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

TRACEABILITY OF PHARMACEUTICAL PRODUCTS REGULATIONS, 2022

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS (ending 18th October, 2022).
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ARRANGEMENT OF REGULATIONS

Regulation

TRACEABILITY OF PHARMACEUTICAL PRODUCTS REGULATIONS, 2022

[ ] 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, Drugs 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. **Scope of application**
   These Regulations shall apply to the Traceability of drugs and related products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.
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2. **Prohibition**
   (1) Drugs and related products shall not be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless the packaging has Traceability features in accordance with the provision of these Regulations.

   (2) Notwithstanding the provisions of Regulation 2 (1) of these Regulations, the Agency may grant permit for the manufacture, importation, exportation, advertisement, sale, distribution or use for the purpose of:
   (a) Pharmaceutical products imported for personal use only.
   (b) Non-registered pharmaceutical products imported with the Approval of the Agency.
   (c) Pharmaceutical products for clinical trials
   (d) Pharmaceutical products for the purpose of research
   (e) Extemporaneous preparations.
   (f) Any other product as may be prescribed by the Agency.

3. **Labelling Information**
   Drugs and related products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria shall be labelled in accordance with the Agency's extant Drugs and Related Products Labelling Regulations.

4. **Unique Identification**
   (1) Drugs and related products trade items manufactured, imported, exported, advertised, sold, distributed or used in Nigeria shall be identified with a unique identifier.
   (2) The unique identifier for drug and related product trade item shall be assigned, at the latest, when the drug and related product trade item is physically created by the manufacturer of the product.

(3) Notwithstanding the provisions of Regulations 4 (2), when a new drug and related products 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.

(4) The unique identification data carrier for all secondary and higher packaging levels in scope shall remain on the drug and related product throughout the life cycle.

5. **Composition of the unique identifier**

(1) The unique identifier shall be constructed according to the global accepted GS1 General Specifications and as may be required by the Agency.

(2) The unique identifier shall be a sequence of numeric or alphanumeric characters that is unique to a given packaging level.

(3) The unique identifier of the secondary and tertiary package shall consist of the following data elements:
   (a) Global Trade Item Number
   (b) Batch or lot number
   (c) Expiry date
   (d) Serial number

(4) The combination of the Global Trade Item Number and Serial Number shall be unique to a pharmaceutical product and as stated by the GS1 General Specifications.

(5) Notwithstanding Regulation 5(3) of this Regulations, the manufacturer shall notify the Agency of the need to add any information other than the data elements in Regulation 5(3) and obtain approval before implementation.

(6) Unique identification shall be assigned to all package label levels.

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

(8) When the logistic unit is an orderable trade item, the logistic unit shall be identified with a Serial Shipping Container Code and the unique identifier.

(9) A Serial Shipping Container Code may be re-used as indicated in the GS1 General Specifications.

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

6. **Data Carrier**

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

(2) The unique identifier of the 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) If the required unique identifier is only the Global Trade Item Number, appropriate data carrier according to the GS1 General Specifications shall be used.

7. **Data carrier specifications**

(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 shall not be allowed.

(2) An additional barcode according to the GS1 General Specifications, besides a GS1 DataMatrix for the identification of the package in dispensing shall be allowed.

(3) Further to Regulation 7(2), the Global Trade Item Number for the identification of the product in both barcode symbols shall be the same.

(4) The data carrier shall be as specified by the Agency for placing, printing and quality according to the GS1 General Specifications.

8. **Data carrier quality and readability**

(1) The data carrier quality measurement processes and minimum quality levels detailed in the GS1 General Specifications shall be followed.

(2) The manufacturer shall have a procedure in place to control and document the print quality of the data carrier and shall be able to provide documentation to the Agency upon request within 48hours.

(3) The manufacturer shall ensure consistent printing quality across packages.

(4) The manufacturer shall verify the data carrier durability and other external factors possibly influencing the data carrier quality.

9. **Placing of the data carrier on the label**

(1) The data carrier shall be printed on a flat surface of the product label and shall be prominent, legible and distinct.

(2) The data carrier shall not be covered by anything which prevents scanning of the data carrier.

(3) The data carrier shall be placed on the same side of each package.

10. **Human Readable Interpretation**

The data elements of the unique identifier encoded within the data carrier shall be printed on the secondary and tertiary label or package as Human Readable Interpretation (HRI) containing Global Trade Item Number, Batch or lot number, Expiry date and Serial number following the rules and recommendations of GS1 General Specifications and as may be specified by the Agency.

11. **Master Data**

(1) The 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) All supply chain stakeholders as required by these Regulations, shall share legal, functional and location master data with the Agency.

