IMPACT OF POST MARKETING SURVEILANCE ON FALSIFIED MEDICINE IN NIGERIA

Research dissertation presented in partial fulfilment of the requirements for the degree of MSc in Pharmaceutical Business and Technology (QQI)

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I certify that the dissertation entitled: "Impact of post marketing surveillance on falsified medicine in Nigeria" submitted for MSc in Pharmaceutical Business and Technology is a research work carried out by me and references were made to literatures from other writers.

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Acknowledgement:

I am forever thankful to God for the gift of life, His unending graces and the blessings of family and loved ones.

This dissertation is specially dedicated to my father Chief Fidelis Chukwudi Mgboko of his blessed memory, who I know I always made proud, and my mother Mrs. Pauline Chinyere Mgboko, who continuously through her unwavering love, prayers and sacrifices has given me shoulders to stand on and wings to fly. I love you so much mum.

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Abstract:

The thesis aims to evaluate the impacts of post marketing surveillance on falsified medicines among healthcare professionals (medical doctors and pharmacists) and consumers in Nigeria by conducting a questionnaire-based survey for quantitative research. in order to achieve this, the awareness and knowledge of falsified medicines, factors affecting effective post marketing surveillance in Nigeria and recommendations to improve adequate post marketing surveillance of falsified medicine in Nigeria.

The healthcare professionals (medical doctors and pharmacists) and consumers were evaluated to ascertain their level of awareness and knowledge of falsified medicines, healthcare professionals' direct experiences to post marketing surveillance guidelines and frequencies of falsified medicine cases during their experience. The efficiency of Mobile Authentication Services (MAS). Sixty-six (66) respondents voluntarily participated and responded accordingly to the questionnaire structured survey. 20 (30.0%) respondents were medical doctors, 24 (36.0%) respondents were pharmacists while 22 (33.0%) respondents were consumers. There was an absolute 100.0% respondents to willingness to update their knowledge about guidelines and regulations of post marketing surveillance of falsified medicine. Their most preferred method was through current guidelines from regulatory bodies.

There were factors associated with inadequate impacts of post marketing surveillance which included NAFDAC regulatory policies, social economic status of the country and cost implications. Increasing awareness of falsified medicines was recommended to be implemented by continuous advertisements through

internet, radios and newspapers. Designing and implementing new applicable regulations to help improve post marketing surveillance.

Key Words: Post Marketing Surveillance (PMS), falsified medicines, counterfeit drugs, challenges, knowledge and awareness of falsified medicines, pharmacovigilance, National Agency for Food and Drug Administration and Control (NAFDAC), National Pharmacovigilance Center (NPC),

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ABBREVIATIONS:

NAFDAC- NATIONAL AGENCY FOR FOOD DRUG ADMINISTRATION AND CONTROL

MAS- MOBILE AUTHENTICATION SERVICE

PMS- POST MARKETING SURVEILLANCE

NPC- NATIONAL PHARMACOVIGILANCE CENTER

ICH- INTERNATIONAL CONFERENCE OF HARMONIZATION

NDLEA- NATIONAL DRUG LAW ENFORCEMENT AGENCY

CRO- CLINICAL RESEARCH ORGANIZATION

EDC- ELECTRONIC CAPTURE DEVICE

UNODC- UNITED NATIONS OFFICE ON DRUG AND CRIME

DIFD – DEPARTMENT FOR INTERNATIONAL DEVELOPMENT

NMEP—NATIONAL MALARIA ELIMINATION PROGRAM

WHO – WORLD HEALTH ORGANIZATION

ADR – ADVERSE DRUG REACTIONS

GMP – GOOD MANUFACTURING PRACTICES

RFID- RADIO FREQUENCY IDENTIFICATION

API- ACTIVE PHARMACEUTICAL INGREDIENTS

PCN- PHARMACISTS COUNCIL OF NIGERIA

COI- CONFLICT OF INTEREST

CHAPTER 1

1.1 INTRODUCTION

Medicine has been described to be involved in the business of health, wellness and healing. It is used either as prophylactic, curative, conservative or palliative form of therapy in the cases of diseases or medical/surgical emergencies. There are also designated healthcare practitioners (Doctors, pharmacists, physiotherapists, Dentists etc.) who are authorized to write prescriptions according to global acceptable standards.

There are processes which medicines/drugs go through which involve drug discovery and development, preclinical and clinical trials phases, marketing authorization and post marketing surveillance. All new medicines must undergo clinical trials before they can be authorized by the competent regulatory agencies. Clinical trials significance cannot be over emphasized because it examines the safety, dosage and efficacy of drugs for human use at various stages.

The phase 1 is concerned with smaller number of people who are administered with the right dosage and being carefully monitored, and also inactive ingredients (placebo) is used. At this stage there would also be evaluation of safety of the participants after being administered the dose. (ACS, 2020) while phase 2-3 requires more participants and there are evaluations of safety and efficacy respectively and inactive ingredients may/may not be used at this stage. Larger numbers of participants are required, and it also takes longer duration of time. Phase 4 involves majorly the post market surveillance which is a continuous process after the approval of the drug by the competent regulatory authority of a country (FDA, NAFDAC,

EMA) and they are available to health care practitioners which can be prescribed to over thousands of people.(ACS, 2020)

	Phase I	Phase II	Phase III	Phase IV
Number of participants	**20–80** participants	**100–300** participants	**1,000–3,000** participants	**Thousands** of participants
Duration	Up to **several** months	Up to **two** years	**One–four** years	**One** year +
Purpose	Investigates the safety profile of the drug and aims to identify a safe dose that can be used in humans	Investigates the safety of the drug at the dose selected for use in humans and looks for signs of efficacy	Investigates both safety and efficacy of the selected dose, often comparing against standard treatment	Investigates long-term effectiveness, benefits and cost effectiveness of treatment. Phase IV trials are conducted once a medicine has been approved for use and is on the market

Figure 1.1 Clinical Trials phases (Norvatis, 2021)

1.11 WHAT IS POST-MARKET SURVEILLANCE?

Post Market Surveillance is defined by the United States Food and Drug Administration as the "active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device." It is therefore said to be a continuous events or approach to maintaining safety and efficacy of pharmaceutical and medicinal products for human use (Spencer Heaton, 2020). It is also an important scheme that enables the regulatory authorities to monitor medicinal products even after years the medicinal products are released into the market. There have been significant changes as the years goes on, the

regulatory agency adopted proactive methods instead of reactive methods (Raj et al., 2019). As far back as 2004, Nigeria joined the WHO International Drug Surveillance Program. Nigeria is the largest country in Africa with over 150 million people. Post marketing surveillance is harmonized by the National Pharmacovigilance Center liaising with National Agency for Food and Drug Administration and Control (NAFDAC) (Olowofela et al., 2016). The World Health Organization established a worldwide surveillance scheme in 2013 to inspire and strengthen countries to document several cases of falsified medicinal products in a well-structured follow up protocol (WHO, 2018)

1.12 WHAT ARE THE GOALS OF POST-MARKET SURVEILLANCE?

Pharmaceutical and medical system organizations depend upon the actual-global insights they benefit through the market surveillance they put up to:

- They maintain monitoring and act accordingly in the events of unfavorable occasions or risks as they arise in the course of use of unsafe drug practices.
- They compare new biological materials, active pharmaceutical ingredients or therapies with current options and the usual of care.
- They also update clinical guidelines so as to secure safer populations or organizations as well as healthier environments.
- Follow regulatory necessities. (Spencer Heaton, 2020)

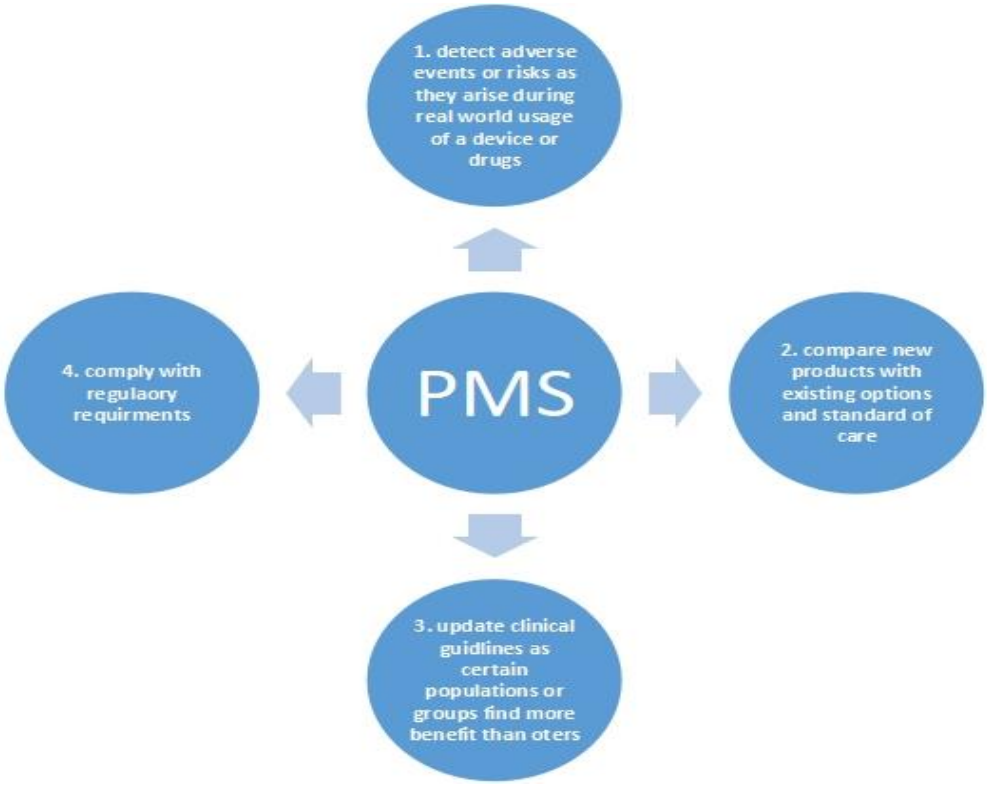

Figure 1.12 Key Goals of Post Marketing Surveillance

1.2 REGULATORY AUTHORITIES

The approval process of novel medicinal products differs in each country. In recent times different countries have sent up a regulatory authority to control and regulate the affairs of pharmaceutical companies. As time evolves, there is an increase in circulation of medicinal products to meet up with the increasing demands. This increased supply has however, brought about safety and efficacy concern. This is the task of these licensed regulatory authorities, to ensure that medical products manufactured fulfill all set standards, regulations and guidelines. This has proven to be necessary because of various reasons, one being that there is always a risk related to taking any type of medication but in some cases, the risks outweighed the benefits and causes harm to the patients. The regulatory body is charged with certifying the

components of these medications especially as regards the active ingredients to avoid adverse events as much as possible.

1.21 INTERNATIONAL CONFERENCE ON HARMONIZATION (ICH)

This is internationally recognized organization that has put together different guidelines and standards for production of medicinal products to ensure the quality, safety and efficacy of these products. The ICH focuses on 4 main topics, they include:

Q - this contains guidelines for quality control

S – this contains guidelines for safety control

E – this contains guidelines for Efficacy control

M - this contains information about Multidisciplinary guidelines

These guidelines have been authorized for use in about 10 different countries, but Nigeria is not one of them. Nigeria has its own regulatory systems and its own established good pharmacovigilance practices. Nigeria has 3 regulatory bodies that is in charge of drugs and biologics control:

- The National Agency for Food Drugs Administration and Control
- The National Drug Law Enforcement Agency
- The Federal Ministry of Health

The regulatory body in charge of licensing of drugs and other biologics in Nigeria is NAFDAC (National Agency for Food Drug Administration and control). This agency was established in the year 1993 so as to deal with the fact that the sale and use of counterfeit and falsified medicines was at a constantly rising pace and it was affecting the country adversely. NAFDAC is in charge of certifying that the products manufactured are done so according to the good manufacturing practices of the NAFDAC. (NAFDAC, 2019)

The National Drug Law Enforcement Agency is regulatory body in charge of controlling the production, use and marketing of all kinds of hard drugs. They are also in close contact with international drug units all over the world to control the transportation of these hard drugs.

The Federal Ministry of Health is the overall organization that controls the affairs of the NDLEA and NAFDAC as well as other health regulatory bodies. They set all activities to ensure that everything goes in the proper order. (Health.gov, 2021)

The NAFDAC is the competent authority which has the obligation of controlling the influx of this falsified medicines and illegal drugs. According to Decree No. 15 of 1993, their major role is to ensure and establish standard quality, safety and harmless, and efficacy of food and medicinal ingredients. (Gloria Ono and Chiazor Chiaghana, 2020)

Akinyandenu argued that the increased cost of original medicines gave ways for the penetration of falsified medicines in Nigeria thereby giving it an advantage to escalate. There is a strong agreement that most of the original, standardized drugs are not cost effective and perpetrators of this heinous acts used that opportunity to manufacture and distribute counterfeit medicines to the consumers and community. (Akiny, 2013a)

NAFDAC carried out assessment on the level of awareness by the consumers on the prevalence of falsified medicines by using media means to increase consumer's awareness. It is said to be an effective tool to exhibit high fractions of the bigger populations to schemes like messages through current handling of the television, newspapers, radios and even mobile phones. (Wakefield et al., 2010)

It was later stated that there was some level of awareness and publicity to the various awareness campaign and it was also discovered that they do not adhere to the ads to prevent health hazards. This further brought so many insights on the

varying strength of the proliferation of the counterfeit and illegal medicines. There was also recommendation for NAFDAC to deepen, reinforce and not to relent on their ads campaign and strengthen post marketing surveillance to identify and eliminate all illicit manufacturing drug sources and facilities. (Gloria Ono and Chiazor Chiaghana, 2020)

Nigeria is one of the countries with the highest number of cases of falsified and illicit medicines in Africa.(Rip et al., 2016) there has also been a significant reduction of the prevalence of illicit medicines from 67% in 2001 to about 5%-10% in 2012 with so many reports of increased admissions and mortalities as a result of consumptions of falsified and counterfeit medicines. (Rip et al., 2016)

NAFDAC adopted various approaches and schemes to control the proliferations of falsified medicines and this include TRUSCAN a product authentication tool for evaluation of authenticity of drug products and the Mobile Authentication Scheme (MAS). This scheme requires the consumers' utilization of mobile technologies and gadgets to detect and verify authenticity medicinal products at the point of transactions at every medicinal outlet. (Oyetunde *et al.*, 2019a).

The MAS is a mobile tech developed to prohibit the dispensing and peddling of illegal and falsified medicines to consumers. It is NAFDAC authorized and in view of their current guidelines, all market authentication personnel who wants to use the MAS must inform the NAFDAC agency and get necessary documentations moving forward. (Oyetunde *et al.*, 2019a). This also provides routine access to pharmaceutical companies to the scratch panel which is fixed to the medicinal products. This contains an alphanumeric digital code which is a single utilization products private detection. The consumers and users are to reveal the panel after scratching it off and send the numbers (PIN) which is followed by actual time short

message service (SMS) text message to authenticate medicinal products. So it's either it is genuine or the product is unregistered and probably a counterfeit which is dangerous to health and safety of consumers. (Oyetunde *et al.*, 2019a)

1.3 FALSIFIED MEDICINE

Falsified medicines are defined asymmetrically according to several regions and different countries however, we can say the world health Organization appear to have a comparative definition. They definition stress on consciously faking and mislabeling of medications in other to copy and mimic the genuine medicines. To this effect, falsified medicines integrate medicinal materials with right or wrong pharmaceutical materials, with or without dynamic materials, insufficient amounts or incorrect dose of active ingredient(s), and with fake packaging. Nigeria's Counterfeit and Fake Drugs and unwholesome Processed Foods (Miscellaneous Provisions) Decree (1999) characterizes counterfeit and fake medications as:

- Any item which isn't what it implies to be OR
- Any medication or medication item which is hued, coated, powdered, or cleaned that the harm is hidden, or which is made to give off an impression of being better or of more noteworthy restorative esteem than it truly is, which isn't marked in an endorsed way or which name or holders or anything accompanying the medication bears any assertion, plan or gadget which makes a bogus case for the medication or which is false or deceiving OR
- Any medication or medication item whose compartment is so made, framed or filled as to be deluding OR
- Any medication item whose name doesn't bear satisfactory course for use and such sufficient admonition against using those neurotic conditions or by

kids where its utilization might be risky to wellbeing or against dangerous use or methods or length of utilization, OR

- Any medication item which isn't enrolled by the organization as per the arrangements of the Food, Drugs and Related Products Decree 1993, as corrected. (nafdac.gov, 2004)

Also, (Agbaraji et al., 2012) characterized fake drugs as those medications that have been manufactured utilizing incorrect amounts, or wrong labeling, to either diminish the intensity, or suppress the potency of medication. Hence, falsified medications in simple terms imply to drugs that are manufactured, delivered and sold in ways and intents that misleadingly address their source, substance, and authenticity or viability. (Agbaraji et al., 2012)

Nigeria as a whole continues to fight the rising level of circulation of falsified medicines especially with drugs that are considered to be important for public health like the drugs used in treatment of malaria. A 2011 study showed that 64% of antimalaria medicines in circulation were substandard. This is due to some major contributing factor including: The open drug markets throughout the country, aiding continuous distribution of medicines distribution of medicines without prescriptions. One of the major medicine open market is located in the eastern part of Nigeria called “the Onitsha head-bridge market” (Fatokun, 2016). In a bid to control the importation and sale of possible falsified medicines, the Nigerian Government has established a “drug distribution guideline”. This guideline aims to revamp the drug distribution system in Nigeria so as to monitor drug usage and improve post marketing surveillance. This chain of events is then expected to impact on the detection of falsified medicines and their usage. (Fatokun, 2016)

1.4 RESEARCH PURPOSE

This research work was carried out to study the level of awareness and explore the impacts of post-marketing surveillance on falsified medicine. Post-marketing surveillance is essential as a way to guard patients against avoidable dangers from a harmful, unsafe medicinal products with the aim of protecting the public and ensuring safety, efficacy and quality. Spontaneous reporting on unfavorable and adverse drug reactions is a short approach, but under-reporting is and may still be a problem. Prospective research is an informative way to gain outcomes however they take time, but they are quite resourceful. Given that all drugs go through clinical trials from phases I - IV before it's far made available for standard use, post-marketing surveillance assumes an essential role in detecting rare detrimental reactions and results.

The research work hereby aims at the effects post-marketing surveillance has on falsified pharmaceutical and medicinal products. It also evaluates the awareness of healthcare professionals (medical doctors and pharmacists) and consumers of falsified medicines as well as their source of knowledge. The level of implementation of regulations as regards post marketing surveillance of falsified medicine set up by NAFDAC. The purpose of this research also goes deeper to the level of awareness of healthcare professionals and consumers concerning the Mobile Authentication Service and its level of efficiency. Lastly the factors that challenges effective post marketing surveillance of falsified medicine in Nigeria.

1.5 SIGNIFICANCE OF THE STUDY

When manufacturing a novel medical product, active pharmaceutical ingredients, or creating new treatment options, pharmaceutical agencies and various clinical research organizations (CRO) go through clinical trials to ensure that products are secure, effective, and efficacious without also lowering or compromising quality. Even though those trials are heavily regulated procedures, not all side effects of a drug can be anticipated making it essential to reveal, perceive and assess negative events that did not appear during the drug clinical trial phases and approval method. This post-marketing surveillance (PMS) can be carried out through several agencies which include pharmaceutical manufacturers, universities, competent authorities, companies, private organizations, CROs and customer advocacy organizations.

Post-marketing surveillance makes use of some schemes to monitor drug, which includes spontaneous reporting databases, prescription tracking and monitoring, digital fitness records, comprehensive patient histories, and document links between several health databases. The information may be captured electronically or computerized at its supply (known as e-source), or in paper form and later transcribed into an electronic data capture (EDC) device. This information is reviewed to focus on capability safety issues in a method referred to as information mining.

There is a continuous growing trend in the rates of falsified medicine in the world and it is particularly high in third world countries like Nigeria where there is vast level of corruption which has transcended to all sectors of the country including the healthcare. Although there are regulatory agencies involved in the affairs of drug development and distributions, the major regulatory agency is NAFDAC and National Pharmacovigilance Center plays major roles in pharmacovigilance with particular focus on post marketing surveillance reporting areas and its efficiencies.

They both regulate, monitor and maintain the safety, quality and efficacy of any medicine without losing focus on the benefit-risk ratio. There are also responsible for educating the public, healthcare professionals about effective awareness and reporting of any falsified medicine. However, there are so many challenges that might be encountered in the events of routine monitoring and effectiveness of post marketing surveillance and this study shows how much impacts post marketing surveillance has on falsified medicine.

1.6 RESEARCH OBJECTIVES:

- Evaluation of the level of awareness of the public and healthcare professionals about Mobile Authentication Service used to curb falsified medicine in Nigeria.
- Identifying the healthcare professional's role in post marketing surveillance of falsified medicine in Nigeria
- Identifying and evaluating the level of implementation of the regulatory systems put in place to curb falsification of medicine and medicinal products.
- To evaluate the cost and socioeconomic impact of falsified and substandard medicines in eastern Nigeria

1.7 RESEARCH QUESTIONS:

- Are the healthcare professionals and consumers aware of the falsified medicines and what is their source of knowledge?
- Are healthcare practitioners aware of the regulations as regards post marketing surveillance on falsified medicine set up by NAFDAC?

- Is there healthcare professionals and consumers' awareness of the established MAS design and utilization by NAFDAC to detect falsified medicines?
- Are there factors that challenges effective post marketing surveillance of falsified medicine in Nigeria.
- Recommendations?

