectation standard works well for many product defects but not if the consumer lacks the expertise to evaluate a complex or scientific product such as a medical device. Some courts also use the misrepresentation theory in finding products defective. Product defects generally fall into three categories: manufacturing defects, design defects and failure to warn.

Consequently, a product is defective when it fails to provide the safety which the consumer expects, while taking all circumstances into account. These circumstances include, the

[747] Ibid.
[748] Op. Cit., Keeton, W.P., Dobbs, D.D. Keeton, R.E., Owen, D.G.

presentation of the product, the use to which it could reasonably be expected that the products would be put, by the time when the product was put into circulation.[749]

In Tort, the principle of strict liability is applied to cases of product liability in order to hold a seller liable for defective or hazardous products that threaten consumers' personal safety. This is founded on the principle that when a manufacturer presents his goods for sale to the public, he represents that they are suitable for their intended use.[750].For such action to succeed, it must be proved that the product was defective when it was placed in the market.

Consequently, anyone who sells a defective product in a defective condition, which is unreasonably dangerous to the user or consumer, or his property, is subject to liability, for physical harm thereby caused to the user/consumer or his property.[751]

A product contains a *manufacturing defect* when as produced, it does not conform to the manufacturer's own design. This means that a flaw was not present in the product design but despite due care, the defect resulted from the construction process. Manufacturing defects tend to be random and usually do not affect the entire product line. Since it is usually difficult for customers to detect a manufacturing flaw, courts impose liability on the seller. Thus, injured consumers do not have to demonstrate that the manufacturer used faulty materials, lacked due care in construction or failed to inspect properly.

A product contains a *design defect* when it is defective although produced as planned by the manufacturer. Consequently, a design defect is usually apparent in an entire product line. Manufacturers are liable for design defects when "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design…and the omission of the alternative design renders the product not reasonably safe." "Reasonable design alternative" is a liability –limiting test because it requires the plaintiff to show that the product could have been made safer" The design

[749] Goicovici J. 2011. European Union Law on Defective Production Essential Aspects of Producers' Responsibility; Studia Ubb. *Europaea*, 56(1): 81 – 94**.**
[750] Op. cit. p.28.
[751] *Ibid*. p.28.

defect theory is controversial because the manufacturer intended the "defective" design feature with due consideration of price, attractiveness, and functionality.

A product has a "*failure to warn" defect* when the seller fails to inform consumers adequately about the risks or provide instructions for safe use. The theory underlying this product defect is consumer sovereignty, the notion that customers deserve sufficient data to make informed purchasing choices. Courts use a "reasonableness" test in evaluating failure to warn cases: could the foreseeable risks have been reduced by reasonable instructions or warnings, and did the omission of instructions or warnings render the product unreasonably dangerous? The fact that "failure to warn" cases often turn on the reasonableness of the action suggests a similarity to negligence theory. Some courts, however, unabashedly adopt strict liability for failure to warn, even if the dangers were "undiscoverable" at the time.

Closely related to the failure to warn theory is misrepresentation, where the seller misinforms consumers orally, in writing or through other conduct calculated to convey a false impression. Misrepresentation is established through labels, packet inserts, or advertisements that are inaccurate, deceptive, or misleading. Intentional concealment of the truth also can be misrepresentation, such as when a tobacco company fails to disclose internal research of the harmful effects of cigarettes on smokers.

Products liability says that "common and widely distributed products, such as alcoholic beverages, firearms, and above ground swimming pools" may be held defective only if they are sold without reasonable warning or if reasonable alternative designs could have been adopted. The rationale is that, since these hazardous products have received long-term market acceptance, the legislature is thought to be the acceptable regulatory agency. However, many would find it odd that tobacco and firearms are immunized from strict liability (along with vaccines and prescription drugs).[752]

[752] Gostin L O. *Op. Cit*

Defective goods create liability for damages for the manufacturer under the Consumer Protection Act and in the test of negligence. Product liability claims may be brought in tort, contract and criminal law. As a tort, the consumer may bring an action in negligence. With regards negligence, the consumer need not establish privity of contract. Negligence occurs where a person fails to exercise duty of care as a result of which harm is done to another. Consequently, where a drug manufacturer fails to exercise due care in manufacturing his product and harm results, he will be held liable for negligence.

For an action in negligence to stand, the plaintiff must establish the following: (i) that there was a duty care owed to him; (ii) that there was a breach of that duty of care by the defendant; and (iii) that he suffered some consequential damage as a result of that breach by the defendant.

4.2.1 Consumer Protection

This refers to protecting the pecuniary, health, safety and security interests of the citizenry against misleading, fraudulent and harmful business practices, including manufacturing, trading, packaging, advertising, distributing and selling of products/goods and services to the ultimate consumer.[753]

The Consumer Protection Council Act[754] defines a consumer as a person who purchases, uses, maintains or disposes of products or services. The rights of the consumer are set out in Chapter 4 of the 1999 Constitution, which contains the fundamental rights of all citizens and persons. These include, rights to life, dignity of person personal liberty, fair hearing, private and family life, freedom of thought, conscience and religion, freedom of expression and the press, peaceful assembly and association, freedom of movement, freedom from discrimination, and the right to acquire and own immovable property anywhere in Nigeria.

[753] Ladan M T. 2008. The Limits of Legal and Enforcement/Regulatory Frameworks in Consumer Protection Against Counterfeit and Pirated Products: The Nigerian Experience. *Review of Nigerian Laws and Practice*. pp. 3-4.
[754] Cap C25 LFN 2014

While some of these provisions do not have direct bearing with consumer protection, some do. An example is the principle of fair hearing and access to justice, on which consumer protection is hinged.[755]

Others include the right to hold personal opinion and to receive and import ideas and information without hindrance;[756] the right to form associations for promoting their cause;[757] and the right to approach the court or any other appropriate body for redress where their rights have been violated.[758]

The fundamental human rights, as contained in the Constitution are of utmost importance. In *Ransome-Kuti v. Attorney-General of the Federation,*[759]

Eso, JSC noted that,

> it is a right which stands above the ordinary laws of the land and which infact is antecedent to the political society itself. It is a pre-condition to a civilised existence and what has been done by our constitution, since independent……. is to have these rights enshrined in the constitution so that the rights could be "immutable" to the extent of non-immutability.

The consumer protection covers manufacturer/product liability, the liability of retailers, wholesalers, distributors and others in the supply chain of goods and services. The legal machinery to advocate consumer issues between the purchasers and users of goods and services and the vendor, manufacturer/ producer or other person(s) concerned with their production, supply, distribution and sale.

With regards to consumer protection and drug counterfeiting, the effect of the latter, on consumers includes, extorting a higher price from consumers, for the infringing product, than they would be ready to pay for, consumer deception about the quality of the

[755] Section 36(1) 1999 Constitution. See also Section 39 which provides for the right to hold personal opinions and to receive and import ideas and information without hindrance. This ensures the consumer's right to be heard and to be informed. Section 40 gives consumers the right to come together to form associations for promoting their cause. In its part, Section 46 makes provision for the right to approach the court or any other appropriate body for redress where their rights have been violated.
[756] Section. 39 1999 Constitution of the Federal Republic of Nigeria.
[757] Section 40 1999 CFRN
[758] Section 46 1999 CFRN
[759] (1985) 2 NWLR (pt6) 211.

counterfeit product, with the consequent risk to health and safety, the absence of after-sales service or any effective recourse in the event of damage or injury.[760]

The counterfeiting is generally accompanied by the deliberate cheating of the consumer as to the quality entitled to be expected from branded products, given that the goods are produced without the quality checks imposed by public standards authority and by the brand proprietor, which will inevitably be concerned to protect the quality standards associated with registered brands.[761] Under the Consumer Protection Law, a third party who qualifies as a consumer, may seek redress as a consumer under the law of negligence, where he/she is injured by a product bought by another or where he/she is adversely affected by an injurious product.[762]

4.2.2 Sale of Goods

This law imposes some obligations and confers some rights on parties to a sale of goods contract. The Nigeria Sale of Goods Laws is based on the English Sale of Goods Act, 1893 – a legislation of general application.

Section 1(1) SOGA 1893 defines sale of goods as *a contract whereby the seller transfers or agrees to transfer the property in goods to the buyer for a money consideration called price*.

To establish a sale of goods contract, the elements of a valid contract must be present. With regards to sale of goods, it could occur in one of two situations, namely, a contract of sale, where the property in the goods is transferred from the seller to the buyer; and an agreement to sell, in which the transfer of the property takes place "in future", or on the fulfilment of certain conditions.

---

[760]Blakenay M. 2009. International Propaganda for the Criminal Enforcement of IPRights: International Concern with Counterfeiting and Piracy. *Queen Mary University of London, School of Law Legal Studies Resource Paper No. 291 2009.* Retrieved from http://ssm.com on 17/8/2016. p.10.
[761]*Ibid*, p. 15.
[762] See*Donoghue v. Stevenson*(1932) AC 562*; Okwejiminor & Anor v. Nigeria Bottling Plc.*[2008] 5 NWLR (pt. 1079) 172 SC.

The breach of these implied terms by a seller entitles the buyer to a right of action and a remedy for the breach. These terms impose strict liability on the seller and they are actionable per se. The seller's awareness of the alleged defective good is not material.[763]

The Sale of Goods refer to the ordinary commercial Act of buying and selling of goods and services. It is contractual in nature, therefore a specie of contract. The basic rules of Law of Contract apply to a typical sale of goods contract. Consequently, the contractual rules on the issues of capacity, offer and acceptance, consideration, privity, and illegality, including agency rules apply.

The laws apply to parties to the contract of sale, namely the seller and the buyer. The seller is someone who sells or agrees to sell goods while a buyer is a person who buys or agrees to buy goods – Section 1. These go to show that there must be a contractual relationship between the buyer or the seller.

Going by the strict interpretation given to a contract of sale, only parties to the contract may sue on it. Where a third party is injured by a defective product, his/her cause of action is in negligence or through a party to the contract, suing on his/her behalf. The implication of this is that a consumer of a counterfeit drug, given as a gift, will not have a right of action under this provision. The principle of Privity of Contract limits the ability of non-contractual consumers to make claims under the Sale of Goods Laws.

4.2.2.1 Elements of Sale of Goods

Section 1(1) provides that a contract for the sale of goods, is one *whereby the seller transfers or agrees to transfer the property in the goods to the buyer for money, a consideration called the price*.

For a contract to be one for the sale of goods, it must have the following elements, namely:

[763] Kenyip B B. 2005. Service Liability under the Nigerian Consumer Law. *Consumer Journal.* 1(1) pp. 90 – 95].

(1) Property – This is ownership over goods, which is the subject matter of a sale of goods contract. The goods which are the subject matter of the contract can be classified as:

(a) Unascertained goods – Section 16 provides that ownership of unascertained goods does not pass to the buyer until the goods are ascertained. In *Boro v. Kenney,*[764]goods were to be sold by measurement. It was held that the stipulation of measurement and of delivery at a particular place rendered the sale conditional and incomplete until the occurrence of these events.

(b) Specific Goods – here, the property passes at such time (if any) that the seller and buyer stipulate, either expressly or impliedly in the contract of sale.[765]Where the contract of sale is silent, however, the Act recommends certain principle on how to determine this:

(i) where the contract is one for the sale of specific goods, which are in a deliverable state, the ownership of a goods is transferred to the buyer, when the contract is made not withstanding that the time payment is to be made or both are expressly postponed by the contract.[766] The goods are in a deliverable state, once they have been put in a condition, that the buyer is bound to take them.[767]

(ii) where in a contract for the sale of specific goods, the seller has to do something to put them in deliverable state, ownership of the goods will not pass until such action has been taken and the buyer has notice of it.[768]

(iii) In a contract of sale of specific goods which though in deliverable state, but has to be weighted, measured, tested, or have some other action or things done, in order to determine the price.

[764] (1955) WACA 51
[765] Section17 SOGA
[766] Section 18 SOGA.
[767] See *Talabi v. Mandila*(1976) 3 OYSAC79.
[768]*Underwood Ltd v. Bough Castel Bricked Cement Syndicate* (1921) All ER Rep 515.

(2) Parties - the parties to a sale of goods transaction are the seller and the buyer. The Seller, sells or agrees to sell, while the buyer, buys or agrees to buy.

(3) The Price - Whilst the consideration for a regular contract could be money or money's worth, some forbearance or a *qui proquo*.[769] The consideration in a sale of goods contract is money, which is called the price. The price could be partly money or partly goods.

With regards to price, Section 8 provides that it may be fixed by the contract, be left to be fixed in a manner to be agreed, or where no price is fixed, by payment of reasonable price depending on the circumstances of each case.

(4) The Goods – Section 62 defines goods as *all personal chattels other than things in action and money and include emblements industrial growing crops and things attached to or forming part of the land which are agreed to be severed before the sale or under the contract of sale.*

The definition given above states that money [except those that constitute collectors' item], real property and right of action are not goods. The goods must be specific, that is, they must be identified and agreed on at the time the contract of sale is made. In *Mary Ajayi v. Alice Ebwu,*[770] where the Plaintiff sold £98 worth of gold in the form of trinkets, lockets, earrings, rings and chains for which the Defendant paid £20. She was unable to pay the balance, arguing that her own customers returned the articles, as they were adulterated. The Defendant rejected the goods, demanding for a refund of her deposit. The Plaintiff sued for her balance. The court dismissed her action on the grounds that the goods were unascertained and the Defendant rejects them.

For there to be a sale of goods, there must be a transfer of property in goods from the seller to the buyer for a price in money.[771] Being first and foremost a contract, it must contain all the essential elements of a valid contract, namely, offer, acceptance, consideration

[769] A favour, or advantage granted in return for something
[770] (1964) MNLR41
[771] Akanki E O (eds.) 2007. *Commercial Law in Nigeria*. University of Lagos Press. Lagos. p. 268.

intention and other aspects of general contract law. According to SOGA, *a contract of sale of goods is a contract whereby the seller transfers or agrees to transfer the property in goods to the buyer for a money consideration called the price.*

Where the transfer of property takes place at the time of the transaction, the contract is called a sale, however, where the transfer of the property in the goods is to take place at a future time or subject to some condition thereafter to be fulfilled, the contract is called an agreement to sell.[772] Where the time elapses or the conditions are fulfilled subject to which the property in the goods is to be transferred, then an agreement to sell becomes a sale.[773]

The subject matter of the contract must be "goods". Section 62 defines "goods" as *all chattels personal other than things in action and money … the term includes emblements, industrial growing crops, and things attached to or forming part of the land which are agreed to be severed before sale or under a contract of sale.*[774]

The Act covers private sale i.e. sale where the seller, in the course of business, sells goods that are ordinarily bought for private use or consumption to a buyer who wants them for his own private purposes. From the foregoing, buying and selling of counterfeit drugs falls within the area that covered by SOGA as a contract for the Sale of Goods.

4.2.2.2 Implied Terms under the Sale of Goods Laws

[772] Section 1(3) SOGA.
[773] Section 1(4) SOGA
[774] (a) Chattels Personal – tangible personal things excluding things in action and money.
(b) Emblements – products of the land which do not grow naturally but are the annual result of annual agricultural labour e.g. vegetable, maize, potatoes etc.
(c) Industrial growing crops – include things that are grown by the industry of man. It is however wider than emblements in that it includes crops which do not mature annually.
(d) Things attached to and farming part of the land – these include things that are growing naturally on the land such as timber or grass. They must however have been severed before sale or under a contract of sale.

Contracts are made up of terms which may be express or implied.[775] These terms have been classified as conditions and warranties.

A "warranty" is an *agreement in reference to goods which are the subject matter of sale, but collateral to the main purpose of such a contract, the breach of which gives rise to a claim for damages but not a right to reject the goods and treat the contract as repudiated*.[776]

A "condition" in its part, though not defined in the Act, but can be inferred from the definition of a warranty, as being more important. A breach of a condition, would give the aggrieved party, the right to reject the goods and treat the contract as repudiated.[777]

Section 61of the United Kingdom SOGA, defines a warranty as "an agreement with reference to goods, which are the subject of a contract of sale, but collateral to the main purpose of such contract, the breach of which may give rise to a claim for damages but not a right to reject the goods and treat the contract as repudiated". By this definition, conditions are more important than warranties.

The use of the word "collateral" has raised arguments amongst scholars. Professor Monye, opined that a warranty is a term of the contract and something collateral to it.[778] Atiyah notes that the term "collateral" may give the impression that warranty is a term which is somehow outside the contract, whereas it is in fact part of a term of the contract.[779]

Sagay argues that a warranty is collateral to the main purpose of the contract, a condition must at least be essential to it.[780]

Consequently, where there is a breach of a warranty, the innocent party can only claim damages. He/she would still be required to perform his part of the contract. On the other

[775] Relevant to this study are the statutory implied terms as contained in Sections 12-15 SOGA.
[776] Section 62 (2) SOGA
[777] Section 11 (1)(b) SOGA
[778] Monye F M. 2005 *Law of Consumer Protection*. Ibadan. Spectrum Books Ltd. p.196.
[779] Atiyah P S. 1995. *The Sale of Goods*. London Pitman p. 63.
[780] Sagay I E. 2000. *Nigeria Law of Contract* (2nd ed.) Ibadan. Spectrum Books Ltd. p. 100

hand, in a breach of a condition, the innocent party, in addition to claiming damages, would be discharged from his obligation under the contract. Determining whether a term is a condition or a warranty depends primarily on the construction of a contract. Sometimes, a term may be a condition, but described as a warranty in the contract.[781]

It is pertinent to note that under common law, conditions and warranties relating to quality or fitness for purpose cannot be implied into a contract. It is expected that a buyer ought to ensure that the goods he is buying have no defects. Where the goods are open for inspection, the buyer cannot subsequently reject the goods on the grounds of it being defective unless the seller is guilty of misrepresentation. This is based on the principle of 'caveat emptor' (Buyer beware). However, under SOGA 1893 terms, as to fitness for purposes merchantable quality can be implied into a sale of goods contract.[782]

By these provisions, it could be agreed that the SOGA has ousted the effect of caveat emptor. As the maxim, it cannot be employed to escape liability under SOGA. In *Akoshile v. Ogidan,*[783] the court held that caveat emptor cannot operate to oust the provisions of Section 12(1) SOGA.

4.2.2.3 Duties of the Seller and the Buyer

In a contract of sale of goods, the seller and buyer owe each other certain duties.The seller owes the buyer six duties, namely; the existence of the goods,[784] pass good title,[785] deliver the goods,[786] supply the goods at the right time,[787] supply the goods in the right quantity,[788] and supply the goods in the right quality.[789]The duties to supply the goods in the right quantity and right quality are applicable at the time of entering into and the execution of the contract.

[781] Section 11 (1) (a) SOGA.
[782] Sections 10-15 SOGA.
[783] (1970) 19NLR87
[784] S.6 SOGA
[785] S.12(1) SOGA
[786] S.27 SOGA
[787] S.29(5) SOGA
[788] S.30(1) SOGA
[789] S.14(1)(2) SOGA

By virtue of S. 30(1) SOGA, where a seller delivers to the buyer, goods which are of lesser quality than that which the latter contracted for, the buyer may reject them. However, if the buyer accepts them as delivered, he must pay for them at the contract rate.

Be that as it may, Section 14(2)(3) and Section 15(2) provide that the goods must be fit for the purpose for which they are bought and must be of merchantable quality. It has been argued that the provision in respect of fitness for purpose is a move away from the common law rule of caveat emptor.[790] Being implied conditions, they give the buyer some degree of protection when read together, even where though the goods are of merchantable quality, but not fit for the buyer's purpose, he may reject them.[791]

4.2.2.4 Implied Terms

The implied terms imposed by SOGA are essentially to protect the consumer. The SOGA provided for five (5) implied terms, namely, right to sell compliance with description, fitness for purpose, merchantable quality, compliance with sample, and time stipulations.[792]For the purpose of this study, the implication terms in respect of fitness for purpose and merchantable quantity will be discussed.

4.2.2.4.1 Fitness for Purpose

At Common Law, fitness for purpose was neither an implied condition nor warranty in a contract of sale. The buyer was required to acquaint himself with any possible defects of the goods he was purchasing. He would only be entitled to remedy in the event of fraud or misrepresentation. This position has also been maintained by SOGA. Section 14 provides that,

> subject to the provisions in it or any other statute, there is no implied warranty or condition as to the quality or fitness for any particular purpose of goods supplied under a contract of sale….

By virtue of Section 14(1),

[790]Atiyah P S. 1981. *The Sale of Goods* (6th ed.) Pitman Publishing Ltd. London. p.85
[791]*Ibid*. p.86.
[792] See Research Report on the State of Consumer Protection in Nigeria: A Review of Consumer Protection in the Telecom Sector in Nigeria. p. 104 – 106.

> where a buyer expressly or by implication makes known to the seller the purpose for which the goods are required, so as to show that the buyer relies on the seller's skill and judgement and the goods are of a description which it is on the course of the seller's business to supply (whether he be a manufacturer or not), there is an implied condition that the goods shall be reasonably fit for such purpose…..

This provision will however not apply to goods sold under its patent or trade name. Given this exception, can it be argued that this takes drugs out of these provisions?

There are certain requirements which must be fulfilled for the conditions in Section 14 (1) to apply. The seller must know the purpose for which the goods are required. The buyer must have either expressly or impliedly made the purpose known to the seller. More often than not, the buyer would usually not be specific as to the purpose for the goods. In such cases, notification of the purpose for which the goods are required will clearly be implied from the purchase of the goods.[793] Consequently, where a buyer buys a drug for treating headache, he would expect it to be reasonably fit to cure the headache.[794]

Where the goods may however be used for several purposes and the buyer has in mind a particular purpose, he must expressly notify the seller of this if he is to rely on the sector. In *Adeola .v. Henry Stephens and Sons Ltd*,[795] the Plaintiff bought flour from the Defendants. The flour turned out to be unsuitable for baking bread, but suitable for baking biscuits. In an action for breach of the condition for fitness of purpose under Section 14, the court held that the buyer could not succeed as he did not make known to the seller the particular purpose for which she required the flour.

Express notification to also necessary where there are circumstances which make it necessary for the goods to be fit for a purpose than its normal purpose. In *Griffiths .v. Peter Conway Ltd*,[796] a lady bought a coat and she did not disclose to the seller that she had a particular sensitive skin. She suffered an allergic reaction from wearing the coat and brought an action for damages under Section 14(1). The skin of normal person would not

[793] Akanki. *Loc. cit*. p.286.
[794] *Osemobor .v. Nigeria Biscuit Co. Ltd* (1973) NCLR 382.
[795] (1975) CCHCJ 1023
[796] (1935) 1 All. ER 685.

have been affected by the coat. The court held that there was no breach of the condition, given that she had not made her special condition known to the seller.

Similarly, in *Khalil .v. Mastroni Kolis*,[797] the buyer took delivery of engine oil which turned out to be unsuitable for use in internal combustion engines. The oil was suitable for other purposes. The buyer was precluded from bringing an action based on Section 14 (1) given that he did not make the purpose for which he needed the engine oil known to the seller.

Furthermore, the buyer cannot plead the exception, unless he relied as the seller's skill and judgement. Reliance is a question of fact and is determined on a case by case basis.[798] All that the buyer needs to do is 'merely disclose the purpose' to the seller. Where the sale is by a manufacturer or retailer to a consumer, the inference can easily be drawn.[799] The buyer's reliance does not necessarily have to be totally exclusive, partial reliance of the seller's skill and judgement will suffice. The seller's liability is however limited to the extent of the reliance placed on him.

In addition, this implied condition will be applicable where the goods are of a description which *it is in the course of the seller's business to supply*. Where it is the seller's business to supply goods of the buyer's description, he will be taken to be capable of exercising sufficient skill or judgement in selecting goods fit for the particular purpose for which he knows the buyer wants them. A buyer who buys by way of private sales is not protected by the subsection.

This implied condition will not be applicable where the goods are sold under its patent or trade name. Where goods are described in the contract by its trade name, it does not necessarily make the sale under that trade name. In *Baldry .v. Marshall*,[800] the buyer informed the seller that he wanted a comfortable car suitable for touring. The seller (Defendant) recommended a 'Bugatti' 8-cylinder car, which the Plaintiff (Buyer) bought.

[797] (1949) 12 WACA 462
[798] Akanki. *Ibid*. p.288.
[799] *Cammell Laird & Co. Ltd .v. Manganese Bronze & Brass Co. Ltd* (1934) AC 402.
[800] (1936) 1 KB 260.

The car turned out to be uncomfortable and unsuitable for touring purpose. The court held that, the mere fact of a car being sold under its trade name which is part of the description of the car, does not necessarily exclude the conditions of fitness and if the buyer, while asking to be supplied with a named make of car, indicates to the seller that he relies on his skill and judgement for it being fit for a particular purpose, he does not buy the car under its trade name within the meaning of Section 14 (1). The buyer's (Plaintiff) claim therefore succeeded.

From the foregoing, would buying a malaria medicine under its trade name preclude the seller from being under the reliance of his skill and judgement, if it is found not to be fit for purpose? The author would align with the decision of the court in the *Baldry case*, that the mere fact that a drug is being sold under its trade name which is part of its description, does not necessarily exclude the conditions of fitness and if the buyer, while asking to be supplied with branded drug, indicates to the seller that he relies on his skill and judgement for it being fit for a particular purpose, Section 14(1) will therefore not be applicable to this type of situation.

4.2.2.4.2Merchantable Quality
Section 14 (2) provides that,

> Where goods are bought by description from a seller who deals in goods of that description (whether he be the manufacturer or not), there is an implied condition that the goods shall be of merchantable quality; provided that if the buyer has examined the goods then there shall be no implied condition as to records defects which such examination ought to have revealed.

Firstly, this provision applies only to goods bought by description. "Description" is in the same context as in *Section 13*. Secondly, the goods must be those in which the seller ordinarily deals in. In *British & Overseas Credit Ltd .v. Animashaun,*[801] it was shown that

[801] (1961) All NLR 357

the seller ordinarily dealt in goods of the kind in question, therefore the court held that the implied condition as to merchantable quality did not apply.

The Act does not define 'merchantable quality'. Consequently, it has been the subject of numerous judicial pronouncements. The goods are often regarded as of merchantable quality when they are of use for the purpose for which such an article is ordinarily used, and in such condition and of such quality that a reasonable man, acting reasonably, would after full examination accept them in performance of the contract. In *Plastic Manufacturing Co. Ltd. v. Toki of Nigeria Ltd*,[802] the Plaintiff agreed to supply the Defendants with plastic containers made of the same materials as in the sample, but of polythene. They were duly supplied, but when they put their products (cosmetics) in the containers, the product changed colour after about a month. The Defendant did not inform the Plaintiff of the chemical composite of their products. The Defendants were sued for the price and they counter-claimed for damages for defective containers. It was held that 'merchantable' in this case meant that the goods in the containers should be suitable for the purpose for which such plastic containers are normally used and that in the circumstances they were merchantable.

The concept of merchantability is flexible and it requires different considerations. It has been described, *as a composite quality comprising of description, purpose, condition and price. The relevant significance of each of these elements will vary from case to case characteristics of the market which exists for them*.[803]

What is important is that the goods live up to the buyer's reasonable expectations. If the goods are sold under a description which they fulfil, and if goods under that description are reasonably capable of being used for several purposes, they are of merchantable quality if they are reasonably capable of being capable of being used for any one or more of such purpose, even if unfit for that one of those purposes which the particular buyer intended.[804]

[802] (1976) 12 CCHCJ 2701
[803] Per Omrod LJ in *Cehave N.V .v. Bremer Handelsgesell Schaft mbH* (1975) 3 All ER 733 at p.763.
[804] *Beer .v. Walker* (1877) 46 LJQB 677.

The obligation regarding merchantable quality does not apply in the following circumstances, namely,

(i) In respect of defects specifically drawn to the buyer's attention before the contract is made; or

(ii) If the buyer examines the goods before the contract is made, as regards defects which that examination ought to have revealed.

With regards to examining the goods before purchasing to reveal its quality, this may not be applicable to situations involving counterfeit drugs. This is because physical examination of the counterfeit drugs may not readily reveal its status. Examination of the product before the contract is made may not be applicable to this situation.

There is no obligation on the buyer to examine the goods and so the mere opportunity to examine the goods before the contract is made will not defeat the implication of the condition. Where the examination is merely perfunctory, the buyer's right to complain about the defect which an examination could not be expected to reveal, is unaffected. If the buyer is given the opportunity to examine the goods and he leads the seller to believe he has done so, he (buyer) may be estopped from denying that he has made full examination, he will be bound by the defects which a full examination would have revealed. In *The British & Overseas Credit Ltd .v. Animashaun*,[805] the Plaintiff imported one thousand (1000) cases of tinned tomato paste and stored them at the Defendant's premises. The Health Authorities inspected the goods and condemned three (300) cases as being unfit for consumption. The Defendant was aware of this and had access to the stores where the goods were kept. He nevertheless purchased the remaining seven (700) cases and started selling them. The Health Authorities subsequently inspected and destroyed three hundred and eleven (311) cases. The Defendant then refused to pay the balance of the purchase price on the grounds that there was a breach of the condition as to merchantable quality. The court held that the condition as to merchantable quality did not apply, given that the Defendant saw the goods, was put on inquiry, accepted them and had

[805] (1991) 1 All NLR 357

full opportunity of examining them, he must be taken to have examined them within the meaning of the proviso to Section 14(2).

The positionthat there is no obligation on the buyer to examine the goods before purchase may have been altered in relation to counterfeit drugs. This is can be attributed to the introduction of the Mobile Authentication System (MAS) by NAFDAC, as an anti-counterfeiting technology. MAS, enables a consumer to check the authenticity of medication with a simple text message. A code on the packaging of the medication is sent to a specified phone number and the buyer gets a confirmation authenticating the medication. Given the availability of this facility, it is the opinion of the writer that a buyer who fails to avail him/herself of the opportunity cannot claim against the seller should there be any problem subsequently.

4.2.2.5 Remedies for Parties

With regards sale of goods, the Seller is entitled to Personal and real remedies.

Real remedies include, right of liens or retention, stoppage of goods in transit, and the right to resell the goods. These are however subject to certain conditions which the seller must satisfy. For instance, he can only exercise the right of liens if he is still in possession of the goods.

On their part, personal remedies for the seller include action for the contract price and damages for non-acceptance. For a claim of personal remedy to succeed, it must be shown that the person making the claim is an unpaid seller. He is an "unpaid seller" where the whole of the price has not been paid or tendered; and a bill of exchange or other negotiable instrument has been received as conditional payment and the condition on which it was received has not been fulfilled by reason of the instrument being dishonoured or otherwise.[806]

With regards the buyer, damages available include, for non-delivery, specific performance, damages for breach of warranty, action for refund of price and rejection of goods.

[806] See*Afrotec Technical Services (Nig.) Ltd v. MIA & Sons Ltd*(2002) 12 SC (pt2)1.

Rejection of goods must be done within a reasonable time and before property passes to the buyer. Where however, the goods are defective, as to amount to a breach of a condition, the buyer can reject them, as long as he has not done any act amounting to acceptance.[807]

Sale of Goods Law, offers a consumer who is privy to a contract of sale of goods some measure of remedy. This is irrespective of the origin of the product. Consequently, a course of action can be maintained against a seller or distributor whether or not he is the manufacturer of the offending product. In *Nigerian Bottling Co. v. Ngonadi*,[808] a buyer successfully claimed against a distributor. The court applied Section 15(1) Sale of Goods Law[809] of the defunct Bendel State and held that it made no different that the appellants were mere distributors and not the manufacturer of the refrigerator. Privity of Contract however limits the ability of non-contractual consumers to make claims under the sale of goods laws.

Drugs are goods within the definition in SOGA and they are available for anyone who needs them to buy. The Pharmacies and patent medicine stores can be described as the market place for the sale of these drugs. Anyone who buys is a buyer within the definition in SOGA. He/she is entitled to all rights that accrue to a purchaser by virtue of the Act. At the point of sale, a contractual relationship is established. Consequently, when a buyer is injured/harmed by the drugs he bought, he may be entitled to remedies.

4.3. Human Rights

Human rights are inherent to all human beings. Human rights are interrelated, interdependent and indivisible. They are expressed and guaranteed by laws, both national and international. These laws set obligations for governments to act or refrain from certain acts, in order that human rights and fundamental freedoms of citizens are promoted and protected.

---

[807] F. Monye. 2006. *Commercial Law: Sales of Goods, Hire Purchase and Carriage of Goods by Sea*. Enugu, Cherylo Ltd, pp. 103-105

[808] (1985) 5 SC 713,

[809] Cap 150. See also Monye, F. *ibid.* pp. 132 – 136.

Human rights entail both rights and obligations.[810] Under international laws, states take on obligations and duties to respect, to protect and to fulfil human rights. The obligation to respect implies that States must refrain from interfering with or curtailing the enjoyment of human rights. The obligation to protect requires States to protect individuals and groups against human rights abuses. By the obligation to fulfil, States must take positive action to facilitate the enjoyment of basic human rights. At the individual level, while we are entitled our human rights, we should also respect the human rights of others.

