ADVERSE DRUG REACTIONS AND THE LIABILITY OF PHARMACEUTICAL COMPANIES IN NIGERIA

BY

Rebecca Fair DAVID

LAW2009703

FACULTY OF LAW
UNIVERSITY OF BENIN
BENIN CITY

NOVEMBER, 2025

ADVERSE DRUG REACTIONS AND THE LIABILITY OF PHARMACEUTICAL COMPANIES IN NIGERIA

BY

Rebecca Fair DAVID

LAW2009703

FACULTY OF LAW, UNIVERSITY OF BENIN, BENIN CITY, BEING AN ESSAY WORK WRITTEN AND SUBMITTED TO THE FACULTY OF LAW UNVIVERSITY OF BENIN, IN PARTIAL FULFILLEMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF BACHELOR LAWS (LLB) OF THE UNIVERSITY OF BENIN, BENIN CITY

NOVEMBER, 2025

CERTIFICATION

I, Rebecca Fair DAVID, with matriculation number **LAW2009703**, hereby certify that, with the exception of references to the works and opinions of other writers duly acknowledged herein, this entire project is a product of my personal research and findings. It has, neither in whole nor in part, been presented for another degree elsewhere.

_____

Rebecca Fair DAVID
LAW2009703

APPROVAL

We certify that this project work was researched, written, and completed by **Rebecca Fair DAVID,** with matriculation number **LAW2009703** in partial fulfillment of the requirements for award of the degree of bachelor of laws (LLB) of the University of Benin.

Prof. (Mrs.) M.P Ezekiel
Project Supervisor _____
Signature and Date

Dr (Mrs) O.F Osuji
Project Coordinator _____
Signature and Date

Prof. Bright Bazuaye
Dean, Faculty of Law _____
Signature and Date

DEDICATION

This research is dedicated to El Echad, The one God Almighty, who is Elohim Avram, Elohim Yitzhak, Elohim Yacuv and Elohim Dahveed. His attributes always spoke for me. His infinite love, grace and boundless mercy has guided every step of this educational voyage. This research is dedicated to Him First, as a tribute of gratitude for seeing me through this great feat.

I also want to dedicate this research to My Father Mr David, who has brought this to be by providing for me the wherewithal to begin strong, accelerate in the middle and finish strong. This accomplishment is yours first, before it is ever mine.

Finally, I want to dedicate this research to the woman I'm becoming, the best version of myself that I will be. Dear Future Barrister Rebecca Fair David, you are unstoppable. You've accomplished this, you will yet accomplish more.

ACKNOWLEDGEMENTS

I will begin my acknowledgments by first resounding the verity encapsulated in the fine lines of Ecclesiastes 9:11 KJV: "I returned, and saw under the sun, that the race is not to the swift,

nor the battle to the strong, neither yet bread to the wise, nor yet riches to men of understanding, nor yet favor to men of skill; but time and chance happeneth to them all". Upon the precipice of this scripture, I acknowledge, that after attaining such an achievement, it is indeed great vanity to attribute all credit to the singularity of oneself. For behind every great achievement, is the input of a multitude of helpers; from family, friends and favoring factors, they all, both directly and indirectly join hands to bring to reality the broadest of dreams. And for the satisfaction of success to fully settle, it is apt that honour be given to whom honor is due. I will go on now to present my unreserved appreciation to the multitude of helpers without whom, this achievement would not have been made possible.

Firstly, I must give the first place to He who is the First, The Last, and The In-between. He who specializes in doing the Impossible. The Great Magnanimous Father of Spirits, who fills every expanse and determines in every trend, Jesus Christ, The Almighty God. I love you Lord, because you have first loved me, and it is because your love has spoken for me once again that I can mark this milestone. You indeed are the giver and sustainer of success. I express my most profound gratitude Father, for seeing me through this educational pursuit, I have reached this milestone by your grace. Thankyou Lord for good health and sound mind. Thank You Lord for your provision and protection, and for adorning me with the wherewithal to undertake this great feat and come out victorious. "Blessed be the Lord my strength, which teacheth my hands to war, and my fingers to fight:" It has been you Lord, all the way. All I have and all I am is for Your pleasure and glory. ALL the glory belongs to Thee and Thee alone.

Vehemently, I want to extend my most genuine appreciation to Mr David, My Beloved Father. You are PERFECTION. I will forever be grateful to you for all the investments you've made

into my life. You have been My Anchor, My Comforter, My Balance, My Light, and Hugest supporter. Things that you would have never dreamt of having or enjoying in your youth, you provided for me. You carried much so load so I don't be burdened, you handled the pressure so I be free, you absorbed the pain so I can smile, you gave me comfort in your discomfort, you made it possible that I never lack a thing, You played the roles of both parents alone, you labored that I may have it easy. For all these things and much more, I am wholeheartedly grateful. I thank you for your unconditional love, care, provision, protection, leadership and sacrifice. I Thankyou specially for your prayers, your prayers sustained me in this journey. I could never have done it without you. I owe you everything I have, everything I am and everything I will be. This success is yours first before it is mine.

I must go on to give my undiluted appreciation to my sisters. Firstly, Miss Ruth Regal David, My Big Bold and Beautiful Elder sister, who has tested the pressure of life before me so she could guide me through it. Without you I would have never attained this achievement. I am grateful for your words, your prayers, your encouragements and your financial support. Your extended arm of love preserved me all these years. You are simply amazing and I pray that God bless you in all your endeavors. Secondly, My baby sister Miss Rachael Diamond David who gives me purpose and reasons to strive to be better. There's honestly nothing in this world that is in my power that I will not do for you. Thankyou for always cheering me on, for celebrating me and celebrating my victories with me. You have made my journey much more colorful. For giving me a more beautiful story to tell, may God multiply your wins and answer your silent prayers.

Now to my God-given family, THE HARMONIZERS and THE MUSICIANS who give me essence, you have challenged me and shapened me to be my best version. I am sincerely grateful to

you all for standing by me through thick and thin and always showing up for me whenever I call. Your support, love and care means the world to me. How can I ever possibly thankyou? God bless and uplift you guys always.

I must give credit to the family God blessed me with in Uniben. I recognize that I have been undoubtedly lucky to be blessed with these exceptional individuals: Daniel Ololade Idowu, everyday was a blessing with you, you kept me safe, kept me sane and kept me going, I am forever grateful. Ivie Irabor Great, Thankyou for becoming my sister, for being my rock and sticking with me through the beautiful days and ugly ones. Alaran Muhammed, My personal person, I am forever indebted to you for never hesitating to shine some light so I could see, to build and furnish me so I could be. My brother from another mother, I am grateful. Darwin Osama Osadolor, My day 1, you are just simply amazing. Thankyou so much for bearing my pains as yours and celebrating my wins as yours. You were always there for me, I am grateful for everything. Charles, Thankyou so much for everything, without you this will not have been possible.

And to my wonderful friends who always brought joy my way: Deborah Oluwasola Ogunsanya, there is never a dull moment with you, thankyou for your genuine love and care. Uduak Ben, the beautiful younger sister faculty of law gave to me, thankyou for your warm friendship. Agbro Fortune, my importer and exporter, thankyou for making my dreams a reality, I am grateful to you always. Nosamudiana Eghianruwa, Komonibo Desmond, thankyou for everything, I am grateful.

I am thankful to my Project Supervisor Prof. Mrs Ezekiel Mobolaji. I am grateful to God for ending this first phase of my legal journey with you. Thankyou very much for your patience, for your love and for your zeal to make us better, I pray that God bless you continually. I want

to appreciate all Professors and lecturers of the faculty of law, for laboring so hard that our future be bright, may you all reap the fruits of your labor in good health.

And finally, I want to thank myself David Rebecca Fair for enduring, for pushing and for never giving up. I am proud of you, and I am even more proud of the woman you're becoming. You are stronger, wiser, tougher and much better than when you started, it will only get better and you will only continue to go higher by his grace. Thankyou for believing and thank you for being.

TABLE OF CONTENT

TABLE OF CASES

TABLE OF STATUTES

Nigerian Statutes

Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, Cap C34 LFN 2004 (formerly Cap 73 of 1990)

Dangerous Drugs Act, Cap D1 LFN 2004 (formerly Decree No. 48 of 1989)

Drugs and Related Products Registration Regulations 2021

Federal Competition and Consumer Protection Act (FCCPA), 2018

Food and Drugs Act, Cap F32 LFN 2004 (formerly Cap 150 of 1990)

National Agency for Food and Drug Administration and Control (NAFDAC) Act, Cap N1 LFN 2004 (formerly Decree 15 of 1993)

Pharmacists Council of Nigeria Act, Cap P17 LFN 2004 (Repealed)

Pharmacy Council of Nigeria (Establishment) Act, 2022

Poisons and Pharmacy Act, Cap 366 of 1990

Standards Organization of Nigeria Act, 2015

Foreign/International Policy Documents

Affordable Medicines Act (Philippines)

National Drug Policy (Nigeria) 1990 (Revised 2005)

National Drug Distribution Guidelines 2012

Decree No. 48 of 1989 (NDLEA Decree)

LIST OF ABBREVIATIONS

ADDO	Accredited Drug Dispensing Outlets
ADR	Adverse Drug Reaction
GDP	Good Distribution Practice GDP
GSMF	Ghana Social Marketing Foundation
IMPACT	Anti-counterfeiting Task-Force
MCC	Medicine Control Council
MHRA	Medicine and Health care products Regulatory Agency
NAFDAC	National Agency for Food and Drug Administration and Control
NPC)	Pharmaco-Vigilance Centre
NWLR	Nigeria Weekly Law Reports
OTC	Over-the-Counter
TFDA	Tanzanian Food and Drug Authority
U.K	United Kingdom
US	United States
WHO	World Health Organisation

ABSTRACT

Adverse Drug Reactions (ADRs) pose a significant public health challenge in Nigeria, contributing to increased morbidity, mortality, and weakened trust in the pharmaceutical and health care systems. Despite the crucial role of pharmaco-vigilance in identifying, assessing, and preventing drug-related harm, ADR reporting in Nigeria remains profoundly inadequate due to low awareness, insufficient training of health professionals, weak regulatory enforcement, systemic corruption, and poor reporting infrastructure. Pharmaceutical companies are legally obligated to ensure drug safety; however, gaps in Nigeria's legal and regulatory frameworks hinder effective accountability when ADRs occur. Although the National Agency for Food and Drug Administration and Control (NAFDAC) and the Federal Competition and Consumer Protection Act (FCCPA) provide statutory safeguards for drug regulation and consumer protection, enforcement challenges persist, enabling substandard, adulterated, or counterfeit drugs to penetrate the market. This research examines the liability of pharmaceutical companies under Nigerian law in relation to ADRs, focusing on the statutory, institutional, and legal mechanisms designed to protect consumers. It explores negligence, product liability, and strict liability principles, highlighting obstacles that prevent victims from seeking legal redress. The study further evaluates the pharmaco-vigilance system in Nigeria, assessing barriers such as inadequate funding, lack of skilled manpower, limited public awareness, and poor inter-agency collaboration. Through doctrinal analysis of legislation, case law, and scholarly sources, the research identifies critical deficiencies in drug safety oversight and calls for reforms to strengthen pharmaco-vigilance, enhance legal accountability, and improve patient protection. The findings underscore the need for a more effective regulatory framework to ensure drug safety, foster transparency, and uphold the rights of consumers within Nigeria's pharmaceutical sector.

CHAPTER ONE
GENERAL INTRODUCTION

1.3 INTRODUCTION

Adverse drug reactions (ADRs) represent a significant public health concern, defined as harmful and unintended responses to medications, ranging from mild symptoms to severe, life-threatening conditions.[1] In Nigeria, the implications of ADRs extend beyond individual health outcomes, affecting patient safety, health care practices, and the accountability of pharmaceutical companies. The issue of ADRs is particularly notable due to alarming under reporting rates, which compromise the effectiveness of pharmaco-vigilance systems designed to ensure drug safety and efficacy in the population.[2]

A study revealed that approximately 24.7% of patients experienced at least one ADR, yet only a fraction reported their experiences, citing ignorance and trivialization of symptoms as primary reasons for non-reporting.[3] This silence is exacerbated by demographic factors, with younger patients exhibiting better reporting habits than their older counterparts. Additionally, systemic challenges, such as a lack of accessible reporting mechanisms and inadequate training for health care professionals, hinder effective ADR monitoring and contribute to patient safety risks.[4] The legal liability of pharmaceutical companies for damages resulting from ADRs adds another layer of complexity to this issue in Nigeria. The regulatory landscape, governed by the National Agency for Food and Drug Administration and Control (NAFDAC), aims to ensure the safety of drugs on the market, yet enforcement of

---

1 <**https://www.pharmaceuticalpress.com/resources/article/a-guide-to-adverse-drug-reaction-reporting/**> accessed 6th August 2025.

2 R Adisa, TI Omitogun, 'Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary health care centres in Ibadan, southwestern Nigeria' *BMC Health Serv Res* 19, 926 (2019) <**https://doi.org/10.1186/s12913-019-4775-9**>accessed 6th August 2025.

3 Ibid

4 <**https://pmc.ncbi.nlm.nih.gov/articles/PMC6175912/**>accessed 6th August 2025.

accountability remains a challenge.[5] If ADRs are deemed predictable, pharmaceutical companies may be exempt from liability; however, unexpected severe reactions could result in legal consequences, prompting ongoing debates about corporate responsibility and patient rights within the health care framework.[6]

Thus, addressing the challenges of ADR reporting and the associated liabilities of pharmaceutical companies in Nigeria is crucial for enhancing patient safety and regulatory compliance. Stakeholders must work collaboratively to raise awareness, improve reporting mechanisms, and foster a culture of accountability in the pharmaceutical industry, ultimately leading to better health outcomes for the Nigerian population.

1.4 BACKGROUND TO THE STUDY

Nigeria is a major consumer of pharmaceutical products in sub-Saharan Africa due to its large population, widespread use of over-the-counter medications, and rising burden of both communicable and non-communicable diseases[7]. However, the regulation of drug safety has not evolved in tandem with the growth of the pharmaceutical market. This has led to an increasing number of ADR cases ranging from minor allergic reactions to life-threatening events such as organ failure and death without sufficient legal redress or institutional intervention. A drug is any substance or combination of substances known to have properties capable of treating or preventing diseases in human and animals[8]. The role of drugs in disease management is substantial. However, when drugs are administered within their therapeutic dosing regimen, they can produce effects that are unwanted, which may threaten the life of patients. Harmful and unintended effects of drugs are known as Adverse Drug Reactions

---

5 M Asiamah and others, 'Spontaneous reporting of adverse drug reaction among health professionals in Ghana' *Arch Public Health* 80, 33 (2022). **https://doi.org/10.1186/s13690-021-00783-1**>accessed 6th August 2025.

6 Ibid

7 R Adisa (n2)

8 AM Danraka, 'Assessment of Knowledge, Attitude and Practice of Drug Reaction Reporting Among Health Workers in Selected Health Facilities in Abuja' *Journal of Biology, Agriculture and Healthcare.* Vol. 11, (2021) 8.

(ADR), which is an unwanted action that manifest as part of a drug pharmacological action[9]. ADRs are universal challenge of immense concern. Children and adults are affected with relative degree of morbidity and mortality[10]. The incidence of adverse drug reaction has been reported to be about 16.2 %, with 6.5 % of hospitalization directly caused by ADRs[11]. Medicinal products pose safety challenges due to several factors which include the pharmacological activities of the product, the genetic disposition and culture of the patient, the treatment seeking behavior of the patients, (including extensive self - medication), abuse of psychotropic agents, unbridled access to prescription only medicines, misuse of antibiotics and preference for injections), disease pattern and co-morbidities. Other factors include drug manufacturing processes, distribution and storage conditions, substandard and falsified medicinal products, and indiscriminate use of traditional, complementary and alternative medicines.[12]

Pharmaceuticals are critical for the health and well-being of populations. Their access and consumption can be likened to a double-edged sword: on one hand, they alleviate the manifestation of disease but on the other hand, if they are inappropriately used, or worse, counterfeit or substandard, they may be ineffective and even toxic to the individuals who take them[13]. As such, it is necessary for countries to adhere to the highest standards of quality in the manufacture, regulation, and distribution of drugs. Because of the many steps involved in the process of regulating drugs, the pharmaceutical system is particularly vulnerable to unethical and corrupt practices. In many developing countries such as Nigeria, these vulnerabilities are capitalized on and adherence to such high regulatory standards is severely

---

9 M Asiamah, 'Spontaneous Reporting of Adverse Drug Reaction among Healthcare Professionals in Ghana' *Archives of Public Health 80:33* (2022) <https://doi.org/10.1186/s13690- 021-00783-1>accessed 6th August 2025.

10 AM Danraka (n8) 11.

11 AS Igbinlade and others, 'SuRvey Of Knowledge Of Pharmacovigilance And Adverse Drug Reactions Reporting Among Healthcare Providers In Abuja, Nigeria' *African Journal of Educational Management, Teaching and Entrepreneurship Studies* VOL.13 (2024) 2. <https://ajemates.org> accessed 6th August 2025.

12 Ibid

13 PN Newton and others, 'Manslaughter by fake artesunate in Asia - will Africa be next?' *PLoS Med (*2006) 197.

impaired by a lack of transparency, weak regulatory control, and the preponderance of corruption in the public pharmaceutical sector[14] which negatively impact health outcomes, weaken the nation's economy, and decrease public trust in the government. Corruption, defined by Transparency International as "the abuse of entrusted power for private gain"[15], was identified as one of the major reasons for the preponderance of counterfeit drugs in Nigeria, in addition to inadequate legislation, ineffective enforcement of existing laws, non-health professionals in the drug business, loose control systems, high cost of drugs, greed, and ignorance[16]. Examples of corrupt practices that facilitated counterfeiting of drugs included extortion of bribes from applicants for drug registration, deliberate over-supply of drug samples for resale, and acceptance of perquisites and material gifts from companies being inspected, to name a few. Counterfeit drugs are defined by the WHO as those that are "deliberately and fraudulently mislabeled with respect to identity and/or source" [17]. Counterfeit drugs fall under the general umbrella of substandard drugs genuine products which do not meet the quality specifications set for them[18]. Counterfeited drug preparations in Nigeria included those without active ingredients, toxic preparations, expired drugs that were relabeled, drugs issued without complete manufacturer information, and drugs that were unregistered with NAFDAC. Over the past decade and a half, Nigeria struggled to curtail the production and trafficking of counterfeit drugs without adequate infrastructure or the political will to properly enforce legislation and standards.

In 2001, under the leadership of Dr. Dora Akunyili as the new Director General of the NAFDAC, the agency underwent dramatic restructuring and reform such as the re-orientation

---

[14] JC Cohen, 'Pharmaceuticals and corruption: a risk assessment' *Global Corruption Report 2006* London, Transparency International (2006)77-84.

[15] Ibid

[16] WO Erhun, 'Drug regulation and control in Nigeria: the challenge of counterfeit drugs' *J Health Popul Dev Ctries (*2001) 3-4.