1.8 Structure of The Study

The primary research for this dissertation executed using a quantitative approach which involved the use of questionnaires and qualitative approach using telephone interviews as necessary as possible. The use of questionnaires was designed for healthcare professionals with varying level of experience as regards post marketing surveillance and falsified medicine and also to be given to some consumers to evaluate their level of awareness and also knowledge on about post marketing surveillance on falsified medicines as well as possible recommendations. The major healthcare practitioners would be the medical doctors and the pharmacists in Nigeria. Each questionnaire has five distinctive segments

- The first segment collects information on basic inclusions like bio data, level of experience, professional status.
- The second segment collects data on the level of knowledge of post marketing surveillance on falsified medicines
- Third segment is concerned with information of their level of awareness about post market surveillance
- The fourth segment collects information on factors that supports inadequate post market surveillance among healthcare professionals
- The fifth segment collects information on possible improvement areas where necessary.

A qualitative study was also carried out by conducting phone interviews with a varying level of experience and opinions regarding the practice of post-marketing surveillance and its impacts on falsified medicine in Nigeria. The data obtained from these healthcare professionals regarding the knowledge, awareness, possible recommendations, and challenges associated with PMS helped in complementing results obtained from the survey to present a significant conclusion on the subject.

1.9 CONCLUSION

As mentioned earlier, post-marketing surveillance has come to stay, and it is not a one-time activity and also not a short approach. The adverse effects of counterfeit drugs on patients can only be seen after drug have been administered and that is when post marketing surveillance commences. It is therefore imperative that drugs go through this surveillance which in turn will reduce the use of falsified drugs and subsequent dangers to the public health sector as well as the country. This research study therefore seeks to bring out the impacts of this post-marketing surveillance, its depths and how it has helped or affected products consumed by the public. The regulatory agency (NAFDAC) is mainly in charge of post marketing surveillance by providing schemes and supports on the best approach to combat this striving illegal and criminal business capable of destroying human lives and wrecking the economy of Nigeria. Identifying the healthcare professional's role as well as the role of the consumers cannot be over emphasized because all hands are expected to be on deck to make sure we fight together and significantly reduce business of falsified medicines.

Chapter 2

2.0 Literature review

2.1 Falsified Medicines: A Serious Threat to Public Health

Falsified medicines have been said to be a serious threat to both public health in general and individual health. These sets of medicines could contain either the wrong pharmaceutical ingredients, or even ingredients that are of low quality and quantity. Patients or individuals who consume any of drugs which contain any one of the above may fail to see improvement in the patients' condition, and it could also cause avoidable mortality and morbidity. In many recorded cases, it has been found that it could also lead to drug resistance, which may under circumstances impair patients' response to future medication of such kinds of medicine. (Dégardin *et al.*, 2014)

According to (Akiny, 2013b), he particularly cited in a literature that falsified medicine is more prevalent in developing or underdeveloped countries although its estimated to be a global problem. There is also an estimation that there are more falsified medicines in the public circulation than the genuine medications. There were also factors that made it possible for falsified medicines to thrive in Nigeria and this includes corruption, inadequate implementation of already existing laws, non-experts in pharmaceutical business, high level of uneducated citizens, illegal and corrupt practices of importation and exportation of medicines (Akiny, 2013b).

In the events where this causes harm to patients, falsified medicines could also result in serious financial loss to the pharmaceutical industry generally, the organization manufacturing them could also run into serious financial loss if and when caught,

and this will without doubt erode the level of confidence the public has in their genuine medications and also their trust in the national healthcare system will have been tarnished Some researchers however, argue about this problem as not only a health emergency, but it could be termed a "macroeconomic pandemic in the making" (Yamamoto, 2014). Furthermore, some researchers like (Cannon, 2015) are indicating that certain terrorist organizations also have the tendency to take part in the manufacture of substandard and low-quality medicines and set up the business in a bid to fund their terrorist activities. In a low to middle income country like Nigeria, where diseases like malaria and other infections reign like a plague, the country is considered. Hotspot for the manufacture and sale of substandard medicines to desperate low-income earners. (Cannon, 2015).

The continuous production and use of these medicines are an issue that disrupts the country's growth towards a sustainable level of development. The falsified medicines are usually completely ineffective in treatment of disease condition or in poor quality and so cannot effectively treat. In some cases these medicines have even been seen to worsen an existing medical problem. (WHO. int, 2017)

It is a general healthcare problem that affects everybody especially the women and children. During gestation, healthcare professionals cannot over emphasize the importance of Oxytocin injections which is key during labor, delivery and after labor to manage post-partum hemorrhage (PPH). There is also need for proper storage of the Oxytocin to be very effective and it is important to note that genuine Oxytocin is very important. PPH happens to be among the first five leading cause of maternal mortality in Nigeria. According to (Adham Yehia, 2020), physicians prescribe a specific brands of Oxytocin because of trust issues and if the consumers fail to afford

it based of its high cost then they become victims of falsified medicines thereby causing causalities like mortalities and morbidities to maternal sectors.

Figure 2.1a A Nurse Examines a Pregnant Woman During Antenatal Clinic in Nigeria (Adham Yehia, 2020)

According to (Anyakora *et al.*, 2018), 159 samples of Oxytocin were evaluated and underwent the proper verification and registration with competent authority like national medicine regulatory agency. All forms of labelling, dosages, active ingredients and batch product number were provided including the dates of expiry which was one year away. It was observed that even though every sample batch passed visual monitoring and analysis, High performance liquid chromatography (HPLC) assay analysis revealed that 118 (74.2%) did not meet the specifications of the HPLC assay. It was also deduced from the packages that they were imported from China, India and Germany. (Anyakora *et al.*, 2018)

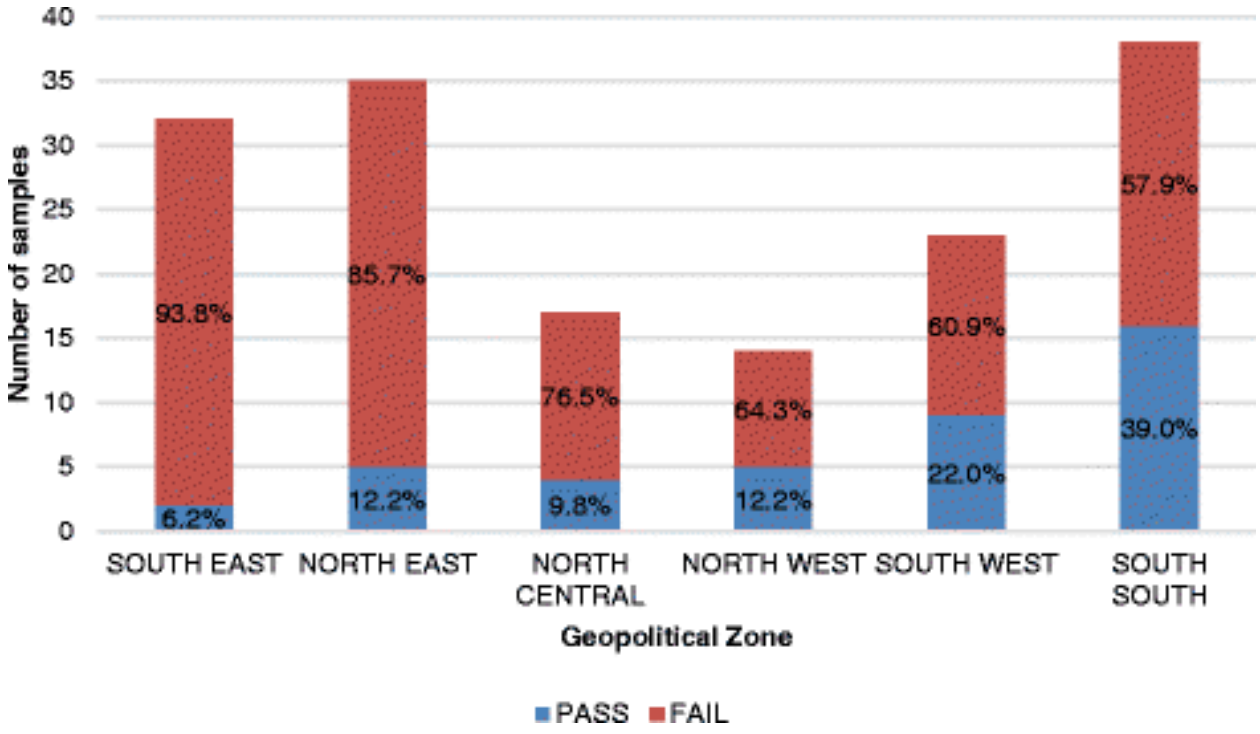

Figure 2.1b Percentage Failure of Oxytocin Samples by Geopolitical Zone in Nigeria (Anyakora *et al.*, 2018)

2.1.1 Nature of Falsified Medicines and Falsified Medicines in The Wake of COVID-19

The question here is, what are the components of the falsified medicines? Studies found that some of the falsified medicines was not made up of any active ingredient like some meningitis vaccines were seen to only contain salt water. Some of the Falsified medicines contained an unhealthy or outrightly harmful amount of the active ingredients an example can be seen in some of the local antidiabetic medicines that were made up of very high doses of gibenclamide. Other falsified medicines either had the wrong active ingredient or the formulation formular was wrong. Some

even had high levels of impurities coupled with the above mention factors. (Rahman et al., 2018)

A report worldwide operation carried out by the international police in July of 2020 stated that the Interpol seized numerus falsified medicines related to the probable treatment of COVID. Medicine products seized was valued at 14 million USD. The medicines seized includes unlicensed antiviral medicines and unlicensed chloroquine (an antimalaria drug) that was previously approved for the treatment of COVID. As seen in most underdeveloped and developing countries, criminals have taken the opportunity to take advantage of the situation in a bid to maximized profit no matter the cost. According to studies carried out by United Nations Office on Drugs and Crime (UNODC), there is currently a massive growth in the production and sale of falsified and substandard medicines in the wake of the current COVID. This is because there is a current increase in demand of medicines for treatment of the COVID as well as other symptoms that occur with the disease. currently, Nigeria imports majority of her medicinal products. Due to the ongoing pandemic, there is tension in the supply chain of medicines, and this has led to increase in cost of good quality medicines and so the medium to low-income earners lean more to buying cheap medical products that almost always happen to be substandard or falsified. According to (UNODC.org, 2020) between April and May of 2020, NAFDAC had already confiscated over 36 substandard medicines which was made up of tramadol, codeine and other substandard medical products associated with safety in the COVID time like hand sanitizers, nose masks and even chloroquine. The world market for falsified and substandard medicine and medicinal products is estimated to be worth almost 200 billion dollars per year. This figure acts as an incentive to lure people into the illegal business of falsification and substandardisation of medicine and medical products.(UNODC.org, 2020)

2.1.2 Therapeutic Categories of Falsified Medicines

According to study carried out by (Rahman et al., 2018) it was seen that drugs for treatment of sexual dysfunction, sedative drugs and hypnotics were the drugs that were most frequently falsified that stood a high risk of increased morbidity and mortality. Even so, the falsification of antipyretics, and analgesics was seen to be the major problem in underdeveloped countries. The figure below illustrates this.

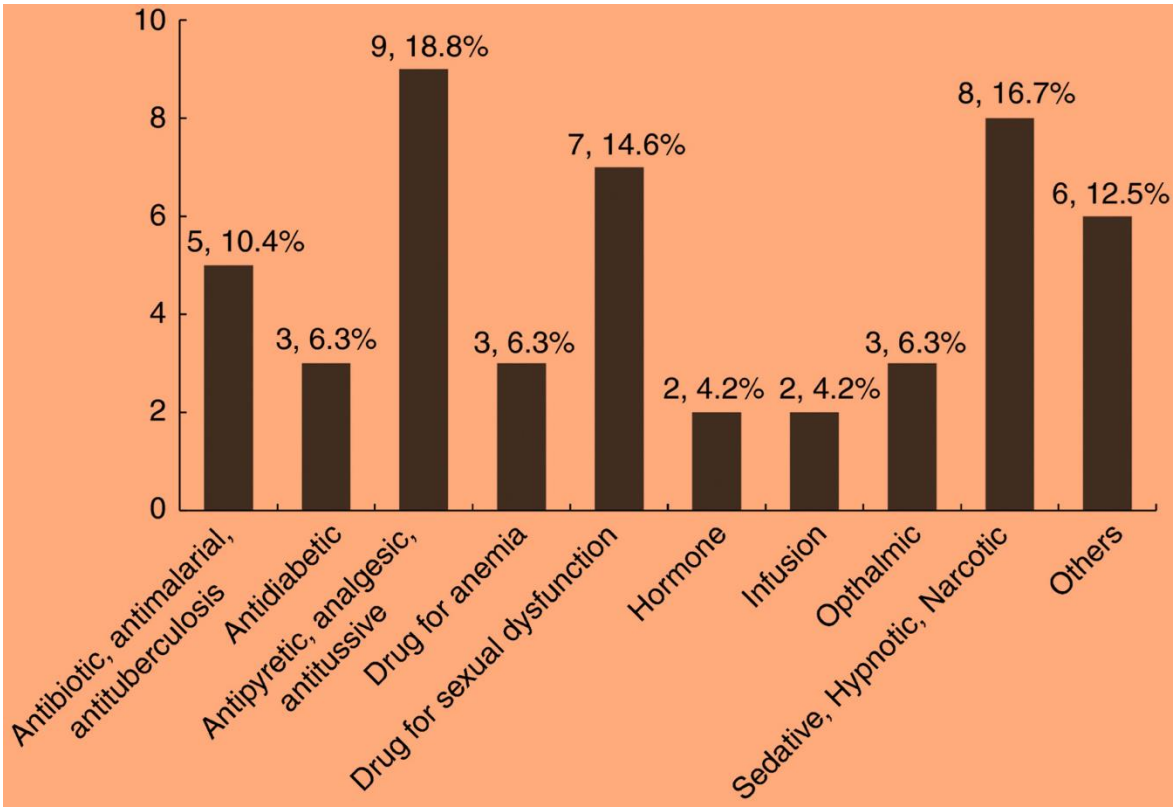

Figure 2.1.2 Therapeutic Categories of Falsified Medicine

2.1.3 Level of Awareness of The Public and Healthcare Professionals on Falsified Medicine

when it comes to how aware the pubic and health care professionals are about falsified medicine and its problems, we cannot overemphasize that the NAFDAC has been doing some level of campaign since its inception to curb the production, marketing and sale of falsified medicine. Nigeria being a third world country and with the level of illiteracy of the public can only do so much. However, this is an ongoing global fight that keep humanity safe and also help to better life and wellness of the people. The health care system of Nigeria is in a dilapidated state, there is high level of corruption and illiteracy, so falsifiers use this disadvantage to gain more presence into the Nigerian market knowing fully well that Nigeria is the heart of Africa. NAFDAC deployed use of media campaign such as TV, radio, and newspapers to create some level of awareness so as to enable every citizen (the members of the public and health care professionals) young and old to join the fight against the prevalence if falsified medicines in Nigeria. They thought that by so doing, they could reach more than half of the population of nor all through the media campaign. According to some researchers, “by the age of 18, a young person will have seen 350,000 commercials and spent more time being entertained by the media than any other activity except sleeping”. With this, one would think that everyone would be aware and join the fight against falsified medicine but there are some factors which are evident in opposing the strategies and also negatively affects the anticipated outcome. These factors include lack of basic social amenities like electricity, such high level of poverty that people cannot afford a basic mobile phone let alone be able to fund the network service provider. Also, people have grown increasing lazy to source and anticipate relevant existing information. Furthermore, due to the high level of corruption, adequate funds are not available to NAFDAC to

efficiently carry out these campaigns. (Gloria Nneka Ono and Chiazor Anthonia Chiaghana, 2020)

2.2 Post Marketing Surveillance of Falsified Medicines in Nigeria

There have been previous studies on substandard and falsified medicine and one of the previous studies by NAFDAC, WHO and Department for International Development (DFID) revealed that SFM was at 16.7% in 2005 as opposed to the 40% realized in 2001. There has been continuous monitoring of medicinal products especially the commonly falsified medicines and there are several medical tech tools deployed by NAFDAC in which one of them called Truscan device was used for surveillance between 2010 and 2012. The estimated number of about 5790 was tested and 6.4% failed the test. Nigeria is an endemic place for malaria, and it has always been continuous therapeutic improvement on the development and production of antimalarials to eradicate malaria in Nigeria. NAFDAC teamed up with National malarial Elimination program (NMEP) in 2015 discovered that 3.6% failed in an 800-sample study. Post marketing surveillance has always been key in the establishment of quality medicines but there are still so many defaulters in the country owing to so many factors and the major fact that Nigeria is a underdeveloped country with high level of corruption. They also realized that the failure might be as a result of improper storage as seen in 2016 when 162 samples of oxytocin was tested and 74% failed. There is continuous effort to see improvements in the level of implementations of regulations or create new and stricter ones.

Post-marketing surveillance of Pharmaceutical and medicinal products is a very crucial source of information and data that can be utilized in ensuring quality of the medicinal products available for purchase. It is important for this surveillance scheme to be set up in such a way that stakeholders, global organizations,

procurement agencies, NGOs, or educational and research groups like CROs are actively involved in the process and information gathered.

The PMS program is expected to be able to carry out analysis and cater to the healthcare priorities and extremely demanding situations this is because the information gathered from these PMS activities would potentially aid in improving the quality, safety and efficacy of the medicinal products manufactured and improve the health care system of the country Nigeria as a whole. (NAFDAC.GOV, 2019)

Pharmacovigilance framework.

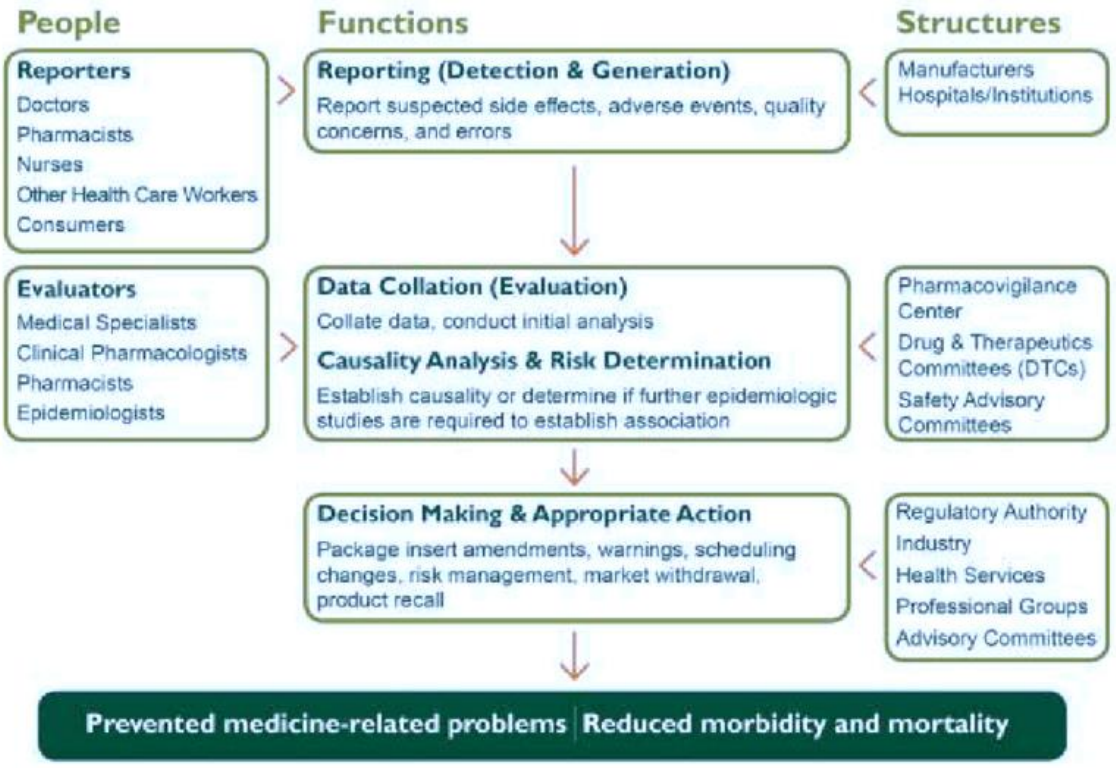

Figure 2.2 Pharmacovigilance framework (Devendra Singh Rathore, 2014)

2.2.1 The Role of Healthcare Professionals in Post Marketing Surveillance

Healthcare practitioners are mandated to constantly look for novel research studies and findings that may add or contribute to improve an effective patient care and ensure safety. There is some level of expectation from healthcare professionals (medical doctors and pharmacists) to help in the fight of falsified medicines and to be vigilant. The healthcare professionals (medical doctors and pharmacists) are interestingly the closest point of call to patients and consumers and are therefore expected to monitor and report any form of adverse drug reactions they encounter in the course of practice. These reactions may involve a new authenticated or approved medicinal products and a generic or already existing medicinal products. (Steinman *et al.*, 2011). According to (Steinman *et al.*, 2011) who said that deaths and comorbidities relating to adverse drug reactions could be diminished efficiently by identifying drug complications. Healthcare professionals are charged to have some level of responsibilities in effective post marketing surveillance. There is need of engagement between the healthcare professionals and patients after drug prescription and dispensary. The healthcare professionals are ethically obligated to educate this patients on the needs to report any form of reactions as a result of prescribed medications and also effectively inform them about the use of Mobile Authentication Service since every average Nigeria is presumed to have a basic mobile phone. (Steinman *et al.*, 2011)

