ZAMBIA MEDICINES REGULATORY AUTHORITY

GUIDELINE ON TRACEABILITY OF MEDICINES

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TABLE OF CONTENTS

GUIDELINE DEVELOPMENT HISTORY

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ACRONYMS

2D	two-dimensional
AI	GS1 Application Identifier
AIDC	automatic identification and data capture
FNC1	Function 1 Symbol Character
GDSN	GS1 Global Data Synchronization Network
GLN	Global Location Number
GTIN	Global Trade Item Number
HRI	human readable interpretation
MAH	marketing authorization holder
MO	GS1 Member Organization
NPC	National Product Catalogue
SSCC	Serial Shipping Container Code
ZAMRA	Zambia Medicines Regulatory Authority

DEFINITIONS

In this guideline, unless the context otherwise requires -

“Aggregation” means the Aggregation defines the hierarchy relationship between the unique identifiers for parent and child packaging hierarchies, where each packaging level will carry a unique identifier encoded in a data carrier. uniquely identified allowing the receiver of the product to scan one code and understand exactly what is in the whole shipment—every case, bundle, or individual carton;

“Automatic identification and data capture (AIDC)” means a technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics, and radio frequency identification devices;

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

“Batch/lot” means the batch or lot number associates an item with production information that the manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained in it;

“Data Matrix” means a standalone, two-dimensional (2D) matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Data Matrix symbols are read by two-dimensional imaging scanners or vision systems;

“EAN-13 barcode” means a barcode of the EAN/UPC symbology that encodes a GTIN for retail purposes;

“Expiration date” means the date up until which the drug manufacturer can guarantee that the medicine is fully potent and safe to take based on scientifically-sound product testing;

“Function 1 Symbol Character (FNC1)” Means a Function 1 Symbol Character (FNC1) indicates that the barcode is a GS1 symbology so that the scanner understands how to decode it. It is a separator in between different Application Identifiers that do not have a fixed character count (e.g., AI (10) Batch/Lot, AI (21) Serial Number);

“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;

“GS1” Means a neutral, not-for-profit, global organization that develops and maintains the most widely used supply chain data standards in the world;

“GS1 Application Identifier” Means the field of two or more digits at the beginning of an element string that uniquely defines its format and meaning;

“GS1 Member Organization” Means a member of GS1 that is responsible for administering the GS1 system in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GS1 system; have access to education, training, promotion, and implementation support; and have opportunity to play an active role in the Global Standards Management Process;

“GS1-128 linear barcode” Means a barcode symbology using bars and spaces in one dimension that leverages a subset of Code 128 that is used exclusively for GS1 system data structures;

“Homeopathic medicine” Means homeopathic medicine, or homeopathy, is a form of complementary and alternative medicine that uses very small amounts of natural substances, which in higher amounts may cause a disease or symptom;

“Human readable form” Means Characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The human readable form is a one-to-one illustration of the data encoded in a data carrier. However, start, stop, shift and function characters, as well as the symbol check character, are not shown in the human readable form;

“Marketing Authorisation” Means the authorisation granted under section thirty-nine of the Medicines and Allied Substances Act (No. 3) of 2013 of the laws of Zambia for the placement of a medicine or allied substance on the Zambian Market;

“Label” Means Any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any medicines and allied substances;

“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. It is identified with an SSCC;

“Marketing Authorization Holder (MAH)” means any legal entity which holds a marketing authorization issued by ZAMRA to distribute and sell its medicine or allied substance in Zambia;

“Master data” means the identification number and descriptive attributes of an object that are static or nearly so that provide more information or characteristics of the object identified;

“Package” means any material that may be used for filling, inserting or wrapping or packing regulated products and includes the immediate container and other wrapping materials;

“Medicine” means a human medicine, veterinary medicine, medicinal product, herbal medicine or any substance or mixture of substances for human or veterinary use intended to be used or manufactured for use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person or animal;

“Primary packaging” means the first level of packaging for the product marked with an AIDC 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. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.

“Secondary packaging” means a level of packaging marked with an AIDC carrier 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.

“Tertiary homogenous pack” means a tertiary pack that consists entirely of the same trade item with the same batch number and expiration date.

“Tertiary mixed pack” means a tertiary pack that contains either more than one unique trade item or entirely the same trade item with different batch numbers or expiration dates.

“Tertiary packaging” means the highest level 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.

“Tertiary partial pack” means a homogenous pack of products that is not to be considered a trade item because it is less than full.

“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.

“Trade item” means any item (product) upon which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in any supply chain.

“Traditional medicine” means also known as indigenous or folk medicine; comprises medical aspects of traditional knowledge that developed over generations within the folk beliefs of various societies before the era of modern medicine.

“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.