[17] PN Newton (n13) 199

[18] The National Agency for Food and Drug Administration and Control (NAFDAC) 'Fake Drugs and Substandard Regulated Products' <http://www.nafdacnigeria.org/identified.html> accessed 6th August 2025.

and retraining of NAFDAC staff, establishment of more NAFDAC state offices, refurbishment of drug analysis laboratories, stricter enforcement of drug regulations, public confiscation and destruction of counterfeit drugs, and public awareness campaigns[19]. The aim was to a revitalize NAFDACs mandate to "safeguard the health of the nation". As a result, the circulation of counterfeit drugs was reported to have been reduced by over 80% from what it was in 2001[20], the amount of drugs unregistered by NAFDAC in circulation was reduced from 68% to 19%, and the production capacity of local pharmaceutical industries increased tremendously[21]. Prior to these reforms, the presence of counterfeit drugs had an obvious and detrimental impact on those who used them inadvertently. In 1990, 109 children died as a result of taking paracetamol syrup produced with toxic ethylene glycol instead of propylene glycol, a tragedy that occurred more than 50 years after its occurrence in the United States. Despite NAFDAC's reported successes, examples of the spread and impact of counterfeit drugs in Nigeria still abound. In 2004, 3 Nigerian hospitals reported cases of adverse reactions from the use of contaminated infusions produced by 4 Nigerian companies[22]. It was confirmed that the infusions were heavily contaminated with microorganisms and 147 of the 149 brands of screened water for injection were found to be unsterile. Many of the other substandard drug products in Nigeria were/are present as a result of bad manufacturing practices and weak regulatory control[23]. Also previous studies in Nigeria generally reported poor knowledge and practice of PV and ADRs reporting. A study among 350 resident doctors

---

19 The National Agency for Food and Drug Administration and Control (NAFDAC), 'Journey So Far' <http://www.nafdacnigeria.org/journey.html> accessed 6th August 2025.

20 Ibid

21 The National Agency for Food and Drug Administration and Control (NAFDAC), 'Gains' <http://www.nafdacnigeria.org/gains.html> accessed 6th August 2025.

22 D Akunyil, 'Counterfeit and Substandard Drugs, Nigeria's Experience: Implications, Challenges, Actions and Recommendations, In *Talk for NAFDAC at a Meeting for Key Interest Groups on Health* The World Bank (2005).

23 O Shakoor and others, 'Assessment of the incidence of substandard drugs in developing countries' *Trop Med Int Health (*1997) 39-45.

in 4 teaching hospitals in Edo and Lagos States of Nigeria[24] reported that most of them (78.1%) had inadequate knowledge of Pharmaco-vigilance (78.1%), and were unaware of the yellow form for reporting ADRs (71.2%). And while most of them (92.4%) had observed ADRs in the course of their training and practice, only 25.5% of cases were reported. Similarly, a study among community pharmacists by Oreagba[25], found that only 55% of respondents were aware of Pharmaco-vigilance, and of these, only 18% knew its correct definition. In addition, whereas 40% of respondents had obtained reports of ADRs from their clients at least once a month, only 20% of these had reported to relevant authorities, and only 3% actually reported to the National Pharmaco-vigilance Centre. A study among patent medicine vendors (PMVs) in Ekiti State, Nigeria,[26] reported very low ADRs reporting (3.8%) and this was majorly attributed to lack of training on ADRs reporting (92.5%) and fear of indictment (61.3%). While these findings elucidate the importance of assessment of knowledge and practice of Pharmaco-vigilance among health care providers by identifying the factors responsible for the weak Pharmaco-vigilance system in the country, it emphasizes the need to conduct such studies in other parts of the country where such studies have not been carried out to know the local pattern and peculiarities. This would contribute significantly in generating vital information for designing appropriate strategies for developing strong systems and optimal ADRs reporting in such places.

This study therefore emerges as a response to the growing gap between pharmaceutical expansion and consumer protection. It seeks to understand the legal responsibilities of pharmaceutical companies, the effectiveness of the existing pharmaco-vigilance system, and the institutional capacity to detect, report, and respond to ADRs. By focusing on the Nigerian

---

[24] JO Ohaju-Obodo, OI Iribhogbe, 'Extent of pharmacovigilance among resident doctors in Edo and Lagos States of Nigeria' *Pharmacoepidemiol Drug Saf* (2010) 1-5.

[25] IA Oreagba and others, 'The knowledge, perceptions and practice of pharmacovigilance amongst community pharmacists in Lagos State, South West Nigeria' *Pharmacoepidemiol Drug Saf* (2011) 20.

[26] O Awodele and others, 'Pharmacovigilance amongst patent medicine vendors (PMVs) in Ekiti State, Nigeria' *Int J Risk Saf Med* (2012) 65-72.

context, the research addresses both the structural weaknesses and the potential for reform in the legal and regulatory framework governing drug safety.

1.3 STATEMENT OF THE PROBLEM

Adverse drug reactions contribute significantly to morbidity and mortality in Nigeria, with rates in hospital in patients reaching around 10 % (e.g. LASUTH recorded 10.7 per 100 patients)[27]. Despite this prevalence, under reporting is endemic: only roughly 10 % of expected ADRs are reported Nigeria submitted about 4,600 ADRs in 2024 versus an anticipated 46,000 by WHO standards[28]. Health care professionals and pharmacists often lack awareness of reporting procedures, and formal pharmaco-vigilance systems remain weak or under resourced[29]. At the same time, regulatory enforcement is undermined by corruption, fragmentation, and political interference, limiting the ability to hold pharmaceutical companies responsible for defective, substandard or counterfeit products. This creates a gap between the legal liability regime and actual accountability when ADRs occur. The research seeks to clarify this gap: what legal frameworks exist, how they function, and why victims of ADRs rarely hold companies liable in practice.

Research Questions

i. What legal bases exist in Nigerian law for imposing liability on pharmaceutical companies when Adverse Drug Reactions (ADR) arise?

ii. How effective is the Nigerian pharmaco-vigilance system (including ADR reporting rates, data completeness, infrastructure, enforcement)?

---

[27] WA Adedeji and others, 'Adverse drug reactions reporting practice and associated factors among community health extension workers in public health facilities, Southwest, Nigeria' *Pan African Medical Journal (*2021) 165. <https://www.panafrican-med-journal.com//content/article/40/165/full> accessed 6th August 2025.

[28] <https://punchng.com/report-adverse-drug-reactions-nafdac-urges-nigerians/?> accessed 6th August 2025.

[29] S Chinecherem and others, 2022 'Practices and Barriers towards Pharmacovigilance and Adverse Drug Reporting Among Intern Pharmacists in Nigeria' *Journal of Advances in Medical and Pharmaceutical Sciences* (2022) 27-40. <https://doi.org/10.9734/jamps/2022/v24i11587>accessed 6th August 2025.

iii. What examples or precedents are there of litigation or regulatory sanction targeting pharmaceutical companies for ADRs or faulty products?

iv. Which institutional, professional, or systemic barriers prevent effective liability and accountability?

v. What changes to law, policy, or institutional practice are needed to improve patient protection and corporate accountability?

1.4 AIM AND OBJECTIVES

Aim:

The primary aim is to examine the liability of pharmaceutical companies under Nigerian law when Adverse Drug Reactions (herein-after ADR) occur.

Consequent upon this aim, I intend to achieve it through the following objectives

Objectives:

i. Analyse Nigeria's existing laws and regulations on drug safety, pharmaco-vigilance, and product liability (including NAFDAC Act[30] and related regulations).

ii. Analyse the current pharmaco-vigilance infrastructure its strengths and weaknesses, particularly in ADR reporting and data quality.

iii. Analyse judicial activism on regulatory enforcement against pharmaceutical companies.

iv. Identify practical and institutional barriers impeding holding pharmaceutical companies accountable.

v. Getting lessons from other jurisdictions towards reforms and the improvement of ADR responses.

1.5 SCOPE AND LIMITATIONS OF THIS STUDY

The **scope of this study** is clearly defined within the parameters of public health law, pharmaceutical regulation, and civil liability in the Nigerian legal and health care context. It

[30] Cap N1 LFN 2004.

addresses the systemic, legal, and institutional frameworks surrounding adverse drug reactions (ADRs), focusing on the responsibility of pharmaceutical companies and the gaps in Nigeria's pharmaco-vigilance system. Jurisdictionally, the research is limited to **Nigeria**, examining the Nigerian regulatory landscape, health care reporting culture, and legal institutions responsible for drug safety. The relevant bodies in this context include the **National Agency for Food and Drug Administration and Control (NAFDAC)**, the **National Pharmaco-vigilance Centre (NPC)**, and Nigerian civil courts that interpret liability claims involving pharmaceutical products. The study does not cover comparative international jurisdictions in detail, though it references global standards such as those of the **World Health Organization (WHO)** for contextual understanding.

1.6 SIGNIFICANCE OF THE STUDY

This research sheds light on the pervasive issue of under reporting of adverse drug reactions (ADRs) in Nigeria. Globally, pharmaco-vigilance systems rely heavily on ADR data to guide regulatory decisions, recall unsafe drugs, and issue warnings. However, this research highlights that less than 20% of Nigerian patients report ADRs, mainly due to ignorance, apathy, or lack of awareness. Health care professionals also contribute to this gap due to fear of legal repercussions, poor access to reporting tools, and limited understanding of reporting protocols. The under reporting issue compromises drug safety monitoring and weakens public health protection mechanisms. This is a serious gap, given Nigeria's exposure to substandard, counterfeit, and inadequately tested drugs.

The study also examines the extent and limitations of pharmaceutical companies' liability in Nigeria for ADR related damages. It reveals a significant legal vacuum in the regulation of product liability for drugs. The National Agency for Food and Drug Administration and Control (NAFDAC) is the primary regulator, but its enforcement capacity is limited by budget constraints, corruption, and poor inter-agency collaboration. Pharmaceutical

companies, both local and multinational, operate in a system where oversight is fragmented and often poorly implemented. In this context, legal liability is difficult to enforce. While companies may be held liable under civil law for unexpected and severe ADRs, predictable or disclosed reactions often do not attract liability. This means the burden often shifts to consumers and health care professionals, many of whom lack the legal literacy or resources to pursue redress. The legal significance of this research lies in its critique of Nigeria's current product liability framework and its advocacy for stronger pharmaceutical regulation. It makes a case for the establishment of explicit statutory regimes that address the duty of care owed by pharmaceutical companies to end-users. The study supports the argument that the existing patchwork of laws based on general tort principles or consumer protection statutes is insufficient to hold pharmaceutical firms accountable for harm caused by defective or inadequately tested drugs. This gap in law has serious implications for access to justice, especially for low-income victims of ADRs who cannot afford prolonged litigation or who may be unaware of their rights.

Furthermore, the research links pharmaco-vigilance to broader health governance challenges. Nigeria's pharmaco-vigilance infrastructure, anchored by the National Pharmaco-vigilance Centre (NPC), lacks nationwide reach and is often underutilized. This reduces the system's ability to gather data, analyze trends, and enforce standards. Without accurate ADR data, regulatory bodies cannot make evidence-based decisions, and pharmaceutical companies are not incentivized to improve safety practices or transparency. The research underscores the need for reforms such as compulsory ADR reporting by health professionals, simplified reporting procedures (including digital platforms), and public education campaigns to raise awareness of ADR risks.

Economically, the research outlines how weak ADR reporting and limited corporate liability can distort drug markets by allowing unsafe or poorly monitored drugs to remain on the

market. It highlights the role of corruption in distorting regulatory oversight, where pharmaceutical companies may use bribes to avoid scrutiny. This erodes public trust in health care institutions and deepens health inequalities. A strong regulatory system with clear liability rules would enhance drug quality, protect vulnerable populations, and strengthen investor confidence in Nigeria's pharmaceutical sector.

This research also calls for integration of pharmaco-vigilance into the training of health professionals. Many medical workers in Nigeria have limited understanding of ADR reporting procedures. By incorporating pharmaco-vigilance into medical and pharmacy school curricula and through continuous professional education, the health sector can build capacity to identify, document, and respond to drug-related harm. Such institutional reforms are essential for long-term change and for aligning Nigeria's pharmaco-vigilance system with international standards set by the World Health Organization (WHO).

1.7 RESEARCH METHODOLOGY

This research employs doctrinal research methods. The study relies on two primary sources of information: primary and secondary materials.

Primary sources comprise authoritative texts, online articles, legislation, and judicial decisions. Secondary sources include scholarly articles, textbooks, online resources, and other relevant publications that support the research objectives.

1.8 CONCLUSION

Addressing the multifaceted challenges surrounding ADR reporting and pharmaceutical company liability in Nigeria is paramount for strengthening the nation's health care system. The persistent issues of under reporting, stemming from factors such as knowledge gaps, attitudinal barriers, and systemic inadequacies, must be tackled head-on through targeted educational initiatives, improved reporting mechanisms, and the assurance of legal protection for reporters. Furthermore, a collaborative effort involving NAFDAC, health care

professionals, pharmaceutical companies, and the community is essential to foster a culture of accountability and vigilance. By prioritizing patient safety and regulatory compliance, Nigeria can significantly enhance its pharmaco-vigilance framework, leading to better health outcomes and a more responsible pharmaceutical industry.

CHAPTER TWO

CONCEPTUAL CLARIFICATIONS, THEORETICAL AND HISTORICAL FOUNDATION, AND LITERATURE REVIEW

2.1 CONCEPTUAL CLARIFICATIONS

i. Drug

The Food and Drugs Act[1], in its interpretation clause defines "drug" to include any substance or mixture of substances manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of disease in humans or animals, and substances intended to affect the structure or any organic function of the body. This is the general, cross-cutting definition that regulators, courts and practitioners rely on when determining whether a product is within the medicines regime and therefore subject to the safety and liability architecture discussed below. That general definition is reinforced by the NAFDAC framework, which governs registration, post-marketing surveillance and safety reporting for drug products[2]. Which applies to "drug products" as defined in the parent law and provide for suspension or cancellation of registration where quality, safety or efficacy grounds arise[3]. The National Cancer Institute defines drug as any substance (other than food) that is used to prevent, diagnose, treat, or relieve symptoms of a disease or abnormal condition. Drugs can also affect how the brain and the rest of the body work and cause changes in mood, awareness, thoughts, feelings, or behavior. Some types of drugs, such as opioids, may be abused or lead to addiction.

Once a product meets the statutory definition of a "drug," any noxious and unintended response at normal doses that is at least reasonably attributable to the drug is an ADR. If a company fails to satisfy its pharmaco-vigilance obligations, collecting reports, timely

---

1 Cap. F32 LFN 2004
2 Drug and Related Products Registration Regulations 2021
3 *Ibid* Section 7

notifying NAFDAC, updating labeling and risk information, or initiating recalls when indicated, NAFDAC can impose administrative measures up to suspension or cancellation of registration, while injured consumers can pursue civil claims under the FCCPA's[4] defective-product provisions and under tort law for negligent failure to warn or to take reasonable care in post-marketing surveillance.

ii. Adverse Drug Reactions

An **adverse drug reaction** (ADR) is defined as a noxious, unintended response to a medicine. While some are relatively minor, others can be life-altering or even fatal. ADRs are different from side effects, which tend to be more predictable. It is well established, for example, that diarrhoea and sickness are potential side effects of many antibiotics.[5]

ADR can also be defined as 'an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product.'[6] Adverse drug reactions are classified into six types (with mnemonics): dose-related (Augmented), non-dose-related (Bizarre), dose-related and time-related (Chronic), time-related (Delayed), withdrawal (End of use), and failure of therapy (Failure). Timing, the pattern of illness, the results of investigations, and re-challenge can help attribute causality to a suspected adverse drug reaction.[7]

The importance of ADR reporting lies in its role in pharmaco-vigilance, which is essential for identifying and mitigating potential safety risks associated with medications. In Nigeria, the awareness and reporting of ADRs are critical issues that impact patient safety and health care practices.

---

4 Federal Competition and Consumer Protection Act 2018

5 A guide to adverse drug reaction reporting, <https://www.pharmaceuticalpress.com/resources/article/a-guide-to-adverse-drug-reaction-reporting/> accessed 17th August 2025.

6 R Edwards, J K Aronson, 'Adverse drug reactions: definitions, diagnosis, and management' <https://pubmed.ncbi.nlm.nih.gov/11072960/> accessed 17th August 2025.

7 R Edwards (n6)

iii. Pharmaceutical Liability

The liability of pharmaceutical companies for damages arising from adverse drug reactions (ADRs) is a complex and often contentious issue in Nigeria. Civil liability typically depends on whether the side effects of a drug are deemed normal and predictable to consumers. Precedents from the Superior Court of Justice (STJ) suggest that if ADRs are considered inherent to the medication and foreseeable, the pharmaceutical company may be exempt from civil liability; conversely, if the reactions are unexpected or severe, the company could be held liable for damages[8].

The regulation of pharmaceutical companies in Nigeria is primarily overseen by the National Agency for Food and Drug Administration and Control (NAFDAC), which is responsible for ensuring that drugs on the market are genuine, safe, and effective[9]. Despite existing regulations, challenges remain in enforcing accountability among pharmaceutical manufacturers, particularly regarding the reporting and management of ADRs. Many health care professionals express a willingness to report ADRs; however, systemic issues such as the lack of accessible reporting forms and insufficient training hinder effective pharmaco-vigilance[10].

It is crucial for pharmaceutical companies to adhere strictly to the drug development process, including thorough investigation of potential side effects during clinical trials. Proper due diligence during this phase not only aids in mitigating liability risks but also enhances the safety and efficacy of medications before they reach the market. Moreover, the absence of

---

8 YK Avong and others, 'Addressing the under-reporting of adverse drug reactions in public health programs controlling HIV/AIDS, Tuberculosis and Malaria: A prospective cohort study' <https://pmc.ncbi.nlm.nih.gov/articles/PMC6104922/> accessed 17th August 2025.

9 A Rohlfs, 'Adverse Drug Reaction: The Complex Question Of Civil Liability' <https://rucrlaw.com/en/pharmaceutical-companies-liability-drug-effects/> accessed 17th August 2025.

10 A Umeike, 'Market dynamics and legal implications: analyzing product liability in Africa's medical device sectors' <https://www.ibanet.org/market-dynamics-legal-africa-medical-device> accessed 17th August 2025.

explicit product liability laws in Nigeria means that consumer protection relies heavily on general laws that safeguard against unsafe products, which underscores the importance of proactive compliance by pharmaceutical firms[11].

Ultimately, the relationship between pharmaceutical companies and their liability for ADRs in Nigeria hinges on both legal precedents and the evolving landscape of regulatory practices, necessitating that companies remain vigilant in their legal and ethical obligations to consumers[12].

iv. Pharmaco-vigilance

The term pharmaco-vigilance connotes varied meaning to different health stakeholders in the field of science. Notwithstanding, it must revolves round adverse effect of drugs. In line with this, pharmaco-vigilance is a process that encompasses all the activities involves in the monitory, testing, surveying drugs to prevent it's negative effect on patients. In same similitude[13] contended that pharmaco-vigilance (PV or Phv) is also called drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and preventing of adverse effects with pharmaceutical products. Pharmaco-vigilance is a special branch of science that is concern with drug safety. In light of this,[14] emphasis that pharmaco-vigilance heavily focuses on Adverse Drug Reactions (ADRs), which are defined as any response to a drug which is noxious and unintended, including lack of efficacy. It can also be a special field of study that is concern with effect-and-benefit analyses to drug, that is, it is geared towards ensuring a possible removal of adverse drug effect on patients. Pharmaco-vigilance is concern with overseeing the chain of activities from the production point of the

---

[11] MA Eruaga and others, 'Pharmacovigilance in Nigeria: Addressing challenges in ensuring drug safety and monitoring adverse effects' <https://gsconlinepress.com/journals/gscarr/content/pharmacovigilance-nigeria-addressing-challenges-ensuring-drug-safety-and-monitoring-adverse> accessed 17th August 2025.

