Extraordinary

Federal Republic of Nigeria Official Gazette

No. 224 **Lagos - 30th October, 2024** **Vol. 111**

Government Notice No. 54

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

S. I. No.	*Short Title*	*Page*
49	NAFDAC (Pharmaceutical Products (Traceability)) Regulations, 2024	..B1011-1021

Printed and Published by The Federal Government Printer, Lagos, Nigeria
FGP 80/112024/150

Annual Subscription from 1st January, 2024 is Local : ₦100,000.00 Overseas : ₦130,000.00 [Surface Mail] ₦150,000.00 [Second Class Air Mail]. Present issue ₦3,500 per copy. Subscribers who wish to obtain *Gazette* after 1st January should apply to the Federal Government Printer, Lagos for amended Subscriptions.

B 1010

NAFDAC (PHARMACEUTICAL PRODUCTS (TRACEABILITY)) REGULATIONS, 2024

ARRANGEMENT OF REGULATIONS

Regulation :

PART I — OBJECTIVE AND APPLICATION

1. Objective
2. Application

PART II — LABELLING, UNIQUE IDENTIFICATION, DATA CARRIER, ETC.

3. Labelling information
4. Unique identification
5. Composition of the unique identifier
6. Data carrier
7. Data carrier specifications
8. Data carrier quality and readability
9. Placing of the data carrier on the label
10. Human readable interpretation
11. Master Data
12. Traceability, data capturing and sharing
13. Traceability data aggregation
14. Reporting
15. Prohibition

PART III —OFFENCES AND PENALTIES

16. Offences and penalties
17. Forfeiture after conviction

PART IV — MISCELLANEOUS

18. Enforcement of these Regulations
19. Interpretation
20. Citation

B 1012

S. I. No. 49 of 2024

NAFDAC (PHARMACEUTICAL PRODUCTS (TRACEABILITY)) REGULATIONS, 2024

[16*th Day of October*, 2024] Commencement

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

Part I — Objective and Application

Objective

1. These Regulations provides regulatory framework for the traceability of drugs and related products manufactured, imported, distributed, sold or used in Nigeria.

Application

2. These Regulations shall apply to the traceability of drugs and related products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

Part II — Labelling, Unique Identification, Data Carrier, Etc.

Labelling information

3.—(1) Drugs and related products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria shall be labelled in accordance with the Agency's Regulations on Drugs and Related Products Labelling Regulations and other relevant Guidelines.

Unique identification

4.—(1) Drugs and related product trade items manufactured, imported, exported, advertised, sold, distributed or used in Nigeria shall be identified with a unique identifier created by the brand owner.

(2) A brand owner of a drug and related product trade items manufactured, imported, exported, advertised, sold, distributed or used in Nigeria shall assign the unique identifier when such drug or related product trade item is physically created by the brand owner.

(3) Notwithstanding the provisions of subregulation (2) of this regulation, where a new drug and related product trade item is created by co-packing of two or more physical items, the manufacturer who does the co-packing shall assign a new unique identifier different from the unique identifier.

(4) The unique identification data carrier at packaging levels, shall remain on the drug and related product throughout the life cycle.

Composition of the unique identifier

5.—(1) The unique identifier shall be created in accordance with globally acceptable Global Standard Organisation (GS1) General Specifications and as may be required by the Agency.

(2) The unique identifier shall be in a sequence of numeric or alphanumeric characters that is unique to a given packaging level and shall consist of the following data elements —

(*a*) for primary or secondary packaging —

(*i*) Global Trade Item Number (GTIN),
(*ii*) batch or lot number,
(*iii*) expiry date, and
(*iv*) serial number; and

(*b*) for tertiary packaging —
(*i*) Global Trade Item Number (GTIN),
(*ii*) batch or lot number, and
(*iii*) expiry date.

(3) The combination of the GTIN and serial number shall be unique to a pharmaceutical product and in accordance with GS1 General Specifications.

(4) Notwithstanding subregulation (2) of this regulation, the manufacturer shall —

(*a*) notify the Agency where there is need to add any information other than the data elements; and
(*b*) obtain approval before implementation.

