



FEDERAL MINISTRY OF HEALTH

**NIGERIAN NATIONAL
PHARMACOVIGILANCE
POLICY AND IMPLEMENTATION
FRAMEWORK**

FIRST REVISION JUNE 2020

**NIGERIAN NATIONAL PHARMACOVIGILANCE
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First Revision

June 2020

NIGERIAN NATIONAL PHARMACOVIGILANCE POLICY AND IMPLEMENTION FRAMEWORK

Foreword

I am pleased to write the foreword for the second edition of the Nigerian National Pharmacovigilance Policy. The first policy came into operation in 2012 and has since guided the science and activities of drug safety monitoring in Nigeria, cutting across all tiers of the healthcare delivery systems.

In the last 8 years, efforts toward ensuring best treatment outcomes for patients, leaning on the science and practice of pharmacovigilance, have been sub-optimal. We have recognized gaps and weaknesses that need to be addressed to strengthen the pharmacovigilance practice and system, while also consolidating on the gains made.

This revised Policy clarifies the roles and responsibilities of all stakeholders in the public and private health sector and at the various tiers of government in ensuring efficient monitoring of safe use of medicines. The need to monitor the safe use of herbal medicines, which is on the increase across the country, is also given due attention.

The implementation framework of this policy was also reviewed to ensure easy integration of the pharmacovigilance practice into the overall healthcare delivery system. This implementation framework sets out milestones and targets that are clear, unambiguous and realizable through the cooperation and collaboration of relevant stakeholders.

Finally, I wish to enlist the support and commitment of all stakeholders toward the effective implementation of this policy to ensure safe use of medicines at all levels of healthcare system in Nigeria.



Dr. Osagie Ehanire, MD, FWACS

Honourable Minister of Health

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Preface

In 1968, the WHO established an International Drug Monitoring Programme as a forum for member state to collaborate in the monitoring of drug safety, and notably, the identification and analysis of new adverse reaction signals from data submitted. This laid the foundation for the current global pharmacovigilance activities.

Pharmacovigilance activities in Nigeria are being coordinated by the National Agency for Food and Drug Administration and Control (NAFDAC) under the supervision of the Federal Ministry of Health. The Nigerian National Pharmacovigilance Policy and Implementation Framework were developed in 2012 and this is the first revision of the policy. Essentially, this document comprises policy provision and a well-articulated framework for its implementation. The revised and updated edition of the policy integrates recent developments and advances in pharmacovigilance in line with global best practices.

The situational analysis reveals the number of Adverse Drug Reaction (ADR) reports emanating from each of the geopolitical zones and further highlights the series of trainings conducted for healthcare providers and Marketing Authorization Holders (MAH). It also delves into the deployment of e-reporting tool along with the conventional yellow form for the reporting of ADRs.

The policy underscores the incorporation of pharmacovigilance system into all the on-going Public Health Programmes and the need for donors supporting Public Health Programmes to provide annual report on the safety of the medicines used at healthcare facilities. Also, healthcare providers, government, non-governmental organizations, and the end users of health products are expected to play their roles in achieving excellent pharmacovigilance system in Nigeria.

Section 9 highlights the regulatory framework for pharmacovigilance. It stresses the reporting of ADRs as the ethical and professional responsibility for health professionals and traditional herbal medicine practitioners or any other healthcare provider. Also, MAH shall appoint a qualified person responsible for pharmacovigilance (QPPV) who shall have the responsibility of returning ADR reports to the NPC. The pharmacovigilance structure and functions and the roles and responsibilities of stakeholders are coherently presented in section 11 of the document. The pharmacovigilance structure in Nigeria is schematically presented in Figure 2.

The funding of pharmacovigilance system and pharmacovigilance research and development are presented in section 12 and 15 respectively. It is important to note that research and development play a major role in pharmacovigilance system and there must be constant collaboration with institutions and researchers in the tracking of pharmacovigilance.

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The second part of this document (section 16) deals with the implementation framework of the policy. It further identifies the operators and outlines the template for implementation of the policy. The need for institutionalization of the policy and the roadmap for the realization of the objectives are highlighted. Realistic targets are set for the policy objectives with the hope that efforts directed towards their implementation will ensure the safe use of medicines across all levels of healthcare system in Nigeria.

Overall, the Policy implementation Framework would leverage on appropriate Policy provisions to ensure safe use of medicines in Nigeria.



A. M. Abdullahi
Permanent Secretary

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Reproductive Health/Family Health FMOH
National Product Supply Chain Management Programme
National Primary Health Care Development Agency
National Institute for Pharmaceutical Research and Development
The Global Fund Country Coordinating Mechanism
Pharmacists Council of Nigeria
Medical and Dental Council of Nigeria
Nursing and Midwifery Council of Nigeria
National Drug Safety Advisory Committee
Pharmaceutical Society of Nigeria
Association of Pharmaceutical Importers of Nigeria
Nigerian Representatives of Overseas Pharmaceutical Manufacturers
Association of Hospitals and Administrative Pharmacists of Nigeria
Pharmaceutical Manufacturing Group -Manufacturers Association of Nigeria
Family Health International 360
Institute of Human Virology of Nigeria
Catholic Relief Services
Society for Family Health
Clinton Health Access Initiative
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World Health Organization
United Nations Children's Fund
United States Pharmacopoeia
KNCV Tuberculosis Foundation Nigeria
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LIST OF ACRONYMS / ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Events
DAIDS	Division of Acquired Immunodeficiency Syndrome
FBO	Faith Based Organization
FHI	Family Health International
FMoH	Federal Ministry of Health
GF	Global Fund
ICSR	Individual Case Safety Report
IHVN	Institute of Human Virology of Nigeria
LMIS	Logistics Management Information System
MAH	Marketing Authorization Holder
MDA	Ministries Departments and Agencies
MDCN	Medical and Dental Council of Nigeria
MQM	Monitoring Quality of Medicines
NAFDAC	National Agency for Food and Drug Administration and Control
NDSAC	National Drug Safety Advisory Committee
NGO	Non-Governmental Organization
NIMR	Nigerian Institute of Medical Research
NIPRD	National Institute for Pharmaceutical Research and Development
NMCN	Nursing and Midwifery Council of Nigeria
NMEP	National Malaria Elimination Programme
NPC	National Pharmacovigilance Centre
NPS	National Pharmacovigilance System
NTBLC	National Tuberculosis and Leprosy Control
PASS	Post Authorization Safety Studies
PAES	Post Authorization Efficacy Studies
PBRER	Periodic Benefit/Risk Evaluation Report
PCN	Pharmacists Council of Nigeria
PHC	Primary Health Care Centre
PHP	Public Health Programme
PMS	Post-Marketing Surveillance
PRASCOR	Pharmacovigilance Rapid Alert System for Consumer Reporting
PSUR	Periodic Safety Update Report

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PV	Pharmacovigilance
QPPV	Qualified Person Responsible for Pharmacovigilance
RMP	Risk Management Plan
SF	Substandard and Falsified
SFH	Society for Family Health
SPHARTI	Structured Pharmacovigilance Training Initiative
TSR	Targeted Spontaneous Reporting
UMC	Uppsala Monitoring Centre
WHA	World Health Assembly
WHO	World Health Organization

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DEFINITIONS

Adverse Drug Reaction (ADR)	A response to a drug which is noxious and unintended, which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.
Adverse Drug Reaction Reporting Form	A form designed and distributed by the National Pharmacovigilance Centre (NPC) for reporting ADRs.
Adverse Event	Any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have a causal relationship with the treatment.
Active Pharmacovigilance	Active measures that are taken to detect adverse events. This is managed by active follow up after treatment and the events may be detected by asking patients directly or screening patient records. The most comprehensive method is Cohort Event Monitoring (CEM).
Causality Assessment	The method used for estimating the strength of relationship between product(s) exposure and occurrence of adverse reaction(s). Causality assessment includes, evaluation of temporal relationships, association with (or lack of association with) underlying disease, presence (or absence) of a more likely cause, and biologic plausibility.
Drug	Any substance which has a physiological effect when ingested or otherwise introduced into the body.
Expedited Adverse Event Reporting	Refers to urgent reporting of selected adverse events through the Division of Acquired Immunodeficiency Syndrome (DAIDS) Adverse Experience Reporting System. All reported events must also be entered into Adverse Event Log.
Expected Reaction	A reaction that is consistent with the applicable product information or characteristics of the drug. The reaction can be explained from the mechanism of action of the drug.
Health Product	Any product, substance or a mixture of substances used or purported to be suitable for use that is manufactured or sold for use in the diagnosis, treatment, mitigation, modification or prevention of a disease, abnormal physical or mental state, or the symptoms thereof, in humans or animals; or for restoring, correcting or modifying any somatic, psychic or organic

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function in humans or animals. A health product can include medicines, herbal products, vaccines, antisera, biological and blood products.

