NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

GOOD VIGILANCE PRACTICE REGULATIONS

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS (ending 21st November, 2019).
PLEASE SEND ALL INPUT TO REGULATORYAFFAIRS@NAFDAC.GOV.NG

ARRANGEMENT OF SECTIONS

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act Cap NI Laws of the Federation of Nigeria (LFN) 2004 and all 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 Honourable Minister of Health hereby makes the following Regulations:-

1. **Scope**

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

2. **Prohibition**

   No medicinal product shall be manufactured, imported, exported, advertised, sold, and distributed in Nigeria without a pharmacovigilance plan in place.

3. **Pharmacovigilance system for Certificate of Registration Holders**

   (1) The Certificate of Registration holder shall:

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

   (b) have the responsibility to ensure that the pharmacovigilance system is in place, is adequately resourced, the effectiveness continually improved and that roles, responsibilities, and authorities are defined, communicated and implemented.

   (c) have permanently and continuously at its disposal an appropriately Qualified Person for Pharmacovigilance (QPPV) responsible for its pharmacovigilance system, who shall reside in Nigeria.

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

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

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

4. **Good Pharmacovigilance Practice**

   (1) Certificate of Registration holder shall comply with the following Good Pharmacovigilance Practice requirements-

   (a) establish and implement a quality system to ensure;

   (b) continuous monitoring of pharmacovigilance data,

(c) scientific evaluation of products risks,
(d) submission of accurate and verifiable data on serious and nonserious 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 responsibilities to persons 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 all 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) or any other requirements as may be prescribed by the Agency.

5. **Training of personnel for pharmacovigilance**
(1) The Certificate of Registration holder shall ensure there is initial and continuing training of employee in the particular operations that the employee performs and in good pharmacovigilance practices.
(2) Training effectiveness shall be verified and records of training shall be kept.

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

7. **Record management and documentation**
(1) The Certificate of Registration holder shall;
(a) maintain and control comprehensive, up-to-date, appropriately authorized, retrievable and traceable written instructions, records and reports of all activities relating to pharmacovigilance operations.
(b) ensure that the documentation system is traceable, retrievable, secure and access restricted only to authorized personnel. Management of records of adverse reactions shall ensure that the right to privacy is fully and effectively guaranteed.

8. **Requirements for Pharmacovigilance System Master File**
(1) Certificate of Registration holders shall
(a) maintain Pharmacovigilance System Master File (PSMF).
(b) make a copy of the PSMF available upon request by the Agency.

(2) The PSMF shall be available at the Certificate of Registration holder's premises.
(3) The Certificate of Registration holder shall perform regular audits of the pharmacovigilance system and shall develop and implement appropriate corrective and preventive actions based on audit findings.

9. **Pharmacovigilance inspection and audit**
(1) The Agency shall at any time it deems fit conduct pharmacovigilance inspections to determine if the Certificate of Registration holder is operating in compliance with the provisions of these Regulations and other statutory requirements.
(2) Certificate of Registration holder shall
(a) permit the Agency to access, copy, and verify any records or reports made with regard to pharmcovigilance activities.
(b) carry out a self-audit and the records shall be kept.

10. **Risk management system**
(1) The Certificate of Registration holder 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 minimization measures which are contained in the risk management plan and take appropriate measures as necessary.

11. **Adverse reaction reporting**
(1) The Certificate of Registration holder shall
(a) take appropriate measures to collect and collate all reports of suspected adverse reactions associated with its own medicinal products originating from unsolicited or solicited sources.
(b) ensure the collection and recording of all reports of suspected adverse reactions brought to its attention by health care professionals or consumers or occurring in the context of post-approval study.
(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 the scientific evaluation of suspected adverse reaction reports of its own medicinal products.
(e) maintain detailed records of all suspected adverse reactions relating to its products occurring within and outside Nigeria.
(f) maintain records of all suspected adverse reactions which have occurred within and outside Nigeria and report same to the Agency not later than fifteen (15) calendar days following the receipt of information.
(g) maintain records of all suspected serious adverse reactions which have occurred within and outside Nigeria and report same to the Agency not later than seventy-two (72) hours following the receipt of information.

(h) 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 three (3) working days of first knowledge.
(i) release all necessary information including confidential information to the Agency on request.

12. **Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER)**
(1) The Certificate of Registration holder shall submit to the Agency Periodic Safety Update Reports from within and outside Nigeria based on all available data, including clinical trials data in unauthorized indications and populations.
(2) The PSUR/PBRER reports shall be as specified by the Agency.
(3) PSUR/PBRER for new drug molecules in Nigeria shall be submitted within the first ten (10) years of registration, at least every six (6) months for the first two (2) years, annually for the three (3) following years, and every five (5) years at the time of renewal of Licence.
(4) Where a new medicinal product is already being marketed elsewhere, existing PSUR/PBRER reports shall be submitted to the Agency not later than thirty (30) days after submission of documents requesting for registration in Nigeria.
(5) Where a medicinal product is Listed, the Certificate of Registration holder shall submit a PSUR/PBRER report every six (6) months for the two (2) year Listing period (Provisional Registration).

13. **Safety communication**
(1) The Certificate of Registration holder shall
(a) obtain approval from the Agency on any information intended for the health practitioner and public on pharmacovigilance concerns in relation to the safety, quality, and irrational use of a medicinal product.
(b) ensure that information to the public is presented objectively and is not misleading.