1.0 INTRODUCTION

1.1 The Authority

The Medicines and Allied Substances (Marketing Authorisation of Medicines) Regulations, 2019 in particular regulation 20 (j) promulgated under the Medicines and Allied Substances Act No. 3 of 2013, gives the Zambia Medicines Regulatory Authority (ZAMRA) the mandate to enforce a 'suitable coding" system for all medicines meant for the Zambian market as part of "Product Labelling and Packaging Requirements". The Authority adopted the use of the global standards in identification, sharing and capturing of data labelled on medicines as it is widely accepted globally and is robust enough to meet the needs of the Authority and various stakeholders. Therefore, this guideline shall apply to all medicines which are meant for supply to the Zambian market.

1.1 Purpose

Established by the Act of Parliament, the Zambia Medicines Regulatory Authority's main objective is to ensure that all medicines and allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy. With this mandate comes a need to provide guidelines for the implementation of existing global standards which provide simplicity and consistency by enabling the identification, automated data capture, and exchange of data about these items in ways that can be used in any industry, in any country, and with any Marketing Authorisation Holder.

By leveraging on existing global standards for labelling and packaging of medicines, ZAMRA hopes to create efficiencies in the public and private health supply chains through standardized identification, automated data capture, and decreased cost in gaining compliance. Specifically, global standards for labelling and packaging are aimed at:

- Supporting interoperability between supply chain information systems;
- Increasing quality of data for decision-making by regulators and supply chain stakeholders.
- Enabling efficiencies across the supply chain;
- Promoting trust in the pharmaceutical sector and healthcare system;
- Creating visibility into and enabling controls to address the pilferage of commodities on the market;

- Facilitating new controls against substandard and falsified medicines ultimately increasing patient safety

This document is intended to provide manufacturers, marketing authorization holders, and/or other supply chain stakeholders seeking to import and distribute pharmaceuticals in Zambia with further information on how to implement labelling requirements as outlined under Regulations 20 (j) of Statutory Instrument No. 79 of 2019 and regulations on traceability and tracking of medicines on the Zambian market.

1.3 Scope of the guideline

This guideline applies to all medicines to be placed on the Zambian market with the exception of:

- Products submitted to the Authority for quality analysis;
- Whole blood and blood components;
- Homeopathic medicines and allied substances;
- Extemporaneous preparations;
- Medicines imported for personal use only subject to authorization by the Authority;
- Unregistered medicines imported on special authorization by the authority;
- Donated medicines imported for emergency cases subject to authorization by the Authority; and
- Products manufactured and labelled prior to their unique identification compliance dates.

2.0 Overview of Relevant Global Standards

This guideline is based on the use of the GS1 General Specifications as the primary reference document for technical specifications to implement traceability of medicines in accordance with current GS1 global standards and the GS1 General Specifications.

2.1 GS1 Identifier

The GS1 Identifiers (AI) referenced in this section are used for identifying trade items and their locations.

2.1.1 AI (00) Serial Shipping Container Code (SSCC)

The GS1 Application Identifier (AI) (00) indicates that the data field contains an SSCC. The SSCC is used to uniquely identify a logistic unit. The SSCC must remain unique and not be reallocated for

a minimum of one year from the shipment date of the logistic unit, in accordance with GS1 General Specifications.

The SSCC format is as follows:

GS1 Application Identifier	Serial Shipping Container Code (SSCC)		
	Extension digit	GS1 Company Prefix → ← Serial Reference	Extension digit
0 0	N_1	N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12} N_{13} N_{14} N_{15} N_{16} N_{17}	N_{18}

For information on how to generate an SSCC and apply it to a logistics label, please refer to the GS1 General Specifications and the following resources:

- http://www.gs1.org/barcodes/technical/idkeys/sscc
- https://www.gs1.org/docs/tl/GS1_Logistic_Label_Guideline.pdf

2.1.2 AI (01) Global Trade Item Number (GTIN)

The GS1 AI (01) indicates that the data field contains a GTIN. The GTIN is the globally unique GS1 identification number used to identify trade items. GTINs are assigned by the brand owner (MAH) of the trade item and are used to identify trade items as they move through the global supply chain to the end user.

The GTIN may be comprised of 8, 12, 13, or 14 digits. The format of the GTIN-14 is as follows:

GS1 Application Identifier	Global Trade Item Number (GTIN)		
	GS1-8 Prefix or GS1 Company Prefix →	← Item Reference	Check digit
0 1	N_1 N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12} N_{13}		N_{14}

For information on how to generate and maintain a GTIN, please refer to the GS1 General Specifications and the following resources:

- http://www.gs1.org/gtin
- https://www.gs1.org/1/gtinrules/en/healthcare

2.1.3 AI (10) Batch/lot

The GS1 AI (10) indicates that the data field contains a batch or lot number. The batch or lot number field is alphanumeric.

The format of the batch or lot number is as follows:

GS1 Application Identifier	Batch or Lot Number
1 0	X_1 → variable length → X_{20}

2.1.4 AI (17) Expiration date

The GS1 AI (17) indicates that the data field contains an expiration date. The structure of the expiration date should be as follows:

Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory

Month: the number of the month (e.g., January = 01), which is mandatory

Day: the number of the day of the relevant month (e.g., second day = 02), which is optional

The format of the expiration date is as follows:

GS1 Application Identifier	Expiration Date					
	Year		Month		Day	
1 7	N_1	N_2	N_3	N_4	N_5	N_6

2.1.5 AI (21) Serial number

The GS1 AI (21) indicates that the data field contains a serial number. When combined with a GTIN, a serial number uniquely identifies an individual item. The manufacturer determines the serial number.