Health Products Regulation	All the processes involved in the pre-marketing evaluation, marketing authorization, and post-marketing review of medicines, vaccines, devices, and other health products to ensure compliance with established standards of quality, safety, and efficacy.
Healthcare Professional	A healthcare professional is a qualified person who has acquired the requisite knowledge, skills and competences to deliver proper health care in a systematic and acceptable way to any individual in need of healthcare services.
Healthcare Provider	A healthcare provider may refer to a health professional or other officially recognized persons or organizations that provide healthcare services.
Marketing Authorization Holder (MAH)	The holder (an individual, institute, manufacturer, company, importer, distributor, development partner/donor agency, etc) of a marketing authorization to market a medicinal product. For the purpose of this policy document, the MAHs will have full responsibility and liability for their product(s) on the market and full responsibility for ensuring that appropriate action can be taken when necessary.
Medication Errors	Any preventable events that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer. Such events may be related to professional practice, healthcare products, procedures and systems including prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.
Medicine	Any substance or product administered to humans for the prevention, diagnosis or treatment of any disease or its symptoms or for the modification of physiological function.
National Agency for Food and Drug Administration and Control (NAFDAC)	An agency established by the Federal Government of Nigeria through promulgation of the NAFDAC Decree 15 of 1993 (as amended) now cited as Act Cap N1 LFN 2004 to control and regulate the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices and all drinks including packaged water.

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National Pharmacovigilance System (NPS):	The nationwide medicine safety system, coordinated by the Nigerian drug regulatory agency (NAFDAC) in order to improve benefits and reduce harm related to the use of medicines by the public through the efficient mobilization of various stakeholders and resources at all levels and in all sectors.
Passive Pharmacovigilance	This means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns. Reporting is entirely dependent on the initiatives and the motivation of the potential reporters. This is the most common form of pharmacovigilance. It is commonly referred to as spontaneous or voluntary reporting. In some countries this form of reporting is mandatory.
Periodic Safety Update Report (PSUR)	A report produced by an MAH intended to provide an update of a worldwide safety experience (with some focus on Nigeria) of a medicinal product to the competent authorities at defined times post authorization.
Pharmacovigilance	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.
Post-marketing surveillance (PMS)	The practice of monitoring safety and effectiveness of pharmaceutical products or other consumable medical products after it has been released into the market with the objectives to decrease mortality and morbidity associated with adverse events and improving understanding of effectiveness in real-world situations.
Reporter:	Any person who describes a suspected adverse effect to the relevant regulatory or competent authority (NPC, NAFDAC etc).
Serious Adverse Event or Reaction	<p>A serious adverse event or reaction is any untoward medical occurrence that at any dose results in death, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity or is life-threatening.</p> <p><i>To avoid any confusion or misunderstanding of the difference between the terms “serious” and “severe”, the following clarification should be noted. The term “severe” is not synonymous with “serious”. Severity is used to describe the intensity of a specific event (i.e., mild, moderate or severe). The event itself may be of relatively minor medical significance (such as severe headache). Seriousness (not severity) which is based on patient/event outcome or action criteria serves as guide for defining regulatory reporting obligations.</i></p>

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Side Effect	Any unintended effect of a health product occurring at doses normally used in man which is related to the pharmacological properties of the drug.
Signal	Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.
Spontaneous Report	An unsolicited communication by MAHs, healthcare professionals, or consumers that describes one or more adverse drug reactions in a patient who was given one or more medicinal products and that is not derived from a study or any organized data collection scheme.
Spontaneous Reporting	A system whereby case reports of adverse drug events are voluntarily submitted by health professionals and MAHs to the National Pharmacovigilance Centre.
Unexpected Adverse Reaction:	An adverse reaction, the nature or severity of which is not consistent with the applicable product information or characteristics of the drug.

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1. INTRODUCTION

Adverse reactions to medicines represent serious health problem. The incidence of adverse drug reactions (ADRs) has been reported to be about 16.2% with 6.5% of hospitalizations directly caused by ADRs. Adverse reactions to medicines have been known to result in hospitalization, permanent disabilities, and even deaths. A 12-year-old girl in Delta State died in 2005 following severe Toxic Epidermal Necrolysis (TEN) after being injected with metamizole (dipyrone). This led to the withdrawal of metamizole from the market in Nigeria (January 2006).

In addition to the impact of adverse drug reactions on human health, adverse drug reactions (ADRs) also have significant impact on healthcare costs. These costs are essentially hospital costs, particularly arising from increase in length of stay caused by an ADR.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of drugs or other possible drug related problems such as drug abuse and misuse, medication errors, and lack of efficacy.

The thalidomide tragedy which occurred in the late 1950's and the early 1960's, raised concerns regarding the safety of medicines and the potential dangers to public health associated with unexpected adverse reactions to medicines. Disasters associated with the use of other medicinal products had occurred in many countries after the thalidomide tragedy. In response, developed countries established reporting schemes to capture adverse reactions to medicines. The World Health Organization (WHO) following the World Health Assembly Resolution (WHA 20.51 of 1967) established an international drug monitoring scheme with 10 member countries in 1968 with focus on collection, collation, analysis and dissemination of relevant information.

By December 2019, the number of participating countries had risen to 136, with 30 associate member countries in the early stages of establishing their pharmacovigilance systems. There are thirty-one (31) African member countries. Nigeria became the 74th member of the WHO programme for international drug monitoring in September 2004.

2. SITUATIONAL ANALYSIS

In Nigeria, there is limited awareness about drug safety issues among consumers. Irrational use of medicines is highly prevalent and the safety profile of most medicines in the population is not well characterized. The thrust of pharmacovigilance activities in Nigeria is on creating awareness; and improving the detection and reporting of ADRs by healthcare providers, institutions and consumers. This strategy aims at early detection of new ADRs, detection of increase in frequency of known ADRs, identification of risk factors and possible mechanisms underlying ADRs as well as the estimation of quantitative aspects of benefit/risk analysis.

2.1 ADR Reports

The National Pharmacovigilance Centre has received Twenty-three thousand nine hundred and ninety-three (23,993) ADR reports since its inception in 2004. A total of Thirteen thousand six hundred and twenty-nine (13,629) ADR reports were received from January 2012 to December 2019. Causality assessment of over 80% of these reports have been conducted and uploaded into the WHO database (Vigiflow). The analysis of the ADRs on the basis of their sources is presented as Figure 1.