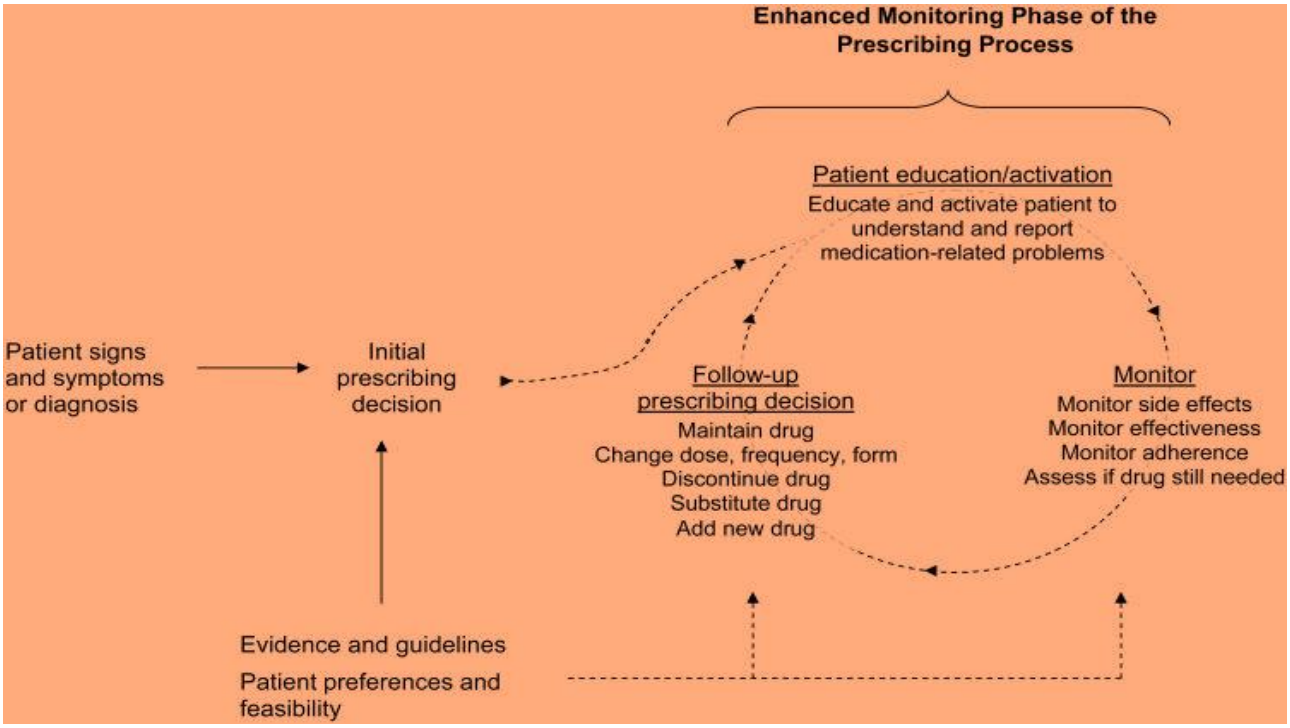

Figure 2.2.1a Enhanced Monitoring Framework (Steinman *et al.*, 2011)

Regrettably, the application of most research results and findings doesn't occur as frequently as possible and a lot of research scholars have recorded gaps among proof-based practices and ordinary clinical methods of healthcare practitioners. Some of the duties of the healthcare professionals in post marketing surveillance include distribution and delivery of clinical products and also adequate reporting of falsified products where necessary.

The production of biopharmaceutical and medicinal products is a closely authorized scheme to ensure safety and efficacy. The distribution and delivery of biopharmaceutical or medical products is also vital process in ensuring that consumers are given clinical products of highly valued quality and also promote safety of consumers. However certified and authorized healthcare specialists (medical doctors and pharmacists) have obligation to conform and adhere to right storage and distribution practices and also need to make themselves available to

routine checks and surveys with the aid of the competitive authority like NAFDAC. Pharmaceutical distributors and retailers should have the ability of showing regulatory authorities manual or electronic evidence like receipts and verified documents in which they purchased or sourced the medical products. Every healthcare professionals have the ethical role to report any case they come across to their direct superiors and also to the regulatory authority. (WHO, 2021)

Figure 2.2.1b Regulatory Bodies During a Market Survey (WHO, 2021)

The researchers use different methods and approach to sample the market and they range from random methods to focused sampling of specific medicinal products. The WHO is constantly open to finding new ideas on recommendations on the quality of a survey protocol on quality of medicines. Surveying is another

important tool in assessing access to quality, safe and efficacious medical products.

2.3 Regulatory Systems and The Level of Implementation in Nigeria

Nigeria is classified as an underdeveloped or going through the states of development and as such there are high level of corruption coupled with the dilapidated state of the healthcare system. Corruption is therefore defined as disregard and exploitation of established and allocated power for personal use. It was also one of the reasons for the continuous prevalence of falsified medicines in the country. However, there are so many other factors that also cause preponderance which are greed, ineffective implementation of already established laws, flooding of the pharmaceutical business with non-medical professionals, the high cost of original drugs. However, the highest fight for falsified and substandard medicines was fought during the tutelage of Dr Akunyili when she was the Director General of NAFDAC, with also the proper rebuilding and restrategizing of NAFDAC without losing its competent staff, restructuring of the laboratories. During this period of stricter measures, there was serious and evidential cutback of falsified medicine and also cutback of unregistered medicines in Nigeria. (Garuba *et al.*, 2009)

There have been many undocumented cases of falsified medicines in Nigeria because there is no database and among the documented ones are the case of 109 children who died as an outcome of ingesting paracetamol mixed with harmful ethylene glycol. There were documented cases of ADRs from utilization of infected infusions with microorganisms which were manufactured by 4 Nigerian pharmaceutical companies. There were also reports that many tested brands of injection water came back unsterile. There are various key organizations that see that regulations are carried out efficiently and the Standard Organizations of Nigeria and

the National Food Drug Administration Control are constantly taking stricter protocols to control the imports of falsified and substandard medicine in Nigeria. They have continuously updated ways to curb a lot of influx of fake medicines and to prevent Nigeria from being a "dumping zone". Since the increasing concern of health issues like HBV, cancer, HTN and liver diseases, the regulatory bodies adopted stern measures because most of the increasing cases is as a result of increasing falsified medicines. There is another theory that there are connections that exists between falsifiers in Asia, Europe and Nigeria. They also sell these falsified medicines unlicensed public areas and that also poses serious threats to the consumers and society (Proshare Ecosystem, 2020)

NAFDAC and Standards Organization of Nigeria (SON) were at one point asked to vacate the port by the task force on the issue that the ports needed to be decongested and were only asked to come only when they are invited (NAFDAC news, 2013). The Organizations criticized and antagonized the idea because it has the tendency of promoting and encouraging the importation of fake and falsified medicines and this also hinders the work of NAFDAC because every drug is supposed to be registered in the country. Also, one of the criteria for registration is the testing and evaluation of medicinal products to ensure quality and safety of these products. Meanwhile, there is also the problems of infrastructure because according to (NAFDAC, 2014), report stated that the Forensic laboratory located at Oshodi in Lagos, which was supposed to be the major public lab facility for the purpose of ensuring top quality system, is not up to standard adequately equipped to run activities of analysing, testing and evaluation of drugs and this causes so many imported drugs to be left unattended. NAFDAC officials are also required to go on routine evaluation and surveillance to places where drugs are manufactured to ensure they comply and adhere to Good Manufacturing practices (GMP), but due to logistic problems,

NAFDAC rarely go for the surveillance and it was reported that lack of sufficient funds is also a very triggering barrier. There is also the problem of increasing level of bribery, offering money and gift items is very prevalent especially in a 3rd world country like Nigeria. It has also been estimated to be one of the major causes of the rise of falsified medicine in the country. One of the reasons for the bribery of some of NAFDAC officials was because of the very low standard of living which has enabled this perpetrator to succeed and this has constantly made falsifiers to continue to endanger the public and put Nigerian economy at risk. So, a lot of them were fired when Dr Dora Akunyili assumed office. (Garuba *et al.*, 2010)

Another issue with implementation of regulation is the fact that the rural areas are hard to access. A lot of them lack the basic amenity like electricity and good telecommunication networks and the funds to provide other things like generators are not even made available even when the generators are made available fuel scarcity still pose a problem.

2.4 Level of Awareness and Use of Mobile Authentication Service (Mas) And Other Systems By NAFDAC

NAFDAC has set up some topnotch technologies in a bid to arrest the current falsified and substandard medicines situation. They include: “Truscan”, “Black Eye” and “Radio Frequency Identification” (RFID). The Truscan was a portable device that could detect substandard and falsified medicines on the spot. The black eye utilized infrared rays to spot substandard medicine and the RFID technology used to validate sensitive documents. All these systems where deployed and active but faced various challenges that lead to the establishment of the NAFDAC mobile authentication system (MAS).

The MAS is a mobile tech developed to prohibit the dispensing and peddling of illegal and falsified medicines to consumers. It is NAFDAC authorized and in view

of their current guidelines, all market authentication personnel who wants to use the MAS must inform the NAFDAC agency and get necessary documentations moving forward. (Oyetunde *et al.*, 2019a). This also provides routine access to pharmaceutical companies to the scratch panel which is fixed to the medicinal products. It contains a numeric digital code which is a single utilization products private detection. The system was for the consumers and it was easily accessible. To use the system, the consumers just had to send the 12-digit pin number on the scratch panel on the medicine they had purchased to the number 38353. After this, they would receive an immediate feedback from the NAFDAC as the originality of the drug. This system puts the power to detect the genuity of the medicinal products in the hands of the consumers and so it becomes necessary to assess the awareness of the consumers of this system that has been put in place. (Uzochukwu and Chinedu-Okeke, 2017). This scheme was available for use throughout the country from the year 2012. After years of authorization and proposed utilization of this scheme, it seems like the public is not very aware of it and the scheme is underutilized. Due to this fact the marketing and sale of substandard medicinal products has continued to rise. According to the research carried out by (Adekoya and Ekeh, 2021), it is evident that different parts of the country have different levels of awareness with some areas where the people are not aware at all about the system. The MAS was only utilized by few people and some of them stated that they did not get any response. According to (Uzochukwu and Chinedu-Okeke, 2017) some of the causes of this limited awareness is poor network service, improper programming of the system leading to partial outcomes of the service. (Justine and Ilomuanya, 2016) who carried out a study in the 6 geopolitical zones of Nigeria stated that about 78% of the people that responded to his research knew about the MAS but only about 58% out of those that knew about it has actually tried to use it. Out of the 58% that had used it, only 48% received a response while 4.7% didn’t get any response. (Adekoya and Ekeh, 2021)

Also, according to the research carried out by (Oyetunde *et al.*, 2019b) to assess the acceptance of the mobile authentication service among community pharmacists stated that only about 53% of the responding pharmacist were enthusiastic about the use of the service and even so, only about 51% of the above 53% considered creating awareness about it to their colleagues and patients. They were able to conclude that the effectiveness of the system is dependent on the awareness of the system as well as how effective the system is perceived to be by the users. So, various other issues come into play like the inefficiency on the part of the local network providers, power shortage and even poor socio economic status of the users. (Oyetunde *et al.*, 2019b)

Figure 2.4a A Photograph Showing the Scratch-off Verification Code on A Coartem (Hamilton *et al.*, 2016)

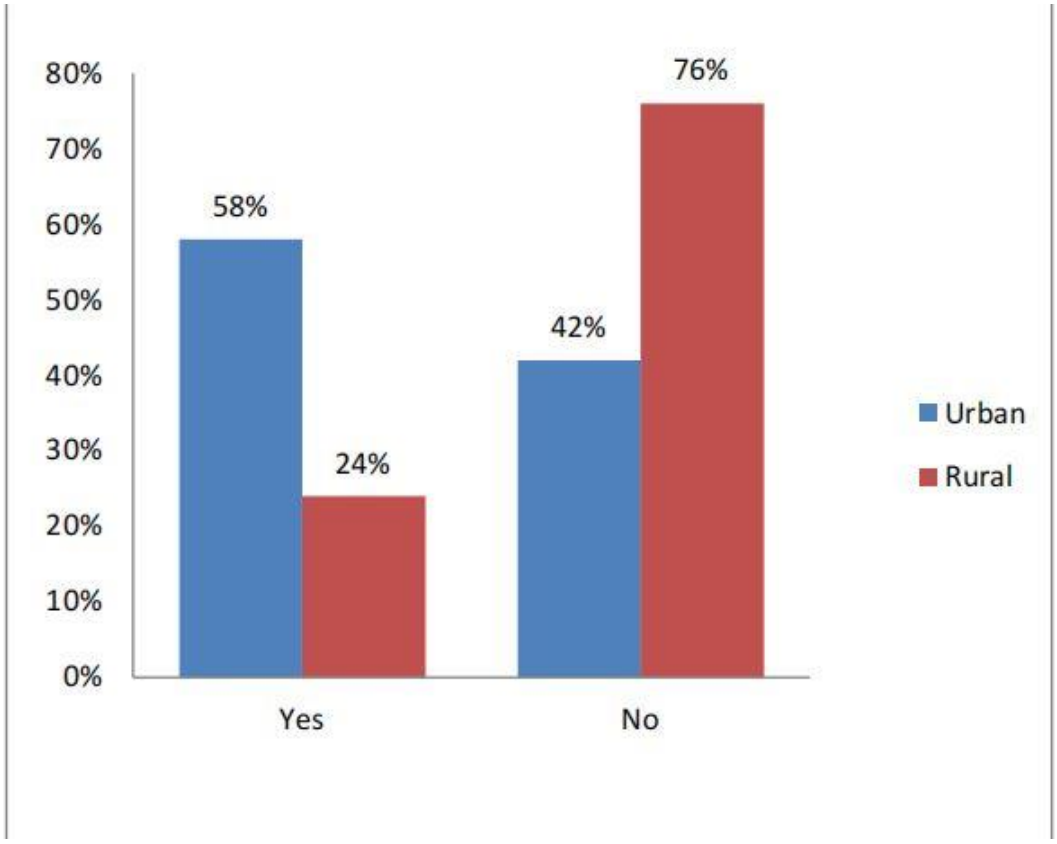

Figure 2.4b Bar chart Showing That Usage Of MAS In Rural And Urban Areas According To Research Carried Out By (Uzochukwu and Chinedu-Okeke, 2017)

2.5 Socioeconomic Impacts of Falsified and Substandard Medicine in Nigeria

Results from research carried out by (Beargie et al., 2019) stated that up to 12,300 death were recorded to have occurred due to use of poor quality anti malaria medicines and these poor quality antimalarials cost up to 892 million dollars per year. It is important to note that continuous use of poor-quality medicinal products can lead to the development of resistance and so even when treated with the good

quality medications, it produces little to no effect as regards treatment. In this case if the cases of antimalaria resistance should continue to increase, the cost of the medication to the country per year will increase by up to 11%. The country as a whole suffers an economic loss of up to 700million dollars every year due to the continuous production of substandard and falsified medicines especially essential medicines like antimalarials. (Beargie et al., 2019)

The impact of poor-quality medical products is often thought to be only health-wise. However, continuous use of poor-quality medical product can be very cost intensive for the patients and health care system as a whole. These costs are incurred as a result of continuous ineffective treatment and treatment of complications that occurs as a result of using substandard medicines. When a person's illness is prolonged due to ineffective treatment, the person is unable to be productive at work and this leads to reduction in tax revenue for the state. Additionally, the continuous use of personal saving in treatment of diseases can potentially lead to accumulation of debt on the part of the patient. This fact increase poverty in the country as most of the issues are suffered by low to middle income countries, Nigeria included. (Ozawa et al., 2018)

Figure 2.5a Photograph Showing Open Drug Market in Onitsha, Nigeria (Isaac Adewale, 2017).

Summary of Literature

Authors	Publication year	Key points from article
Adekoya, et al	Awareness and Adoption of Drug Mobile Authentication Service: A Conscious Approach in Eradication of Fake and Counterfeit Drugs in Nigeria', KIU Journal of Social Sciences, (2021)	Shows the level of awareness by the consumers about the Mobile Authentication service and the error encountered by the consumers.
Akiny, O.	Counterfeit drugs in Nigeria: A threat to public health', African Journal of Pharmacy and Pharmacology. (2013)	The increase of falsified medicine in developing and underdeveloped countries although it is a global problem. Other factors could also favor its prevalence.

Beargie, S. M. et a	The economic impact of substandard and falsified antimalarial medications in Nigeria. 2019	The downward spiral of the economic burden of falsified medicines and the damaging state it places on Nigeria
Cannon, D. T.	War Through Pharmaceuticals: How Terrorist Organizations Are Turning to Counterfeit Medicine to Fund Their Illicit Activity' 2015	There are certain terrorists that uses falsified medicine business to fund their activities
Dégardin, et al	'Understanding and fighting the medicine counterfeit market', Journal of Pharmaceutical and Biomedical Analysis, 2014	The threats of falsified medicine to the public in which these falsified medicines could be empty or contain lower constituted doses causing harm and possibly death to consumers.
Garuba, Habibat A. et al	Transparency in Nigeria's public pharmaceutical sector: perceptions from policy makers', Globalization and Health, 2009	There are some policy and regulations established but there are factors that affects their level of implementation.
Gloria Nneka Ono et al	Assessment of Consumers' Awareness and Exposure Levels to NAFDAC Media Campaign in South East Nigeria', 2020	Evaluating the level of awareness to various schemes deployed by NAFDAC
Justine, A. and Ilomuanya, M.	Securing the pharmaceutical supply chain: A study of the use of Mobile Authentication Service (MAS) among the Nigerian populace utilizing antimalarials. 2016	Study into the causes of limited awareness was estimated to be poor service delivery.
Oyetunde, O. et al	Mobile authentication service in Nigeria: An assessment of community pharmacists' acceptance and providers' views	A general overview on the med techs already established with special focus on the Mobile Authentication Service.

	of successes and challenges of deployment. 2019	
Ozawa, S. et al.	Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries' 2018	Falsified medicines can lead to increase failure in treatment and this affects the physical and mental capacity of the consumers. This also affects low to middle income earners
Rahman, M. S. et al	The health consequences of falsified medicines- A study of the published literature', Tropical Medicine & International Health. 2018	The potential effects of falsified medicine, the falsified medicines were found not to be made of any useful constituents or are made of unhealthy amounts of active ingredients.
Uzochukwu, C. E. and Chinedu-Okeke, C. F.	'Audience awareness and use of Mobile Authentication Service (MAS) in identifying fake and substandard drugs in Nigeria'2017	The effectiveness of the MAS and the role of consumers in helping fight the business of falsified medicine
NAFDAC.GOV	'Curbing Substandard, Falsified (SFS) And Counterfeit Medicines – NAFDAC' 2019	There has been several electronic schemes deployed by NAFDAC to curb substandard and falsified medicines but they have not been very effective.
Polgreen, L.	'84 Children Are Killed by Medicine in Nigeria', The New York Times, 2009	The "My Pikin" was a very harmful chemical products for very young children and this killed a lot of children decades ago.

2.6 FALSIFIED MEDICINE IN NIGERIA

Nigerian health professionals are involved in the inflow of fake and substandard pills into the country, which they complain is endangering the general public's health. Dr. Dora Akunyili, who was the director-general of the national agency for food and drug administration and control, stated that fake capsules are liable for the increasing range of occurrences of HTN, coronary heart failure, stroke, and different ailments in Nigeria. While people are taking falsified or substandard antihypertension capsules, their BP will be poorly managed and it will begin to rise because they are taking falsified medication which eventually will lead to stroke or even death, she said. Some of these fake tablets include nothing. A number of them contain chalk, milk in drugs, and a number of them incorporate little of the active components. We cannot underestimate the culprits of this acts as they are very smart. For example, a drug like chloroquine is sour and that if they omit constituents of chloroquine entirely in their fake chloroquine, human beings will realize that it isn't chloroquine. So rather than the 200 mg chloroquine that ought to be inside the tablet (OSD), they will place 41 mg." Dr. Akunyili stated there was an increase incidence of antibiotic resistance of patients induced via prior consumption of fake antibiotics. However, all fake medicines in Nigeria do not come from oversees as there are some local manufacturers committing this grievous crime within the country (Raufu, 2012)

There was a spectacular case of a very harmful chemical that killed lots of children (between age 2 months and 7years) between November 2008 and February 2009 and about 84 Nigerian children died from acute kidney failure and liver failure caused by the economic solvent diethylene glycol in teething syrup. The toxic medicinal product, "MY PIKIN", become registered with the Nigerian regulatory authority and made in Lagos. (Polgreen, 2009)

2.6 A photograph showing “my pikin” cough syrup (CNN international, 2021)

An evidence-based study by the national agency for food drug administration and control (NAFDAC) has shown that Nigeria as a country has delt with numerus counterfeit drug problems over the years. The study shows that in 2002 almost 41% of prescription drugs inside the country was found to be counterfeit and also up to 70% was found to be unregistered. The country has put so much effort into reducing the amount of counterfeit and unregistered drugs in circulation, even so this problem persists. (Habib et al., 2014)

Due to the general socio-economic state of the country, salespersons in possession of these counterfeit medicines are in a better position to dispense these drugs at a cheaper price to individuals that would otherwise not be able to afford the original medicines. So, by this we can see that the most common falsified and counterfeit medicines are those which are in high demand such as: anti-malarial, anti-hypertensives antibiotics and even anti diabetic. According to the world health

organization, up to 100,000 deaths in Africa are linked to counterfeit and falsified medicines

The direct selling model is a very good approach to solving this issue. In this case the products use a micro-franchise model to ensure the availability of medicinal products at a cheap rate. This method will make ways for authorized personnel to deliver original medication to patients in their homes at the cheapest available price. By this way, the Avon Lady approach was created. The personnel undergo training programs in order to know how to identify common illnesses and how to offer preventive measures and treatments. How do they afford this training? They forfeit a certain percentage of their wages. Their duty is to know the individuals of the community and what health situations they are in. these trained personnel are also expected to always be nearby with medication especially on short notice.

