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**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004**

**GOOD PHARMACOVIGILANCE PRACTICE
REGULATIONS, 2021**



ARRANGEMENT OF REGULATIONS

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S. I. No. 74 of 2021

**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004**

**GOOD PHARMACOVIGILANCE PRACTICE
REGULATIONS, 2021**

[7th Day of July, 2021]

Commence-
ment.

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap N1 LFN) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and all other powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Minister of Health makes the following Regulations—

1. These Regulations shall apply to pharmacovigilance activities with regards to medicinal products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

Scope of
application.

2. A medicinal product shall not be manufactured, imported, exported, advertised, sold, and distributed in Nigeria without pharmacovigilance system in place.

Prohibition.

3.—(1) A holder of Certificate of Registration shall—

(a) operate a pharmacovigilance system for the fulfilment of pharmacovigilance activities and regulatory responsibilities ;

(b) have the responsibility of ensuring that pharmacovigilance system is in place, adequately resourced, the effectiveness is continually improved upon and the roles, responsibilities and authorities are defined, communicated and implemented ;

(c) have permanent and continuously at its disposal, qualified person for Pharmacovigilance (QPPV), who shall be responsible for its pharmacovigilance system and resides in Nigeria ;

(d) have sufficient number of competent and qualified personnel to perform pharmacovigilance activities.

Pharmaco-
vigilance
system for
Certificate of
Registration
Holders.

(2) The pharmacovigilance system shall cover organisational structure, responsibilities, procedures, processes and resources as well as appropriate resource management, compliance management and record management.

(3) Where a holder of Certificate of Registration subcontracts any pharmacovigilance activities to another organisation, the arrangement shall be subject to a written contract and the holder of Certificate of Registration shall retain the responsibility for ensuring that an effective quality system is applied in relation to those activities.

B 3190

Good
Pharmaco-
vigilance
Practice.

4. A holder of Certificate of Registration shall comply with the following good pharmacovigilance practice requirements—

- (a) establish and implement a quality system ;
- (b) continuous monitoring of pharmacovigilance data ;
- (c) scientific evaluation of products risks ;
- (d) submission of accurate and verifiable data on serious and non-serious adverse reactions to the Agency ;
- (e) update of product information and communication of relevant safety information to healthcare professionals and patients ;
- (f) assign tasks and responsibility to a person involved in implementation of the pharmacovigilance system ;
- (g) continuous product monitoring and provision of new safety information to the Agency, healthcare professionals, patients and the public in relation to the safety of medicines ;
- (h) conduct and maintain continuous quality improvement by parties implementing the pharmacovigilance system ;
- (i) allocate resources and tasks to support proactive, risk-proportionate, continuous and integrated conduct of pharmacovigilance ;
- (j) seek evidence on the risk-benefit balance of products and all relevant aspects, which could impact on the risk-benefit balance and the use of a product, to be considered for decision-making ; and
- (k) any other requirements as may be prescribed by the Agency.

Training of
personnel
for
pharmaco-
vigilance.

5.—(1) A holder of Certificate of Registration shall ensure that there is initial and continuing training of employee in the area of operations and promoting good pharmacovigilance practices.

(2) Training effectiveness shall be verified and records of training shall be kept.

Facilities and
equipment
for
pharmaco-
vigilance.

6. Facilities and equipment for the conduct of pharmacovigilance shall be subject to checks, qualification and validation, in order to prove their suitability for the intended purpose.

Record
management
and
documenta-
tion.

7. A holder of Certificate of Registration shall—

- (a) maintain and control comprehensive, up-to-date, authorised, retrievable and traceable written instructions, records and reports of activities relating to pharmacovigilance operations ;
- (b) ensure that the documentation system is traceable, retrievable, secure and access restricted only to authorised personnel ; and

(c) manage records of adverse reactions so as to ensure that the right to privacy of person affected is fully and effectively guaranteed.

8.—(1) A holder of Certificate of Registration shall—

- (a) maintain Pharmacovigilance System Master File (PSMF) ; and
- (b) make a copy of the PSMF available upon request by the Agency.

(2) The PSMF shall be made available at the premises of a holder of Certificate of Registration.

(3) The holder of Certificate of Registration shall perform regular audits of the pharmacovigilance system, develop and implement appropriate corrective and preventive actions based on audit findings.