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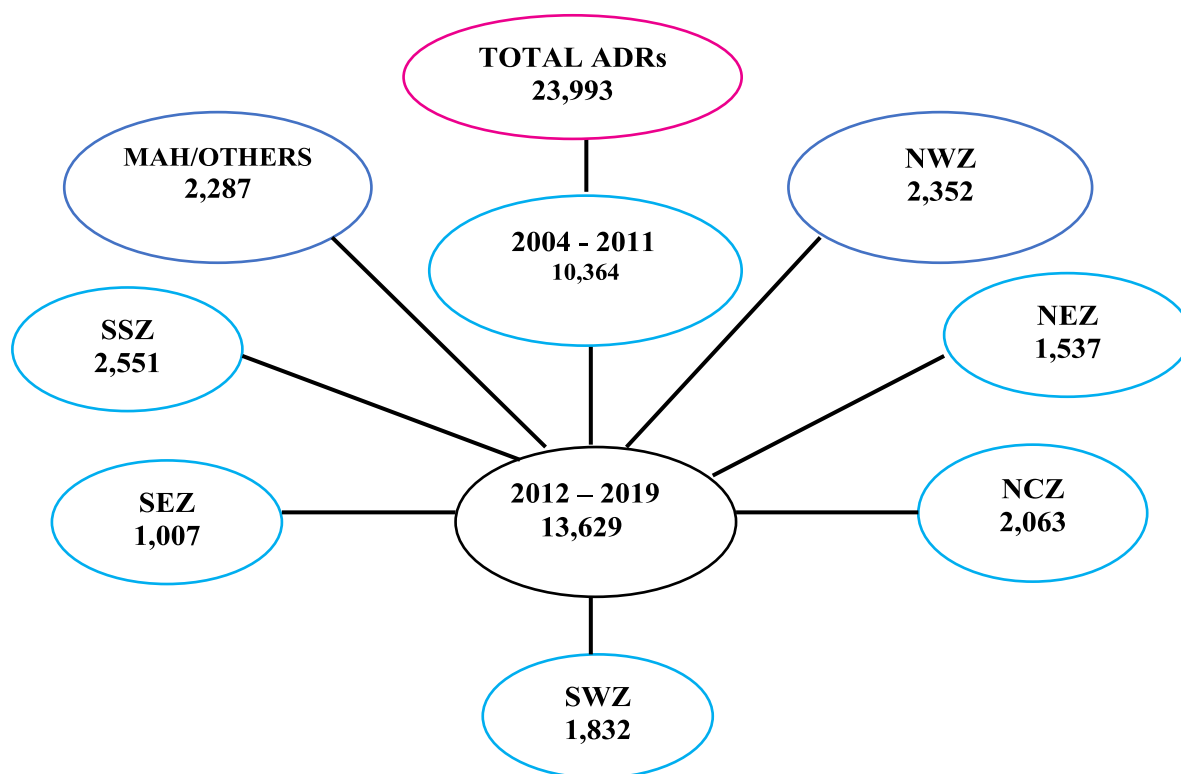


Figure 1: Segregation of ADRs by geo-political zones

2.2 Training of Healthcare Providers

NAFDAC in collaboration with National Malaria Elimination Program (NMEP) with the support of Global Fund (GF) conducted series of trainings on pharmacovigilance for Healthcare Providers from 2012-2019. The Agency in collaboration with the Society for Family Health (SFH) also trained Healthcare Providers on pharmacovigilance with support from Global Fund. Family Health International (FHI) 360 also collaborated with NAFDAC in 2019 to conduct two (2) training sessions of five (5) days each for Healthcare Providers. A total of 148 Healthcare Providers from different health facilities were trained. National Tuberculosis and Leprosy Control (NTBLC) Program have incorporated pharmacovigilance component in its Logistics Management Information System (LMIS) trainings for both junior and senior categories of Healthcare Providers. The Institute of Human Virology (IHVN), a research institute collaborated with NAFDAC to train 55 healthcare providers drawn from Malaria, TB and HIV treatment facilities using the Structured Pharmacovigilance Training Initiative (SPHARTI). The training adequately prepared the participants to effectively detect and report ADRs associated with medicines and other health commodities.

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2.3 Training of Marketing Authorization Holders

Furthermore, the Agency trained 50 Pharmacovigilance representatives of the Marketing Authorization Holders between 2013 & 2014. Several stakeholder sensitization workshops were also conducted. The Marketing Authorization Holders (MAHs) are key players in the Pharmacovigilance (PV) structure. It is mandatory for all MAHs to put in place a PV system which shall be managed by a Qualified Person Responsible for Pharmacovigilance (QPPV). The Agency developed Good Pharmacovigilance Practice Guidelines 2016 to assist MAHs to effectively comply with safety regulatory requirements. There is need for periodic training for QPPVs to empower them to comply with the safety regulatory requirements.

2.4 Survey on Quality of Medicines

The National Agency for Food and Drug Administration and Control in collaboration with United State Pharmacopoeia (USP) conducted 6 rounds of survey on the quality of anti-malarial medicines in Nigeria. The report of the Monitoring Quality of Medicines (MQM) Round 4 presented to stakeholders on 12th December, 2018 established that fourteen (14) samples of antimalarial medicines out of 741 (1.9%) failed quality tests. The report of MQM Round 5 presented on 13th March, 2019 established that twelve (12) samples of antimalarial medicines out of 907 (1.3%) failed quality tests. The failure rate of Round 4 is 1.9% while that of Round 5 is 1.3%. This shows a reduction in failure rate from 1.9% in 2018 to 1.3% in 2019.

2.5 Pharmacovigilance Africa Project (PAVIA)

The National Pharmacovigilance Centre is currently participating in Pharmacovigilance Africa project to strengthen pharmacovigilance systems to address the current challenges of PV in Nigeria. The project is funded by the European-Developing Countries Clinical Trials Platform, a funding mechanism under the EU's Horizon 2020 research program, which is aimed at strengthening pharmacovigilance in four African countries. The countries are Ethiopia, Nigeria, Eswatini and Tanzania. The activities undertaken in PAVIA project include the Nigeria country specific meeting at Abuja in 2018, the annual Consortium Meeting on Pharmacovigilance Africa Project held at Addis Ababa –Ethiopia from 1st-5th April 2019, and the development of Pharmacovigilance Road Map for NAFDAC, NPC in February 2020.

2.6 NAFDAC E-Reporting

NAFDAC deployed e-Reporting of ADRs in 2019 in addition to the conventional ADR Reporting Form to encourage reports from Health Care Providers (HCPs) and other members of the public. This was achieved through the support of WHO UMC. The form can be accessed from NAFDAC website <https://www.nafdac.gov.ng/>

2.7 Medicines Safety Application

The Med Safety App is a customized platform for reporting ADRs using smart phones. This application is used for reporting ADRs, track drug related safety information, build watchlist of medications for signal detection and management and to view the number of ADR reports received in WHO Vigibase.

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2.8 Capacity Building of NPC Staff

The Agency has invested in the capacity building of staff of the National Pharmacovigilance Centre. However, in ensuring sustained delivery on its mandate, the skills and competence of its staff requires continuous capacity improvement.

3. RATIONALE AND SCOPE OF THE POLICY

3.1 Rationale

Medicinal products pose safety challenges due to several factors which include the pharmacological properties of the product, the genetic disposition and culture of patient, treatment-seeking behaviour of patients (including extensive self-medication, abuse of psychotropic agents, unbridled access to prescription-only medicines, misuse of antibiotics and preference for injection), disease pattern and co-morbidities. Other factors include drug manufacturing processes, distribution and storage conditions, substandard and falsified medical products, and indiscriminate use of traditional, complementary and alternative medicines. Furthermore, pre-marketing information (i.e. information on adverse reactions available at the time a medicine is registered for use), is usually limited to data obtained from controlled clinical trials, pharmacokinetic and pharmacodynamics studies. Generally, only a few thousand patients (less than 5000) are studied pre-registration. As a result, only the early and most frequent adverse reactions are likely to be detected at the time of registration. Some adverse reactions may not be known at the time of registration and can only be detected after the medicine is in use by a larger population of patients. The need for post-marketing surveillance for adverse drug reactions is therefore evident.

The data derived from Nigeria will have greater clinical and educational value and assist the national regulatory authority to make evidence-based decisions. Information obtained in one country (e.g. the country of origin of the medicinal product) may not be relevant to other parts of the world where demographics, disease profiles, genetic makeup and medical practices differ. Pharmacovigilance helps ensure that patients obtain safe and effective medicines and other pharmaceutical products.