(3) All supply chain stakeholders as required by these Regulations shall obtain a Global Location Number (GLN), to identify their organizations and important locations, including locations where items are manufactured and orders are received and distributed.

(4) The data elements of the Global Location Number shall be according to the GS1 Healthcare GLN Guideline.

12. **Traceability**

(1) **Data Capture and Share**

(a) The manufacturer or supplier shall share the data for the unique identifier of the product with the Agency before placing the pharmaceutical product on the market.

(b) All pharmaceutical supply chain stakeholders shall electronically capture and share with the Agency, the unique identifier with associated traceability information when they receive and distribute the product.

(c) The traceability information that shall be captured and shared includes:

(i) The date, time and time zone in which the product was received and distributed.

(ii) The physical location where the product is received and distributed.

(iii) The source of the product received.

(iv) The destination of the product distributed.

(v) Logistics processing including receiving, packing, unpacking and shipping, which identifies what was taking place from a business perspective at the time of the event.

(vi) Disposition, which identifies the business subsequent to the event of the trade item including in transit, expired, recalled, stolen, sold and dispensed.

(vii) Business transaction, which is relevant to the event that is occurring, possibly Purchase Order, Order Confirmation or Invoice.

(d) All pharmaceutical supply chain stakeholders shall;

i. keep record of the linkage between the products created, received, processed or dispatched.
ii. keep records of activities for a minimum period of one (1) year after the expiry date of the pharmaceutical product.
iii. transmit at the request of the Agency any record of activities as may be required.
iv. capture and share possible errors with the Agency within 48 hours of identification of the error.

(e) The unique identifier of the product must appear in all accompanying documents or electronic messages containing information related to the traceable item.

(f) The data capture shall be done by scanning of the data carrier on the label with a scanner. Where scanning of the data carrier is not possible, the manufacturer or supply chain stakeholder shall within 48 hours inform the Agency of the issue before any further action.

13. **Data aggregation**

(1) The manufacturers shall aggregate

i. batch numbers or serial numbers to establish a parent-child relationship between a serialized, uniquely identified parent (which effectively serves as container), and one or more objects, which are contained.
ii. all products to the next higher (less granular) packaging level, up to and including the logistics level, identified by a Serial Shipping Container Code.

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

14. **Reporting**

(1) Any supply chain stakeholder that encounters products within the specific scope without required unique identification captured in the required data carrier or non-scannable data carrier shall inform the Agency within 48 hours.

(2) The supply chain stakeholder shall inform the Agency within 24 hours about any stolen or lost pharmaceutical products with their unique identifiers.

15. **Offences and Penalties**

(1) Any 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 (1) year or to a fine not exceeding N800,000.00 or to both such imprisonment and fine; 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 severally liable to be proceeded against and punished for the 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**

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.

17. **Enforcement of the Regulations**

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

18. **Interpretation**

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 given 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.

"**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 have been specified.

"DataMatrix" 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 thereof 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) are expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture;

"Extemporaneous preparation" means preparations of medicines intended for individual Patients based on a written prescription by a licensed medical professional.

"GS1" means a global standards organization that develops and maintain Global Standards used by all stakeholders to identify, capture, and share information in the pharmaceutical supply chain.

"Global Location Number (GLN)" means the GS1 identification key used to identify physical locations or parties. The key comprises a GS1 Company Prefix, location reference, and check digit.

"Global Trade Item Number (GTIN)" means the GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference and check digit.

"Human Readable Interpretation (HRI)" means characters, such as letters and numbers, which can be read by persons and are encoded in GS1 Automatic Identification Data Capture (AIDC) data carriers confined to a GS1 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 (see drug).
(a) used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof;

(b) used in restoring, correcting or beneficial modification of organic or mental functions in humans;
(c) 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 clause (a), (b) or (c)

"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.

"Secondary level packaging" means a level of packaging that may contain one or more primary packages or a group of primary packages containing a single item.

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

"Serial Shipping Container Code (SSCC)" means the GS1 identification key used to identify logistics units. The key comprises an extension digit, GS1 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 is involved in related activities.

"Traceability" means the ability to identify, track forward the movement through specified stage(s) 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, or 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.

"Verification" means determining whether the unique identifier affixed to, or imprinted upon, a pharmaceutical package corresponds to the unique identifier assigned to the product by the manufacturer or the repackage.

19. **Citation**

These Regulations may be cited as the Traceability of Pharmaceutical Products Regulations, 2022.

MADE at Abuja this ……. day of …….2022

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Chairman of the Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)

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