14. **Post Authorization Safety Study (PASS)/Post Authorization Efficacy Study (PAES)**
(1) The Certificate of Registration holder shall;
(a) conduct Post Authorization Safety Studies (PASS)/Post Authorization 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 Authorization Safety Study (PASS))/Post Authorization Efficacy Study (PAES) protocol to the Agency for approval before conducting the study.
(c) after a PASS/PAES study has commenced, shall submit any substantial amendments to the protocol to the Agency for approval before implementation.
(d) monitor the data generated from a PASS/PAES and consider its implications for the benefit-risk balance of the medicinal product concerned. Any new information which might influence the evaluation of the benefit-risk balance of the medicinal product shall be immediately communicated to the Agency

(e) submit the final report of the PASS within six (6) months of the completion of data collection.
(f) not promote the use of the medicinal product during PASS/PAES.

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

15. **Signal detection, Identification and management**

(1) Certificate of Registration holder shall have mechanisms in place 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 product, including the clinical development, manufacturing or in the post-market setting in a timely manner;
(b) have written procedures in place that adequately describes the way in which signal detection shall be performed;
(c) roles and responsibilities of each person involved in the signal detection process shall be clearly identified and documented;
(d) the source of the information, the 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 adequately;
(f) data regarding changes of what is known about the risks and benefits of the drug shall be sent to the Agency and shall 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.

16. **Vigilance of other products**

(1) A Certificate of Registration holder shall

(a) establish a cosmecovigilance system for monitoring of cosmetic products and inform the Agency accordingly.
(b) shall undertake corrective actions following assessment of the post marketing surveillance data and any other sources of safety data and inform the Agency accordingly.
(c) submit to the Agency annually, Cosmetics Product Safety Report (CPSR) of new products.
(d) make a report of all known serious and non-serious undesirable effects of the cosmetic product concerned, along with a causality assessment report, to the Agency within fifteen (15) days from the date of becoming aware of the serious undesirable effects.

17. **Reporting of counterfeit, unregistered, substandard and falsified products**

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

18. **Regulatory reliance**

(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 to its national decision without compromising the quality, safety and efficacy of the medicinal products.

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

19. **Pharmacovigilance system**

(1) **Roles of National Pharmacovigilance Centre**

(a) the National Pharmacovigilance Centre (NPC) shall be domiciled in the Agency and coordinate all pharmacovigilance activities in Nigeria.

(b) the NPC shall maintain all pharmacovigilance information and database.

(c) The NPC shall 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.

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

(2) **Roles of National Drug Safety Advisory Committee (NDSAC)**

(a) There shall be established a National Drug Safety Advisory Committee (NDSAC) made up of medical and pharmaceutical experts and specialists in relevant fields.

(b) The members of the Committee shall be appointed by the Minister of Health on the recommendation of the Director-General of NAFDAC.

(c) The Head of the National Pharmacovigilance Centre shall serve as the Secretary of the Committee.

(d) The Committee shall assess all safety issues on all regulatory products

(e) The Committee shall perform all advisory and related activities to ensure the proper functioning of the NPC.

(3) **Roles of Zonal Pharmacovigilance Centre (ZPCs)**

The ZPC shall coordinate all pharmacovigilance activities at the zonal level and transmit all such information to the National Pharmacovigilance Centre.

20. **Non-compliance with GMP requirements**

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 this Regulation.

21. **Penalty.**

(1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N50,000 or to both such imprisonment and fine; and

(b) a body corporate, to a fine not exceeding N100, 000.

(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; or

(b) partner or officer of the firm or

(c) trustee of the body concerned ;or

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

(e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

22. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-

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

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

(2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

23. **Interpretation**

In this Regulations, unless the context otherwise requires;

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 organization to accomplish its objective by using systematic, disciplined approach to evaluate and improve the effectiveness of the system.

Audit finding(s) means results of the evaluation of the collected audit evidence against audit criteria

Medicinal products means pharmaceuticals, vaccines, biologicals and medical devices.

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 marketing authorization holder at defined time points 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 marketing authorization holder to fulfill the tasks and responsibilities and designed to monitor the safety of authorised medicinal products and detect any change to their benefit-risk ratio. In general, a pharmacovigilance system is a system used by an organisation to fulfill its legal tasks and responsibilities in relation to pharmacovigilance and designed to monitor the safety of authorised medicinal products and detect any change to their benefit-risk ratio.

Pharmacovigilance system master file (PSMF) means a detailed description of the pharmacovigilance system used by the marketing authorization holder with respect to one or more authorised medicinal products. See also Pharmacovigilance system

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. See also Clinical trial, Non-interventional trial.

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 .To this end, it must 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 marketing authorization.

Risk minimisation measure means An intervention intended to prevent or reduce the probability of the occurrence of an adverse reaction associated with the exposure to a medicine, or to reduce its severity should it occur. These activities may consist of routine risk minimisation (e.g. product information) or additional risk minimization activities (e.g. healthcare professional or patient communications/educational materials).

Benefit-risk ratio means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks i.e. any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health. See also Risks related to use of a medicinal product.

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/birth defect.

24. **Citation**

These Regulations may be cited as Good Pharmacovigilance Regulations.

MADE at Abuja this …….day of ……..2019

Inuwa Abdulkadir Esq
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)