3.2 Scope of the Policy

This policy shall serve as a tool for providing an enabling environment for effective planning, implementation, monitoring and evaluation of the pharmacovigilance system by the three tiers of government in Nigeria, including partners, private health sectors, parastatals and not-for-profit private sectors (e.g. Non-Governmental Organizations and Faith-Based Organizations}). The policy addresses issues related to the systems and structures that are required for pre and post-authorization monitoring of safety, quality and efficacy of health products in Nigeria.

This monitoring system should lead to early detection of adverse reactions, interactions and other medicine-induced problems as well as the detection of previously unknown adverse reactions. It should facilitate the identification of suspected products of poor quality, cases of therapeutic ineffectiveness, medication errors and overall monitoring for safety and effectiveness after the registration of a medicine. The system should ensure the identification of predisposing risk factors and possible mechanisms underlying adverse reactions. The system should ensure feedback mechanism by communicating the changes in risk/benefit balance to stakeholders with a view to promoting rational and safe use of medicine.

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4. VISION AND MISSION STATEMENTS

4.1 Vision Statement

To establish and sustain an excellent pharmacovigilance system that ensures rational use of medicines in Nigeria.

4.2 Mission Statement

To set up an efficient surveillance mechanism for the early detection of adverse reactions to medicines and vaccines administered to human, and other medicine related problems, receive and process reports from a safety-conscious population of healthcare providers and consumers and take appropriate measures to prevent or minimize medicine-induced harm.

5. GUIDING PRINCIPLES

The policy shall be based on the following guiding principles:

- a) Good quality healthcare shall be assured through application of pharmacovigilance principles and practice at all levels in order to ensure patient safety.
- b) Patients' access to safe, quality and efficacious medicines.
- c) Healthcare professionals shall regard pharmacovigilance practice as a professional and ethical responsibility.
- d) It shall be mandatory for Marketing Authorization Holders, including all public health programmes to report ADRs.
- e) Integration of pharmacovigilance into the overall health system.
- f) Effective and sustained partnerships and collaboration with all stakeholders.
- g) Political and financial commitments at all levels are required for sustained safety monitoring of medicines and other medicine related issues.

6. PHARMACOVIGILANCE POLICY DECLARATION AND COMMITMENT

The National Pharmacovigilance Policy shall be guided by the following declarations and commitments:

- a) The Federal, State, and Local governments; and all other stakeholders in the public and private sectors of the health system hereby commit themselves to all actions necessary to achieve the goal and objectives of this policy.
- b) Governments at all levels and the private sector are committed to pharmacovigilance as a vital component of quality healthcare delivery and as such shall deploy resources to the performance of pharmacovigilance and related activities.
- c) All healthcare practitioners are required to detect and report ADRs and other medicine related problems; this is not only their professional and ethical responsibility but also contributes to better healthcare delivery and improves the quality of life.
- d) Development partners shall participate actively and collectively in promoting pharmacovigilance activities as well as resource mobilization.
- e) The pharmacovigilance system in Nigeria shall be coordinated by the National Pharmacovigilance Centre.

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7. GOAL AND OBJECTIVES OF THE NATIONAL PHARMACOVIGILANCE POLICY

7.1 Goal

The goal of the National Pharmacovigilance Policy is to provide a strategic framework for the entrenchment of pharmacovigilance in the healthcare system in Nigeria to ensure overall safety in the use of medicines and other related products.

7.2 Objectives

The objectives of the National Pharmacovigilance Policy are:

- a) To ensure effective and prompt reporting of ADRs and other medicine related problems in public healthcare institutions (primary, secondary and tertiary), public health programmes, pharmaceutical industry and the private sector including not-for-profit and faith-based organisations.
- b) To ensure the development and implementation of systems for pre and post-marketing surveillance activities including the monitoring of safety and effectiveness of all medicinal products.
- c) To promote patient safety through rational use of medicines by prescribers, dispensers and consumers.
- d) To entrench sound pharmacovigilance principles and practice in the Nigerian healthcare system by promoting its understanding and training of health professionals on the subject.
- e) To promote research and periodic analysis of ADRs data to generate signals
- f) To serve as a tool for advocacy to Government and other stakeholders in promoting pharmacovigilance.

8. PHARMACOVIGILANCE SYSTEM

The pharmacovigilance system shall involve the detection, reporting, collection, collation and analysis of ADRs; generation of signals and subsequent communication of changes in benefit/risk balance to stakeholders. It shall also involve measures to prevent or minimize the occurrence of adverse events of medicines and other medicine-related products. The entire chain of healthcare providers, Marketing Authorization Holders, healthcare professionals (pharmacists, doctors, nurses, medical laboratory scientists etc.), and consumers shall be involved in achieving the stated objectives. The National Pharmacovigilance Centre shall operate this system in collaboration with the WHO Collaborating Centre for International Drug Monitoring.

8.1 Scope of Pharmacovigilance

The scope of pharmacovigilance includes adverse drug reaction/events, medication errors, interaction of medicines, and abuse/misuse of medicines, substandard and falsified medicines, and lack of effectiveness. The products shall include but not limited to pharmaceuticals, nutraceuticals, herbal products, vaccines, antisera, X-ray contrast media, biologicals, blood products, and other consumable medical products.

8.2 The Strategic Thrust

The strategic thrust for the National Pharmacovigilance System shall consist of the following:

- a) Active pharmacovigilance.
- b) Passive pharmacovigilance (spontaneous reporting of ADRs).

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- c) Reporting of suspected cases of substandard and falsified medicines and other health products.
- d) Appropriate feedback mechanism on reported ADRs to healthcare providers, stakeholders and patients/consumers.
- e) Establishment of pharmacovigilance system in health facilities including public health programmes.
- f) Promote rational use of medicines.
- g) Integration of pharmacovigilance into the curricula of relevant undergraduate and postgraduate programmes.

8.2.1 Passive Pharmacovigilance (Spontaneous reporting of ADRs)

Spontaneous reporting of adverse events identified during the use of any health product is mandatory for the manufacturer or marketing authorization holder (MAH) of that product. Serious adverse events occurring during clinical trials conducted in Nigeria should also be mandatorily reported. Spontaneous reporting of adverse events suspected to be related to the use of a health product is an ethical responsibility for all healthcare providers. No claims of medical malpractice can be based solely on a submitted report.

8.2.2 Active Pharmacovigilance

Due to the inherent limitations of passive pharmacovigilance (spontaneous reporting), the MAH in collaboration with relevant stakeholders shall undertake active forms of pharmacovigilance when necessary. Active pharmacovigilance could be in the form of Cohort Event Monitoring, Targeted Spontaneous Reporting, Prescription Event Monitoring, Intensive Medicines Monitoring Programme, Record Linkages, and Pregnancy Registers; as may be necessary. NPC shall also put in place a process for the detection of signals of public health importance that require further evaluation through active surveillance.

8.2.3 Motivation of Reporters

Through the monitoring and reporting of drug therapy problems, health professionals get satisfaction for the fulfillment of a moral and professional obligation to patients by:

- a) Improving the quality of care offered to patients through reducing drug related problems leading to better treatment outcomes.
- b) Guaranteeing patient safety and enhancing patients' confidence in their healthcare services.
- c) Contributing to global knowledge on drug safety issues.
- d) Providing access to feedback information on drug related problems reported within the country and internationally.

The NPC shall, as a matter of priority, strive to solicit the needed cooperation, collaboration and support of healthcare providers and health professionals' associations through the following activities that will encourage or motivate the reporters:

- a) Organization of advocacy and sensitization workshops, seminars, conferences, consultative meetings for or with the relevant health practitioners, groups, organizations and associations in both the public and private sectors.

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- b) Prompt acknowledgement of reports and feedback of information (e.g. on similar ADRs) to the reporters to improve their practice.
- c) Effective and timely communication on medicine safety issues with the health professionals through newsletters, bulletins, publications in journals, NAFDAC website (www.nafdac.gov.ng), etc.

8.2.4 Confidentiality of Reports:

The NPC shall ensure confidentiality of all submitted Individual Case Safety Reports. Reports received by the Centre shall not be used against reporting health professional or the patient.

