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Medicines Control Authority of Zimbabwe

MCAZ/LED/GL-22

GUIDELINES FOR IMPLEMENTING TRACEABILITY FOR MEDICAL PRODUCTS IN ZIMBABWE

EFFECTIVE DATE: 18/07/2025

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1.0 APPLICATION

These guidelines shall apply to the traceability of medical products manufactured, imported, exported, advertised, sold, distributed or used in Zimbabwe.

2.0 PURPOSE

The purpose of this guideline is to provide a comprehensive framework for the traceability of medical products manufactured, imported, exported, advertised, sold, distributed or used in Zimbabwe. By following this guideline, organizations can ensure accurate tracking of medicines from production to the end-consumer, thereby reducing falsification of medical products, improving recall management, and enhancing consumer trust.

3.0 BACKGROUND / INTRODUCTION

This guideline covers the implementation of traceability of medical products manufactured, imported, exported, advertised, sold, distributed or used in Zimbabwe. It is intended for pharmaceutical manufacturers, suppliers, distributors, retailers, health institutions and regulatory bodies involved in the supply chain who aim to enhance product traceability, authenticity, and consumer safety.

4.0 DEFINITIONS

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

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

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

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

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

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

4.7 **"GS1"** 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;

4.8 **“Global Location Number (GLN)”** means the GS1 identification key used to identify physical locations or parties, which comprises a GS1 company prefix, location reference, and check digit;

4.9 **“Global Trade Item Number (GTIN)”** means the GS1 identification key used to identify trade items, which comprises a GS1 company prefix, an item reference and check digit;

4.10 **“Global Service Relation Number (GSRN)”** means the GS1 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 GS1 company prefix, a service reference, and a check digit;

4.11 **“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;

4.12 **“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;

4.13 **“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);

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

4.15 **“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;

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

4.17 **“Secondary packaging material”** means packaging material in which primary packaging material is enclosed;

4.18 **“Serial number”** means a numeric or alphanumeric sequence of maximum of 20 characters, generated by a deterministic or a nondeterministic randomisation algorithm;

4.19 **“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;

4.20 **"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;

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

4.22 **"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;

4.23 **"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;

4.24 **"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

4.25 **"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.

5.0 LEGAL BASIS FOR THESE GUIDELINES

Section 37(3) of the **Medicines and Allied Substances Control (General) Regulations, 1991** (Statutory Instrument 150 of 1991) outlines the requirements for the labelling of packaging materials of all medicines supplied in Zimbabwe, as follows:

"Every medicine shall, where possible, be marked with the housemark of the principal or manufacturer of the medicine, as the case may be, and such other distinguishing mark for the purpose of identifying such medicine."

Additionally, Section 37(1)(o) of the said Regulations provides for the Authority to prescribe any other particulars as it may direct, to the labelling of the packaging of a medicine, in addition to those provided for under Section 37(1)(a) to 37(1)(n). This proviso empowers the Authority to provide further guidance and impose further regulatory requirements regarding labelling of products, in addition to those already prescribed.

Sections 37(3) provides for the inclusion of distinguishing marks to identify medicines and, read with Section 37(1)(o) both hereby provide for the requirement for the placement of a **unique identification number** on each **outer packaging**, in order to facilitate the **tracking and tracing** of medical products throughout the supply chain.

Given the **global rise in falsified medical products**, there is an urgent need to ensure suitable traceability measures are in place for all medical products that are **manufactured,**

imported, exported, advertised, sold, distributed, or used in Zimbabwe. The Authority asserts that the above legal provisions, read together, provide for sufficient legal basis for the implementation of a tracking and tracing framework for medical products in Zimbabwe.

To this end, the Authority adopts the **GS1 standards** as the basis for implementing a traceability system, with slight variations as outlined in these guidelines.

All supply chain stakeholders including **manufacturers, importers, wholesalers, retailers, health institutions, and consumers** are required to comply with the provisions of these guidelines to ensure that medical products are traceable throughout the supply chain.

5.1 Labelling, Unique Identification, Data Carrier etc.

5.1.1 Labelling Information

Medical products manufactured, imported, exported, advertised, sold, distributed or used in Zimbabwe shall be labelled in accordance with the Medicines and Allied Substances Control Act *(Chapter 15:03)* and the Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991.

5.1.2 Unique Identification

5.1.2.1 Medical products manufactured, imported, exported, advertised, sold, distributed or used in Zimbabwe shall be identified with a unique identifier created by the brand owner.

5.1.2.2 A brand owner of a medical product manufactured, imported, exported, advertised, sold, distributed or used in Zimbabwe shall assign the unique identifier when such medical product is physically created by the brand owner.

5.1.2.3 Notwithstanding the provisions of 5.2.3 of this guideline, where a new medical product 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.

5.1.2.4 The unique identification data carrier at packaging levels, shall remain on the medical product throughout the life cycle.

5.1.3 Composition of the unique identifier

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

5.1.3.2 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;

for primary or secondary packaging —

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

for tertiary packaging —

i. Global Trade Item Number (GTIN),
ii. batch or lot number, and
iii. expiry date.

5.1.3.3 The combination of the GTIN and serial number shall be unique to a medical product and in accordance with GS1 General Specifications.

5.1.3.4 Notwithstanding the provision in 5.2.6.1 of this guideline, the manufacturer

shall —

i. notify the Authority where there is need to add any information other than the data elements; and
ii. obtain approval before implementation.

5.1.3.5 A unique identifier shall be assigned to secondary and tertiary package label levels.

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

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

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

5.1.3.9 An SSCC may be reused as indicated in the GS1 General Specifications.

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

5.1.4 Data carrier

5.1.4.1 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.