Human rights are based on values such as dignity, respect, fairness, equality and independence. They can be classified into two (2) main types, namely, civil and political rights, and social, cultural and economic rights. The first category includes the right to life and liberty, freedom of expression, equality before the law and the right to be free from discrimination. The second category consists of the right to participate in culture, the right to work, the right to an adequate standard of living, right to health, and the right to education.

Relevant to this study are the right to life and right to health. These will be discussed in this section.

4.3.1. Right to Life

The right to life is guaranteed under the Nigerian Constitution. Section 33 of 1999 Constitution, provides as follows:

> (1) Every person has a right to life, and no one shall be deprived intentionally of his life, save in execution of the sentence of a court in respect of a criminal offence at which he has been found guilty in Nigeria.
>
> (2) A person shall not be regarded as having been deprived of his life in contravention of this section, if he dies as a result of the use, to such extent and in such circumstances as are permitted by law of such forces as is reasonably necessary:
>
> (a) For the defence of any person from unlawful violence or for the defence of property;

[810] "What are Rights?" A publication of the Office of the Commissioner, UN Human Rights. Retrieved from www.ohchr.org on 28th August, 2017.

(b) In order to effect a lawful arrest to or to prevent the escape of a person lawfully detained; or

(c)For the purpose of suppressing a riot insurrection or mutiny …"

This right is however not absolute but qualified.[811] According to Ajomo, life is sacrosanct. Consequently, deliberate killing is prohibited in all societies. What this provision means is that all individuals are entitled to respect for his or her life and safety. The Constitution makes some exception to the rule relating to preservation of life.[812]

According to Uchegbu S, the right to life presupposes the existence and availability to all of certain basic facilities such as food, health, shelter and education.[813] In *Jonah Gbemre v. Shell Petroleum Development Corporation of Nigeria Limited (Shell & Nigeria National Petroleum Corporation (NNPC),*[814]the plaintiff, brought an action against Shell Nigeria, NNPC and the A.G. of the Federation seeking a declaration that the constitutionally guaranteed fundamental rights to life and dignity of human person provided in sections 33(i) and 34(i) of the Constitution of Federal Republic of Nigeria 1999… inevitably includes the right to clean, poison free, pollution free and healthy environment.

The court declared that the actions of the 1st and 2nd respondents in continuing to flare gas in the course of their oil exploration and production activities in the applicant community was a violation of their fundamental right to life (including healthy environment) and dignity of human person guaranteed by the constitution and the African Charter. The court further declared that the 1st and 2nd respondents, that isShell and NNPC, were to be restrained from further flaring of gas in the applicants' community and were to take immediate steps to stop the further flaring of gas in the plaintiffs' community.[815]

---

[811] Section 33 1999 Constitution of the FRN; see also, *Kalu .v. State* (1998) 13 NWLR (pt 583) 531 SC

[812] Ajomo M A. Fundamental Human Rights under the Nigerian Constitution in *Perspective on Human Rights*. (ed. Kalu A. U. and Osinbajo, Y.) Federal Ministry of Justice. Lagos. pp. 80-81.

[813] Uchegbu S. The Concept of Right to Life under Nigerian Constitution in Essays in Honour of Judge T. O. Elias (ed. By J. O. Omotola) pp151-152. Referred to in Aduba, J. N. 2011. *The Right to Life under the Nigerian Constitution: The Law, The Courts and Reality*. A Publication of the Nigerian Institute of Advanced Legal Studies, Abuja. p. 3

[814] Suit no. FHC/B/CS/53/05 Federal High Court Benin Judicial Division. 14. November 2005 and (2005) AHRLR 151(Nig. HC 2005).

[815] Aduba. Ibid. p.6

Counterfeit drugs and other medical products have been found to violate the right to life or right to good quality life. They have led to serious public health issues, including treatment failures, death, increased hospital admission, prolonged hospital admission and development of drug resistance.

4.3.2 Right to Health

The right to health is one of the natural rights that a person has. The right is recognized by almost all countries of the world and by many international Conventions, Declarations and Treaties. The usage of counterfeit drugs has harmful effects on the public and it undermines their right to health which eventually affects their right to life. The right to health is a fundamental part of our human rights and of our understanding of a life of dignity.[816] It is the right to the enjoyment of the highest attainable standard of physical and mental health.[817]Health, on the other hand, is the state of being sound or whole in body, mind, or soul; the freedom from pain or sickness.[818] According to the preamble of the WHO Constitution, it is "a state of complete physical, mental and social well – being and not merely the absence of disease or infirmity". The 1948 Universal Declaration of Human Rights, states that health is a part of the right to an adequate standard of living.[819] In addition, the Commission on Human Rights in its resolution 2002/31 created the mandate of Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The right to health is an inclusive right, as it contains freedoms and entitlements.[820]The 'freedoms' include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference such as the right to be free from torture, non-consensual medical treatment and experimentation.[821] On the other

[816] The Right to Health Fact Sheet No.31, p. 1. Retrieved from www.who.int.org on 1st August, 2013.
[817] WHO Constitution of 1946.
[818] Bryan A.G. (ed.) *op. cit*. 737
[819] Art 25, Universal Declaration of Human Rights, 1948. See also the International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966.
[820] General Comment 14 to the ICESCR.
[821] Kinney E D. 2001. The International Human Right to Health: What does this mean for our Nation and the world? *Indiana Law Review* Vol. 3:14757: 146

hand, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.[822]

This right covers two areas, the underlying determinants, which include, water, sanitation, food, nutrition, housing, healthy occupation and environmental conditions, education and information, and healthcare. In upholding the right to health, all services, goods, and facilities must be available, accessible, acceptable and of good quality. That is, they must be scientifically and medically appropriate and of good quality.[823]

The elements of the right to health are[824]:

a. Availability, which entails sufficiency in quantity and quality, within their jurisdiction, of functioning public health and health care facilities, goods and services, and programmes. In accomplishing this, states should effectively promote the development and availability of medicines, medical care and facilities, and provide incentives, which will influence research and development in the medical field.

   The responsibility of the state spans to ensuring that good quality existing medicines are available and that new ones are developed and are readily available.

b. Accessibility - health facilities, goods and services must be accessible to everyone. Accessibility is four folds, namely, non – discrimination, physical accessibility, economical accessibility (affordability) and accessible information. This implies that, health care must be accessible nationwide, whether rural or urban. It must also be economically accessible, in that, it must be affordable to all. To this end, state parties must look into their import duties and other taxes on medicines, which will affect the pricing of medication. Furthermore, medicines must be accessible without discrimination on any prohibited grounds, such as sex, race and socio-economic status. Finally, reliable information about medicines must be accessible

[822] The Right to the Highest Attainable Standard of Health, UN. Doc. E/C: 4th Dec, 2000: ICESCR, Gen. Comment 14 (2000).
[823] See note 44.
[824] General Comment No. 14 (2000) to ICESCR.

to both patients and healthcare providers to enable them make informed medical decisions.

c. Acceptability – all health facilities, goods and services must be respectful of medical ethics and culturally appropriate as well as sensitive to gender and life cycle requirements; and

d. Quality – health facilities, goods and services must be scientifically and medically appropriate and of good quality. In line with this, medicines rejected in developed countries must not be recycled to developing countries.This is possible through the use of discriminatory regulations in some foreign countries, which encourages the growth of drug counterfeiting. This results in double standards in international drug distribution. In this instance, substandard drugs which are restricted or banned in countries with more stringent regulations in respect of drugs consumed locally, but less stringent standards/regulations in respect of drugs meant for export, are sold into developing countries.[825]

To curb counterfeiting, therefore, states must establish a regulatory system to check medicine safety and quality.

The right imposes a duty on each state party

> to take whatever steps that are necessary to ensure that everyone has access to health facilities, goods and services so that they can enjoy, as soon as possible, the highest attainable standard of physical and mental health.[826]

State parties, therefore, have an obligation to - Respect, Protect and Fulfil. They are not to interfere with the enjoyment of the right to health.[827]This obligation requires that, state parties ensure that health policies are not discriminatory against women, ethnic minorities or other disadvantaged groups. With regards the duty to protect, they are to ensure that

[825] Bate R and Boateng K. 2007. Bad Medicine in the Market. *Health Policy Outlook*. Retrieved from http://www.aei.org/publications/pubID.263688/pub_details.asp on 21st July, 2017.
[826] "The Right to the Highest Attainable Standard of Health", UN. Doc. E/C, Dec 4, 2000. ICESR, General Comment 14(2000).
[827] This is a duty "not to cause harm' or 'non malificience'.

third parties (non-state actors) do not infringe on the enjoyment of the right to health, by regulating non-state actors. The UNGP framework, which directs that corporations must conduct their businesses in a manner that does not violate the human rights of the citizens. State parties, should therefore provide an enabling environment for ensuring that the right to health of their citizens are protected against violation by third party actors. Consequently, state parties ought to enact legislations against counterfeiting, for which there must be provision for enforcement. Lastly, state parties must take positive steps to realize the right to health by adopting appropriate legislative, administrative, budgetary, judicial, promotional measures. They are to adopt "national strategies that ensure that all citizens enjoy the right to health indicators and bench marks".[828] In addition, available resources, in the most cost-effective way, should be identified to ensure that enjoyment of this right. The National Health Strategies and Plan of Action should be "based on the principles of accountability, transparency, and independent judiciary, given a good governance is essential to the effective implementation of all human rights, including the realization of the right to health.

The right to health therefore includes access to timely, acceptable, and affordable health care of appropriate quality and implies that governments must provide an environment in which everyone can, to a considerable extent enjoy healthy living. Such conditions range from ensuring availability of qualitative health services, healthy and safe working conditions, adequate housing and nutritious food. It should however be noted that the right to health does not mean the right to be healthy.[829]

State parties are expected to establish accessible, transparent and effective mechanisms of monitoring and accountability. This is to make room for review of how their obligations have been discharged, thereby permitting reforms of legislations and policies.

[828] *Op.cit.* fn.73

[829] WHO Factsheet No.323 of November, 2012; see also The role of the government is to uphold it citizens right to health by providing facilities and product conducive for healthy living. However, being healthy is the responsibility of each citizen.

The right to health is also recognized in several regional instruments, such as the African Charter on Human and Peoples Rights[830]; the Additional Protocol in the American Protocol to the American Convention on Human Rights in the area of Economic, Social and Cultural Rights, also known as the Protocol of San Salvador[831]; the European Social Charter[832]; American Convention on Human Rights[833]; the European Convention for the Promotion of Human Rights and Fundamental Freedom.[834]

Chapter Four of the 1999 Constitution of the Federal Republic of Nigeria makes provision for the fundamental human rights recognised by the Constitution. The right to life is the first right provided for in the chapter but the right to health is not mentioned in the Chapter. The Constitution however makes provision for the right to health under its chapter two.[835] difference between chapter two and chapter four is that the rights provided for under chapter four are enforceable in courts of law while those provided for under chapter two are deemed to be Fundamental Objectives and Directive Principles of State Policy which are not enforceable in courts. Rather, the country is enjoined to carry out its duties and responsibilities as stated in the chapter.

Thus, although the Constitution denies legal recognition of the right to health as well as other social and economic (socio-economic) rights, the domestication of the African Charter in 1983 has introduced monumental changes to the legal status of these rights in the country. No longer may constitutional denial of legal recognition to these rights be relied upon to shield the government or its agencies from obligations regarding the right. More specifically, article 16 of the Charter guarantees the right to health.

Nigeria recognizes the right to health and has committed itself to its protection as a result of ratifying relevant international treaties and domestic legislation mandating specific conduct with respect to the health of individuals within its jurisdiction. These include the

[830] 1981; Art 16
[831] 1988. See Art, 10.
[832] 1961, revised in 1996. See Art. 11.
[833] 1969. Part B.
[834] 1950.
[835] Section 17(3)(d) of the 1999 Constitution of the Federal Republic of Nigeria provides that: The State shall direct its policy towards ensuring that there are adequate medical and health facilities for all persons.

International Covenant on Economic, Social and Cultural Rights (ICESCR)[836], Convention on the Elimination of all Forms of Discrimination (CERD)[837], the Convention on the Elimination of all Forms of Discrimination against Women (CEDAW)[838] and the Convention on the Rights of the Child (CRC)[839], the International Covenant on Civil and Political Rights (ICCPR)[840] and the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment.

In addition, Nigeria has ratified Conventions of the International Labour Organizations (ILO), some of which contain provisions on the health of workers[841]. In all, Nigeria has ratified forty (40) ILO conventions, out of which thirty (30) are in force, while ten (10) have been denunciated[842]. Nigeria is also a party to the Geneva Conventions and Additional Protocols[843] that prescribe rules for conduct of warfare, including health-related obligations. Nigeria also adheres to several non-binding instruments/standards that address health issues, such as the 1993 Vienna Declaration and Programme of Action, 1993 UN International Conference on Population and Development and the 1995 Beijing Declaration and Platform for Action (UN Fourth World Conference on Women). At a regional level, Nigeria is a party to the African Charter on Human and Peoples' Rights (African Charter), the African Charter on the Rights and Welfare of the Child and the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa.[844]

It is pertinent to note that, Nigeria adopts a dualist approach in receiving international law. Consequently, treaties and conventions have to be domesticated before it can be applicable[845]. However, with the promulgation of the Constitution of the Federal Republic

[836] 1976.
[837] 1969.
[838] 2011.
[839] 1990.
[840] 1966.
[841] Example include ILO Convention C155 – Occupational Safety and Health Convention of 1981.
[842] 'Ratification for Nigeria'. Retrieved from www.ilo.org on 17th March, 2015.
[843] 1949-2005.
[844] 1995.
[845] S. 12(1) Constitution of the Federal Republic of Nigeria, 1999. (2001) 51 WRN.29. (*Registered Trustees of National Association of Community Health Practitioners of Nigeria and others .v. Medical and Health Workers Union of Nigeria* (2008) 2 NWLR (Pt. 1072) 575, 623.

of Nigeria (3rd Alteration) Act, 2010, which amongst other things, made it possible for claimants to invoke before the National Industrial Court (NIC) relevant provisions of International Treaties and Conventions relating to laboúr, employment, workplace and industrial relations issues, which have been ratified by Nigeria, notwithstanding that same has not been domesticated by an Act of the National Assembly[846]. The effects of this are that, the constitutional clog in the wheel of enforcement of ILO conventions which have been duly ratified by Nigeria[847]; in *Abacha .v. Fawehinmi,*[848] where, the Supreme Court, in discussing the provisions of the African Charter on Human and Peoples' Rights (Ratification and Enforcement) Act, held that the provisions of the Charter have become part and parcel of the body of the Nigerian law because it has been re-enacted by the National Assembly. In giving his lead judgement, Ogundare JSC said as follows:

> Before its enactment into law by National Assembly, an international treaty has no such force of law as to make its provisions justiciable in our courts. See the recent decision of the Privy Council in Higgs & Anor. V. Minister of National Security & Ors. The Times of December 23, 1999 where it was held that-
>
> In the law of England and the Bahamas, the right to enter into treaties was one of the surviving prerogative powers of the Crown. Treaties formed no part of domestic law unless enacted by the legislature. Domestic Courts had no jurisdiction to construe or apply a treaty, nor could unincorporated treaties change the law of the land. They had no effect upon citizen' right and duties in common or statute law. They might have an indirect effect upon the construction of statues or might give rise to a legitimate expectation by citizens that the government, in its act affecting them, would observe the terms of the treaty
>
> In my respectful view, I think the above passage represents the correct position of the law, not only in England, but in Nigeria as well.
>
> Where, however, the treaty is enacted into law by the National Assembly, as was the case with the African Charter which is incorporated into our municipal (i.e. domestic) law by the African Charter on Human and Peoples' Rights (Ratification and Enforcement) Act Cap. 10 Laws of the Federation of Nigeria 1990 (hereinafter is referred to simply as Cap. 10), it becomes binding

[846] See S.254(c) (2), 3rd Alteration Act, 2010.
[847] Atilola B and Morocco-Clarke. 2011. National Industrial Court and Jurisdiction over International Labour Treaties under the 3rd Alteration Act, 2010. *Labour Law Review*. Vol. 5, No.4 p.3.
[848] *Supra.*

> and our Courts must give effect to it like all other laws falling within the Judicial power of the Courts. By Cap. 10 the African Charter is now part of the laws of Nigeria and like all other laws the Courts must uphold it. The Charter gives to citizens of member states of the Organisation of African Unity rights and obligations, which rights and obligations are to be enforced by our Courts, if they must have any meaning. It is interesting to note that the rights and obligations contained in the Charter are not new to Nigeria as most of these rights and obligations are already enshrined in our Constitution. See Chapter IV of the 1979 and 1999 Constitutions.
>
> No doubt Cap. 10 is a statue with international flavour. Being so, therefore, I would think that if here is a conflict between it and another statute, its provisions will prevail over those of that other statute for the reason that it is presumed that the legislature does not intend to breach an international obligation. To this extent I agree with their Lordships of the Court below that the Charter possesses "a greater vigour and strength" than any other domestic statue. But that is not to say that the Charter is superior to the Constitution as erroneously, with respect, was submitted by Mr Adegbrouwa, learned counsel for the respondent. Nor can its international flavour prevent the National Assembly, or the Federal Military Government before it removing it from our body of municipal laws by simply repealing Cap. 10. Nor also is the validity of another statute to be necessarily affected by the mere fact that it violates the African Charter or any other treaty, for that matter- see: Chae Chin Ping v. United States 130 US. 181 where it was held that Treaties are of no higher dignity than acts of Congress, and may be modified or repeal by Congress in like manner: and whether such modification or repeal is wise or just is not a judicial question.

It is now trite law that all international treaties are not enforceable in Nigerian courts where they have not been ratified by the National Assembly. Also in the *Registered Trustees of National Association of Community Health Practitioners of Nigeria and others .v. Medical and Health Workers Union of Nigeria*[849], where the court in discussing the provisions of an ILO convention, held that it cannot be invoked and applied by a Nigeria court until same has been re-enacted by an Act of the National Assembly, would be decided otherwise.

Nigeria is a signatory to over two hundred (200) bilateral and multilateral Treaties, Agreements and Protocols, but less than fifteen (15) have been domesticated.[850] It has been

[849] *Supra*.
[850] Anon. Nigeria Bilateral Ties: House Calls for Domestication/Ratification. Retrieved from www.placng.org on 17th March, 2015.

argued that the dualistic nature of the country's parliamentary system has hitherto reflected in the domestication of international conventions. Hence, these have to undergo National Assembly scrutiny, which takes a longer duration before enactment, if at all.[851] Similarly, the Federal Government fails to measure the implications of implementing these conventions on the nation's economy, before ratifying them.[852]Lastly, the main reason for not domesticating international conventions is the lack of political will to enforce economic, social and cultural rights.

It is therefore significant to note that with the exception of the African Charter, which has been domesticated, no other treaty, having direct bearing on the right to health is enforceable. The implication of domesticating the African Charter is that, it has changed the legal status of the right to health and other economic and social rights. No longer may constitutional denial of legal recognition to these rights be relied upon to shield the government or its agencies from obligations regarding the right. More specifically, Article 16 of the Charter guarantees the right to health.[853]

As noted earlier, the availability of counterfeit drugs is a direct infringement on the right to health, which provides that health care must not only be affordable, accessible and acceptable, but must be of good quality. The requirement for quality applies to facilities, goods and services, which must be scientifically and medically appropriate and of good quality.

As it relates to its obligations under the right to health, Nigeria in principle, has done a lot. This is because, the government has in place legislation, guidelines and policies geared towards protecting, respecting and fulfilling this right, particularly, in relation to drug counterfeiting. The results of these efforts are however not obvious, as some of it policies

[851] Eroke L. 2013. Beyond Global Conventions and Implementation Hitches. *This Day*, 27th August, 2013. Retrieved from www.thisdaylive.com on 17th March, 2015.
[852]*Ibid.* p.3
[853] Nnamuchi O. 2007. The Right to Health in Nigeria. *Right to Health in the Middle East Project*, Law School, University of Aberdeen. Retrieved from http/www.ssrn.com, on 5th May, 2013.

have effects that are counterproductive.[854] This and other related matters will be examined in the next chapter.

[854]An example is the new import duties on medicines, which have the effect of increase the cost of medication. See Ifijeh M. 2017. 20% Tax on Medicaments and the Incoming Pain. *This Day.* February 16, 2017. Retrieved from https://www.thisdaylive.com on 25/3/19

CHAPTER FIVE

COMBATING DRUG COUNTERFEITING IN NIGERIA: PROSPECTS AND CHALLENGES

Having examined the legal issues in drug counterfeiting as it relates to the right to health and the journey so far in combating drug counterfeiting in Nigeria, as a way of the government fulfilling its obligation towards respecting, protecting and fulfilling the citizens' right to the highest attainable standard of health, this chapter discusses the findings from the study, the prospects and challenges to the efforts thus far. In doing this, this chapter is divided into two (2) sections, which will look into combating drug counterfeiting in Nigeria, and combating drug counterfeiting in Kenya and India. In conducting the study, key informant and focus group discussions were carried out with doctors, pharmacists, lawyers, patent medicine vendors and patients, the reports of these will also be discussed.

5.1 Combating Drug Counterfeiting in Nigeria

Drug counterfeiting in Nigeria and the right to health in Nigeria can, and will be discussed under three (3) heads. The first is the use of legislative instruments and common law principles, the second is the role of relevant regulatory agencies in the fight against drug counterfeiting and lastly, the use of technology.

5.1.1 The Law as a Tool for Combating Drug Counterfeiting in Nigeria

In combating drug counterfeiting and enforcing the right to the highest attainable health, numerous legislative instruments have been promulgated. These have been discussed in Chapter 3. An assessment of these legislative instruments was carried out in this chapter, with the view to assessing the extent to which they have been effective. In addition, certain common law principles have been applied to situations of drug counterfeiting. These have also been discussed fully in Chapter 4 and will only be assessed in this part of the work.

5.1.1.1 Legal Framework

The legal framework for regulating production and distribution of medicines and related products in Nigeria is very robust. In addition to national laws, policies, guidelines and regulations, Nigeria has commitments to other regional and international agreements, which regulate and control drug manufacture and distribution.

The legislative instruments, which have been discussed in Chapter 3, make provisions for regulating, controlling, distributing, packaging and storing medicines and medical products. Others deal with pre-shipment inspections, labelling, registration of premises where products are made and stored, registration of the manufacturers, wholesalers, retailers and those dispensing the drugs in health care centres. Some of the laws[855] go as far as establishing corporate criminal liability, with officers' liability clauses[856] in relation to drug counterfeiting. Also regulated are weights and content of the products and advertisements.

A core obligation of the right to health requires that national public health strategies and action plan be adopted and implemented. This must be devised and periodically reviewed on the basis of a participatory and transparent process, with indicators and benchmarks for monitoring progress. Particular attention must be given to all vulnerable or marginalised groups.

From the discussions in chapter 3, it is obvious that Nigeria has a lot of statutory instruments in place to guaranty the right to health. Be that as it may, these instruments overlap, giving room to confusion as to what angle a prosecution should proceed from. Their provisions sometimes conflict, creating loopholes for offenders, thereby making prosecution and convictions difficult.

In addition, most are outdated, with ridiculously lenient penalties. As discussed in chapter 3, the penalty is three (3) months to fifteen (15) years prison term and a maximum fine of

[855] Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, Food, Drugs and Related Products (Registration) Act, Pre-Shipment Inspection of Imports Act, and Pre-Shipment Inspection of Export Act.
[856] See Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, Food, Drugs and Related Products (Registration) Act and Pre-Shipment Inspection of Exports Act.

Five Hundred Thousand Naira (₦500,000).[857]These penalties, though adequate at the time of enacting the laws, going by the severity of the effect of counterfeit drugs on people, the penalties are not commensurate with the crime. There is therefore an urgent need for law reform, to meet present day realities. Stiffer penalties will deter offenders by making the business harder and less lucrative. NAFDAC is however seeking for stiffer penalties for drug counterfeit. The proposed law seeks life jail term and confiscation of assets upon conviction and compensation of victims, where fake drug is found to be the proximate cause of injury.[858]One other thing that affects efforts at curbing drug counterfeiting is Nigeria's dualist approach in receiving international laws. Consequently, regardless of what benefits accrue from these laws, if they have not been domesticated, Nigerians cannot appropriate them.

It is expected that there are effective, transparent and accessible monitoring and accountability mechanisms available at the national level. The challenges of Nigeria's drug regulation is in relation to implementation and enforcement. This is caused by corruption and conflicts of interests on the part of the law enforcement officers. Corruption, adversely affects personnel efficiency, with the result that, criminals often escape arrest, prosecution and conviction, whilst the counterfeit and substandard drugs find their way into the legitimate drug distribution chain. In addition, there is the lack of political will to do all that is possible for the realisation of the enjoyment of the highest attainable standard of health. This is evident in the slow speed with which law reforms are made. There are also laws and policies made in other areas which have negative effect on the accessibility and affordability of the right to health.[859]

The challenge of implementation and enforcement of these laws have resulted in chaotic drug distribution system. Drugs are marketed indiscriminately. Hawkers, drugs sellers and health professionals buy from the same markets. Another consequence of this issue is the avenue for the evasion of inspection and detection by some importers, who make false

[857] At today's exchange rate is equivalent to One Thousand Four Hundred US Dollars ($1400).
[858] Anon, 2013. Stiffer Penalties will Reduce Drug Counterfeiters – NAFDAC. *Business Day*. 17th May, 2013.
[859]For instance the increase in import duties which resulted in the increase in price of medicines and medical products, alongside other consumables.

declarations in respect of the nature or content of their products. Some camouflage their products with other products to avoid detection.

A contributory factor to the ineffectiveness of the move at controlling drug counterfeiting is the lack of uniformity in the definition of counterfeit drugs across nations. The WHO defines counterfeit drugs as 'drugs which are deliberately and fraudulently mislabelled with respect to identity and source[860]. For instance, in 2012, the WHA agreed to adopt the terms "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" in relation to drug counterfeiting.

Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous) Act, on its part, defines fake drugs as,

(a) Any products which is not what it purports to be,

(b) Any drug or drug product which is coloured, coated powdered, or polished that the damage is concealed or which is made to appear to be better or of greater therapeutic value than it really is, which is not labelled in the prescribed manner or which label or containers or anything accompanying the drug bears any statement, design or device which makes a false claim for the drug or which is false or misleading; or

(c) Any drug or drug product whose container is so made, formed or filled as to be misleading; or

(d) Any drug product whose label does not bear adequate direction for use and such adequate direction for use and such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe usage or methods or duration of use; or

(e) Any drug product which is not registered by the agency in accordance with the provisions of the Food, Drugs and Related Products Acts, Cap F33.

[860] 'WHO Guidelines for the Development of Measures to Combat Counterfeit Drug'. Retrieved from www.who.int on 30th June, 2013.

Kenya, in Section 2 of its Anti-Counterfeiting Act, defines 'counterfeiting' as,

> taking certain actions without the authority of the owner of the IP Rights subsisting in Kenya or elsewhere in respect of protected goods.

And in relation to medicine, section 2(d) defines counterfeiting as,

> the deliberate and fraudulent mislabelling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging.

Going by this definition, Kenya brings them under the 'falsified' drugs within the WHO's definition. This definition has been criticised for being vague, resulting in undermining access to affordable generic medicines since it failed to clearly distinguish between counterfeit and generic medicines.

India does not use the same definitions as the WHO in distinguishing between sub-standards and counterfeits. Rather, she identifies "spurious medicines," which include fake and adulterated medicines, and "grossly substandard" medicines, defined by percentage of active ingredient present.

There is so much confusion between the words counterfeit, fake, illicit and substandard, so much so that, it is often difficult to determine whether what is being referred to, is an actual or suspected counterfeit or a substandard product that may or may not be counterfeit. The result is uncertainty as to whether or not to prosecute and for what.

In order to formulate establish a common understanding of what is meant by substandard and falsified medical products, and to facilitate a more thorough and accurate comparison, and analysis of data, the WHA, at its seventieth assembly, held on 29th May, 2017, has formulated a new definition, which focuses on public health implications of substandard

and falsified products but does not cover the protection of IP rights.[861]The WHA agreed to adopt "substandard and falsified" (SF) medical products instead of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" (SSFFC). It noted that "substandard" medical products are those authorized by national regulatory authorities, but which fail to meet either national or international quality standards or specifications or both, as the case may be.

"Falsified" in its part, refer to medical products whose identity have been deliberately or fraudulently misrepresented. Identity here, refers to composition and source.Also agreed on, was the definition of "unregistered" or "unlicensed" medical products. These are those products which have not been assessed or approved by the relevant national or regional drug regulatory authority, in respect of a market, where the drug is being marketed, distributed or used.Though not meant to be exhaustive, it is meant to simplify the current terminologies from a public health perspective.

From the above, it obvious that Nigeria has laws to tackle drug counterfeiting and its consequences. However, they have failed to put an end to or curb the menace, as the laws are outdated, overlap, causing confusion and penalties are very lenient, compared with the economic situation of the country and the profits which accrue to the counterfeiters. There is therefore an urgent need for reform in order for the people to enjoy their rights

5.1.1.2 Legal Remedies

The legal issues identified in relation to drug counterfeiting and the right to health are, Contract, Criminal law including Corporate Criminal Liability, Public Health and the law of Tort, Consumer Protection, Sale of Goods, and Human Rights. These will be discussed below.

5.1.1.2.1 Contract

[861] WHO Member State Mechanism on Substandard/Spurious/Falsely Labelled/Falsified Counterfeit (SSFFC) Medical Products. Retrieved from www.who.int/medicines/regulations/ssffc/A70_23-en1.pdf on 13th June, 2018.

Of relevance are the contractual principles of privity, caveat emptor, freedom of contract and misrepresentation. The principle of privity of contract provides that only parties to a contract can take a right or assume an obligation under it. The doctrine has been found to be a severe limitation on the efficacy of consumer rights, given that only an individual who obtains goods directly from the supplier has a right of action against the latter, where the goods are found to be unsatisfactory. In this situation, a victim of counterfeit drug is left with no redress from the manufacturer.

Under the doctrine of *caveat emptor* (buyer beware), it is expected that the buyer would have examined, tested, measured, weighed or done all that is necessary before making a purchase, as he would not be entitled to reject the goods, nor will he be entitled to any remedy should he find them defective subsequently. The Mobile Authentication Service (MAS) allows a buyer to authenticate drugs before purchase, by sending an SMS to a toll-free number. Each drug comes with a code which is forwarded to a verification centre and the buyer is expected to get a report on its authenticity.

Issues are however raised, where there is failed network service of the mobile operator and reply does not come or the SMS does not get delivered, in the first instance. Will the seller be entitled to a new packet, where the buyer rejects the drug for lack of authentication?Exceptions to the caveat emptor doctrine include, fraud, mistake and express guarantee/warranty which may not be applicable in relation to counterfeit drugs.By virtue of the freedom to contract principle, persons of full capacity could make contracts as they like, thereby allowing parties to provide for the terms and conditions that will govern the relationship. It may not be a reality for a customer, ailing or otherwise, as against a corporation, for instance a pharmaceutical company.

Misrepresentation is an untrue statement made by one party to another before or at the time of contracting with regards to some existing facts or to some past events which is one of the causes that induced the contract.[862] For misrepresentation to be actionable, it must

[862] I. E. Sagay. *Loc cit*. See *Abba .v. Mandillas and Karabeis Ltd* (1964) 2 ALR Comm.337.

have had an effect on the Plaintiff's mind. It must consist of facts, past or present, not a statement of opinion, intention or law.[863]

With regards counterfeit drugs, the manufacturer of a counterfeit or substandard drug can be said to have made a misrepresentation of fact. The fact, being that both the packaging and instruction leaflet, would contain claims relating to the ingredients and the efficacy of the drugs knowing same to be false. These claims, the buyer would have relied on. This will entitle him/her to rescind the contract or bring an action for damages.Of the four (4) contractual principles, the caveat emptor appears to offer the consumer limited protection to the extent that the MAS has functional telecom network to confirm authenticity of the drug. Misrepresentation, offers the best respite. This is however assuming that the buyer is aware of his/her rights and is in a position to pursue it. Four out of six of the patients and patent medicine vendors, and 2 out of six of the pharmacists and doctors were not aware of the rights available to victims of drug counterfeiting. This is a fair illustration of population and their awareness of their legal rights.

5.1.1.2.2Criminal Law

With regards counterfeit drugs, this relates to the safety and health of the consumer. In this regard, some offences have been classified as strict liability offences. Some laws create corporate criminal liability, thereby making the corporations liable for their actions or omissions. There are several legislations which create various levels of criminal liabilities and penalties. These have been discussed in chapter four. These legislations however overlap, thereby complicating issues as it relates to their enforcement. Most are outdated, providing for ridiculously lenient penalties, as it compares with the gravity of the crime. Akin to this is the issue of effective implementation machineries.

All these contribute to the lack of noticeable success in curbing the growth of the menace, nor give comfort to the victims of counterfeit drugs. There is therefore the need to consolidate and reform these legislations into a comprehensive anti-drug counterfeiting legislation, in line with present day requirements.