These reports represent suspected and non-validated reactions until they have been analyzed, evaluated and validated or confirmed or otherwise. Any injudicious or ill-advised use of non-validated data could have serious negative consequences for an otherwise valuable medicine.

The Centre shall ensure the following:

- a) The anonymity of patients and reporters.
- b) Dissemination of relevant information about a medicine (as outcome of ADR-reporting) to health professionals or the public shall be made by NAFDAC.

8.2.5 Reporting of Medication Errors

The generation of information on medication errors and its dissemination minimizes similar occurrence in clinical practice. To achieve this goal, the National Pharmacovigilance Centre shall ensure:

- a) That healthcare providers report any case of medication error to the zonal pharmacovigilance centre, NPC, nearest NAFDAC office nationwide.
- b) The maintenance of a database for medication errors.
- c) The carrying out of an appropriate root cause analysis on the reported medication errors.
- d) The dissemination of information on medication errors to prevent future occurrence.

8.2.6 Reporting of Suspected Cases of Substandard and Falsified Medical Products

Recognizing the menace of substandard and falsified medical products, pharmacovigilance shall be used as an additional vital tool towards checking the trend. Existing pharmacovigilance processes shall be strengthened for the purpose of detecting substandard and falsified medical products. Suspected lack of efficacy observed by healthcare providers and consumers of any medical products shall be reported to the NPC, zonal pharmacovigilance centre, or the nearest NAFDAC office nationwide.

8.2.7 Collaboration with Public Health Programmes

Active collaboration and open line of communication with Public Health Programmes shall be an important focus for pharmacovigilance. Therefore, under this policy, governments at all levels shall ensure that:

- a) Pharmacovigilance is a core component of all on-going Public Health Programmes.
- b) Health care practitioners involved in these programmes shall take necessary measures to detect and report all ADRs, medication errors and other medicine related

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problems resulting from the use of products (medicines, chemicals, etc.) in the programme.

- c) Public awareness is raised on any observed ADRs of such products.
- d) Those involved in Public Health Programmes (including the coordinators and senior staff), should receive basic PV training prior to commencement of the programme and this should be periodically reinforced.
- e) National and international donors supporting Public Health Programmes shall through their National Coordinators provide an annual report on the safety of the medicines used by the programmes. An immediate report (not exceeding 72 hours) of any serious ADR shall be made to NPC and other appropriate authorities.

9. REGULATORY FRAMEWORK FOR PHARMACOVIGILANCE

9.1 Mandatory or Voluntary Reporting

Healthcare providers should note that the reporting of ADRs and other medicine related problems is a professional and ethical responsibility which enhances the quality of healthcare given to the patient. The reporting of ADRs and other medicine related problems shall apply as follows:

9.1.1 Voluntary reporting

- a) It shall be an ethical and professional responsibility for health professionals and traditional herbal medicine practitioners or any other healthcare provider.
- b) It is advisable for consumers in their own interest to report ADRs.

9.1.2 Mandatory reporting

- a) It shall be mandatory for all MAHs to report to the National Pharmacovigilance Centre, any adverse reactions associated with their products that come to their notice from Nigeria or anywhere in the world.
- b). MAH shall appoint a qualified person responsible for pharmacovigilance (QPPV) who should have the responsibility of returning ADR reports to the NPC.

9.2 Sources of Reports

Sources of ADR and other medicine related problems shall include:

- a) Institutions: Healthcare institutions (including hospitals, clinics, medical centres, Primary Health Centres, community pharmacies), research institutes and Public Health Programmes operating in the public or private sectors.
- b) Traditional/herbal medicinal institutions/centres/associations/herbal clinics.
- c) Other units of NAFDAC such as the Drug Quality Control Laboratories, Drug Information Centres and the Consumer Affairs Division.
- d) Manufacturers or importers/distributors of products covered by this policy.
- e) Any other relevant sources.

9.3 Who is to Report?

- a) Medical doctors, pharmacists, nurses, medical laboratory scientists, and traditional herbal medicine practitioners or health care practitioners or healthcare providers working in the public, private and Non-Governmental sectors shall report adverse

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drug reactions and other medicine related problems to the zonal pharmacovigilance centre, NPC, or nearest NAFDAC office nationwide.

- b) Patients/consumers are strongly encouraged to report all ADRs and medicine related problems to their healthcare providers who will in turn forward the report to the NPC, zonal pharmacovigilance centre, or the nearest NAFDAC office nationwide.
- c) Importers/distributors, retailers, Marketing Authorization Holders of pharmaceutical products, traditional/herbal medicinal products and other medical products.

9.4 Reporting Tools

- a) Safety of medicines in Nigeria, guide for reporting ADRs for Pharmaceutical Marketing Authorization Holders in Nigeria.
- b) Safety of medicines in Nigeria, guide for reporting ADRs for Healthcare Professionals.
- c) NAFDAC ADR Reporting Form.
- d) NAFDAC e-Reporting Platform.
- e) Pharmacovigilance Rapid Alert System for Consumer Reporting (PRASCOR) text messaging system for reporting ADRs.
- f) Medicine Safety Mobile Application.

9.5 What is to be Reported

- a) All suspected reactions to all products covered under the scope of pharmacovigilance (Section 8.1).
- b) All other medicine related problems such as medication errors, lack of efficacy, etc. shall also be reported.
- c) All ADRs recorded during clinical trials and other studies.

9.6 How to Report

All suspected ADRs and medicine related problems shall be reported timely to NPC, zonal pharmacovigilance centre, or the nearest NAFDAC office nationwide using appropriate reporting tools.

10. HUMAN RESOURCES FOR PHARMACOVIGILANCE

To ensure the effective implementation of pharmacovigilance activities in the healthcare system, human resources should be deployed appropriately. These shall entail the engagement of staff to facilitate the various activities as follow:

- a) The National Pharmacovigilance Centre shall be headed by a qualified and experienced pharmacist in the field of pharmacovigilance, not below the rank of a Director. He or she shall be assisted by a team of appropriate health professionals and supporting technical and clerical staff.
- b) The Zonal Pharmacovigilance Centres situated in a tertiary health institution with high pharmacovigilance activity in each of the 6 geopolitical zones shall be operated by the institution with support from the NPC. The zonal pharmacovigilance

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coordinators shall liaise with other institutions within the zone to establish a viable structure for sustainable operation.

- c) Pharmacovigilance committees at tertiary and secondary health facilities shall be headed by a qualified and experienced healthcare professional. He or she shall be assisted by a team of appropriate health professionals, supporting technical and clerical staff that shall be staff of the hosting institutions.
- d) Pharmacovigilance activities at State level shall be coordinated by a competent pharmacist appointed by the Honourable Commissioner for Health.
- e) At the Local Government Level, the Head of Primary Health Care or any other competent official shall serve as focal person for pharmacovigilance.
- f) All personnel involved in pharmacovigilance shall undergo periodic training to update their knowledge and increase their capacity to deliver on the job.

11. PHARMACOVIGILANCE STRUCTURE AND FUNCTIONS: ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

11.1 Roles and Responsibilities of the National Pharmacovigilance Centre (NPC)

The National Pharmacovigilance Centre shall be a Directorate of NAFDAC and shall report directly to the Director-General/Chief Executive of NAFDAC. It shall be the operational hub of pharmacovigilance activities. The Centre shall have the following functions:

- a) Coordinate all pharmacovigilance activities in Nigeria.
- b) Sustain the established functional database on ADRs and other medicine related problems.
- c) Receive, document, follow-up, analyze and evaluate ICSRs for completeness, correctness, validity and signal detection. Forward same to Vigibase and WHO Uppsala Monitoring Centre.
- d) On a regular basis, acknowledge ICSRs, conduct causality assessment of ICSRs, ensure feed-back information, and disseminate information to health professionals and the public as appropriate through the use of adverse drug bulletins and newsletters, NAFDAC website (www.nafdac.gov.ng) and articles in journals.
- e) To conduct relevant research and coordinate signal detection and management activities.
- f) Periodically send out alert on medicine safety concerns.
- g) Coordinate the quarterly meetings of the National Drug Safety Advisory Committee (NDSAC) and consult NDSAC at other times as necessary.
- h) Support the establishment of active pharmacovigilance units in healthcare institutions in the country.
- i) Pay advocacy visits to decision makers including MDAs, opinion leaders and other stake holders.
- j). Create awareness and sensitize health policy makers, managers, professionals and healthcare providers on pharmacovigilance.
- k) Maintain multilateral relationship with other National Pharmacovigilance Centres and bilateral relationship with the Uppsala Monitoring Centre (UMC) as a

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participating member of the WHO Collaborating Centre for International Drug Monitoring.