[12] Overcoming Regulatory Challenges in the Pharmaceutical Industry in Nigeria, <https://businesscardinal.com/overcoming-regulatory-challenges-in-the-pharmaceutical-industry-in-nigeria/> accessed 17th August 2025.

[13] K Akarowhe, 'A Case Study of Pharmaco-vigilance in Nigeria:Challenges and Solutions' *American Journal of Biomedical Science & Research* (2020) 36.

[14] *Ibid*

drug to the final consumption of same drug by the patients and giving necessary feedback to producers on the need to improve, discard drugs proven to have adverse negative effect on their health. Pharmaco-vigilance is the ongoing process to monitor drug safety and to make available new information and knowledge about ADRs[15]. This entails the fact that it involves the acting of inculcating desirable skills and competence on a person through awareness through safety measures. Pharmaco-vigilance is a cyclic process of signal detection, signal strengthening and follow up ISoP[16]. In the same vein, it has been opined that pharmaco-vigilance is aimed at early recognition of previously unknown adverse drug reactions (ADRs), recognition of frequency of known ADRs, identification of risk factors and mechanism of ADRs, quantitative analysis of benefit/ risk ratio and dissemination of safety information for rational drug prescribing and regulation. While medication errors and product quality concerns have always been important aspects of drug safety surveillance, their integration into pharmaco-vigilance systems has increased in recent years[17]. The scope of drug safety surveillance is expansive and is becoming increasingly complex because the safety of a medicine is related not only to its pharmacological properties but also to how it is used in actual practice and to the integrity of the product's quality throughout the supply chain. Pharmaco-vigilance is concerned with identifying the health hazards associated with pharmaceutical products and with the aim of minimizing the risk of any harm/hazard that may come to patients[18]. It is pertinent to point out that, it tend to assist in marketability of a given pharmaceutical drug to a target population through a techniques of removal of adverse effect on a drug. Nigeria been admitted into the WHO International Drug Monitoring Programme in 2004, marked a new era of pharmaco-vigilance in Nigeria[19]. The National

---

15 KC Santosh and others, 'Pharmaco-vigilance: An Overview' *Journal of Pharmaceutical Science* (2011) 40.
16 K Akarowhe (n13) 40.
17 JG Dal Pan, 'Ongoing Challenges in Pharmacovigilance' *Drug Saf* (2014) 30.
18 K Akarowhe (n13)
19 A Olowofela and others, 'Pharmaco-vigilance in Nigeria: An Overview' *Pharmaceutical Medicine* (2006) 87-94.

Pharmaco-vigilance Centre (NPC), which is an offspring under the National Agency for Food and Drug Administration and Control (NAFDAC) is charged with the task of pharmaco-vigilance in Nigeria. NPC serves as a repository for reported adverse drug reactions from health workers and also liaises with other international groups such as the WHO, US Food and Drug Administration and the European Medicines Agency in improving drug safety in Nigeria[20].

2.2 THEORETICAL FRAMEWORK

The theoretical foundation for the liability of pharmaceutical companies in Nigeria concerning adverse drug reactions (ADRs) is a critical aspect of the country's evolving legal landscape, influenced by both national legislation and international standards. As the Nigerian pharmaceutical industry grows, so does the importance of ensuring the safety and efficacy of drugs, particularly as the incidence of ADRs can have serious implications for public health and consumer rights. The National Agency for Food and Drug Administration and Control (NAFDAC) plays a pivotal role in regulating this sector, aiming to protect consumers from harmful medications and enhance accountability among pharmaceutical firms[21]. Historically, Nigeria's regulatory framework has faced challenges, with early legislation like the Poisons and Pharmacy Act of 1990 focusing primarily on substance regulation rather than establishing clear liability standards for pharmaceutical companies. The landscape began to shift significantly with the enactment of the Federal Competition and Consumer Protection Act (FCCPA) in 2019[22], which introduced a more comprehensive approach to consumer protection and product liability, specifically addressing issues arising from pharmaceuticals. Additionally, judicial precedents have emerged, increasingly holding pharmaceutical companies accountable for ADRs, though the reliance on foreign legal

---

[20] *Ibid*

[21] NLC, 'Regulatory Compliance For Nigerian Pharmaceutical Companies You Need To Know' <https://nigerianlawyerscenter.com/blog/regulatory-compliance-for-nigerian-pharmaceutical-companies-you-need-to-know/> accessed 17th August 2025.

[22] Federal Competition and Consumer Protection Act, 2018.

principles highlights the need for further development of domestic case law in this area[23]. Key controversies surrounding this issue include the ethical implications of clinical trials, particularly the Pfizer Kano trial of 1996, which raised significant concerns about informed consent and regulatory compliance in the testing of new drugs[24]. This case exemplifies broader issues within the Nigerian pharmaceutical sector, including the under reporting of ADRs due to inadequate awareness and training among health care professionals and patients. As such, improving regulatory frameworks and public health education remains essential to enhance the accountability of pharmaceutical companies and safeguard consumer health in Nigeria. In summary, the liability of pharmaceutical companies for ADRs under Nigerian law is rooted in tort principles, encompassing both negligence and product liability claims. The increasing scrutiny of pharmaceutical practices, reinforced by regulatory changes and growing public awareness, underscores the need for effective mechanisms to ensure safety and accountability in the industry. The ongoing evolution of this legal framework is critical to fostering a safer health care environment for Nigerian consumers.

The liability of pharmaceutical companies in Nigeria concerning adverse drug reactions (ADRs) is primarily rooted in tort law, particularly the doctrines of negligence and product liability. Negligence claims typically require the plaintiff to establish that the pharmaceutical company breached a duty of care owed to the patient, leading to harm due to an adverse drug reaction[25]. In contrast, product liability claims can arise from defects in the pharmaceutical

---

[23] HA Okeri, E Okeri, 'Medicinal Products Liability of the Pharmacists: An Overview of Some Emerging Legal Issues in Nigeria' <https://www.longwoods.com/content/19597/world-health-population/medicinal-products-liability-of-the-pharmacists-an-overview-of-some-emerging-legal-issues-in-nigeri> accessed 17th August 2025.

[24] NAFDAC, 'Pharmaco-vigilance FAQ's' <https://nafdac.gov.ng/about-nafdac/nafdac-organisation/directorates/pharmacovigilance-pv-directorate/pharmacovigilance-faqs/> accessed 17th August 2025.

[25] Intra Hub, 'Why Embracing Pharmaco-vigilance Compliance is the Key for African Pharma Companies to Compete Globally' <https://www.intrahub.africa/blog/our-blog-1/why-embracing-pharmacovigilance-compliance-is-the-key-for-african-pharma-companies-to-compete-globally-2> accessed 17th August 2025.

products themselves, where the plaintiff must demonstrate that the product was not safe for use as intended[26].

Central to the liability of pharmaceutical companies is the concept of informed consent, which has evolved over time. Pharmaceutical companies are expected to ensure that participants in clinical trials are fully informed about the potential risks and benefits of the medication they are testing. A failure to meet these obligations can lead to significant legal repercussions, including the possibility of lawsuits for informed consent misconduct[27]. The legal framework governing informed consent is essential for protecting the rights of trial participants and for upholding the broader "right to health" as articulated in international human rights documents.

Pharmaceutical companies are required to engage in robust pharmaco-vigilance practices to monitor the safety of their products post-marketing. This involves detecting, assessing, and preventing adverse effects associated with medications, which is crucial given that ADRs may not become apparent until a drug has been widely used by diverse populations[28]. Inadequate pharmaco-vigilance can lead to significant patient safety risks, as potential harmful effects may not be identified and addressed promptly. The World Health Organization (WHO) defines an ADR as a noxious and unintended response to a medicine that occurs at doses normally used in humans. This underscores the necessity for pharmaceutical companies to maintain comprehensive safety monitoring systems. Failure to fulfill these responsibilities can lead to legal actions claiming negligence due to the breach of duty.

---

[26] *Ibid*

[27] Vanguard News, 'NAFDAC intensifies efforts to strengthen Pharmacovigilance in Nigeria' <https://www.vanguardngr.com/2025/05/nafdac-intensifies-efforts-to-strengthen-pharmacovigilance-in-nigeria/> accessed 17th August 2025.

[28] IJ Onakpoya and others, 'Post-marketing withdrawal of 462 medicinal products because of adverse drug reactions: a systematic review of the world literature' *BMC Med* (2016) 10.

When an ADR occurs and it is found that a pharmaceutical company did not meet the established safety standards or reporting requirements, this can result in legal ramifications. Courts often examine whether the company acted in accordance with prevailing regulations and industry standards concerning the monitoring and reporting of ADRs. A breach of duty may be substantiated if it can be demonstrated that the company neglected its responsibilities, leading to preventable harm to patients[29]. Moreover, the enforcement of informed consent obligations during clinical trials has also been scrutinized, particularly in cases where companies conduct trials in regions with less stringent regulations. The implications of such actions can lead to claims of negligence and breach of duty, especially if trial participants suffer adverse effects that were not adequately disclosed or managed.

2.3 HISTORICAL OVERVIEW OF DRUG REGULATION IN NIGERIA

Colonial and early post-colonial controls focused on narcotics and poisons rather than comprehensive medicines regulation. The Dangerous Drugs Act[30] retained in Nigeria's statute book set out control of narcotic drugs and psychotropics and cross-refers to the pharmacist regulator for the handling of poisons. The profession itself was governed later under the Pharmacists Council framework (1992)[31], but the older Dangerous Drugs law shows the lineage of state control over scheduled substances. Through the 1970s–1990s the core "safety, quality, efficacy" regime for all medicines coalesced under two federal Acts still cited today. The Food and Drugs Act[32] provides prohibitions on the sale of adulterated drugs and empowers the Minister to make regulations on composition, labeling and standards; in parallel, the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act[33] criminalized the manufacture, sale and distribution of counterfeit medicines

---

[29] *Abdullahi v. Pfizer*, Inc. <https://en.wikipedia.org/wiki/Abdullahi_v._Pfizer,_Inc.> accessed 17th August 2025.
[30] Cap D1 LFN 2004
[31] Cap P17 LFN 2004 which was replaced by the Pharmacy Council of Nigeria (Establishment) Act, 2022
[32] Cap F32 LFN 2004
[33] Cap C34 LFN 2004

nationwide and authorized seizures and prosecutions. Widespread circulation of fake and substandard medicines in the 1980s, regional trade frictions, and domestic poisoning incidents exposed gaps in enforcement. In response, the federal government created a dedicated regulator by Decree No. 15 of 1993, now the National Agency for Food and Drug Administration and Control Act[34]. The Act established NAFDAC to register and control drugs, inspect facilities, and prosecute offences in tandem with other bodies. Its governance design formally linked NAFDAC to sister regulators such as Standards Organization of Nigeria and NDLEA, signaling a system approach rather than a single law fix.

The Pharmacists Council of Nigeria Act of 1992[35] created the statutory regulator for pharmacy education, licenses and premises control. In 2022, that framework was repealed and replaced by the Pharmacy Council of Nigeria (Establishment) Act 2022, which modernized oversight of pharmacists, pharmacy technicians and practice premises and embedded cooperation with NAFDAC at Board level. This change matters historically because it completes the pivot from fragmented professional self-regulation to a statutory council with explicit system-wide duties across the supply chain. From 2001 the agency enforcement era intensified. Under the Obasanjo administration a new NAFDAC leadership prioritized market raids, product seizures and criminal prosecutions, and began public risk communication[36]. Contemporary official records and speeches document the scale of operations over a thousand raids and dozens of convictions in the early 2000s, illustrating a shift from paper regulation to active market surveillance. Independent academic work has

[34] Cap N1 LFN 2004
[35] Cap P17 LFN 2004
[36] 'Women Leadership In Emerging Democracy, My NAFDAC Experience', An Address By The Director General Of The National Agency For Food & Drug Administration And Control (NAFDAC), Prof. Dora Nkem Akunyili, Delivered On 29 April, 2006. <https://www.wilsoncenter.org/sites/default/files/media/documents/event/Akunyili_speech.pdf?> accessed 17th August 2025.

since evaluated both the gains and the limits of the "task force style" approach, but there is no dispute that these years reset regulatory expectations[37].

Two mass-poisoning events then marked the public health stakes and led to system refinements. In late 2008 early 2009, diethylene-glycol contaminated "My Pikin" teething mixture killed at least dozens of children; the CDC's MMWR details the federal investigation and laboratory confirmation, and contemporary media recorded the death toll and enforcement actions that followed[38]. Earlier accounts also record diethylene-glycol poisonings as a recurring international risk, underscoring why Nigeria tightened post-market controls thereafter[39].

Nigeria adopted a maiden National Drug Policy in 1990 and issued a first major revision in 2005[40] to secure access, quality assurance, local production, and rational use. To address wholesale/retail chaos that fueled counterfeiting, the Federal Ministry of Health published the National Drug Distribution Guidelines in 2012[41], with phased implementation from 2015 and subsequent updates that instruct states to establish State Drug Distribution Centres and regulate Mega Drug Distribution Centres. These instruments remain key references for supply-chain governance today.[42]

Pharmaco-vigilance was institutionalized mid-2000s. On 9 September 2004, NAFDAC launched the National Pharmaco-vigilance Centre[43] (Drug Safety Monitoring Centre) and

---

37 *Ibid*

38 CDC, 'Fatal Poisoning Among Young Children from Diethylene Glycol-Contaminated Acetaminophen Nigeria, 2008-2009' <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5848a2.htm?> accessed 17th August 2025.

39 *Ibid*

40 Federal Ministry of Health Nigeria, 'National Drug Policy' <https://policyvault.africa/wp-content/uploads/policy/NGA1477.pdf?>accessed 17th August 2025.

41 Federal Ministry of Health Nigeria, 'National Drug Distribution Guidelines 2nd Edition 2012' <https://www.medbox.org/document/national-drug-distribution-guidelines-2nd-edition-2012?> accessed 17th August 2025.

42 A closer look at the new national drug distribution guidelines, <https://pharmanewsonline.com/a-closer-look-at-the-new-national-drug-distribution-guidelines/?> accessed 17th August 2025.

43 KO Cliff-Eribo and others, 'Adverse drug reactions in Nigerian children: a retrospective review of reports submitted to the Nigerian Pharmaco-vigilance Centre from 2005 to 2012' *Paediatr Int Child Health* (2016) 300-304.

Nigeria became the 74th full member of the WHO Programme for International Drug Monitoring managed by Uppsala Monitoring Centre. This anchoring in the WHO system is now standard for post-marketing safety and signal detection.

The wider enforcement landscape also includes the National Drug Law Enforcement Agency (NDLEA), established in 1989 to control narcotic drugs and psychotropic substances, complementing NAFDAC's quality and safety remit. The NDLEA Act's continued presence signifies the long-standing bifurcation between medicine regulation and narcotics law enforcement within Nigeria's "drug" governance.[44]

2.4 LITERATURE REVIEW

Research on ADR reporting and pharmaco-vigilance in Nigeria shows a persistent gap between regulatory expectations and front line practice. Several peer-reviewed studies and program reports document low reporting rates among clinicians and other health workers, gaps in knowledge about how and what to report, and variable completeness of reports submitted to NAFDAC. These empirical works examine determinants (awareness, training, workload, reporting channels) and recommend system strengthening training, clearer reporting procedures, and active surveillance because spontaneous reporting remains the main safety signal source in Nigeria.[45]

Case studies of major poisoning events remain central to the literature because they show how regulatory failure and supply-chain vulnerabilities translate into mass harm. The 2008-2009 "My Pikin" diethylene-glycol (DEG) contaminated teething syrup outbreak is the leading empirical reference point: CDC's MMWR report and later clinical and toxicology studies document dozens of child deaths, laboratory confirmation of DEG contamination, and the public-health and enforcement aftermath. Subsequent medical articles have revisited the

---

[44] Sherloc, 'Decree No. 48 of 1989 on the establishment of the National Drug Law Enforcement Agency'<https://sherloc.unodc.org/cld/en/legislation/nga/decree_no._48_of_1989_on_the_establishment_of_the_national_drug_law_enforcement_agency/articles_11-14/decree_48.html?> accessed 17th August 2025.

[45] SC Eze and others, 'Assessment of pharmaco-vigilance activities among pharmacist interns in Nigeria: a cross-sectional study' *Futur J Pharm Sci* (2023) 11.

My Pikin episode to analyse clinical effects and trace contamination sources, and these works are regularly cited in legal arguments about foresee-ability, quality controls and criminal/regulatory accountability.[46]

Legal and doctrinal literature assesses how Nigeria's statutory architecture frames private remedies for ADR harms. Since the FCCPA 2018, scholarship has focused on whether Nigeria has moved toward a stricter consumer protection regime for defective products and what that means for medicines. Law firm analyses, practitioner notes and academic articles examine the interplay between common law negligence/contract, criminal offences (Food and Drugs Act; Counterfeit and Fake Drugs Act) and the FCCPA's product-liability provisions. Several authors argue that FCCPA's provisions and modern consumer policy shift Nigeria closer to strict or statutory liability for defective goods, thereby lowering barriers for injured consumers even though practical obstacles (expert evidence, causation, enforcement resources) remain. These doctrinal treatments are essential when framing civil causation strategies and remedies in ADR litigation.[47]

Policy and reform literature looks at practical remedies and system strengthening. Recent articles and policy briefs recommend better integration of pharmaco-vigilance into clinical practice, electronic and active surveillance systems, strengthening NAFDAC inspection capacity, clearer chain-of-custody and distribution regulation, and use of consumer-law remedies to create deterrence. Scholarship on product liability law similarly recommends clearer procedural pathways for mass harm claims and improved regulatory record-keeping to

---

[46] 'Fatal Poisoning Among Young Children from Diethylene Glycol Contaminated Acetaminophen Nigeria, 2008-2009'(n38)

[47] FO Ukwueze, 'Product liability in Nigeria: a paradigm shift from fault-based to strict liability regime'<https://www.researchgate.net/publication/342901515_Product_liability_in_Nigeria_a_paradigm_shift_from_fault-based_to_strict_liability_regime/citations> accessed 17th August 2025.

make civil enforcement workable. These proposals appear across public-health journals, legal commentaries and governmental guidance documents.[48]

Taken together, the literature establishes three practical points relevant to litigation and policy work. First, Nigeria has the regulatory and statutory building blocks to hold manufacturers accountable (NAFDAC framework, criminal statutes, FCCPA), but implementation gaps in pharmaco-vigilance and supply-chain oversight reduce the frequency of successful enforcement or mass civil recoveries. Second, the My Pikin event remains the paradigmatic example used to demonstrate regulatory and industry failures and to press both criminal and civil claims; it is frequently relied upon in medico-legal argument about foresee-ability and adequacy of safeguards. Third, academic and practitioner scholarship converges on recommending system and legal reforms, stronger passive and active surveillance, better record-keeping, clearer product liability pathways and more robust regulatory enforcement, as necessary to translate legal rights into compensatory and deterrent outcomes.

2.5 CONCLUSION

This chapter delves into the complex landscape of drug regulation and pharmaceutical liability in Nigeria. It begins by clarifying key concepts like "drug" (defining it broadly as any substance intended for diagnosis, treatment, or affecting bodily functions), "adverse drug reactions" (ADRs, which are noxious and unintended responses to medication), pharmaceutical liability (the responsibility of drug companies for harm caused by their products), and pharmaco-vigilance (the process of monitoring and preventing adverse effects of drugs).