[863] *Udogwu .v. Oki*., *supra.*

5.1.1.2.3Public Health and Law of Torts

A tort is a breach of civil duty imposed by law and owed to all persons, which is usually redressed by an award of unliquidated damages, injunction or other appropriate civil remedy. Tort law has been deployed as a tool of protecting public health. Tort litigation has been identified as a potential effective tool to reduce the burden of injury and disease. It is useful in preventing risk behaviour and providing incentives for safer product designs, may therefore be used in curbing the growth of counterfeit drugs and protecting the right of citizens to enjoy accessible, affordable and good quality healthcare.

Under this area of law, some offences have also been classified as strict liability offences, thereby requiring no proof of *mens rea*. These cover acts that endanger the public welfare or actions which affect or endanger the environment or vegetation of Nigeria. It has been applied to cases of product liability in order to hold a seller liable for defective or hazardous products that threaten consumers' personal safety.

Negligence requires that there is a duty owed by one party to the other. It is hinged on the principle of "love your neighbour". This duty extends to all that are likely to be harmed by the act or omission of the Defendant. For an action in negligence to subsist, the duty must have been bridged, and the resulting injury must be a foreseeable consequence of the Defendant's action, and whether the Defendant could have anticipated harm at the time he engaged in the risk behaviour. A drug counterfeiter would know that his concoction would cause harm, he therefore owes the end user a duty of care, which he/she is in breach of by producing the drug and will be liable for if the drug is used and it causes harm. Where there is a breach of duty, the party who suffers harm, as a result of the breach, will be entitled to compensatory damages.

5.1.1.2.4Consumer Protection

This relates to protecting the pecuniary, health, safety and security interests of the citizenry against misleading, fraudulent, and harmful business practices, including manufacturing, trading, packaging and advertisement.

Consumer protection is hinged on the human rights principles of fair hearing, access to justice, right to hold personal opinion, and receive and import ideas and information

without hindrance, the right to form associations for promoting their cause and the right to approach the court or any other appropriate body for redress, where their rights have been violated.[864] It covers manufacturers'/product liability, liability of retailers, wholesalers, distributors and others in the supply of goods and services chain.

As it relates to drug counterfeiting, it covers the act of extorting a price higher than they would be ready to pay for, from consumers for the substandard product, consumer deception about the quality of the counterfeit drugs, with the resulting risk to health and safety, the absence of after-sales service or any effective recourse in the event of damage or injury.By virtue of the consumer protection laws, a third party may seek redress as a consumer, under the law of negligence, where he/she is adversely affected by an injurious product.[865] Consumer protection, gives comfort to the consumer even when the product is a gift.

5.1.1.2.5Sale of Goods

The sale of goods is a contract whereby a seller transfers or agrees to transfer the property in goods to the buyer for a money consideration called price. It refers to the ordinary commercial act of buying and selling of goods and services. There are certain terms which are implied into a contract for the sale of goods, a breach of which would entitle the buyer to a right of action and a remedy for the breach. These terms impose strict liability on the seller and are actionable per se. These implied terms could be a warranty or a condition. A warranty is one which gives rise to a claim for damages, but not a right to reject the goods and treat the contract as repudiated.[866] A condition is one which if breached gives the aggrieved party the right to reject the goods and treat the contract as repudiated.[867]

The contract of sale of goods has been given a strict interpretation. Consequently, only parties to the contract of sale may sue another on it. A third party has a course in action in negligence or a representative action. Consequently, a consumer of counterfeit drugs,

[864] See generally, Sections 36(1), 39, 40, 46 of the Constitution of the Federal Republic of Nigeria, 1999.
[865] *Donoghue .v. Stevenson*, *supra*. See also, *Okwejiminor and Another .v. Nigeria Bottling Plc.supra*.
[866] Section 62(2) SOGA
[867] Section 11(1)(b) SOGA

which was a gift, has no recourse under the laws of sale of good. This is due to the principle of privity of contract.

The implied terms relevant to drug counterfeiting are, “fitness for purpose” and “merchantable quality”. Others are compliance with description, compliance with sample and time stipulation. Fitness for purpose requires that the buyer acquaint himself with any possible defects of the goods he was purchasing. He would only be entitled to remedy in the event of fraud or misrepresentation. As it relates to counterfeit drugs, given the availability of authenticating technology, the buyer would have been expected to have used such methods, before purchase, thereby eliminating risks. If the pre-purchase investigation fails to reveal the defect, the buyer should be entitled to redress by a claim in misrepresentation.

Where a buyer buys by description from a seller who normally deals in goods of that description, it is expected that the goods will be of merchantable quality. To be applicable, the goods must have been bought by description and must be those in which the seller deals with in his ordinary course of business. The test is that the goods must meet the buyer’s expectation. There is no obligation on the buyer to examine the goods and so the mere opportunity to examine the goods before the contract is made will not defeat the implication of the condition. However, the situation may be different now, with the introduction of the MAS, an anti-counterfeiting technology feature by NAFDAC. This is because the buyer is expected to authenticate the drug before purchase.

5.1.1.2.6 Human Rights

These are rights inherent to all human beings. Of relevance are the right to life and right to health.

5.1.1.2.6.1 The Right to Life

The right to life, protects the life of all citizens. Life, is sacrosanct. Therefore, deliberate killing is prohibited. For this right to be enjoyed, basic facilities must be in place. These include food, health, shelter and education. Dealing in counterfeit drugs and other medical products is a violation of the right to life or in the least, right to good quality life, as they

result in serious public health issues, including treatment failures, death, increased hospital admission, prolonged hospital admission and development of drug resistance.

5.1.1.2.6.2 The Right to Health

The right to health is a fundamental right to the enjoyment of the highest attainable standard of physical and mental health. Health is the state of being sound or whole in body, mind and soul. It does not mean an absence of disease or infirmity.The right to health is inclusive. It contains freedoms and entitlements.[868] The "freedom" includes the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference such as the right to be free from torture, non-consensual medical treatment and experimentation.[869] The "entitlements" include right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.[870]

The elements of the right to health are, availability, accessibility, acceptability and quality. State parties are expected to Respect, Protect and Fulfil this right, by taking all necessary steps to ensure that everyone has access to health facilities, goods and services that enable them enjoy, as soon as possible, the highest attainable standard of physical and mental health.[871] This is contained in the African Charter on Human and People's Rights and Section 2 of the 1999 Constitution of the Federal Republic of Nigeria, amongst others. The issue of justiciability of Section 2 has been laid to rest by the domestication of the African Charter in 1983.

Drug counterfeiting undermines the right to health and living a dignified life, and this eventually affects the right to life. It is a direct violation of the right to health, which is that healthcare must be affordable, accessible, acceptable and qualitative. These requirements are applicable not only to facilities, but goods and services. These must be scientifically and medically appropriate and of good quality.

[868] General Comment 14 to the ICESCR.
[869] Kinney E D. *Loc cit*. p.146.
[870] See 'The Right to the Highest Attainable Standard of Health". UN Doc. E/C. 4th December, 2000: ICESCR General Comment 14. 2000.
[871] General Comment 14.

From the examination of the legal issues in drug counterfeiting, it can be established that it is a violation of the right to qualitative healthcare. Contractually, there is no contractual relationship between the manufacturer and the end user. Consequently, the principle of privity of contract will not be applicable. Applying the caveat emptor principle to the situation, may also have unfair consequences. This is because, the means of authenticating the drugs, MAS, is characterised by challenges, chief of which are electricity and mobile phone network.

In the same vein, the end user and the manufacturer of the drug cannot be said to have equal bargaining powers. The end user may however be able to rely on misrepresentation, given that the medicine does not comply with the standard/specification that it claims to have. The alleged claims on the packaging and instruction leaflet would have induced the buyer to buy the drug believing that it will be fit for the purpose that it is needed for, thereby entitling him to rescind the contract.

There is no contract between him and the manufacturer but between the buyer and the seller. It is not the seller, however, that made the statements as contained in the instruction leaflet and packaging. The buyer, therefore has no right of action against the seller.

Applying the principles of criminal law to this situation, offences of strict liability makes manufacturers culpable for their actions, not just in their personal capacities, but their corporations as well.Tort is another area of the law that has been used in safeguarding public health. Under the law of Tort, negligence, product liability, and passing off have been used to safeguard the interests of the consumer and the brand owners.

Consumer protection offers solace to the consumer, in that it makes provisions for manufacturer/product liability which bear strict liability, and provides for a right of action against wholesalers, retailers, manufacturers, distributors and anyone in the supply of goods and services chain.Under Sale of Goods laws, there is a relationship between the buyer and the seller, and the requirement is that the goods must meet the buyer's expectation. A counterfeit drug would not meet the buyer's expectation. It will therefore

entitle him to a cause of action.Counterfeiting is an infringement of IPRs and would entitle the brand owner to a form of redress.

Lastly, drug counterfeiting is a violation of the right to health and ultimately the right to life. Member states of the UN and WHO are obliged to Respect, Protect and Fulfil this right. Consequently, there should be adequate and enforceable laws in place to ensure that this right and indeed others are not violated. Nigeria is yet to achieve this level of compliance.

5.1.2 How Efficient is the "Watchdog"?

In this part of this chapter, the findings on the examination of the regulatory authorities will be discussed. Regulating standards for goods and services in Nigeria are NAFDAC, SON, and CPC. They have been discussed in chapter 3. Of the three however, NAFDAC is directly responsible for regulating drugs, food, cosmetics and medical products. Consequently, the activities of NAFDAC as a regulatory body, in its effort at curbing drug counterfeiting will be assessed here.

5.1.2.1 NAFDAC

NAFDAC was inaugurated to regulate and control the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs and cosmetics, medical devices, chemicals and pre-packaged water.[872] It has been in the fore front of the fight against drug counterfeiting in Nigeria and to a considerable extent, its efforts have yielded some fruits. For instance, in a survey by NAFDAC and WHO and the Department for International Development (DFID)[873] showed that counterfeit drugs in Nigeria had decreased from 40% in 2001 to 16.7% in 2005. Similarly, in 2012, a test was conducted on 5790 drug samples using TRUSCAN, 6.4% failed the test. This is a marked improvement in the rate of incidences of counterfeit drugs.[874]

[872] Preamble to the NAFDAC Act, Cap N1, LFN 2004.
[873] A UK government department responsible for administering overseas aid.
[874] Ogune M. 2017. Nigeria: NAFDAC Refutes Report on Prevalence of Fake Drugs. *The Guardian*. 9th November, 2017. Retrieved from www.allafrica.com on 20th November, 2017.

NAFDAC embarked on its responsibility by restricting and modernising its structure by expanding and upgrading its facilities and formulating new and more efficient guidelines and regulations. The Agency has been active in its public enlightenment activities. It carries out public awareness campaigns through local or national media and at educational institutions and events. This it done by erecting bill boards, jingles, TV programmes and advertisement. Public awareness campaign in schools which includes quiz competitions, with prizes given based on their understanding of fake and counterfeit drugs and medical appliances. These are public enlightenment strategies to meet the needs of the different people in the society.

It collaborates with ports authorities, through its Directorate for Inspection and Enforcement, and co-ordinates surveillance operations at markets and retail outlets. It co-opted the banks in its fight against counterfeit medicines. Banks who finance drug importation, require NAFDAC clearance before processing financial documents for the transaction.Discriminatory regulations in some foreign countries, encourage the growth of drug counterfeiting. This results in double standards in international drug distribution. In this instance, substandard drugs which are restricted or banned in countries with more stringent regulations in respect of drugs consumed locally, but less stringent standards/regulations in respect of drugs meant for export, are sold into developing countries.[875] To prevent these categories of medicines getting into Nigeria, NAFDAC ensures that the drug is being used in its country of origin. To achieve this, imported drugs must be accompanied with a Certificate of Free Sale signed by the Minister of Trade or Industry in that country and authenticated by the Nigerian Embassy or any Commonwealth Mission in a country without a Nigerian Embassy.

In carrying out its duties, NAFDAC has two (2) Directorates, namely, the Ports Inspectorate Directorate (PID) and the Establishment Inspectorate Directorate (EID). The former is in charge of imported products while the latter regulates locally manufactured products. With regards inspection, NAFDAC uses the WHO guidelines, though it rarely embarks on oversea inspection, due to financial constraints. It inspects oversea

[875]Bate R and Boateng K. 2007. Bad Medicine in the Market. *Health Policy Outlook*. Retrieved from http://www.aei.org/publications/pubID.263688/pub_details.asp on 21st July, 2017.

manufacturers during product registration only. There is therefore no means of ensuring that foreign manufacturers remain compliant, as follow up visits and inspections are not carried out. However, local inspections are carried out routinely and unscheduled.[876]

NAFDAC lacks sufficient laboratories for testing samples before product registration. This inefficiency is an avenue for loopholes in the control of the production of medicines and medical products, leaving room for fakes to get into the licit market. In addition, as a result of pressure due to the volume of work and limited time frame within which to complete the product registration process, quality control officers are worn out and sometimes do not give accurate results. In order to avoid delays, imported products are sometimes registered before Good Manufacturing Practice (GMP) inspection is done.[877]

With regards its enforcement role, NAFDAC sometimes acts on tip offs in carrying out raids. Fake goods recovered as a result of these raids are confiscated and destroyed. Sometimes the markets are closed for a period of time. The Onitsha drug market was closed down in 2007. In Nigeria, drug markets are unlicensed, unregulated and chaotic open markets. The major ones are situated in Kano, Onitsha and Aba. These are illegal as the law prohibits sale of drugs in open market without proper permission from the body in charge of drug regulations.[878] Drugs sold at these open markets, range from over the counter medicines to prescription drugs. The traders are sometimes the manufacturers of these drugs. Supplies are also received from importers of registered and unregistered products vendors and even pharmacies. Closing these markets down, has been a challenge to NAFDAC, due to inadequate funding, materials and personnel.[879]

Major challenges to the oversight functions of NAFDAC are the threat to lives of, and actual attacks on the staff,[880] and the attitude of the Nigerian judiciary, which does not help matters as there are delays in dispensing with cases. The result of this is that the Agency is sometimes being denied justice even though it presents adequate evidence and witnesses

[876] Chiwendu O. 2008. The Fight Against Fake Drugs by NAFDAC in Nigeria. Retrieved from www.who.int on 12th June, 2017. P.30
[877] Chiwendu O. *ibid*. p. 30
[878] Counterfeit and Fake Drugs (Miscellaneous Provisions) Act.
[879] Chiwendu O. *Loc. cit*. p. 36
[880] Garuba, et al. 2009. *Loc. cit.* pp. 5-8. See also Chiwendu, O. *ibid* p. 36.

against counterfeit drug dealers. Added to these, are the activities of some staff of NAFDAC and other relevant regulatory agencies. These activities are characterized by greed, ignorance and corruption, which affects their effectiveness. Poor enforcement of drug regulations, is a direct consequence of corruption and conflict of interests, and this in turn encourages drug counterfeiting.[881]

The West African Drug Regulatory Authorities Network (WADRAN) is a forum initiated by NAFDAC, in 2005, for heads of drug regulatory agencies in West Africa to interact. This was necessitated by the fact that drug counterfeiters chased out of Nigeria found solace in neighbouring West African countries.The forum was therefore initiated to ensure co-operation among the countries so as to make West Africa uncomfortable for them.[882]

Towards addressing the problems of drug counterfeit, NAFDAC collaborates with the US Pharmacopeia Convention (USP) and the US Agency for International Development (USAID). The two (2) agencies created a joint programme, Promoting Quality Medicines in Developing Countries (PQM), to train and deploy technology for detecting falsified and substandard drugs in developing countries.[883] In 2014, a study conducted by NAFDAC and USP, showed that Nigeria had 3.6% of fake anti-malaria drugs in the Nigerian market.[884]NAFDAC as a watch dog has been able to achieve considerable victory in controlling drug counterfeiting. Be that as it may, it battles with challenges such as low-level compliance, slow pace in processing registration documents, financial constraint, inadequate personnel for a decentralised supply chains, and corruption.

5.1.3 The Use of Technology in Combating Drug Counterfeiting

[881] WHO, 2007. *Good Governance for Medicines: Curbing Corruption in Medicines Regulation and Supply*. Retrieved from www.who.int/medicines/policy/good governance/home/en/inde.html on 23rd July, 2016

[882] The Situation of Medicine Counterfeiting in Africa. Retrieved from www.whpa.org/background_medicines_counterfeiting_in_africa_chiom on 23rd July, 2016.

[883] USP, 2013. Promoting the Quality of Medicines in Developing Countries. Referred to in Kovac, S. et al. Technology for Detecting Falsified and Substandard Drugs in Low and Middle-Income Countries. *Plos ONE Journal. Vol. 9, Issue 3, p. 2.*

[884]Anon. 70% of Drugs in Nigeria Not Fake – NAFDAC. *Vanguard News*. 12th November, 2017. Retrieved from www.vanguardngr.com on 20th November, 2017.

Counterfeit is a problem of product security. Associated with counterfeiting are products side tracked from their proper distribution channel or sold past their expiry date, or by modification of the package are associated with the problem of counterfeiting.[885]

Drug counterfeiting is a high volume, high profit business which causes the infringement of IP rights, medicine legislations and other aspects of criminal law.[886] Protecting products will guard against such infringements.

Brand owners, manufacturers have various anti-counterfeit technologies available to them. Some are simple, but effective, whilst others are highly sophisticated and extremely secure. Some can be applied at the product level, whilst others could have direct marking or by using physical or chemical markers. They are primarily for authenticating any product and can be used by government, industry investigators or the wider public. It also acts as a deterrent to those contemplating counterfeiting, vis-à-vis the cost involved and the likelihood of detection and subsequent prosecution. The essence of these security devices is to make detection of counterfeits easier and not necessarily to put an end to it. This is evident in the success rate of the various methods.Technology methods have been described by their vendors as "solution providers". This has been described, and the writer agrees, as an overkill, as there is no singular method that can completely eradicate pharmaceutical counterfeiting.[887]

5.1.3.1 Anti-Counterfeiting Technologies

The Anti-Counterfeiting technologies can be classified into four (4). These are:

- Overt or visible features
- Covert or hidden markers
- Forensic technology
- Serialization, otherwise known as Track and Trace

5.1.3.1.1Overt Features

[885] Shah R Y., Prajapati P N and Agrawal Y K. 2010. Anti-Counterfeit Packaging Technologies. *Journal of Advanced Pharmaceutical Technology and Research. October – December; 1(4). p. 368*
[886] *Ibid*. p. 369
[887] Davison m. 2011. *Pharmaceutical Anti-Counterfeiting: Combating the Real Danger from Fake Drugs*. Wiley. New Jersey, USA. p. 36.

These are otherwise known as visible features. They enable end users to verify the authenticity of a pack of drugs. The features will be visible, difficult and expensive to reproduce.[888] They add to cost and restrict supply availability. Given their visible features, utmost security is required in their supply, handling and disposal to prevent unauthorised diversion. It is expected that end user will be educated on how to apply them. With regards to overt techniques, counterfeiters have been found to copy them, in such a way as to confuse consumers.[889]

In their application, it is pertinent that they cannot be reused and removed without being defaced or effecting damage to the pack.[890] This is to prevent the use of genuine components with fake contents, thereby creating an impression of authenticity. Consequently, overt features are usually incorporated with the Tamper Evident feature for added security.[891] Examples include, holograms, optical variable devices, colour shifting security ink and films, security graphics, sequential product numbering and On-product marking.

The overt technique is user verifiable. Recent updated versions are more secure therefore a deterrent to counterfeiters. They also add decorative appeal to the product. Be that as it may, the users need to be educated on its application and this may not be generally understood by the end users. Some are easily copied. However, the more secure they are, the more expensive and may require covert features to achieve utmost security level.

Another disadvantage is that they are sometimes refillable and re-usable and give false assurance.It puts the burden of authentication on the general public, who require education and awareness. This may not be easily accomplished in some societies. It is pertinent to note that, its wide usage attracts the resolve of counterfeiters to decode it.[892]The overt features should be used at the discretion of manufacturers. They would however need to

[888] Davison M. *ibid*. p.2
[889]*Ibid*. p.2
[890]*Ibid*. p.3
[891] *Ibid*. p.3
[892]*Ibid*. p.5

educate the consumers, wholesalers, distributors and healthcare providers on how to authenticate their products.

5.1.3.1.2 Covert (Hidden) Features

This enables the brand owner to distinguish his/her products from that which is counterfeited. It is not easily detected without specialist knowledge.Details are usually available on a "need to know" basis.[893]Invisible printing, embedded image, digital watermarks, hidden marks and printing, anti-copy or anti-scan design, laser coding, substrates and odour are examples of covert feature anti- counterfeiting technology.

The covert features are simple and cost effective. They require no regulatory approval and they can be easily added to or modified. They are applicable in-house or through component suppliers. They however require strict secrecy and are made available only on a 'need to know' basis. To have stricter security options, there are added supply complexities and cost. If widely used, it is susceptible to copying and applying them at component suppliers, opens them to risk of compromise.[894]

They are more effective when applied by industry specialists. Though very valuable, counterfeiters are able to replicate the simpler features, unless they have been skilfully applied and their details kept secret. In-house application can limit costs and third-party involvement. This technology offers more to the manufacturers but little to the drug monitoring authorities and the public because of the risk of compromise, if widely known or used. It should therefore not be used on all products and for all markets, as it cannot be relied on to solve on-going problems of counterfeiting.[895]

5.1.3.1.3 Forensic Markers

These are a range of high-tech solutions which require laboratory testing or specialised test kits to prove authenticity. They are a sub-set of covert technology. However, the scientific methodology for authentication is different. Examples include, chemical taggants,

[893]*Ibid*. p.5
[894] Davison M. *Ibid*. p.7
[895]*Ibid.* p.12

biological taggants, DNA taggants, ISOtope works and micro-taggants. Forensic technology is high technique and secure against replicating. They provide positive authentication and may be disclosed for overt purposes. However, they are licensed technology and usually limited to one source and expensive. They may be difficult to implement and control across many markets. They are not readily available to authorities or the public.[896]

Forensic markers offer sufficiently robust security and may bridge the gap between the less secure convert features and the unreliable overt features. Its use should be encouraged in high risk areas.

5.1.3.1.4 Serialisation/Track and Trace Technology

It involves assigning a unique ID to each stock unit during manufacture. This ID remains with the drug, through supply chain till consumption. The ID is made up, amongst others of, product name, strength, lot number and expiry date. Alternatively, it could take the form of a unique pack coding which enables access to the same information held on a secure database.[897]

Its uses include, tracking items through supply chain, to each point where there is the facility for data capture, providing traceability with regards to history of any item, subject to limitation of number of control points and enabling authentication of the data at any time, by implication, of the pack of unit on which it is applied. Serialisation, bar codes, Radio Frequency ID (RFID) and Unique surface marking or topography are examples of serialization or track and trace technology.

This method is high tech and secure against copying, it is capable of remote authentication through phone and internet and may be accessible to authorities and investigating without compromise.It aids in eliminating dispensing errors, whilst facilitating recall of defective products. The technology helps in combating theft and fraud. In addition, it aids supply efficiency.Its implementation and monitoring are however expensive and cumbersome

[896] Davison M. *Ibid*. p.8
[897] *Ibid*. p.8

especially across multiple. The technology is vulnerable to hackers when labels are damaged, they may not be readable. They are not accessible to the public and standards need to be harmonised. It has the potential to deliver robust solutions to fraud and counterfeiting of pharmaceuticals. It has however not been fully developed. The bar code systems use proven existing technology, it however lacks the advantage of automation and remote scanning possibility of RFID. On its part, the RFID tags may be vulnerable to deliberate and invisible alteration or corruption.

Serialization technology protects supply chain against infiltration and abuse and provide additional benefits of safety. It has been noted that the problem of counterfeiting is greatest in markets where the IT infrastructure needed to support track and trace is lacking and traders in counterfeits have no incentive to encourage its development. Consequently, for speed and economy, a barcode system should be developed as a priority, allowing natural progression to RFID, if, when and where feasible.

5.1.3.2 Technology Features in Use in Nigeria

The fight against drug counterfeiting in Nigeria has over the years been intensified, as a result of the activities of NAFDAC (the Agency). NAFDAC in achieving this, has employed different methods. Previously used, was the NAFDAC registration numbers on drug packaging.[898] This has however not been effective, due to sophistication and easy access to printing technology and the use of fake NAFDAC Registration Numbers on packaging of the fake and sub-standard drugs. The Agency adopted a policy of 'zero tolerance to counterfeit, fake, sub-standard, spurious, adulterated and expired medicines in the country." Consequently, it resorted to use of technology features to rid the country of the activities of counterfeiters who are merchants of death, trying to benefit at the expense of the health of others.[899]

The technology features used by NAFDAC include Truscan, a hand-held spectroscope which quickly and easily detects counterfeits. A covert feature, used for on the spot detection and authentication of drugs at the borders. The Black Eye, is characterized by its

[898] NAFDAC News, 2013. Issue 4, p.11. Retrieved from www.nafdac.gov.ng on 7th February, 2018.
[899] *Ibid*. p.4.

capacity to screen multiple drug samples at once. It uses the infra-red technology. It screens by comparing the tablets to be authenticated with the manufacturer's information on the medication, in order to confirm whether fake, substandard or genuine. Another technology feature used in Nigeria is the RFID, a serialisation/track and trace technology, used for tracking and tracing of medicines and medical products. Forgery of documents can be prevented using this feature.

The use of these features is however saddled with challenges and this resulted in the launching of the Mobile Authentication Service (MAS) in 2010.[900] This is a consumer centred technology, in that the consumer is empowered to verify the drug by him/her self. The consumer sends a message to a 12-digit pin assigned to the drug to NAFDAC on 38353, and receives an instant reply authenticating the drug, or otherwise. This is done at the point of purchase, making it possible for the consumer to detect counterfeits before payment is made.[901]

The MAS, though consumer centred, is not widely used. This is due to the low awareness level, especially among rural and illiterate population, telecom network problem, delay in receiving response. Some of those interviewed alleged that the response may never be received for a number of days, if at all. This defeats the essence of the feature since time is of essence. Others noted that, not all drugs have the scratch panels on their packaging, especially those dispensed from large packs. However, some admitted to being negligent in the sense that they could not take the trouble of going through the process of authenticating the drugs. Other reasons given for the low usage rate of the feature is the lack of electricity, hence the ability to charge phone batteries as and when due.

The MAS, if administered properly is an effective way of detecting counterfeits. Given the above-mentioned feedback from consumers, though the challenges affect other industries in Nigeria, NAFDAC would need to increase awareness of its availability through the media and contact with the consumers, for instance through town hall meetings. There

[900] Akpotaire U. 2013. Companies that Provide Anti-Counterfeiting Technology in Nigeria. *Nigeria Law Intellectual Property Watch*. Retrieved from https://nlipw.com on 8th February, 2018.
[901] NAFDAC News. *Loc. cit*. p. 20

should be collaboration with the telecom service providers regarding their networks, so the SMS can be sent and replies received immediately. Drugs counted and sold from large packs should be discouraged and manufacturers should be encouraged to use mini-packaging, so there can be scratch panels on all drugs sold.

There are varying types of technologies which can and have been employed to combat any form of counterfeiting. They all carry some degree of cost and administrative burden. They vary in the amount of training required to be able to use them effectively. Some, especially the portable ones require little training, whilst others require sophisticated laboratory equipment and high level of expertise. However, no single solution can be proffered for one problem and a secure strategy may require the use of a combination of more than one technology.[902]

There are at least 42 technology features that have been identified for use in combating drug counterfeiting.[903] Consequently, identifying an appropriate technology feature would involve considering a number of things, such as cost of acquiring it, its portability, and requirement for sample preparation.[904] Also to be considered are testing site, the purpose for testing and electricity supply. Also required are well-trained personnel to use the technology features, legal framework which will remove the incentives for producing and distributing fake and substandard drugs and well-designed screening systems.

An ideal anti-counterfeiting technology, however, would ensure that a high level of security. It must be capable of wide product application and fast and efficient authentication process and proven standards. They must be difficult to re-apply or remove, easy to check and possess automatic authentication, be consumer friendly and legally compliant.[905]

---

[902] Davison M. *loc cit*. p.12

[903] Kovac S., Hawes S., Malay S N., Mosites E., Ling W and Stergachis A. 2014. Technology for Detecting Falsified and Substandard Drugs in Low and Middle Income Countries. *PloS One Journal. Vol.9. Issue 3. p.9*.

[904] Kovac S et al. *ibid.*

[905] Bansal D., Malla S., Gudala K and Tiwari P. 2012. Anti-Counterfeit Technologies: A Pharmaceutical Industry Perspective. *Scientia Pharmaceutica*. Retrieved from www.scipharma.at on 24th March, 2015.

5.1.4 Counterfeit and Fake Drugs and Unwholesome Processed Food (Miscellaneous Provisions) Act (Amendment) Bill, 2015[906]

This is a Bill for an Act to amend the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act[907] [CF&UPF(MP) Act] and other related matters. The Bill was passed to law by the Senate on 3rd November, 2016.

It is divided into four (4) sections. It seeks to amend sections 3 and 4 of the principal Act, to make up for its deficiencies. The essence of the Bill is to make provision for a means of deterring people from indulging in drug counterfeiting.

A. Section 1 identifies the CF&UPF(MP) Act as the Act to be amended.

B. Section 2 contains a proposal to amend Section 3 of the principal Act by substituting its subsection (1) with a new subsection (1) which provides thus,

(1) Any person who commits an offence under:
(a) Section 1 of this Act is liable on conviction to life imprisonment.
(b) Section 2(1) of this Act, is liable on conviction to a fine not exceeding Two Million Naira (₦2,000,00) or imprisonment for a term of not less than four (4) years or to both such fine and imprisonment.

C. Section 3 seeks to amend Section 10 of the principal Act to read:

3. (a) Section 10 of the Principal Act is to be amended by substituting for the existing Section 10 the following new Section (10):

> Any drug, poison or unwholesome processed food products seized by a Task Force established by this Act shall be forfeited to the Federal Government and shall be Destroyed by the Agency.

3. (b) Section 10 is to be amended by inserting immediately after the existing Section 10 the following new sections 10A and 10B:

> 10A-(1) A person convicted of an offence under this Act shall forfeit to the Federal Government all the assets, money in bank

[906] Retrieved from https://lawpavillion.com on 10th February, 2018.
[907] Cap C34 LFN 2004.

and properties which may have been acquired with the proceeds of the crimes;

(2) For the avoidance of doubt and without any further assurance than this Act; all the properties of a person convicted of an offence under this Act and shown to be derived or acquired from such illegal act shall be forfeited to the Federal Government.

(3) Where a person is arrested for an offence under this Act, the Agency shall immediately trace and attach all the assets, money in bank and properties acquired as a result of such illegal act and shall thereafter cause to be obtained an interim order by the court.
(4) Where:

(a) The assets, money in bank or property of any person arrested for an offence under this Act has been seized; or

(b) any assets, money in bank or property has been seized by the Agency under this Act, the Agency shall cause an application to be made to the Court for an interim order forfeiting the money in bank or property concerned to the Federal Government and the Court shall if satisfied that there is prima facie evidence that the property concerned is liable to forfeiture, make an interim order forfeiting the money in the bank or property to the Federal Government.

(5) Where an arrested person is convicted of an offence under this Act, the Agency or any authorized officer shall apply to the Court for the order of confiscation and forfeiture of the convicted persons' assets, money in bank and properties acquired or obtained as a result of the crime already subject to an interim order under this Act.

(6)(a) A copy of every final order forfeiting the asset, money in bank and property of a person convicted under this Act shall be forwarded to the Agency;

(b) Upon receipt of a final order pursuant to this section, the Secretary to the Agency shall take steps to dispose of the property concerned by sale or otherwise and where the property is sold, the proceeds thereof and the money in bank shall be paid into the Consolidated Revenue Fund of the Federation.

Provided a "Victims Compensation Fund" shall be created from which victims of crimes under this Act shall be compensated from.

(c) Where any part of the property included in a final order is money in a bank account or in the possession of any person, the Agency shall cause a copy of the order to be produced and served on the manager or any person in control of the head office or branch of the bank concerned and that manager or person shall forthwith pay over the money to the Agency without any further

assurance than this Act and the Agency shall pay the money received into the Consolidated Fund of the Federation and the Victims Compensation Fund.

(7)(a) Where a person is discharged or acquitted by a court of an offence under this Act, the Court may make an order of revocation or confirmation as the case may be, of an interim order made pursuant to this Act whichever order is considered just, appropriate or reasonable within the circumstances; (b) Where an interim order is revoked by a court under paragraph (a) of this section, all assets, money in bank and properties of the person concerned shall be released to him by the Agency.

10B. The Minister may with the approval of the president make rules and regulations for the effective implementation of the provisions of this Act including the percentage to be paid into the victim's Compensation Fund, the procedure for its operation and for the disposal or sale of any property or assets forfeited pursuant to this Act.

D. Section 4 relates to citation.

The Bill seeks to impose sterner punishments on offenders. For instance, instead of a fine of Five Hundred Thousand Naira (₦500,000) and or term of imprisonment of not less than two (2) years, the Bill proposes a fine not exceeding Two Million Naira (₦2,000,000) and/or imprisonment for not less than four (4) years. Secondly, it proposes not just the forfeiture of the infringing products, but also the forfeiture of all assets, money in ban and properties which may have been acquired with the proceeds of the crime. Thirdly, the Bill proposes a change from the Minister's power to determine, from time to time, how to dispose of the offending products, to giving the Agency the power to destroy them. It further provides that proceeds of the crime are to be disposed of by NAFDAC by paying it into the Victims Compensation Fund.