- l) Coordinate the training and capacity building for pharmacovigilance.
- m) Engage a biostatistician to manage national pharmacovigilance database.
- n) Support the Zonal PV Centres to carry out their activities.
- o) Collaborate with relevant institutions and stakeholders to develop curriculum for training in the educational institutions and healthcare professionals in pharmacovigilance.
- p). Work in collaboration with the states to establish state pharmacovigilance units.

11.2 Roles and Responsibilities of Zonal Pharmacovigilance Centres.

The roles of the Zonal Pharmacovigilance Centre shall include:

- a) Distribution of ADR forms and collection of ICSRs from reporters within the zone for preliminary evaluation and submitting them promptly to the national centre and WHO Uppsala monitoring centre.
- b) Transmitting acknowledgements and feedback information to the reporters and disseminating information from the National Pharmacovigilance Centre to the health professionals and the public as appropriate.
- c) Monitoring progress of pharmacovigilance activities at all levels in the zone.
- d) Supporting training and capacity building on pharmacovigilance.
- e) Periodically give update to NPC on the activities in the zone.

11.3 Roles and Responsibilities of the State Pharmacovigilance Units

The roles of the State pharmacovigilance unit shall include:

- a) Ensure availability of nationally approved ADR form in the health facilities in the State.
- b) Distribution of ADR forms and collection of ICSRs from reporters within the state for preliminary evaluation and submitting promptly to the State NAFDAC office.
- c) Transmitting acknowledgements and feedback information to the reporters and disseminating information from the National Pharmacovigilance Centre to the health professionals and the public as appropriate.
- d) Provide adequate human and financial resources for pharmacovigilance activities in the State.
- e) Monitoring progress of pharmacovigilance activities at all levels in the State
- f) Supporting training and capacity building on pharmacovigilance in collaboration with NPC.
- g) Periodically give update to NPC on the activities in the State.

11.4 Functions of the National Drug Safety Advisory Committee.

The National Drug Safety Advisory Committee shall comprise experts in herbal medicines, medical and pharmaceutical experts/specialists in such fields as clinical medicine, pharmacy, pharmacology, toxicology, epidemiology, etc. Members of the Committee shall be appointed by the Minister of Health on the recommendation of the Director-General of NAFDAC for a renewable tenure of 2

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years. The Head of the National Pharmacovigilance Centre shall serve as the Secretary of the Committee.

The Committee shall have the following functions:

- a) Provide medical and scientific advice on current and emerging issues related to pharmacovigilance.
- b) Assess safety issues related to rational use of medicines.
- c) Validate assessments including causality assessment of ICSRs and possible medication errors.
- d) Recommend pharmaco-epidemiological studies or other research activities related to safety of medicines.
- e) Make appropriate recommendations to the Director-General of NAFDAC on any necessary regulatory actions and/or information dissemination related to medicine safety.
- f) Advice on specific issues related to pharmacovigilance.
- g) Signal review in collaboration with NPC.

11.5 Roles and Responsibilities of the Federal Ministry of Health

FMOH shall:

- a) Appoint members of NDSAC on recommendation of the Director-General of NAFDAC.
- b) Make available comprehensive policy guidance on pharmacovigilance activities.
- c) Provide adequate human and financial resources for pharmacovigilance activities.
- d) Provide political support for the establishment and sustenance of pharmacovigilance in healthcare institutions across the country.
- e) Monitor and evaluate the pharmacovigilance programmes for compliance with the objectives of the policy.
- f) Educate healthcare practitioners in public health programmes to recognize pharmacovigilance practice as professional and ethical responsibility.
- g) Coordinate the monitoring and evaluation of the implementation of the policy with the NPC, NAFDAC and independent PV experts.

11.6 Roles and Responsibilities of the State and Local Government

All States and Local Governments shall:

- a) Implement the national policy by ensuring that health facilities within their areas of jurisdiction are actively involved in ADR reporting.
- b) Establish PV units in healthcare facilities in their states in context of the National Pharmacovigilance System.
- c) Provide political and financial support needed for pharmacovigilance activities.
- d) Support the training of their personnel in pharmacovigilance activities.
- e) Shall carry out public awareness activities on pharmacovigilance.

11.7 Roles and Responsibilities of Marketing Authorization Holders

Manufacturers, importers and distributors of health products covered by this policy shall:

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- a) Make provision for PV which is integrated in the national pharmacovigilance system.
- b) Establish and sustain a pharmacovigilance system managed by a resident QPPV
- c) Report any serious ADR during clinical trials as required by extant guidelines.
- d) Conduct post-marketing surveillance on distributed products.
- e) Collaborate with the National Pharmacovigilance Centre on safety issues concerning the products distributed.
- f) Promptly forward PSURs to the National Pharmacovigilance Centre (biannually for two years for new products, annually for a further two years and thereafter every five years).
- g) Provide adequate information to consumers on the products distributed.
- h) Report any serious international incidence relating to their products.

11.8 Roles and Responsibilities of Healthcare Providers.

Healthcare providers include medical doctors, pharmacists, dentists, nurses, midwives, medical laboratory scientists, traditional medical/herbal practitioners and other relevant healthcare providers. They shall:

- a) Detect and report ADRs and other medicine related problems occurring in patients/consumers and intervene as appropriate.
- b) Educate patients on rational use of medicines.
- c) Educate and counsel patients on the need to report ADRs and other medicine related problems when they occur.
- d) Review and evaluate patients for ADRs during follow-up.
- e) Inform other healthcare providers on pharmacovigilance.

11.9 Roles and Responsibilities of Health Facilities.

All health facilities in which health products covered by this policy are used shall be involved in pharmacovigilance activities. Specific roles shall include the following:

- a) Setting up of pharmacovigilance units.
- b) Generation and sending of ADR reports to State pharmacovigilance unit.
- c) Educating and counseling of patients and clients about safety issues associated with health products.
- d) Training of personnel on pharmacovigilance in collaboration with State pharmacovigilance unit/NPC.
- e) Provision of high-level manpower and enabling environment for participation in pharmacovigilance activities.

11.10 Roles and Responsibilities of Consumers.

Consumers of health products shall report suspected ADRs to their healthcare provider and when not practicable, report to the NPC, zonal pharmacovigilance centre, or the nearest NAFDAC office.

12. FUNDING OF PHARMACOVIGILANCE SYSTEM

For effective and sustainable implementation of Pharmacovigilance System, adequate funding is required. Therefore:

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- a) Governments at all levels shall adequately fund pharmacovigilance activities through appropriate budgetary provisions.
- b) Funding of pharmacovigilance activities by governments shall not preclude assistance from donor agencies.
- c) Marketing Authorization Holders shall **NOT** directly fund pharmacovigilance centres.

13. TECHNICAL SUPPORT

To achieve the objectives of the National Pharmacovigilance Policy, technical support shall be expected from the following:

13.1 Health Training Institutions and Professional Regulatory Bodies

Shall:

- a) Ensure the incorporation of pharmacovigilance into undergraduate/postgraduate curricula for the teaching of medical, dental, pharmacy, medical laboratory science, nursing students as well as students of other health professions.
- b) Promote the development of pharmacovigilance as a discipline or specialty at the postgraduate level.
- c) Collaborate with NPC in investigating pharmacovigilance signals.

13.2 Research Institutes.

Shall collaborate with NPC in investigating pharmacovigilance signals.