(5) Unique identifier shall be assigned to secondary and tertiary package label levels.

(6) Where primary package is a trade item, unique identifier shall be assigned to the primary package.

(7) Logistic units shall be identified with a Serial Shipping Container Code (SSCC).

(8) Where the logistic unit is an orderable trade item, the logistic unit shall be identified with SSCC and the unique identifier.

(9) An SSCC may be re-used as indicated in the GS1 General Specifications.

(10) The relationship between the unique identifier of the different packaging levels shall be captured in the manufacturer's electronic internal systems.

Data carrier

6.—(1) The GS1 General Specifications shall be used to create the unique identifier in the data carrier, to allow for the identification and accurate decoding of each data element of which the unique identifier is composed.

(2) The unique identifier of the primary and secondary package shall be encoded in a GS1 data matrix.

(3) The unique identifier of the tertiary package shall be encoded in a GS1 data matrix, or GS1-128 linear barcode.

(4) The unique identifier of the logistics unit with a serial Shipping Container Code shall be encoded as stated in the GS1 General Specifications.

(5) The unique identification encoded in the appropriate data carrier shall be used in accordance with GS1 General Specifications.

Data carrier specifications

7.—(1) The use of multiple two-dimensional barcodes on a single packaging of a pharmaceutical product for the purposes of identification and verification of the authenticity of a product, is prohibited.

(2) Additional barcode that is in line with GS1 General Specifications, besides a GS1 data matrix for the purpose of identification of the package in dispensing or at the point of sale is permitted.

(3) In addition to subregulation (2) of this regulation, the GTIN for the identification of the product in both barcode symbols shall be the same.

(4) The data carrier for placing, printing and quality shall be in accordance with GS1 General Specifications and as may be prescribed by the Agency.

Data carrier quality and readability

8. A brand owner or manufacturer shall —

(*a*) comply with data carrier quality measurement processes and minimum quality levels detailed in the GS1 General Specifications;

(*b*) have a procedure to control and document the print quality of the data carrier and shall provide documentation to the Agency upon request within 48hours; and

(*c*) ensure consistent printing quality and durability of the data carrier across packaging levels.

Placing of the data carrier on the label

9. The data carrier shall —

(*a*) be printed on the flat surface of the product label in a conspicuous, legible and distinct character;

(*b*) not be covered by anything as to prevent scanning of the data carrier; and

(*c*) be placed on the same side of each package.

Human readable interpretation

10. The data elements of the unique identifier encoded within the data carrier shall be printed on the product label as Human Readable Interpretation (HRI) containing GTIN, batch or lot number, expiry date and serial number in accordance with the rules and recommendations of GS1 General Specifications and as may be prescribed by the Agency.

Master Data

11.—(1) The brand owner or manufacturer shall share product master data with the Agency for drug and related product trade items and logistics items as may be required by the Agency.

(2) Supply chain stakeholders as required by these Regulations, shall —

(*a*) share legal, functional and location master data with the Agency; and

(*b*) obtain a Global Location Number (GLN), to identify organisations and important locations, including locations where items are manufactured and orders are received, distributed and dispensed.

(3) Locations referred to in subregulation (2) to this regulation shall have a valid license issued by the Pharmacy Council of Nigeria, where the trade item is a medicine.

(4) The data elements of the GLN shall be in accordance with the GS1 Healthcare GLN Guidelines.

Traceability, data capturing and sharing

12.—(1) The brand owner or manufacturer shall share the data of the unique identifier of the product with the Agency before placing the pharmaceutical product on the market.

(2) Pharmaceutical supply chain stakeholders shall electronically capture and share with the Agency, the unique identifier with associated traceability information, when the product was manufactured, received and distributed or dispensed.