9.—(1) The Agency shall at any time it deems fit conduct a pharmacovigilance inspection to determine, whether the holder of Certificate of Registration is operating in compliance with the provisions of these Regulations and other statutory requirements.

(2) A holder of Certificate of Registration shall—

- (a) allow the Agency to access, copy, and verify any records or reports made with regard to pharmacovigilance activities ; and
- (b) carry out self-audit and the records shall be kept.

10.—(1) A holder of Certificate of Registration shall—

(a) establish pharmacovigilance plan for collection of data relevant to the safety profile of the medicinal product as well as identifying the risks from continuous evaluation of safety signals from within and outside Nigeria ;

(b) monitor the outcome of risk minimisation measures as contained in the risk management plan and take appropriate measures where necessary ;

(c) submit the Risk Management Plan (RMP) in a format as prescribed by the Agency for the following conditions—

(i) new pharmaceutical submissions that include a new active substance,

(ii) biologics and subsequent entry of biologics, which include biotechnology products, vaccines and fractionated blood products,

(iii) radiopharmaceutical drugs,

(iv) any drug that is coming back to the market that was previously withdrawn due to a serious safety issue,

(v) drugs with a significant change in indication,

(vi) medicinal products under the Public Health Programs,

(vii) marketed drug for which a serious safety issue has been identified,

Requirements
for
Pharmaco-
vigilance
System
Master File.

Pharmaco-
vigilance
inspection
and audit.

Risk
management
system.

(viii) a previously acceptable RMP which has undergone significant changes,

(ix) drugs new to a class for which a serious or potentially serious safety issue is identified,

(x) safety issues associated with a generic drug,

(xi) part of an ongoing review or other situations in order to make or support informed regulatory decision about the drug, and

(xii) for a marketed drug, if the Certificate of Registration holder identifies that there has been a significant change to what is known about the benefits, harms, or uncertainties associated with the drug, an RMP or an update to the RMP should be submitted to the Agency.

(2) The provisions of sub-regulations (1) (c) (xii) applies to cases where no previous RMP exists or when an update is needed to a previously acceptable RMP.

Adverse
reaction
reporting.

11. A holder of Certificate of Registration shall—

(a) take appropriate measures to collect and collate reports of suspected adverse reactions associated with its own medicinal products originating from unsolicited or solicited sources ;

(b) ensure the collection and recording of reports of suspected adverse reactions brought to its attention by health care professionals or consumers or occurring in the context of post-approval study are properly documented ;

(c) not refuse to consider reports of suspected adverse reactions received from patients and healthcare professionals ;

(d) establish procedures in order to obtain accurate and verifiable data for scientific evaluation of suspected adverse reaction reports of its own medicinal products ;

(e) maintain detailed records of suspected adverse reactions relating to its products occurring within and outside Nigeria ;

(f) maintain records of suspected serious adverse reactions, which have occurred within Nigeria and report same to the Agency not later than 72 hours from the receipt of information ;

(g) maintain records of suspected serious adverse reactions which have occurred outside Nigeria and report same to the Agency not later than 15 days from the receipt of information ;

(h) maintain records of suspected non-serious adverse reactions, which have occurred within Nigeria and report same to the Agency not later than 90 days following the receipt of information, while non-serious adverse reactions occurring outside Nigeria shall be contained or reported within Periodic Safety Update Report ;

(i) report to the Agency any action relating to their product safety that has been taken by a regulatory authority outside Nigeria, including the basis for such action not later than 3 working days of first knowledge ; and

(j) release necessary information including confidential information to the Agency on request.

12.—(1) A holder of Certificate of Registration shall submit to the Agency Periodic Safety Update Reports from within and outside Nigeria based on available data, including clinical trials data in an unauthorised indications and populations.

(2) The PSUR and PBRER reports shall be as prescribed by the Agency.

(3) PSUR and PBRER for new drug molecules in Nigeria shall be submitted within the first 10 years of registration, at least every 6 months for the first 2 years, annually for the 3 subsequent years, and every 5 years at the time of renewal of Licence.

(4) Where a new medicinal product is already being marketed elsewhere, existing PSUR and PBRER reports shall be submitted to the Agency not later than 30 days after submission of an application for registration in Nigeria.

