Extraordinary

Federal Republic of Nigeria
Official Gazette

No. 147 **Lagos - 6th September, 2021** **Vol. 108**

Government Notice No. 173

The following is published as Supplement to this *Gazette* :

Printed and Published by The Federal Government Printer, Lagos, Nigeria
FGP 162/092021/150

Annual Subscription from 1st January, 2021 is Local : ₦45,000.00 Overseas : ₦60,500.00 [Surface Mail] ₦75,000.00 [Second Class Air Mail]. Present issue ₦2,500 per copy. Subscribers who wish to obtain *Gazette* after 1st January should apply to the Federal Government Printer, Lagos for amended Subscriptions.

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

GOOD DISTRIBUTION PRACTICE FOR PHARMACEUTICAL PRODUCTS REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 72 of 2021

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

GOOD DISTRIBUTION PRACTICE FOR PHARMACEUTICAL PRODUCTS REGULATIONS, 2021

[*7th Day of July*, 2021] Commencement.

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 preseribe the minimum requirements for good distribution practice in the public and private sectors for finished pharmaceutical products and shall apply to— Scope of application.

(*a*) a person involved in any aspect of the distribution of pharmaceutical products from the manufacturing site to the point of use ; and

(*b*) governments at all levels, public and private health institutions and storage facilities, manufacturers of finished pharmaceutical products, importers, exporters, distributors, wholesalers, suppliers, retailers, freighters, forwarding agents and transporters.

2. A person shall not import, export, forward, distribute, wholesale, supply, retail or transport any pharmaceutical product except in accordance with the provisions of these Regulations. Prohibition.

3.—(1) A distributor shall— Distribution authorisation.

(*a*) be an entity that is authorised by the Pharmacists Council of Nigeria (PCN) to perform extended functions and shall be held accountable for its activities ;

(*b*) obtain supply of pharmaceutical products only from persons who are themselves in possession of appropriate distribution authorisation issued by the PCN ; and

(*c*) supply pharmaceutical products only to a person in possession of appropriate distribution authorisation.

(2) 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 authorisation issued by the Agency for the product.

4. The Agency shall enter and inspect the premises and delivery vehicles of distributors and audit their records and written operating procedures to the extent as authorised by law. Inspection.

Organisation and personnel.

5. For the purposes of maintaining drug quality—

(*a*) there shall be an adequate organizational structure that clearly defines the responsibility, authority, inter relationships and qualification of all personnel ;

(*b*) there shall be a suitably qualified management representative appointed at each distribution point, who shall have defined authority and responsibility for ensuring that a quality system is implemented and maintained ;

(*c*) person engaged in the distribution of pharmaceutical products shall have necessary education, training and experience, or any combination thereof, to enable that person to perform the assigned functions ;

(*d*) there shall be an adequate number of qualified personnel to perform and supervise the distribution of pharmaceutical products ; and

(*e*) personnel engaged in the distribution of pharmaceutical products shall wear clothing appropriate for the duties they perform.

Location, design and construction of building facilities.

6. All locations where pharmaceutical products are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported, shall—

(*a*) be located, constructed and of suitable size to facilitate cleaning, maintenance and proper operation as appropriate ;

(*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 ; and

(*d*) be maintained in clean and orderly condition, free from infestation by insects, rodents, birds, or vermin of any kind.

Documentation or Record keeping.

7.—(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.

(2) The records referred to in sub-regulation (1) of this regulation shall contain information, including—

(*a*) the source of the pharmaceutical products, the name and principal address of all distributor or transfer or and the address of the location 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 ; and

(*d*) the name, address (postal and location) and professional license number of the business, licensed by the regulatory authority as appropriateor the licensed practitioner.

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

(4) Records shall—

(*a*) be kept at the inspection site or retrievable with computer or other electronic means and made readily available at the time of inspection ; or

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

(5) The distributor shall obtain a written authorisation from the Agency, in order to store the required records outside the inspection site and provide the Agency, in writing, the name, address and all the necessary contact of the custodian.