(3) The traceability information to be captured and shared, shall include —

(*a*) date, time and time zone in which the product was manufactured, received and distributed or dispensed;

(*b*) physical location where the product is received and distributed or dispensed;

(*c*) source of the product received;

(*d*) destination of the product distributed;

(*e*) Global Service Relation Number (GSRN) and associated master data of persons handling or using the product, where it is available;

(*f*) logistics processing, including receiving, packing, unpacking and shipping, which identifies activities from a business perspective at the time of the event;

(*g*) disposition, which identifies the business subsequent to the event of the trade item, including in transit, expired, recalled, stolen, sold and dispensed; and

(*h*) any other information as may be required by the Agency.

(4) Pharmaceutical supply chain stakeholders shall —

(*a*) keep record of the linkage between the products created, received, processed or dispatched;

(*b*) keep records of activities for a minimum period of one year after the expiry date of the pharmaceutical product;

(*c*) transmit at the request of the Agency, any record of activities as may be required; and

(*d*) capture and share identified errors with the Agency, within 48 hours of being aware of such error in the unique identifier data.

(5) The unique identification of the product shall appear in all accompanying documents or electronic messages containing information related to the traceable item.

(6) The data capture shall be done by scanning of the data carrier on the label with a scanner.

(7) Where scanning of the data carrier is not possible, the manufacturer or supply chain stakeholder shall within 48 hours inform the Agency of the inability to scan before taking any further action.

Traceability data aggregation

13.—(1) A manufacturer shall aggregate —

(*a*) batch numbers or serial numbers to establish a parent-child relationship between a uniquely identified parent, which effectively serves as container, and one or more objects in the container; and

(*b*) products to the next higher, less granular packaging level, up to, and including the logistics level, identified by a SSCC.

(2) Where a pharmaceutical product is contained within a higher packaging level and parent-child relationships are maintained, supply chain stakeholders may capture records of the movements and locations of the higher-level item.

Reporting

14. A supply chain stakeholder —

(*a*) that encounters products within the specific scope without the required unique identification captured in the required data carrier or non-scannable data carrier shall inform the Agency within 48 hours; and

(*b*) shall inform the Agency within 24 hours of any stolen or lost pharmaceutical products with their unique identifier.

Prohibition

15.—(1) Drugs and related products shall not be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria, except the packaging has traceability features in accordance with the provision of these Regulations.

(2) Notwithstanding the provisions of subregulation (1) of this regulation, the Agency may grant permit for the manufacture, importation, exportation, advertisement, sale, distribution or use of —

(*a*) pharmaceutical product imported for personal use;

(*b*) non-registered pharmaceutical product imported with the approval of the Agency;

(*c*) pharmaceutical product for clinical trials;

(*d*) pharmaceutical product for research purposes;

(*e*) extemporaneous preparations; and

(*f*) any other product as may be approved by the Agency.

Part III —Offences and Penalties

Offences and penalties

16.—(1) A person who contravenes any of the provisions of these Regulations commits an offence and is liable on conviction, in the case of —

(*a*) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding ₦800,000 or both; and

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

(2) Where an offence under these Regulations is committed by a body corporate, firm or any 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 regulation,

is liable to be proceeded against and 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

17.—(1) 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*) any of the person's property or instrument used in any manner to commit or facilitate the commission of the offence.

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

PART IV — MISCELLANEOUS

Enforcement of these Regulations

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

Interpretation

19. In these Regulations —

"*Agency*" means the National Agency for Food and Drug Administration and Control;

"*Batch or Lot number*" means the number or a combination of numbers and letters specifically assigned to a drug and related product, which is linked to the manufacturing history of the drug and related product;

"*Barcode*" means a symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces;

"*Brand owner*" means the holder of certificate of registration issued by the Agency;

"*Data carrier*" means a graphical representation of data in a machine readable form, used to enable automatic reading of the element strings;

"*Data element*" means a unit of data for which the identification, description and value representation is specified;

"*Data Matrix*" means a standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern;

"*Drug*" includes any substances of vegetable, animal or mineral origin or any preparation or admixture manufactured, sold or advertised for use in —

(*a*) the diagnosis, treatment, mitigation, in man or animal,

(*b*) restoring, correcting or modifying organic function in man and animal,

(*c*) disinfections or the control of vermin, insects or pest, or

(*d*) contraception;