Owing to the fact that most drugs with proper regulations are expensive and patients need to travel long distance to acquire them, the patients tend to wait till they are in dire need before traveling the distance. This fact leads to high event of urgent cases in the health care facility that are more often understaffed. So instead of people to go through the hassle, they seek out a short cut which is seeking drugs from the black market.

The “Avon girl” approach gives patients the availability of medical products they need, and the patients are always able to get medication from a registered and licensed source

They might additionally have access to medicines whenever it is needed due to the fact that vendors are easily assessable and always fully stocked. (Berkeley, 2020)

2.7 REGULATORY AUTHORITIES

The approval process of novel medicinal products differs in each country. In recent times different countries have sent up a regulatory authority to control and regulate

the affairs of pharmaceutical companies. as time evolves, there is an increase in circulation of medicinal products to meet up with the increasing demands. This increased supply has however, brought about safety and efficacy concern. This is the task of these licensed regulatory authorities, to ensure that medical products manufacture fulfill all set standards, regulations and guidelines. This has proven to be necessary because of various reasons, one of being that there is always a risk related to taking any type of medication but in some cases, the risks have proven to be more than the benefits and thus causing harm to the patients. The regulatory body is charged with certifying the components of these medications especially as regards the active ingredients to avoid adverse events as much as possible

2.7.1 INTERNATIONAL CONFERENCE ON HARMONIZATION

This is internationally recognized organization that has put together different guidelines and standards for production of medicinal products to ensure the quality, safety and efficacy of these products. The ICH focuses on 4 main topics, they include: Q - this contains guidelines for quality control, S – this contains guidelines for safety control, E – this contains guidelines for Efficacy control, M - this contains information about Multidisciplinary guidelines

These guidelines have been authorized for use in about 10 different countries, but Nigeria is not one of them. Nigeria has its own regulatory systems and its own established Good pharmacovigilance practices. Nigeria has 3 regulatory bodies that is in charge of drug and biologics control:

- The national agency for food Drugs administration and control
- The national Drug law enforcement agency
- The Federal ministry of Health

The regulatory body in charge of licensing of drugs and other biologics in Nigeria is NAFDAC (National Agency for Food Drug Administration and control). This

agency was established in the year 1993 so as to deal with the fact that the sale and use of counterfeit and falsified medicines was at a constantly rising pace and it was affecting the country adversely. NAFDAC is in charge of certifying that the products manufactured are done so according to the good manufacturing practices of the NAFDAC. (NAFDAC, 2019)

The National Drug Law Enforcement Agency the regulatory body in charge of controlling the production, use and marketing of all kinds of hard drugs. They also in close contact with international drug units all over the world to control the transportation of these hard drugs.

The Federal Ministry of Health is the overall organization that controls the affairs of the NDLEA and NAFDAC as well as other health regulatory bodies. They set of all activities to ensure that everything goes in the proper order. (Health.gov, 2021)

2.7.2 NAFDAC GOOD PHARMACOVIGILANCE PRACTICE (GVP) GUIDELINES

According to the world health organization (WHO) pharmacovigilance has to do with the detection, assessment and prevention of adverse reactions or other issues upon the use of medicinal products. The main aim of pharmacovigilance is to establish a secure and judicious utilization of medicinal products and by so doing, enhance public health.
the “ACT Cap N1, LFN 2004” of NAFDAC legitimizes the organizations ability to regulate the production, storage, marking and distribution as well as importation and exportation of all forms of medicines within the country. The above stated

ACT demands that the organization established safety of all medicinal products that has been registered.

The set-up guidance was put together so as to provide aid to all stakeholders and ensure that they adhere to the GVP guidelines. They properly describe the process and procedures involved in certification of the stakeholders that have been registered on the best methods and designs to uphold a decent and functional pharmacovigilance system. This pharmacovigilance system would include quality management, adverse reaction reporting, post authorization safety studies, pharmacovigilance audits and risk management.

2.7.3 MAIN PRINCIPLES OF THE PHARMACOVIGILANCE GUIDELINES

The main principles of the guidelines are still centered upon the objectives which is establishment of overall safety and efficacy of medicinal products and enhancement of public health in the long run. However, the guideline follows certain principles which direct and guide the design of process and framework. They include but are not limited to, the safety and efficacy of the medicines produced should meet the need of the consumers, there should always be an established leadership in charge of implementation of the set up quality systems, there should be room for constant training of employees, all crucial issues should be adequately considered in decision making, all activities, processes and procedure are to be carried out by licensed and authorized personnel. (NAFDAC.GOV, 2021)

2.7.4 GUIDELINES FOR POST MARKETING SURVEILLANCE (PMS) IN NIGERIA

Post marketing surveillance is supervisory operation carried out by the national medicine regulatory authority which was instituted in 2018. This operation involves the continuous analysis and evaluation of the safety, efficacy and quality of all medicinal products throughout its useful period. This operation was set up with the aim of constantly supervising all the medicinal products in circulation at the different stages of the supply chain. To this effect, NAFDAC has set up certain regulatory activities to establish good quality of medicines in Nigeria, these activities include:

- Authorization and certification of all medicinal products depending on their results of their assessment of quality, efficacy and safety
- Continuous and constant monitoring and examination of producers of medicinal products to ensure compliance with the set NAFDAC GMP and also to ensure that all products for use have been approved for use especially the active pharmaceutical ingredient (API)
- Constant and continuous monitoring and examination of the facilities used in manufacturing and storing the medicinal products
- Proper control of all methods used for marketing and advertisement
- Ensuring that enough information is provided to the healthcare professional as well as the consumers and patients
- Ensuring that all substandard, falsified or counterfeit medicine is recalled and destroyed
- Implementation of national medicine legislation. (NAFDAC.GOV, 2018)

2.7.5 AIMS OF THE POST MARKETING SURVEILLANCE GUIDELINES

The main aim of the guidance to is to aid NAFDAC in carry out a more effective PMS of medicinal and pharmaceutical products and by so doing, they will be able to develop a scientific proof of the safety and efficacy of all medicinal and pharmaceutical product. This factor of scientific credibility for all provided information is very important in Nigeria in order to attain and sustain high safety and efficacy standards.

2.7.6 PMS OF PHARMACEUTICAL PRODUCTS IN NIGERIA

The PMS of pharmaceutical products in Nigeria is put together in such a way as to include the stakeholders, international organizations and NGOs. The system is expected to be very responsive with regards to health issues. Due to the fact that it is impossible to quality-check all products that have be registered and so the system works according to priorities. The highest on the list are the pharmaceutical product and so much focus is placed in them dependent on their possible ability to cause harm to the consumers. The information derived from these processes are imperative in setting up operations for the improvement on medicines in cases where unacceptable reports are brought back. (NAFDAC.GOV, 2018)

2.8 CONCLUSION

Healthcare professionals are quite aware of the regulations and guidelines put in place to curb the marketing and distribution of falsified medicines. However, this does not totally eliminate the fact that there is still a wide spread of large degrees of substandard and falsified medicines. NAFDAC as a well-recognized competent authority in Nigeria as a whole have continuously drafted credible and reliable means by not only placing down regulations but also ensuring there is a testing

system with authorizable verifications which allows not only NAFDAC officials and general healthcare professionals identify false medicines but also a consumer of falsified medicine can verify the product even before use and also help with fighting perpetrators of falsified medicines.

Therefore, in cases where healthcare professionals are aware of the regulations set up by NAFDAC, they should also estimate a check and balance system which comes in form of a post marketing surveillance

A world health organization (WHO) study in 2011 evaluated that a huge 64% of anti-malarial medicines circulating in Nigeria were both fake and sub-standard according to verifiable standards. Notwithstanding how endemic Nigeria is to malaria, fake anti-malarial medication in the circulation becomes a danger to the society and fail to meet the requirements for saving lives of consumers. They studied six African countries and Nigeria took the lead when it comes to creating counter-offensive measures to fight falsified medicines by way of using various technologies which has also put Nigeria on a global watch worthy of emulation because this fight is going to a be continuous and long one.

The principal tech that NAFDAC has deployed is its mobile authentication system (MAS) where consumers can scratch off a panel on the pack of a medicine to expose a unique number then with the aid of texting this unique code to a toll-free number, the consumer can straight away verify whether or not the product is authentic.

Other powerful technology in use consists of the radio frequency identification (RFID) system, which allows tag and track authentic products; black eye, a system that could look at the components of several capsules at the same time; and Truscan, a hand-held spectroscope which could speedy and easily locate counterfeit medicines. In an interview in 2011, the previous head of NAFDAC, Paul Orhii,

reportedly stated that Nigeria was the first country to utilize the Truscan technology to evaluate for counterfeit pills at its borders. “these devices undergo tests and various experiments to ensure their effectiveness,” says Chioli Pascal Chijioke, a rep physician in pharmacology and therapeutics at the college of Nigeria teaching medical institution.

CHAPTER 3

3 RESEARCH METHODOLOGY

3.1 RESEARCH APPROACH

There are three (3) research approaches explained by Saunders used to develop theories. The first one is deduction which describes beliefs and theories developed before the research process. The second one is induction which involves beliefs, data and concepts that are collected during the research process while the last one is abduction is when the data is utilized to develop and discover facts, new theories as well as disputing or countering old theories (Saunders *et al.*, 2019)

The primary evaluations on adverse drug results usually come from individual physicians and pharmacists who document suspected or reported issues to clinical journals, a drug reporting command or to the competent regulatory agency.

The research work hereby aims at the effects post-marketing surveillance has on falsified pharmaceutical and medicinal products.

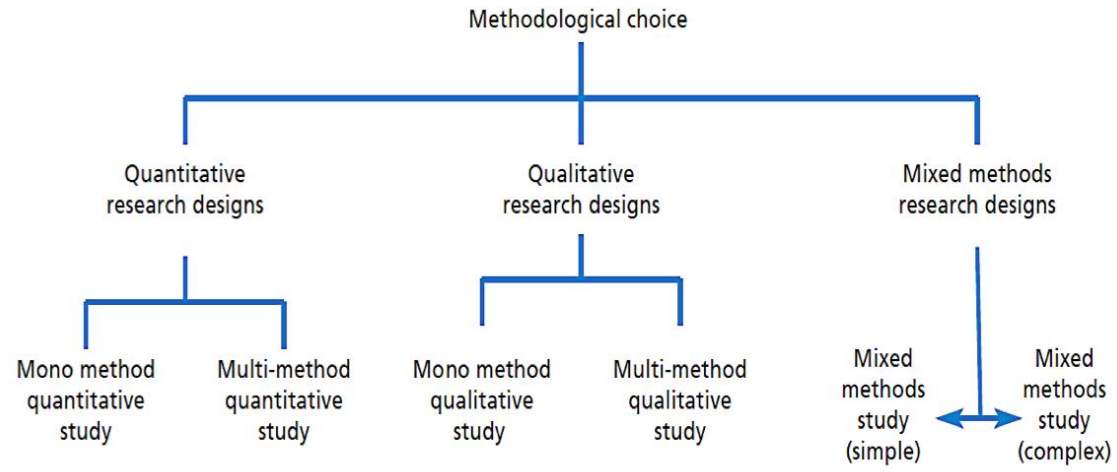

Figure 3.1 Methodological Choices (Saunders *et al.*, 2019)

The quantitative research approach would be conducted in form of a survey disseminated to healthcare practitioners (medical doctors and pharmacists) and

consumers who are key in this research. It also evaluates the awareness of healthcare professionals (medical doctors and pharmacists) and consumers of falsified medicines as well as their source of knowledge. The level of implementation of regulations as regards post marketing surveillance of falsified medicine set up by NAFDAC. The purpose of this research also goes deeper to the level of awareness of healthcare professionals and consumers concerning the Mobile Authentication Service and the level of its efficiency. Lastly to study factors that challenges effective post marketing surveillance of falsified medicine in Nigeria.

3.2 RESEARCH PHILOSOPHY

Research philosophy is described as a structure of notions, concepts and hypothesis about building and collection of knowledge. This is very vital as a key during a research process. It is believed that assumptions are unavoidable at some stages in the research. some assumptions are observed as real-time experiences during a research process, and this is known as ontological assumptions. Epistemological assumptions are beliefs based on human instincts. (Saunders *et al.*, 2019)
This research philosophy was considerably that of positivism and also interpretism. It was utilized for this study with the potential goal of evaluating and interpreting data collected from respondents which also helped in foreseeing appropriate unbiased conclusion. This stem of questions was very practical and were guided by many quantitative reviews which aided in the analysis of data received from the respondents. The study aimed to proceed through inferences, interpretations and possible deductions as the study being carried out is measurable and respondents are randomly selected among medical doctors, pharmacists and consumers.

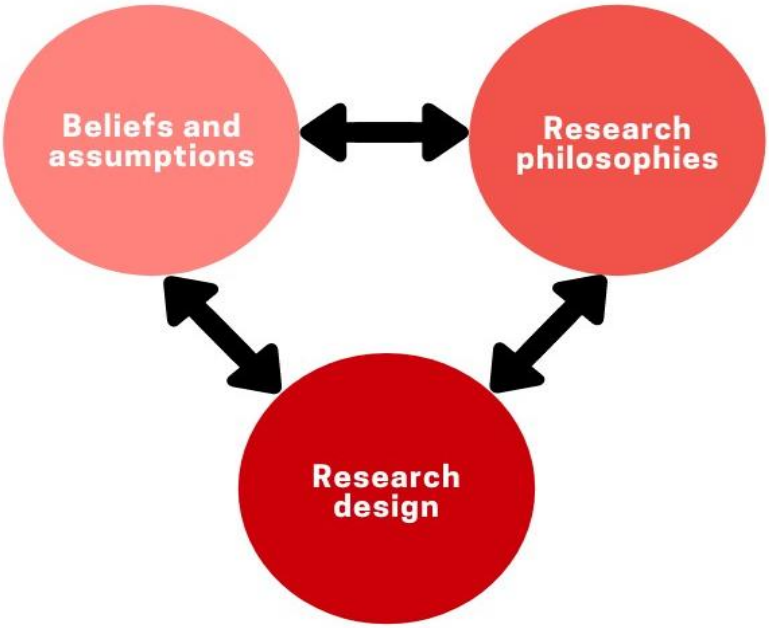

Figure 3.2 connection between research philosophies, beliefs and assumptions and research design. (statswork, 2020)

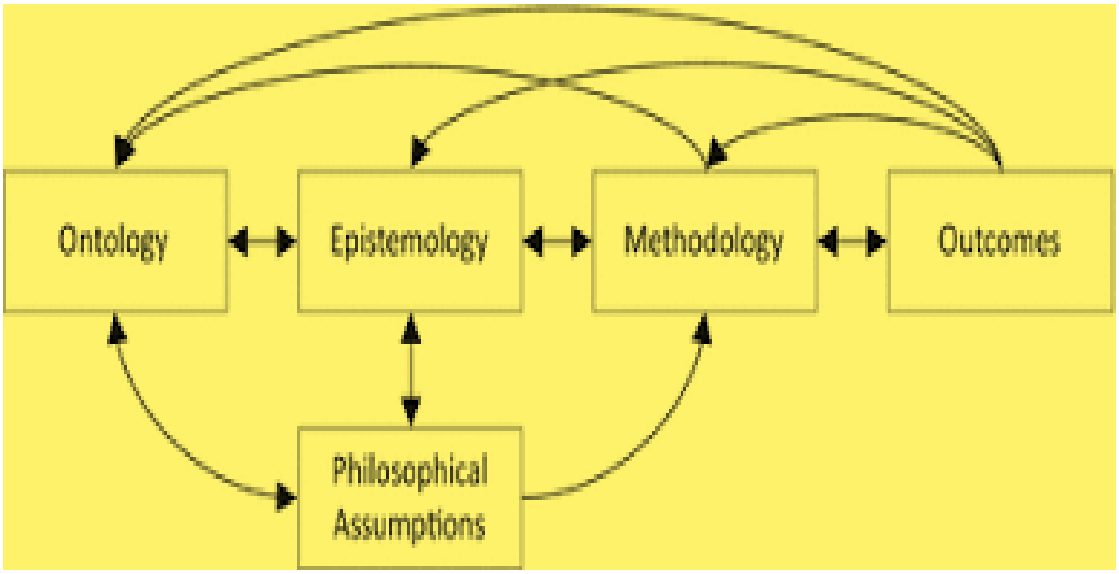

Figure 3.3 Research philosophical assumptions (Schlegel, 2015)

The participants were provided a carefully designed questionnaire from which information were gathered, reviewed, analyzed and interpreted objectively and efficiently. The author was very careful and objectives as there was no personal attachments to the study so as to avoid conflicts of interests and only focused on available data. The questions were structured in survey settings due to the ongoing covid-19 pandemic to adhere to government recommendations, adhered to social distancing protocols and also maintained minimal physical interactions between the participants. It also helped to limit or eliminate subjectivity, minimized bias as much as possible considering that the author is a medical practitioner.

3.4 RESEARCH STRATEGY

The strategy of this study was to access and evaluate the awareness, knowledge and impacts of post marketing surveillance on falsified medicines. This also emphases on the impacts of falsified medicine on the public health sector, socioeconomic status of Nigeria and also possible recommendations. Several literatures reviewed suggested that there wasn’t enough continuous post marketing surveillance carried out, inadequate implementable regulations and follow up protocols and inadequate knowledge of the Mobile Authentication Service (MAS).

The participants (medical doctors, pharmacists and consumers) who received the surveys were adequately informed that it was a voluntary participation and their consent gotten on the research by the author as part of the criteria for the award of Masters in Pharmaceutical Business and Technology. The questionnaire was designed in a very easy form, targeted at getting distinctive and objective information from the participants. It was sent to about 40 healthcare professionals

across 68 Nigerian Army Reference Hospital and 20 randomized consumers who willingly wanted to join in the study.

Survey questionnaire for Healthcare Professionals and Consumers:
The questionnaire was designed to include 26 carefully structured questions under 5 categories to comply with the purpose of the research for the Nigerian healthcare framework and its healthcare professionals with the inclusion of consumers using Microsoft Forms. The questionnaire was disseminated electronically, and it was completed objectively without bias in the absence of the author.

The first question had an introduction that was structured to gain informed consent from participants, giving access and allowing the use of their answers for the research purpose. They were also guaranteed that the data gathered from this survey was handled in line with the guides of the general data protection regulation (GDPR) and their response was highly confidential.

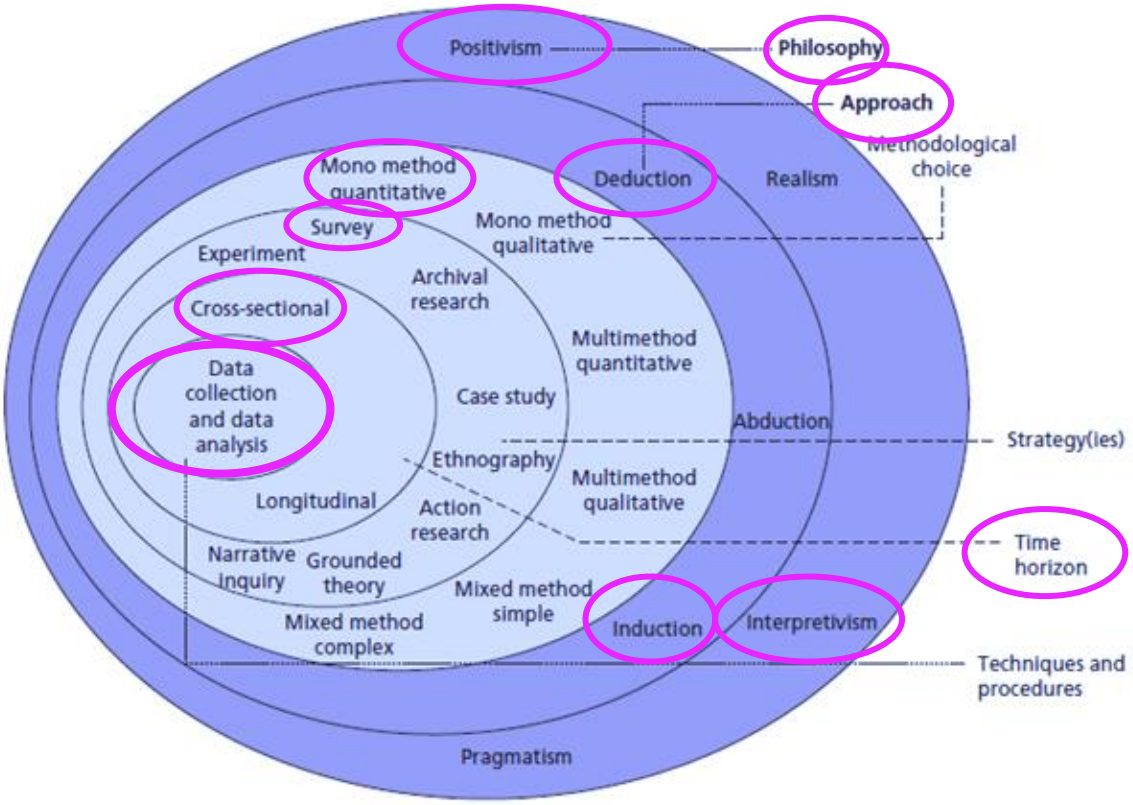

FIG 3.4 Research Onion (Saunders *et al.*, 2019)

3.4 COLLECTION OF PRIMARY DATA

As earlier stated, the primary data was collected mainly using questionnaire for medical doctors, pharmacists and consumers as the participants in the study. The questionnaire was designed in a very easy form, targeted at getting distinctive and objective information from the participants and also aimed at satisfying the objectives of the study without leaving gaps.