It emphasizes that an ADR is a negative consequence resulting from the use of a medicinal product, posing a potential risk with future use. They are classified into six types: dose-

[48] Jackson, Etti & Edu, 'Product Liability A Crisis Of Disintegration Of The Manufacturer?' <https://oldsite.jee.africa/wp-content/uploads/2020/06/PRODUCT-LIABILITY-A-CRISIS-OF-DISINTEGRATION-OF-THE-MANUFACTURER.pdf?> accessed 17th August 2025.

related, non-dose-related, dose- and time-related, time-related, withdrawal, and failure of therapy. Detecting the cause of ADRs is vital for patient safety.The legal definition of pharmaceutical liability, especially in Nigeria, is complicated. If the side effects are considered to be normal and predictable, then the pharmaceutical company may not be held liable for damages. But if the reactions are unexpected or severe, the company can be held accountable. However, even with regulatory bodies like NAFDAC, enforcing accountability is difficult.

Pharmaco-vigilance is heavily emphasized as a critical component of drug safety. The chapter highlights the importance of monitoring, testing, and surveying drugs to prevent negative effects on patients, with a focus on adverse drug reactions (ADRs) and includes the overall drug monitoring program from production to consumption. The chapter then examines the theoretical and historical foundation of pharmaceutical liability in Nigeria. It traces the evolution of drug regulation from early laws focused on narcotics to the establishment of NAFDAC as a dedicated regulator. Historical mass poisoning events are highlighted, such as the "My Pikin" teething mixture scandal, which exposed regulatory gaps and led to system refinements. The theoretical underpinnings for this liability stem from tort law, primarily negligence and product liability. Specifically, pharmaceutical companies have a duty of care to ensure the safety of their products, and a failure to do so can result in legal repercussions. A review of existing literature reveals persistent gaps in ADR reporting and pharmaco-vigilance practices in Nigeria. Low reporting rates, lack of knowledge among health care workers, and incomplete reports are identified as key challenges. Finally, it points to the need for system reforms, stronger surveillance, better record-keeping, and more robust regulatory enforcement to improve pharmaceutical accountability.

CHAPTER THREE

LEGAL AND INSTITUTIONAL FRAMEWORKS FOR ADRs AND PHARMACEUTICAL LIABILITY IN NIGERIA

3.1 STATUTORY FRAMEWORK

3.1.1 Poisons and Pharmacy Act[1]: The Act regulates the compounding, distribution, marketing and dispensing of drugs and medicinal products in Nigeria.

3.1.2 Food and Drugs Act[2]**:** This prohibits the sale of certain drugs, foods, cosmetics and devices in some disease conditions, as well as export, import, distribution and sale of specific drugs. It further proscribes misinformation regarding drugs and the manufacture of food and drugs in unclean environments.

3.1.3 Counterfeit and Fake Drugs (miscellaneous provisions) Act[3]**:** This Act bans the production, importation, distribution and sale of any banned, counterfeit, adulterated or fake drugs in the country. It also disallows persons to sell drugs in open markets without permission from regulatory authorities

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

Prior to the establishment of NAFDAC, the Directorate of food and drug Administration and control in the federal ministry of Health was responsible for the control and regulation of food drugs, cosmetics and other regulatory products in Nigeria. Under the directorate, the regulatory structure in Nigeria had most of the necessary components expected of a regulatory authority.

Here were drug laws (with deficiencies no doubt) quality control laboratories and provision for inspection enforcement and even a fairly equipped drug manufacturing laboratory.

---

1 Cap 366 of 1990
2 Cap 150 of 1990
3 Cap 73 of 1990

However, product registration was not in place, and as such drug importation and manufacturing was a free for all affair. Drug information and adverse drug reaction monitoring processes were not also in place; hence there were no effective drug recall procedures.[4]

Despite the fact that Nigeria had a relatively well developed regulatory process, civil service bureaucracy‟ corruption, political instability and a host of other lapses averted this process. To remove these bottlenecks and ensure effectiveness, the then honourable minister of Health Prof. Olikoye Ransome kuti, directed in September 1992 that a blue print be prepared for the establishment of a food and drug regulatory agency[5].NAFDAC therefore was founded in 1993 under the country's health and safety law. The Administration set up her first governing council in 1992. NAFDAC was established by Decree 15 of 1993 as amended by Decree 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act[6]. NAFDAC replaced a former Federal Ministry of Health body, the Directorate of Food and Drug Administration and Control after it was viewed as ineffectual.

The National Agency for Food and Drug Administration and Control (NAFDAC) Act, enacted in 1992, serves as the legal framework for regulating food, drugs, and related products in Nigeria. Established in response to significant public health concerns, including the proliferation of counterfeit medications and unsafe food products, the Act empowers NAFDAC to oversee the manufacture, importation, exportation, distribution, and advertisement of these commodities, thereby safeguarding public health and ensuring product quality.[7]The establishment of NAFDAC marked a pivotal shift in Nigeria's approach to health regulation, transitioning from the ineffective Directorate of Food and Drug

---

4 WO Erhun and others (2001), 'Drug Regulation and Control in Nigeria: The Challenges of Counterfeit Drugs' *Journal of Health and Population in Developing Countries* (2001) 23-34.

5 *Ibid*

6 Cap N1 LFN 2004.

7 Wikipedia, 'National Agency for Food and Drug Administration and Control' <https://en.wikipedia.org/wiki/National_Agency_for_Food_and_Drug_Administration_and_Control> accessed 23rd August 2025.

Administration and Control to a more structured and accountable agency tasked with critical oversight functions.[8]. A prominent feature of the NAFDAC Act is its emphasis on pharmaco-vigilance the ongoing monitoring and evaluation of drug safety, particularly concerning adverse drug reactions (ADRs). As ADRs pose significant health risks and can lead to increased morbidity and mortality, the Act mandates the implementation of robust reporting systems and continuous monitoring to address these issues effectively.[9]

Despite these provisions, challenges persist, including under reporting of ADRs by health care professionals and ongoing concerns about regulatory capture, where enforcement may be compromised due to external influences. Furthermore, the NAFDAC Act encompasses strict guidelines for pharmaceutical liability, allowing the agency to prohibit the manufacture and sale of counterfeit and substandard drugs[10].The enforcement mechanisms established under the Act are crucial for maintaining compliance among pharmaceutical companies; however, the effectiveness of these measures has been questioned due to inadequate resources and weak penalties for violations, which undermine public trust and safety in drug regulation. In recent years, NAFDAC has pursued amendments to its legal framework to enhance its operational capacity and address evolving health challenges, particularly concerning the efficacy of pharmaco-vigilance and the regulation of

---

8 SRJ, 'Impact Of NAFDAC's Revised Policy On Small And Medium Enterprises In Nigeria' <https://srjlegal.com/impact-of-nafdacs-revised-policy-on-small-and-medium-enterprises-in-nigeria/> accessed 23rd August 2025.

9 Section 11 National Agency for Food and Drug Administration and Control (NAFDAC Act) Cap N1, LFN, 2004

10 Federal Ministry of Health Nigeria, 'Nigerian National Pharmaco-vigilance Policy and Implementation Framework' <https://msh.org/wp-content/uploads/2021/03/nigerian_national_pharmacogilance_policy_implementation_framework.pdf> accessed 23rd August 2025.

pharmaceuticals[11]. These developments underscore the agency's ongoing commitment to improving public health outcomes in Nigeria amidst persistent challenges in enforcement and accountability.

3.1.5 Pharmacists Council of Nigeria Act

The Pharmacists Council of Nigeria Act, enacted in 1992, is a pivotal piece of legislation that establishes the legal framework for the regulation of the pharmaceutical profession in Nigeria. This Act plays a critical role in overseeing the registration, discipline, and professional standards of pharmacists, thereby ensuring the delivery of safe and effective pharmaceutical care in the country[12].Given the significant impact of pharmaceutical practices on public health, the Act's provisions are crucial for addressing public concerns regarding Adverse Drug Reactions (ADRs) and pharmaceutical liability, highlighting its importance in the Nigerian health care system. The primary aim of the Pharmacists Council of Nigeria Act is to regulate the conduct of pharmacists, mandating adherence to educational, training, and practice standards. By enforcing these standards, the Act seeks to minimize the incidence of ADRs and enhance accountability among pharmacy professionals, thereby safeguarding the health of the Nigerian populace.

The establishment of the Pharmacists Council of Nigeria as the regulatory body under the Act allows for the effective monitoring and implementation of these essential standards. The Act empowers the Council to create rules and regulations that govern the pharmaceutical profession, with oversight provided by the Pharmaceutical Society of Nigeria. This regulatory framework includes provisions for professional discipline, public tribunal proceedings, and

---

[11] NAFDAC, 'Nigerian Guidelines for Detecting & Reporting of Adverse Reactions For Pharmaceutical products and Medical Devices' <https://www.nafdac.gov.ng/wpontent/uploads/Files/Resources/Guidelines/PVG_GUIDELINES/Nigerian-Guidelines-for-Detecting-and-Reporting-of-Adverse-Reactions-for-Pharmaceutical-Products-and-Medical-Devices.pdf> accessed 23rd August 2025.

[12] Section 17 Pharmacy Council of Nigeria (Establishment) Act, 2022

penalties for misconduct, reinforcing the integrity and accountability of pharmacy practice in Nigeria[13].

These measures are particularly relevant in addressing controversies surrounding pharmaceutical liabilities, ensuring that pharmacists are held to high professional standards. Additionally, the Act outlines financial provisions for the Council's operations, mandating the establishment of a fund supported by registration fees and contributions from pharmaceutical establishments. This financial framework is vital for the Council's operational sustainability, enabling it to fulfill its regulatory duties effectively and promote safe pharmaceutical practices across Nigeria[14]. Through these mechanisms, the Pharmacists Council of Nigeria Act not only facilitates the professional regulation of pharmacists but also serves as a safeguard for public health against potential pharmaceutical-related risks.

3.1.6 Consumer Protection Act (Federal Competition and Consumer Protection Act 2018)FCCPA

The FCCPA is the primary federal statute on consumer protection and competition. It establishes the Federal Competition and Consumer Protection Commission (FCCPC) and the Competition and Consumer Protection Tribunal (CCPT). The Act applies economy-wide and prevails in consumer protection matters over conflicting enactments unless otherwise provided. Core consumer rights and implied guarantees relevant to medicines and health products. The FCCPA creates baseline rights and implied warranties that apply to “goods,” which includes medicines and medical devices. Of particular relevance:

- a statutory right to return goods that fail to meet mandatory standards or are defective[15];

---

[13] Harlem Solicitors, ‘A Circumspect View Of The PCN Act, 2022 and Pharmaceutical services in Nigeria’ <https://www.harlemsolicitors.com/2023/06/17/a-circumspect-view-of-the-pcn-act-2022-and-pharmaceutical-services-in-nigeria/> accessed 23rd August 2025.

[14] Sections 5,6,7 Pharmacy Council of Nigeria (Establishment) Act, 2022

[15] Section 122 Federal Competition and Consumer Protection Act, 2018.

- an implied warranty that goods are of good quality, in good working order, free from defects, and compliant with applicable standards[16]; and
- express product-liability provisions[17]. Part XVI of the FCCPA codifies product-liability rules. The enacted text expressly provides "Liability for defective goods" and restricts exclusion/limitation clauses[18]. The same Part also addresses "product liability" and "warnings concerning the use of goods," which are directly engaged for pharmaceuticals and devices. NAFDAC's enabling statutes sit alongside the FCCPA and supply safety/quality baselines that feed into FCCPA liability analysis and remedies:
- Food and Drugs Act[19], regulates manufacture, sale, labeling and advertisement of drugs, cosmetics and devices. Non-compliance supports FCCPA breach and tort claims.
- Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act[20], criminalizes production and distribution of counterfeit/adulterated or expired drugs and establishes federal/state task forces. Evidence of breach is powerful in civil claims and FCCPC enforcement.
- Standards Organization of Nigeria Act 2015 empowers SON to enforce product standards and run certification/inspection schemes. Where a drug fails a compulsory standard, that non-conformity underpins the FCCPA's implied guarantees and defect analysis[21].

Nigerian courts continue to apply negligence principles given in *Donoghue v*

---

16 Federal Competition and Consumer Protection Act, 2018 s. 132
17 *Ibid* section 136
18 Section 137 Federal Competition and Consumer Protection Act, 2018.
19 Cap F32 LFN 2004
20 Cap C34 LFN 2004
21 Section 5 Standards Organization of Nigeria Act 2015

Stevenson[22] case. The Supreme Court has recognized manufacturer liability to consumers (including where the retailer is intermediate). Two useful authorities to cite in a pharma-adjacent liability discussion are: *Nigerian Bottling Co Ltd v Ngonadi*[23] and *Okwejiminor v Gbakeji & Nigerian Bottling Co Plc*[24], both analyzed in practitioner texts and academic pieces. They remain the leading expositions on manufacturer duty of care and causation in consumer product injury.

3.2 Legal Principles Governing Liability of Pharmaceutical Companies (Negligence, product liability, strict liability)

The legal principles governing the liability of pharmaceutical companies are critical to understanding the accountability mechanisms in the health care sector. These principles encompass various forms of liability, including negligence, strict liability, and breach of statutory duty, each reflecting distinct standards for assessing manufacturers' and sellers' responsibilities when their products cause harm to consumers. The pharmaceutical industry is notable for its complex regulatory environment and the high stakes involved in ensuring public safety, making the implications of liability particularly significant.

Negligence represents a different legal theory in which liability arises from the failure of a manufacturer or seller to exercise reasonable care in the product's design, manufacture, or distribution. To establish a negligence claim, the injured party must prove that the defendant owed a duty of care, breached that duty, and that this breach directly resulted in harm to the plaintiff[25]. In the context of pharmaceutical companies, this might involve inadequate testing

---

22 [1932] A.C. 562
23 [1985] 1 NWLR (Pt 4) 739
24 [2008] 5 NWLR (Pt 1079) 172
25 Sarah Lee, 'Navigating Pharmaceutical Liability Law' <https://www.numberanalytics.com/blog/navigating-pharmaceutical-liability-law> accessed 23rd August 2025.

of drugs, failure to provide sufficient warnings, or not adhering to regulatory requirements, thereby exposing consumers to unnecessary risks[26].

In contrast, Strict liability is a legal doctrine that holds manufacturers and sellers accountable for defective products, irrespective of whether negligence is proven. Under strict liability principles, the focus shifts from the conduct of the manufacturer or seller to the defectiveness of the product itself. If a pharmaceutical product is found to be defective and causes injury, the responsible party can be held liable without the need to demonstrate fault or negligence[27]. This doctrine underscores the responsibility of all parties involved in bringing a product to market, ensuring that they uphold rigorous safety standards[28].

Breach of warranty is a third legal theory that is relevant to pharmaceutical liability law. It refers to the failure of a drug manufacturer or supplier to fulfill their promises or guarantees about the safety and effectiveness of a drug. To establish a breach of warranty claim, a plaintiff must show that the defendant made a warranty or representation about the drug, that the warranty or representation was false or misleading, and that the plaintiff relied on the warranty or representation to their detriment.[29]For example, if a drug manufacturer advertises a medication as being safe and effective for a particular condition, but it is later found to cause serious side effects, the manufacturer may be held liable for breach of warranty.

As the landscape of pharmaceutical liability continues to evolve, emerging trends such as changes in regulatory frameworks, class action mechanisms, and the impact of artificial intelligence are shaping how these legal principles are applied. The increasing scrutiny from regulatory bodies and the potential for enhanced collective litigation underscore the critical

---

[26] McCune Law Group, 'Strict Liability vs. Negligence in Product Liability Cases' <https://mccunewright.com/blog/2023/10/strict-liability-vs-negligence-in-product-liability-cases/> accessed 23rd August 2025.

[27] *Ibid*

[28] Cornell Law School, ' Product liability' <https://www.law.cornell.edu/wex/products_liability> accessed 23rd August 2025.

[29] McCune Law Group (n26)

need for pharmaceutical companies to uphold rigorous safety standards and maintain transparency in their operations to mitigate liability risks in this ever-evolving environment[30].

3.3 INSTITUTIONAL FRAMEWORKS

3.3.1 Role of NAFDAC in drug approval, surveillance, and recall

The Act that established the National Agency for Food and Drugs Administration

Control NAFDAC has spelled out the statutory functions of the agency thus;

i. Ensures Compliance to Standard[31]: The major functions of the National Agency for Food and Drugs Administration Control NAFDAC is that of ensuring compliance to standard. Going by this what National Agency for Food and Drugs Administration Control does is to carry out test in locally manufactured food and drugs and, sometimes, those food and the likes imported into the country with a view to ensure that these products meet specified standard. There is standard specifications designated to every product manufactured within Nigeria or imported into the country and until these products are approved by the council, such food or drugs is not consumable. There must be total consent by the council for the effective quality control of these goods, such as food, and drugs, and cosmetics, and medical devices, and packaged water, and chemicals, etc.

ii. Investigates Into Production Houses[32]: It has been primary functions of the National Agency for Food and Drugs Administration and Control to ensure that premises, where these good are produced are in order and hygienic. From time to time, the Agency will embarked on investigation tours to these places, where these good are manufactured, and its investigation into these production houses is always appropriate and proper. Without leaving any Stone unturned, the National Agency for Food and Drugs Administration & Control will investigate and inspect raw materials for these goods, be it food or be it drugs or be it

---

[30] Fulmer Sill, 'What Responsibility Does the FDA and Pharmaceutical Companies Have to Consumers?' <https://www.fulmersill.com/blog/what-responsibility-does-the-fda-and-pharmaceuti/> accessed 23rd August 2025.

[31] Section 5(a) National Agency for Food and Drug Administration and Control Act Cap N.1 LFN 2004

[32] Section 5(c) National Agency for Food and Drug Administration and Control Act Cap N.1 LFN 2004

cosmetics or be it chemicals or medical devices, NAFDAC would check all accurately. The National Agency for Food and Drugs Administration Control would ensure that quality assurance is established, and this include and not limited to certification of the production premises, as well as, regulated products.

iii. Inspects Imported Food[33]: In this one, you cannot fool the National Agency for Food and Drugs Administration Control, it must ensure that what comes into the country meets the standard and the specification. Some of the goods imported into the country include, imported foods, imported drugs, imported cosmetics, imported medical devices, imported bottled water, and imported chemicals among others. Just like what happened after proper investigation into the production premises, after inspection of the of the imported products, the National Agency for Food and Drugs Administration & Control would make sure that there is an establishment of the relevant quality assurance system. NAFDAC must also ensure that, there is certification of the products and regulated products.

iv. Compiles Standard Specification for Production, Importation, etc[34]: National Agency for Food and Drugs Administration & Control will always set standard specification to every product manufactured or imported. The Agency carried this function by compiling the specification and the standard of every product, in such a way that will not threaten the health of Nigerians. Apart from standard specification of products, the National Agency for Food and Drugs Administration & Control would compiled guidelines, including regulations for production, and importation, and exportation, and sale, as well as, distribution of food, and drugs, and cosmetics, and medical devices, bottled water, and chemicals among others.

v. Registration of Food and Drug Products[35]: No products within this sector can thrive without National Agency for Food and Drugs Administration & Control knowing about such

---

[33] National Agency for Food and Drug Administration and Control Act Section 5(d)
[34] Section 5(e) National Agency for Food and Drug Administration and Control Act Cap N.1 LFN 2004
[35] National Agency for Food and Drug Administration and Control Act Section 5(f)

product that is why NAFDAC itself has been in the business l registering these product. These products include, the aforementioned products, which falls within the powers of the National Agency for Food and Drugs Administration & Control, such as food, and drugs, and medical devices, and bottled water and chemicals, and etc,etc.

vi. Controls Exportation[36]: Exportation control remains one of the functions of the National Agency for Food and Drugs Administration & Control, so far such product for exportation is product controlled and regulated by the National Agency for Food and Drugs Administration & Control (NAFDAC), like food and drugs and packaged water and chemicals and medicals devices among others. NAFDAC will make sure that, quality certification of all these products for export are issued.

vii. Establishes and Maintains Laboratories[37]: One tool that is relevant to the NAFDAC is laboratories, since it is in such laboratories that products can be tested to ascertain the standard specification of such products, as well as, knowing the extent at which participants in comply efficiently to set standard, and regulations. Apart from such relevant laboratories, NAFDAC can partner with relevant institutions in strategic areas of interest within Nigeria, and such areas of interest may be necessary in aiding NAFDAC carried out its functions.