The Bill also makes provision for the creation of a Victims Compensation Fund (The Fund). Its Section 10A (3) empowers the Agency to trace and attach all assets, money in bank and properties acquired as a result of such illegal act and apply for an interim order of forfeiture in respect of money in the bank, or property concerned to the Federal Government by the court. On conviction, the Agency or any authorised officer shall apply to the court for an order of confiscation and forfeiture of the convicted person's assets,

money in the bank and properties acquired or obtained as a result of the crime already subject to an interim order, under the Act to be made final. A copy of all final orders forfeiting the asset, money in bank and property of a person convicted under the Act shall be forwarded to the Agency.

The Secretary of the Agency would then take necessary steps to dispose of the property concerned by sale or otherwise and where the property is sold, the proceed thereof and the money in the bank is to be paid into the Consolidated Revenue Fund of the Federation, out of which the Victims Compensation Fund which is proposed to created will be funded. The Fund is to be created for the purposes of compensating victims of this crime.

5.1.4.1 Proposed Implementation

The proposed Section 10(B) provides that the Minister, with the approval of the President, may make rules and regulations for the effective implementation of the provisions of the Act, including the percentage to be paid into the Fund, the procedure for its operation and for the disposal or sale of any property or assets forfeited pursuant to the Act. This ensures effectiveness and accountability.

Although the Bill had been read by the Senate for the third (3rd) time and passed, there is no evidence that it was put forward for the President's assent, nor any other action taken on it till date.

5.1.5 The United Nations Guiding Principles on Business and Human Rights (UNGP)

The need to manage the negative impact of businesses on human right of their employees, consumers and communities led to the development of the UNGP. In 2008, the UN endorsed the framework of "Protect, Respect and Remedy" as prescribed by the UNGP. The Human Right Council of the UN endorsed the UNDP by its resolution 17/4 of 16th June, 2011.

The UNGP are grounded on the principles that, States have existing obligations to respect, protect and fulfil human rights and fundamental freedoms. Secondly, businesses are specialised organs of the society and they perform specialised functions. They must

therefore comply with all applicable laws, as well as respecting human rights. Lastly, rights and obligations of all concerned should be commensurate with available remedies in the event of a breach of duty.

The UNGP is applicable to all member states and businesses, whether transnational or otherwise. It is expected that their provisions will be implemented in a non-discriminatory manner. In implementing the provisions, cognizance should be taken of the challenges faced by individuals, who face the risk of being vulnerable or marginalised.

According to John Hagee, the Framework addresses the question, "*what States and business enterprises need to do to ensure business respect for human rights*". It elaborates the implications of existing standards and practices for States and businesses, integrating them within a single, logically coherent and comprehensive template, and identifying where the current regime falls short and how it should be improved."[908]

The UNGP within its pillars of 'Protect, Respect and Remedy', provides for general regulatory and policy means by which States ought to foster business enterprises' respect for human right throughout their operations. In addition, it addresses steps which member states should take where they own enterprises or provide them with substantial support and services. The role of the state in assisting enterprises to assess and address the increased risk of involvement in human rights abuses in conflict affected areas, and take stronger measures as the situation may demand, was also addressed. The Framework further considered the need for States to take note of their human right obligations in negotiating international economic arrangements.

With regards business enterprises,[909] the UNGP provides for human rights due diligence process. The process involves assessing actual and potential human rights issues, integrating and taking actions on findings, monitoring how effective the responses are, and

[908]Report to UN Human Rights Council. The Report was presented by Prof. John Hagee, Special Representative of the Secretary General for Business and Human Rights, at Geneva, on 30th May, 2011, p. 2
[909] Principles 11-24 UNGP

to communicate how the human rights issues are to be dealt with. The due diligence extends to third (3rd) parties connected to the enterprise in question.

The UNDP also deals with ensuring that victims have greater access to adequate remedy. Highlighted also is the need to deal with legal and practical barriers which victims may face in obtaining judicial remedy, recommending steps for strengthening state-based non-judicial mechanisms and need for enterprises to create and or co-operate in effective operational -level grievance mechanism.

States' existing duty to protect their citizens against human rights abuse, covers abuses that may originate from businesses. Consequently, States must prevent, investigate, punish and redress human rights abuses that occur in domestic business operations. To accomplish this, States are enjoined to have in place, enact enforceable laws, create a regulatory environment that will encourage businesses to respect human rights. State laws must be uniform across departments and functions taking cognizance of existing multilateral obligations on human rights.[910]

The Framework prescribes that, business enterprises must prevent, mitigate and remedy, when necessary, human rights violations caused by them. Businesses must respect all human rights as provided by the Bill of Rights and International Labour Organisation Declaration on Fundamental Principles and Rights at Work. This responsibility applies to all business, irrespective of size, location and sector. Action to be taken, in order to fulfil this responsibility, will depend on their scale or complexity.[911]

In carrying out this responsibility, companies must have policies to show their commitment to respecting human rights, they must exhibit due diligence in identifying, preventing, mitigating and accounting for their human rights impacts. There must also be processes in place in respect of paying compensation for any violation of human rights by them.

[910] See Principles 1-10
[911] The UNGP on Business and Human Rights: An Introduction. A Publication of the UN Working Group on Business and Human Rights. Retrieved from www.un.org on 19th January, 2018. p. 3.

The findings of the due diligence processes are to be integrated into their policies and procedures at all appropriate levels and resources made available. There should be constant monitoring and evaluation of their efforts and they should share information on their procedure regarding human rights issue when required. Compensation should be readily available, in the event of violation.

A fundamental principle of international human rights system is that when a right is violated, victims must have access to an effective remedy. The State, in protecting the human rights of her citizens, must ensure that businesses within her territory do not violate the human rights of the citizens, and provide access to remedy, should the rights be violated. It is the responsibility of the State to ensure that the National judicial system can deal with business-related human rights abuse and that the business-related human right violation. In their part, businesses are to provide for, or be involved in effective grievance settlement mechanism for human right violation(s) resulting from the company's activities. The Framework prescribed that effective grievance mechanism, should be legitimate, accessible, predictable, equitable, transparent and rights-compatible. They must be capable of providing genuine remedies for victims of human rights violations by business enterprises.

With respect to UNGP and drug counterfeiting, it has been established that drug counterfeiting is a violation of the right to health. A victim of counterfeit drugs will therefore be entitled to remedy for the abuse of his/her right to health. In the same vein, counterfeiters are businesses within the context of the Framework. And as stated in the Framework, the size and the industry of the enterprise is immaterial.

The challenge of applying the Framework to drug counterfeiting in low and medium income countries like Nigeria is that, the counterfeiters may be based in other countries, therefore, invisible. Those based within the territory, may still be difficult to trace, especially if the business is transacted on the internet. The Framework, by requiring the State to provide enforceable laws and judicial and non-judicial legal system to handle business related human right violation, has provided a way out of this predicament. The provisions of the Counterfeit and Fake Drugs and Unwholesome Processed Food

(Miscellaneous Provisions) Act (Amendment) Bill 2015, complies with the requirement of the Framework, thereby ensuring the protection of the human rights of the Nigerian citizens. It is therefore important for the government to do all necessary to see that the Bill receives Presidential assent.

5.1.6 Corporate Manslaughter Bill 2018

This is a bill for an Act to provide for corporate manslaughter by making corporate organisations criminally liable for death of employees arising from their acts of omission, and for related matters.

The bill provides that where death occur as a result of how a corporation is being managed or organised and the death was as a result of a gross breach of relevant duty of care, which the organisation owed the deceased, the organisation commits an offence of corporate manslaughter.[912] With regards the bill, duty of care is as under the law of negligence.[913]

The offence has three (3) ingredients, namely, occurrence of death, gross breach and relevant duty of care. Firstly, regardless of the level of danger of the operation, a corporation will not be liable where death has not occurred. Secondly, relevant duty of care has been described as, duty owed to an individual or employee, by an organisation. This includes, duty owed under occupier's liability, in relation to supply of goods and services, construction or maintenance or in relation to anything that is dangerous to health. The bill appears to have codified the "neighbourhood principle" judging by the extent of those covered by its relevant duty of care provision. Thirdly, gross breach has been described as an action which falls below the standard expected of such organisation, given the circumstances.[914] The applicable test here, is the objective test.

The provisions of the bill apply to public or private corporate organisations, government departments, whether at Federal, State or Local Government levels, police force, armed

[912] Section 1(1) Corporate Manslaughter Bill, 2018.
[913] Section 2(3) Corporate Manslaughter Bill, 2018.
[914] See Section 1(4)(b) Corporate Manslaughter Bill, 2018.

and para military forces and partnerships, trade unions or employers' associations.[915] For a cause of action to arise, the offence committed must be the result of breach of duty which occurs due to the way and manner in which its senior management manages or organises its activities.[916] Section 14 however exempts individual liability, regardless of how substantial the contribution of an individual may be in committing the offence.

By virtue of Section 2(6), the rules of common law which prevent or restrict duty of care from being owed, as a result of acceptance of risk, harm or engagement in unlawful conduct, are expressly excluded. Consequently, a corporation will be liable in spite of the fact that the victim was involved in an unlawful act or that the risk involved was accepted by him/her.

In this instance, the test is whether or not the corporation carried on its activities, in a way that resulted in the death which occurred due to a gross breach of a relevant duty of care.

From the foregoing, it would appear that the bill excluded the doctrine of *volenti non fit injuria,* a defence in tort, which provides that, where a person being aware of inherent risk, goes ahead to undertake the activity, he cannot later complain nor seek compensation for an injury suffered, or resulting therefrom or seek compensation for an injury suffered in carrying out the activity.

By virtue of the bill, the court determines whether an organisation owes a person a duty of care or not. Sections 3 and 4 make provisions for what does not amount to relevant duty of care. These include, duty owed by a public authority in respect of decisions as to matters of public policy, such as allocation of public resources or weighing competing public interest, and duty owed in the exercise of exclusive public functions.

By virtue of Section 1(5), the penalty for a conviction on a corporate manslaughter charge, is a fine. The bill however did not prescribe the amount payable. This presupposes that the fine payable is at the discretion of the court. Furthermore, the court may make

[915] Section 1(2) Corporate Manslaughter Bill, 2018.
[916] Section 1(3) Corporate Manslaughter Bill, 2018.

remedial orders. This is intended to direct the corporation to take steps to remedy the deficiencies relating to health and safety that caused the offence.[917] Failure to comply with the remedial order will attract a fine.[918] The amount for the fine was however not prescribed by the bill.

Section 9(1) empowers the court to make an order that a publication to the effect that an organisation has been convicted, giving the details of the offence and penalty, be issued. In addition, Section 15 provides that a conviction for corporate manslaughter does not preclude the organisation from being tried for other offences relating to health and safety, whether on the same facts or not.

With regards its scope, the bill is applicable throughout Nigeria and all areas within the seaward limits of the territorial sea adjacent to the Federal Republic of Nigeria. Furthermore, it is applicable to all Nigeria controlled ship, aircraft and hovercraft, and to areas covered by the Petroleum Act.[919]

Actions in relation to the bill can be instituted in either the Federal or State High Court. This is the prerogative of the prosecution.[920] Liability as provided for in the bill, is transferable, where the functions of the corporation have been transferred to another, as in the case of a corporate reconstruction.[921] By virtue of Section 2(1) Administration of Criminal Justice Act, 2015, the provisions of said Act will be applicable to the Bill when it is passed into law.

For any action to be instituted in respect of corporate manslaughter, the consent of the Attorney General of the Federation or of the State concerned must be sought and obtained.

[917] Section 8(1) Corporate Manslaughter Bill, 2018.
[918] Section 8(6) Corporate Manslaughter Bill, 2018.
[919] See Section 16 Corporate Manslaughter Bill, 2018. The Petroleum Act, Cap P10 LFN 2004.
[920] Section 1(6) Corporate Manslaughter Bill, 2018.
[921] Section 12(1) Corporate Manslaughter Bill, 2018.

The bill had been presented for Presidential assent, along with others, but the President refused to sign it into law,[922] on the grounds that it contravenes Section 36(5) of the 1999 Constitution of the Federal Republic of Nigeria, as amended, which provides that an individual is presumed innocent, until he/she is found guilty by a court of competent jurisdiction.

The Corporate Manslaughter bill has been greatly criticised for various reasons. Majorly, compensation, as provided under the bill, which is to be paid to the deceased employee's family, amounts to a mere duplication as it has already been provided for under the Employees Compensation Act. The latter provides for a scale of compensation which is payable to a spouse, child or parent, paid on a monthly basis of a percentage. Also, terms are vaguely defined, especially, the term 'senior management', leaving it unclear who in an organisation would fit under the designation.

The bill further omits to impose liability, albeit secondary on directors by holding. To maintain an action against an individual director would require persecution under some other legislation as a criminal offence of manslaughter or gross negligence. The bill is insufficient in this regard and invariably compounds the work of prosecuting such actions.

5.2 Report on the Unstructured Interviews on Drug Counterfeiting

Introduction

This report is on drug counterfeiting, the legal issues in drug counterfeiting, legal relationship between the manufacturer of counterfeit drugs and the end users, adequacy of the existing legal and institutional framework for combating drug counterfeiting and knowledge of the UN guiding Principles on Business and Human Rights. The unstructured interview was carried out in Ibadan, Oyo state. As stated in the protocol submitted for ethical approval, the participants were selected to represent the six (6) geo-political zones in Nigeria.

[922]Nwabuguiogu L. 2018. 'Buhari Declines Presidential Assents on Four Bills Passed by National Assembly'. *Vanguard* 12th July, 2018. Retrieved from https://www.vanguardngr.com on 4th August, 2018.

5.2.1 UnstructuredInterview among Patients, Doctors, Pharmacists and Patent Medicine Vendors

a. Understanding of drug counterfeiting and the legal issues involved

All the respondents defined counterfeit drugs as illegal and fake or substandard, with reduced or no active ingredients.They all acknowledged the harmful effect of such drugs. In addition, a respondent from the pharmacists group talked about the authenticity and life span of such drugs, noting that drug counterfeiting includes activities such as, Production of fake drugs, change of expiring date of drugs on label, bringing into a country a banned drug, setting or disposing expired drugs". Among the six (6) patients that were interviewed, a respondent defined counterfeit drugs as also fake drugs that are manufactured illegally. He went on to explain that by 'Illegally', he meant they are not backed up with the production or source from the government and they are drugs that could be bought over the counter. Meanwhile, a patent medicine vendor defined a counterfeit drug as a drug without a NAFDAC registration number.

Although almost all the respondents know that there are some existing legal issues relating to drug counterfeiting, a respondent from the patients group said,

> "Yes….there are key laws that bind these illicit set of drugs, but I can't really place my hand on one precisely but I know there are laws that has been delegated or powers to deal with such people has been given to NAFDAC and I can't really precisely quote the laws but NAFDAC has a constitution that deals and tackles and proffers penalty of fake drugs in our society", however, another respondent stated that he or she doesn't know much about these laws and their implementation, the person said "there are some laws waging war against drug counterfeiting. So, but some of the laws to me are not really implemented, although there are but most of us did not even know these rules including myself but I know at least they exist."

Some of the respondents had conflicting ideas on the regulatory organizations. Some were not sure whether SON is the major regulatory body or NAFDAC. Most believed that NAFDAC is the one that is in charge of regulating drugs really that comes to the country. Therefore, it is their duty to make sure that fake drugs do not get to the country, nor circulate within the country, and that anyone found with fake drugs, or

importing fake drugs or fake product, will be liable to be charged into court and prosecuted by NAFDAC. And all the respondents in the Pharmacists group agreed to knowing that there are legal issues related to drug counterfeiting.

b. Institutional Framework

Most of the respondents stated that NAFDAC is the body fighting against drug counterfeiting. A respondent from the patients' group was of the opinion that NDLEA works hand in hand with NAFDAC.

c. Relationship between counterfeit drug manufacturers and end userse

All the patent medicine vendors said there are no relationships between counterfeit drug manufacturers and end users, while respondents from the patients group stated that the communities encourage drug counterfeiting because of the low cost of these drugs. However, the respondents from the Doctors and Pharmacists groups were not sure of whether a relationship existed between the manufacturer and the end users.

There were contrasting opinions among the patients pertaining to the issue of the duties that arise from the relationship, with some saying there is no role played by people in the society and some said there is. However, most of the pharmacist insisted that the production of counterfeit drugs is a criminal act. These drugs can kill and shouldn't be bought but should be reported to the right quarters just as a respondent suggested saying *"Counterfeit drugs produced can kill or harm the end user"*.

d. Adequacy of the existing institutional frame work for combating drug counterfeiting

The respondents mentioned SON, NAFDAC and NDLEA mostly as the legal organisations involved. The patients said that these legal institutions are adequate and effective. As for the six (6) patent medicine vendor, most of them indicated that these organizations exist and they are aware of their activities but one of the respondents said they are not fully effective. The respondent noted that, they are trying their best, but

these counterfeit producers still exist, because the law is not yet fully effective to stop this menace, because some are still producing counterfeit drugs.

However, the doctors were not sure of the implementation of the laws established by most of these legal institutions (SON, NAFDAC and NDLEA). The patent medicine vendors also mentioned the Pharmaceutical Council of Nigeria and the Police as some of these organizations, while a pharmacist named Association of Pharmacist Council of Nigeria as being part. Also, the pharmacists reiterated that the laws are moderately adequate and not so effective with one of them saying *"They are trying but they need to employ other means to battle drug counterfeiting."*

e. On Technology features used for authenticating drugs.

They are all aware of the MAS, though some in the doctor and pharmacist group know of other features, such as TruScan. They all agreed that the MAS is consumer centred, but it is not widely used. This is due to the low awareness level, especially among rural and illiterate population, telecom network problem and delay in receiving response. Some of the patients interviewed alleged that the response may not be received for a number of days, if at all. This defeats the essence of the feature since timeliness is key. However, some admitted to being negligent in the sense that they could not take the trouble of going through the process of authenticating the drugs. Other reasons given for the low usage rate of the feature is the lack of electricity, hence the inability to charge phone batteries as and when due. The Pharmacist and patent medicine vendors noted that, not all drugs have the scratch panels on their packaging, especially those dispensed from large packs.

f. UN Guiding Principles On Business And Human Rights as a means of combating the menace of drug counterfeiting

Most of the respondents are not aware of the UN laws. However, a respondent from the doctors group said "I think there is a right to health, and people have the right to life. They won't be alive if they are not healthy." So, infringing on their right because of business activities would not be right as they are being exposed to hazards. That amounts to an infringement of their right to health. The doctors agreed that, being

doctors, they lack knowledge about this human right but are comfortable with issues relating drug, medical products, their uses and effects.

In conclusion, majority of the respondents know about drug counterfeiting and its effects on the population at large. Also, the respondents know about the organizations involved in the fight against drug counterfeiting but were not sure of the implementation of their laws. Finally, majority of the respondents did not know about the UN Guiding Principles on Business and Human Rights.

5.2.2 Report of the Unstructured Interview with Lawyers

The lawyers were of the opinion that the best way to approach the issues was the use the rights-based argument. This is because, the manufacturers have the right to make a living, whilst the consumer have the right to life and health. There seems to be a conflict between both rights. The consumers' right to good quality medicines, gives rise to the manufacturer's duty to ensure that his/her product is fit for purpose.

a. Whether there is a relationship between the manufacturer and the end user of the drug:

   It was agreed that there may be no contractual relationship between them. Some were however of the opinion that the decision of the court in Carlill .v. Carbolic Smokeball case was applicable.[923] This was based on the principle that putting his/her drugs on the market was an invitation to treat to which the buyer makes an offer. That arrangement, in their opinion, created a relationship between them.

   It was noted that under Consumer Protection Laws, the manufacturer owes a duty to produce goods that are consumable, and the consumers do not expect to take a drug that will affect their health adversely. Consequently, the manufacturer owes the end user a duty of care.

b. Relationship and a duty

[923] (1893) 1QB 256.

They all said that the manufacturer owed the end user a duty of care, at least under the consumer protection laws. Under the law of contract, it was felt that there was no relationship. However, applying the principles of Donoghue .v. Stevenson,[924] the law of trust, third party insurance and tort of negligence, there was as established duty of care.

c. Adequacy of existing laws

This group admitted that, although, various laws were available, they were old and did not meet the requirements for the present day. They should therefore be reviewed and expanded. It was suggested by one of the participants that competition law should be introduced to this area. It was jointly agreed to that the legal framework as it is not adequate. The issue of enforcement of the existing law was raised. And it was noted that enforcing the existing laws was almost impossible and the effects of the law was not being felt as result of the enforcement challenges. They noted that the laws do not make provisions for compensation. The group argued that if Hart's theory is applied, the laws are inadequate.

d. Adequacy of Monitoring.

They advocated stiffer penalties for the offence of drug counterfeiting. It was noted that the retailer should be able to extract an indemnity clause from the manufacturer.

e. Adequacy of the institutional framework

It was agreed that though NAFDAC appears to be working, there is virtually little or no effect of their effort.

f. UN Guiding Principles on Business and Human Rights

Not all of them had heard of it, but all agreed that adopting it will aid in combating the menace. It was noted that stiffer penalty and the requirement for payment of

[924] *Supra*

compensation will make the business unattractive to the counterfeiters. It was agreed that the adoption of the principles of the UNGP, would ensure that the victims get redress for the violation of their rights.

g. Use of technology features, they all knew one or other of these features, but noted that some of them are now being counterfeited, thereby resulting in authentication of counterfeit medicines. It was therefore necessary for newer and stronger method be introduced.

h. Whistle Blowing Scheme

It was suggested that the whistle blowing scheme should be extended to this area.

In conclusion, all the lawyers were able to identify the legal issues involved in drug counterfeiting and that under the different areas of the law, a relationship which gives rise to a duty of care could be established. This duty was breached with the production of the counterfeit drugs. Consequently, the victim should be entitled to compensation. The consensus was that the legal framework, though comprehensive, was deficient in many areas and should be submitted for reform. Identifying NAFDAC's challenges, they agreed that the Agency was making efforts but could be changed in many ways for better efficiency at its duties.

5.3 Lessons from other Jurisdictions

In carrying out this study and to present a holistic picture, it is essential to examine the situation of drug counterfeiting in other jurisdictions. To this end, the drug counterfeiting situation in India and Kenya will be examined. The reason for choosing these countries are as stated in the Methodology section of this work in chapter one.

5.3.1 Drug Counterfeiting in Kenya

Kenya has the largest market in East Africa and a major distribution point for surrounding countries like Rwanda, Uganda and Ethiopia. She is also a recipient of drugs and medical products from health initiatives, especially for HIV/AIDS, malaria and tuberculosis. Like other African countries, it is afflicted with corruption, counterfeiting as well as high cost of

transacting business,[925] with the prevalence of counterfeit medicines in Kenya being a real threat.

In 2008, Kenya's Ministry of Health was split into two (2), namely, Ministry of Medical Services and the Ministry of Public Health and Sanitation. The effect of this split has been mainly negative, as responsibilities are duplicated, funds are being competed for and there is confusion as to duties.The former is the oversight for regulatory bodies for Pharmacy and Medicare, whilst the latter oversees health inspection and government pharmacists.[926]

The Pharmacy and Poisons Act of 1957, created the Pharmacy and Poisons Board. It was the first pharmaceutical legislation in Kenya. The Board is responsible for making regulations and enforcing them. It is a body independent of the two (2) Ministries. Amongst its duties is, organising public awareness campaigns.

In 1994, the Kenyan National Drug Policy came into being. It has however been poorly implemented and lacks key management structure.

Pharmaceuticals are distributed in Kenya through the Kenya Medical Supplies Agency.[927] These supplies are funded through government financing, donations, subsidised fees and private funds.[928]

Under the Kenyan law, counterfeiting is defined as the manufacture, production, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods.[929]Counterfeits

[925] Luoma M, Doherty J,Muchiri S, Barasa T andHofler K. 2010. *Kenya Health Systems Assessment*. Retrieved from https://www.hfgproject.org on 31st May, 2018.
[926] Luoma, et.al. *Ibid*. p. 5
[927] Luoma, et.al*, ibid*. p. 36
[928] Luoma et.al. *ibid p*.36
[929] Muthiani M and Wanjau K. 2012. Factors Influencing the Influx of Counterfeit Medicines in Kenya: A Survey of Pharmaceutical Importing Small and Medium Enterprises Within Nairobi. *International Journal of Business and Social Science.* Vol. 3, No. 11, p. 87

are infringements of protected IP rights or the imitation of same, in order that the other goods are calculated to be confused with the original ones.[930]

In Kenya, pharmaceutical products are one of the common counterfeit products.[931]The earliest counterfeit drugs encountered in Kenya were skin preparations.[932] Newer cases however involve anti-malarial drugs, antibiotics and fast-moving analgesics and expensive life style medicines.[933]

The extent of drug counterfeiting in Kenya has not been quantified. The absence of universally accepted definition not only makes information exchange between countries very difficult. It also limits the ability to understand the extent of the problem at the global level. Be that as it may, the Kenya Association of Pharmaceutical Industry (KAPI), in 2011, estimated that counterfeit drug sales in Kenya amounted to Nine (9) Billion Kenyan Shillings.[934]

A UN study ranked Mombasa a major hub for trafficking fake pharmaceutical and veterinary drugs. The study was carried out by the World Customs Organisation (WCO) and the International Institute for Research Against Counterfeit Medicine (IRACM) and it cites Mombasa as one of the biggest trafficking points in Africa. The Report which was released in May 2017, stated that Thirteen Million illicit and potentially dangerous medicines were seized in Africa, with a total of estimated value of Fifty Million Euro (€50,000,000). The study also revealed that of the Two Hundred and Forty -Three (243) containers inspected during "Operation ACIM (Action Against Counterfeit and Illicit

[930] Otieno-Odek. 2010. *Pharmaceutical Products, Protected goods and Counterfeit Medicines in Kenya*. A publication of Kenya IP Institute, Nairobi, Kenya.
[931] Muthiani M and Wanjau K. *ibid*. p.88.
[932] Government of Kenya. 2008. The Kenyan Counterfeit Goods Bill (2008): Proposed Regulations on Infringement on Property Rights Under the Trade Act 2005. No. 4. Government Printers. Nairobi. Kenya.
[933]*Ibid*. p. 88
[934] An equivalent of One Hundred Million US Dollars ($100,000,000). See 'Pharmacists Tell How to Identify Fake Drugs Shop'. Daily Nation Online. 29th June, 2011. Retrieved from www.nation.co.ke on 12th January, 2018

Medicines) in Kenya in September 2016, One Hundred and Fifty (150) contained illicit or counterfeit products.[935]

The Kenyan legal system addresses counterfeit trade under the criminal law and the civil law.[936] The Criminal aspect is enshrined in the Kenyan Penal Code, while the Civil is in the tortious and contractual liabilities. The Kenyan Constitution is the basis for IP rights protection. It is premised on the provisions of its Section 40(5), which states that the State has a duty to support, promote, protect the IP rights of the people of Kenya, having realised that the protection of IP right plays a great role in curbing counterfeit trade.

The Constitution that Kenyan had at Independence did not provide for justiciable socio-economic rights. Kenya is a dualist state under its Constitution but had failed to domesticate various international human rights treaties socio-economic rights. Consequently, it had been difficult for individuals and non-governmental organisations to seek enforcement of these rights in court.

The enactment of the 2010 Constitution however, saw the inclusion of the socio-economic rights, under the Bill of Rights, thereby making them justiciable.[937] Also included in the 2010 Constitution is the right to health under Article 43(1)(a).

The 2010 Constitution makes provision, amongst others for the protection of IP Rights in Kenya. It is pertinent to note that these were not contained in the 1969 Constitution. Art. 260(c), in its definition of property, includes intellectual property. Art 40 (5) further provides that, the State shall support, promote and protect the IP Rights of the people of

[935] Murumba S. 2017. Fake China, India Drugs Put Kenya at Risk. *Daily Nation*, 4th June, 2017. Retrieved from www.nation.co.ke on 12th January, 2018.

[936] Sikanya B. 2011. IP Confronts Counterfeiting in Africa: Protecting Innovations and Consumers in Cyber Society. *Consumer Law in Information Society*. Thomas W, et al. Eds. *Kluwer Law International*. London. 329- 364.

[937] With regards justiciability of socio-economic rights, the CESCR General Comment No. 3 outlines the obligations of the member states under the ICESCR. [ICESCR (16/12/1966) 993 UNTS 3; S. Exec. Doc D 95-2 (1978)]. It required member states to make appropriate provisions which should include availability of judicial remedies with respect to socio-economic rights. Comment No.3 sets strict standards in respect of the nature of states' obligations under the ICESCR, namely, (a) provision for justiciable socio-economic rights nationally. (b). implementation of socio-economic rights in an expeditious and effective manner. (c). A member state was not permitted to derogate from obligations under the ICESCR. In addition, the exceptions set out in the instrument did not extend to the core obligations under the right to health.

Kenya. Art 69(c) and (e) directs the State to protect and enhance IP, traditional or indigenous knowledge of biodiversity and the genetic resources of the communities and protect the genetic resources and biological diversity.

Art 11(1) recognizes culture as the foundation of the nation and as the cumulative civilization of the Kenyan people and nation. The State is to promote all forms of national and cultural expression through literature, the arts, traditional celebration, science, commerce, information, mass media, publications, libraries and other cultural heritage. It also recognises the role of science and indigenous technology in the development of the nation and promote the IP Rights of the people of Kenya.

Other laws put in place to curb counterfeiting in Kenya include the Industrial Property Act, Copyright Act, Trade Description Act, the Seeds and Plant Varieties Act, the Trade Marks Act and the Anti-Counterfeiting Act 2008.

In addition to institutions set up under the law, such as the Pharmacy and Poisons Board[938] and the Anti-Counterfeiting Agency[939], the public is sensitised on counterfeits and their ills by lobbyists from different industries. Example include the Kenya Association of Manufacturers (KAM).

Measures taken at combating counterfeiting in Kenya takes the following forms, firstly, legislative, this involves the enactment of various legislation, such as the Copyright Act. Secondly, Judicial Approach, which is done through civil and criminal procedures. However, these are not without their challenges. For instance, civil remedies, though adequate are costly, whilst the criminal remedies are not adequate.Furthermore, the courts on their part, have limited knowledge of IP laws, though they have general legal expertise. This often leads to misunderstanding and wrong judgement. Thirdly is theNon-Judicial Approach. This is by way of Alternative Dispute Resolution (ADR). ADR is the decision-making process, other than litigation, which includes negotiation, enquiry, mediation, conciliation, expert determination and arbitration. The 2010 Kenyan Constitution in its Art.

[938] Established under the Pharmacy and Poisons Act, Cap 244 Laws of Kenya
[939] Established under the under the Anti-Counterfeiting Act, No.13 of 2008.

159 makes provision for ADR mechanisms. The Constitution provides that the courts and tribunals in exercising their judicial authority are to be guided by alternative forms of dispute resolution, such as reconciliation, mediation, arbitration and traditional dispute resolution mechanisms.

It is pertinent to note however, that, ADR is not always an appropriate anti-counterfeiting mechanism. This is because, ADR depends on the consent of the parties to the disputes. Parties in counterfeiting cases hardly have pre-existing relationships. Consequently, they may not be pre-disposed to consenting to ADR. In addition, the requirement of urgency in avoiding further loss and obtaining relief for counterfeiting would not be obtainable in an ADR proceeding.

Fourthly are Administrative Measures. The administrative measures put in place in Kenya to combat counterfeiting include, the Office of the Registrar – General in the Attorney-General's Chambers under which the Kenya Bureau of Standards fall, the MD, KIPI and the Anti-Counterfeiting Agency (ACA). [940] These bodies are responsible for granting the innovators their respective IP amongst others.

Border Measures have also been deployed. These are actions taken by the local customs authority regarding goods under their control at the entry and exits of goods in the internal market. By virtue of Art. 51 TRIPS Agreement, member states are to make it possible for right holders, who truly believe that infringing copies of his/her goods are being imported, to lodge a complaint in writing, with the competent authority, for the suspension by the Customs Authority of the release of the goods into free circulation.

In line with the requirements of Art 51 of the TRIPS Agreement, Kenya Revenue Authority (KRA) set up the Anti-Counterfeiting and Smuggling Unit. This is charged with the task of ensuring that no counterfeits or smuggled items get into Kenya. The unit has the power to seize suspected products at the port of entry and prosecute importers.

[940] Kamerimbote P. 2010. IP Protection in Africa: An Assessment of the Status of Laws, Research and Policy Analysis on IP Rights in Kenya. *IELRC Working Paper*. Retrieved from www.ielrc.org on 12th January, 2012.

Border measures in Kenya is saddled with challenges. This is due mainly to the fact that the laws are inadequate. For instance, Section 34 of the Anti-Counterfeit Act 2008 provides that the owner of an IP Right may apply to the Commissioner where he has valid grounds for suspecting that the importation of counterfeit goods may take place. This provision may be interpreted as that the Commissioner can only act after receiving a complaint from the rights owner who suspects importation of counterfeit good. Where a rights owner is unaware of the importation, then the counterfeit goods get into the market. It is therefore pertinent for there to be an enhanced information sharing mechanism. The law is silent on border enforcement measures with regards to exports and goods in transit. This is a gap in the law.