Section 1: This was on participants voluntary agreements which had enabled them to give their informed consent and was also guaranteed their data will be used for

research purpose and the data will be protected in line with the general data protection regulation (GDPR).

Section 2: This was as on demographics containing five 5 questions with unique options available for respondents. The questions were to distinguish participants into medical doctors, pharmacists and consumers, their level of experience, age group and level of their education.

Section 3: This section is on knowledge and awareness of post marketing surveillance on falsified medicines which consisted of 11 questions aimed at collecting and evaluating data based on knowledge, awareness, preferred methods they would like to update their knowledge on post marketing surveillance in Nigeria.

Section 4: This section is about direct experiences of both the healthcare professionals and the consumers. It consisted 8 questions targeted at how frequently the healthcare professional treated falsified medicine cases, methods of reporting falsified medicine cases, factors impacting post marketing surveillance on falsified medicine in Nigeria.

Section 5: This section is solely on recommendations to improving post marketing surveillance on falsified medicine in Nigeria and there is only 1 question in this section.

3.5 SOURCES

The survey questions designed was disseminated to about 60 participants which comprised of 20 medical doctors, 20 pharmacists and 20 consumers electronically

using Microsoft forms. The author collected this information from the participants, used Microsoft excel sheet to collate, analyze and evaluate this information, made use of pie and bar diagrams to present the results as well as comparing the data between participants.

Selection of medical doctors:

The author reached out to his professional colleagues from his hospital of internship where the topic of research and the purpose was explained with the goal at studying the impacts of post of post marketing surveillance on falsified medicine and also exploring the awareness, knowledge and factors affecting post marketing surveillance on falsified medicines. They were interested to partake in the study voluntarily.

Selection of pharmacists

The author sent out the surveys to his healthcare professionals who are pharmacists and other pharmacists he has worked professionally with during the course of practice in Nigeria. The importance of the topic was explained, and their level of awareness and knowledge was also accessed while keeping an open mind on recommendations to improve the post marketing surveillance of falsified medicine in Nigeria.

Selection of consumers

The consumers were randomly selected based on the relations of patients during the course of practice and the relevance of the study was explained thoroughly with the goal at studying the impacts of post of post marketing surveillance on falsified medicine and also exploring the awareness, knowledge and factors affecting post

marketing surveillance on falsified medicines. They were interested to partake in the study voluntarily.

3.6 Access and Ethical Issues

The introductory section contained a quick explanation of the research topic which was provided to all healthcare professionals and consumers voluntarily involved in the study and they were duly informed that it was part of an academic requirement for completion of a master's program.

There was careful structuring of the questionnaire to avoid collecting personal information or sensitive data. The survey was designed with the aim of fulfilling the research objectives.

3.7 Inclusion and Exclusion Criteria

The main participants included in this research were medical doctors and pharmacists who the author believed plays important roles in post marketing surveillance of falsified medicines and also the consumers who are exposed to the effects of poor PMS schemes and falsified medicines. The other para medicals were excluded from the research so as to target the focused group of healthcare professionals. They were informed they could withdraw at any time they feel uncomfortable and the study was voluntary.

3.8 CONCLUSION

For this research, both qualitative and quantitative approach was used. The qualitative approach for this study was based on information gathered about post marketing surveillance on falsified medicines in Nigeria from the NAFDAC website as well as other peer reviewed articles, journals and literature online. The quantitative aspect involves the use of a questionnaire survey. The survey was

made up of 25 questions in 5 sections. The survey was distributed to medical doctors, pharmacists and consumers.

All information collected from the qualitative and quantitative study will be objectively evaluated and the result of the analysis would be used to determine the level of awareness of the of the public about falsified medicines as well as the impact of post marketing surveillance on falsified medicines produced in Nigeria.

CHAPTER 4: FINDINGS AND ANALYSIS

4.1 Overview

This chapter demonstrates the events of analysing and interpreting the data from the survey questionnaire that was sent out to participants. As a result of carrying out this study, there was a proper observation and understanding of the data generated from the survey about the awareness, knowledge and insights on impacts of post marketing surveillance on falsified medicines in Nigeria. There was also knowledge into the challenges that hindered post marketing surveillance and also recommendation that can improve post marketing surveillance of falsified medicines

4.2 Demographic information (Question 1-6)

4.2.1 Review

The survey questionnaire was disseminated to about 66 participants, consisting of 20 medical doctors, 24 pharmacists and 22 consumers with a response rate of 100.0% from all 66 participants. Received 38 female respondents and 28 male respondents. There was improved feedbacks after LinkedIn, emails and text message reminders were sent out intermittently through the time limits required. The impacts of this feedback was as a result of the reminders generated responses.

4.2.2 Age and Level of Experience

None of the respondents received was below 20 years. More than 50% of the respondents were principally young. There were more respondents in the 20-35 years age group which was about 56 people with 85.0% mark while 8 respondents of 12.0% were in the 36-45 years age group and the lowest respondents are in the 46 years + age group with 2 respondents with 3.0% mark.

Considerable respondents about 47 (71%) people who carried out the survey had experience between 1year, and 5 years and 13 (20%) respondents had between 5-10 years' experience. There were also 3 (5%) respondents who had less than 1 year experience and also 3 (5%) respondents who had more than 10 years' worth of experience.

4.3 Knowledge and Awareness of Post Marketing Surveillance and Falsified Medicines (Question 7-18).

Question 7:

The general knowledge and awareness of post marketing surveillance and falsified was accessed with the question "Do you know about Falsified Medicines", 54 (82.0%) respondents claimed having the knowledge and awareness while 12 (18.0%) respondents admitted to not having any knowledge and awareness of post marketing surveillance and falsified medicines. See Figure 4.1

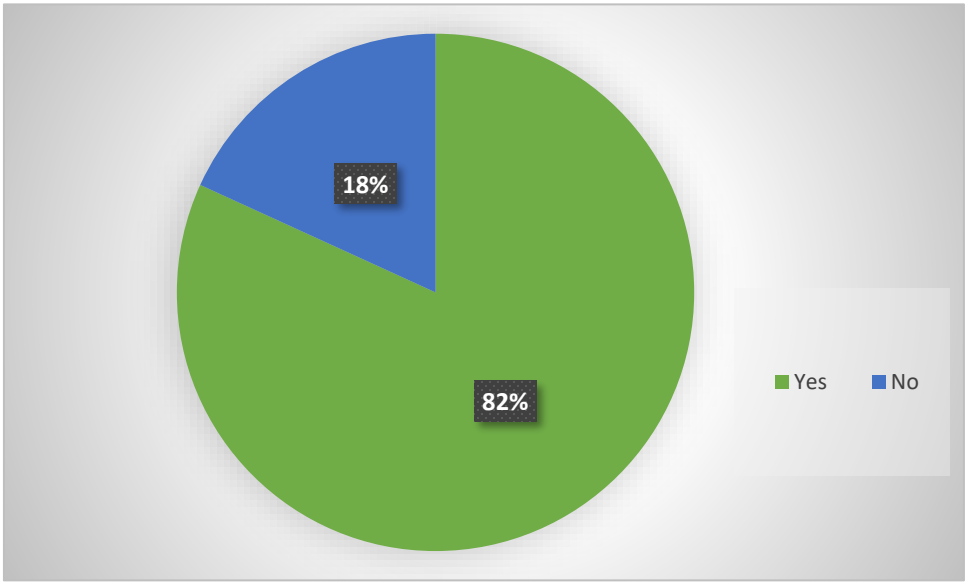

Figure 4.1: Knowledge of falsified medicine in Nigeria.

There is a general knowledge among the participants and 82.0% of about 54 respondents admitted to knowing about falsified medicines. It is interesting to know that there was still some level of uninformed category who don't know or heard of falsified medicines despite the success rates of falsified medicine in a country that is categorized as either an underdeveloped or a developing country.

Question 8:

After the above question was used to access their level of knowledge, this further inquired the source of knowledge of falsified medicine. There were 20.0% (30) respondents on knowledge through journals and newspaper while 25.0% (34) respondents admitted to knowing about falsified medicine through discussions among peers. About 12.0% (16) respondents admitted to learning about falsified medicines through advertisements even though the lowest source, 23.0% (31) respondents claimed to know about falsified medicines through information from regulatory agencies and 19.0% (26) respondents were from knowledge through formal education, seminars or conferences.

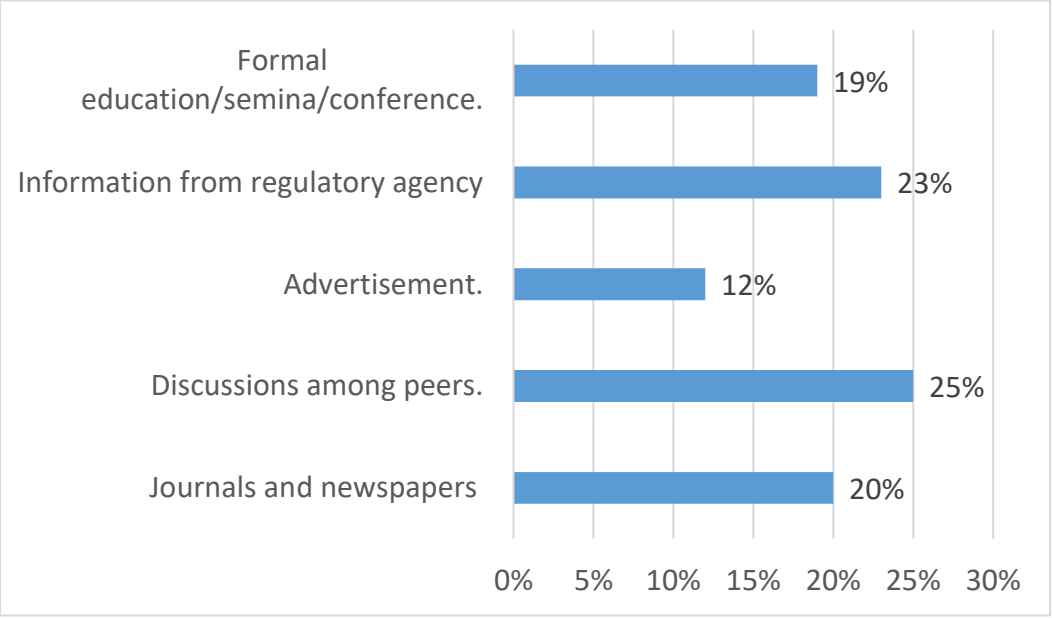

Figure 4.2: Source of Knowledge of Falsified Medicine

It is interesting to observe and acknowledge that the highest source of knowledge of falsified medicines is by discussion among peers while the lowest is through knowledge from advertisement as this confirms the gap in the awareness of falsified medicines. Information from regulatory agencies had 23.0% which is closest to the discussion among peers categories. The responses from formal education/seminars/conferences were significantly low considering healthcare professionals (medical doctors and pharmacists) were involved in the survey.

Question 9:

This specific question accessed better their understanding about the governmental bodies responsible for post marketing surveillance of falsified medicines in Nigeria. Out of the 60 respondents, about 5.0% (3) respondents said that pharmacists council of Nigeria was responsible for post marketing surveillance of falsified medicines while the overwhelming 91.0% (55) of the respondents admitted that it was the responsibilities of National Agency for Food, Drugs, Administration and Control (NAFDAC) which is not very surprising as this is a common and household name among residents and citizens in Nigeria. The lowest numbers were from respondents who said that the responsibilities lie among the Medical and Dental Council (MDCN) and the World Health Organization (WHO) and they are 2.0% (1) and 2.0% (1) respondents respectively. See fig 4.3

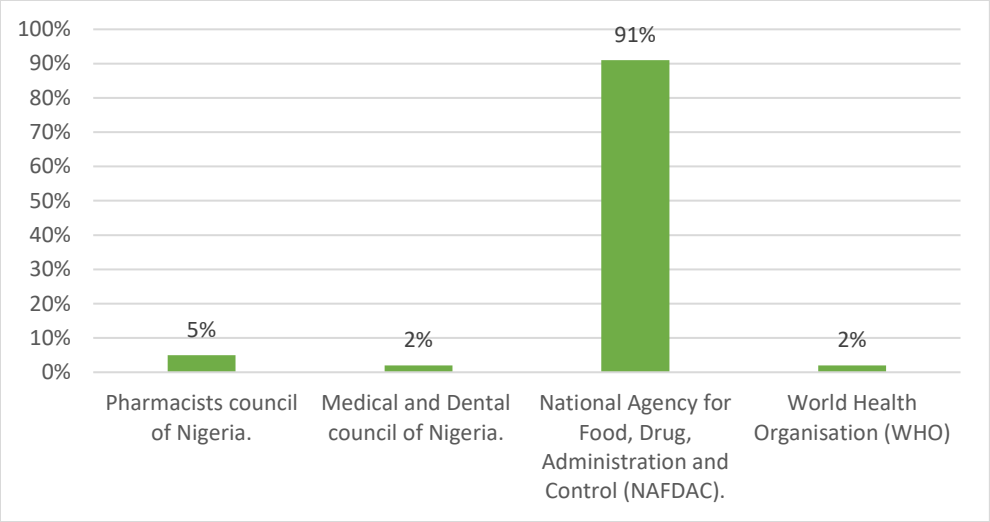

Figure 4.3: Governmental bodies responsible for post marketing surveillance of falsified medicines in Nigeria.

Question 10:

In accessing if the Nigerian guidelines and regulations regarding post marketing surveillance was familiar to the respondents, 54.0% (35) respondents admitted to being aware of the Nigerian guidelines and regulations concerning post marketing surveillance of falsified medicines while 46.0% (30) respondents admitted they didn't know about the Nigerian guidelines and regulations regarding post marketing surveillance of falsified medicines. See fig 4.4

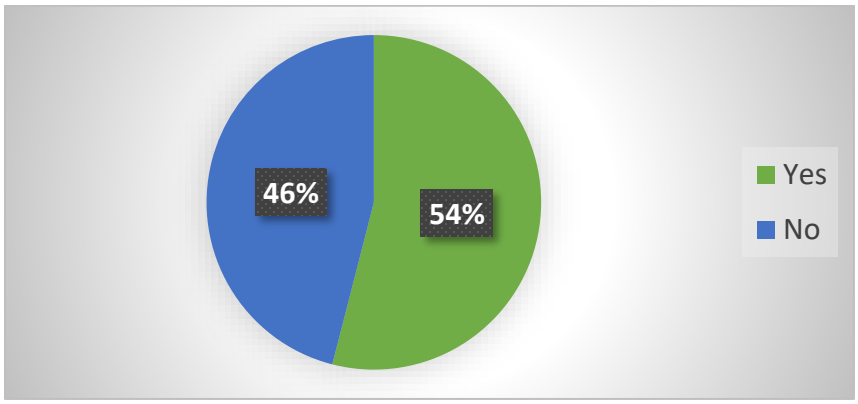

Figure 4.4: Familiar with the Nigerian guidelines and regulations about post marketing surveillance of falsified medicines.

As confirmed by the survey result, it was gathered that a significant majority agreed to be familiar to Nigerian guidelines and regulations about post marketing surveillance of falsified medicines while a significant minority said they were not aware of the Nigerian guidelines and regulations about post marketing surveillance of falsified medicines.

Question 11:

This question specifically accessed which post marketing surveillance guidelines are familiar to them since about 54.0% (35) respondents admitted to being familiar with the Nigerian guidelines and regulations regarding post marketing surveillance. 60.0% (40) respondents were aware of the continuous safety monitoring of authorized medicinal products guideline and 5.0% (15) respondents chose establishing and implementing risks. 15.0% (38) respondents chose ensuring medicinal products were updated with the current guidelines while 20.0% (10) respondents admitted to being familiar with non-communication between registration holders and the regulatory agency. See fig 4.5

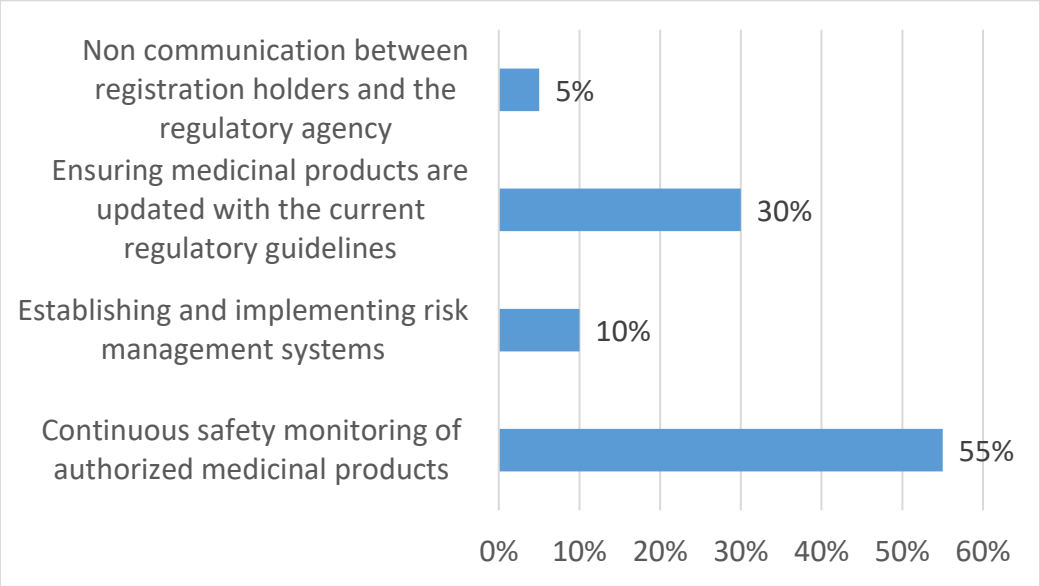

Figure 4.5: Post marketing surveillance guidelines.

As confirmed by the survey result, while few respondents incorrectly selected non communication between registration holders and the regulatory agency, an overwhelming majority of the respondents correctly recognised the other options like continuous safety monitoring of authorised medicinal products and ensuring medicinal products are updated with current regulatory guidelines.

Question 12:

This question was asked to evaluate if they would consider updating their knowledge about the regulations and guidelines regarding post marketing surveillance of falsified medicines and there were 100.0% (66) respondents agreeing to the need of updating their knowledge on the regulations and guidelines regarding post marketing surveillance of falsified medicines. See fig 4.6

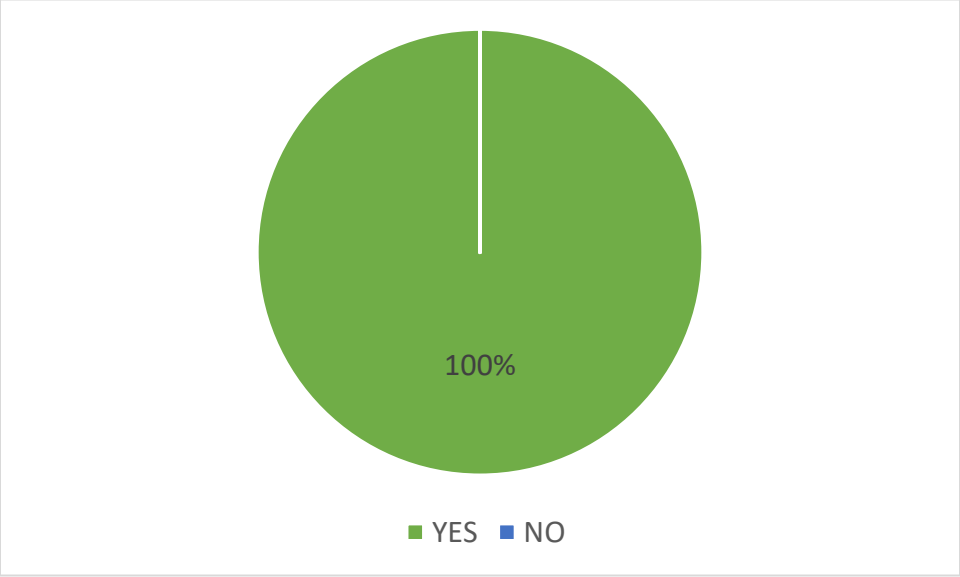

Figure 4.6: updating knowledge on post marketing surveillance guidelines and regulations.

As confirmed by the survey result, a significant 100% respondents both healthcare professionals and consumers agreed to updating their knowledge on post marketing surveillance guidelines and regulations.

