RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING THE IMPLEMENTATION OF IDENTIFICATION, DATA CAPTURE AND DATA SHARING FOR TRACEABILITY OF PHARMACEUTICAL PRODUCTS

(Rwanda FDA law N° 003/2018 of 09/02/2018, Article 9)

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ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these regulations No.: DFAR/HMDAR/TRG/003 Rev_0 governing the Implementation of Identification, Data Capture, and Data Sharing for Traceability of Pharmaceutical Products on this 15/08/ 2022.

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CHAPTER I: GENERAL PROVISION

Article One: Purpose of these regulations

The purpose of these regulations are to:

a) protect the public from falsified, substandard, expired, recalled or other unfit pharmaceutical products;

b) improve efficiency in the pharmaceutical supply chain to ensure that the right pharmaceutical products are available at the right time in a cost-effective manner;

c) provide the measures for placing a unique identifier on the package of pharmaceutical products for human use allowing for identification and authentication of the product;

d) provide the measures for assurance of traceability to track and trace the product from point of manufacture through point of use;

e) Establish mechanisms for information sharing on pharmaceutical products.

Article 2: Citation

These regulations shall be cited as "*Rwanda FDA Regulations Governing the Implementation of Identification, Data Capture and Data Sharing for Traceability of Pharmaceutical Products.*"

Article 3: Application

These regulations shall apply to all pharmaceutical products intended for human use including products registered and/or donated as pharmaceutical products with the exception of:

a) Products imported for personal use;

b) Non-registered pharmaceutical products ordered by authorized institutions/organizations;

c) Samples for regulatory and promotional purposes;

d) Blood or blood components;

e) Homeopathic pharmaceutical products;

f) Traditional medicines;

g) Extemporaneous preparations.

Article 4: Definitions

In these regulations, unless the context otherwise requires:

1. "**Authority**" means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under Article 2 of Law No. 003/2018 of 09/02/2018;

2. "**Brand Owner**" The organization that is responsible for allocating the unique identifier to the product;

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

4. "**Batch/Lot number**" means a unique number or combination of numbers or symbols for tracing back its processing history of each product during a specific period of time by the manufacturer;

5. "**Data Carrier**" means any type of physical media (e.g. barcode, QR code, Data Matrix, or RFID) that encodes machine readable data;

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

7. **"EAN-13 barcode**" means barcode of the EAN/UPC symbology that encodes a Global Trade Item Number (GTIN) for retail purposes.

8. "**Expiration Date**'' means the date up until which the manufacturer can guarantee that the medicine is fully potent and safe to take based on scientifically-sound product testing.

9. "**Global Location Number (GLN)**" means the GS1 identification Key used to identify physical and digital locations, legal entities and functions that needs to be identified in the supply chain.

10. "**GS1-128 Linear Barcode**" means a barcode symbology using bars and spaces in one dimension that leverages a subset of Code 128 which uses the function that allows the encoding of element strings.

11. "**Global Trade Item Number**" means the GS1 identification key used to identify trade items.

12. **"Human Readable Interpretation"** means a one-to-one illustration of the data encoded in a data carrier using characters such as letters and numbers that can be read by persons.

13. "**Label**" means any tag, brand, mark, pictorial or other descriptive matter, written, printed stencilled, marked, embossed or impressed on or attached to a container of any medicinal product.

14. "**Logistic unit**" means an item of any composition established for transport and/or storage of pharmaceuticals that needs to be managed through the supply chain.

15. **"Manufacturer"** means a person or a firm that is engaged in the manufacture of pharmaceutical products.

16. **"Marketing authorization holder (MAH)"** means any legal entity which holds are marketing authorization issued by the Rwanda FDA to distribute and sell its pharmaceutical products in Rwanda.

17. "**Master data**" means the identification number and descriptive attributes of a pharmaceutical product that are static or nearly so that provide more information or characteristics of the pharmaceutical product identified.

18. "**Package**" means any article that may be used for filling, inserting or wrapping or packing pharmaceutical products and includes the immediate container and other wrapping materials.

19. "**Patient**" means the end user of the pharmaceutical product.

20. "**Pharmaceutical product**" means any substance, or mixture of substances manufactured, sold, or presented as capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises in which food and drugs are manufactured, prepared or stored, for cleaning hospitals, equipment and farmhouses. It does not include medical devices or their components, parts or accessories.

21. "**Pharmaceutical supply chain**" means the flow from the point of manufacture to the point of dispense of pharmaceuticals covering the manufacturing, import, distribution, transportation, storage and dispensing stages.

22. "**Pharmaceutical supply chain actor''** means an entity that is registered with the registrar of companies or its equivalent or a recognized public entity, that is engaged in the pharmaceutical supply chain.

23. **"Primary packaging"** means the first level of packaging for the product marked with a data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy such as a kit.

24. **"Secondary packaging"** means the level of packaging marked with a data carrier that may contain one or more primary packages or a group of primary packages containing a single item.

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

26. "**Serial Shipping Container Code (SSCC)**" is used by companies to identify a logistic unit, which can be any combination of trade items packaged together for storage and/ or transport purposes.

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

28. **"Tertiary packaging"** means higher levels of packaging that may include a pallet that contains (one or usually) several cases or a case that contains (one or usually) several items in its primary or secondary packaging. Tertiary packaging may refer to either a logistic unit or a trade item.

29. "**Traceability**" means the ability to 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.

30. "**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.

31. "**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. In this instance, unique identifier refers to the combination of GTIN with Expiration Date, Batch/Lot and serial number.