Lastly,are theInternational Instruments. Kenya, like Nigeria, has ratified various international instruments. These include, TRIPS, Madrid Agreement Concerning the International Regulation of Marks, Patent Co-operation Treaty, Berne Convention for the Protection of Literary and Artistic Works, Paris Convention for the Protection of Industrial Property and the WIPO Copyright Treaty. In spite of these, Kenya ranks poorly in the international indices of IP Rights enforcement. This laxity has been identified as a challenge for businesses.[941]

5.3.1.1. The Kenya Anti-Counterfeiting Act

The Anti-Counterfeit Act[942] was enacted as a means of prohibiting trade in counterfeit goods and establishing an Anti-Counterfeiting Agency. The Act is divided into six (6) parts. It deals with counterfeiting generally.

The Act in Section 2 defines 'counterfeiting' as, *taking certain actions without the authority of the owner of the IP Rights subsisting in Kenya or elsewhere in respect of protected goods.*

Section 3 establishes the Anti-Counterfeiting Agency, as a body corporate, having all the powers of a body corporate. The functions of the Agency are set out in Section 5. These

[941] BASCAP Study: IP Protection Key to Kenya's Economic Development and Growth. Retrieved from https://www.iccwbo.org on 17th May, 2018.
[942] No. 13 of 2008

include, public enlightenment in respect of counterfeiting, combating counterfeit trade and other counterfeiting activities in Kenya, devising and promoting training programmes on combating counterfeiting, co-ordinating with National, regional or international organisations which are involved in counterfeiting, carrying out any other function as may be prescribed by the Act or any other written law, and to perform any other duty that may directly or indirectly contribute the attainment of the above listed functions.

Section 22 empowers the Board to appoint inspectors as it deems appropriate. The inspectors will hold offices on such terms and conditions as may be determined by the Board. The inspectors, in exercising their duties have the powers of the Police. The other public officers may be designated as inspectors by the Board.[943] The Board has powers to amend or withdraw the appointment of any appointed or designated inspector.[944]

By virtue of Section 23(1), an inspector has powers to enter upon and inspect any place, premises or vehicles, where it is reasonably suspected that counterfeit goods are stored, manufactured, produced or made. The inspectors have an 'enter and search' power. The search could be conducted on any premises, vehicle or person. Vehicles may be stopped on any public road or at any other public place.[945] In addition, inspectors may take necessary steps to terminate the manufacturing of production or making of counterfeit goods or any other form of dealing in counterfeit goods and prevent such re-occurring.[946]This includes destroying or alienating such goods, unless otherwise is ordered by a court of competent jurisdiction.

The inspectors also have powers to seize, detain and remove for detention the infringing goods and tools used in their packaging and manufacture.[947] In addition, an inspector may

[943] Section 22(4) Anti-Counterfeiting Act.
[944] Section 22(5) Anti-Counterfeiting Act.
[945] Section 23 (1)(a) Anti-Counterfeiting Act.
[946] Section 23(1)(b) Anti-Counterfeiting Act.
[947] Section 23(1)(c)&(d) Anti-Counterfeiting Act

question any person found at the inspection sight and request for books, documents, articles, items or objects which in any way may be relevant.[948]

An inspector may, where appropriate, seal off any place, premises or vehicle used for the manufacture, production or packaging of the infringing goods.[949]An inspector may arrest, without a warrant, anyone he reasonably suspects of committing an offence under the Act.[950] He/she may however not arrest any person unless that person obstructs or hinders the inspector or refuses to furnish the inspector with his name and address or any satisfactory evidence regarding his identity, or his details with which the inspector believes to be false. A proviso to Section 23(3) states that, 'A person who the inspector reasonably believes may disappear or is expedient that he/she be made answerable to justice without unreasonable delay, trouble or expenses, may also be arrested.

By virtue of Section 24(1), it is an offence to wilfully obstruct an inspector whilst discharging his duties or fails to render assistance or give information which is needed for the inspector to perform his/her duty, or wilfully make a statement which he/she does not believe to be true.

Where an individual breaks or tampers or damages a seal applied by an inspector or removes any goods, documents, articles, items, objects or things sealed or sealed-off by an inspector or detained or stored at a counterfeit goods depot, he/she commits an offence.[951]

Section 25 provides that, where an inspector seizes suspected counterfeit goods, he/she should immediately seal, identify clearly and categorise the goods, and prepare, in quadruplicate, an inventory of such goods. The owner of the goods is to cross-check for correctness and sign the inventory, with the inspector endorsing.[952] Subsection (1)(b) provides that a copy of the inventory is to be given to the owner of the seized goods and the complainant, if any.

[948] Section 23(1)(e)(i)&(ii) Anti-Counterfeiting Act.
[949] Section 23(1)(f) Anti-Counterfeiting Act.
[950] Section 23 (3) Anti-Counterfeiting Act.
[951] Section 24 (2)(a)&(b) Anti-Counterfeit Act.
[952] Section 25 (1)(a) Anti-Counterfeit Act.

Where the goods are movable, the inspector is to move them to a counterfeit depot as soon as possible. Where the goods are moveable, the inspector should declare that the goods seized in situ and immediately seal off or lock up the goods and put them under guard and the place will be deemed a counterfeit goods depot.[953] With regards seizure of goods, the inspector is expected to inform, in writing, the owner of the goods, the complainant, where one exists, or any person who is a holder of IP Rights, his successor- in- title, licensee or agents, but is yet to make a complaint.[954] By virtue of subsection 2, an inspector may require relevant additional information from a complainant.

A person who is aggrieved because his goods were seized, has a right of appeal to a court of competent jurisdiction, for a declaration that his/her goods are not counterfeits.[955] The court may grant or refuse to grant the relief sought and make any order for payment of damages and costs.[956]

Section 28(1) provides that goods seized shall be returned, less the portion used for test(s) or analysis, within three (3) months, where the person from whom they were seized, had not been charged with any offence under the Act. Where a prosecution for an offence has occurred, and a person has been convicted of that crime, the court may order that the goods be forfeited to the government for destruction at the expense of the convicted person.[957]

The Board may, by notice on the Gazette, designate any place a counterfeit goods depot, and appoint fit and proper persons to be in charge of the depot.[958]

By virtue of Section 32, it is an offence to possess or control, in the course of trade, manufacture, produce or make the course of trade, sell, hire out, barter or exchange or offer or expose for sale, expose or exhibit, distribute, import into, transit through, tranship within or export from Kenya, except for private or domestic use of the importer or exporter, counterfeit goods, or dispose of any counterfeit goods in the course of trade. It

[953] Section 25 (1)(c) Anti-Counterfeit Act.
[954] Section 25 (1)(d) Anti-Counterfeit Act.
[955] Section 25(3) Anti-Counterfeit Act.
[956] Section 25(4) Anti-Counterfeit Act
[957] Section 28(2) Anti-Counterfeit Act.
[958] Section 29 Anti-Counterfeit Act

appears from the provisions of Section 32, that it the product was for private or domestic use, it is permissible, so long as it not for trade purposes.

Where a person has been convicted of an offence under the Act, if he is a first offender, he will be sentenced to imprisonment for a term of not exceeding 5 years, or to a fine in respect of each article of item involved in the particular act of dealing in counterfeit goods to which the offence relates, not less than thrice (3ce) the value of the prevailing retail price of the goods, or both.[959]

A subsequent offender will be liable on conviction to imprisonment for a term not exceeding fifteen (15) years or a fine of not less than five times (5ce) the value of the prevailing retail price of the goods or both.[960]

A person who is convicted for disclosing information regarding manufacturing process or trade secret which he obtained by virtue of carrying out his duties under the Act, or for impersonating an inspector, is liable to imprisonment for a term not exceeding three (3) years or a fine not exceeding Two (2) Million Kenyan Shillings or both.[961]

In determining appropriate penalty, the court may consider any risk to human or animal life, health or safety or danger to property, that arise from the presence or use of the counterfeit goods.[962]

The court, in mitigating the sentence, may take into account, the fact that such person had fully, truthfully and to the best of his ability, had assisted, by disclosing all relevant information, during the course of investigation, relating to source of the goods, identity of the persons involved in the importation, exportation, manufacture, production or making of

[959] Section 35(1) Anti-Counterfeit Act.
[960] Section 35(2) Anti-Counterfeit Act.
[961] Section 35 (2) Anti-Counterfeit Act.
[962] Section 35(3) Anti – Counterfeit Act.

the counterfeit goods, identity, and demanded, the address or whereabout of those involved in the distribution of the goods and the channels of distribution of the goods.[963]

Where an offence has been committed by a body corporate and it is proved to have been committed with the consent and connivance of, or it is attributable to neglect on the part of any senior officer of the corporation, or any person acting in that capacity, such a person will likewise be liable for an offence.[964]

The provisions of the Act, on what amounts to counterfeit, especially as it affects access to medicine, was tested in the *Asero &2 Ors.v. Attorney General*,[965] an action filed by three(3) petitioners living with HIV/AIDS, challenging the legislation.

The petition raised critical issues pertaining to the constitutional rights of citizens to the highest attainable standard of health. The petitioners being apprehensive that their rights under the Constitution were threatened by the provisions of Sections 2, 32 and 34 of the Anti-Counterfeit Act 2008. Section 2 is the definition section. It defines 'counterfeiting' as,

> taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya or elsewhere in respect of protected goods:
>
> (a) the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;
>
> (b) the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his licence;
>
> (c) the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author's rights or related rights;
>
> (d) in relation to medicine, the deliberate and fraudulent mislabelling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong

[963] Section 35(3)(b) Anti-Counterfeit Act.
[964] Section 35 (4) Anti-Counterfeit Act
[965] Petition No. 403 of 2009.

> ingredients, have sufficient active ingredients or have fake packaging;
>
> Provided that nothing in this paragraph shall derogate from the existing provisions under the Industrial Property Act.

Section 32 provides thus:

> It shall be an offence for any person to
>
> (a) have in his possession or control in the course of trade. Any counterfeit goods;
>
> (b) manufacture, produce or make in the course of trade, any counterfeit goods;
>
> (c) sell; hire out, barter or exchange, or offer or expose for sale, hiring out; barter or exchange any counterfeit goods;
>
> (d) expose or exhibit for the purposes of trade any counterfeit goods;
>
> (e) counterfeit goods for of trade or any other distribute purposes purpose;
>
> (f) import into, transit through, tranship within or export from Kenya, except, for private and domestic use of the importer or exporter as the case may be, any counterfeit goods;
>
> (g) in any other manner, dispose of any counterfeit goods in the course of trade.

In its part, Section 34 makes provisions for the powers of the Commissioner as it relates to dealing with counterfeit goods.

The petitioners were adults, who have been living with HIV. They have been taking HIV medication for the last ten (10) years or more, since generic anti-retroviral (ARV) HIV drugs became available, with the enactment of the Industrial Property Act 2001. All the petitioners were unemployed and received the medication free of charge through one agency or the other.

They saw these provisions as affecting or likely to affect their access to affordable and essential drugs and medicines including generic drugs and medicines thereby infringing their fundamental right to life, human dignity and health as protected by Arts. 26(1), 28 and 43 of the 2010 Constitution of Kenya.

Section 26(1) provides that, *every person has a right to life*. Section 28, in its parts states that, *every person has an inherent dignity and the right to have that dignity respected and protected*. Section 43 provides that,

> (1) Every person has the right—
>
> (a) to the highest attainable standard of health, which includes the right to health care services, including reproductive health care;
>
> (b) to accessible and adequate housing, and to reasonable standards of sanitation; (c) to be free from hunger, and to have adequate food of acceptable quality;
>
> (d) to clean and safe water in adequate quantities;
>
> (e) to social security; and
>
> (f) to education.
>
> (2) A person shall not be denied emergency medical treatment.
>
> (3) The State shall provide appropriate social security to persons who are unable to support themselves and their dependents.

The issue before the court was whether, by enacting Section 2 in its present form, and by making provisions for the enforcement of Sections 32 and 34, the State is in violation of its duty to ensure conditions are in place under which its citizens can lead a healthy life, and whether these provisions will deny the petitioners access to essential medicines and thereby violate their rights under Arts. 28 and 43(1), as well as Section 53, with regards to the rights of children[966],[967]

The petitioners sought declarations amongst others that, the fundamental right to life, human dignity and health as protected and envisaged by Arts 26(1), 28 and 43 of the Constitution encompassed access to affordable and essential drugs and medicines including generic drugs and medicines, that in so far as the Anti-Counterfeit Act 2008 limited access to affordable and essential drugs and medicines for HIV and AIDS, it

[966] Para 67 Judgement on Petition 409 of 2009. p. 35
[967] The second petitioner had a child who was living with HIV. The action was also brought on behalf of the child.

infringed on their right to life, human dignity and health as guaranteed under Arts. 26(1), 28 and 243 of the Constitution; that the enforcement of the 2008 Act, in so far as it affects access to affordable and essential drugs and medicines, especially generic drugs, is a breach of their rights to life, human dignity and health, which were guaranteed by the Constitution.

The Kenyan High Court held that the Act did not clearly distinguish between counterfeited drugs and generic medicines. With the effect of causing confusion and subsequently, hindering access to life-saving medicines, particularly for people living with HIV. The court noted that,the right to life, dignity, and health of people like the petitioners who are infected with the HIV cannot be secured by a vague provision in a situation where those charged with the responsibility of enforcement of the law may not have a clear understanding of the difference between generic and counterfeit medicine.[968]

The court noted further that,

> the Act has prioritised enforcement of IP rights in dealing with the problems of counterfeit medicine. It failed to focus on quality and standards which would achieve…the protection of the petitioners in particular and the general public from substandard medicine.[969]

The decision was welcomed by several advocacy groups in Kenya. The Kenyan High Court ordered a review of the controversial Anti-Counterfeit Act of 2008, on the grounds that it could interfere with the supply of legitimate generic medicines to patients.

The legislation has been criticized on the grounds that its provisions cannot deal with the complexities of counterfeit and substandard medicine trade. Generic drugs, by their nature appear to be included in the definition of counterfeits given by the law. The effect of this is that it will reduce the range of generic medicines available. This argument was upheld by the court in ruling that, the Act is vague and could undermine access to affordable generic medicines since it failed to clearly distinguish between counterfeit and generic

[968] Para 84 Judgement on Petition 409 of 2009. p. 44
[969] Para. 83 Judgement on Petition 409 of 2009. p. 43

medicines. The court, holding that IP rights should not override the rights to life and dignity, directed the Kenyan Parliament to review the Act by removing the ambiguities that could result in arbitrary seizure of generic medicines, whilst fighting drug counterfeiting. This decision has been lauded by many health advocacy groups in Kenya.

5.3.2 Drug Counterfeiting in India

India is one of the leading manufacturers of counterfeit and substandard medicines in Asia.[970] The country is also regarded as the "pharmacy of the world," as its robust generic drug industry serves as the main source of medicines for most countries in low- and middle-income countries which has greatly reduced the attention to the safety, efficacy and quality of the medicines that are exported[971].

According to WHO, 35% of fake drugs sold all over the world come from India, whilst 20% of the drugs sold in India are fake.[972] In 2003, the then President of India's Organisation of Pharmaceutical Producers in India (OPPI), commenting on the modus operandi of spurious drugs manufacturers in India, pointed out that,India is fast becoming the capital for counterfeit drugs and accounts for one third of the counterfeit drugs produced worldwide.[973]

[970] It has been reported that, at least, 75% of the counterfeit drugs supplied globally originate from India. See Verma, S., Kumar, R. and Phillip, P. J. 2014. The Business of Counterfeit Drugs in India? A Critical Evaluation. *International Journal of Management and International Business Studies*. 4(2):141-148.

[971] Ahmad A I. 2012. "Addressing Variability in Drug Quality: Finding the Right 'Quality' Framework(s)". A thesis submitted in conformity with the requirements for the degree of Master of Science, Graduate Department of Pharmaceutical Sciences University of Toronto.

[972] See report by Rama Lakshmi in The Washington Post at http://www.washingtonpost.com/wp-dyn/content/article/2010/09/10/AR20/0091003435.html. Referred to in Singh A and Kane H. 2011. Report on Anti-Counterfeiting in India, in *Anti-Counterfeiting Committee Report*, presented at the 59th Council Meeting Held at Manilla. Philippines, on 12th – 15th November 2011. A Publication of the Asian Patent Attorneys Association, p. 2

[973] Retrieved from https://thehindubusinessline.com/2003/08/03/stories/2003080301260500.html on 7th July, 2015.

According to India's Department of Food Safety and Drug Administration, over 10% of the counterfeit drugs are already in the market and 38% of drugs are not effective as they are of low quality.[974]

India's Central Drugs Standards Control Organisation (CDSCO) has identified three (3) types of counterfeit medicines in India. These are, drugs with minor defects, spurious and adulterated drugs and grossly sub-standard drugs.[975] Spurious and adulterated drugs are drugs that have been passed on as someone else's. They have been referred to as "misbranded drugs". They may or may not have active ingredients. Grossly sub-standard drugs on their part do not offer what it claims to have. They may actually constitute a danger to the health of the user, due to one missing ingredient or the other.

Indian counterfeiters are usually unlicensed manufacturers with small cottage factories, otherwise known as 'fly by night' manufacturers. This is because, they can fold up as soon as they get wind of a proposed raid. However, some counterfeiters are licensed, but mix their brand with some fake. Others are importers who import fake drugs from China. These drugs are then repackaged.[976]

5.3.2.1 Factors Responsible for the Growth of Drug Counterfeiting in India

In 2003, the Indian Ministry of Health and Family Welfare commissioned a report ('Mashelkar Committee Report') that identified the factors contributing to the proliferation of "spurious" medicines to include lack of enforcement of existing laws; weak penal action; very remunerative trade; large-scale sickness in small scale pharmaceutical industry; availability of improved printing technology that helps counterfeiting; lack of

[974] Majority of the Drugs Found in India are either Fake or Ineffective. A publication of Think Change India. Retrieved from https://www.yourstory.com on 6th June, 2017.
[975] CDSCO, 2005. Guidelines for Taking Action on Samples of Drugs Declared Spurious not of Standard Quality in the light of Enhanced Penalties under the Drugs and Cosmetics (Amendment) Act 2008. Retrieved from http://www.cdsco.inc.in/DCC%20Guidelines%20on%20NSQ%20Drugs...pdf on 23rd June, 2016.
[976] Chaudry P E and Stumpf S A. 2013. The Challenges of Curbing Counterfeit Prescription Drugs Growth': Preventing the Perfect Storm. *Business Horizons*. p. 192.

coordination between various agencies; too many retail and wholesale outlets; inadequate cooperation between stakeholders; lack of control by importing/exporting countries."[977]

It should however be noted that India's definition of counterfeit drugs is a contributory factor to the growth of drug counterfeiting. She does not use the same definitions as the WHO in distinguishing between sub-standards and counterfeits. Rather, it identifies "spurious medicines," which include fake and adulterated medicines, and "grossly substandard" medicines, defined by percentage of active ingredient present. Unlike the WHO definitions, therefore, these categories do not distinguish based purely on type of manufacturer, since legitimate manufacturers may produce adulterated drugs. By blurring the line between legitimate and illegitimate manufacturers, India is trying to fight two problems with a single solution and this has proved largely ineffective with respect to substandard drugs and a bit effective with respect to counterfeit drugs[978].

5.3.2.2 Counterfeit Drugs Regulatory System in India

The drug regulatory system in India is saddled with two (2) fundamental challenges, namely, the country has a single regulatory agency which is not effective, given her size. Secondly, her regulatory system is decentralised. The effect of this is inconsistent standards, weak enforcement strategy and limited accountability.[979]

India divides the role of regulation and enforcement mechanism of medicines between the national and state institutes. Drug manufacturing standards are issued by the central government. This is overseen by the Central Drug Standards Control Organisation (CDSCO). Its role is to regulate clinical research and trials and authorize new drugs. In their part, state agencies license, monitor, approve and regulate drug manufacturing,

[977] Ahmad A I. 2012. "Addressing Variability in Drug Quality: Finding the Right 'Quality' Framework(s)". A thesis submitted in conformity with the requirements for the degree of Master of Science, Graduate Department of Pharmaceutical Sciences University of Toronto.
[978] Christian L, Collins L., Kiatgrajai M., Merle A., Mukherji N and QuadeA. 2012. The Problem of Substandard Medicines in Developing Countries. *Workshop in International Public Affairs*. University of Wisconsin, Madison. Retrieved from www.lafollette.wisc.edu/publications/workshops.html on 24th August, 2017
[979] Bates R. 2009. China's Bad Medicine. *The Wall Street Journal* 5th May, 2009. Retrieved from http://onlinewsi.com/article/SB124146383501884322.html on 23rd October, 2016.

establish drug testing laboratories, the quality of drugs and drug formulations. Due to the decentralisation of monitoring, the level of effectiveness varies. A study revealed that seventeen (17) out of thirty-one (31) states in India have functional drug testinglaboratories.[980] Of these 17, only seven (7) are reasonably equipped and staffed. Similarly, the quality of the medicines sold in India are different.[981]

Furthermore, the medicine regulatory system in India is said to be suffering from some fundamental problems which include geographic size, decentralized, weak and non-comprehensive regulatory structures, and lack of adequate testing facilities. India lacks centralized enforcement of regulatory standards, and significant regional variation exists in the proliferation of counterfeit drugs. Also, the division of labour between state and central government mandates gives states too much leeway in licensing, regulating, and enforcing medicine production[982].

5.3.2.3 Enforcement

Enforcement of regulatory control in India is carried out by the Police Force, which has powers to look into counterfeit matters and act on complaints made by individuals. In addition, the Police assist in carrying out raids on suspected counterfeiters and their premises. The Customs have powers to seize goods which infringe on IP rights of others, at the point of entry. The Health Department and the Drug Controller General of India, have oversight functions in respect of counterfeit/fake drugs and other medical products. Lastly, the Food and Drug Authority (FDA) which is present in each state, is responsible for dealing with counterfeit matters.

The courts in India have become more aware of the dangers of drug counterfeiting. They are therefore more receptive and have reformed their procedure, making it more flexible.

---

[980] Khan and Ghilzazi, 2007. Counterfeit and Sub-Standard Quality of Drugs: The Need for an Effective and Stringent Regulatory Control in India and Other Developing Countries. *India Journal of Pharmacology*. 39:206-207.

[981] Tortstenss, David and Pugetch M. 2010. Keeping Medicines Safe. Final draft. Referred to Report of the Anti-Counterfeiting Committee, *loc. Cit.*, p. 16.

[982] Christian L, Collins L, Kiatgrajai M, Merle A, Mukherji N and Quade A. 2012. The Problem of Substandard Medicines in Developing Countries. *Workshop in International Public Affairs*. University of Wisconsin, Madison. Retrieved from www.lafollette.wisc.edu/publications/workshops.html on 24th August, 2017

To this end, ad-interim ex-parte injunctions are now being granted, as well as orders to inspect and seal off premises, where offences are suspected to be committed. IP cases are now tried within the shortest possible time. [983]

5.3.2.4 Legislative Framework

The laws regulating drug counterfeiting in India are varied. These include,Trade Marks Act 1999, Trade Marks (Amendment) Act 2010), IP Rights (Imported Goods) Enforcement Rules 2007 [Customs Notification No. 47/2007. Customs (NT) dated 8/5/0), The Standard of Weight and Measure (Packaged Commodities) Rules 1977, The Drugs and Cosmetics (Amendment) Act 2008 and the Prevention of Food Adulteration Act 1954.

5.3.2.5 Remedies for IP Infringement in India

The remedies available for IP infringement are injunctions, Anton Piller Order, roving orders, John Doe orders, damages, which could be compensatory or punitive or exemplary, costs, lock breaking powers, police aid for civil raids and Quia timet actions.

5.3.2.6 Efforts by the Indian Government to Combat Drug Counterfeiting

The Indian government has taken steps in curbing drug counterfeiting. The steps taken so far will be discussed below.

In 2008, the Drug and Cosmetics (Amendment) Act was promulgated. The Act amongst others created a central FDA and increased the penalties for manufacturers and traders of fake drugs. Under Section 6(B) of the 2008 Act, the minimum penalty for manufacturing and selling fake drugs and cosmetics is ten (10) years imprisonment which may extend to life and a minimum fine of Rs. Ten (10) lakh, or thrice the value of the drugs confiscated,

[983] Report of the Anti-Counterfeiting Committee. *Loc. cit*. p. 9

whichever is higher.The offence is non-bailable in some cases. The fine is to be used in compensating the victim(s).[984]

The proviso to section 6(C) provides that compensation payable to the victim may be received by the spouse of the deceased, or a minor legitimate son or unmarried legitimate daughter or a widowed mother. Where the victim is a minor, the money may be received by the parent.

With regards spurious or misbranded drugs and cosmetics, the penalty is a minimum of three (3) years imprisonment with a fine of not less than Rs. Fifty Thousand (50,000), or thrice the value of the drug or cosmetics confiscated, whichever is higher.[985]

In addition, a whistle blowing scheme was commenced. Under the scheme, those who report manufacturers of spurious medicines were rewarded.[986] According to CDSCO, monetary reward of twenty percent (20%) of the total value of any drugs seized, as a result of the information to a maximum of Rs. Twenty-five (25) Lakh. If the information was offered by a government official, he/she gets Rs Five (5) Lakh for one case and a maximum of Rs Thirty (30) Lakh in his/her entire service.[987] The informant gets Twenty-five (25%) upfront, twenty-five (25%) when they give evidence in court and the balance of the accused is convicted.[988]

Most of the efforts at managing drug quality in India have been made in respect of counterfeit, as opposed to substandard medicines. For instance, in 2011, a legislation was

[984] Section 6(C) Drugs and Cosmetics (Amendment) Act 2008.
[985] Section 7 Drugs and Cosmetics (Amendment) Act
[986] CDSCO of India. Reward Scheme for Whistle Blowers in the Fight against the Menace of spurious or Fake Drugs, Cosmetics and Medical Devices. Retrieved from http://cdsco.nic.in on 23rd October, 2016. See also
[987] Ministry of Health and Family Welfare, 2014. Reward Scheme for Whistle Blowers in the Fight against the Menace of Spurious or Fake Drug, Cosmetics and Medical Devices. *Paras. 7*. Retrieved from www.cdsco.nic.in on 6th June, 2018.
[988] *Ibid*. Para. 8

passed, to the effect that all manufacturers must put a 2D barcode on medicine packaging for tracking and verification of authenticity purposes.[989]

In addition to promulgating the legislation, an online monitoring system was initiated.[990] This mandatory online system is for monitoring the supply and sale of drugs. It was developed by CDSCO, an arm of India's Ministry of Health and Family Welfare (MHFW).

The aim of the system is to *ensure that the medication meets required standards, to regulate the sale of medicines online and help control the spread of drug resistant microbes*. It also aims to address public complaints made to the government about the quality of drugs in the country and the *need for plugging the gaps* in the online sale of drugs.

There has not been any mandatory system for tracking drugs domestically, through the supply chain. Under the new system, every part of the supply chain would have to report on the drug it handles. All manufacturers would be required to register with the e-platform and provide information on the drugs that they sell to distributors and wholesalers, including batch numbers, quantities and expiry dates. Also required to register are stockists, wholesalers and other distributors. They are to provide details on stock received and account for all medication- whether sold, returned or disposed of in other ways. Outlets must be registered on the system to be ready to carry on business. Retailers must have registered bricks and mortar facility before it can carry on business or sell online. The proposed system, according to the MHFW, would work on mobile devices, whilst rural pharmacies will have the benefit of updating their register fortnightly.

Other technologies used to detect counterfeit drugs in India include,[991] the 2D bar codes and scratch off labels on the packaging of the medicines. The label is scratched off and the patient texts the ID numbers to a phone number to authenticate the medicines. The Quick

[989] Report on Anti-Counterfeiting in India, *ibid*. p.25
[990] Churchill F. 2017. *India to Crack down on Fake Drugs with Online Monitoring*. Retrieved from www.cips.org on 29th March, 2017.
[991] Kannan S. 2011. Counterfeit Drugs Targeted by Technology in India. *BBC News*, Delhi. 11th October, 2011. Retrieved from www.bbc.com/news/business-15208595 on 22nd January, 2018.

Response (QR) code is another type of counterfeit drug detecting device. The codes are printed squares in advanced 2D bar codes version. They can be scanned by anyone with a camera-enabled phone and web access and forwarded instantly to the pharmaceutical company's website to authenticate the drug. Also employed is the Global Authentication Service. This is used by pharmaceutical companies who already have 2D barcodes which are printed on the packaging. The manufacturer's cloud service will then be used to monitor the movements of products through their global supply chains. This system is also being used in Nigeria and Ghana. The hand-held scanner is used in tracking their security technology non-clonable IDT. This is like putting a fingerprint on each product. It provides the means of tracing products across the supply chain, from the manufacturer to the consumer. The Unique Identification Mobile Verification is another method used. It is a unique number for each product which can be verified by sending text messages to the number provided. These codes are printed on the packaging and monitoring begins the minute the product leaves the factory. This protects the consignment while in transit until they reach their destination. Lastly, consumers can obtain information on fake drugs from the certification system for pharmacists. This is an open source website.

There have been instances of fake drugs causing harm to people in India. There are however no evidence of the government penalizing the counterfeiters.[992] For instance, in 2013, eight thousand (8,000) patients died over a period of 5 years as a result of using an antibiotic, for preventing post-operation infection, which had no active ingredients. There was no evidence of any action taken by the government against the counterfeiters.[993]Although the penalties for drug counterfeiting is now stiffer in India, cases where the alleged offenders were convicted are hard to find.[994]

The risk of substandard drug manufacturers, is low in India. The Drug and Cosmetics (Amendment) Act 2008, whilst increasing the penalty for spurious drugs and cosmetics,

[992] Singh B R. 2017. Why India Failed to Penalize Those Responsible for the Circulation of Sub Standard Medicines and Vaccines while China Succeeded? *Global Journal of Pharmacy and Pharmaceutical Science*. Vol.2 Issue 5. p. 002

[993] Ossola A. 2015. The Fake Drug Industry is Exploding and We Can't Do Anything About It. *Newsweek*. Retrieved from www.newsweek.com on 30th May, 2018.

[994] Singh B R. *ibid*. p.002

introduced the requirement for proof of criminal intent or gross negligence before an action in respect of sub-standard drugs can be entertained administratively or a prosecution entered.[995] Consequently, manufacturers of substandard drugs are rarely punished because of this sort of regulation deficiencies and the requirement of a heavy burden of proof.[996]

The offers made to whistle blowers have also rarely been taken. This is because those who took the offer have suffered losses. An instance is the case of N K Reddy, who lost his job at G V K Biosciences (GVK), for reporting the latter, who had been forging test data for drug efficacy tests. G V K was black listed as a result of the information given by Reddy and Reddy was subsequently portrayed as a disgruntled employee, who was indulging in extra marital affairs. He was prosecuted for criminal defamation. Needless to say, he lost his job.[997]A Whistleblowers' Protection Amendment Bill has been proposed, though nothing has come out of the proposal.

India lacks a strong regulatory system. The states have large powers and discretion in respect of licensing, regulating and enforcing medicines production. A centralised drug manufacturing and licensing authority would improve the situation on ground. India's port administration should be strengthened and testing laboratories increased.

5.4 Secrecy and Drug Counterfeiting

There is evidence to show, that Pharmaceutical companies and governments are reluctant to publicise the problem of counterfeit drugs to medical personnel and the general public.[998] They actively keep the activities of counterfeiters' secret. This is as a result of the belief that the publicity will harm sales of branded products given the competitive

[995] CDSCO Guidelines for Taking Action on Samples of Drugs Declared Spurious or not Quality in light of Enhanced Penalties Under the Drug and Cosmetics (Amendment) Act, 2008. Retrieved from http://cdsco.nic.in on 24th October, 2017.
[996] Anti-Counterfeiting Committee Report. *Loc. cit.*
[997] Rajagopal D. 2016. How Drug Whistle Blowers in India Have to Fight Long Battle. Economic Times 19th May, 2016. Retrieved from https://economictimes.indiatimes.com on 6th June, 2018.
[998] Cockburn R., Newton P N., Agyarko E K., Akunyuli D and White J N. 2005. Why Industry and Governments Must Communicate the Dangers. *Plos Medicine*. Vol. 2, Issue 4-e100. Retrieved from www.plosmedicine.org on 22nd January, 2018. p.0302

business environment. In their opinion, publicity will have the effect of deterring patients from using their genuine products, thereby damaging their legitimate business.[999]

The effect of this secrecy is that in the long run, it is against the interest of the company and patients, resulting in harm to the public. Another effect is the dearth of reliable accessible databases where current information on drug counterfeiting can be obtained. This is counterproductive, in the sense that, curbing the growth of drug counterfeiting requires information on what is being counterfeited and in what country.