Question 13:

In the act of ascertaining what their preferred method of updating their knowledge about post marketing surveillance would be, 35.0% (48) respondents preferred to update their knowledge through current guidelines from regulatory bodies and 24.0% (33) respondents chose the option of updating their knowledge through conferences/seminars. About 18.0% (25) respondents preferred the National Pharmacovigilance Center while 23.0% (31) respondents preferred to use the method of continuous personal development courses to update their knowledge on guidelines and regulations of post marketing surveillance on falsified medicines. See fig 4.7

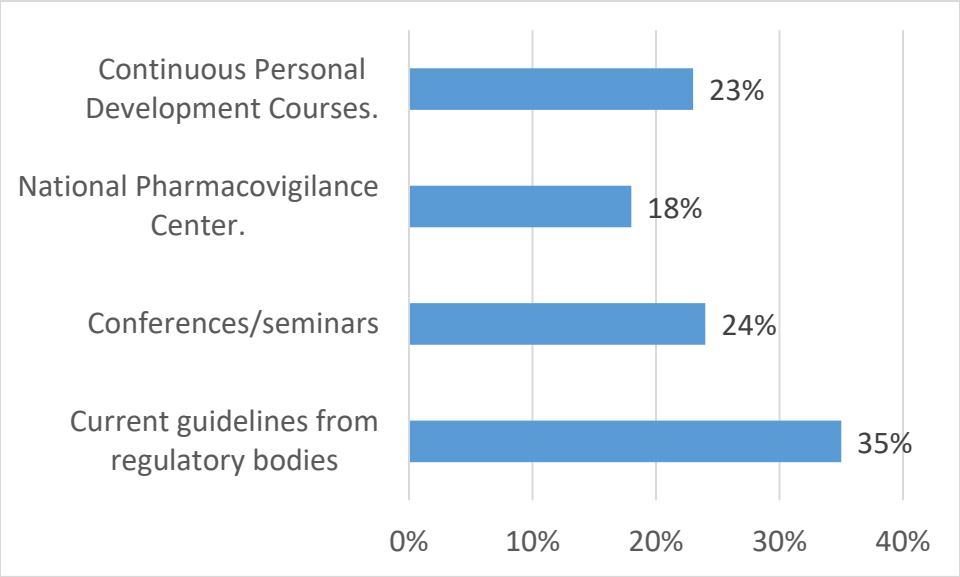

Figure 4.7: Methods of updating guidelines and regulations on post marketing surveillance

As confirmed by the survey result, the respondents agreed to updating their knowledge on post marketing surveillance. From the results, an overwhelming majority of respondents admitted to updating their knowledge on post marketing surveillance through current guidelines from regulatory bodies, continuous personal development courses and conferences.

Question 14

In trying to ascertain if they knew of the Mobile Authentication Service deployed by NAFDAC to detect falsified medicines, 68.0% (44) respondents knew about the Mobile Authentication Service deployed by NAFDAC while 32.0% (21) respondents had no knowledge of the Mobile Authentication Service deployed by NAFDAC to curb falsified medicine in Nigeria. see fig 4.8

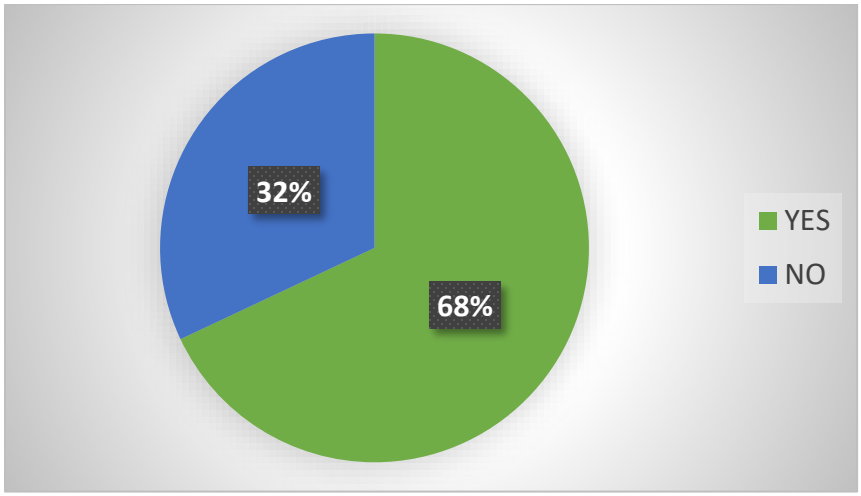

Figure 4.8: knowledge about the Mobile Authentication Service

Question 15

This question was created to ascertain how the participants found out about Mobile Authentication Service (MAS) and through what channels they heard about the Mobile Authentication Service. 48.0% (31) respondent admitted have been

informed by the pharmacist of the Mobile Authentication Service and 17.0% (11) respondents agreed to have been informed by the doctor. 23.0% (15) respondents claimed they knew about the MAS from the National Agency for Food and Drug Administration and Control (NAFDAC) websites while 12.0% (8) respondents claimed they heard about Mobile Authentication Service from the National Pharmacovigilance Center. See fig 4.9

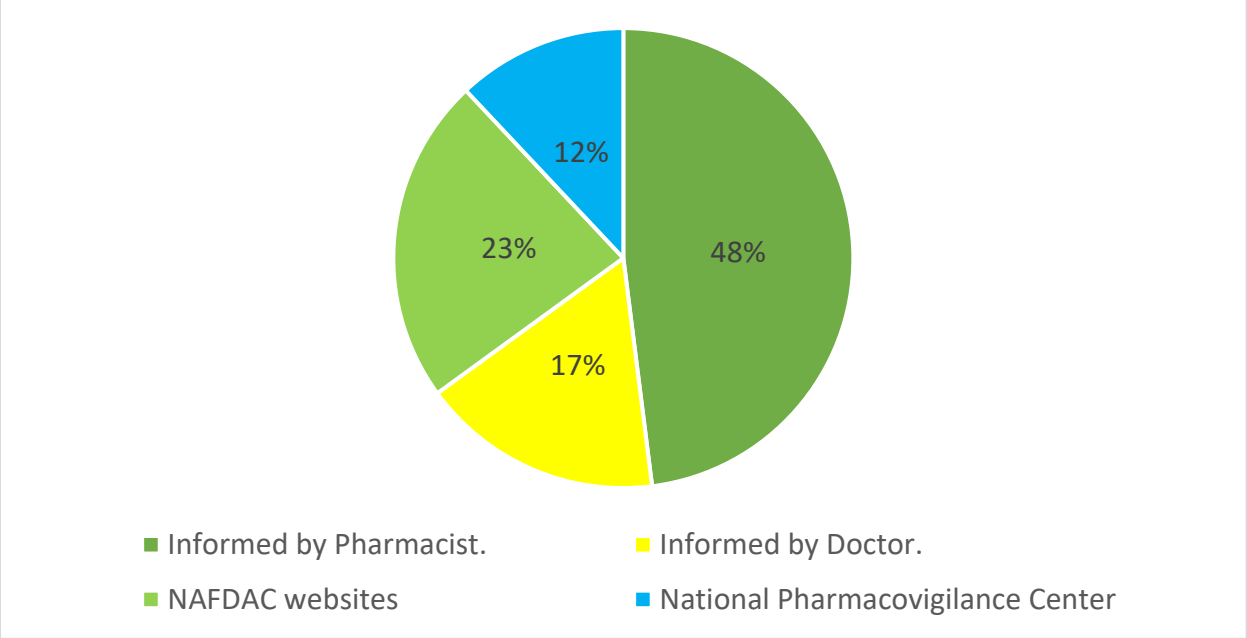

Figure 4.9: How they found out about the Mobile Authentication Service (MAS)

This confirms the level of awareness and the key healthcare professionals who play important roles in post marketing surveillance of falsified medicines to inform the consumers on the effects of falsified medicines on public health.

QUESTION 16:

In the process to ascertain if they had used Mobile Authentication Service before, 54.0% (30) respondents admitted having utilized it before while 46.0% (26)

respondents admitted they had not utilized the Mobile Authentication Service before. This generally affects the post marketing surveillance on falsified medicines negatively because an astounding minority claimed not to have used the Mobile Authentication services. See fig 4.10

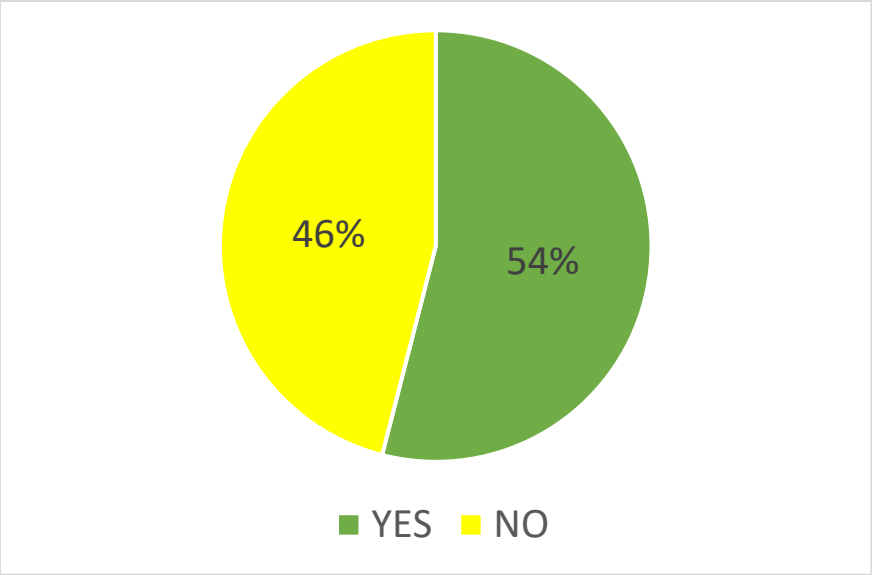

Figure 4.10: Utilization of Mobile

As depicted from the result gathered, despite the introduction and awareness of the Mobile Authentication Service (MAS), an above average respondents admitted they had used the Mobile Authentication Service while an astounding minority claimed not to have used the MAS. This survey results affects the impacts of post marketing surveillance on falsified medicines negatively.

QUESTION 17:

In the process of accessing how they rated the Mobile Authentication Service from their personal experiences which is vital to the goals of this research. 36.0% (16)

respondents admitted that the Mobile Authentication Service was effective, 18.0% (8) respondents admitted the Mobile Authentication Service was ineffective while 46.0% (21) respondents claimed they were neutral regarding the experience they had using the Mobile Authentication Service. See fig 4.11

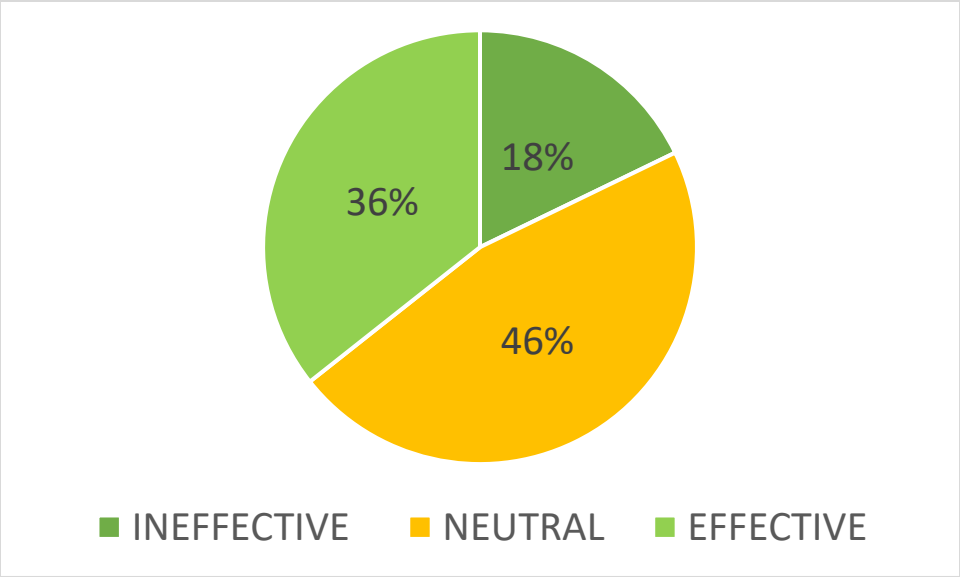

Figure 4.11: Experience rate of Mobile Authentication Methods.

As depicted from survey result, it was deduced that an astounding minority of the respondents admitted that the Mobile Authentication Service was effective while an overwhelming majority claimed the Mobile Authentication Service (MAS) was not effective.

QUESTION 18

In the process to analyse this question (To the best of your knowledge, do you believe that there is enough awareness about the MAS (Mobile Authentication Service) deployed by NAFDAC to detect falsified medicines), 17.0% (9)

respondents admitted that they were aware of the Mobile Authentication System while 83.0% (43) respondents admitted that there is not enough awareness on the Mobile Authentication Service deployed by NAFDAC to curb falsified medicines. See fig 4.12

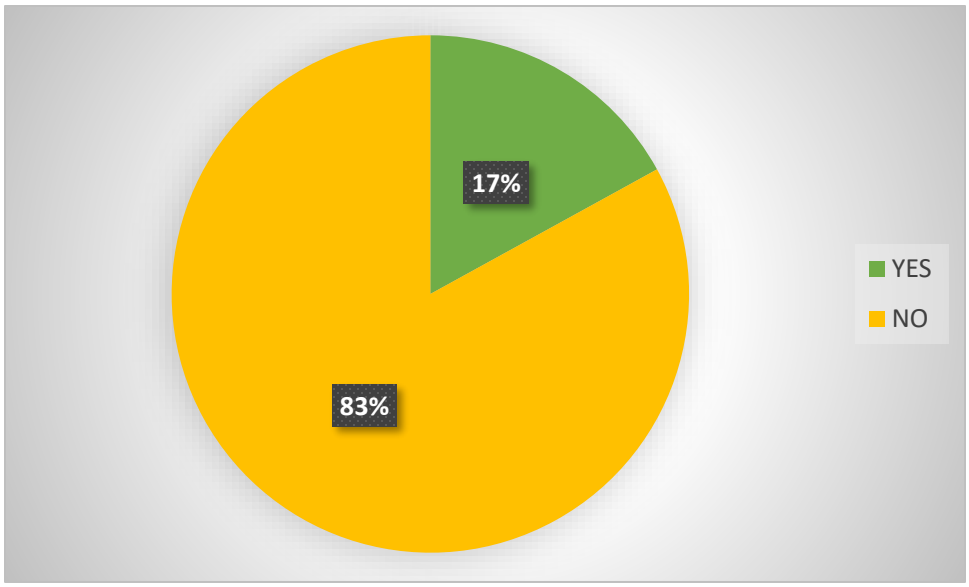

Figure 4.12: Awareness of the Mobile Authentication System.

The responses showed that majority of the public did not know about the Mobile Authentication Service despite the facts that NAFDAC claimed to have done enough awareness to alert the public about the dangers of falsified medicines

4.4 DIRECT EXPERIENCES (QUESTION 19-25)

QUESTION 19:

This question was designed to ascertain the general overview of what they think about falsified medicines in Nigeria and the effects it has on the public health. 76.0% (46) respondents agreed that Nigeria is a growing hotspot for falsified medicines, 24.0% (16) respondents decided to remain neutral on the questions

about Nigeria being a growing hotspot for falsified medicines while 6.0% (4) respondents disagreed on the statement that Nigeria is a growing hotspot for falsified medicines. fig 4.13

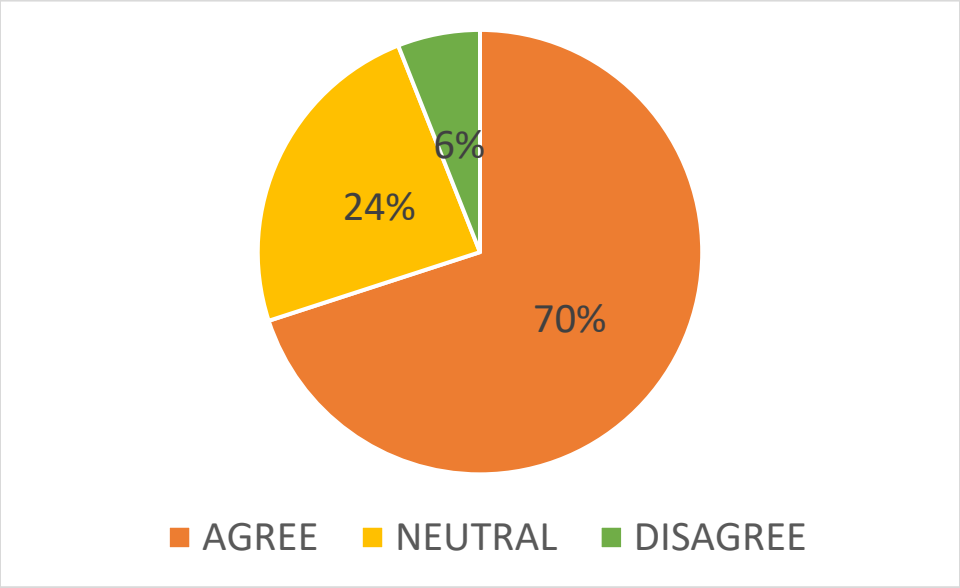

Figure 4.13: Falsified Medicine is a growing hotspot in Nigeria.

The extent of the problems of falsified medicines in the public health is a continuous global problem even to the developed countries and comparing the extent of the growing trends of falsified medicines in Nigeria a developing country, an overwhelming majority of 70.0% agreed that Nigeria is a growing hotspot of falsified medicine.

QUESTION 20:

In trying to ascertain the direct experiences of healthcare professionals (medical doctors and pharmacists) based on the number of times they treated cases, 17.0% respondents admitted that they saw and treated 2 – 3 cases a week and 31.0% respondents admitted they received less than 5 cases a month. However, 37.0%

respondents said they rarely received cases of falsified medicines while 15.0% respondents claimed they received and treated less than 10 cases in a year. This further gives an insight on the prevalence of falsified medicines based on the responses received. See figure 4.14

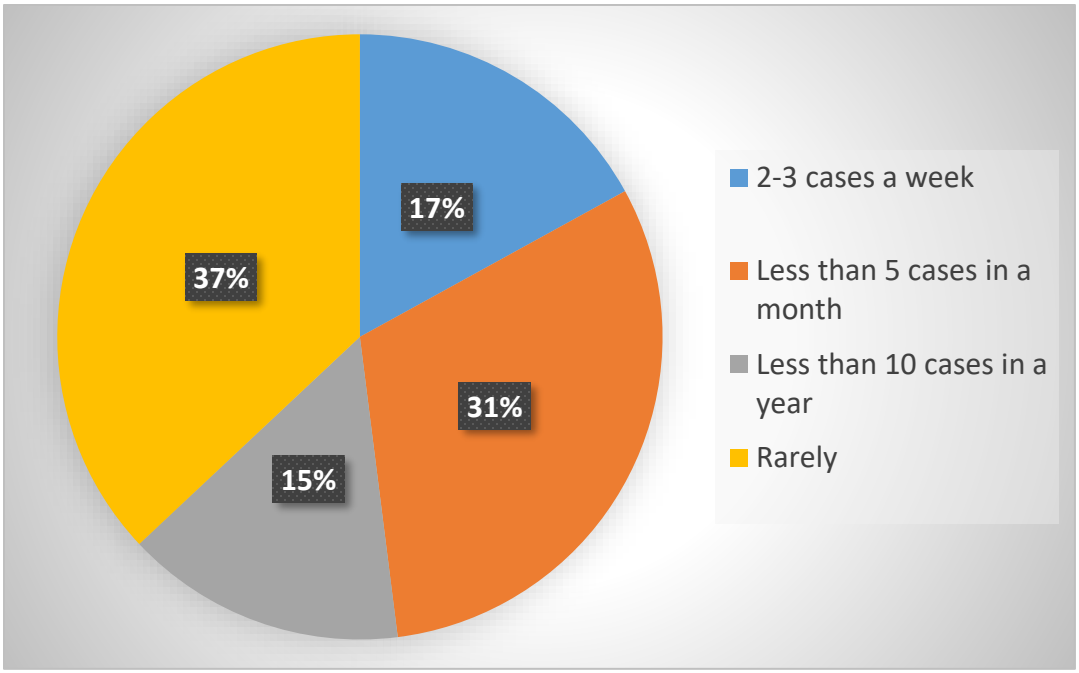

Figure 4.14: Frequency of cases of falsified medicine.

It also shows that there are 17.0% weekly cases and 31.0% monthly cases which on the average is a lot of cases of falsified medicines and considering the fact that many cases go unreported. There were possibilities with the fact that some cases may occur as a result of medicines bought in nearby open local dealers which may or may not be discovered at all. Some falsified medicine cases might even be reported as major morbidities without properly tracing the origin of this diseases.

QUESTION 21:

In the process to ascertain the extent the respondents were exposed to the adverse effects of falsified medicine on public health, 72.0% (46) respondents claimed they developed no adverse effects from falsified medicines while 28.0% (18) respondents claimed that they had suffered from adverse reactions as a result of using falsified medicines. see figure 4.15

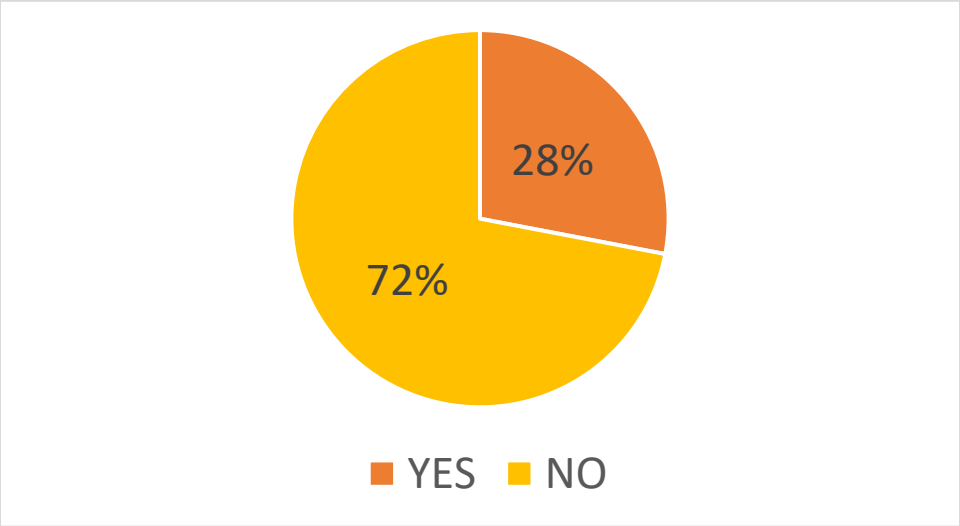

Figure 4.15: Adverse reactions after using falsified medicines.