3.3.2 Factors Influencing Fake Drug Production, Sale and Demand

The influencing factors to be discussed are: non-professionals in drug business, chaotic drug distribution network, poor implementation of existing drug laws, ignorance, inefficient cooperation between stakeholders, illegal drug importation, corruption and greed, high cost of good quality drugs and demand exceeding supply.

i. Non-professionals in drug business: A study carried out by Erhun[38], showed 6 out of 7 respondents who believed that the presence of non-professionals in drug business is a major

---

36 Section 5(g) National Agency for Food and Drug Administration and Control Act Cap N.1 LFN 2004

37 *Ibid* Section 5(h)

38 WO Erhun and others, 'Drug Regulation and control in Nigeria: The challenge of counterfeit drugs' *Journal of health and population in developing countries* (2001) 23-34.

contributing factor to the availability of fake drugs in Nigeria. Under the Nigeria drug law, pharmacists have the authority to manufacture, sell, distribute, import, export, dispense and compound drugs. Community or retail pharmacists can acquire premises for sale and drug dispensing such premises are usually registered. However, we also have the non- pharmacists such as the licensed medicine vendors that are holders of "patent and proprietary medicine vendors right" which is granted to them by government, they are non-professionals who might be less capable of identifying genuine from fake drugs. The minimum academic requirement for them to obtain a license is the first school leaving certificate[39].

These vendors are only allowed to sell over the counter (OTC) drugs but rather they sell different categories of drugs both prescription and over the counter drugs as long as they will make profit from it, such drugs can include antibiotics, narcotics, toxoids and anti-hypertensive for profit purposes with no adequate monitoring systems in place to check them. Sometimes, they are seen prescribing drugs to their customers or even treating them and giving injections, these vendors are supposed to be monitored by the state ministry of health (MOH) pharmacy division. However, they are not monitored adequately because the officials can be corrupt and overlook many issues or may be incapable of the work.

ii. Chaotic drug distribution network: Drug distribution network in Nigeria consists of chaotic open markets that acts as major source for purchase to medicine stores, pharmacy outlets, private and public hospitals, wholesalers/retailers and pharmaceutical manufacturers, the result of these chaotic drug distribution makes drug monitoring very difficult. In addition, gives room to drug hawking in buses, kiosks, motor parks by illiterate vendors whose aim is profit oriented. The medicines are often time left under the sun in such conditions that could facilitate the deterioration of the active ingredients[40]. Medicines are sold just like any other commodity of trade. Poor drug regulation which has eaten deep into the system over the year,

[39] *Ibid*
[40] WO Erhun and others (n39) 30.

helped in the evolution of drug markets which are not registered premises and are well established all over the country. Most of the drug wholesalers and importers supply drugs to these open drug markets because they make more profit from there. Drug sellers, health professionals have easy access to patronize the drug markets; it also gives services to the street drug hawkers and commercial drug sellers in buses[41]. Efforts from NAFDAC, such as various raids and seizures of fakes to close the existing chaotic drug market and create an orderly Drug Distribution System suffered a set back due to its unacceptability from some pharmacists and politicians that are key stakeholders in drug matters who benefits from such open markets supports the existence[42]. According to Brains[43], drug distribution chain consists of different actors in legitimate supply chain and the illegitimate supply chain. The legitimate supply chain consists of originality of products from the designers down to consumers; it is regulated and monitored at all levels. The original designers of the brand contracts to manufacturer who produces with the aid of the trusted suppliers. The products are then bought by wholesalers for distribution, from there the authorized retailers buys and dispenses to the consumers. Moreover, in case the product did not match expected specifications; the process of recall takes place. In Nigeria, the problem with the legitimate supply chain, where good manufacturers have there products registered with good intentions is in the area of monitoring each chain network to ensure that fakers don't come in between the line to supply or sell their products portraying it as original product. Drug registration licensing in NAFDAC stops with the manufacturers, who/how, the products are distributed and sold to the wholesalers, retailers etc is supposed to be checked as stipulated in the drug laws, but such functions are not carried out, maybe due to lack of finances and workforce.

---

41 DN Akunyili, 'Fake and counterfeit drugs in the health sector' *Annals of Ibadan Postgraduate Medine* (2004) 2.

42 DN Akunyili (n41) 2.

43 Olike Chiwendu, 'The fight against fake drugs by NAFDAC in Nigeria'<https://bibalex.org/baifa/Attachment/Documents/193922.pdf> accessed 23rd August 2025.

The illegal supply chain is made up of drug faker who can copy other products and present them as original. The product design is faked with the aid of fake manufacturer in criminal organization who distributes the drugs in the market and through the internet. The products then gets to an unauthorized retailer who buys it for profit purposes even when he knows the source, dispenses the fake product to an unwilling victim of counterfeit.

iii. Poor implementation of existing drug laws/inadequate legislation:

The weakest point in Nigeria's drug regulation is probably in the area of implementation and enforcement. The harsh socio-political interplay of the country for over thirty years caused some constraint and contributed to the weakening of drug regulation that is still suffered presently. Weak regulation contributed to faking and dumping of fake products and the chaotic drug distribution network. Nigeria also has drug laws that have become overlapping and sometimes conflicting each other, these results to a legal framework that will fail to deter drug offenders or moves very slowly when allegation of wrongdoing is identified, making it difficult to try the offenders. Legislation and regulation forms the basis for drug regulation and where these two does not exist criminal activities associated with drug cannot be treated as a crime and drug counterfeiters will be encouraged to continue because there won't be any fear of being apprehended. Penalties of drug offences are not commensurate with the severity of the crime. Example, the maximum punishment for contravening the decree on fake drugs is less than N500, 000 (US $ 3,600) or a prison sentence up to 5 years, with such fines, the offender pays easily and goes back to his drug business[44]. Stiffer penalties can help sharpen the attitudes of fake drug dealers[45]. Chinese government had put stiffer penalties in their drug laws for fake drug manufacturers and sellers, such as withdrawal of company's license, prohibition from drug production up to ten years. In addition death sentence as was the case

[44] Olike Chiwendu (n43)

[45] S Ratanawijitrasin and E Wondemagegnehu, 'Effective drug regulation- A multi country study' A book published by World Health Organization (2002).

of their former director general of their State Food and Drug Administration (SFDA) who took a bribe from a company and approved some fake drugs that killed some people[46]

iv. Ignorance:

Ignorance as a factor contributing to availability of fake drugs can be due to the literacy level of population in Nigeria and it will be difficult for such people to distinguish between genuine drug products from fake and being that they want cheap and easy access to medicines, they patronize drug vendors. Others patronize because it is cheap and affordable for them and do not bother if it is genuine or not.

v. Inefficient cooperation between stakeholders:

Lack of cooperation between the regulatory authorities, and other stakeholders such as the judiciary that oftentimes delays or averts judgments, police and customs services due to conflict of interest, bribery and corrupt practices makes the control of drug markets and enforcement of drug legislation very difficult. Such inefficiencies can create avenues for a drug faker to escape detention, arrest and penal sanctions and the problem still flourishing[47]. For example when NAFDAC inspectors where told to vacate from the ports of entry by the customs who feels that they were being prevented from making extra money for themselves. It is thus, difficult for NAFDAC to stand alone in the fight against fake drug proliferation

vi. Illegal drug importation:

This is a major constraint at the ports. Some drug importers, in order to evade inspection and detection, can make false declarations about the nature/content of the products in their containers. They employ unimaginable concealment methods for their nefarious activities. In 2003, a large consignment of a controlled narcotic analgesic was concealed in T-shirts and imported from India via Lagos airport. In 2004, 32 containers of various pharmaceuticals were imported and manifested as motor vehicle spare parts. They were moved to various

[46] Olike Chiwendu (n43)
[47] Olike Chiwendu (n43)

locations within the ports to avoid detection, NAFDAC inspectors have also found drugs concealed in the inner part of containers containing textiles, candles, shoes, etc.[48]

vii. Corruption and greed:

Corruption and greed can be seen from the drug regulating authorities as well as the drug manufacturers/importers. Corruption and conflict of interests are the driving forces behind poor regulation, which, in turn encourages drug counterfeiting. The result is poor enforcement of law because the corrupt official has already collected huge sum from the drug counterfeiter, hence averting arrest and prosecution/conviction.

vii. High cost of good quality drugs:

There are higher chances for fake drug proliferation when medicine prices are high; counterfeiters take the advantage to supply cheap fake drug products to consumers especially those who cannot afford the high priced good quality version in the legal sector. A survey conducted by World Health Organization (WHO) and Health Action International (HAI) in Nigeria 2004 to determine the prices people pay for their medicines showed a high rise in the prices for example people pay between 2 to 64 times international reference prices for medicines in various health facilities. In addition, that (90.2%) majority of Nigerians cannot afford good medicines as they live below income level of US$ 2 a day[49]. The baseline survey also showed a low availability of essential medicines in the health facilities, only 46% of key medicines were found in the health facilities.[50] In Philippines, for example, there senate recently approved a bill called affordable medicines Act that will help lower the prices of drug so that it can be affordable and their domestic pharmaceutical companies to have a larger stake in their drug market. In addition, it will help reduce the incidence of imported fake drug into the country.

---

48 DN Akunyil (n41)

49 HAI Africa (2008) 'Medicine prices in Nigeria, prices people pay for medicines' <http://www.haiafrica.org/downloads/price_SDurveys/Nigeria.pdf> accessed 23rd August 2025.

50 *Ibid*

ix. Demand exceeding supply:

When the demand for a particular type of medicine exceeds the supply, criminal minded people tend to take advantage of that by producing and distributing fake as a substitute for the genuine type. Consumers in the other hand can purchase such product with hope that they are buying the genuine one, and most of the time these drugs are distributed through unauthorized channels[51]. There is always demand for cheap drugs maybe due to easy access, it is more affordable or there is always stock out from the health facility. Hence, the illegal traders will want to quickly fill the gap of supply, and there are at all time market for them. Putting such illegal traders to jail or seizing/sealing their shops might not give a lasting solution to the problems. The Tanzanian Food and Drug Authority (TFDA) started the accreditation and certification of drug dispensing outlet (ADDO) by legalizing such illegal sector through the network program and allowing them sell only medicines listed in their essential drug list. Such way, the illegal drug dealers comes out from their hidings and TFDA now has easy assess to them in monitoring what they do.

3.4 PHARMACO-VIGILANCE SYSTEMS IN NIGERIA

In any nation for pharmaco-vigilance to accomplish its set goals and objectives some pharmaco-vigilance department components must be functional;

i. Qualified Person for Pharmaco-vigilance (QPPV)

These are pharmacologists who have the needed skills and competency in ensuring that the entire process of drug safety/drug surveillance is accomplished. In other words, QPPV are specialist embedded with saleable and working knowledge on ensuring surveillance on drug in a nation to avert adverse drug reaction on patients. Considering the forgoing, they ensure drug effectiveness and efficacy which will in the long-run enhance public health. It comprises of pharmacologist and some health stakeholders.

---

[51] WO Erhun and others (n39) 33.

ii. Safety System Support/Data Base Support

The safety system support comprises of safety catalyst for ensuring drugs safety by QPPV personnel. Data base support comprise of a body of information warehouse that will help to achieve drug safety cases of either adverse drug reaction or way of enhancing drug safety surveillance. The data base/safety system support assists the QPPV in storage, retrieval of proven information about drug safety. The data base helps to facilities practitioner on pharmaco-vigilance.

iii. Safety Case Processing and Review

This revolves round the examining a particular drug which is observed to have an adverse effect on a given national of a nation. Here, enormous data are gathered which will assist the QPPV in discharging their job effectively.

iv. Medical Writing (Aggregate Report and Labels)

Here, the QPPV report cases of perceived effect of drugs on a patient(s). It involves reporting a particular case of harmful drug on patients. This is done in other to ensure absolute reduction or even banning of harmful drug which on the long-run will help in the process of drug safety.

v. Standard Operation Procedure (SOPs)

Standard operation procedure assists in standardizing a given drugs for the betterment of patients' health condition. SOPs help to ensure quality assurance in the production quality of a particular drug.

vi. Signal and Risk Analysis

In this component, the QPPV intensify efforts in noting sign and risks of drugs on patients. In other words, drugs are taking into absolute consideration by QPPV through effects-benefits approaches in ensuring drug safety.

vii. Global Safety Reporting

This involves information channeling among QPPV in a particular nation and among nations of the world. Global safety reporting involves a global drug safety surveillance. In other words, global safety reporting involves a global pharmaco-vigilance. Global pharmaco-vigilance capacity allows round-the-clock pharmaco-vigilance[52].

3.4.1 Challenges Facing Pharmaco-vigilance in Nigeria and Possible Solutions

In developing countries such as Nigeria, the following are some of the challenges facing pharmaco-vigilance.

i. Lack of Skilled/Qualified Manpower

In any country of the world be it developed, developing or less developed the benefit of qualified manpower cannot be overemphasized in manning any institution learning, health among others. Nigeria been among developing countries, due to lack of skilled/qualified manpower the task of pharmaco-vigilance as put forward by that pharmaco-vigilance system must continue to engage practitioners to submit high-quality reports of suspected adverse drug reactions has been hindered. Lack of qualified manpower impedes the progressive actualization of drug safety. This may be due to the fact that most of the personnel for pharmaco-vigilance have little education experience on how to perform their job of ensuring that pharmaceutical drug does not have negative effect on patients[53]. In line with the forgoing, noted that insufficient manpower contributed to poor development of pharmaco-vigilance. Similarly, those who seems to be qualified in engaging in drug safety process are predisposed to theoretical aspect as a substitute for practical aspect of pharmaco-vigilance which is usually a field and experimental study. In a different development, there seems to be lack of

---

[52] Kingsley Akarowhe, 'A Case Study of Pharmaco-vigilance in Nigeria: Challenges and Solutions' *American Journal of Biomedical Science & Research* (2020) 10.

[53] Kingsley Akarowhe (n52) 11.

in service training for members of the national Pharmaco-Vigilance Centre (NPC) in Nigeria. It is worth noting that in-service training is an effective means of raising competencies of QPPV involved in the safety process of pharmaceutical drugs and especially those in the National Pharmaco-vigilance Centre (NPC). Observation seems to show that little effort has been taking concerning staffs training, while they perform their professional responsibilities. This is due to the reduction in the number of QPPV who may intend to study abroad to learn a specific course so as to improve the quality of pharmaco-vigilance in Nigeria with best global practice. Lack of in-service training does not only hinder practitioners in the discharge of their duties effectively, but on the aggregate actualization of pharmaco-vigilance objectives in Nigeria.

ii. Lack of Sufficient Funding

Adequate funding is a driving force to achieve a predetermined outcome in any organization, establishment or facet of human endeavor. Pharmaco-vigilance in Nigeria has not in recent time achieved it's ultimate priority due to lack of sufficient funding from relevant stakeholder. In line with this, a study[54] revealed poor budgeting for pharmaco-vigilance in Nigeria. This scenario has hindered mostly the monitory, assessment and detection of drugs adverse effect on patients. Additionally, pharmaco-vigilance personnel's do not embark on emergence inspection of some pharmaceutical establishments and other related bodies involves in drug production due to insufficient fund. This may be due to the fact that such fund if sufficient would have cater for their transport and other welfare packages among others in the process. In same view of lack of sufficient funding has overtime led to lack of appropriate facilities. In Nigeria there are no sufficient facilities such as equipped laboratories, tablet testing equipment among other to carry out effective and efficient pharmaco-vigilance. Due to this fact most pharmaceutical drugs that are considered sub-standard infiltrate the market for

[54] OA Opadeyi and others, 'Assessment of the state of pharmaco-vigilance in the South-South zone of Nigeria using WHO pharmaco-vigilance indicators' *BMC Pharmacol Toxicol* (2018) 19(1): 27.

patients, and the resultant effect is of national concern. Sequence to this odd situation, pharmaco-vigilance has not yielded much result as anticipated by relevant stakeholders.

iii. Corruption

Corruption is a continental problem, which has deepened itself in the vein of every society. Corruption is used to describe all forms of unprofessional ethical behavior such as bribery, illegal gratification and so forth that tends to hinder the actualization of corporate goals/objectives of an establishment. It is observed that most personnel involve in pharmaco-vigilance often compromise, in terms of taking bribes, and other form of illegal gratification from individuals, pharmaceutical outlets and companies who ought to be penalized for producing harmful drugs for patient consumption. This in recent time might be due to the wide economic gyration facing National Pharmaco-vigilance Centre (NPC) personnel's in Nigeria, which may propel them to take unlawful gratification at the detriment of the job they are set to do. It is worth noting that most times in Nigeria, when new drugs are introduced into the market some QPPV and assessment officials are giving money for such drug to be accepted, hence much assessment is not done on such drug due to the gratification made by the producers or other third parties in the chain of distribution of the said drug.

iv. Lack of Communication

Pharmaco-vigilance process requires utmost communication among patients, pharmaceutical agent, NPC personnel and other stakeholders. In Nigeria there seems to be lack of keen communication among various stakeholders that would have ensure a smooth pharmaco-vigilance. Most times patients often find it difficult to report cases of adverse effect of a drug to the NPC and other relevant agencies involved in drug safety. Overtime this has led to increase rate of death per-head of patients. Similarly, most agents in the chain of distribution of drug find it difficult to report cases of drugs considered to be harmful to patient's to the

National Pharmaco-vigilance Centre (NPC) for upward review. But, some report from patient on the effect of a given drug seem to be not only time wastage but also futile exercise.

v. Lack of Prerogative to Persecute Defaulters

Persecution prerogative is an important aspect for effective drug safety. In developing countries of the world such as Nigeria, there is usually lack of the prerogative to persecute individuals who are involved in one form of unethical/unlawful production, distribution and sales of pharmaceutical products. Most defaulters often apprehended due to political and partisan politics are pardon in the corridor of man-know-man, political appointment and monetary gains. This scenario has open door for most individual to carry out illegal practices in the pharmaceutical environments.

vi. Challenges of Strong Collaboration

Collaboration is a driving force for ensuring the achievement of a set goal. Pharmaco-vigilance requires keen collaboration from all health stakeholders. In the process of carrying out the task of drug safety by practitioners, there seems to be no collaboration with other agencies. This may be due to its broad scope, pharmaco-vigilance systems cannot function in isolation from other public health agencies. In Nigeria lack of strong collaboration tends to retard the effort of NPC official involves in ensuring drug safety. This lack of strong collaboration has resulted in lack of sufficient awareness programs for pharmaceutical practitioners and other health practitioners. Most patients are not given the adequate information on how to ensure drug safety during attending to the health challenges they face. In same vein, it was submitted that though most doctors know about the pharmaco-vigilance programme, there are some who still do not. Similarly, patients often do not have adequate understanding of patient-directed prescription drug information, this may be due to non-sensitization of patients through prior channels of information dissemination, such as the radio, television, internet, magazine among others. Due to this fact, most patients, doctors and

other relevant health stakeholders that would have helped in actualization of the goal and objectives of pharmaco-vigilance tend to be rendered unproductive.