(5) Where a medicinal product is listed, the holder of Certificate of Registration shall submit a PSUR and PBRER report every 6 months for the 2 year listing period, known as Provisional Registration.

13. A holder of Certificate of Registration shall—

(a) obtain approval of the Agency on any information intended for the health practitioner and public on pharmacovigilance concerns in relation to safety, quality and irrational use of a medicinal product ; and

(b) ensure that information to the public is presented objectively and is not misleading.

14.—(1) A holder of Certificate of Registration shall—

(a) conduct Post Authorisation Safety Studies (PASS) or Post Authorisation Efficacy Study (PAES), in pursuance to obligations by the Agency for the purpose of identifying, characterising or quantifying a safety hazard, confirming the safety profile of a medicinal product or measuring the effectiveness of risk management measures ;

(b) submit the Post Authorisation Safety Study (PASS)) or Post Authorisation Efficacy Study (PAES) protocol to the Agency for approval before conducting the study in Nigeria ;

(c) submit any substantial amendments to the protocol to the Agency for approval before implementation, after a PASS or PAES study has commenced ;

Periodic
Safety
Update
Report
(PSUR) or
Periodic
Benefit-Risk
Evaluation
Report
(PBRER).

Safety
communica-
tion.

Post
Authorization
Safety Study
(PASS) or
Post
Authorization
Efficacy
Study
(PAES).

(d) monitor the data generated from a PASS or PAES and consider its implications for the benefit-risk balance of the medicinal product concerned and any new information which might influence the evaluation of the benefit-risk balance of the medicinal product shall immediately be communicated to the Agency ;

(e) submit the final report of the PASS within six (6) months of the completion of data collection ; and

(f) not promote the use of the medicinal product during PASS or PAES.

(2) All Adverse Events observed during Post Authorization Safety and efficacy study should be submitted to Agency.

Signal
detection,
Identification
and
management.

15. A holder of Certificate of Registration shall put in place mechanisms for signal detection and investigation, including the following—

(a) have a system in place for detecting and investigating safety issues or signals that may arise at any stage in the life cycle of a medicinal product, including the clinical development, manufacturing or in the post-market setting in a timely manner ;

(b) formulate written procedure that adequately describes the way in which signal detection is to be performed ;

(c) roles and responsibilities of each person involved in the signal detection process shall be clearly defined and documented ;

(d) the source of information, analysis and the method used for signal detection shall be documented ;

(e) actions taken based on the outcome generated from the signal detection activities shall be documented ;

(f) data regarding changes about the risks and benefits of the drug shall be sent to the Agency and be documented ; and

(g) safety monitoring activities shall include a review of cumulative cases in order to allow for a comprehensive review of potential safety issues.

Reporting of
counterfeit,
unregistered,
substandard
and falsified
products.

16. A holder of Certificate of Registration shall report to the Agency any cosmetic or medicinal product suspected to be counterfeit, unregistered, substandard or falsified.

Regulatory
reliance.

17.—(1) The Agency shall adopt regulatory reliance mechanisms in making regulatory decisions, where the quality, safety and efficacy of medicinal products have been confirmed or where any of the phases of a clinical trial has been initiated or approved in a jurisdiction with a well-resourced regulatory Agent or where the NRA is a WHO listed Authority or where the product has been assessed by experts within a competent body.

(2) The Agency shall maintain its right and sustain its decision without compromising the quality, safety and efficacy of the medicinal products.

(3) Safety information or reports shall be evidence based and verifiable.

18.—(1) The National Pharmacovigilance Centre (NPC) shall—

Pharmaco-
vigilance
system.

(a) be domiciled in the Agency and coordinate all pharmacovigilance activities in Nigeria ;

(b) maintain all pharmacovigilance information and database ;

(c) maintain multilateral relationship with other National Pharmacovigilance Centres and bilateral relationship with the Uppsala Monitoring Centre (UMC) as a participating member of the WHO Collaborating Centre for International Drug Monitoring ; and

(d) carry out any other activity as the Agency may from time to time deem fit.