From the survey results above, it was confirmed that an overwhelming majority had no exposure of adverse reactions and it was also deduced that they had not used falsified medicines as compared to the respondents who had adverse drug reactions as a result of use of falsified medicines

QUESTION 22:

A follow up question (Have you ever reported a falsified medicine case?) was asked to evaluate the extent of the post marketing surveillance and its follow up procedures. 78.0% (50) respondents said they had not reported any case of falsified

medicine while 22.0% (14) respondents admitted they had reported cases of falsified medicines.

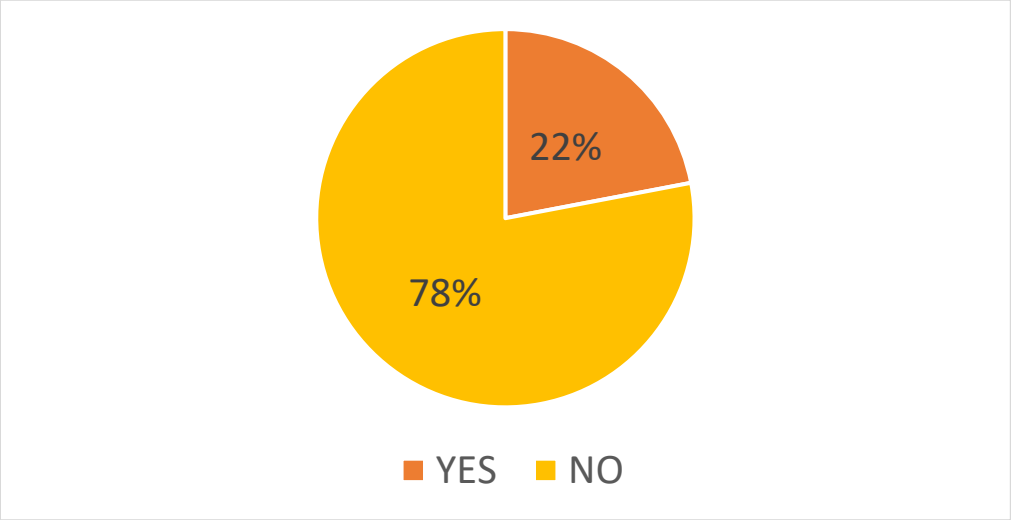

Figure 4.16: Reported cases of falsified medicines.

As confirmed by the survey result, there was an overwhelming majority who had never reported any case of falsified medicine as they also have not had any adverse reaction from its use while some respondents claimed they had reported cases of adverse reactions from use of falsified medicines.

QUESTION 23:

As a follow up question to question 22, this was to deduce where or who they reported cases of falsified medicine. 33.0% respondents said that they reported falsified medicine cases to the nearest pharmacy, 14.0% respondents claimed they reported their falsified medicine cases to the nearest hospital. However, 43.0% respondents admitted they reported falsified medicine cases to National Agency for Food and Drug administration and Control (NAFDAC) while 10.0% respondents claim to have reported the falsified medicine cases to the pharmaceutical company. See figure 4.17

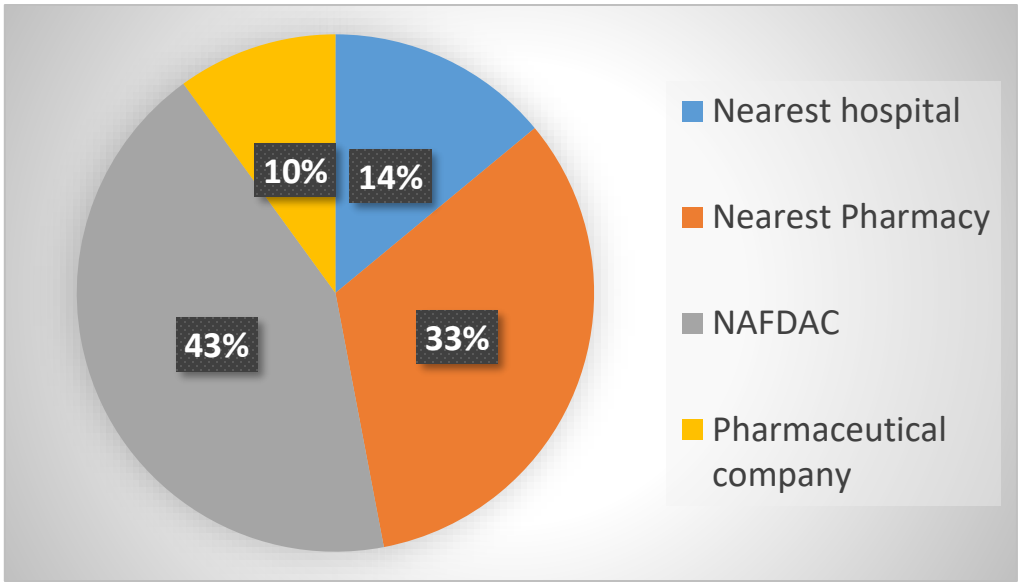

Figure 4.17: Who did they report falsified medicine to?

As confirmed from the survey result, an astounding majority of respondents claimed to report cases of falsified medicine to National Agency for Food and Drug Administration and Control (NAFDAC) while another significant respondent admitted to reporting to the nearest pharmacy.

QUESTION 24:

The respondents were assessed on the extent of their knowledge, awareness and observations on impacts of post marketing surveillance on falsified medicines and this was used to generate data on how much they believed the regulatory system is implemented adequately. 87.0% respondents believed that there is no adequate post marketing surveillance in Nigeria while 13.0% admitted there was enough post marketing surveillance in Nigeria. See fig 4.18

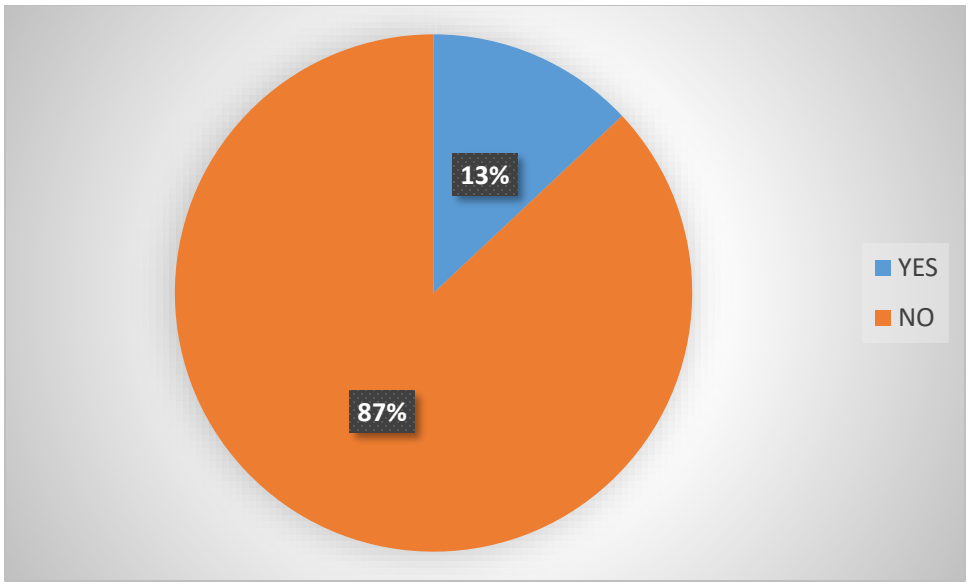

Figure 4.18: Adequate post marketing surveillance in Nigeria.

As confirmed by the survey result, an overwhelming majority agreed that the level of post marketing surveillance was not adequate. A minority admitted the level of post marketing surveillance was adequate. This confirms there is still a gap when it comes to post marketing surveillance on falsified medicines which keeps recking havoc in the Nigerian public health and healthcare delivery system.

QUESTION 25:

This question accessed the factors that impacts the post marketing surveillance in Nigeria and also show its relationship with the effects on falsified medicines. 50.0% respondents admitted that NAFDAC regulatory policies will have a positive impact on post marketing surveillance and this will positively affect falsified medicines to be reduced in the country as the case of stronger NAFDAC regulations while 37.9% respondents said there will be no impacts of NAFDAC regulatory policies, and 12.1% respondents admitted there will be negative impacts of NAFDAC regulatory policies on post marketing surveillance.

In assessing the social economic factor of Nigeria, 22.7% respondents admitted the social economic status of the country will positively affect post marketing surveillance while 25.0% respondents admitted that there will be no impact relating to social economic status and 52.3% respondents said there be negative impacts of socioeconomic status of the country on post marketing surveillance.

In accessing the cost implications in post marketing surveillance, 30.2% respondents claimed that cost implication will have a positive impact on post marketing surveillance, 14.0% respondents admitted that there will be no impacts of cost implications as regards post marketing surveillance and 55.8% respondents admitted that cost implications will have negative impacts to the post marketing surveillance of falsified medicines in Nigeria. See figure 4.19

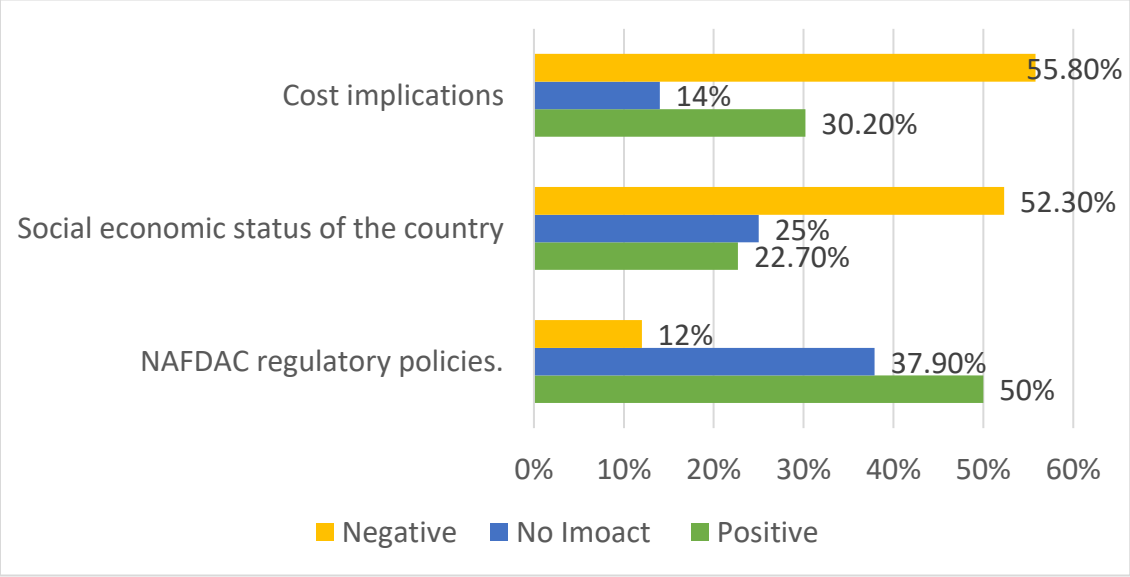

Figure 4.19: Factors affecting post marketing surveillance in Nigeria.

4.5 RECOMMENDATION (QUESTION 26)

QUESTION 26:

At the end of the questionnaire, the respondents were evaluated using this line of question “Do you think the following factors can improve the activities of post marketing surveillance as regards falsified medicines?” to get their view on recommendations of post marketing surveillance of falsified medicines.

As a result of updating respondent’s level of awareness by continuous advertisement through internet, radio, newspapers”, 1.7% respondents disagreed with the statement, 10.0% respondents remained neutral about the statement while 88.3% respondents agreed that there needs to be an increase awareness of falsified medicines by means of advertisement.

On the factor of increasing government funds and manpower to the pharmacovigilance sector, 2.0% respondents disagreed that it would have no effect, 13.7% respondents remained neutral about the statement while 84.3% respondents agreed with that there should be increased government support and manpower to the pharmacovigilance sector.

When it comes to continuous survey and routine checks of all marketers and distributors to ensure that they are authorized, 11.3% responses remained neutral on the statement, 0.0% respondents disagreed while 88.7% responses agreed that there should be continuous survey and routine checks of all marketers and distributors.

When it comes to comes to designing and implementing new regulations that boosts PMS on falsified medicine, 14.5% respondents remained neutral on the statement about designing and implementing new regulations while 85.5% responses agreed to the act of designing and implementing new regulations that boosts post marketing surveillance.

On the factor of formal education of the public about falsified medicine, 11.3% respondents were neutral about the option of educating the public about falsified medicine and 88.7% responses agreed to formally educating the public about dangers of falsified medicine.

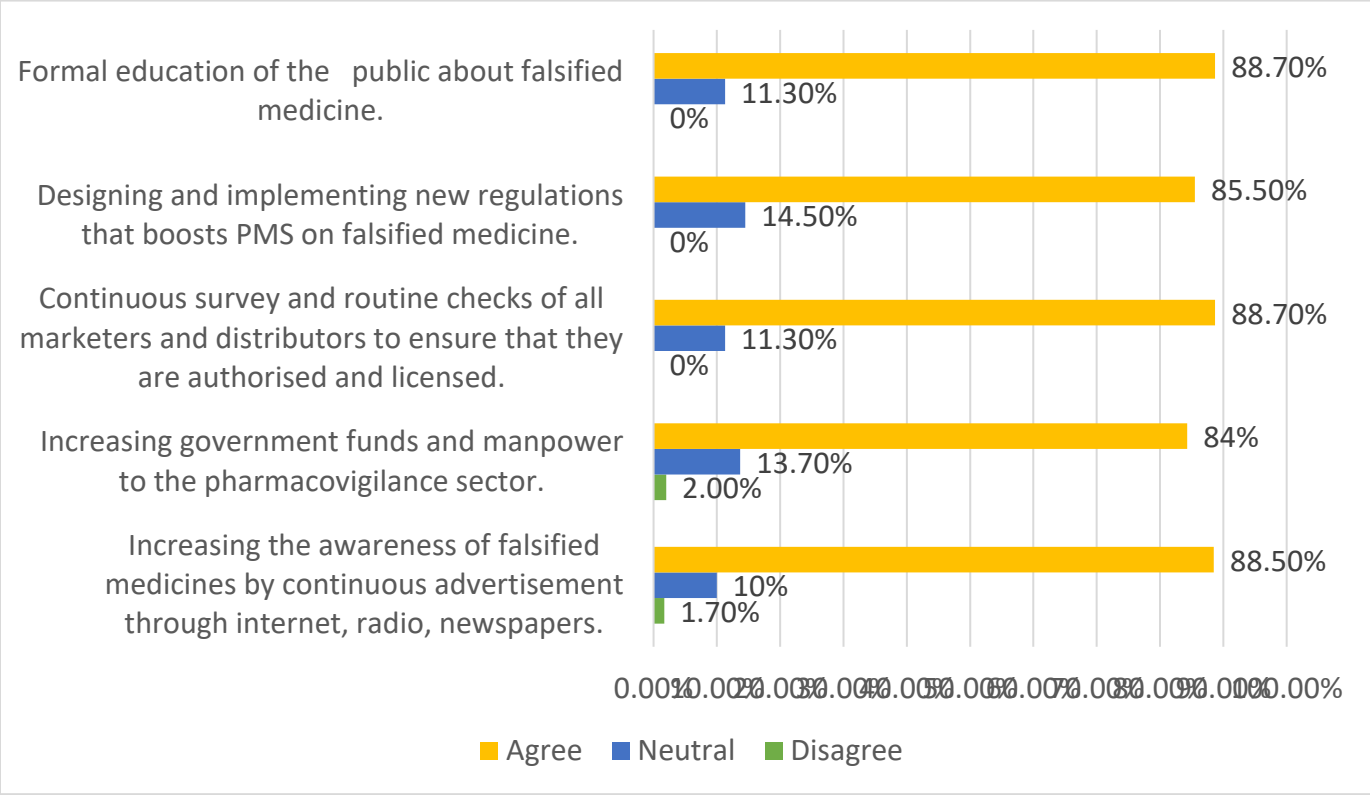

Figure 4.20 Showing the response of participants to the factors that can improve post marketing surveillance of falsified medicine

4.6 CONCLUSION

Based on the objective evidence drawn from the quantitative analysis, findings and interpretation above, it was interesting to note that there are lots of loopholes in the post marketing surveillance of falsified medicine. The questionnaire was drafted for Medical doctors, pharmacists and consumers and the survey was sent electronically to them through various contact channels. From the analysis it was

interesting to deduce that the public have heard of falsified medicine or about fake drugs but there is a major gap on the level of awareness and knowledge. This ignorance or lack of information puts their lives and Nigeria at an unsafe situation although National Agency for Food and Drug Administration and council (NAFDAC) has stated that there is enough information and awareness about post marketing surveillance of falsified medicines. What they fail to comprehend is the fact that this awareness may not have been enough, may not have gotten to everyone and the need for feedbacks to know where to strengthen the weak areas.

From the analysis above, there were varying degrees of knowledge about falsified medicines with the largest source being discussion among peers was considered as direct contact with one another where information can be shared willingly. The second source was from regulatory agencies which is as expected especially on the ground the healthcare professionals got acquainted with current guidelines for future references. Another remarkable one was from the journals and newspapers which has become obsolete since the impacts of the social media era it is interesting to note that the advertisement had the least responses which goes a long way to interpret that the weakness in the awareness of falsified medicines.

The respondents were also evaluated based on the level of awareness and knowledge on the guidelines of post marketing surveillance; some key parameters were used to test their level of awareness. The result revealed that they did not have adequate knowledge on the post marketing surveillance guidelines especially the consumers as some of the respondents answered incorrectly. The respondents were also willing to update their knowledge on post marketing surveillance guidelines and majority of them also chose they would prefer to update their knowledge through the current guidelines from regulatory bodies. Some

respondents chose through conference and seminars and others preferred through continuous personal development courses. The insight from the analysis was that so many people do not know about the Mobile Authentication Service (MAS) deployed by NAFDAC and the people that knew about the MAS got their knowledge through information from the pharmacists, the doctors and through the NAFDAC websites although some significant audience said they have not used the service before.

From the analysis, majority of the respondents said they do not believe there was enough awareness about Mobile Authentication Service deployed by NAFDAC about falsified medicines although NAFDAC claimed that there is enough awareness on Mobile Authentication Service. Nigerian being a third world country continues to be a growing hotspot for falsified medicine and this has given grounds for falsifiers to thrive and keep wrecking the public health and the economy of Nigeria. They also believed that post marketing surveillance is not carried out adequately to the best of their knowledge. There are also rooms for improvement based on recommendation that is believed to help improve the impacts of post marketing surveillance on falsified medicines.

CHAPTER 5: CONCLUSION

5.1 Answering the Main Questions and Fulfilling the Objectives of The Research Study.

This chapter is the concluding part of the research where the author focuses on the research objectives and also the questions that was drafted at the beginning of the study.

Question 1: Are the healthcare professionals and consumers aware of the falsified medicines and what is their source of knowledge?

As evidenced from the questionnaire survey carried out among experienced healthcare professionals (medical doctors and pharmacists) and consumers, it is important to note there is significant level of awareness or at least above average knowledge of falsified medicines. According to the research study, an astounding major respondents acknowledged that they were aware of falsified medicines while there were still minor respondents that did not have any knowledge about falsified medicine. There was also a section of the question that accessed their source of knowledge and the major respondents was in support of discussion among peers which seemed to be the most relevant answer considering that there could have been discussions among professionals and colleagues. While information from regulatory agencies got a significant increased number of respondents which supports National Agency for Food and Drug Administration and Control (NAFDAC)'s claim that there was adequate awareness of falsified medicines on their website, also published articles to educate the public on falsified medicines. However, the advertisement got very little responses as respondents claimed that they had not receive much

information of falsified medicines. The NAFDAC severally admitted that they had in the past ran advert campaigns to create awareness, the level of impacts of these campaigns and also the continuous follow up is still unknown as there are still gaps which needs to be filled on the level of awareness through advertisement considering we are at the era of social media. The National Agency for Food and Drug Administration and Control failed to continuously transform these campaigns to enhanced better awareness of the dangers of falsified medicines to public health and ways to curb it in Nigeria. The participants in this research supported consistent and continuous post marketing surveillance schemes with enhanced follow-up and feedback protocols.

QUESTION 2: Are healthcare practitioners aware of the regulations as regards post marketing surveillance on falsified medicine set up by NAFDAC?

From the survey carried out in this research, the author accessed their level of awareness concerning the regulations concerning post marketing surveillance of falsified medicines. In assessing the governmental bodies responsible for post marketing surveillance in Nigeria, the major respondents picked the National Agency for Food and Drug Administration, and Control (NAFDAC) while very few respondents said the Pharmacists Council of Nigeria (PCN) was responsible which is incorrect considering that the PCN is responsible for pharmacist registration and licensing and the Medical and Dental Council of Nigeria which fewer respondents said was responsible for the registration and licensing of Nigerian Medical Doctors and Dentists. Regarding their awareness of regulations and guidelines of post marketing surveillance, an average number of respondents claimed they knew, and some significant number of respondents claimed they were not aware. There is an article on NAFDAC websites regarding guidelines on post marketing surveillance and pharmacovigilance. Also, the author received a hundred percent (100.0%)

respondents' response agreeing that they would like to update their knowledge on post marketing surveillance guidelines and regulations. The respondents also preferred updating their knowledge through current guidelines from regulatory agencies while some respondents preferred conferences, seminars and also through continuous personal development courses.