Possible Solution

For pharmaco-vigilance to surmount the challenges it face in Nigeria, the following aspect should be taking into keen consideration.

i. Training and Retraining of Needed Manpower

Training and retraining is a form of in-service or on-the-job training for increasing workers productivity. Training and retraining help to upgrade the skill, knowledge and competencies of QPPV involve in drug safety. Considering this, Pan[55] suggested that more involvement of health professionals in pharmaco-vigilance, their education would ideally include instruction on recognition of drug-induced disease and adverse drug reactions, on the need to be engaged with pharmaco-vigilance systems and on the characteristics of a high-quality, though concise, case report. This may involve the QPPV undergoing short courses programme so as to discharge their duties more efficiently and effectively. Similarly, it can be done by organizing workshops, seminars, symposia and field-trips for QPPV which will help them in improving their work performance.

ii. Supply of Sufficient Funds

Provision of sufficient fund is keen for enhancing the entire process of ensuring pharmaco-vigilance in Nigeria. Sufficient fund is a phase of non-human resources that can aid pharmaco-vigilance in Nigeria to an advance global setting. Provision of such fund will help the QPPV for pharmaco-vigilance to undertake some field surveillance of some pharmaceutical drug, thus aiding their pro-activeness in their job engagement mechanism. Additionally, sufficient fund will helps in the provision of necessary facilities and

---

[55] JG Dal Pan, 'Ongoing Challenges in Pharmacovigilance' *Drug Saf* (2014) 37(1): 1-8.

equipment's. For effective and efficient pharmaco-vigilance to be carried out, adequate facilities must be provided to assist NPC personnel's in process. Provision of infrastructural facilities and equipment's such as laboratories, tablet testing equipment (such as friability testers, dissolution samplers, refractometer, powder handling among others) which will assist NPC personnel's to ensure that pharmaceutical drugs that are detrimental to patient's health do not penetrate the market. In other words, provision of these facilities will help to ensure effective detection, assessment and monitory of drug is done, hence removing drugs considered to have negative effect on the well being of patients. Similarly, this will assist persons for pharmaco-vigilance to carry out their job efficiently without any hindrance which was often encountered by them due to lack of these facilities.

iii. Awareness Campaign

Awareness is a means of enlighten the public about a given issue of concern which seems to affect them. Awareness campaign helps to enlighten patients, QPPV and other health stakeholders on drug safety measures. Awareness campaign adopt various agent of communication such as television, radio, newspapers, to relay information to patients. In light of this, Dal Pal[56] submitted that pharmaco-vigilance systems must also provide patients and practitioners with useful, actionable information about medicines. This will assist Nigerians to report cases of adverse drug reaction of pharmaceutical product on their health. Similarly, it will avail qualify person for pharmaco-vigilance of the opportunity of being enlighten on how to ensure drug safety practice.

iv. Proper Remuneration of Qualified Persons for Pharmaco-vigilance (QPPV)

Remuneration is a motivating variable that cater for workers welfare. Proper remuneration of QPPV in the National Pharmaco-vigilance Centre (NPC) in terms of payment of salaries, giving accrued benefit as at when due will help to reduce the level of illegal gratification and

[56] JG Dal Pan, 'Ongoing Challenges in Pharmacovigilance' *Drug Saf* (2014) 37(1): 1-8.

corruption among some of the QPPV. This is due to the fact that in recent time most drugs at pharmaceutical store do not pass required test, but due to corruption they are usually approved not with standing the adverse effect on patients. Additionally, this will pave way for adherence to ethical norms that will help to actualize drug safety practices in Nigeria.

3.4 CONCLUSION

This chapter examines the legal and institutional frameworks for Alternative Dispute Resolution (ADR) and pharmaceutical liability in Nigeria. It discusses key legislation, including the Poisons and Pharmacy Act, Food and Drugs Act, Counterfeit and Fake Drugs Act, and the National Agency for Food and Drug Administration and Control (NAFDAC) Act, highlighting NAFDAC's role in drug regulation, surveillance, and recall. The chapter also explores factors influencing the production, sale, and demand for fake drugs, such as non-professionals in the drug business, chaotic distribution networks, and corruption. Furthermore, it analyzes the challenges facing pharmaco-vigilance in Nigeria, including a lack of skilled manpower and funding, and suggests potential solutions like increased training and awareness campaigns.

CHAPTER FOUR

ADVERSE DRUG REACTIONS CASE STUDIES, CHALLENGES IN ADDRESSING ADRS, CHALLENGES IN PROVING LIABILITY OF PHARMACEUTICAL COMPANIES AND COMPARATIVE ANALYSIS OF DRUG REGULATING AGENCIES IN OTHER COUNTRIES

4.1 ANALYSIS OF THE EXTENT AND IMPACT OF ADVERSE DRUG REACTIONS IN NIGERIA

Adverse drug reactions (ADRs) in Nigeria is a significant public health concern, as ADRs contribute to increased morbidity and mortality within the health care system. With prevalence rates reported between 24.3% to 51.2% across different demographics, the issue is particularly pronounced among vulnerable populations, including the elderly and pediatric patients[1]. Despite being a critical factor in patient safety, the awareness and reporting of ADRs among health care professionals are alarmingly low, with estimates suggesting that only 6-10% of ADRs are reported, undermining pharmaco-vigilance efforts in the country.[2]

4.1.1 Types of Adverse Drug Reactions

Adverse drug reactions (ADRs) are classified into several categories based on their characteristics and mechanisms. Understanding these classifications is crucial for effective pharmaco-vigilance and patient safety. ADRs are typically categorized into two main types: Type A and Type B reactions, along with further classifications into Type C, D, E, and F reactions.

---

1 JJ Coleman and SK Pontefract, 'Adverse drug reactions' *Clin Med (Lond) (*2016) 16(5):481-485 <https://pmc.ncbi.nlm.nih.gov/articles/PMC6297296/> accessed 25th August 2025.

2 FA Ayeni and others, 'Assessing the knowledge, attitude, and practice of hospital-based pharmacists in reporting adverse drug reactions in Lagos, Nigeria' *Am J Pharmacother Pharm Sci* (2024)12 <https://ajpps.org/assessing-the-knowledge-attitude-and-practice-of-hospital-based-pharmacists-in-reporting-adverse-drug-reactions-in-lagos-nigeria/> accessed 25th August 2025.

Type A Reactions

Type A reactions, also known as augmented reactions, are dose-dependent and predictable. These reactions are usually an extension of the drug's pharmacological effects and occur with both therapeutic and overdosed doses. Common examples include side effects such as drowsiness from antihistamines or bleeding from anticoagulants due to excessive dosing[3]. It is estimated that Type A reactions are responsible for a significant proportion of ADRs, making them more prevalent than other types.

Type B Reactions

Type B reactions, also known as bizarre reactions, are not dose-dependent and are unpredictable. These reactions may arise from idiosyncratic responses to a medication or allergic reactions, which do not correlate with the drug's pharmacological action. Type B reactions tend to be less common but can be more severe, resulting in serious health consequences[4].

Other Classifications

In addition to Types A and B, ADRs can be further classified into:

- Type C: Chronic reactions resulting from the long-term use of a drug, typically associated with cumulative dosing
- Type D: Delayed reactions that occur some time after drug administration, often seen in cancer therapies or medications that affect fetal development
- Type E: Withdrawal reactions occurring after discontinuation of a medication, which can cause rebound symptoms[5]

---

[3] PO Nwani and AO Isah, 'Frequency and Patterns of Adverse Drug Reactions among Elderly In-Patients in a Nigerian Teaching Hospital' *J Basic Clin Pharma* (2017) 245-250 <https://www.jbclinpharm.org/articles/frequency-and-patterns-of-adverse-drug-reactions-among-elderlyinpatients-in-a-nigerian-teaching-hospital-3939.html> accessed 25th August 2025.

[4] Prof Ralph Edwards and others, 'Adverse drug reactions: definitions, diagnosis, and management' <https://www.thelancet.com/journals/lancet/article/PIIS0140673600027999/abstract> accessed 25th August 2025.

[5] Prof Ralph Edwards and others (n4)

- Type F: Treatment failure or ineffective therapy, which may also be classified under specific circumstances depending on the drug and context

Understanding the different types of ADR is crucial for health care professionals. Studies indicate that while 100% of pharmacists recognize the importance of ADR reporting, there is often a decline in knowledge about specific ADR classifications among health care workers post-graduation. This lack of training and continued education contributes to the under reporting of ADRs, which poses a significant challenge in managing patient safety effectively in Nigeria[6]. Given that ADRs are a leading cause of morbidity and mortality, particularly affecting about 15% of all patients and leading to fatal outcomes in a small percentage of cases, continuous education and monitoring practices are vital for improving reporting and reducing the burden of ADRs in clinical settings[7].

4.1.2 Extent of Adverse Drug Reactions in Nigeria

Adverse drug reactions (ADRs) represent a significant public health challenge in Nigeria, with varying prevalence reported across different studies. A study conducted among health professionals in government hospitals in Katsina State found that nearly 60% of health workers had encountered at least one case of ADRs in their practice, indicating a notable awareness of ADR occurrences in clinical settings[8]. The overall prevalence of adverse drug events (ADRs) among the adult population was reported at 24.3% in one review, while a pooled prevalence across all age groups reached 51.2%. Specifically, in pediatric patients, the prevalence was recorded at 34.3%[9]. These figures suggest a higher occurrence of ADRs in outpatient settings compared to earlier studies, which documented lower prevalence rates, such as 12.8% in ambulatory settings and 8.3% in primary care. Furthermore, specific studies

---

6 FA Ayeni and others (n2)

7 Texila International Journal Of Public Health, 'Adverse Drug Reactions Reporting among Health Professionals in Government Hospitals in Katsina State, Nigeria' <https://www.texilajournal.com/public-health/article/1906-adverse-drug-reactions> accessed 25th August 2025.

8 FA Ayeni and others (n2)

9 JJ Coleman and SK Pontefract (n1)

indicated that a significant portion of elderly patients (over 65 years) experience ADRs, with reported rates ranging from 14.3% to 48.9%. This heightened risk in older adults is attributed to factors such as *polypharmacy* and the complexities associated with managing multiple *comorbidities*.[10]

4.1.3 Factors Influencing Adverse Drug Reactions

Several factors contribute to the incidence of ADRs in Nigeria, including patient demographics (age and gender), the number of medications prescribed, and the underlying health conditions of patients. The phenomenon of polypharmacy, especially prevalent in elderly patients due to multiple chronic illnesses, increases the likelihood of ADRs[11]. Additionally, inadequate knowledge and awareness of pharmaco-vigilance practices among health care professionals have been cited as barriers to effective ADR reporting and management.

4.1.4 Impact of Adverse Drug Reactions

Adverse drug reactions (ADRs) represent a significant challenge to health care systems, particularly in Nigeria, where they contribute to increased morbidity and mortality among patients. Studies indicate that ADRs are responsible for approximately 5% to 35% of preventable hospital admissions, leading to substantial financial burdens on health care resources[12]. The impact of ADRs is particularly pronounced in older populations, where a study found that 1.7% of admitted older patients experienced fatal ADRs, highlighting the higher incidence of serious outcomes in this demographic compared to lower rates observed in the United States and the UK[13]. The economic implications of ADRs are considerable,

---

[10] *Ibid*

[11] Texila International Journal Of Public Health (n7)

[12] R Adisa and TI Omitogun, 'Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary health care centres in Ibadan, southwestern Nigeria' *BMC Health Serv Res* (2019) 12.

[13] K Oshikoya, 'Medical Students' Knowledge Of Risk Factors For Adverse Drug Reactions In Children' *The Internet Journal of Medical Education* (2009) <https://ispub.com/IJME/1/2/3883> accessed 25th August 2025.

with evidence suggesting they impose an economic drain on health care systems. In addition to direct medical costs, preventable ADRs contribute to inpatient morbidity and mortality, necessitating longer hospital stays and additional treatments[14]. This exacerbates the already strained health care infrastructure in Nigeria, which struggles with a high patient-to-doctor ratio and limited resources. The socio-demographic characteristics of patients also play a role in the awareness and reporting of ADRs. A study revealed that a significant majority of patients were self-employed or civil/public servants, with a notable portion of the population being young adults[15]. This demographic data underscores the necessity for targeted education on pharmaco-vigilance and ADR reporting, particularly given that a substantial number of patients had only secondary or post-secondary education, which may influence their understanding of medication risks.

4.1.5 Reporting Practices

A significant number of patients experience ADRs; in a study, it was reported that approximately 24.7% of patients had encountered at least one form of ADR.[16]Among these patients, the most common actions taken included informing a health care provider (38.8%) and stopping the medication (21.4%). Notably, 54.2% preferred direct reporting of ADRs to health care professionals, reflecting a demand for more efficient communication channels between patients and the health care system. However, a concerning finding was that only 18.6% of patients had previously reported their experienced ADRs, largely due to ignorance regarding the importance of reporting and the perceived triviality of some ADRs.

4.1.6 Demographic Factors Influencing Reporting

Age appears to influence the likelihood of ADR reporting, with patients aged 18 to 40 demonstrating significantly better reporting habits compared to those over 40. This suggests

---

[14] Innopharma Education, 'Enhancing pharmaco-vigilance in Nigeria: Challenges faced by NAFDAC in monitoring of Adverse Drug Reactions in Nigeria' <https://repository.innoskills.com/items/26b198b1-fbcd-4541-a8d6-f313894ea264/full> accessed 25th August 2025.

[15] FA Ayeni and others (n2)

[16] R Adisa and TI Omitogun (n14)

that targeted educational initiatives should be developed to raise awareness among older populations about the significance of ADR reporting. Furthermore, increasing direct patient participation in ADR reporting could enhance the overall efficacy of the pharmaco-vigilance system in Nigeria.

4.1.7 Underreporting Issues

The phenomenon of under reporting ADRs remains a critical challenge in Nigeria. Studies have indicated that various factors contribute to this issue, including a lack of knowledge about ADR reporting processes and fear of legal repercussions associated with reporting.[17] The Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) has documented that only a fraction of suspected ADR cases are reported, highlighting the urgent need for systematic improvements in ADR reporting mechanisms.[18] Initiatives such as public education campaigns and improved accessibility of reporting tools, including SMS reporting systems, may prove beneficial in addressing these barriers and enhancing patient safety outcomes.

4.2 CHALLENGES IN ADDRESSING ADRS

Several factors contribute to the low reporting rates of ADRs among health care professionals. A systematic lack of awareness and knowledge regarding pharmaco-vigilance and ADR reporting procedures is prevalent. In one study, only 28.3% of ADRs encountered by health professionals were reported, revealing a significant gap in compliance with reporting obligations[19]. Additionally, barriers such as the unavailability of ADR reporting forms and insufficient clinical training in completing these forms further exacerbate the situation.

4.2.1 Barriers to Reporting

---

[17] O Awodele and others, 'Patterns of adverse drug reaction signals in NAFDAC pharmaco-vigilance activities from January to June 2015: safety of drug use in Nigeria' *Pharmacol Res Perspec*t (2018) <https://pmc.ncbi.nlm.nih.gov/articles/PMC6175912/> accessed 25th August 2025.

[18] *Ibid*

[19] Sharratt Kommu and others, 'Adverse Drug Reactions' <https://www.ncbi.nlm.nih.gov/books/NBK599521/> accessed 25th August 2025.

One of the primary barriers to effective ADR reporting is the lack of access to reporting forms. Studies have highlighted that many health care professionals struggle to obtain the necessary documentation to report ADRs, which has resulted in a concerning low reporting rate of only 28.3%. Additionally, a significant proportion of health workers, approximately 25.1%, reported having observed ADRs but did not complete the corresponding forms due to systemic challenges[20].

i. Knowledge and Awareness Gaps: Furthermore, knowledge deficits among health care workers regarding ADR reporting procedures significantly hinder effective pharmaco-vigilance. A reported 58.3% of respondents had limited knowledge of these procedures, which indicates a need for comprehensive training and educational interventions[21]. This lack of understanding can lead to complacency, indifference, and procrastination in reporting ADRs. There is also evidence suggesting that some health professionals fear legal repercussions associated with reporting ADRs, which adds to the reluctance to engage in the reporting process[22].

ii. Patient Involvement in Reporting: Patients also play a critical role in the ADR reporting process. Research indicates that direct patient participation can significantly enhance the efficiency of pharmaco-vigilance systems and help bridge the gap caused by under reporting from health care providers. For instance, a study found that 24.7% of patients reported experiencing at least one ADR, yet only 18.6% had previously reported these reactions[23]. The most common actions taken by patients experiencing ADRs included informing a health care

---

[20] TEXILA INTERNATIONAL JOURNAL OF PUBLIC HEALTH, 'Adverse Drug Reactions Reporting among Health Professionals in Government Hospitals in Katsina State, Nigeria' <https://www.texilajournal.com/public-health/article/1906-adverse-drug-reactions> accessed 25th August 2025.

[21] *Ibid*

[22] M Asiamah and others, 'Spontaneous reporting of adverse drug reaction among health professionals in Ghana' *Arch Public Health* 80, 33 (2022) <https://archpublichealth.biomedcentral.com/articles/10.1186/s13690-021-00783-1#citeas> accessed 25th August 2025.

[23] FA Ayeni and others (n2).

provider and stopping the medication, highlighting the importance of encouraging patients to report ADRs directly to health care professionals.

4.3 MITIGATION STRATEGIES

To address the significant challenges posed by adverse drug reactions (ADRs) in Nigeria, a multi-faceted approach is necessary. This approach should encompass strengthening pharmaco-vigilance frameworks, enhancing health care professional training, and improving public awareness regarding ADRs.

i. Strengthening Pharmaco-vigilance Frameworks: Improving the regulatory framework for pharmaco-vigilance is critical. This includes establishing robust reporting systems and enhancing collaboration among regulatory agencies, health care institutions, and pharmaceutical companies. The current fragmentation in reporting systems hinders effective surveillance of ADRs, which can lead to compromised patient safety[24]. Regulatory reforms are essential to create a cohesive structure that supports efficient monitoring and reporting of adverse drug effects.

ii. Enhancing Health care Professional Training: Education and continuous training of health care professionals in pharmaco-vigilance principles are paramount. Studies indicate that many health care workers lack adequate knowledge and training in ADR detection and reporting, leading to under reporting and gaps in patient care. By integrating pharmaco-vigilance themes into educational curricula and providing mandatory continuing education programs, health care workers can be better equipped to recognize and report ADRs effectively. This proactive approach will not only increase reporting rates but also foster a culture of patient safety within health care facilities.

---

[24] OO Akunne and others, 'Insight into Nigeria's pharmaco-vigilance landscape: stakeholder perspectives on strengthening medicine safety systems' *Discov Health Systems* 4, 52 (2025) <https://link.springer.com/article/10.1007/s44250-025-00234-6#> accessed 25th August 2025.

iii. Public Awareness and Patient Engagement: Raising public awareness about ADRs and the importance of reporting them is another vital strategy. Campaigns should focus on educating the public about their role in the pharmaco-vigilance system, emphasizing that patients are often the first to notice ADRs. Strategies such as utilizing social media platforms and designated hotlines for ADR reporting can enhance engagement and streamline the reporting process. Encouraging patients to report their experiences directly to health care professionals will improve the efficiency of the pharmaco-vigilance system and aid in the detection of ADRs.