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

CHAPTER II: TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

Article 5: Requirements for unique identification

The unique identifier for a trade item shall consist of a GTIN, expiration date, batch/lot number, and/or serial number that shall be assigned and labelled, at the latest, when the trade item is physically created and packaged by the manufacturer of the product.

When a new trade item is created by co-packaging of two or more physical items (e.g., creating a kit, overpacking), the re-packager shall assign a new unique identifier.

The unique identification data carrier for all secondary and higher packaging levels in scope shall remain on or attached to the pharmaceutical product throughout the life cycle.

Article 6: Composition of the unique identifier

The unique identifier shall be constructed according to the globally accepted GS1 General Specifications.

The unique identifier shall be 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 unique to a given secondary packaged trade item, tertiary packaged trade item or logistic unit.

The unique identifier of the secondary and tertiary package indicated by product lists published by the Authority shall consist of the following data elements:

i) GTIN
ii) Batch/lot number
iii) Expiration date
iv) Serial number

Notwithstanding to the third paragraph of this article, the manufacturer shall notify the Authority if he or she needs to add information other than the data elements in the unique identifier.

Logistic units shall be identified with a SSCC. When the logistic unit is an orderable trade item, the logistic unit shall be identified with an SSCC and/or a GTIN.

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

CHAPTER III: DATA CARRIERS

Article 7: General requirements for data carriers

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.

The unique identifier of the secondary package shall be encoded in a GS1 Data Matrix and the unique identifier of the tertiary package(s) shall be encoded in a GS1 Data Matrix, and/or GS1-128 linear barcode.

The unique identifier of the logistics unit shall be encoded as stated in the GS1 General Specifications.

Article 8: Data carrier specifications

It is prohibited to use multiple two-dimensional barcodes on a single packaging of a pharmaceutical product for the purposes of identification and verification of the authenticity.

An additional barcode according to the GS1 General Specifications, besides a GS1 Data Matrix for the identification of the secondary package in dispensing is allowed (e.g., use of the EAN-13 for retail purposes). The GTIN for the identification of the product in both barcode symbols, however, shall be the same.

For the data carrier specifications regarding placing, printing and quality, the GS1 General Specifications shall be followed.

Article 9: Quality and readability of data carrier

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

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 Authority upon request at any time. The manufacturer shall ensure consistent printing quality across packages.

The manufacturer shall verify through testing that the data carrier can stand moisture, abrasion and other external factors possibly influencing the data carrier quality. Any data carrier not readable will be considered as non-compliant to the GS1 general specifications.

Article 10: Placing of the data carrier on the label

The placing of the data carrier on the label shall comply with the following requirements:

a) The data carrier shall be printed on the label of the product in a good visible manner.

b) The data carrier shall be printed on a flat surface.

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

d) The data carrier shall be placed on the same side of each package of the same product.

e) The data elements of the unique identifier encoded within the data carrier shall be printed on the label or package as Human Readable Interpretation following the rules and recommendations of the GS1 General Specifications.

CHAPTER IV: MASTER DATA SHARING AND TRACEABILITY SYSTEM

Article 11: General requirements for master data sharing

The manufacturer shall share product master data with the Authority for all trade items within the scope of these regulations:

i) At the time that an application for marketing authorization is submitted;

ii) Upon request by the Authority at any other time.

The manufacturer shall ensure that product master data is maintained for all trade items and notify the Authority within 30 days of any effective change.

A unique identification number in the form of a Global Location Numbers (GLN) must be assigned to and shared with the Authority to identify the following legal entities or locations associated with a trade item:

i) the Brand Owner of the trade item
ii) the manufacturing location of the trade item
iii) the legal entity applying for or holding a marketing authorization of the trade item in Rwanda

A guideline will be issued by the Authority to guide the submission of product and location master data.

Article 12: General requirements for traceability reporting system

All actors of the pharmaceutical supply chain shall establish a system to electronically record and communicate data including location, date and time and event occurring corresponding to traceability events.
All actors of the pharmaceutical supply chain shall record and communicate traceability data to a national traceability system.

Proven impossibility of complying with the requirements of capturing and sharing traceability data shall be communicated to the Authority immediately.

The Authority shall issue guidelines for the specification on how to comply with the traceability requirements and how to connect to the national traceability system.

CHAPTER V: MISCELLANEOUS PROVISIONS

Article 13: Notifications to the Authority

Any supply chain actor that encounters products within the specific scope without required unique identification captured in the required data carrier or non-scannable data carrier must inform the Authority immediately.

Article 14: Duty to cooperate

The pharmaceutical supply chain actors supplying pharmaceutical products shall have the duty to cooperate with all appropriate organs to execute their responsibility given in this regulation. Any supply chain actor that does not comply with the unique identification and traceability requirement shall not manufacture, import, distribute and dispense pharmaceutical products.

Article 15: Transitional provision

Within 2 year of the effective date of these regulations, master data for all authorized pharmaceutical products, their packaging levels, and their associated locations and legal entities and pharmaceutical products shall be shared with the Authority.

Within 3 years of the entry into force of these regulations, secondary packages and higher packaging levels of authorized pharmaceutical products shall be identified with a GTIN, batch/lot number and expiration date encoded in the specified data carrier.

Within 4 years of the entry into force of these regulations, secondary packages and higher packaging levels of authorised pharmaceutical products shall be identified with a GTIN, batch/lot number, expiration date, and **serial number** encoded in the specified data carrier.

Within 5 years of the entry into force of these regulations, logistic units containing authorized pharmaceutical products shall be identified with a SSCC encoded in the specified data carrier.

Article 16: Commencement

These regulations shall enter into force on date of their signature and publication.

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