According to the WHO 1999 Guidelines for The Development of Measures To Combat Counterfeit Drugs, the secrecy by the pharmaceutical companies could impede national authorities from successfully taking measures against counterfeiting.[1000]

The Royal Pharmaceutical Society of Great Britain is of the opinion that, matters relating to drug counterfeiting should be handled with little or no publicity, so as not to damage public confidence in medicine.[1001] There is however a recent contrary view, that there should be dissemination, but it should be done responsibly, so as not to undermine public confidence in medicine.[1002]

Government's attitude to adopting secrecy with regard to the problem of drug counterfeiting in their countries, reflect their inaction on the matter. It has been noted that some countries issue false certification, while some others actively suppress information on counterfeit drugs.[1003]

It has however been suggested that, in dealing with the issue of secrecy as it relates to drug counterfeiting, the model used by the United Kingdom Civil Aviation Authority be adopted. Under the model, suspected unapproved aircraft parts must, by law, be reported.[1004] Consequently, counterfeit drugs must be reported to the appropriate body in

---

[999] Cockburn R. 1982. *Counterfeit Drugs- the other Killer in Lebanon*. The Guardian (London). p.18.
[1000] WHO Department of Essential Drugs and Other Medicines. (1999). *Counterfeit Drugs: Guidelines for the Development of Measures to Combat Counterfeit Drugs*. Retrieved from https://whqlibdoc.who.int/hq/1999/who_EDM_QSM_99.1 on 22nd January, 2018.
[1001] Anon, 1989. More UK Debate on Counterfeits. *Scrip*. 1468:3.
[1002] Cockburn R, et al. *op cit*. p.0304
[1003] *Ibid*. p.0303
[1004] *Ibid*. p.0307

the respective countries. Once a report has been confirmed, the drug regulatory authority would assess the public health importance of the information and decides when and how to alert the country's police, trade, customs authorities, public and drug regulatory authorities of other nations that may be affected, using the Interpol as may be necessary. That way, where a counterfeit drug has been intercepted before getting to the outlets, alerting the public may not be necessary.

The pharmaceutical companies are also victims and should enjoy governmental support in the war against drug counterfeiting. Those who report counterfeit incidences should remain anonymous and receive security protection.

This study has identified and evaluated the legal and institutional framework on drug counterfeiting in Nigeria, with the result that these are comprehensive, but not efficient. Reforms have not been forthcoming as at when needed, as a result of lack of political will on the part of the government and ignorance of their rights, due to illiteracy.Therefore, the efforts at combating drug counterfeiting has not yielded significant fruits.

With regards the legal issues in drug counterfeiting and the right to health, certain aspects of the law have been identified and assessed. Applying Hart's principle of minimum content of law, the legal framework does not meet the purpose for which they were promulgated, that is putting an end to drug counterfeiting. It is obvious that in spite of the robust legal framework the menace is still wide spread. In the same vein, the law does not protect the interest of the victims of this hideous crime. Consequently, there is a need for law reform, as prescribed by the UNGP. Other factors found to be militating against curbing the menace are, false declaration at the ports of entry, so as to evade inspection, sophistication of technologies used in counterfeit drug manufacturing, and inadequate co-operation between government regulatory agencies on one part and governments amongst themselves.

CHAPTER SIX

SUMMARY, CONCLUSION AND RECOMMENDATIONS

6.1 SUMMARY

Counterfeit drugs are those drugs that have been deliberately and fraudulently produced and/or mislabelled to make it appear to be a genuine product.They include medicines that contain no active pharmaceutical ingredient (API), an incorrect amount of API, an inferior-quality API, a wrong API, contaminants, or repackaged expired products.Others may have been formulated incorrectly and produced under substandard conditions. Both branded and generic medical products can be counterfeited. As a matter of fact, generic medicines are often confused with the counterfeit ones. This confusion has resulted in being an obstacle to the availability and use of these generics.

The right to health is the right to the enjoyment of the highest attainable standard of physical and mental health.[1005] Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. Consequently, the right to health guarantees the right to life, on which other social, economic and political rights are hinged. The right to health demands that health care, health products and health systems must be available, accessible, acceptable and of good quality. The availability of counterfeit drugs is a direct infringement on the right to health, which provides that health care must not only be affordable, accessible and acceptable, but must be of good quality. Counterfeit drugs are a violation of the right to qualitative health care.

Over the years, technology has been deployed in the fight against drug counterfeiting. Methods such as the Mobile Authentication Service (MAS), which allows consumers to verify that products bought are genuine, by simply using a mobile phone and a free SMS message, and TRUSCAN handheld instrument used to identify counterfeit and sub-standard drugs imported and sold in Nigeria. It identifies the slightest differences in drug formulation. This has however not recorded a notable change in the fight against

[1005] WHO Constitution of 1946.

counterfeiting, as the counterfeit drug manufacturers have also used technology to perfect their 'act'.

Given the rapid growth in the drug counterfeit trade, in spite of global efforts at combating it, its effect on the individual, and nations, and the criminal component of drug counterfeiting, there arose the need to conduct a study on the effective means of combating the menace, which is a violation of the right to qualitative health care, the right to life, the right to dignity and self-determination of the citizenry, which member states of the WHO have an obligation to protect and uphold. This study, examined the legal issues in drug counterfeiting, as it relates to the right to health of the citizens and evaluated the legal mechanism put in place to combat drug counterfeiting, so as to establish how effective they have been and why, and is proposing alternative approach.The study proposed the application of the "all embracive approach" as propounded by the United Nations Guiding Principles on Business and Human Rights.[1006]

This study examined drug counterfeiting and its effect on the right to health in Nigeria. Counterfeiting and human rights were discussed generally. It analysed applicable or relevant laws relating to drugs, counterfeiting, health and human rights. The topic, drug counterfeiting, has received massive global attention.However, this has been done either from the public health, criminal law and intellectual property perspectives. Consequently, this study raised other legal issues involved in drug counterfeiting, such as the existence of contractual relationship, between the manufacturers of these counterfeits and the end users of the drug. If there was such a relationship, what duty (or duties) and consequentially, civil and criminal liabilities does (do) the relationship create? In addition, the implication of the sale of goods law on counterfeiting was examined. The law implies a condition that a buyer of a product is entitled to have products which are of merchantable quality and fit for the purpose for which it was purchased. Finally, it examined the human rights issues involved in drug counterfeiting and proposed the all embracive approach to combat the menace of drug counterfeiting in Nigeria. The foregoing were discussed from the Nigerian and other international legal frameworks.

[1006] See footnote 8 on p. 2.

This study applied the doctrinal examination of law dealing with counterfeit drugs and the right to health in Nigeria, and a comparative approach. The theoretical framework adopted for this study was the Sociological School of Jurisprudence as propounded by Roscoe Pound, Jhering and Jeremy Betham. Also applied was the theory of Hart's minimum content of law. The study employed primary and secondary sources of data.

In achieving its objectives, the study undertook a comparative study of the laws of Kenya, a developing African Nation and India, to determine how and to what extent they have been able to develop a framework to combat Drug Counterfeiting, thereby upholding the right to health, within the ambit prescribed by the World Health Organisation (WHO).

For the study, focused unstructured interviews were conducted among relevant stake holders. These are pharmacists, NAFDAC officials, patients, lawyers and doctors. The interview sought to probe their knowledge, understanding and assessment of the effects of drug counterfeiting on the right to health. Questions were asked in relation to their views on the existing provisions of the law and how drug counterfeiting can be curbed, if not totally eradicated.

Studies have been carried out on different aspects of drug counterfeiting by researchers in the public health field. These researchers have been concerned with determining what amounts to a counterfeit drug.They have found that there is no singular definition. This according to them, is an obstacle to combating drug counterfeiting. From previous studies, it has been established that drug counterfeiting is both a public health and an IPR issue.[1007] Furthermore, previous studies have concluded that the effect of counterfeit drugs include, economic losses, loss of confidence in orthodox medicines, harm to health from therapeutic failure, development of adverse drug reactions, increased disease severity, development of complications and death. It also impedes pharmaceutical innovation. Various factors have been said to be responsible for the growth of drug counterfeiting. These are poverty, high cost of medication, legislative lacunae, ineffective law enforcement machinery, lenient penalties, double standards in the regulatory status of

[1007] Some countries like Kenya, treat it under IP laws.

pharmaceuticals, where foreign pharmaceutical companies dump medicines, whose use are restricted or banned in their home countries in developing countries with less stringent regulations, and the internet, to name a few.

The legal issues identified in relation to drug counterfeiting are contract, torts, criminal law, human rights, intellectual property rights, strict liability and product liability. From the examination of the legal issues in drug counterfeiting, it can be established that it is a violation of the right to qualitative healthcare, for which compensation is due. Contractually, given that there is no contractual relationship between the manufacturer and the end user, the principle of privity of contract will be applicable. The caveat emptor principle may have unfair consequences, in instances where authenticating the drug with the MAS has not been possible due to electricity or telecom network failure.

The end user may be able to rely on misrepresentation, given that the medicine does not comply with the standard/specification that it claims to have. The alleged claims on the packaging and instruction leaflet would have induced the buyer to buy the drug believing that it will be fit for purpose. This will entitle him to rescind the contract. The buyer however has no right of action against the seller, as it was not the seller that is responsible for the misrepresentation.

Given all the circumstances surrounding the legal issues, a victim of counterfeit drug can get remedy under the principle of negligence in tort and product liability. All he needs to show is that he is owed a duty of care, which has been breached and the breach has resulted in harm/injury to him. This will entitle him to compensatory damages.

The legal and institutional frameworks for drug counterfeiting in Nigeria are mainly derived nationally, regionally and internationally. The National legal instruments are legislations, policies and guidelines, which are issued pursuant to one legislation or the other. Amongst which are, NAFDAC Act, Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, Food, Drugs and Related Products (Registration, etc.) Act, Foods and Drugs Act, Poisons and Pharmacists Act, Trade Malpractice (Miscellaneous Offences) Act, Criminal Code Act, Pre-Shipment Inspection

of Imports Act, Pre-Shipment Inspection of Export Act, Standards Organisation of Nigeria Act, Consumer Protection Act. Policies, Guidelines, and Regulations range from the National Drug Policy to Guidelines on National Drug Distribution and Drug Labelling Regulations, to name a few. All these were discussed in Chapter three.

Nigeria is a signatory to quite a number of regional and international treaties conventions, protocols and guidelines. These give rise to obligations on the part of the country. They have also been discussed in Chapter three of the work. Implementation of these regional and international legal documents has been hindered by Nigeria's dualist approach in receiving international laws. Aside of the African Charter on Human and Peoples' Rights (ACHPR) and the UDHR that have been domesticated, others have not been. Consequently, Nigerians cannot enjoy any benefits of their provisions.

An examination of the legal framework, revealed that Nigeria has a robust and comprehensive legal framework. However, their effect is not being felt due to enforcement challenges. Some of these instruments have been found to be outdated, overlapping and conflicting, thereby making enforcement almost impossible. Penalties are lenient. All these leave room for offenders to manoeuvre. Law reform has also been delayed by lack of political willpower to change the situation.

The regulatory bodies are NAFDAC, SON, and CPC. Of the three (3), NAFDAC, being the direct oversight, was evaluated. As a result of the activities of NAFDAC, incidences of counterfeit drugs in Nigeria has substantially reduced.A survey by NAFDAC and WHO and the Department for International Development (DFID)[1008] showed that counterfeit drugs in Nigeria had decreased from 40% in 2001 to 16.7% in 2005. Similarly, in 2012, a test was conducted on 5790 drug samples using TRUSCAN, 6.4% failed the test. This is a marked improvement in the rate of incidences of counterfeit drugs.[1009]

[1008] A UK government department responsible for administering overseas aid.
[1009] Ogune M. 2017. Nigeria: NAFDAC Refutes Report on Prevalence of Fake Drugs. The Guardian. 9th November, 2017. Retrieved from www.allafrica.com on 20th November, 2017

The Agency embarks on public enlightenment on the ills of counterfeit drugs, collaboration with other relevant regulatory authorities, setting up laboratories for testing samples, registering products and manufacturers, surveillance of factories, markets and business premises, raids and seizures. NAFDAC staff have faced threats to their lives and have actually been victims of attacks. Their efforts at prosecuting offenders have also been hindered by the attitude of the Nigerian Judicial system, which is characterised by delays in dispensing with cases and denial of justice, lack of funds, and inadequate qualified personnel. Some of the NAFDAC staff have exhibited greed, ignorance, corruption and conflict of interest in dispensing their duties.

NAFDAC as an oversight in the drug regulation sector has recorded considerable progress in its war against counterfeit drugs. Its efforts have however, been slowed down by challenges mentioned above.

With regards to anti-counterfeiting technology features, there are at least forty-two (42) different types. In picking an appropriate feature, cost of acquisition, portability and electricity, to name a few, should be considered. In fulfilment of its role as a regulatory body, the Agency introduced certain Anti-Counterfeiting Technology features. These are NAFDAC Registration number, on drug packaging, TRUSCAN, which quickly detects counterfeits, the Black Eye, used for screening multiple drug samples at once and the MAS, which empowers the consumer to authenticate the drug himself/herself, using the SMS. The MAS technology would have been an effective way of detecting counterfeiting, but for challenges of telecom network, electricity for charging phones and awareness, especially among rural dwellers.

The Counterfeit and Fake Drugs and Unwholesome Processed Food (Miscellaneous Provisions) Act (Amendment) Bill 2015 was passed to law by the Senate in 2016. The Bill seeks to amend the Act by making provisions for sterner penalties, confiscation and forfeiture of assets of a convicted counterfeiter, disposal of confiscated assets by sale or otherwise and compensation of victims.

To compensate victims, the Bill proposes a Victims Compensation Fund, which will be funded out of the Consolidated Revenue Fund. Proceeds of sale of the assets of convicted counterfeiters will be deposited into the Consolidated Revenue Fund. The Bill empowers the Agency to trace and attach all assets of convicted counterfeiters.Although the Bill has been read by the Senate for the third time and passed, there is no evidence that it has been forwarded for Presidential assent nor any other necessary action.

The study referred to drug counterfeiting incidences in Kenya and India, for lessons which can be learnt by Nigeria. It was discovered that all three countries have serious problems of counterfeit drugs. India is both a producer and a victim, as such drugs are also sold and used there. All three countries have challenges of corruption, inadequate enforcement machinery, inadequate funding of the regulatory bodies, and other challenges.

Kenya treats drug counterfeiting as an IPR infringement. This has led to confusion, especially as it brought generic drugs within the ambit of counterfeits. India's adoption of 'spurious and substandard'makes enforcement difficult, as ascertaining what amounts to substandard is difficult. Nigeria's definition is more encompassing.

Kenya and India have reformed laws, especially as it relates to penalties. They have sterner penalties for drug counterfeiters although instances of prosecution are very rare in India.[1010] Nigeria's proposed amendment is yet to receive presidential assent. With regards to justiciability of socio-economic rights, the CESCR General Comments No.3 provides that member states should make appropriate provisions which should include availability of judicial remedies with respect to socio-economic rights. Kenya has amended its Constitution to comply with this requirement. India however, protects them by linking them to enforceable rights such as right to life and right to human dignity.[1011]Nigeria is yet to comply.

[1010] Singh B R. 2017. *Loc. Cit.* p. 002

[1011] See *Municipal Council Ratlem .v. Vardhichand & Ors* (1980) AIR 1622; (1981) SCR (1) 97, where it was held that the right to life and human dignity under the Indian Constitution has been interpreted to include various socio-economic rights.

All three countries have challenges, although India is a few steps ahead of Nigeria and Kenya. For instance, India has a whistle blowing scheme. The benefit of this scheme is however yet to be realised. Those who have dared to blow the whistle have been victimised, scaring others from coming forward. In addition, India has in place, a victims' compensation scheme.

With regards to the definition of counterfeit drug, if the latest WHO definition is adopted, Kenya and India will have to reform theirs. The WHO's definition, brings drug counterfeiting out of the sphere of IP into that of public health. This will remove confusion, such as that which arose in Kenya, in relation to generic drugs.

The study employed the UNGP to buttress the argument for a need for a legislation which will provide for compensating the victims of counterfeit drugs. The legislation will remove the issue of enforcing consumer rights from the ambit of the Consumer Protection Council Act and the requirement of proving their case before the Council or state committee before they can be permitted to institute an action in court.

The UNGP is hinged on three pillars of Protect, Respect and Remedy. Under it, States are to protect the human rights of their citizens, businesses must respect the rights of the citizens of their business territories and the States are to make provisions for access to judicial and/or non-judicial remedy for victims of corporate related human rights violation.

Although the UNGP was endorsed by the UN Human Rights Council, there is no legally binding instrument to back it up. It is a soft law, with limited powers for monitoring for compliance.

The study further found that, in spite of national, regional and international efforts at combating drug counterfeiting, the menace has remained rooted worldwide. With gross and continuous violation of the right to health and sometimes, the right to life of their victims, who are left without redress.Given the obligations on the State, from its commitment to the UN, it is pertinent for provisions to be made for access to remedy, through a legislation to fill this gap.

6.2 CONCLUSION

Medicines ought to treat and prevent diseases, however, counterfeit medicines cause harm and even death in certain circumstances. Counterfeit drugs have been described as the most dangerous goods on the market.[1012] In the same vein, drug counterfeiting is one of the greatest atrocities in this age and it affects both developing and developed countries. Responsible for its growth are corruption and conflict of interest, poor health seeking behaviour of Nigerians, high price of locally manufactured drugs, due to high tariffs and taxes, legislative lacunae and erratic drug distribution network.

Efforts at eradicating drug counterfeiting have taken place nationally, regionally and internationally. However, these have yielded little success. Reasons for the low level of achievement have been discussed earlier in the study. However, it is believed that, given the international nature of the menace, international collaboration will go a long in solving the problem.Drug counterfeiters are motivated by the enormous profit that can be derived from the business.

It is however a human right issue. Producing the counterfeit drugs is a violation of the right to qualitative health and the consequence of using them could amount to a violation of life and/or human dignity. In recognition of the possible violation of human rights by business enterprises, the UNGP were formulated. These principles, amongst others recommended that member states make provisions for access to remedy by victims of human right violations by businesses. India has fulfilled this obligation. Nigeria has also complied, in principle,with the proposals in the Counterfeit and Fake Drugs and Unwholesome Processed Food (Miscellaneous Provisions) Act (Amendment) Bill 2015, which is awaiting Presidential Assent before it can come into force.

The activities of the Anti-Counterfeiting Collaboration (ACC), Nigeria is worth mentioning. ACC is a non-governmental organization, which came into being in 2006, to bring together, brand owners, enforcement agencies, law firm concerned with IP matters, representatives of manufacturing companies and other interested parties, to counter the activities of counterfeiters.[1013] ACC in furtherance of its purpose undertakes public enlightenment through its television programme, “Light Fingers”, which brings to light the

[1012]NgEirwamungu. 2009. Counterfeit Drugs Puts Lives at Risk. Irin News. 15/1/2009. Retrieved from www.irinnews.org on 14th June, 2018.
[1013]https://www.anticounterfeiting.com.ng

ills and negative effects of counterfeiting, piracy and infringement of trademarks and brads, and to ensure the quality assurance of products in the market place.

In conclusion and judging by the efforts that have been made at combating the menace, it may be more appropriate to seek to "control" drug counterfeiting rather than seeking to eradicate it, as eliminating it appears to be a herculean task. This will be accomplished by making drug counterfeiting unattractive for the counterfeiters. Be that as it may, the victims are at the worst end of the stick. It is therefore pertinent to give them access to remedy. It is therefore hoped that serious effort will be put into providing and an enforceable mechanism for victims' compensation.

6.3. RECOMMENDATIONS

Drug counterfeiting is a major challenge to achieving an effective health care system in many developing nations. There have been efforts at combating drug counterfeiting, which have yielded little results.From the findings of the study, however, there are certain area which could be improved on to achieve more success.

6.3.1 Remedy for Victims of Counterfeit Drugs

6.3.1.1 Enacting and enforcing the laws that will provide adequately for compensation and protection of the rights of affected individuals, would be a long-term strategy, not just for combating drug counterfeiting, but a means of granting the victim access to remedy for the violation of their rights.

6.3.1.2 There should be a Victims' Compensation Fund, and provision should be made for ensuring that the scheme is adequately funded, so that victims and their families are taken care of. As provided by the Counterfeit and Fake Drugs and Unwholesome Processed Food (Miscellaneous Provisions) Act (Amendment) Bill 2015, the funds for compensating the victims can be got from disposing the goods seized from and forfeiter by counterfeiters. Where a victim is dead, the spouse and children will be entitled to collect the compensation.

6.3.2 National Level

The steps at combating drug counterfeiting should be directed at both the supply and the demand levels.

6.3.2.1 Countries should create incentives, for instance through tax relief, for manufacturers to imbibe high production standards. In addition, medicine procurers should be encouraged to procure drugs from compliant manufacturers.

6.3.2.2 The WHO Pre-Qualified Medicines List and US Pharmacopeia Convention's Medicines Quality Database or their National Drug lists should be used as guide in procuring drugs. Where possible, stakeholders in the supply chain could be given incentive, either to act as "watch dogs" for each other in the supply chain.

6.3.2.3 The manufacturers being at the top of the supply chain, must ensure that their ingredients are of good quality and that drugs maintain their quality along the supply chain. They therefore should monitor their products from the production stage till it gets to the retailer. To accomplish this, they should only work with tried, tested and trusted transporters, warehouses, wholesalers and retailers.

6.3.2.4 Where drugs are procured by an international buyer and it is to be distributed by a local distributor, the buyer should monitor the drug until it gets to the retailer(s). Packaging should bear codes that can be scanned for tracking and authentication. The buyer should ensure that packaging complies with national laws, in respect of packaging and attached leaflet.

6.3.2.5 Distribution network is an area that creates difficulty for international organisations and national governments. This is because the distribution network is vast and not easy to monitor. The distribution network should be monitored diligently, at local levels, through collaboration of relevant agencies. These agencies should, from time to time, organise public enlightenment programmes.

6.3.2.6 In line with the Nigerian whistle blowing scheme, there should be financial incentives for whistle blowers.[1014]The funds could be From the Indian experience, the whistle blowing scheme may not work, unless there is sincerity on the part of the government.

6.3.3 Legal Framework

Legal framework is the first most important tool that the government can deploy against drug counterfeiting. This must provide for a high probability of not just being caught but being penalised. To achieve this, there has to be unambiguous, stern and enforceable legal framework, as well as well qualified and adequately trained and uncompromising personnel. Although Nigeria has a comprehensive legal framework for drug counterfeiting, the laws have one deficiency or the other. Effective drug regulation will go a long way in promoting and protecting public health by ensuring the quality, safety and efficacy of medicines before they get into the drug market.

6.3.3.1 Consequently, a reformed legal framework and enforcement mechanism should be put in place. There should be uniform standards and effective regulations for domestic and export drugs. In addition, there should be improved and regular ports, borders and marketssurveillance.Drug counterfeiting has been equated to murder, or at least manslaughter. It is therefore essential for its punishment to be commensurate with the crime. If penalties are not adequate, the laws will not be a deterrent to combat a crime as lucrative as drug counterfeiting.

6.3.3.2 In Nigeria, for instance, the presence of a comprehensive legal framework, does not by itself ensure protection against counterfeit medicines.Rigorous and consistent enforcement of these laws are necessary to achieve notable successes in the fight against drug counterfeiting. To this end, law enforcement agencies and regulatory bodies should be funded adequately. They should be equipped and well trained for the job. They are to have

[1014]The Nigerian Whistleblowing Policy prescribes a 2.5% -5% of the recovered funds by the Nigerian Government. See Federal Ministry Finance – Whistleblowing Frequently Asked Questions. Retrieved from www.whistleblowing.finance.gov.ng on 31st March, 2019.

sufficient and well-trained personnel, to carry out all necessary functions to ensure that counterfeit drugs do not get into the legitimate drug chain.

6.3.3.3A major setback to enforcement is corruption. Fighting corruption is a battle on its own. It may however be controlled if the officers concerned are well paid and motivated. Salaries should also be paid as and when due. This is because accepting a bribe may be the difference between the officers being able to keep his/her child in school, especially when salaries are owed.

6.3.3.4The government should also promote effective co-operation between private and public authorities and agencies. Right holders have the technical expertise to distinguish counterfeit from original products and can assist government in investigation and enforcement actions. Therefore, collaboration between the rights owners and government agencies, will provide technical expertise to enable authorities intervene.

6.3.3.5 Adoption of secure business practices by all participants in the drug supply chain as well as a system that helps ensure effective reporting of counterfeit drugs to the Agency and one that strengthens NAFDAC's rapid response to such reports, are important.

6.3.3.6 The Counterfeit and Fake Drugs and Unwholesome Processed Food (Miscellaneous Provisions) Act (Amendment) Bill 2015 should be revisited. Given that, the Bill was passed to law by the Senate on 3rd November, 2016, and has not been granted Presidential Assent till date, it would have expired. It will therefore be necessary for the bill to be processed again, for Presidential Assent, so it can come into force and be operative.

6.3.3.7 The Corporate Manslaughter Bill 2018 should be made to pass through the National Assembly before being represented to the President for assent. It should make provision for actions to be held against individual directors of corporations. The bill as is, dictates that corporations be liable to pay punitive fines where an employee is deceased because of their negligent acts. All this does is incur a loss of value for the shareholders of the company and may not necessarily punish the culpable acts of management. Likewise,

the scope of the bill should be extended to other areas where businesses can cause death and not only employment situations.

6.3.4 Quality Control

It is the responsibility of the governments, especially those of developing countries to improve quality control. This is a requirement for fulfilling its obligation under the right to health. There must be the political will to use and improve on existing technology and to enforce compliance with good manufacturing practices. The effect of this is to pave way for effective registration of imported and locally manufactured products. Secondly, monitoring for compliance should be continuous, so also, post-marketing surveillance systems be set up.

6.3.5 NAFDAC

NAFDAC, as a regulatory body has achieved considerable success. However, there is room for improvement.

6.3.5.1 Provisions should be made for more testing laboratories and warehouses.

6.3.5.2 There should be improved staff orientation and motivation. This will involve, retraining, effective delegation of duties, staff empowerment, and compensation for hard work.

6.3.5.3 There should also be updated guidelines and regulations and best practice guidelines for all stakeholders in the supply chain.

6.3.5.4 The Agency should educate consumers and health professional about the risk of counterfeit drugs and how to protect against such risks and should embark on massive awareness campaigns, especially in relation to the anti-counterfeiting technology features. This will amongst others, help break the silence and secrecy culture that surrounds drug counterfeiting.

6.3.5.5 There should be provision for post-registration monitoring of drugs and manufacturers, especially those outside Nigeria.The officials of the Agency should be required to disclose areas of conflict of interest. The Agency should also disclose external and internal audit reports, in addition to the qualification requirements of its officials.

6.3.6 Technology Features

New technologies, to better protect drug supply should be employed. Technology features for combating counterfeit drugs have to be evolving because, the counterfeiters are constantly devising new ways to prevent their being caught. Given the existence of counterfeit drug in spite of the different technology features, there is evidence that there is no supernatural method for long term assurance of drug authentication technology. There has to be rapid and timely improvement on existing technologies.

6.3.7 International and Regional Collaboration

Drug counterfeiting is an international problem, however, there are no international enforcement or regulatory body. It is a crime that transcends territories.

6.3.7.1 Collaboration at the international level is therefore key in the fight against drug counterfeiting, especially with regards to sharing information, extraditing offenders, where necessary. An example is the European Observatory on Counterfeit and Piracy, a platform created by the European Union, for consumers' public administration and industry to join forces, exchange experiences and information, and share best practices on enforcement.[1015] The observatory's approach of resource sharing can be copied by other groups and countries in their fight against drug counterfeiting. Membership of the observatory is made up of people from the private and public sector. Its focus is handling issues such as gathering of data, public awareness and existing legal frameworks.

6.3.7.2 At the international level, there should be incentive for governments to have tighter regulatory and enforcement structures. This could be by way of giving aids, developed countries and international agencies, to countries who show evidence of commitment to

[1015] https://euipo.europa.eu

improving regulatory and legal frameworks, and those who have established plans for implementing means of combating drug counterfeiting, and assistance for consumers who have fallen victims of counterfeit drugs and means of avoiding such in the future.

6.3.7.3 WHO to conduct studies intermittently to discover countries, complying with Best Manufacturing Practices. The reports of these studies should be published as a guide for those buying drugs to identify where and who to buy from. There should also be opportunities for blacklisting offenders.

6.3.8 Definition

One major challenge to combating drug counterfeiting is the definition of counterfeit and substandard medicine. Different countries adopt different definitions, for instance, Nigeria has adopted the WHO definition with an addition to suit its local situation. Some countries, like Kenya have brought it within the ambit of IP Rights, which has led to confusion. It is essential that there is a consensus on the definition of what constitutes counterfeit drug. In doing this, it may be advantageous to adopt the latest WHO definition, which has brought drug counterfeiting strictly within the scope of public health.

BIBLOGRAPHY

BOOKS

Aquinas, T. 1988. *St. Thomas Aquinas: On Law, Morality and Politics*. Baumgarth, W. and Regan, R. eds. Indianapolis. Hackett Publishing.

Aduba, J. N. 2011. *The Right to Life under the Nigerian Constitution: The Law, The Courts and Reality*. A publication of the Nigerian Institute of Advanced Legal Studies, Abuja.

Ajomo, M. A. Fundamental Human Rights under the Nigerian Constitution in *Perspective on Human Rights*. (ed. Kalu, A. U. and Osinbajo, Y.) Federal Ministry of Justice. Lagos, pp. 80-81

Akanki, E. O. (ed.) 2007. *Commercial Law in Nigeria*. University of Lagos Press. Lagos.

Ahmad, A. I. 2012. *Addressing Variability in Drug Quality: Finding the Right "Quality" Framework(s).* A thesis submitted in conformity with the requirements for the degree of Master of Science. Graduate Department of Pharmaceutical Sciences University of Toronto.

Atiyah, P. S. 1995. *The Sale of Goods*. Pitman Publishing Ltd. London.

Bamgbose, O. and Akinbiyi, S. 2015. *Criminal Law in Nigeria*. Evans Brothers (Nigeria Publishers) Ltd. Ibadan.

Bates, R. 2008. *Making a Killing: The Deadly Implications of Counterfeit Drug Trade*. The American Enterprise Institute Press. Washington, D. C.

Bentham, J. 1907. *An Introduction to the Principles of Morals and Legislation*. Burns and Hart. Eds. Oxford. Claredon Press.

Bentham, J. 1988. *A Fragment on Government*. Harrison R. eds. Cambridge. Cambridge University Press.

Bryan, A. G. (ed.) *Black's Law Dictionary*, 9th edition.

Card, R. and Molloy, J. 2016. *Card, Cross and Jones Criminal Law*. (22nd ed.) Oxford University Press. Oxford. Online Ed. p. 7 retrieved from www.oxfordlawtrove.com on 22nd January, 2018.

Christian, W. (ed.) 2015. *Street on Torts*. (14th edition) Oxford University Press. New York.

Cockburn, R. 1982. *Counterfeit Drugs- the other Killer in Lebanon*. The Guardian (London). p.18

Cornish, W. and Llewelyn, D. 2007. Intellectual Property: Patent, Copyright, Trade Marks and Allied Rights. (6th ed.) Sweet & Maxwell. London.

Curzon, L. B. *Jurisprudence*. 2nd ed. London. Cavendish Publishing Ltd.

Dias, R. W. M. 1985. *Jurisprudence*. Butterworth and Company (Publishers) Ltd. London.

Davison, M. 2011. *Pharmaceutical Anti-Counterfeiting: Combating the Real Danger from Fake Drugs*. Wiley. New Jersey, USA. p. 36.

Douzinas, C. 2001. *The End of Human Rights*. Oxford. Hart's Publishing.

Eban, K. 2005. *Dangerous Doses: A True Story of Cops, Counterfeiters, and the Contamination of America's Drug Supply*. Harcourt. Inc. Florida.

Elegido, J M. 2010. *Jurisprudence: a Textbook for Nigerian Students.* Ed. Aguda, A. Spectrum Books, Ibadan.

Etomi, G. 2014. A*n Introduction to Commercial Law in Nigeria: Text, Cases and Materials*. MIJ Professional Publishers Ltd. Lagos.

Ezeani, A. O. N. and Ezeani, R. U. 2014. *Law of Torts (with Cases and Materials)*. Odade Publishers. Lagos.

Furmston, M. P. (ed.) 1986. *Cheshire, Fifoot and Furnston Law of Contract*. (11th ed.) Butterworth. London.

Gasiokwu, M. O. U. *Legal Research and Methodology: A-Z of Writing Theses and Dissertations in Nutshell.*

Godoy, A. S. 2013. *Of Medicines and Markets*. Stanford University Press. Stanford, California.

Gostin, L. O. (ed.) 2002. *Public Health Law and Ethics*. University of California Press Ltd. California.

Hart, H. L. A. 1961. *The Concept of Law*. Claredon Law Series, 2nd Edition. Oxford University Press. Oxford.

Hayden, P. 2001. *The Philosophy of Human Rights*. Paragon House. St. Paul, Minnesota.

Herring, J. 2016. *Criminal Law: Text, Cases and Materials*. Oxford University Press. Online Ed. Chapter 13. P.2. Retrieved from www.oxfordlawtrove.com on 22nd January, 2018.

