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

GOOD DISTRIBUTION PRACTICE FOR PHARMACEUTICAL PRODUCTS REGULATIONS 2009

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS (ending 20th September, 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 NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all the 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 Honorable Minister of Health hereby makes the following Regulations:-

1. **Scope**

   These regulations prescribe the minimum requirements for good distribution practice in the public and private sectors for finished pharmaceutical products and shall apply to all persons and companies involved in any aspect of the distribution of pharmaceutical products from the manufacturing site to the point of use. These include but are not limited to governments at all levels, public and private health and storage facilities, manufacturers of finished pharmaceutical products, importers, exporters, distributors, wholesalers, suppliers, retailers, freighters, forwarding agents and transporters.

2. **Prohibition**

   No person shall import, export, forward, distribute, wholesale, supply, retail or transport any pharmaceutical product except as provided for in these regulations. Failure to comply with the provisions set forth in these regulations in respect of distribution of pharmaceutical products shall render such product(s) substandard and such pharmaceutical products as well as the person who is responsible for the failure to comply shall be subject to regulatory action.

3. **Distribution authorization**

   (1) A distributor shall be an entity that is authorized by the competent authority as appropriate to perform the intended function and which can be held accountable for its activities.

   (2) The distributor shall:

      (a) Notify the competent authority as appropriate of the name, address, qualification and experience of the person who will carry out the functions of responsible person

      (b) Notify the competent authority as appropriate of any change to the responsible person and;

      (c) Not permit any person to act as responsible person other than the person named in authorization as the responsible person

      (d) Notify the competent authority as appropriate of any change or discontinuance of use of premises to which the authorization relates or premises which have been approved from time to time by the competent authority

   (3) A distributor or transferor shall not receive, store, warehouse, handle, hold, offer, market, display or transport any pharmaceutical product unless there is a valid marketing authorization issued by the Agency for the product.

(4) A distributor shall obtain supplies of pharmaceutical products only from persons who are themselves in possession of appropriate distribution authorization issued by the competent authority.

(5) A distributor shall supply pharmaceutical products only to persons who are themselves in possession of appropriate distribution authorization.

4. **Inspection**

The Agency shall enter and inspect the premises and delivery vehicles of distributors, and to audit their records and written operating procedures to the extent authorized by law.

5. **Organization and Personnel**

(1) There shall be an adequate organizational structure that clearly defines the responsibility, authority, interrelationships and qualification of all personnel.

(2) There shall be a suitably qualified management representative appointed in each distribution point, who shall have defined authority and responsibility for ensuring that a quality system is implemented and maintained.

(3) Each person engaged in the distribution of pharmaceutical products shall have education, knowledge, training, and experience, or any combination thereof, to enable that person to perform the assigned functions.

(4) There shall be an adequate number of qualified personnel to perform and supervise the distribution of pharmaceutical products.

(5) Personnel engaged in the distribution of pharmaceutical products shall wear clothing appropriate for the duties they perform.

6. **Location, design and construction of building facilities**

(1) All locations where pharmaceutical products are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported to or from shall:

(a) Be adequately located, constructed, and of suitable size to facilitate cleaning, maintenance, and proper operation as appropriate and as otherwise prescribed by the competent authority.

(b) Have defined areas of adequate size for receipt of products, quarantine of products, prescription medicines, cold storage, narcotics and other dangerous pharmaceutical products, medical gases, rejected products, expired products, quality control (where applicable), highly active and radioactive materials and hazardous products presenting special risks such as fire or explosion, which shall be subject to appropriate additional safety and security measures,

(c) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions

(d) Be maintained in a clean and orderly condition

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind

7. **Documentation/Record keeping**

(1) Distributors of pharmaceutical products shall establish and maintain inventories and records of

all transactions regarding the receipt and distribution or other disposition of pharmaceutical products. These records shall include the following information:

(a) The source(s) of the pharmaceutical products, including the name(s) and principal address of all distributor(s) or transferor(s), and the address(es) of the location(s) from which the pharmaceutical products were shipped;

(b) The identity and quantity of the pharmaceutical products received and distributed or disposed of

(c) The dates and time of receipt and distribution or other disposition of the medicines.

(d) The name, address (postal and location) and professional license number of the business, licensed by the regulatory authority as appropriate and/or the licensed practitioner.