"*Event data*" means a report of the activities that a product goes through as it moves through the supply chain;

"*Expiry date*" means the date given on the individual container (usually on the label) of a product up to and including the Active Pharmaceutical Ingredient (API) and Finished Pharmaceutical Product (FPP), which are expected to remain within specifications, if stored correctly;

"*Extemporaneous preparation*" means preparations of medicines intended for individual patients based on a written prescription by a licensed medical professional;

"*GSI*" means a global standards organization that develops and maintains Global Standards used by stakeholders to identify, capture, and share information in the pharmaceutical supply chain;

"*Global Location Number* (*GLN*)" means the GSI identification key used to identify physical locations or parties, which comprises a GSI company prefix, location reference, and check digit;

"*Global Trade Item Number* (*GTIN*)" means the GSI identification key used to identify trade items, which comprises a GSI company prefix, an item reference and check digit;

"*Global Service Relation Number* (*GSRN*)" means the GSI identification key used to identify the relationship between the organisation offering the service and either the service provider or the service recipient and the unique identification number comprise of a GSI company prefix, a service reference, and a check digit;

"*Human Readable Interpretation* (*HRI*)" means characters, such as letters and numbers, which can be read by persons and are encoded in GSI Automatic Identification Data Capture (AIDC) data carriers confined to a GSI standard structure and format, the human readable interpretation is a one-to-one illustration of the encoded data, however, start, stop, shift and function characters, as well as the symbol check character, are not shown in the human readable interpretation;

"*Label*" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to a package or container of drug and related product;

"*Logistics unit*" means an item of any composition established for transport or storage of pharmaceutical products that needs to be managed through the supply chain, it is identified with a Serial Shipping Container Code (SSCC);

"*Master data*" means attributes of a real-world entity that are static (unchanging through the life of the entity) or nearly so;

"*Pharmaceutical*" means drug or related product —

(*i*) used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or symptoms,

(*ii*) used in restoring, correcting or beneficial modification of organic or mental functions in humans, or

(*iii*) which are articles other than food, intended to affect the structure or any function of the body of humans, and which includes articles intended for use as a component of any articles specified in subparagraphs (*i*), (*ii*) or (*iii*) of this paragraph;

"*Pharmaceutical supply chain*" means the flow from the origin to the consumption of pharmaceutical products covering the manufacturing, import, distribution, transportation, storage and dispensing stages, as well as other types of flows;

"*Primary packaging material*" means packaging material that comes in direct contact with the product, such as bottle, blister, aluminum foils and any other material;

"*Secondary packaging material*" means packaging material in which primary packaging material is enclosed;

"*Serial number*" means a numeric or alphanumeric sequence of maximum of 20 characters, generated by a deterministic or a non-deterministic randomisation algorithm;

"*Serial Shipping Container Code* (*SSCC*)" means the GSI identification key used to identify logistics units and the key comprises an extension digit, GSI Company Prefix, serial reference, and check digit;

"*Supply chain stakeholder*" means any person in the supply chain to manufacture, import, distribute, transport, store or dispense pharmaceutical products or involved in related activities;

"*Tertiary packaging material*" means outer carton in which multiples of saleable units are packed, such as shipper carton;

"*Traceability*" means the ability to identify, track forward the movement through specified stages of the extended supply chain and trace backward the history, application or location of a pharmaceutical product;

"*Trade item*" means any pharmaceutical product upon which there is a need to retrieve pre-defined information and that may be priced, ordered, or invoiced at any point in any supply chain;

"*Unique identifier*" means a numeric or alphanumeric string captured in a machine-readable data carrier and human-readable form on the label of the pharmaceutical package that is associated with a single product or product group; and

"*Verification*" means determining whether the unique identification number affixed to, or imprinted upon, a pharmaceutical package corresponds to the unique identification number assigned to the product by the manufacturer or the repackager.

20. These Regulations may be cited as the Pharmaceutical Products (Traceability) Regulations, 2024. Citation

MADE at Abuja this 16th day of October, 2024.

MUHAMMAD ALI PATE, CON
Coordinating Minister of Health and Social Welfare