Hobbes, 1958. *Leviathan: One Party One and Two.* New York. The Liberal Arts Press.

Holyoak and Torremans, 1988. *Intellectual Property Law*. (2nd ed.) Butterworth. London.

Jhering, R. 1913. *Law as a Means*. Boston. The Boston Book Company.

Keeton, W. P., Dobbs, D. D., Keeton, R. E. and Owen, D. G. 2004. Prosser and Keeton on Torts. (5th ed.) West Publishing Company. Minnesota, USA.

Kodinliye, G. and Aluko, O. 1999. *The Nigerian Law of Torts*. Spectrum Books Ltd. Ibadan.

Llyod and Freeman M. D. A. 1985. *Lloyd's Introduction to Jurisprudence*. 5th ed. London. Stevenson & Sons.

Locke, J. 1994. *Two Treatises of Government*. Berman, D. eds.London: Everyman Publishing.

Michaels, A. 2002. *A Practical Guide to Trade Mark Law*. (3rd ed.) Sweet & Maxwell. London.

Monye, F. 2006. *Commercial Law: Sales of Goods, Hire Purchase and Carriage of Goods by Sea*. Cherylo Press Ltd. Enugu.

Okonkwo and Nash. 1990. *Criminal Law in Nigeria*. Spectrum Books Ltd. Ibadan.

Olayinka, A. I., Taiwo, V. O., Raji-Oyelade, A. and Farai, I. P. 2006. *Methodology of Basic and Applied Research* (2nd ed.) PG School, University of Ibadan, Ibadan.

Otieno-Odek, 2010. *Pharmaceutical Products, Protected goods and Counterfeit Medicines in Kenya*. A publication of Kenya IP Institute, Nairobi, Kenya.

Phillips, T. 2005. *Knockoff: The Deadly Trade in Counterfeit Goods*. Kogan Publishers, London.

Sagay, I. 2000. *Nigerian Law of Contract*. Spectrum Books Ltd. Ibadan.

Salmon, J. W. and Heuston. *Law of Tort.* (18th ed.)

Taiwo, A. 2011. *Basic Concepts in Legal Research Methodology: A Practical Guide on Writing Excellent Master's and Doctoral Theses*. St Paul's Publishing House, Ibadan.

Thomas, W, et al. Eds. *Kluwer Law International*. London. 329- 364.

Treitel, G. H. 1983. *The Law of Contract*. (6th ed.) Stevens & Sons. London.

Uloko, G. 2010. *Modern Approach to Intellectual Property Law in Nigeria*. Princeton Press. Lagos.

Walliman, N. 2005. *Your Research Project*. (2nd ed.) Sage Publication, London.

Winfield, (ed.) 1998. *Winfield and Jolowicz on Tort*. (15th ed.) Sweet and Maxwell. London.

Yerokun, O. 2015. *Casebook on Law of Contract*. Princeton & Associates Publishing Co. Ltd. Lagos.

JOURNAL PUBLICATIONS

Akinyandenu, O. 2013. Counterfeit Drugs in Nigeria: A Threat to Public Health. *African Journal of Pharmacy and Pharmacology*, Vol. 7(36), pp. 2571-2576.

Akpotaire, U. 2013. Companies that Provide Anti-Counterfeiting Technology in Nigeria. *Nigeria Law Intellectual Property Watch*. Retrieved from https://nlipw.com on 8th February, 2018.

Akunyili, D. 2004. Fake and Counterfeit Drugs in the Health Sector: The Role of Medical Doctors. *Annals of Ibadan Postgraduate Medicine*. Vol. 2, No. 2, p. 19.

Akunyili, D. 2006. Lessons from Nigeria: The Fight against Counterfeit Drugs in Africa. *Diabetes Voice*. September 2006 Volume 51 Issue 3.

Aldhous, P. 2005. Murder by Medicine. *Nature* 434:132-136.

Ambroise-Thomas, P. 2012. The Tragedy Caused by Fake Anti-Malarial Drugs. *Mediterranean Journal of Haematology and Infectious Diseases*. Vol.4 (1) 1-4. Available on line at www.mjhid.org. Last accessed on 12th January, 2014.

Amon, J. J. 2008. Dangerous Medicines – Unproven AIDS Cures and Counterfeit Antiretroviral Drugs. *Globalization and Health* 4(5)

Anon, 2013. Stiffer Penalties will Reduce Drug Counterfeiters – NAFDAC. *Business Day*. 17th May, 2013.

Atilola, B. and Morocco-Clarke. 2011. National Industrial Court and Jurisdiction over International Labour Treaties under the 3rd Alteration Act, 2010. *Labour Law Review*. Vol. 5, No.4.

Bamitale, K. D. S. 2007. Effects of Fake and Expired Drugs on Health. Available on http//:netacad.oauife.edu.ng/faculties/dentistry/Inotes/FAKE%20DRUG%20AND%20HEALTH%20IMPLICATIONS%20Bamitale.doc. Retrieved on 12th June, 2014.

Bates, R. 2009. China's Bad Medicine. *The Wall Street Journal* 5th May, 2009. Retrieved from http://onlinewsi.com/article/SB124146383501884322.html on 23rd October, 2016.

Bate, R. and Boateng, K. 2007. Bad Medicine in the Market. *Health Policy Outlook*. Retrieved from http://www.aei.org/publications/pubID.263688/pub_details.asp on 21st July, 2017

Behrens, R. H., Awad, A. I. and Taylor, R. B. 2002. Substandard and Counterfeit Drugs in Developing Countries. *Tropical Doctor*. 32(1):1-2

Bhatla, G. 2008. H. L. A. Hart's Law and Morals and the Minimum Content of Natural Law. *Jurisprudence and the Philosophy of Law*. Retrieved from http://legaltheoryandjurisprudence.blogspot.com.ng, on 12th November, 2015.

Blakenay, M. 2009. International Propaganda for the Criminal Enforcement of IP Rights: Concern with Counterfeiting and Piracy. *Queen Mary University of London, School of Law's Legal Studies Resource Paper No. 291*. Retrieved from https://ssrn.com on 17th August, 2016.

Brieger, W. B., Osamor, P. C., Salami, K. K., Oladepo, O. and Otusanya, S. A. 2004. Interaction between Patent Medicine Vendors and Customers in Urban and Rural Nigeria. *Health Policy Plan*. 19:177-182.

Bunker, A. M. 2007. Deadly Dose: Counterfeit Pharmaceuticals, Intellectual Property and Human Health. 89 *Journal of Patent &Trademark Off. Society*, 493.

Buowari, O. Y. 2012 Fake and Counterfeit Drug: A Review. *AFRIMEDIC Journal* Volume 3, No. 2, pp. 1-4

Chaudry, P. E. and Stumpf, S. A. 2013. The Challenges of Curbing Counterfeit Prescription Drugs Growth': Preventing the Perfect Storm. *Business Horizons*.

Cockburn, R., Newton, P. N., Agyarko, E. K., Akinyuili, D. and White, N. J. 2005. The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers. *Plos Med*. 2940:e100 (Vol. 2. Issue 4, e100)

Dogarowa, L. B. 2013. Overview of Socio-Economic Implications and Management of Product Faking and Adulteration. *Journal of Business Management Studies*. Vol. 3(3), pp. 119-131

Erhum, W. O., Babalola, O. O. and Erhum, M. O. 2001. Drug Regulation and Control in Nigeria: The Challenges of Counterfeit Drugs. *Journal of Health and Population in Developing Countries.* Vol. 4, No.2.

Falk, R. 1964. The Role of Domestic Courts in the International Legal Order. *Indiana Law Journal*. Vol. 39, No.3, pp. 1-18.

Forzley, M. 2003. Counterfeit Goods and the Public's Health and Safety. A publication of the International Intellectual Property Institute. Washington DC. Retrieved from www.iipi.org on 27th September, 2016.

Garba, H. A., Kohler, J. C. and Anna, M. 2009. Transparency in Nigeria's Public Pharmaceutical Sector: Perceptions from Policy Makers. *Global Health* 5.

Gautaum, C. S., Utreja, A. and Singal, G. L. 2009. Spurious and Counterfeit Drugs: A growing Industry in the Developing World. *Postgraduate Medical Journal*, Vol. 85.

Gibson, L. 2004. Drug Regulators study Global Treaty to Tackle Counterfeit Drugs. *British Medical Journal*. 28.

Goicovici, J. 2011. European Union Law on Defective Production Essential Aspects of Producers' Responsibility. *Studia Ubb. Europaea*. 56 (1).

Green, M. D. 2013. Perspectives: Counterfeit Drugs. Retrieved from www.nc.cdc.gov on 20th November, 2013.

Hristovia, H. 2012. The Alien Tort Statute: A Vehicle for Implementing the United Nations Guiding Principles for Business and Human Rights and Promoting Corporate Social Responsibility. *University of San Francisco Law Review*. Vol. 47.

Iyidiobi, C. N. 2015. Rethinking the Basis of Corporate Criminal Liability in Nigeria. *The Nigerian Judicial Review.* Vol.13.

Kenyip, B. B. 2005. Service Liability under the Nigerian Consumer Law. *Consumer Journal*. 1(1).

Khan and Ghilzazi, 2007. Counterfeit and Sub-Standard Quality of Drugs: The Need for an Effective and Stringent Regulatory Control in India and Other Developing Countries. *India Journal of Pharmacology*. 39.

Kinney, E. D. 2001. The International Human Right to Health: What does this mean for our Nation and the world? *Indiana Law Review* Vol. 3.

Kovac, S., Hawes, S., Malay, S. N., Mosites, E., Ling, W. and Stergachis, A. 2014. Technology for Detecting Falsified and Substandard Drugs in Low and Middle Income Countries. *PloS One* Journal, Vol.9, Issue 3.

Lanzarotta, M. 2011. John Ruggie on Business and Human Rights. *Harvard Kennedy School Insight.*

Machemedze, R. 2010. Generics .vs. Counterfeit Drugs: Dynamic Multi – Site Diplomacy. *Journal of Health and Diplomacy*. Vol. 1, Issue 3.

Mackay, T. K. and Liang, B. A. 2011. The Global Counterfeit Drug Trade: Patient Safety and Public Health Risks. *Journal of Pharmaceutical Sciences*, Vol. 100, Issue 11.

Muthiani, M. and Wanjau, K. 2012. Factors Influencing the Influx of Counterfeit Medicines in Kenya: A Survey of Pharmaceutical Importing Small and Medium Enterprises Within Nairobi. *International Journal of Business and Social Science.* Vol. 3, No. 11.

Narula, R. 2014. Taking Issues with Counterfeiting in India. *World Trademark Review*, August/September, 2014.

Newton, P. N., Green, M. D., Fernandez, F. M., Day, J. P. and White, N. J. 2006. Counterfeit Anti-Infective Medicines. *The Lancet Infectious Diseases*. 6.

Newton, P. N., Amin, A. A., Bird, C. 2011. The Primacy of Public Health Considerations in Defining Poor Quality Medicines. *PLoS Medicine* 8(12).

Nishtar, S. 2012. Pakistan's Deadly Cocktail of Substandard Drugs. *The Lancet*. Vol. 379.

Nnamuchi, O. 2007. The Right to Health in Nigeria. In 'Right to health in the Middle East Project, Law School, University of Aberdeen. Accessed from http/www.ssrn.com, on 5th May, 2013.

Ogundana F. 2012. Austerity and Challenges of Health for All in Nigeria. International Journal of Development and Sustainability. Vol. 1. No. 2.

Okumagba, M. 2015. Improving Access to Health Care in Rural Communities by Re-Orienting and Integrating Patent Medicine Sellers into Primary Health Care Service Delivery in Nigeria. *South American Journal of Public Health*. Vol.3.

Oni-Ojo, E. E. and Iyiola, O. 2014. Legal Implications of Manufacturers Negligence and its Effects on Consumers: A Study of South West Nigeria. *Global Scholars Journal of Marketing*, Vol.1.

Onwuka, C. J. 2010. The Situation of Medicines Counterfeiting in Africa. A Publication of the School of Pharmacy, University of London. Retrieved from www.whpa.org on 25th May, 2014.

Pound, R. 1943-44. A Survey of Social Interests. *57 Harvard Law Review*.

Raufu, A. 2002. Influx of Fake Drugs to Nigeria worries Health Experts. *British Medical Journal*, Vol. 324.

Shah, R. Y., Prajapati, P. N. and Agrawal, Y. K. 2010. Anti-Counterfeit Packaging Technologies. *Journal of Advanced Pharmaceutical Technology and Research.* October – December; 1(4).

Singh, B. R. 2017. Why India Failed to Penalize Those Responsible for the Circulation of Sub Standard Medicines and Vaccines while China Succeeded? *Global Journal of Pharmacy and Pharmaceutical Science*, Vol. 2, Issue 5.

Sikanya, B. 2011. IP Confronts Counterfeiting in Africa: Protecting Innovations and Consumers in Cyber Society. *Consumer Law in Information Society*.

Starr, W. C. 1984. Law and Morality in H. L. A. Hart's Legal Philosophy. *Marquette Law Review,* Vol. 67.

USP, 2013. Promoting the Quality of Medicines in Developing Countries. Referred to in Kovac S, et al. Technology for Detecting Falsified and Substandard Drugs in Low and Middle-Income Countries. *Plos ONE Journal*, Vol.9, Issue 3.

Verma, S., Kumar, R. and Phillip, P. J. 2014. The Business of Counterfeit Drugs in India: A Critical Evaluation. *Journal of Management and International Business Studies*. Vol. 4, No.2.

Wertheimer, A. I., Chaney, N. M. and Santella, T. 2003. Counterfeit Pharmaceuticals: Current Status and Future Projections. *Journal of American Pharmaceutical Association*, Vol. 43.

Wilson, J. 2011. The Health and Economic Effect of Counterfeit Pharmaceuticals in Africa. A publication of Michigan University, USA. Retrieved from www.a-capp.msu.edu on 21st December, 2014.

INTERNET MATERIALS

Anon, 2014. *Biologics and Biosimilars: An Overview*.A Publication of AMGEN INC. Retrieved from www.amgen.com on 22/11/2014.

Anon. Chapter 8: Negligence (Part IV): Remedies. Retrieved from https://accesspharmacy.mhmedical.com/content.aspx?bookid=1824&sectionid=126858379 on June 23, 2018

Anon. Compensatory Damages in a Personal Injury Claim. Retrieved from https://www.legalmatch.com/law-library/article/compensatory-damages-in-a-personal-injury-claim.html on June 27, 2018

Anon. Discuss Arguments For And Against Universalism Of Human Rights. Retrieved From www.personal.ceu.hu/.../ind%20and%20human%20rights%20exam.doc on 4 July, 2018

Anon. Eye on the Ball: Medicine regulation – not IP enforcement – can best deliver quality medicines. *Oxfam Briefing Paper 143*. 2011. Retrieved from www.oxfam.org on 22 December, 2014

Anon. "Focus on the Illicit Trafficking of Counterfeit Goods and Transnational Organised Crime".Retrievedfromhttp://www.unodc.org/documents/counterfeit/FocusSheet/Counterfeit_focussheet_EN_HIRES.pdf on 31st August, 2013.

Anon. Freedom of Contract: Law and Legal Definition. Retrieved from https://definitions.uslegal.com on 16th June, 2017.

Anon. Majority of the Drugs Found in India are either Fake or Ineffective. A publication of Think Change India. Retrieved from https://www.yourstory.com on 6th June, 2017.

Anon. Nigeria Bilateral Ties: House Calls for Domestication/Ratification. Retrieved from www.placng.org on 17th March, 2015.

Anon. The Situation of Medicine Counterfeiting in Africa. Retrieved from www.whpa.org/backgroundmedicinescounterfeitinginafricachiom on 23rd July, 2016.

Anon. What is the Human Right to Health and Health Care? Retrieved from https://www.nesri.org/programs/what-is-the-human-right-to-health-and-health-care on 4 July, 2018.

BASCAP Study: IP Protection Key to Kenya's Economic Development and Growth. Retrieved from https://www.iccwbo.org on 17th May, 2018.

Bansal, D., Malla, S., Gudala, K. and Tiwari, P. 2012. Anti-Counterfeit Technologies: A Pharmaceutical Industry Perspective. *Scientia Pharmaceutica*. Retrieved from www.scipharma.at on 24th March, 2015.

Bates, R. and Boateng, K. 2006. Drug Snares: Africans Fighting Malaria. Retrieved from www.fightingmalaria.org/article.aspX?id=28 on 20th July, 2014.

CDSCO, 2005. Guidelines for Taking Action on Samples of Drugs Declared Spurious not of Standard Quality in the light of Enhanced Penalties under the Drugs and Cosmetics (Amendment) Act 2008. Retrieved from http://www.cdsco.inc.in/DCC%20Guidelines%20on%20NSQ%20Drugs...pdf on 23rd June, 2016.

CDSCO of India. Reward Scheme for Whistle Blowers in the Fight against the Menace of spurious or Fake Drugs, Cosmetics and Medical Devices. Retrieved from http://cdsco.nic.in on 23rd October, 2016

Chiwendu, O. 2008. The Fight against Fake Drugs by NAFDAC in Nigeria. Retrieved from www.who.int on 12th June, 2017. P.30

Christian, L., Collins, L., Kiatgrajai, M., Merle, A., Mukherji, N. and Quade, A. 2012. The Problem of Substandard Medicines in Developing Countries. Workshop in International Public Affairs. University of Wisconsin, Madison. Retrieved from www.lafollette.wisc.edu/publications/workshops.html on 24th August, 2017

Churchill, F. 2017. *India to Crack down on Fake Drugs with Online Monitoring*. Retrieved from www.cips.org on 29th March, 2017.

Clift, C. 2010. Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward? Chatham House Briefing Paper. Retrieved from www.chatthamhouse.org.uk on 12th June, 2014.

Counterfeit drugs kill. Accessed at www.who.int on August 1, 2013.

Counterfeit goods: A bargain or a Costly Mistake. Retrieved from www.unodc.org on 9th July, 2013.

Counterfeiting Intelligence Bureau. “Fighting Crimes”. A Publication of the International Chamber of Commerce. Retrieved from www.iccwbo.org on 18th May, 2016.

Counterfeiting Intelligence Bureau. A publication of the International Chamber of Commerce. Retrieved from www.icc-ccs.org on 19th June, 2013.

Daleidan, B. 2009. Systematic Security Protection Traceability. Retrieved from http://secprodonline.com on 23 December, 2014.

Dictionary. Retrieved from www.dictionary.com on 30th June, 2014.

Discuss Arguments For And Against Universalism Of Human Rights. Retrieved From www.personal.ceu.hu/.../ind%20and%20human%20rights%20exam.doc on 4 July, 2018

Fagan, A. 2015. Human Rights. Retrieved from www.iep.utm.edu on 3rd September, 2015.

Falsified Medicines. Published by the European Medicine Agency. Retrieved from www.ema.europa.eu on 30th June, 2014.

Forley, M. 2005. Combating Counterfeit Drugs: A Concept Paper for Effective International Collaboration. Retrieved from www.who.int on 12th November, 2015

Fraudulent Essential Medicines from South Asia and East Asia to West Africa. In Focus on the Illicit Trafficking of Counterfeit Goods and Transnational Organised Crime. A publication of the United Nations Office on Drug and Crime. Retrieved from www.unodc.org on 12th August, 2014.

Fraudulent Essential Medicines from South Asia and South East Asia to West Africa. Retrieved from www.undoc.org on 16th June, 2013.

Green, M D., Perspectives: Counterfeit Drugs. Retrieved from www.nc.cdc.gov on 30th May, 2013

Hamburg M A. 2010. Food and Drug Partnership for Safe Medicine Interchange (Online). Retrieved from www.fda.gov on 30th May, 2013

Hargraves S. Counterfeit Goods Becoming More Dangerous. Retrieved from www.money.cnn.com on 14th June, 2013.

Health and Human Rights. A publication of the World Health Organisation. Accessed from www.who.int on 5th May, 2013.

Heard A. 1997. Human Rights: Chimeras in Sheep's Clothing? Retrieved from http://www.academia.edu/11431763/human_rights_chimeras_in_sheeps_clothing on 4 July, 2018

Human Rights: A Basic Handbook for UN Staff. Retrieved from www.un.org on 8th June, 2015.

Human Rights: Nature and Constituent. Retrieved from http://archieve.mu.acc.in on 8th June, 2015.

IMPACT: Facts|Activities|Documents. Developed by the Assembly and the Working Groups of IMPACT, 2006-2010. Retrieved from www.who.int on 11th February, 2017

International Anti-Counterfeiting Coalition, 2005. The Negative Consequences of International IP Theft. Retrieved from http://counterfeiting.unicri.it (white paper pdf.) on 14th June, 2013

International Trademarks Association, 2015. Factsheet. Retrieved from www.inta.org on 18th May, 2015.

Interpol, 2009. IP Crime. http://www.interpol.int.

Kamerimbote, P. 2010. IP Protection in Africa: An Assessment of the Status of Laws, Research and Policy Analysis on IP Rights in Kenya. *IELRC Working Paper*. Retrieved from www.ielrc.org on 12th January, 2012.

Kannan, S. 2011. Counterfeit Drugs Targeted by Technology in India. BBC News, Delhi. 11th October, 2011. Retrieved from www.bbc.com/news/business-15208595 on 22nd January, 2018.

Luoma, M., Doherty, J., Muchiri, S., Barasa, T. and Hofler, K. 2010. Kenya Health Systems Assessment 2010. Retrieved from https://www.hfgproject.org on 31st May, 2018.

Merriam-Webster Dictionary. Retrieved from www.merriam-webster.com on 30th June, 2014.

Miller, K. 2002. Financing Terror – Profits from Counterfeited Good Pay for Attacks. A publication of the office of Public Affairs, US Treasury, Customs and Border Patrol Today. Retrieved from http://www.cbp.gov/xp/Customstoday/2002/nov/interpol.xml on 23rd June, 2014.

Ministry of Health and Family Welfare. 2014. Reward Scheme for Whistle Blowers in the Fight against the Menace of Spurious or Fake Drug, Cosmetics and Medical Devices. Paras. 7. Retrieved from www.cdsco.nic.in on 6th June, 2018.

Mogalian, E. and Myrdal, P. 2004. What is the difference between brand-name and generic prescription drugs? Retrieved from www.scientificamerican.com on 29th June, 2014.

Murumba, S. 2017. Fake China, India Drugs Put Kenya at Risk. Daily Nation. 4th June, 2017. Retrieved from www.nation.co.ke on 12th January, 2018.

Myers, D. 2010. One European in Five Buys Counterfeit Medicine. Le Figaro (Feb 17 2010), retrieved from http://plus.lefigaro.fr/note/one-european-in-five-buys-counterfeit-medicine-20100217-141835 on 12th January, 2015.

NAFDAC News, 2013. Issue 4. p. 11. Retrieved from www.nafdac.gov.ng on 7th February, 2018.

OECD, 1998. *The Economic Impact of Counterfeiting*. A Publication of the OECD. Retrieved from www.oecd.org on 18th May, 2016, p. 3

Ombija, N. R. 2011. *Case Study of Kenya's Specialised IP Rights Court Regime: International IP Institute.* Retrieved from https://kenyalaw.org/kl/index.php?id=1899 on 17/5/2018.

Ogune, M. 2017. Nigeria: NAFDAC Refutes Report on Prevalence of Fake Drugs. *The Guardian*. 9th November, 2017. Retrieved from www.allafrica.com on 20th November, 2017.

'Operation ACIM: New Record Seizures of Illicit Medicines in 16 African Countries'. Retrieved from www.iracm.com on 29th June, 2018

Ossola, A. 2015. The Fake Drug Industry is Exploding and We Can't Do Anything about It. *Newsweek*. Retrieved from www.newsweek.com on 30th May, 2018.

Papdimos, T. J. 2007 Healthcare access as a right, not a privilege: a construct of Western Thought. *Philosophy, Ethics, and Humanities in Medicine 2007, 2:2 doi:10.1186/1747-5341-2-2.* Retrieved from http://www.peh-med.com/content/2/1/2 on 4 July, 2018

Rajagopal, D. 2016. How Drug Whistle Blowers in India Have to Fight Long Battle. Economic Times 19th May, 2016. Retrieved from https://economictimes.indiatimes.com on 6th June, 2018.

Ramah, R. 2013. Counterfeit Drugs Pose Public Health Threat in Kenya. Retrieved from www.sabahionline.com on 13th July, 2014.

Roscoe, P. 1908. Mechanical Jurisprudence. Retrieved from www.minnesotalegalhistoryproject.org on 5th May, 2016.

Summan, A. 2013. Curbing Counterfeit Drug Production in India. CCS Working Paper for Researching Reality Internship. Accessed from www.ccsinternship.files.wordpress.com on 19th September, 2015.

The Basics of Philosophy. Retrieved from www.philosophybasics.com on 14th October, 2015.

The Globalization of Crime: A Transnational Organized Crime Threat Assessment (United Nations publication, Sales No. E.10.IV.6.2010). Retrieved from www.unodc.org/documents/dataandanalysis/tocta/TOCTA_Report_2010_low_res.pdf on 7th September, 2013.

The Situation of Medicine Counterfeiting in Africa. Retrieved from www.whpa.org/background_medicines_counterfeiting_in_africa_chiom on 23rd July, 2016.

The UNGP on Business and Human Rights: An Introduction. A Publication of the UN Working Group on Business and Human Rights. Retrieved from www.un.org on 19th January, 2018

The Basics of Philosophy. Retrieved from www.philosophybasics.com. On 3rd September, 2015

Trading Away Access to Medicine: How the European Union Trade Agenda has taken a turn. 2009. A publication by Oxfam and HAI Europe. Retrieved from www.haieurope.org on 7th September, 2013.

UNODC. A publication of the UN Office in Vienna. Retrieved from www.unov.org on 15th March, 2017.

US Legal. Retrieved from https://definitions.uslegal.com on 7th September, 2017.

WHO. 2007. Good Governance for Medicines: Curbing Corruption in Medicines Regulation and Supply. Retrieved from www.who.int/medicines/policy/good governance/home/en/inde.html on 23rd July, 2016

WHO Drug Safety Alert No.125, Retrieved from http://www.who.int/medicines/Drug SafetyAlert 125.pdf on 3rd February, 2012.

WHO Department of Essential Drugs and Other Medicines, 1999. Counterfeit Drugs: Guidelines for the Development of Measures to Combat Counterfeit Drugs. Retrieved from https://whqlibdoc.who.int/hq/1999/who_EDM_QSM_99.1 on 22nd January, 2018

WHO Member State Mechanism on Substandard/Spurious/Falsely Labelled/Falsified Counterfeit (SSFFC) Medical Products. Retrieved from www.who.int/medicines/regulations/ssffc/A70_23-en1.pdf on 13th June, 2018.

WHO: About. Retrieved from www.who.int on 11th March, 2013.

'WHO Guidelines for the Development of Measures to Combat Counterfeit Drug'. Retrieved from www.who.int on 30th June, 2013.

"What are Rights?" A publication of the Office of the Commissioner, UN Human Rights. Retrieved from www.ohchr.org on 28th August, 2017.

What is the Human Right to Health and Health Care? Retrieved from https://www.nesri.org/programs/what-is-the-human-right-to-health-and-health-care on 4 July, 2018

World Health Organization. 2006. Counterfeit drugs kill! Retrieved from http://www.who.int/impact/FinalBrochureWHA2008a.pdf on 30th May, 2013.

World Health Organization, "Counterfeit Medicines: An Update on Estimates", Retrieved from www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf on 7th September, 2013.

CONFERENCE/WORKSHOP MATERIALS

Akunyili, D. 2005. "Counterfeit Drugs and Pharmacovigilance". Being lecture delivered at the 10th Pharmacovigilance – The Study of Adverse Drug Reactions Training Course held at the UPSALA Monitoring Centre, Sweden on 25th May, 2005. Retrieved from www.fug.se/ovrigt/akunyili.pdf on 5th Jan, 2015.

Akunyili, D. 2007. "Counterfeit Medicines: A Serious Crime against Humanity". Proceedings of the Director – General of NAFDAC, Nigeria, to the European Union Parliament in Brussels, on 10th April, 2007.

Chandra, M. 2012. 'Strengthening Supply Chain Integrity to Combat Illicit Trade: Counterfeiting Landscape in India' being lecture delivered at the OECD Illicit Trade Workshop held on 26 October, 2012, at the OECD Headquarters, Paris.

Ejiofor, K. 2013. "Consumer Protection and the Dangers of Counterfeit Goods: Combating counterfeit Products that Pose a Threat to Public Health and Safety on the African Continent. The Nigerian Experience". Being a Paper presented at the workshop on the Practical approaches to IP Utilization and Protection in Africa. Held on 19th-21st March, 2013 in Dar Es Salam, Tanzania.

Ladan, M. F. 2008. The Limits of Legal and Regulatory Framework in Consumer Protection against Counterfeit and Pirated Products: The Review of Nigerian Law and Practice. Being a revised paper presented at the 4th Global Conference on Counterfeit and Pirated Products Organised by the Government of the UAE in Collaboration with the World Customs Union, WIPO, the International Chamber of Commerce and Interpol. Held on 3rd – 6th February, 2008.

REPORTS, POLICIES, DIRECTIVES AND GUIDELINES.

National Drug Distribution Guidelines, 2012. A Publication of the Federal Ministry of Health.

Guidelines for Registration of Drugs and Related Products Manufactured in Nigeria. [NAFDAC/RR/003/00]

National Drug Policy, 2005. A publication of the Federal Ministry of Health.

Report to UN Human Rights Council. The Report was presented by Prof. John Hagee, Special Representative of the Secretary General for Business and Human Rights, at Geneva, on 30th May, 2011, p.2.

Research Report on the State of Consumer Protection in Nigeria: a Review of Consumer Protection in the Telecom Sector in Nigeria.

Singh, A. and Kane, H. 2011. Report on Anti-Counterfeiting in India. Presented during the 59th Council Meeting of the Asian Patent Attorneys Association, India. Manila, Philippines on 12th-15th November, 2011

WHO, 2006 "WHO Fact Sheet No: 275: Counterfeit Medicines". Geneva.

Counterfeit medicines. World Health Organization. Fact sheet No. 275 revised 2006. Retrieved from www.who.int on 7th September, 2013.

Fact sheet Protecting Trademarks. Retrieved from www.inta.org on 29th June, 2014

International Medical Products Anti-Counterfeiting Taskforce (IMPACT). 2011 "IMPACT Handbook: Developed by the Assembly and the Working Groups, 2006-2010."

The Directive 2011/62/EU of the European Parliament and the Council of 8th June, 2011

The Right to the Highest Attainable Standard of Health, UN. Doc. E/C: 4th Dec, 2000: ICESCR, Gen. Comment 14. 2000.

United Nations Guiding Principles on Business and Human Rights". Retrieved from www.ohrch.org on 10th December, 2013

WHO, 2004. "The World Medicine Situation." World Health Organization: Geneva.

WHO, 2011. "World Medicines Situation 2011: Good Governance for the Pharmaceutical Sector" WHO/EMP/MIE/2011. World Health Organization: Geneva. Retrieved

fromhttp://www.who.int/medicines/areas/policy/world_medicines_situation/WMSCh6wPricingv6.pdf on 5th May, 2013.

WHO Factsheet No.323 of November, 2012.

WHO. Counterfeit Drugs - Guidelines for the Development of Measures to Combat Counterfeit Drugs. Geneva, Switzerland: s.n., 1999. Retrieved from www.who.int on 30th June, 2013.

"Anti-Counterfeit Laws and Access to Essential Medicines in East Southern Africa". EQUINET Policy No. 22, p.2. (EQUINET- Regional Network for Equity in Health in East and Southern Africa).

"WHO General Information on counterfeit Medicine", Retrieved from www.who.int/medicines/services/counterfeit/overview/en/ on 9th July, 2014.

WHO. 2011. WHO Statistics 2011. Geneva, Switzerland.

WHO. 2011. WHO - The World Health Report: Health Systems Financing – The Path to Universal Coverage. Geneva. Switzerland. www.who.int. Accessed on 11th December, 2015

'Substandard, Spurious, Falsely Labelled, Falsified and Counterfeit (SSFFC) Medical Products'. WHO Factsheet. January 2016. Retrieved from www.who.int on 13th February, 2017.

The Right to Health Fact Sheet No.31, p. 1. Retrieved from www.who.int.org on 1st August, 2013.

INTERNATIONAL INSTRUMENTS

Additional Protocol in the American Protocol to the American Convention on Human Rights in the area of Economic, Social and Cultural Rights, also known as the Protocol of San Salvador.

Agreement on Pre-Shipment Inspection

Agreement on Trade Related Aspects of Intellectual Property Rights

African Charter on Human and Peoples Rights 1986

African Charter on the Rights and Welfare of the Child 1990

American Convention on Human Rights

Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment.

Convention on the Elimination of all Forms of Discrimination (CERD)

Convention on the Elimination of all Forms of Discrimination against Women (CEDAW)

Convention on the Rights of the Child (CRC)

European Convention for the Promotion of Human Rights and Fundamental Freedom.

European Social Charter

General Comment 14 to the ICESCR.