(2) Inventories, records and logs shall be made available for inspection and photocopying by the Agency and shall be retained for a period of 5 years.

(3) Records shall:

(a) Be kept at the inspection site or immediately retrievable by computer or other electronic means and made readily available at the time of inspection or

(b) If kept at a central location and not electronically retrievable at the inspection site, be made available for inspection within 48 hours of a request by the Agency.

(c) The distributor shall obtain a written authorization from the Agency, in order to store the required records outside the inspection site. The distributor shall provide the Agency, in writing, the name and address of the custodian (postal and location) and the telephone number.

(4) All facilities shall have adequate backup systems to protect against the inadvertent loss or deliberate destruction of data.

(5) The facility shall provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of pharmaceutical products.

8. **Written policies and procedure**

(1) Distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of pharmaceutical products, including policies and procedures for identifying, recording, and reporting losses or thefts and to ensure that the distributor prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. Such crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

(2) There shall be written policies and procedures for managing and correcting all errors or inaccuracies in inventories.

(3) There shall be written policies and procedures to ensure that any expired pharmaceutical product shall be segregated from other stock and shall be returned to the source of supply or otherwise destroyed, and this shall be documented.

(4) There shall be a procedure whereby the oldest approved stock (First Expiry/First Out (FEFO) of a pharmaceutical product is distributed first. The procedure may permit deviation from this process provided the deviation is temporary and appropriate for the distribution

9. **Storage condition**

(1) Pharmaceutical products shall be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of such pharmaceutical products or with requirements in the current edition of a recognized compendium.

(2) Where there is no specific storage requirement for a pharmaceutical product, it may be held at controlled room temperature, as defined in the current edition of a recognized compendium to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Appropriate temperature and humidity recording equipment, or logs shall be utilized to document proper storage of pharmaceutical products and the record shall be kept as prescribed in section 7.

10. **Examination of shipments**

(1) Each shipment shall be visually examined for identity to determine if it is contaminated, prohibited, counterfeit, suspected of being counterfeit, damaged, and are otherwise unfit for distribution.

(2) Appropriate measures shall be put in place to check that shipments have not been held under improper transit conditions.

(3) A distributor shall review records for accuracy, completeness, and the integrity of the pharmaceutical product considering the total facts and circumstances surrounding the transactions and the distributors involved.

11. **Returned, damaged and expired pharmaceutical products**

(1) A distributor shall maintain and follow a written procedure to ensure the proper handling and disposal of returned goods.

(2) When conditions under which a pharmaceutical product has been returned cast doubt on the safety, identity, strength, quality, or purity of the pharmaceutical product, then the product shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the pharmaceutical product meets appropriate standards of safety, identity, strength, quality, and purity. In investigating the conditions which cast doubt on the safety, identity, strength, quality, or purity of the pharmaceutical product, the distributor shall consider, among other things, the conditions under which the product has been held, stored, or shipped before or during its return and the condition of the product and its container, carton, or labeling, as a result of storage or shipping.

12. **Vehicles and equipment**

(1) Vehicles and equipment used in the distribution of pharmaceutical products shall be suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind.

(2) All monitoring equipment shall be qualified and/or calibrated as required.

13. **Shipment containers and container labelling**

(1) All pharmaceutical products shall be stored and distributed in shipment containers which do not have an adverse effect on the quality and safety of the products, and which offer adequate protection from external influences, including contamination.

(2) Only internationally and/or nationally accepted abbreviations, names or codes shall be used in the labelling of containers.

14. **Recalls**

(1) A distributor shall maintain and follow written policy for handling recalls and withdrawals of products.

(2) The policy shall cover all recalls and withdrawals of products due to:

(a) Any voluntary action on the part of the manufacturer;

(b) A directive from the Agency

(c) Replacement of existing merchandise with an improved product or new package design

15. **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.

16. **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.

17. **Interpretation**

In these Regulations, unless the context otherwise requires:-

"Agency" means National Agency for Food and Drug Administration and Control

"Batch (or lot)" means a defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogeneous.

"Batch number (or lot number)" means a distinctive combination of numbers and/or letters which uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis.

"Competent authorities" means Pharmacists' Council of Nigeria, National Agency for Food and Drugs Administration and Control

"Container" means the material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and tertiary containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary packaging enclose the primary packaging and tertiary packaging material means outer carton in which multiples of saleable units are packed. Secondary and tertiary containers are not intended to be in direct contact with the product.