13.3 Media

The print and electronic media shall collaborate with the NPC to communicate pharmacovigilance information and decisions. They shall report factually on the successes and challenges of the National pharmacovigilance system as guided by NPC/NAFDAC.

13.4 Non-Governmental Organizations

Shall:

- a) Ensure that ADR reports generated in any facility under their sphere of operation is promptly forwarded to the State pharmacovigilance unit.
- b) Support in educating caregivers and the public on pharmacovigilance.
- c) Participate in advocacy and capacity building for pharmacovigilance activities.
- d) Support funding of pharmacovigilance activities.

14. PHARMACOVIGILANCE INFORMATION SYSTEM

To sustain a successful pharmacovigilance system:

- a) A national data bank shall be operated by the National Pharmacovigilance Centre.
- b) Decisions obtained upon review of ADR reports and other safety documents by NAFDAC shall be communicated to MAHs to effect the appropriate changes (e.g. change in the label, withdrawal, etc.).
- c) The information from the data bank shall be shared as necessary with other national centres and the WHO global drug safety database (Vigibase).

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- d) The National Pharmacovigilance Centre shall communicate information deduced from reports submitted on ADRs and other medicine related problems to stakeholders through “Dear healthcare provider letters”, scientific bulletins, Newsletters, seminars, etc.
- e) Relevant information shall be incorporated into the National Health Management Information System (NHMIS).

15. PHARMACOVIGILANCE RESEARCH AND DEVELOPMENT

Research and Development play a major role in the growth of the discipline. The NPC should collaborate with agencies and research institutions with similar interest to identify and conduct research in PV activities. This Research shall be in line with the peculiarities of the Nigerian population as regards rational use of medicines.

In time frame not exceeding three years, research focus should address formative issues so as to obtain baseline data in various areas of pharmacovigilance and operational research geared towards enhancing the efficiency of the system. Attention should be paid to the peculiarities of the Nigerian population in the handling of medicines. Pharmacogenomic research to characterize genetic issues that may guide the use of medicines and limit the occurrence of adverse effects should also be addressed. In addition, pharmaco-economic research with interest in cost analysis of adverse drug reactions and management should be encouraged.

Areas to be addressed by the National Pharmacovigilance Centre to ensure the safe use of medicines and limit adverse consequences shall include:

- a) Operational research to facilitate ADR-reporting or other medicine related problems, feedback information, dissemination of information and communication to the health professionals and the public.
- b) Development of needed competences for evaluation, causality assessment and validation of case reports, including training of staff in methods of ADR-signal detection and causality assessment.
- c) Strengthening existing pharmacovigilance system to adequately focus on herbal medicines and related products.
- d) Use of appropriate pharmacovigilance methods to enable the early evaluation/detection of adverse events during large scale deployment of medicines in public health programmes.
- e) Building capacity and conducting targeted research in the area of pharmacoepidemiology, pharmacogenomics and drug metabolism as a fundamental tool in active pharmacovigilance.
- f) Large scale surveys to determine PV outcomes in Nigeria; to enable assessment of the WHO PV indicators at 5-year cycle.

16. FRAMEWORK FOR IMPLEMENTATION OF THE NATIONAL PHARMACOVIGILANCE POLICY

16.1 Introduction

Pharmacovigilance is an important discipline which should be integrated into the healthcare system to ensure the safe and rational use of medicines. A holistic approach is recommended in the

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implementation of the National Pharmacovigilance Policy to cover the entire scope of pharmacovigilance and the pharmaceutical products in all tiers of the healthcare system. To achieve the policy goal and objectives, all stakeholders in the healthcare system should be adequately engaged.

16.2 Stakeholders

Essentially the stakeholders identified include:

- a) Federal Ministry of Health and relevant parastatals
- b) National Agency for Food and Drug Administration and Control
- c) State and Local Governments
- d) Marketing Authorization Holders
- e) Public Health Programmes
- f) Healthcare facilities (private and public)
- g) Healthcare providers
- h) Media
- i) Non-Governmental and Faith-Based Organisations
- j) Consumers
- k) Ministry of Education
- l) Ministry of Finance
- m) Health Research Institutes
- n) National Orientation Agency
- o) MDAs
- p) National Universities Commission (NUC)
- q) Health Professionals Regulatory Bodies/Associations
- r) Others

16.3 Institutionalization of the Pharmacovigilance Policy Document

The policy document should, as a matter of priority in protecting the health of Nigerians, be put in the public domain by the *Minister of Health* with the requisite endorsement from Government. State and Local government apparatus should be engaged through the instrumentality of the *National Council of Health, Executive Council of the Federation*, a National dissemination and other fora to further promote the safe and rational use of medicines. Plans should be put in place to further empower the policy provisions by an appropriate legislation within the next five years. The Federal Ministry of Health should publicize the Pharmacovigilance Policy document and support the NPC in doing so to all stakeholders. The document shall be adequately disseminated to all relevant stakeholders within one year of its launch.

16.4 Pharmacovigilance Structures

The establishment of an effective and efficient pharmacovigilance structure is an important step. Pharmacovigilance/Post Marketing Surveillance Directorate was created for greater efficiency following approval for restructuring of NAFDAC by the Establishment Department of the office of the Head of the Civil Service of the Federation. The Directorate took effect on the 8th of November 2012. The Directorate (PV/PMS) hosts the National Pharmacovigilance Centre (NPC) and is headed by the Director; it has four (4) divisions, namely: Pharmacovigilance (PV), Post-Marketing

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Surveillance (PMS), Food & Drug Information Centre (FDIC) and Advocacy & Public Health Collaboration (APHC). The Lagos liaison office of the directorate and the six (6) Zonal Pharmacovigilance Centres situated in various Tertiary Healthcare Institutions within each geopolitical zone complement the work of the NPC. The ZPCs are responsible for creating awareness on pharmacovigilance among Healthcare Professionals within the various zones. This is done in collaboration with either the NAFDAC state offices or the NAFDAC zonal offices.

The six zonal Pharmacovigilance Centres (ZPCs):

- University of Maiduguri Teaching Hospital (UMTH): North-East Zone
- Ahmadu Bello University Teaching Hospital Zaria: North-West Zone
- University of Ilorin Teaching Hospital (UIITH): North-Central Zone
- Lagos University Teaching Hospital (LUTH): South-West Zone
- University of Benin Teaching Hospital (UBTH): South-South Zone
- Federal Medical Centre (FMC) Owerri: South-East Zone

All NAFDAC offices nationwide have Pharmacovigilance officers that coordinate the pharmacovigilance activities within each state/zone. Therefore, Health Care Professionals working in healthcare facilities may report Adverse Drug Reactions (ADRs) to the pharmacovigilance officer in NAFDAC Office in their states, State Pharmacovigilance Unit, ZPCs, or directly to the NPC.

Marketing Authorization Holders shall appoint QPPVs for the effective operations of PV Systems and reporting of ADRs to the NPC.

Public health programs shall have QPPVs for the program to establish an effective system for detecting and reporting ADRs associated with the medicines in used in their Programs to the NPC.

The National Drug Safety Advisory Committee is mandated to among other things evaluate safety, quality and efficacy issues on medical products and recommend interventions that will enhance professional and consumer awareness. Such evaluations shall be based on information provided to the committee, knowledge of drug literature, expertise and experience of members.