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

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

8.—(1) A distributor shall— Written policies and procedure.

(*a*) establish, maintain and adhere to policies and procedures to be followed for the receipt of complaints ;

(*b*) provide security, storage, inventory and distribution of pharmaceutical products,

(*c*) establish policy and procedure for identifying, recording, and reporting losses or thefts at the facility ; and

(*d*) ensure protection against and handling of crisis situations that may constitute security threat to the operation of the facility.

(2) The crises referred to in sub-regulation (1) of this regulation include fire, flood, or other natural disasters and situations of local, state, or national emergency.

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

(4) 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.

(5) There shall be a procedure whereby the oldest approved stock (First Expiry First Out) (FEFO) of a pharmaceutical product is distributed first, which may also permit deviation from this process provided that the deviation is temporary and appropriate for the distribution

Storage condition.

9.—(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 recognised compendium.

(2) Where there is no specific storage requirement for a pharmaceutical product, it may be held at a 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 conditions of temperature, humidity, and light recording equipment, or logs shall be utilized to document proper storage of pharmaceutical products and the record shall be kept as prescribed in Regulation 7 of these Regulations.

Examination of shipments.

10.—(1) A shipment shall be visually examined to determine the identity, damage, prohibition or its status, whether suspected of being contaminated, counterfeited or 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.

Returned, damaged and expired pharmaceutical products.

11.—(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, 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.

(3) 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.

Vehicles and equipment.

12.—(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 or calibrated as required.

Shipment containers and container labelling.

13.—(1) A pharmaceutical product 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 or nationally accepted abbreviations, names or codes shall be used in the labelling of containers.

Recalls.

14.—(1) All recall activity shall be in accordance with NAFDAC Recall, Handling, Disposal and Falsified Medicinal Products Regulations.

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

(3) 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 ; and

(*c*) replacement of existing merchandise with an improved product or new package design.

Offences and Penalties.

15.—(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—

(*a*) an individual, to imprisonment for a term not exceeding 1year or to a fine not exceeding ₦800,000.00 or to both ; and

(*b*) a body corporate, to a fine not exceeding ₦5,000,000.00.

(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.

16. 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.

17. The Agency is exclusively responsible for the enforcement of these Regulations.

Interpretation.

18. In these Regulations—

"*Address*" means a place where the business of the manufacturer, sale, distribution, storage and display of drug and related products are carried out, which includes the house number, plot number, street name town or city, state and country ;

"*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 or letters which uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis ;

"*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 ;

"*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, or to an intermediate point by means of various

transport methods, via various storage or health establishments and distribution involves receiving, storing, warehousing, handling, holding, offering, marketing, displaying, distributing, forwarding and transporting ;

"*Distributor*" means a person or organisation who receives, stores, warehouses, handles, holds, offers, markets or displays pharmaceutical products and is appropriately authorised by the Pharmacists Council of Nigeria (PCN) to perform its duties as prescribed in these Regulations and shall be held accountable for its activities, including 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, which is expected to remain within specifications, if stored correctly and is established for each batch by adding the shelf-life to the date of manufacture ;

"*Finished product*" means a product that has undergone all stages of production, including packaging in its final container and labelling ;

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

"*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 or 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 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 ;

"*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, which include but not limited to medicines, vaccines, biologicals, herbal medicines, medical devices, disinfectants and diagnostics ;

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

"*Product recall*" means 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, and a recall may 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 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 ;

"*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, and the shelf-life is used to establish the expiry date of each batch ;

"*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 authorized agents, distributors, manufacturers or retailers ;

"*Transferor*" means freighter, forwarding agent and transporter of pharmaceutical products ;

"*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 ; and

"*Warehousing*" means a Pharmacist Council of Nigeria registered premises used by manufacturer, importer, exporter and wholesaler for storing controlled medicine.

19. These Regulations shall be cited as Good Distribution Practice Regulations, 2021. Citation.

MADE at Abuja this 7th day of July, 2021

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Honourable Minister of Health