"Contamination" means the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to pharmaceutical product during handling, sampling, repackaging, storage or transport.

"Controlled substances" means medicines that contain substances that are internationally or nationally controlled.

"Counterfeit medicines" means medicines which are deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients".

"Cross-contamination" means Contamination of a raw material or finished pharmaceutical product with another material or product.

"Distribution" means the distribution and movement of pharmaceutical products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health

establishments. Distribution involves receiving, storing, warehousing, handling, holding, offering, marketing, displaying, distributing, forwarding and transporting.

"Distributor" means a person or organization who receives, stores, warehouses, handles, holds, offers, markets or displays pharmaceutical products. A distributor shall be an entity that is appropriately authorized by the competent authority to perform the intended function as prescribed in these regulations, and which can be held accountable for its activities. These include but not limited to governments at all levels, public and private health and storage facilities, manufacturers of finished products, importers, exporters, distributors, wholesalers, suppliers, retailers.

"Expiry date" means the date given on the individual container (usually on the label) of a product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.

"Health facility" means the whole or part of a public or private facility, building or place, whether operated for profit or not, that is operated or designed to provide health care services including the supply of pharmaceutical products to the end user.

"Labelling" means the process of identifying a pharmaceutical product including the following information, as appropriate: name; active ingredient(s), type and amount/quantity; batch number, expiry date; NAFDAC registration number; special storage conditions or handling precautions; directions for use, warnings and precautions; names and address of the manufacturer and/or the supplier.

"Manufacture" means all operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls.

"Narcotics" means drugs listed in the 1961 and 1988 UN convention on Narcotics.

"Packaging material" means any material, including printed material, employed in the packaging of a pharmaceutical product, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary if in direct contact with the product or secondary if not in direct contact with the product.

"Person" means an individual, partnership, corporation, association, government agency, or organizational unit thereof, and any other legal entity.

"Pharmaceutical product" means any substance or combination of substances presented or administered to human beings or animals for treating or preventing disease with a view to making a medical diagnosis or to restoring, correcting, or modifying physiological functions in human beings or in animals. These include but not limited to medicines, vaccines, biologicals, herbal medicines, medical devices, disinfectants and diagnostics.

"Product recall" means product recall is a process for withdrawing or removing a pharmaceutical product from the distribution chain because of defects in the product or complaints of serious adverse reactions to the product. The recall might be initiated by the manufacturer, importer, distributor or a responsible authority.

"Production" means all operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and re-labelling, to completion of the finished product.

"Quality control" means quality control covers all measures taken, including the sampling, testing and analytical clearance, to ensure that finished pharmaceutical products and packaging materials conform to established specifications for identity, strength, purity and other characteristics.

"Quality system" means an appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

"Quarantine" means the status of pharmaceutical products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

"Re-labelling" means the process of putting a new label on the product (see also *labelling*).

"Repackaging" means the action of changing the packaging of the pharmaceutical product.

"Sampling" means Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose, for example acceptance of consignments or batch release.

"Shelf-life" means the period of time during which a pharmaceutical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each batch.

"Standard operating procedure (SOP)" means an authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (for example equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection).

"Storage" means the storing of pharmaceutical products up to the point of use.

"Supplier" means a person or company providing pharmaceutical products on request. Suppliers include agents, distributors, manufacturers or retailers. Suppliers shall be authorized by a competent authority.

"Transferor(s)" means freighter(s), forwarding agent(s) and transporter(s).

"Transit" means the period during which pharmaceutical products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination.

"Validation" means action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results.

"Vehicle" means trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey pharmaceutical products.

"Regulatory action" means Includes but not limited to product hold, recall, forfeiture, or destruction; sealing of distribution facility; withdrawal of registration certificate etc.

"First Expiry/First Out (FEFO)" means A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used; earliest expiry/first out (EEFO) has a similar meaning.

"Registration certificate (Product/premises license, marketing authorization,)" means a legal document issued by the competent authority that authorizes a person to engage as a distributor of pharmaceutical products.

18. **Citation**

These Regulations may be cited as Good Distribution Practice Regulations 2019.

MADE at Abuja this …….day of ……..2019

……..

Inuwa Abdulkadir esq.

Chairman Governing Council

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