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

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

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

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

5.1.5 Data carrier specifications

5.1.5.1 The use of multiple two-dimensional barcodes on a single packaging of a medical product for the purposes of identification and verification of the authenticity of a product, is prohibited.

5.1.5.2 An additional barcode that is in line with GS1 General Specifications, besides a GS1 data matrix for the purpose of identifying the package in dispensing or at the point of sale is permitted.

5.1.5.3 In addition to provision (b) of this guideline, the GTIN for the identification of the product in both barcode symbols shall be the same.

5.1.5.4 The data carrier for placing, printing and quality shall be in accordance with GS1 General Specifications and as may be prescribed by the Authority.

5.1.6 Data carrier quality and readability

5.1.6.1 A brand owner or manufacturer shall —

i. comply with data carrier quality measurement processes and minimum quality levels detailed in the GS1 General Specifications;
ii. have a procedure to control and document the print quality of the data carrier, and shall provide documentation to the Authority upon request within 48 hours; and
iii. ensure consistent printing quality and durability of the data carrier across packaging levels.

5.1.7 Placing of the data carrier on the label

5.1.7.1 The data carrier shall —

i. be printed on the flat surface of the product label in a conspicuous, legible and distinct character;
ii. not be covered by anything as to prevent scanning of the data carrier; and
iii. be placed on the same side of each package.

5.1.8 Human-readable interpretation

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 Authority.

5.1.9 Master data

5.1.9.1 The brand owner or manufacturer shall share product master data with the Authority for medical product trade items and logistics items as may be required by the Authority.

5.1.9.2 Supply chain stakeholders as required by these Guidelines, shall —

i. share legal, functional and location master data with the Authority; and
ii. 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.

5.1.9.3 Locations referred to in subsection (b) to this guideline shall have a valid licence issued by the Authority, where the trade item is a medical product.

5.1.9.4 The data elements of the GLN shall be in accordance with the GS1 Healthcare GLN Guidelines.

5.1.10 Traceability, data capturing and sharing

5.1.10.1 The brand owner or manufacturer shall share the data of the unique identifier of the product with the Authority before placing the medical product on the market.

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

5.1.10.3 The traceability information to be captured and shared, shall include —

i. date, time and time zone in which the product was manufactured, received and distributed or dispensed;
ii. physical location where the product is received and distributed or dispensed;
iii. source of the product received;
iv. destination of the product distributed;
v. Global Service Relation Number (GSRN) and associated master data of persons handling or using the product, where it is available;
vi. logistics processing, including receiving, packing, unpacking and shipping, which identifies activities from a business perspective at the time of the event;
vii. disposition, which identifies the business subsequent to the event of the trade item, including in transit, expired, recalled, stolen, sold and dispensed; and
viii. any other information as may be required by the Authority.

5.1.10.4 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 year after the expiry date of the pharmaceutical product;
iii. transmit at the request of the Authority, any record of activities as
iv. may be required; and
v. capture and share identified errors with the Authority, within 48 hours
vi. of being aware of such error in the unique identifier data.

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

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

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

5.1.11 Traceability data aggregation

5.1.11.1 A manufacturer shall aggregate —

i. 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

ii. products to the next higher, less granular packaging level, up to, and including the logistics level, identified by a SSCC.

5.1.11.2 Where a medical 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.

5.1.12 Reporting

5.1.12.1 A supply chain stakeholder —

i. that encounters products within the specific scope without the required unique identification captured in the required data carrier or nonscannable data carrier shall inform the Authority within 48 hours; and
ii. shall inform the Authority within 24 hours of any stolen or lost medical products with their unique identifier.

5.1.13 Exemptions

5.1.13.1 Medical products shall not be manufactured, imported, exported, advertised, sold, distributed or used in Zimbabwe, except the packaging has traceability features in accordance with the provision of these Guidelines.

5.1.13.2 These Guidelines shall apply to all medical products except for those manufactured, imported, exported, advertised, sold, distributed or used as follows —

i. pharmaceutical product imported for personal use;
ii. unregistered medical product imported with the approval of the Authority;
iii. medical product for clinical trials;
iv. medical product for research purposes;
v. extemporaneous preparations; and
vi. any other product as may be approved by the Authority.

5.1.14 Offences and Penalties

Any person who does not comply with the requirements of these Guidelines shall be penalised according to the provisions laid down in the Medicines and Allied Substances Control Act *(Chapter 15:03)* and the Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991.

5.1.15 Enforcement of these Guidelines

The Authority shall be responsible for the enforcement of these Guidelines.

5.2 Obtaining GTIN Numbers

5.2.1 Registration with GS1: Since GS1 is not present in Zimbabwe, you can register with a GS1 Member Organization from a neighbouring country or directly with the GS1 Global Office. Visit the GS1 Global Office website for more information.

5.2.2 Generating GTINs: Once registered, you can generate GTINs by combining the company prefix with a unique product reference number and a check digit.

5.3 Implementation Timeline

5.3.1 The implementation of this guideline shall follow a phased approach:

i. Phase I (0–12 months): Pilot projects with selected manufacturers and distributors identified for high-risk products.
ii. Phase II (12–36 months): Gradual rollout across the supply chain.
iii. Phase III (36–60 months): Full implementation and regulatory enforcement.

MCAZ will provide periodic updates, technical assistance, and training during the transition period.

6.0 KEY RELEVANT DOCUMENTS

6.1 Medicines and Allied Substances Control Act (Chapter 15:03)

6.2 Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991

6.3 GS1 General Specifications Standard, Jan 2025

6.4 DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry.

6.5 WHO Policy paper on traceability of medical products, 2021

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	New
N/A	N/A	