(2) The National Drug Safety Advisory Committee (NDSAC) shall—

(a) be established and comprise of medical, pharmaceutical experts and specialists in relevant fields ;

(b) have its members appointed by the Minister of Health on the recommendation of the Director-General of the Agency ;

(c) have the Head of the National Pharmacovigilance Centre as the Secretary of the Committee ;

(d) assess all safety issues on all regulatory products ;

(e) perform advisory and related activities to ensure the proper functioning of the NPC ; and

(f) the Zonal Pharmacovigilance Centre (ZPCs) shall coordinate all pharmacovigilance activities at the zonal level and transmit all such information gathered to the National Pharmacovigilance Centre.

19. The Agency may as part of control measures place on hold, recall, destroy, seal manufacturing line or facility, withdraw registration certificate of products not in compliance with these Regulations.

Non-
compliance
with GMP
requirements.

20.—(1) Any person who contravenes any of the provisions of these Regulations, commits an offence and shall be liable on conviction, in the case of—

Offences and
Penalties.

(a) an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding N800,000.00 or to both ; and

(b) a body corporate, to a fine not exceeding N5,000,000.00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals, every—

(a) director, manager, secretary or other similar officer of the body corporate ;

(b) partner or officer of the firm ;

(c) trustee of the body concerned ;

(d) person concerned in the management of the affairs of the association ;
or

(e) person who purports to act in a capacity referred to in paragraphs (a) to (d) of this sub-regulation,

is liable to be proceeded against and be punished for the offence in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture
after
conviction.

21. A person convicted of an offence under these Regulations shall forfeit to the Federal Government—

(a) asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence ; and

(b) the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

Enforcement
of these
Regulations.

22. The Agency shall be responsible for the enforcement of these Regulations.

Interpretation.

23. In these Regulations—

“Agency” means the National Agency for Food and Drug Administration and Control ;

“Adverse reaction” means a response to a medicinal product which is noxious and unintended ;

“Audit” means a systematic, independent and objective activity designed to add value and improve an organization's operation by helping the organisation to accomplish its objective by using systematic, disciplined approach to evaluate and improve the effectiveness of the system ;

“Benefit-risk ratio” means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks, that is, any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health ;

“Medicinal products” means any substance or combination of substances presented as having properties for treating or preventing disease in human beings ; or which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to

making a medical diagnosis and this includes pharmaceuticals, vaccines, biologicals, medical devices and cosmetics that contain active pharmaceutical ingredients (API) ;

“*NRA*” means National Regulatory Authority ;

“*Falsified product*” means medicinal products that deliberately or fraudulently misrepresent their identity, composition or source. Falsified product also means fake and counterfeit medicine ;

“*Person*” means an individual or corporate body ;

“*Periodic safety update report (PSUR)*” means format and content for providing an evaluation of the benefit-risk ratio of a medicinal product for submission by the holder of a Certificate of Registration at defined time during the post-authorization phase ;

“*Pharmacovigilance*” means Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem ;

“*Pharmacovigilance system*” means a system used by the holder of a Certificate of Registration, to fulfil the tasks and responsibilities and designed to monitor the safety of authorised medicinal products and detect any change to their benefit-risk ratio and in general ;

“*Pharmacovigilance System Master File (PSMF)*” means a detailed description of the pharmacovigilance system used by the holder of a Certificate of Registration with respect to one or more authorised medicinal products ;

“*Post-Authorization Safety Study (PASS)*” means any study relating to an authorised medicinal product conducted with the aim of identifying ; characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures. A post-authorization safety study may be an interventional clinical trial or may follow an observational, non-interventional study design ;

“*Proceeds*” means any property derived or obtained, directly or indirectly, through the commission of the offence ;

“*Risk Management System*” means a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those interventions ;

“*Risk management plan (RMP)*” means a detailed description of the risk management system and it shall identify or characterise the safety profile of the medicinal product(s) concerned, indicate how to characterise further the safety profile of the medicinal product(s) concerned, document

measures to prevent or minimise the risks associated with the medicinal product, including an assessment of the effectiveness of those interventions and document post-authorization obligations that have been imposed as a condition of the Certificate of Registration ;

“Serious adverse reaction” means an adverse reaction which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect ; and

“Substandard products” mean approved medicinal products that fail to meet either their quality standards or their specifications, or both such as manufacturing error, expired or degraded.

Citation.

24. These Regulations shall be cited as Good Pharmacovigilance Practice Regulations, 2021.

MADE at Abuja this 7th day of July, 2021

DR. OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health