4.4 CHALLENGES IN PROVING LIABILITY OF PHARMACEUTICAL COMPANIES IN NIGERIA AND BARRIERS TO COMPENSATION CLAIMS

The legal framework governing pharmaceutical liability in Nigeria is multifaceted, incorporating both fault-based and strict liability systems to address issues related to product safety and compliance. Central to this framework is the National Agency for Food and Drug Administration and Control (NAFDAC), established in 1993, which is responsible for regulating the manufacture, distribution, and sale of drugs and pharmaceuticals in the country[25]. NAFDAC's regulatory functions include the issuance of guidelines, monitoring advertisements, and ensuring that all pharmaceutical products meet safety and efficacy standards prior to entering the market[26].

i. Product Liability System: Nigeria's product liability system operates under both fault-based and strict liability paradigms. Under the fault-based system, a plaintiff must demonstrate that

[25] Generis Global Legal Services, 'Understanding Pharmaceutical Regulations in Nigeria: Drug Approval Processes, Manufacturing Standards, and Penalties for Non-Compliance' <https://generisonline.com/understanding-pharmaceutical-regulations-in-nigeria-drug-approval-processes-manufacturing-standards-and-penalties-for-non-compliance/> accessed 25th August 2025.

[26] Harlem Solicitors, 'The Regulatory Requirements for Pharmaceutical Companies in Nigeria' <https://www.harlemsolicitors.com/2022/04/28/the-regulatory-requirements-for-pharmaceutical-companies-in-nigeria/> accessed 25th August 2025.

a manufacturer or seller acted negligently, leading to the injury caused by a faulty product[27]. In contrast, the strict liability framework holds manufacturers and traders liable for defective products regardless of fault, focusing instead on the product's safety and the harm it causes to consumers[28].

ii. Penalties for Non-compliance: The pharmaceutical sector in Nigeria is subject to stringent penalties for non-compliance with established regulations. Violations can lead to severe consequences, including hefty fines and revocation of licenses, emphasizing the critical importance of regulatory adherence to safeguard public health[29]. Such enforcement actions reflect the commitment to maintaining industry standards and preventing the circulation of substandard or counterfeit medications. Despite the existing legal framework, challenges persist in the effective regulation of Nigeria's pharmaceutical industry. Issues such as irregular regulatory inspections and insufficient enforcement of compliance measures contribute to a weakened regulatory environment. These challenges hinder the ability of authorities to ensure that pharmaceutical companies adhere to safety and quality standards, which can ultimately affect public health outcomes.

iii. Recent Developments: Recent years have seen significant reforms in Nigeria's pharmaceutical regulations, primarily driven by NAFDAC's initiatives to enhance drug safety and efficacy. One notable development is the implementation of an electronic registration system, which streamlines the drug approval process and reduces delays in obtaining necessary licenses[30]. Additionally, increased collaboration between regulatory bodies, industry players, and health care professionals is essential for establishing a cohesive strategy to improve compliance and ensure timely access to quality medications.

---

[27] HC Coleman, 'Ethical Considerations in Selling Pharmaceuticals in Emerging Economies' <https://www.researchgate.net/publication/317277480_Ethical_Considerations_in_Selling_Pharmaceuticals_in_Emerging_Economies> accessed 25th August 2025.

[28] *Ibid*

[29] Harlem Solicitors (n26)

[30] Harlem Solicitors (n26)

iv. Challenges in Proving Liability: Proving liability, particularly in the context of pharmaceutical companies, presents numerous challenges that complicate the pursuit of compensation claims by affected consumers. These challenges often arise from the inherent complexities of medical malpractice and product liability laws, as well as the significant power dynamics at play between large corporations and consumers. Also, despite the presence of regulatory frameworks intended to safeguard consumer rights, many pharmaceutical companies can exploit gaps in these regulations. Corporations often wield considerable financial and political influence, which can undermine enforcement efforts and regulatory oversight.[31] This power disparity complicates the ability of consumers to seek redress, as the enforcement of laws and ethical standards frequently falls short against these well-resourced entities. One critical aspect of establishing liability in medical negligence cases is the necessity of expert testimony. The court often requires expert witnesses to elucidate the standards of care applicable in specific situations and to ascertain whether these standards were met.[32] In medical malpractice claims, the role of expert witnesses becomes particularly crucial, as laypersons may lack the requisite knowledge to assess complex medical issues. Consequently, the absence of adequate expert testimony can significantly hinder the plaintiff's ability to prove their case.

v. Establishing the Elements of Negligence: To prove medical negligence, a claimant must demonstrate three core elements: the existence of a duty of care, a breach of that duty, and resultant harm.[33] The burden of proof lies primarily with the claimant, which can be particularly daunting given the sophisticated nature of pharmaceutical products and medical

---

[31] 'Product Liability In Nigeria: Examining The Two Sides Of The Coin', <https://ao2law.com/wp-content/uploads/2024/10/PRODUCT-LIABILITY-IN-NIGERIA.pdf> accessed 25th August 2025.

[32] IJ Usar and BB Bukar, 'Challenges and Opportunities of Pharmaceutical Regulation in Nigeria' <https://www.iosrjournals.org/iosr-jhss/papers/Vol.%2025%20Issue4/Series-6/C2504061118.pdf> accessed 25th August 2025.

[33] Amala Umeike, 'Market dynamics and legal implications: analysing product liability in Africa's medical device sectors' <https://www.ibanet.org/market-dynamics-legal-africa-medical-device> accessed 25th August 2025.

treatments. As the Supreme Court in *Okwejiminor v. Gbakeji*[34] has noted, establishing liability often requires demonstrating a clear connection between the alleged negligence and the harm suffered, a task that can be exceedingly complex.

vi. The Burden of Proof: The legal principle surrounding the burden of proof is pivotal in negligence cases. In civil litigation, this burden typically rests on the party asserting the claim.[35] Thus, plaintiffs must provide compelling evidence to support their allegations, a requirement that can be burdensome, especially when facing powerful corporate defendants. In some instances, plaintiffs may invoke the doctrine of *res ipsa loquitur*, which allows for a presumption of negligence based on the nature of the accident or injury, yet this doctrine's applicability is often contingent on specific circumstances that may not always be present.[36]

4.4.1 Barriers to Compensation Claims

Moreover, victims of medical negligence in Nigeria face practical barriers when attempting to report incidents or file compensation claims. The lack of proper documentation or regulatory oversight can impede victims' ability to substantiate their claims. For a claim to be valid, the plaintiff must have experienced tangible harm resulting from the negligence, which can be difficult to prove in cases involving complex medical interventions. The process of seeking compensation for harm caused by pharmaceutical companies in Nigeria is fraught with numerous challenges. These barriers can significantly hinder the ability of victims to secure justice and appropriate redress for their grievances.

i. Settlement Pressures: One of the most significant barriers to compensation claims is the pressure to settle cases prematurely. Plaintiffs often face substantial financial or emotional stress, leading them to accept inadequate settlements without fully understanding their legal rights or the merits of their claims[37]. This rush to settle can deprive injured parties of a fair

---

[34] (2008) 5 NWLR (Pt 1079) 172
[35] IJ Usar and BB Bukar (n32)
[36] IJ Usar and BB Bukar (n32)
[37] *Okwejiminor v. Gbakeji* (2008) 5 NWLR (Pt 1079) 172

resolution, as they may not receive the compensation necessary to cover their medical expenses or other damages incurred due to negligence.

ii. Meeting the Burden of Proof: Proving liability in cases involving pharmaceutical companies is particularly challenging, especially when it comes to complex medical issues[38]. The intricacies involved in demonstrating negligence or defective products can result in the dismissal of valid claims. As a consequence, many victims struggle to present sufficient evidence to meet the legal burden required to succeed in their claims[39].

iii. Lack of Public Awareness: Public education regarding rights and legal recourse is also limited, which exacerbates the challenges faced by potential claimants. When citizens are not informed about their rights under laws such as the Consumer Protection Act, they may be less inclined to challenge pharmaceutical negligence.

iv. Complex Regulatory Environment: The pharmaceutical industry operates within a complex regulatory framework that often lacks clarity and consistency[40]. This complexity can frustrate efforts to hold companies accountable, as overlapping functions and inconsistent enforcement can result in ambiguous legal interpretations that undermine compensation claims. Consequently, individuals may find themselves navigating a convoluted system without adequate support or guidance, complicating their pursuit of justice and compensation.

4.5 COMPARATIVE ANALYSIS OF DRUG REGULATING AGENCIES IN OTHER COUNTRIES

This is an analysis of the work of different country's drug regulating agencies in the fight against fake drug. The countries were selected from different regions, Africa, Asia and Europe based on developed and developing countries. It will form the basis to compare with the work of NAFDAC in order to identify their weaknesses and ways of intervention. It can

---

[38] CC Ujomudyke and others, 'Government Policies and Performance of Pharmaceutical Firms in South-East, Nigeria', *International Journal of Business and Management Review*, Vol.12, (2024) 85-118.

[39] CC Ujomudyke and others (n38)

[40] CN Tsai, 'How to Rehumanize Clinical Trials: An Antibiotic Perspective' *California Law Review,* (2025) <https://www.californialawreview.org/print/antibiotic-patent> accessed 25th August 2025.

also shed new light on Nigeria drug situation by suggesting ways for improvement. The reasons are that drug problems can spill over from one country to another, drug policy of one country can affect another and the knowledge of what happened in one country can help another prepare for similar challenges in future.

The study below reflects the functions in the regulation of medicines. The administrative elements carries out the regulatory functions which includes licensing of premises, persons and practice, inspection of manufacturers and distributors, product registration and assessment, enforcement, quality control of drugs and public awareness. Without adequate policy, human resources, finances and infrastructure, drug regulation will fail.

4.5.1 Licensing Of Premises And Persons

Before a license is granted either to persons or for the drug premises, the qualification of the person, adequacy of the premises as well as quality of available equipment and processes should be of utmost concern[41].

The South African Medicine Control Council (MCC) is the drug regulating body charged with regulation and control of drugs in South Africa. The only people given license to manufacture, import, distribute or dispense are drug practitioners (pharmacists) registered with their relevant Councils having registered premises. Medical practitioners and nurses are not allowed to dispense drugs unless they possess a dispensing license issued by MCC[42].

In the Netherlands, the general practitioners with license are allowed to open dispensaries. Malaysia allows their health assistants, nurses or pharmacy assistant to dispense drugs in such areas lacking pharmacists[43].

---

41 SWE Ratanawijitrasin, 'Effective drug regulation- A multi-country study' *A book published by World Health Organization* (2002) <http://ndl.ethernet.edu.et/bitstream/123456789/27927/1/58.pdf> accessed 5th November 2025.

42 MCC, 'National Drug Policy for South Africa' (2000) <www.doh.gov.za/docs/policy/drugsjan1996.pdf> accessed 5th November 2025.

43 SWE Ratanawijitrasin (n41)

The Medicine and Health care products Regulatory Agency (MHRA) of the United Kingdom gives license to pharmaceutical companies and any qualified wholesaler that gives satisfactory evidence that the drug they are manufacturing, distributing, supplying meets the stipulated safety and quality standards.[44]

4.5.2 Inspection Of Manufacturers And Distributions

Drug inspection is a very important tool for monitoring pharmaceutical operation to know if they follow the stipulated standard, this is done by inspectors' physical visits to drug facilities and by use of quality assurance laboratories. Well-qualified inspector with good knowledge of pharmacy adequately trained and having the necessary legal power should be used in order to avoid deception.

In South Africa, different provinces make their own inspection of drug distribution and purchasing arrangement which is they do to ensure safety and cost effectiveness.[45]

The U.K MHRA inspectorate group has the responsibility for drug inspection of manufacturers, which they assess with provision of their manufacturing authorization for compliance. They also have Good Distribution Practice (GDP) inspectors charged with assessment of the drug wholesalers. They make use of their large team of GMP and GDP inspector for monitoring both within and outstation[46].

The work force in these country shows they employ professional, but the workers are over used in carrying out a lot assignments except in MHRA.

4.5.3 Product Registration And Assessment

This is where marketing authorization/certificate and product licensing are issued to pharmaceuticals that meet minimum standards of efficacy, safety and quality. The effectiveness of registration process requires a good legal foundation, adequate and qualified

---

[44] MHRA, 'Medicine and Medical Devices Regulation: what you need to know' (2008) <www.mhra.gov.uk> accessed 5th November 2025.
[45] MCC (n42)
[46] MHRA (n44)

staff, adequate resources, a data retrieval system and a system that is free from conflict of interest but with good accountability and transparency.

The validity of certificates issued by all country under study is 5 year except Uganda that gives 1 year. The UK MHRA and MEB are the only countries that can make there own independent assessment on drug safety; others follow WHO guideline for registration and assessment.[47]

These countries under review also make use of external experts for registration assessment as does NAFDAC, primarily through the NAFDAC Drug Registration External Advisory Committee (NDREAC).

4.5.4 Enforcement

Enforcement in any drug regulating authority acts as the intelligence group that investigate cases, brings criminal prosecution, works with information provided by people and consumers, carry out raids and surveillance activities to places under suspicion of fake drug business.

The U.K MHRA enforcement and intelligent group responsible for enforcing drug law in England, Scotland and Wales does so with the use of adequately trained intelligence officers. These officers works in very close collaboration with UK police forces, customs, prescription pricing authority, association of port health officers, environmental health units, Royal Pharmaceutical Society of Great Britain, General Medical Council , USFDA, US Drug enforcement Agency, WHO Anti-counterfeiting Task-force (IMPACT) and all forces and regulatory authorities throughout Europe. With these close collaboration information on fake drug proliferation are easily reported and investigated. The enforcement and intelligent group employs enough staff within London and outstation to ensure that all gaps are covered and for easy case report and management, they are divided into four organized groups.

[47] SWE Ratanawijitrasin (n41)

Intelligence group, Operations, Prosecutions and Business[48]. One major way in which MHRA has successfully reduced the fake drug proliferation in their market is by licensing all steps of medicine distribution channel from manufacturing, distributing, drug storage through the supply chain down to dispensing. Other strategies used in tackling fake drugs are adequate communication to the public and health care professionals by providing 24 hour anti-counterfeiting hotline and provision of counterfeit medicines guideline for both pharmacists and a separate one for the public, the guideline educates them on how to avoid and report fake drugs cases. Uganda collaborates with their National police in carrying out task force activities[49].

4.5.5 Public Awareness

Public enlightenment campaigns is an effective strategy used in raising consumer awareness and combating the faking of regulated products through prints and electronic media, jingles, alert notices, billboards, advertising in journals, publications and workshops and seminars with stakeholders etc. These activities are geared towards educating the public on the rights of consumers to make informed choice, it can empower the public to recognize and reject counterfeit products through enhanced public awareness. Regulating of drug information helps prevent inaccurate and misleading information to the public and gives a clearer understanding to consumers and health providers.

In Malaysia, they have consumer organizations that keep check and make recommendation to the decisions of their drug-regulating agency, they also raise questions to any issues which consumers need clarifications[50].

Good communication network to the public and health care professionals are made available by MHRA by providing 24-hour anti-counterfeiting hotline and provision of counterfeit

---

[48] MHRA (n44)

[49] Olike Chiwendu, 'The fight against fake drugs by NAFDAC in Nigeria'<https://bibalex.org/baifa/Attachment/Documents/193922.pdf> accessed 5th November 2025.

[50] *Ibid*

medicines guideline for both pharmacists and a separate one for the public, the guideline educates them on how to avoid and report fake drugs cases[51].

4.5.6 Controlling Fake Drugs In The Illegal Market (Some Country's Examples)

In Tanzania, the government started the accreditation and certification of drug dispensing outlet (ADDO) which is a public-private partnership, this is because they found out that it constitutes the largest network for drug sale and people will always patronize such drug outlet because most time the consumers feel they get better care, confidentiality, flexible payment without consultancy charges. Rather than closing such outlets, government started conducting appropriate training for them in order for them to understand the laws governing dispensing practices, conducting lessons in skill management, record keeping and pharmacy practice ethics. This they did with the objective of transforming such unregulated outlets into a regulated system that is monitored in order for them to provide professional services to the under-served and ignorant consumers. Incentives were also given to these small drug outlets to stimulate transformation and motivate shop owners and dispensers to come out for accreditation[52]. With the accreditation, only drugs that are approved and registered by Tanzanian pharmacy board is permitted for sale by ADDOs

In Ghana, their licensed chemical sellers are indispensable group for health care provision as many people depend on them as their first line for medicine demand and supply. Some of these sellers though licensed also present threats to public health by providing to consumers incorrect, expired and fake medicines. There initiative of care shop franchising model was created by Ghana Social Marketing Foundation (GSMF) to enable the training of the franchisees that signs agreement and renovates their stores according to the franchise

---

[51] MHRA (n44)

[52] M Ndimondo-Sigonda and others, 'Accrediteded drug dispensing outlets: A novel public private partnership' *An approach to improving access to affordable, high-quality drugs and services in under-served areas* (2003).

guidelines. The idea is that such outlets where demands are high can be easily monitored in addition they will symbolize trust, better services and supply chain to those that patronizes them. The GSMF takes responsibility of medicine procurement, distribution, monitoring and evaluation of franchisee, building the loyalty and trust of these drug sellers[53].

4.6 CONCLUSION

In conclusion, this paper has illuminated the significant challenges posed by adverse drug reactions (ADRs) in Nigeria, from their prevalence and impact on public health to the difficulties in reporting and proving liability against pharmaceutical companies. The analysis underscores the urgent need for a multi-pronged approach, encompassing stronger pharmaco-vigilance frameworks, enhanced training for health care professionals, improved public awareness, and a more transparent and accessible legal system. Addressing these issues is critical to safeguarding patient safety, reducing the burden of ADRs on the health care system, and ensuring pharmaceutical companies are held accountable for their products. Ultimately, a concerted effort from regulatory bodies, health care providers, pharmaceutical companies, and the public is essential to mitigate the risks associated with ADRs and promote a healthier future for Nigeria.

[53] J Segre and J Tran, 'What works: Care-shop Ghana (Improving access to essential drugs through conversion franchising' (2008) <www.nextbillion.net/resources/casestudies> accessed 5th November 2025.

CHAPTER FIVE

SUMMARY OF FINDINGS, RECOMMENDATIONS AND CONCLUSION

5.1 SUMMARY OF FINDINGS

This study presents a coherent and well-documented account of adverse drug reactions (ADRs) in Nigeria, locating the problem at the intersection of clinical practice, regulatory capacity and product-liability law. Empirical material referred to in shows that ADRs are common and regularly under-reported: several studies cited report prevalence estimates that vary widely by setting (for example pooled prevalence figures and outpatient rates) and consistently indicate that only a small fraction of expected ADRs reach the National Pharmaco-vigilance Centre. These reporting gaps are quantified in different parts of the document (for instance, patient self-reporting rates around 18–25% and national submission totals that fall short of WHO benchmarks), which together demonstrate a chronic surveillance deficit with direct consequences for detection and recall of unsafe products.