General Agreement on Tariffs and Trade

International Covenant on Civil and Political Rights (ICCPR) 1966

International Covenant on Economic, Social and Cultural Rights 1966

United Nations Convention on Transnational Organised Crime and its Protocols on Trafficking in Persons, Smuggling of Immigrants and Trafficking in Firearms.

United Nations Declaration of Human Rights (UNDHR) 1948

United Nations Guiding Principles on Business and Human Rights

Vienna Declaration of 1993.

World Health Organisation Constitution of 1946.

NEWSPAPER PUBLICATIONS

Anon. 70% of Drugs in Nigeria Not Fake – NAFDAC. Vanguard News. 12th November, 2017. Retrieved from www.vanguardngr.com on 20th November, 2017.

Anon. 'Pharmacists Tell How to Identify Fake Drugs Shop'. Daily Nation Online. 29th June, 2011. Retrieved from www.nation.co.ke on 12th January, 2018.

"Counterfeit drugs raise Africa's temperature". Accessed last on June 26th 2014 from http://www.sierraexpressmedia.com/archives/58458.

"My Pikni: A case for the Review of NAFDAC Law", The Vanguard Newspaper, 5th June, 2013.

"Stiffer Penalties will Reduce Drug Counterfeiters – NAFDAC". Business Day. 17th May, 2013.

Adekeye, F." Death Merchants", in *Newswatch*, Vol. 35, No. 21, May 27, 2002

Eroke, L. 2013. Beyond Global Conventions and Implementation Hitches. *This Day*, 27th August, 2013. Retrieved from www.thisdaylive.com on 17th March, 2015.

Murumba, S. 2017. How Counterfeit Medication gets into African Countries. Retrieved from news24 at https://www.news24.com on 29th June, 2018.

Ngirwamungu, E. 2009. Counterfeit Drugs Puts Lives at Risk. Irin News. 15/1/2009. Retrieved from www.irinnews.org on 14th June, 2018.

Ogune, M. 2017. Nigeria: NAFDAC Refutes Report on Prevalence of Fake Drugs. The Guardian. 9th November, 2017. Retrieved from www.allafrica.com on 20th November, 2017.

NAFDAC: How My Pikin Tragedy Occurred". *This Day Newspaper*, 12th Feb, 2012.

Nnanna, M. G. 2014. "Counterfeit Drugs: NAFDAC Push for Life Sentence". Leadership. September 19. Accessed from www.leadership.ng on 26th March, 2015.

Ogwuda, A. 2013. “NAFDAC to Medicine Dealers: Buy Your Drugs from Genuine Sources”. Vanguard Newspaper. 22nd October, 2013.

Roberts, M. 2012. Third of Malaria Drugs ‘are fake’. BBC News Online, (22/5/2012). Retrieved from www.bbc.co.uk/news/health-18147085, on 30th May, 2013 on 7th September, 2013

Wanjiku R. 2009. Online Scams up as More Africans use the Internet. Retrieved from www.thestandard.com

UNPUBLISHED WORKS

Ahmad, A. I. 2012. Addressing Variability in Drug Quality: Finding the Right “Quality” Framework(s). A thesis submitted in conformity with the requirements for the degree of Master of Science. Graduate Department of Pharmaceutical Sciences University of Toronto.

APPENDIX I

GLOSSARY

All Embracive Approach refers to the UN Principles on Business and Human Rights: Implementing the United Nation's "Protect, Respect and Remedy" Framework.[1016]

Biosimilars[1017] are similar to, but not identical copies of the original biologic. These are unlike generic medicines, where the active ingredients are identical. It is usually not possible to prove that a biosimilar is the same as the originals.

Branded Drug[1018] is one originally discovered and developed by a pharmaceutical company.

Counterfeiting is the practice of manufacturing goods, often of inferior quality, and selling them under a brand name without the brand owner's authorization[1019]. It is an infringement of another's Intellectual Property Right.

Counterfeit drug[1020,1021] is one which is deliberately and fraudulently mislabelled with respect to its identity and/or source. Counterfeit medicines may include products

---

[1016] Report of the Special Representative of the Secretary General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises, John Ruggie. Human Rights Council. 17th Session. Agenda item 3; Promotion of all Human Rights, Civil, Political, Economic, Social, and Cultural Rights, including the right to development. Retrieved from www.ohchr.org on 7th January, 2015.

[1017] Biologics and Biosimilars: An Overview. 2014. AMOGEN INC.

[1018] E. Mogalian and P. Myrdal. 2004. *What is the difference between brand-name and generic prescription drugs?* Retrieved from www.scientificamerican.com on 29th June, 2014.

[1019] Fact sheet *Protecting Trademarks.* Retrieved from www.inta.org, on 29th June, 2014.

[1020] The WHO defines counterfeit medicine as, "one which is deliberately and fraudulently mislabelled with respect to identity and or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging." See "WHO General Information on counterfeit Medicine", accessed from www.who.int/medicines/services/counterfeit/overview/en/, on 9th July, 2014.

[1021] Member states at the World Health Assembly in May, 2012, given the difficulty in arriving at a consensus on the definition of counterfeit drugs, agreed to "use the term 'substandard/ spurious/falsely – labelled/ falsified/ counterfeit medical products', until a definition has been endorsed by the governing bodies of WHO. See, www.who.int.

with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.[1022]

Diagnostic - a device or substance used in the analysis or detection of diseases or other medical conditions.

Drug[1023,1024] - a chemical substance used in the treatment, cure, prevention, or diagnosis of disease or used to otherwise enhance physical or mental well-being.

Falsified[1025] - used to describe medicines that contain ingredients of low quality or in wrong doses, and deliberately or fraudulently misrepresent their identity or source.

Generic drugs[1026] is a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights. They are frequently as effective as, but much cheaper than, brand-name drugs. Because of their low price, generic drugs are often the only medicines that the poorest can access. They are critical to improving access to essential lifesaving medicines[1027].

Medicine[1028] is any substance(s), used in treating disease or illness.

Passing Offis making some false representation likely to induce a person to believe that the goods or services are those of another.[1029]

[1022] It has been suggested that, drugs which have been rejected by regulators or manufacturers may be sold in markets and that these should be considered counterfeits. The same has been suggested for drugs which have expired and have been re-labelled with a fake later expiry date. (see Wertheimer, A. I. et al. 2003., Counterfeit Pharmaceuticals: Current Status and Future Projections. *Journal of American Pharmaceutical Association,* Vol. 43, p710-18. This was referred to in Gautaum, C. S., et al. 2009. Spurious Drugs: A growing industry in the developing World. *Postgrad Med. Journal,* Vol. 85; p251-56.

[1023] Retrieved from www.dictionary.com on 30th June, 2014.

[1024] The term 'drugs', 'medicines', 'pharmaceutical products' and 'pharmaceuticals' are used interchangeably to refer to medical products intended for prophylactic, diagnostic or therapeutic use.

[1025] "Falsified Medicines". Published by the European Medicine Agency. Retrieved from www.ema.europa.eu on 30th June, 2014.

[1026] E. Mogalian and P. Myrdal, *ibid*.

[1027] Anon, 2009. Trading Away Access to Medicine: How the European Union Trade Agenda has taken a wrong turn. *A publication by Oxfam and HAI Europe*. Available on haieurope.org.

[1028] Retrieved from www.merriam-webster.com/dictionary on 30th June, 2014.

[1029] Legal Dictionary. www.duhaime.org/legaldictionary/p/passingoff

Patent Medicine is a medicine, usually not a very powerful one that you can buy without the permission (prescription) of a doctor.[1030]

Patent Medicine Store an outlet for over-the-counter (OTC) drugs, that is medicine sold directly to a consumer without prescription from any healthcare professional.

Pharmacy an outlet in which medicines are prepared or sold.[1031].

Piracy is the act of illegally copying someone's product or invention without permission.[1032]

Prophylactic is a preventive measure. It is a medication or treatment designed and used to prevent disease from occurring.[1033]

Prophylaxis/Prophylactic drug is a measure taken to maintain health and to prevent the spread of disease.[1034]

Spurious drugs[1035]aredrugs that are imported under a name which belongs to another drug or are an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive, or bears upon it or upon its label or container, the name of another drug.

Substandard medicines are those that do not meet quality standards specified for them. Substandard products result from failures in quality control in the production or handling of a legal or counterfeit product[1036].

Therapeutic is concerned specifically with treatment of disease.[1037]

Therapeutic dose is the amount needed to treat a disease.[1038]

[1030] Cambridge Dictionary Online. Available at http://dictionary.cambridge.org on 4th January, 2016.
[1031] *Ibid*.
[1032] Retrieved from www.merriam-webster.com/dictionary/piracy on 24th November, 2015.
[1033] *Ibid*.
[1034] *Ibid*.
[1035] www.answers.com. On 30th June, 2014.
[1036] "Anti-Counterfeit Laws and Access to Essential Medicines in East Southern Africa". EQUINET Policy No. 22, p.2. (EQUINET- Regional Network for Equity in Health in East and Southern Africa).
[1037] *Ibid.* fn130.
[1038] *Ibid.*

APPENDIX III

THE INFORMED CONSENT FORM

IRB Research Approval Number**:**

This approval will elapse on:

TITLE OF THE RESEARCH:

DRUG COUNTERFEITING AND THE RIGHT TO HEALTH

NAME AND AFFLIATION OF THE APPLICANT:

This study is being conducted by Jadesola Lokulo-Sodipe of the Faculty of Law, University of Ibadan.

SPONSORS OF THE STUDY:

Not Applicable

PURPOSE OF THE RESEARCH

The purpose of the study is to find out the effects of drug counterfeiting on the enjoyment of the right to health and qualitative healthcare services in Nigeria, and to proffer solution to ensuring that this right is not violated.

PROCEDURE OF THE RESEARCH:

The participants, who include 3 each of the following categories of people, lawyers, pharmacists, patent medicine dealers, NAFDAC officials and patients, will take part in unstructured interviews. The essence of the interview is to ascertain their experience with counterfeit drugs, their opinion on whether the laws are adequate, whether the laws are being enforced properly and what can be done to respect, protect and fulfill the enjoyment of the right to health in Nigeria.

EXPECTED DURATION OF RESEARCH AND OF PARTICIPANTS' INVOLVEMENT:

The study is expected to last for 1 (one) year. Your participation in the study, will however be for the duration of the interview, which will be for a period of 2(two) to 3(three) hours.

RISKS:

You will not be exposed to any risk in taking part in this study. This is mere an interview to establish awareness of the law and areas of reforms, if any.

COSTS OF PARTICIPATION TO THE PARTICIPANTS:

Your participation in this research will not cost you anything.

BENEFIT(S):

The aim of this study is to examine the effects of drug counterfeiting on the enjoyment of the right to health and qualitative healthcare services. The findings of the study may lead to law reform, making it more unprofitable for drug counterfeiters. It is hoped that this will drastically reduce incidences of drug counterfeiting.

CONFIDENTIALITY:

Your name will not be given in making the report. You therefore cannot be linked with any information given in aid of this study, in any publication or report from this study.

VOLUNTARINESS

Your participation in this study is entirely voluntary and you may withdraw your consent to participate at any time during or after the interview.

ALTERNATIVE TO PARTICIPATION:

Should you choose not to participate, others will be approached.

DUE INDUCEMENT(S):

You will not be paid any fees for participating in this research. Refreshments will be served during the interview.

CONSEQUENCES OF PARTICIPANT'(S) DECISION TO WITHDRAW FROM RESEARCH AND PROCEDURE FOR ORDERLY TERMINATION OF PARTICIPATION:

Where you choose to withdraw from the research, and some of the information that had been obtained from you has been used in a report or publication, these cannot be retrieved. The researcher however undertakes to honour with your wishes as much as practicable.

CONFLICT OF INTEREST:

There are no areas of conflict of interest.

STATEMENT OF PERSON OBTAINING INFORMED CONSENT:

I have fully explained this research to …….. and have given sufficient information, including information about risks and benefits, to make an informed decision.

DATE……. SIGNATURE……..

NAME……

ILLITERATE JURAT (WHERE APPLICABLE)

This document has been read and explained to the participant in the language he/she understands.

DATE…….

SIGNATURE……

NAME……

……

STATEMENT OF PERSON GIVING CONSENT:

I have read the description of the research or have had it translated into the language I understand. I have also discussed with the researcher to my satisfaction. I understand that my participation is voluntary. I know enough about the purpose, methods, risks and benefits of the research study to judge that I want to take part in it. I understand that I may freely stop being part of this study at any time. I have received a copy of this consent form and additional information sheet to keep for myself.

DATE: …….. SIGNATURE:

……..

NAME:

……

…

WITNESS' SIGNATURE (if applicable):

……

WITNESS' NAME (if applicable):

……..

Detailed contact information including contact address, telephone, fax, email and any other contact information of researcher, institutional HREC and head of the institution.

This study has been approved by the Social Sciences and Humanities Ethics Committee of the University of Ibadan and the Chairman of this Committee can be contacted at Department of Sociology, Faculty of the Social Sciences, University of Ibadan, e-mail: sayjegede@yahoo.com.

In addition, if you have any question about your participation in this study, you can contact the Principal Investigator, Jadesola Lokulo-Sodipe, Department of Commercial and Industrial Law. Phone – 0808 249 7110 and e-mail – jadesolals@gmail.com. You can also contact the Dean of the Faculty of Law, University of Ibadan at Faculty of Law, University of Ibadan.

PLEASE KEEP A COPY OF THE SIGNED INFORMED CONSENT FORM.

APPENDIX IV

QUESTIONS FOR INDEPTH AND KEY INFORMANT INTERVIEW

1. What do you think causes or influences the prevalence of drug counterfeiting (DC)?
2. What, in your opinion, are the effects of using counterfeit drugs on the general health of an individual?
3. Who do you think is more at risk in drug counterfeiting?
4. Are you aware of the existing laws in relation to drug counterfeiting?
5. Do you think the existing laws are effective and sufficient in tackling drug counterfeiting (especially as it pertains to the prescribed penalties)?
6. Do you think there is any loophole in the procedures adopted by the regulatory body in the registration of drugs and the implementation of relevant laws which gives room for drug counterfeiting?
7. Will you push for the amendment of the current laws; the enactment of new laws or better implementation of the current laws?
8. Would the effect of government policies on healthcare delivery be a contributory factor?
9. Are the present national measures sufficient to meet the challenges of counterfeit drugs (CDs)?
10. How do you identify counterfeit drugs? What should a consumer do if he suspects that a drug is a counterfeit?
11. Have you had any training on how to identify CDs?

12. Would you report knowledge of CDs to the police, NAFDAC or any other agency?
13. What can consumers do to protect themselves from counterfeit drugs?
14. What are the remedies available to an individual who is a victim of drug counterfeiting?
15. Would awarding damages/compensation to the victims of CDs help tackle the problem?
16. Would confiscation the assets of offenders help tackle the problem?
17. Major threats to drug distribution are caused by secondary market made up of small and loosely regulated wholesalers and retailers.
18. Involvement of unqualified personnel in procuring and distributing medication has implications in drug regulation and control.
19. Promoting access to essential medicine, e.g. removing import duties from drugs, would help tackle the problem of CDs.
20. How effective are the technological tools, such as TRUSCAN, and MAS, in detecting and combating CDs?
21. What challenges are being faced using these tools?
22. What is the effect of registration on the quality of drugs?
23. Does product registration guarantee the potency of the drugs or status of the goods sold and supplied?
24. To what extent have the task forces put in place been able to control the spread of CDs?
25. What are the challenges faced by the task forces?

26. The right to health includes the right to access to reliable standard of health care and assurance that drugs received are not only genuine, but safe, effective and affordable.

27. What do you think are the effects of drug counterfeiting on the right to health?

28. How are the seized goods prevented from going back into the drug distribution chain?

29. Increased due diligence by health care personnel when purchasing drugs will help in tackling drug counterfeiting.

30. Stiffer penalties for knowingly providing CDs to patients will help combat the problem of drug counterfeiting.

31. Inter-agency collaboration among regulatory bodies, both nationally and internationally would help tackle the problem of drug counterfeiting?

32. What are the challenges faced in respect of cross-border monitoring of DCs?

33. Staff re-orientation will help tackle the problem.

34. Public enlightenment campaign will help tackle the problem?

35. Would providing incentive for whistle blowers help tackle the problem?

ADDITIONAL QUESTIONS FOR NAFDAC STAFF

36. How will you rate NAFDAC in carrying out its duties in respect of CDs?

37. What challenges does NAFDAC encounter in discharging its duties?

ADDITIONAL QUESTIONS FOR PHARMACISTS AND PATENT MEDICINE VENDORS

38. What measures are the Pharmaceutical Society of Nigeria (PSN) and the National Association of Patent Proprietary Medicine Dealers (NAPPMED) employing in tackling the menace of drug counterfeiting?

39. How effective are these bodies in carrying out their oversight roles in respect of CDs?

40. How would you rate the relationship between these bodies among themselves and with NAFDAC?

41. How does drug counterfeiting affect the growth of the pharmaceutical companies and drug innovation?

42. What role do Pharmacists and doctors play in eradication CDs?

43. Suggest how they can improve on their activities to curb the proliferation of CDs.

44. Would you refund the money of a customer who discovers through a technical tool that the medicine he purchased was fake?

45. Are you aware of the legal right of consumers against manufacturers, producers, retailers and intermediaries in the distribution of CDs.

46. Have you attempted or do you know anyone who has attempted to exercise these rights?

47. Do you know anyone who has attempted to exercise these rights?

48. Where they successful?

49. What challenges did you or they face?

50. What factors prevent the exercise of these rights?

ADDITIONAL QUESTIONS FOR LAWYERS

51. Can the consumer recover his/her money in whole or part from the manufacturer, retailer, supplier or intermediary of CDs?

52. Is he/she entitled to other remedy (ies)?

53. How can the 3 contractual principles, namely, privity of contract, caveat emptor and freedom to contract, militate against contract-based protection of consumers?

54. Does the manufacturer, retailer, supplier or intermediary in the CDs supply chain owe any duty to the consumer?

55. Can this duty be extended to cover gratuitous donees, borrowers or casual users?

56. What impact has the creation of statutory offences in relation to the manufacturer, possession and distribution of CDs on the efforts at tackling DC?

57. Can DC be prevented? What in your opinion can be done to prevent drug counterfeiting?

APPENDIX V

REPORT OF INDEPTH INTERVIEWS

METHODOLOGY

Study area:

Primary survey was done at University College Hospital (UCH) Ibadan, Oyo state Nigeria.Oyo state is an area of 28,454 square kilometers. It is bounded in the west by Ogun State and Republic of Benin, in the north by Kwara State, in the east by Osun State and in the south by Ogun State. The study was done among patients, doctors and pharmacist in the university college hospital and chemists in Egbeda Local Government Area in the state.

Study design:

The study was a cross sectional study done to assess the knowledge of patients, doctors, pharmacist and chemists on drug counterfeiting.

Sampling technique:

The respondents were purposively selected in the state. And questions on their knowledge of counterfeiting were asked using a qualitative tool.

Data collection:

Data was collected qualitatively through an interviewer administered questionnaire. The questionnaire was pretested before finally adopted for administration. The

questionnaire was also translated to Yoruba for the purpose of respondents who could not respond in English language. A focus group discussion (FGD) consisting of six (6) persons in each group of doctors, patients, pharmacists and chemists was done to assess the knowledge of these groups on issues relating to drug counterfeiting. The interviewer was well trained for the procedures involved with the assistant interviewer having an HND degree.

Data analysis:

After the interviews were done, the recordings were transcribed and a qualitative analysis was done using Atlas Ti version 7.

A. REPORT ON THE i INTERVIEW ON DRUG COUNTERFEITING AMONG PATIENTS, DOCTORS, PHAMACISTS AND PATENT MEDICINE VENDORS.

Introduction:

This report is on drug counterfeiting, the legal issues in drug counterfeiting, legal relationship between the manufacturer of counterfeit drugs and the end users, adequacy of the existing legal and institutional framework for combating drug counterfeiting and knowledge of the UN guiding Principles on Business and Human Rights in Ibadan, Oyo state.

Understanding of drug counterfeiting and the legal issues involved

All the respondents saw drug counterfeiting as illegal and fake with one of the respondents from the doctor's group saying *"A counterfeit of anything is more like a fake of it, so in drug counterfeiting, it is just that people are producing substandard of fake drugs or drugs that active agent is actually very minimal compared to the original, there is something they call constituted starch composition in medications. So that is probably much more in terms of milligram and you now have the active ingredient very small so I think that would suffice for what counterfeit would*

constitute and the illegal issues is when people import or make available to the populace those kind of drugs" and another respondent from the same group stating the harmful effect of such drugs, he said *"A counterfeit simply means fake, that is, it lack originality, it is not the original what it is meant to be and the mode of action, what its supposed to do, it is rather it would do something else that can harm the user, so it simply means fake drug."*In addition, another respondent from the pharmacists group talked about the authenticity and life span of such drugs saying *"Production of fake drugs, change of expiring date of drugs on label, bringing into a country a banned drug, setting or disposing expired drugs"*. Whereas, among the group of patients that were interviewed, a respondent defined counterfeit drugs as also fake, the respondent said *"As for me Mr E. Drug counterfeiting to my understanding. They are fake drugs that are manufactured illegally. Illegally i mean they are not backed up with the production or source from the government and they are drugs like just over the counter as Mr. A has said."* Meanwhile, a chemist defined a counterfeit drug as a drug without a NAFDAC registration number, the respondent said *"What I know about counterfeit drug is that, suppose some people produce a drug out now, and give it a name and now put it under government's approval in which the NAFDAC registration number is on that particular authorized drug being approved by the government for human consumption, and if eventually another set of people now come up with the manufacture of the prototype of that same drug and buying of the container bearing the name of the same product like that of government approved one, whereas, the prototype has not been authorized by the government for these drug, the government should come and arrest them because it is not good."*

Although almost all the respondents know that there are some existing legal issues relating to drug counterfeiting,a respondent from the patients group said*"Yes….there are key laws that bind these illicit set of drugs, but I can't really place my hand on one precisely but I know there are laws that has been delegated or powers to deal with such people has been given to NAFDAC and I can't really precisely quote the laws but NAFDAC has a constitution that deals and tackles and proffers penalty of fake drugs in our society"*, however, another respondent stated that he or she doesn't

know much about these laws and their implementation, the person said *"As far as I'm concerned Mr.E, there are some laws waging war against drug counterfeiting. So, but some of the laws to me are not really implemented, although there are but most of us did not even know these rules including myself but I know at least they exist."*

Some of the respondents from the Doctors group had conflicting ideas on the regulatory organizations with one of the respondents saying *"Just to add to what has been said, I am not sure whether SON is the major regulatory body or NAFDAC, I think is NAFDAC, NAFDAC is the one that is in charge of regulating drugs really that comes to the country. So it is their duty to make sure that fake drugs do not get to the country not to talk of even circulating within the country. So I think NAFDAC is the major regulatory Organization in charge of that and of course, there are legal issues because if you are found with fake drugs importing fake drugs or fake product, they are liable to be charged into court and prosecute you"*. And all the respondents in the Pharmacists group agreed to knowing that there are legal issues related to drug counterfeiting.

Also, on legal issues related to drug counterfeiting, most of the respondents stated that NAFDAC is the body fighting against drug counterfeiting. All the respondents in the patients group are aware of this. A respondent from this group said *"As far as I am concerned, I know about NAFDAC, it is an organization that are being created by the government in order to check mate and also to ensure that these fake drugs are destroyed or being minimized from our society. And I'm also aware of NDLEA too, they are also working hand in hand with NAFDAC but they also have their role they play in everything that has to do with drug, or drug trafficking or illegal use of drugs are being wage war against, but I'm not really sure if all these issues or the power given to them is highly very very effective in our society as far as these drug counterfeiting is concerned."*. More so, a respondent from a pharmacists group said that those caught in the act will be charged to court, the respondent said*"Anyone caught with offences that are related to drug counterfeiting will be*

charged to court and if found guilty will be imprisoned" and another said *"Selling of counterfeit drugs are liable to jail service"*

Relationship between counterfeit drug manufacturers and end users

All the chemists said there are no relationships between counterfeit drug manufacturers and end users while respondents from the patients group stated that the communities encourage drug counterfeiting because of the low cost of these drugs. A respondent from this group said *"Well thank you, as Mr. A, the community is not in any way helping matters, the Nigerian society is not in any way helping matters because an average Nigerian would prefer to spend less or use his money to buy what will kill him because he is trying to avoid paying more to get quality thing that would make him live long. He would rather pay to buy inferior because it cost less. So they are not in any way helping matters because they help to promote the sales of those things by patronizing them in a way. Thank you".* However, the respondents from the Doctors and Pharmacists groups seem like they didn't really understand the question asked.

There were contrasting opinions among the patients pertaining to the issue of the duties that arise from the relationship with some saying there is no role played by people in the society and some said there is, with a respondent stating that *"As far as I am concern, the role that the society normally plays, most of the society, people in the society are nonchalant and people in the society are ignorant about all these drugs. What people normally do in the society is suppose I'm having headache, let me go to the nearest chemist and buy something that at least I just want to make sure that I'm better and I'm okay. They don't care if it is fake or if it is original. And they also look at the cheaper one because they will be telling themselves that at least I can't spend all my money on drugs, what about food, what about clothing, what about this and what about that?,so they are very ignorant about their wellbeing and consciousness of all these fake drugs counterfeiting. Thank you very much"*.However, most of the pharmacist insisted that the production of counterfeit

drugs is a criminal act. These drugs can kill and shouldn't be bought but should be reported to the right quarters just as a respondent suggested saying *"Counterfeit drugs produced can kill or harm the end user"*.

In addition, most of the respondents from the patients group didn't have an idea of the liabilities with just one saying that *"well, it can result into ill-health and if we are not careful, we will have many people in the population that are sick or sickly due to intake of fake drugs. Thank you."* From the doctors point of view, the question wasn't clear enough but a participant managed to say what he understands about what was asked, he said *"I guess the question is not clear, but asking of legal relationship is just theoretical, so actually as a consequence of that legal relationship and the ethics that we talk about, the manufacturer is liable for criminal infraction which can be activated as we talk about. So yes that one would add to what I said that they can be sued, they have the right to sue, belief that the drug has caused harm that you are not aware of, that the manufacturer did not mention, so you are likely to be sued, if the drug is spoken to be unsafe and did not alert the populace to the potential side effect."* Meanwhile, majority of the pharmacists didn't answer the question but one of them pointed out that such relationship will result in drug abuse.

Adequacy of the existing legal institutional frame work for combating drug counterfeiting

On the adequacy of the existing legal institutional frame work, the respondents mentioned SON, NAFDAC and NDLEA mostly as the legal organizations involved. The patients said that these legal institutions are adequate and effective with one of them saying *"As far as me I'm concern, apart from the NDLEA that we have, the NDLEA are really working and NAFDAC are also working very well especially those drug trafficking, the cocaine, the heroine, even the smokers. You will see it at the back of the something that smokers are liable to die young. They really*

disregard all these things and they still continue to take it. and well everything still bounce back on the society due to diseases, lung cancer and all those things, we have primary smokers, secondary smokers and all those stuffs like that. So I think all these things do not really have impact in the society". As for the chemists, most of them indicated that these organizations exist and they are aware of their activities but one of the respondent said they are not fully effective, the respondent said *"They are trying their best, but these counterfeit producers still exist, because the law is not yet fully effective to stop this habit, because some are still producing counterfeit drugs"*.

However,the doctors weren't sure of the implementation of the laws established by most of these legal institutions (SON, NAFDAC and NDLEA) precisely, with a respondent saying *"I am not sure about the implementation because, if we are really serious about trying to fight drug counterfeiting, then, I think there should be restricted access towards drugs people can get over the counter because in Nigeria, you can basically walk into any pharmacy ask for almost any prescription drugs and you would get it, and I don't know, I think that is a huge loophole where people can buy any drug from anybody and then you will see on almost every street, you see different kind of petted medicine sellers selling all sort of drugs, that you know some of them would have been re-packaged, expiry date changed, reconstituted, to what extent do people monitor the potency of what they have over time. So, distribution of drugs and sales of drugs on our street and in our cities is just so low. You can just buy anything from anybody from anywhere so I think that the framework is not adequate to the point of implementing or monitoring. Thank you."*The chemists also said the Pharmaceutical Medicine of Nigeria and the police are also some of these organizations while a pharmacist named Association of Pharmacist council of Nigeria as being part. Also, the pharmacists reiterated that the laws are moderately adequate and not so effective with one of them saying*"They are trying but they need to employ other means to battle drug counterfeiting"*

The UN guiding principles on business and human rights as a means of combating the menace of drug counterfeiting

Most of the respondents are not aware of the UN laws, they are only aware of the local organization as stated by a chemist who said *"we only know of the local organization that do fight for the law and principles of business and human right within the community, but the organization that you talk about now, although they might be and might be existing, but I have not heard of such kind of organization. I don't know if they are existing, but I am aware of the people or organization within our localities that are fighting on human right."* and a respondent from the doctors group who also said *"I'm not aware of the law so I can't really say but from the name that business and the human right, it is possible that it could be applied but I can't really say anything about it, since I'm not really aware of it , thank you"* with 90 percent of the pharmacist saying they have no idea of the UN law. However a respondent from the doctors group said *"I think there is a right to health, so if because of profit, you want to make profit, you engage in some actions, that will negate people's right or that will deprive them of their right to life through their right to health, then I think, you have fulfilled the UN human right by extrapolation, so I think so, people have the right to life, so they won't be alive if they are not healthy. So if you infringe on their right because of business you engage in activities that would infringe on that right by exposing them to hazards to their health, then you have infringe their right to their health. So, I think it is correct and we don't have so deep knowledge about this human right but as doctors, we appear in health industries we use drugs a lot, we can give that opinion, but don't forget we can't do much maybe lawyers, pharmacists can do much in given more information as regards that."*

In conclusion, majority of the respondents know about drug counterfeiting and its effects on the population at large. Also, the respondents know about the organizations involved in the fight against drug counterfeiting but weren't sure of the implementation of their laws. Finally, majority of the respondents did not know

about the UN guiding principles on business and human rights as a means of combating the issue of drug counterfeiting.

B. REPORT OF THE UNSTRUCTURED INTERVIEW WITH LAWYERS

The lawyers were of the opinion that the best way to approach the issues was the use the rights-based argument. This is because, the manufacturers have the right to make a living, whilst the consumer have the right to life and health. There seems to be a conflict between both rights. The consumers' right to good quality medicines, gives rise to the manufacturer's duty to ensure that his/her product is fit for purpose.

i. On whether there is a relationship between the manufacturer and the end user of the drug, it was agreed that there may be no contractual relationship between them. Some were however of the opinion that the decision of the court in Carlill .v. Carbolic Smokeball case was applicable.[1039] This was based on the principle that putting his/her drugs on the market was an invitation to treat to which the buyer makes an offer. That arrangement, in their opinion, created a relationship between them.

It was noted that under Consumer Protection Laws, the manufacturer owes a duty to produce goods that are consumable, and the consumers do not expect to take a drug that will affect their health adversely. Consequently, the manufacturer owes the end user a duty of care.

j. On whether the relationship created a duty, they all said that the manufacturer owed the end user a duty of care, at least under the consumer protection laws. Under the law of contract, it was felt that there was no relationship. However, applying the principles of Donoghue .v. Stevenson,[1040] the law of trust, third party insurance and tort of negligence, there was as established duty of care.

k. On the adequacy of existing laws, this group admitted that, although, various laws were available, they were old and did not meet the requirements for the present day.

[1039] (1893) 1QB 256.
[1040] *Supra*

They should therefore be reviewed and expanded. It was suggested by one of the participants that competition law should be introduced to this area. It was jointly agreed to that the legal framework as it is not adequate. The issue of enforcement of the existing law was raised. And it was noted that enforcing the existing laws was almost impossible and the effects of the law was not being felt as result of the enforcement challenges. They noted that the laws do not make provisions for compensation. The group argued that if Hart's theory is applied, the laws are inadequate.

l. On the adequacy of Monitoring. They advocated stiffer penalties for the offence of drug counterfeiting. It was noted that the retailer should be able to extract an indemnity clause from the manufacturer.

m. On whether the institutional framework was adequate, it was agreed that though NAFDAC appears to be working, there is virtually little or no effect of their effort.

n. On the UN Guiding Principles on Business and Human Rights, not all of them had heard of it, but all agreed that adopting it will aid in combating the menace. It was noted that stiffer penalty and the requirement for payment of compensation will make the business unattractive to the counterfeiters. It was agreed that the adoption of the principles of the UNGP, would ensure that the victims get redress for the violation of their rights.

o. On the use of technology features, they all knew one or other of these features, but noted that some of them are now being counterfeited, thereby resulting in authentication of counterfeit medicines. It was therefore necessary for newer and stronger method be introduced.

p. It was suggested that the whistle blowing scheme should be extended to this area.

In conclusion, all the lawyers were able to identify the legal issues involved in drug counterfeiting and that under the different areas of the law, a relationship which gives rise to a duty of care could be established. This duty was breached with the production of the counterfeit drugs. Consequently, the victim should be entitled to

compensation. The consensus was that the legal framework, though comprehensive, was deficient in many areas and should be submitted for reform. Identifying NAFDAC's challenges, they agreed that the Agency was making efforts but could be changed in many ways for better efficiency at its duties.