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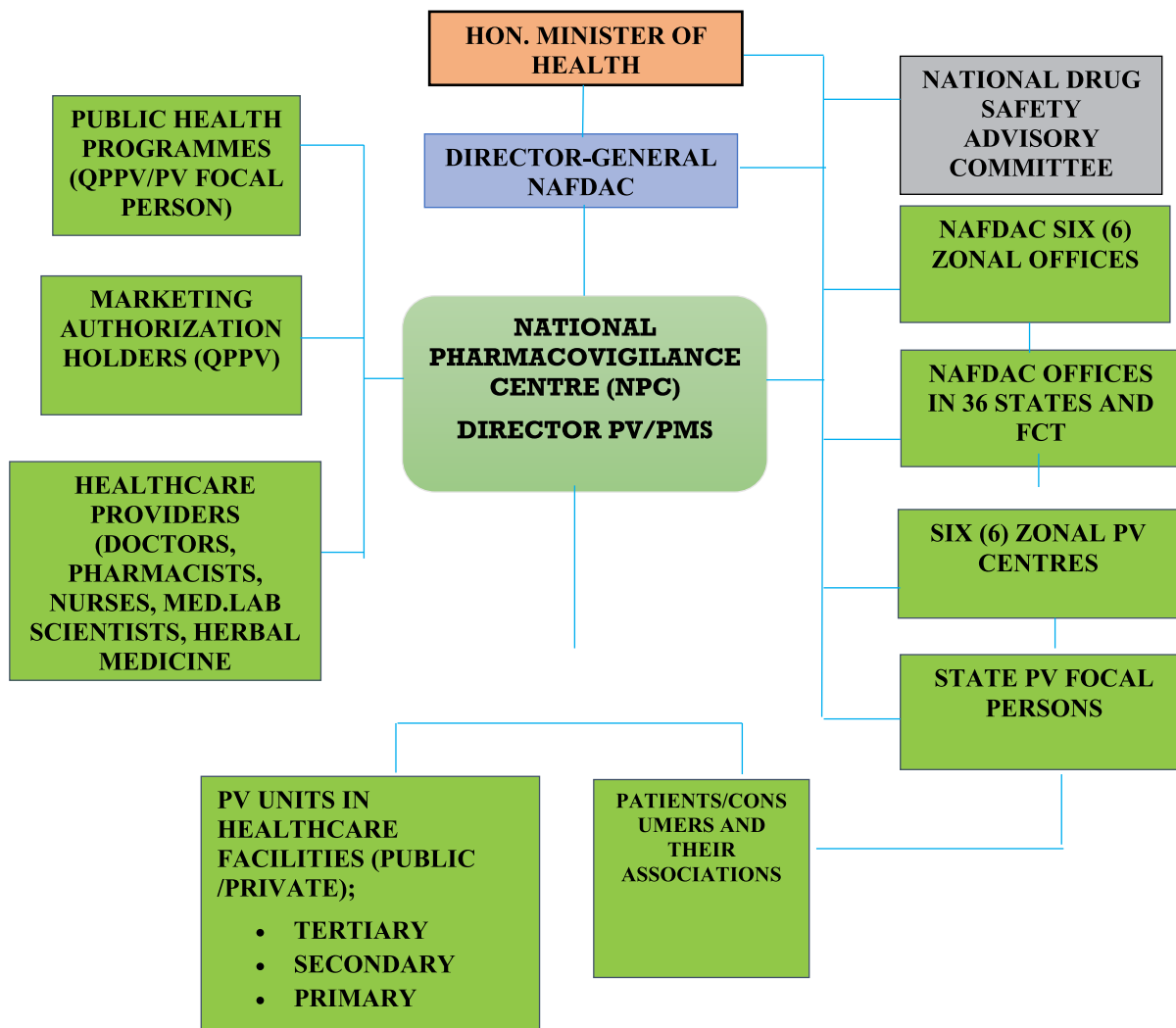


Figure 2: Pharmacovigilance Structure in Nigeria

16.5 Advocacy and Creation of Awareness

The NPC shall provide the expertise and carry out advocacy visits and awareness campaigns amongst the decision makers and the entire stakeholders. The focus on health providers and consumers should be geared at identification and forwarding of reports to the Pharmacovigilance centres and to sustain this, an effective feedback mechanism should be put in place. This would be achieved by workshops, seminars, lectures etc. and the development of relevant materials for information, education and communication. The media (print and electronic) should be engaged to reach the entire population of consumers with correct and appropriate information on

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Pharmacovigilance. The target of 100% sensitization for healthcare professionals and 80% for consumer/public should be achieved within three (3) years.

16.6 Human Resource Development

16.6.1 Capacity Building – Personnel and other Resources

The NPC shall provide a programme for training of personnel to support pharmacovigilance activities in the units/Centres and other health care facilities. Such personnel should be knowledgeable in the concept of pharmacovigilance and be able to provide services in a Pharmacovigilance Centre. Short term in-service programmes should be mounted to achieve a target of 100% coverage of health care facilities in 3 years.

16.6.2 Educational and Professional Training

The NPC shall sustain the advocacy for the development of curriculum and training in Pharmacovigilance for undergraduates, postgraduates and all health professionals. The implementation shall be achieved by advocacy to the National Universities Commission, Registrars of Professional regulatory bodies (MDCN, PCN, NMCN etc.), heads of healthcare and educational institutions and Directors of Pharmaceutical Services. Curriculum development and review to incorporate pharmacovigilance in training programs shall be a priority.

16.7 Marketing Authorization Holders

All suppliers of medical products must be committed fully to ensuring the safety of medicines. Manufacturers: local and multinational, importers, distributors, and retailers shall comply with extant guidelines. The NPC shall engage the MAHs to ensure submission of reports as well as PSURs. Each MAH shall establish an in-house unit with a QPPV to handle pharmacovigilance related matters. All MAHs shall accomplish this in 3years.

16.8 Herbal and other Traditional Remedies

There is extensive use of herbal remedies in Nigeria. The FMOH shall collaborate with NPC, NAFDAC on herbal related Pharmacovigilance.

To achieve this, stakeholders with expertise in herbal remedies, pharmacognosy, pharmaceutical chemistry, pharmacology and toxicology shall be supported to collaborate with relevant bodies/institutions. Effective engagement of greater than 80% of practitioners of traditional and herbal remedies should be achieved in five-year working in concert with the Council and other organs supervising their operations. In effect, a mechanism for capturing adverse events of medicines in this domain should be properly established.

16.9 Public Health Programmes (PHPs) and Donor Agencies

The Public Health Programmes play an important role in the healthcare system with coverage of many common diseases resulting in the use of a large volume of medicines. The commitment of these programmes to pharmacovigilance is of utmost importance considering the number of persons administered medicines with a potential for causing ADRs. The NPC shall liaise with the FMOH and PHPs to institute and streamline PV activities ensuring the *regular reporting* of medicine-related problems to its database.

PHPs and Donor Agencies should appreciate the potential impact of medicines donated and the need to monitor their safety profile and provide an annual report or more frequent updates in the event of serious ADRs.

16.10 Quality of Medicines

Existing machinery to rid the pharmaceutical system of substandard and falsified medicines should be strengthened by NAFDAC to reduce the prevalence of substandard/falsified medicines to less than 3% within five (5) years. To achieve this, extant laws and sanctions must be duly enforced. In addition, more Quality Control Laboratories should be built with at least one WHO certified laboratory strategically located for quality control of medicines.

The hazards inherent in illegal cross border transactions of medicines as well as other sharp practices should be addressed at workshops and other suitable fora where relevant stakeholders engaged, and relevant regulatory bodies strengthened to carry out their statutory mandates.

16.11 Funding

The need for independence, objectivity and integrity of the pharmacovigilance process and the input into decision making requires sound judgement in the sourcing of funds to eliminate conflict of interest. The NPC should be funded directly by Government with an annual budget line and other funding streams that will not compromise pharmacovigilance activities. Budgetary provisions should also be made at the State, Local government and health facility levels. Direct funding from suppliers of medicines is prohibited for the NPC and all other Centres engaged in Pharmacovigilance activities. However, funds may be received from non-governmental not-for-profit organization.

16.12 Monitoring and Evaluation

The implementation of the Pharmacovigilance Policy requires the setting up of pharmacovigilance structures, establishment of processes geared towards achieving defined outcomes and impacts by FMOH, NPC, NAFDAC and independent PV experts from tertiary institutions. To ensure this, a monitoring and evaluation mechanisms to measure performance and impact must be put in place. This can be achieved by a systematic use of WHO pharmacovigilance indicators. There should be selected key performance indicators (KPI) to measure the impact of pharmacovigilance activities yearly. The minimum target of 200 reports per million inhabitants per year should be realizable.