The study identifies a set of interlocking structural drivers that explain poor ADR reporting and weak regulatory outcomes. First, human-resource limitations insufficient numbers of qualified persons for pharmaco-vigilance, weak in-service training and low motivation undermine routine case detection and signal processing. Second, chronic under-funding and scarce laboratory and testing infrastructure constrain both pre-market inspection and post-market surveillance activities. Third, corruption and fragmented regulatory practice (including chaotic distribution channels and porous port controls) permit substandard and counterfeit products to circulate, aggravating clinical risk and complicating attribution. Fourth, the social and professional dimensions of reporting ignorance among patients, limited reporting culture among older patients, fear of litigation among providers, and the absence of clear, user-friendly reporting channels further depress spontaneous reporting rates. These factors are repeatedly evidenced in the document through surveys of clinicians, pharmacists

and patent medicine vendors and through institutional descriptions of the National Agency for Food and Drug Administration and Control (NAFDAC) and the National Pharmaco-vigilance Centre (NPC).

On the legal and institutional front, the study convincingly shows that Nigeria possesses substantive statutory building blocks that could support stronger corporate accountability principally the NAFDAC Act, the Food and Drugs Act, the Counterfeit and Fake Drugs Act and the Federal Competition and Consumer Protection Act (FCCPA) with its product-liability provisions. However, the study persuasively argues that substantive law has not been matched by effective enforcement or by procedural mechanisms that make civil redress tractable for ordinary victims. In practice, liability often turns on contested causation, the foresee-ability of known side effects, limited regulatory records and the resource constraints of claimants; these barriers blunt both criminal and civil enforcement. The study also situates the continuing significance of high-profile mass-poisoning incidents (notably the My Pikin teething syrup case) as both illustrative of systemic failure and catalytic for episodic reform. Overall, the study's legal analysis identifies a gap between normative law and enforceable remedies that must be closed if victims of ADRs are to secure consistent redress.

5.2 RECOMMENDATIONS

Any set of recommendations must flow from the multiple, layered causes evidenced in the study: improving data capture and surveillance; strengthening institutional capacity; remediating distribution vulnerabilities; and clarifying legal pathways for accountability. The recommendations below are therefore organized to address these mutually reinforcing dimensions and are proposed with an emphasis on feasibility and alignment with extant legal instruments.

i. Mandate and operationalise compulsory ADR reporting by health-care institutions and selected private providers, paired with simplified reporting tools (electronic and SMS-based

forms) and a centralized data repository. The document shows that spontaneous reporting currently dominates Nigerian practice but is incomplete; establishing mandatory institutional reporting for sentinel hospitals and primary care networks, and integrating patient self-reporting channels, would increase the sensitivity of national surveillance and create the data necessary to trigger regulatory action.

ii. Invest in human capacity and infrastructure for pharmaco-vigilance. This requires sustained budgetary allocations to NPC/NAFDAC to fund qualified persons for pharmaco-vigilance (QPPVs), laboratory upgrades (dissolution testers, friability machines, microbial testing capacity) and routine inspection activities. The study documents both the staffing shortfalls and equipment deficits that limit credible signal verification; targeted funding would permit regular post-marketing sampling, laboratory confirmation of quality complaints, and robust recall processes.

iii. Incorporate pharmaco-vigilance training into pre-service curricula and mandatory continuing professional education for doctors, pharmacists and patent medicine vendors. Empirical evidence in the research work shows low levels of awareness about reporting mechanisms (for example, unfamiliarity with the ADR "yellow form") and poor reporting practice among front line personnel; embedding ADR recognition and reporting in formal training and linking completion to licence renewal would strengthen the professional norms necessary for sustained reporting.

iv. Reform procedural and substantive aspects of liability so that statutory consumer protections are accessible in practice. This entails clarifying evidentiary rules for mass-harm claims, improving regulatory record-keeping to support causation proof (including chain-of-custody documentation for distribution and batch tracing), and creating specialized administrative or compensation pathways (for example a regulated compensation fund or fast-track tribunal process) to reduce the cost and complexity of litigation for low-income

victims. The study's doctrinal review suggests that while the FCCPA and existing criminal statutes provide theoretical bases for liability, practical barriers such as expert evidence costs and weak regulatory records prevent enforcement; the proposed procedural reforms are therefore proportional and directly responsive.

v. Stabilize the supply chain through a combination of licensing, outlet accreditation and public-private transformation of informal vendors. The document's comparative material (Tanzania's ADDO accreditation and Ghana's franchising models) indicates that regulatory integration of high-volume informal sellers paired with incentives, training and procurement guarantees reduces the illicit market while maintaining access for undeserved populations. Adapting these models would reduce the reach of counterfeiters and make post-market surveillance operationally feasible across the distribution chain.

vi. Strengthen anti-corruption safeguards and inter-agency coordination at ports and supply nodes. Practical measures include deploying properly resourced inspection teams at entry points; making inspection outcomes and product-testing data publicly accessible; and institutionalizing joint task forces between NAFDAC, customs, police and the NDLEA with defined performance metrics. The study identifies corruption and fragmented enforcement as recurring enablers of counterfeit circulation; these measures directly target those enabling conditions.

Finally, implement sustained public education and patient engagement campaigns to normalize ADR reporting and to communicate the practical steps patients should take when adverse effects occur. The study underlines that patients are both under-informed and willing to report when channels exist; therefore, public communication, hotlines and simple reporting apps will materially improve detection while empowering patients as active participants in the safety system.

5.3 CONCLUSION

This study provides a rigorous, evidence-based diagnosis of why adverse drug reactions remain a persistent threat to patient safety in Nigeria and why pharmaceutical accountability is elusive in practice. The core problem is not a single failing but a systemic misalignment: capable statutes and international affiliations coexist with under-resourced regulators, fragmented markets and weak reporting cultures. Correcting this misalignment requires integrated reform that simultaneously improves data capture, builds institutional capacity, tightens supply-chain governance and re-calibrates liability procedures so that legal rights translate into meaningful remedies.

For policy and legal practice, the immediate implication is that incremental technical fixes will be insufficient unless accompanied by durable investments and governance changes that reduce the scope for corruption and strengthen inter-agency cooperation. For regulatory practice, the implication is that NAFDAC and NPC must be resourced to operate as active, data-driven regulators rather than episodic enforcement agencies. For the courts and consumer protection mechanisms, the implication is that procedural innovation (specialist tribunals, compensation mechanisms, improved evidentiary regimes) will materially expand access to justice for victims of ADRs. The combined effect of these reforms would be to shift the system from reactive crisis management to proactive risk reduction, thereby protecting public health while creating clearer expectations and incentives for pharmaceutical companies.

BIBLIOGRAPHY

Articles and Chapters in Books

Adisa R and Omitogun TI, 'Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary health care centres in Ibadan, southwestern Nigeria' *BMC Health Serv Res* (2019) 12.

Adisa R, Omitogun TI, 'Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary health care centres in Ibadan, southwestern Nigeria' *BMC Health Serv Res* 19, 926 (2019) <**https://doi.org/10.1186/s12913-019-4775-9**>accessed 6th August 2025.

Akarowhe K, 'A Case Study of Pharmaco-vigilance in Nigeria:Challenges and Solutions' *American Journal of Biomedical Science & Research* (2020) 36.

Akarowhe Kingsley, 'A Case Study of Pharmaco-vigilance in Nigeria: Challenges and Solutions' *American Journal of Biomedical Science & Research* (2020) 10.

Akunyil D, 'Counterfeit and Substandard Drugs, Nigeria's Experience: Implications, Challenges, Actions and Recommendations, In *Talk for NAFDAC at a Meeting for Key Interest Groups on Health* The World Bank (2005).

Akunyili DN, 'Fake and counterfeit drugs in the health sector' *Annals of Ibadan Postgraduate Medine* (2004) 2.

Asiamah M and others, 'Spontaneous reporting of adverse drug reaction among health professionals in Ghana' *Arch Public Health* 80, 33 (2022). **https://doi.org/10.1186/s13690-021-00783-1**>accessed 6th August 2025.

Asiamah M, 'Spontaneous Reporting of Adverse Drug Reaction among Healthcare Professionals in Ghana' *Archives of Public Health 80:33* (2022) <https://doi.org/10.1186/s13690- 021-00783-1>accessed 6th August 2025.

Awodele O and others, 'Pharmacovigilance amongst patent medicine vendors (PMVs) in Ekiti State, Nigeria' *Int J Risk Saf Med* (2012) 65-72.

Cliff-Eribo KO and others, 'Adverse drug reactions in Nigerian children: a retrospective review of reports submitted to the Nigerian Pharmaco-vigilance Centre from 2005 to 2012' *Paediatr Int Child Health* (2016) 300-304.

Cohen JC, 'Pharmaceuticals and corruption: a risk assessment' *Global Corruption Report 2006* London, Transparency International (2006)77-84.

Dal Pan JG, 'Ongoing Challenges in Pharmacovigilance' *Drug Saf* (2014) 30.

Danraka AM, 'Assessment of Knowledge, Attitude and Practice of Drug Reaction Reporting Among Health Workers in Selected Health Facilities in Abuja' *Journal of Biology, Agriculture and Healthcare.* Vol. 11, (2021) 8.

Erhun WO and others (2001), 'Drug Regulation and Control in Nigeria: The Challenges of Counterfeit Drugs' *Journal of Health and Population in Developing Countries* (2001) 23-34.

Erhun WO and others, 'Drug Regulation and control in Nigeria: The challenge of counterfeit drugs' *Journal of health and population in developing countries* (2001) 23-34.

Erhun WO, 'Drug regulation and control in Nigeria: the challenge of counterfeit drugs' *J Health Popul Dev Ctries (*2001) 3-4.

Eze SC and others, 'Assessment of pharmaco-vigilance activities among pharmacist interns in Nigeria: a cross-sectional study' *Futur J Pharm Sci* (2023) 11.

Igbinlade AS and others, 'SuRvey Of Knowledge Of Pharmacovigilance And Adverse Drug Reactions Reporting Among Healthcare Providers In Abuja, Nigeria' *African Journal of Educational Management, Teaching and Entrepreneurship Studies* VOL.13 (2024) 2. <https://ajemates.org> accessed 6th August 2025.

Newton PN and others, 'Manslaughter by fake artesunate in Asia - will Africa be next?' *PLoS Med (*2006) 197.

Ohaju-Obodo JO, Iribhogbe OI, 'Extent of pharmacovigilance among resident doctors in Edo and Lagos States of Nigeria' *Pharmacoepidemiol Drug Saf* (2010) 1-5.

Olowofela A and others, 'Pharmaco-vigilance in Nigeria: An Overview' *Pharmaceutical Medicine* (2006) 87-94.

Onakpoya IJ and others, 'Post-marketing withdrawal of 462 medicinal products because of adverse drug reactions: a systematic review of the world literature' *BMC Med* (2016) 10.

Opadeyi OA and others, 'Assessment of the state of pharmaco-vigilance in the South-South zone of Nigeria using WHO pharmaco-vigilance indicators' *BMC Pharmacol Toxicol* (2018) 19(1): 27.

Oreagba IA and others, 'The knowledge, perceptions and practice of pharmacovigilance amongst community pharmacists in Lagos State, South West Nigeria' *Pharmacoepidemiol Drug Saf* (2011) 20.

Ratanawijitrasin S and Wondemagegnehu E, 'Effective drug regulation- A multi country study' A book published by World Health Organization (2002).

Santosh KC and others, 'Pharmaco-vigilance: An Overview' *Journal of Pharmaceutical Science* (2011) 40.

Shakoor O and others, 'Assessment of the incidence of substandard drugs in developing countries' *Trop Med Int Health (*1997) 39-45.

Ujomudyke CC and others, 'Government Policies and Performance of Pharmaceutical Firms in South-East, Nigeria', *International Journal of Business and Management Review*, Vol.12, (2024) 85-118.

Online Sources

Adedeji WA and others, 'Adverse drug reactions reporting practice and associated factors among community health extension workers in public health facilities, Southwest,

Nigeria' *Pan African Medical Journal (*2021) 165. <https://www.panafrican-med-journal.com//content/article/40/165/full> accessed 6th August 2025.

Akunne OO and others, 'Insight into Nigeria's pharmaco-vigilance landscape: stakeholder perspectives on strengthening medicine safety systems' *Discov Health Systems* 4, 52 (2025) <https://link.springer.com/article/10.1007/s44250-025-00234-6#> accessed 25th August 2025.

Asiamah M and others, 'Spontaneous reporting of adverse drug reaction among health professionals in Ghana' *Arch Public Health* 80, 33 (2022) <https://archpublichealth.biomedcentral.com/articles/10.1186/s13690-021-00783-1#citeas> accessed 25th August 2025.

Avong YK and others, 'Addressing the under-reporting of adverse drug reactions in public health programs controlling HIV/AIDS, Tuberculosis and Malaria: A prospective cohort study' <https://pmc.ncbi.nlm.nih.gov/articles/PMC6104922/> accessed 17th August 2025.

Awodele O and others, 'Patterns of adverse drug reaction signals in NAFDAC pharmaco-vigilance activities from January to June 2015: safety of drug use in Nigeria' *Pharmacol Res Perspect* (2018) <https://pmc.ncbi.nlm.nih.gov/articles/PMC6175912/> accessed 25th August 2025.

Ayeni FA and others, 'Assessing the knowledge, attitude, and practice of hospital-based pharmacists in reporting adverse drug reactions in Lagos, Nigeria' *Am J Pharmacother Pharm Sci* (2024)12 <https://ajpps.org/assessing-the-knowledge-attitude-and-practice-of-hospital-based-pharmacists-in-reporting-adverse-drug-reactions-in-lagos-nigeria/> accessed 25th August 2025.

Chinecherem S and others, 2022 'Practices and Barriers towards Pharmacovigilance and Adverse Drug Reporting Among Intern Pharmacists in Nigeria' *Journal of Advances in Medical and Pharmaceutical Sciences* (2022) 27-40. <https://doi.org/10.9734/jamps/2022/v24i11587>accessed 6th August 2025.

Chiwendu Olike, 'The fight against fake drugs by NAFDAC in Nigeria'<https://bibalex.org/baifa/Attachment/Documents/193922.pdf> accessed 23rd August 2025.

Chiwendu Olike, 'The fight against fake drugs by NAFDAC in Nigeria'<https://bibalex.org/baifa/Attachment/Documents/193922.pdf> accessed 5th November 2025.

Coleman HC, 'Ethical Considerations in Selling Pharmaceuticals in Emerging Economies' <https://www.researchgate.net/publication/317277480_Ethical_Considerations_in_Selling_Pharmaceuticals_in_Emerging_Economies> accessed 25th August 2025.

Coleman JJ and Pontefract SK, 'Adverse drug reactions' *Clin Med (Lond) (*2016) 16(5):481-485 <https://pmc.ncbi.nlm.nih.gov/articles/PMC6297296/> accessed 25th August 2025.

Edwards R, Aronson J K, 'Adverse drug reactions: definitions, diagnosis, and management' <https://pubmed.ncbi.nlm.nih.gov/11072960/> accessed 17th August 2025.

Edwards Ralph and others, 'Adverse drug reactions: definitions, diagnosis, and management' <https://www.thelancet.com/journals/lancet/article/PIIS0140673600027999/abstract> accessed 25th August 2025.

Eruaga MA and others, 'Pharmacovigilance in Nigeria: Addressing challenges in ensuring drug safety and monitoring adverse effects' <https://gsconlinepress.com/journals/gscarr/content/pharmacovigilance-nigeria-addressing-challenges-ensuring-drug-safety-and-monitoring-adverse> accessed 17th August 2025.

Jackson, Etti & Edu, 'Product Liability A Crisis Of Disintegration Of The Manufacturer?' <https://oldsite.jee.africa/wp-content/uploads/2020/06/PRODUCT-LIABILITY-A-CRISIS-OF-DISINTEGRATION-OF-THE-MANUFACTURER.pdf?> accessed 17th August 2025.

Kommu Sharratt and others, 'Adverse Drug Reactions' <https://www.ncbi.nlm.nih.gov/books/NBK599521/> accessed 25th August 2025.

Ndimondo-Sigonda M and others, 'Accrediteded drug dispensing outlets: A novel public private partnership' *An approach to improving access to affordable, high-quality drugs and services in under-served areas* (2003).

Nwani PO and Isah AO, 'Frequency and Patterns of Adverse Drug Reactions among Elderly In-Patients in a Nigerian Teaching Hospital' *J Basic Clin Pharma* (2017) 245-250 <https://www.jbclinpharm.org/articles/frequency-and-patterns-of-adverse-drug-reactions-among-elderlyinpatients-in-a-nigerian-teaching-hospital-3939.html> accessed 25th August 2025.

Okeri HA, Okeri E, 'Medicinal Products Liability of the Pharmacists: An Overview of Some Emerging Legal Issues in Nigeria' <https://www.longwoods.com/content/19597/world-health-population/medicinal-products-liability-of-the-pharmacists-an-overview-of-some-emerging-legal-issues-in-nigeri> accessed 17th August 2025.

Oshikoya K, 'Medical Students' Knowledge Of Risk Factors For Adverse Drug Reactions In Children' *The Internet Journal of Medical Education* (2009) <https://ispub.com/IJME/1/2/3883> accessed 25th August 2025.

Ratanawijitrasin SWE, 'Effective drug regulation- A multi-country study' *A book published by World Health Organization* (2002) <http://ndl.ethernet.edu.et/bitstream/123456789/27927/1/58.pdf> accessed 5th November 2025.

Rohlfs A, 'Adverse Drug Reaction: The Complex Question Of Civil Liability' <https://rucrlaw.com/en/pharmaceutical-companies-liability-drug-effects/> accessed 17th August 2025.

Segre J and Tran J, 'What works: Care-shop Ghana (Improving access to essential drugs through conversion franchising' (2008) <www.nextbillion.net/resources/casestudies> accessed 5th November 2025.

Sherloc, 'Decree No. 48 of 1989 on the establishment of the National Drug Law Enforcement Agency'<https://sherloc.unodc.org/cld/en/legislation/nga/decree_no._48_of_1989_on

_the_establishment_of_the_national_drug_law_enforcement_agency/articles_11-14/decree_48.html?> accessed 17th August 2025.

Sill Fulmer, 'What Responsibility Does the FDA and Pharmaceutical Companies Have to Consumers?' <https://www.fulmersill.com/blog/what-responsibility-does-the-fda-and-pharmaceuti/> accessed 23rd August 2025.

Tsai CN, 'How to Rehumanize Clinical Trials: An Antibiotic Perspective' *California Law Review,* (2025) <https://www.californialawreview.org/print/antibiotic-patent> accessed 25th August 2025.

Ukwueze FO, 'Product liability in Nigeria: a paradigm shift from fault-based to strict liability regime'<https://www.researchgate.net/publication/342901515_Product_liability_in_Nigeria_a_paradigm_shift_from_fault-based_to_strict_liability_regime/citations> accessed 17th August 2025.

Umeike A, 'Market dynamics and legal implications: analyzing product liability in Africa's medical device sectors' <https://www.ibanet.org/market-dynamics-legal-africa-medical-device> accessed 17th August 2025.

Umeike Amala, 'Market dynamics and legal implications: analysing product liability in Africa's medical device sectors' <https://www.ibanet.org/market-dynamics-legal-africa-medical-device> accessed 25th August 2025.

Usar IJ and Bukar BB, 'Challenges and Opportunities of Pharmaceutical Regulation in Nigeria' <https://www.iosrjournals.org/iosr-jhss/papers/Vol.%2025%20Issue4/Series-6/C2504061118.pdf> accessed 25th August 2025.