QUESTION 3: Is there healthcare professionals and consumers' awareness of the established MAS design and utilization by NAFDAC to detect falsified medicines? From the survey in this study, the respondents were accessed on the awareness and utilization of Mobile Authentication Service (MAS) deployed by NAFDAC to detect falsified medicine. There were deductions that there was some level of awareness of Mobile Authentication Service while some people don't know about the MAS which is part of the post marketing surveillance tools deployed by NAFDAC. Respondents admitted having been informed about the MAS by the Pharmacists while fewer respondents got their awareness through the information by the Medical Doctor and other respondents knew about the Mobile Authentication Service through regulatory agencies like the NAFDAC and NPC. Another observation was that not everyone who knew about the MAS had used it before and this also affects the impacts of post marketing surveillance on falsified medicines. The respondents who had used the MAS admitted it was effective when they used the service while a significant percentage said it wasn't effective and other respondents remained neutral about it. More than 50.0% respondents admitted that they believe there wasn't enough awareness about Mobile Authentication Service (MAS) deployed by NAFDAC to detect falsified medicines. This has created a gap still to be filled in the post marketing surveillance scheme.

QUESTION 4: Are there factors that challenges effective post marketing surveillance of falsified medicine in Nigeria?

From the survey carried out, in ascertaining if they believed that post marketing surveillance was adequately carried out in Nigeria and about 87.0% responded that they didn't believe it was adequately carried out. A larger number of respondents agreed that factors like National Regulatory Policies could play a positive role in effective post marketing surveillance while some respondents agreed it will have no effect and a smaller number of respondents said it will have negative impacts on post marketing surveillance. Major respondents agreed that socioeconomic factor would have negative impact on post marketing surveillance while a significant number agreed that the socioeconomic factor will have positive impacts on post marketing surveillance. Based on the factors of cost implications, 30.0% respondents agreed that the cost implications will have positive impacts on post marketing surveillance while 56.0% respondents had the opinion it would have negative impacts on post marketing surveillance.

Question 5: Recommendations?

As confirmed from the survey, in assessing recommendation that would impact post marketing surveillance, the author was able to gather that increasing the awareness of falsified medicines by continuous advertisement through internet, radio and newspapers is a good way of strengthening post marketing surveillance based on responses from participants. The respondents agreed that post marketing surveillance of falsified medicine could be strengthened by increasing government funds and manpower to the pharmacovigilance sector. Another factor like continuous survey and routine checks of all marketers and distributors to ensure that they are authorized was strongly recommended as a strong factor that can improve post marketing surveillance of falsified medicine.

5.2 Correlating Results of Primary Research and Secondary Research.

As realized from the survey results and finding, there is an average level of awareness and knowledge among healthcare professionals (medical doctors and pharmacists) and consumers regarding falsified medicine in Nigeria. This is way below the level of awareness as compared to the articles from the literature review. The realization that some of the respondents do not know about falsified medicines is still interesting and worthy of note. NAFDAC admitted to deploying the use of media campaign such as TV, radio, and newspapers to create some level of awareness so as to enable every citizen (the members of the public and health care professionals) young and old to join the fight against the prevalence of falsified medicines in Nigeria. They thought that by so doing, they could reach more than half of the population if not all through the media campaign. According to some researchers (Gloria Nneka Ono and Chiazor Anthonia Chiaghana, 2020), "by the age of 18, a young person will have seen 350,000 commercials and spent more time being entertained by the media than any other activity except sleeping". With this, one would think that everyone would be aware and join the fight against falsified medicine but there are some factors which are evident in opposing the strategies and also negatively affects the anticipated outcome. (Gloria Nneka Ono and Chiazor Anthonia Chiaghana, 2020)

From this study, there are still gaps to fill regarding the awareness of falsified medicines and its dangers to the public health. The respondents' willingness to update their knowledge on the issue of falsified medicine awareness remains impressive as a positive culture towards improving post marketing surveillance and falsified medicine. NAFDAC failed to breech the gap concerning the awareness of falsified medicines especially through advertisements which had the lowest response

from participants. There is need to encourage NAFDAC to harness this tool and enhance awareness since this is the era of social media.

The study of impacts of post marketing surveillance of falsified medicine in Nigeria is a global problem that affects every citizen and the fight to curb it is everyone's. healthcare professionals (medical doctors and pharmacists) play key roles in the management of patients directly or indirectly. As confirmed from the survey, there are direct experiences of healthcare professionals and victims of falsified medicine. The findings from the survey revealed that the consumers were informed about falsified medicines by their medical doctors and pharmacists which was very remarkable considering that healthcare professionals have direct contacts with consumers. The survey results showed that healthcare professionals (medical doctor and pharmacists) treat at least 2-3 falsified medicine cases weekly and monthly.

Comparing it to the literature which identified the role of the healthcare professionals in addressing awareness of falsified medicines and post marketing surveillance. According to (Steinman et al., 2011) who said that deaths and comorbidities relating to adverse drug reactions could be diminished efficiently by identifying drug complications. Healthcare professionals are charged to have some level of responsibilities in effective post marketing surveillance. There is need of engagement between the healthcare professionals and patients after drug prescription and dispensary. The healthcare professionals are ethically obligated to educate this patients on the needs to report any form of reactions as a result of prescribed medications and also effectively inform them about the use of Mobile Authentication Service since every average Nigeria is presumed to have a basic mobile phone. (Steinman et al., 2011)

5.3 The Limitations of The Research

The research was completed competently and appropriately having collected information through survey questionnaire from sixty-six respondents notwithstanding the insufficient time allocated for this research. the data was reviewed, analysed and presented in form of charts for better insights, interpretation and impressions. Most research articles about falsified medicine focused on the degrading effects of falsified medicines on the public, NAFDAC's guidelines among healthcare professionals and regulations on falsified medicines while this research focuses on the adequate applicable regulations, continuous post marketing surveillance and the Mobile Authentication Service among healthcare professionals and consumers.

The main hinderances is the current COVID-19 global pandemic that is still ongoing notwithstanding the world has been under siege since 2020. It affected the physical involvements between the author and the respondents. Many respondents refused to participate in the interview the author presented as they had personal reasons. There was also limited number of highly advanced medical doctors and pharmacist. The survey did not reach as much participants as necessary. The COVID-19 pandemic still remained the major factor as this also limited social influences and limited physical communications as the author initially wanted to involve some regulatory officials.

5.4 Recommendations.

From the study results, the awareness and knowledge of falsified medicine among healthcare professionals (medical doctors and pharmacists) emanates from discussions among peers, journals and newspapers and also information from regulatory agency while less from advertisements. Although NAFDAC claimed to have done advert campaigns which have failed to affect the awareness and knowledge needed in post marketing surveillance of falsified medicine. There is a greater need to increase awareness of falsified medicines by continuous advertisements through the use of internets, radio and newspaper considering the world is at its peak of social media era.

The induction realised during the course of the research that there was high level of corruption among NAFDAC officials which affected post marketing surveillance negatively. During the management of late Dr. Dora Akunyili, she figured the corrupt practices of some NAFDAC officials and removed them from the agency. There is a great need to train, hire highly qualified and experienced staff who will help improve post marketing surveillance of falsified medicines. There should be programs or schemes to re-train already existing staff officials to be fully equipped in the task of routine monitoring and inspection.

There should be increased government funds and manpower to the pharmacovigilance sector. The NAFDAC after receiving the money should invest it on updated technology to help highly skilled officials during surveillance programs. The officials blamed poor state of living to the reasons they received bribe and so increased government funds would also improve the socioeconomic status of this officials to avoid corruptions.

During the course of the research, there was conflict of interests (COI) between functions of pharmaceutical sectors. The conflict of interest (COI) lies mainly between NAFDAC, National Drug Law Enforcement Agency (NDLEA) and Nigerian Ports Authorities (NPA). There should be well-documented guidelines regarding the conflict of interest (COI) among these competent authorities in order to carry out surveillance activities of all pharmaceutical and medicinal products. There should be room for updates of all guidelines with proper reviews of training od staff to follow these guidelines thereby limiting the importation, distribution and sale of falsified medicinal products.

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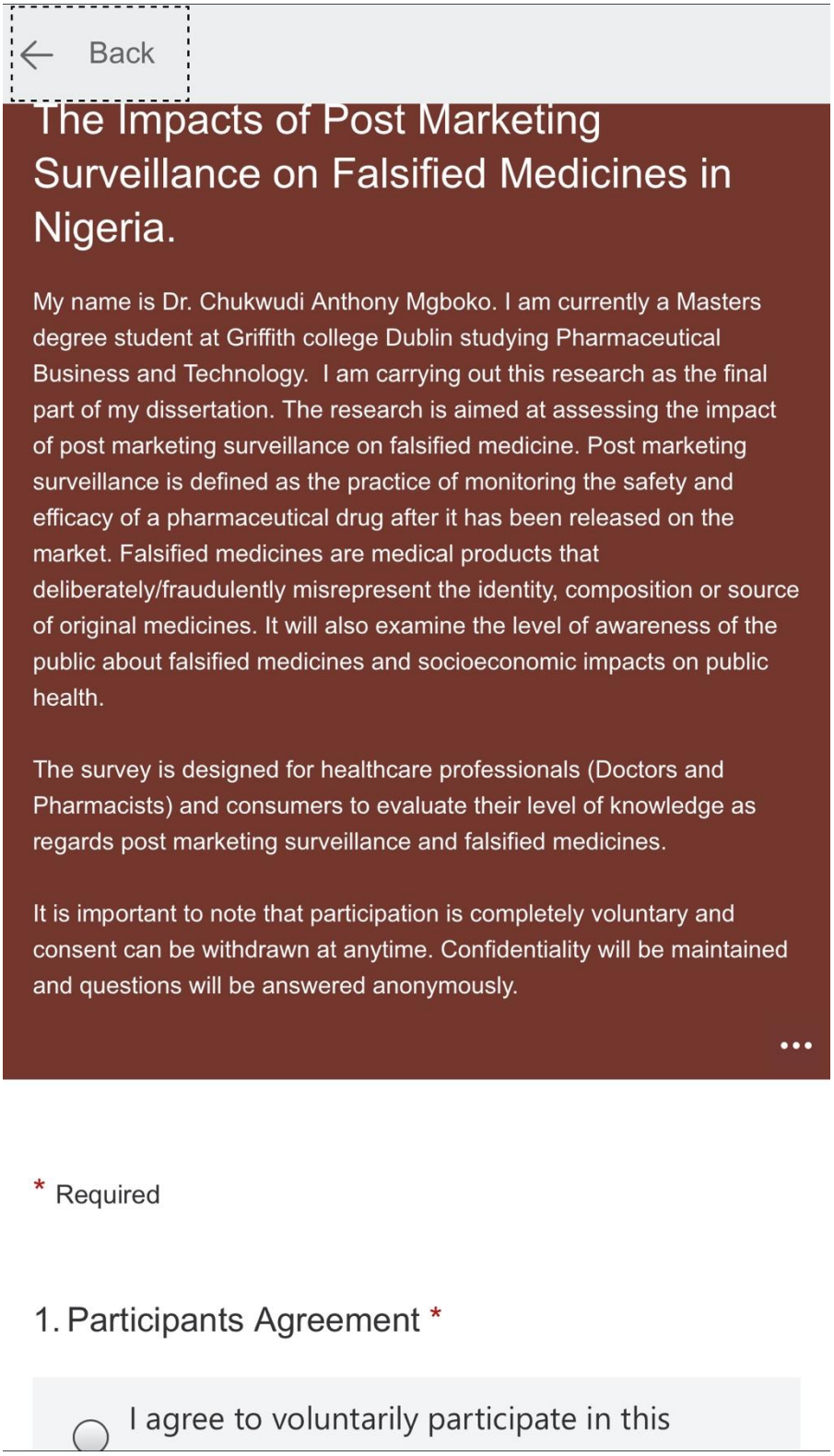
APPENDIX: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The Impacts of Post Marketing Surveillance on Falsified Medicines in Nigeria.
My name is Dr. Chukwudi Anthony Mgboko. I am currently a Masters degree student at Griffith college Dublin studying Pharmaceutical Business and Technology. I am carrying out this research as the final part of my dissertation. The research is aimed at assessing the impact of post marketing surveillance on falsified medicine. Post marketing surveillance is defined as the practice of monitoring the safety and efficacy of a pharmaceutical drug after it has been released on the market. Falsified medicines are medical products that deliberately/fraudulently misrepresent the identity, composition or source of original medicines. It will also examine the level of awareness of the public about falsified medicines and socioeconomic impacts on public health.
The survey is designed for healthcare professionals (Doctors and Pharmacists) and consumers to evaluate their level of knowledge as regards post marketing surveillance and falsified medicines.
It is important to note that participation is completely voluntary and consent can be withdrawn at anytime. Confidentiality will be maintained and questions will be answered anonymously.
* Required
1. Participants Agreement *
I agree to voluntarily participate in this

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Demographics

2. Gender? *

- ◯ Male
- ◯ Female

3. What is your level of education? *

- ◯ High School Certificate
- ◯ Bachelors Degree
- ◯ Masters Degree
- ◯ Postgraduate Degree

4. What is your age group? *

- ◯ <20
- ◯ 20-35 years

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- ◯ 36 - 45 years
- ◯ 46 years +

5. What is your profession? *

- ◯ Medical Doctor
- ◯ Pharmacists
- ◯ Others

6. Years of experience? *

- ◯ <1 year
- ◯ 1-5 years
- ◯ 5-10years
- ◯ 10+ years

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Knowledge and Awareness about Post-Marketing Surveillance and Falsified Medicines

7. Do you know about Falsified Medicines?

IF YES, ANSWER 8 AND 9. IF NO, GO TO QUESTION 10.

- ◯ Yes
- ◯ No

8. What is your source of knowledge about Falsified Medicines?

FEEL FREE TO PICK MULTIPLE OPTIONS

- ☐ Journals and newspapers.
- ☐ Discussions among peers.
- ☐ Advertisement.
- ☐ Information from regulatory agencies.
- ☐ Formal education/semina/conference.

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9. To the best of your knowledge, what governmental body is responsible for post marketing surveillance of Falsified Medicines in Nigeria?

- ◯ Pharmacists council of Nigeria.
- ◯ Medical and Dental council of Nigeria.
- ◯ National Agency for Food, Drug, Administration and Control (NAFDAC).
- ◯ World Health Organisation (WHO).

10. Are you familiar with the Nigerian guidelines and regulations regarding post marketing surveillance?

- ◯ Yes
- ◯ No

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11. Which of the following post marketing surveillance guidelines are you familiar with?

FEEL FREE TO PICK MULTIPLE OPTIONS

- [ ] Continuous safety monitoring of authorized medicinal products
- [ ] Establishing and implementing risk management systems
- [ ] Ensuring medicinal products are updated with the current regulatory guidelines
- [ ] Non communication between registration holders and the regulatory agency

12. Would you consider updating your knowledge about the regulations and guidelines regarding post marketing surveillance?

- ◯ Yes
- ◯ No

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13. What would be your preferred method of updating your knowledge about Post Marketing Surveillance?

FEEL FREE TO PICK MULTIPLE OPTIONS

- [ ] Current guidelines from regulatory bodies
- [ ] Conferences/seminars
- [ ] National Pharmacovigilance Center.
- [ ] Continuous Personal Development Courses.

14. Do you know about the MAS (Mobile Authentication Service) deployed by NAFDAC to detect Falsified Medicines?

IF YES, CONTINUE TO QUESTION 13. IF NO, CONTINUE TO SECTION 4

- ◯ Yes
- ◯ No

← Back

15. How did you find out about the MAS?

FEEL FREE TO PICK MULTIPLE OPTIONS

- [ ] Informed by Pharmacist.
- [ ] Informed by Doctor.
- [ ] NAFDAC websites.
- [ ] National Pharmacovigilance Center.

16. Have you utilised the MAS before?

IF YES, CONTINUE TO QUESTION 17. IF NO CONTINUE TO QUESTION 18.

- ◯ Yes
- ◯ No

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17. In your experience how do you rate the MAS?

- Ineffective
- Neutral
- Effective

18. To the best of your knowledge, do you believe that there is enough awareness about the MAS (Mobile Authentication service) deployed by NAFDAC to detect falsified medicines

- Yes
- No

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Direct Experience

19. To what extent do you agree or disagree with the statement “Nigeria is a growing hotspot for falsified medicines”

- ◯ Disagree
- ◯ Neutral
- ◯ Agree

20. How often do you treat patients with complications arising from the use of falsified medicines?

ONLY FOR DOCTORS AND PHARMACISTS

- ◯ 2-3 cases a week
- ◯ Less than 5 cases in a month
- ◯ Less than 10 cases in a year
- ◯ Rarely

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21. Have you ever developed adverse reactions after using falsified mediations?

- Yes
- No

22. Have you ever reported any falsified medicine?

IF YES, CONTINUE TO QUESTION 23. IF NO CONTINUE TO QUESTION 24.

- Yes
- No

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23. To whom did you report the falsified medicines?

- ◯ Nearest hospital
- ◯ Nearest Pharmacy
- ◯ NAFDAC
- ◯ Pharmaceutical company

24. To the best of your knowledge, do you think post marketing surveillance in Nigeria is carried out adequately?

- ◯ Yes
- ◯ No

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25. What is the impact of these factors on post marketing surveillance in Nigeria?

NAFDAC regulatory policies.

- ◯ Positive
- ◯ No impact
- ◯ Negative

Social economic status of the country.

Cost implications

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Recommendations

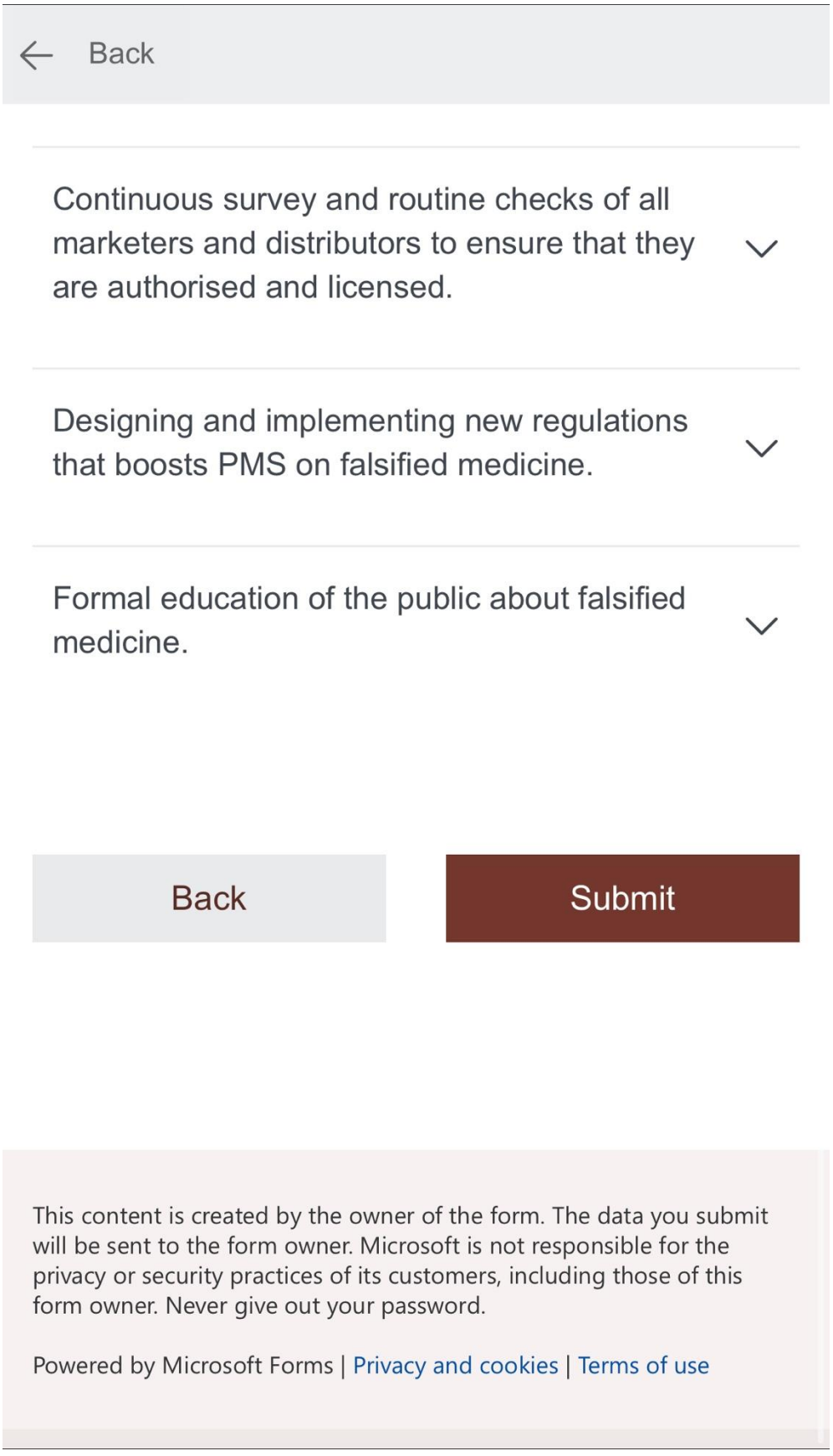
26. Do you think the following factors can improve the activities of post marketing surveillance as regards falsified medicines?

Increasing the awareness of falsified medicines by continuous advertisement through internet, radio, newspapers.

- ◯ Disagree
- ◯ Neutral
- ◯ Agree

Increasing government funds and manpower to the pharmacovigilance sector.

Continuous survey and routine checks of all marketers and distributors to ensure that they are authorised and licensed.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Continuous survey and routine checks of all marketers and distributors to ensure that they are authorised and licensed.
Designing and implementing new regulations that boosts PMS on falsified medicine.
Formal education of the public about falsified medicine.
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