The serial number field is alphanumeric. The character sequence resulting from the combination of the GTIN and the serial number will be unique to a given pack of a trade item at least one year after the pack's expiration date or five years after the pack has been released for sale or distribution, whichever is the longer period.

The format of the serial number is as follows:

GS1 Application Identifier	Serial Number
2 1	X_1 → variable length → X_{20}

2.2 Capture

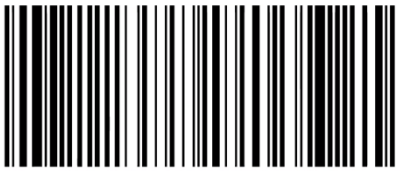
All tertiary and secondary packages are required to be labelled in accordance with the specified barcode requirement, with relevant GS1 Identifiers encoded and printed in their human readable form.

All barcode symbols should meet print-quality “Grade C” (1.5 or above). As part of the regular manufacturing or production process, barcode symbol print quality and data content must be verified and graded in accordance with the appropriate sections within the GS1 General Specifications. Many GS1 Member Organizations provide comprehensive barcode verification services to ensure companies are implementing barcode labelling requirements to specification based on optical and data structure requirements.

2.2.1 GS1-128 barcode

A GS1-128 barcode is a linear barcode symbology using bars and spaces in one dimension that leverage a subset of Code 128 that is used exclusively for GS1 system data structures. A linear barcode can be concatenated (i.e., represent all elements of a data string in a single barcode) or non-concatenated (i.e., represent individual elements of a data string over two or more barcodes). The barcode for the logistic unit shall be presented in a concatenated manner only. The barcode for the trade item may be presented in either a concatenated or non-concatenated manner where necessary.

Example of a GS1-128 barcode for a logistic unit



Example of a GS1-128 barcode for a trade item

Concatenated (preferred)

Non-concatenated (only if necessary)

2.2.2 GS1 Data Matrix

A GS1 Data Matrix is a two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Two-dimensional imaging scanners or vision systems read Data Matrix symbols.

Example of a GS1 Data Matrix for a logistic unit

(00) 0 0614141 123452

Example of a GS1 Data Matrix for a trade item

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

3.0 DESCRIPTION OF PACKAGING LEVELS

This section provides for descriptions of each level of the packaging hierarchy for a trade item or logistic unit. Stakeholders should consult the GS1 General Specifications and the GS1 Automatic Identification and Data Capture (AIDC) Healthcare Implementation Guideline, or their GS1 Member Organization for additional information.

3.1 Tertiary Packaging

Tertiary packaging refers to upper levels of the packaging hierarchy. A tertiary pack may be:

- A pallet that contains one or several cases
- A case that contains one or several items in the items' primary or secondary packaging

Tertiary packaging may be used as either a logistic unit or as a trade item. Tertiary packages can be homogenous (i.e., consisting entirely of the same trade item, batch or lot, and expiration date), partial (i.e., consisting of a homogenous pack of items that is not to be considered a trade item because it is less than full), or mixed (i.e., either more than one unique trade item or entirely the same trade item with different batch numbers or expiration dates).

It is recommended that labels containing the barcode symbols, with associated human readable form, be positioned on two faces of the tertiary packaging to enable ready access for scanning when the trade item or logistic unit is stored, stocked or handled.

3.1.1 Logistic Unit

A logistic unit is an item of any composition established for transport and/or storage that needs to be managed through the supply chain. In many instances, the tertiary package logistic unit takes the form of a pallet, an export carton or other specific authorised form.
The logistic unit is identified using the serial shipping container code (SSCC). This packaging level is marked with a GS1-128 barcode, with the option to also include a GS1 Data Matrix, either on the packaging itself or on a label affixed to the packaging.

3.1.2 Trade Item

The tertiary package trade item will typically be a case or carton but may also be a shrink-wrapped tray or other configuration.

A homogenous pack trade item is identified with a GTIN, batch or lot number, expiration date, and serial number. A mixed or partial pack item is considered a logistic unit and identified with an SSCC. This packaging level can be marked with a GS1-128 barcode or a GS1 Data Matrix, with a strong preference for a GS1 Data Matrix, either on the packaging itself or on a label affixed to the packaging.

Examples of tertiary packaging include, but are not limited to:

3.2 Secondary Packaging

Secondary packaging is a level of packaging that may contain one or more primary packages, or a group of primary packages containing a single item. The secondary pack is always a trade item. This packaging level is marked with a GS1 Data Matrix, either on the packaging itself or on a label affixed to the packaging.

Examples of secondary packaging include, but are not limited to:

Group of primary packages containing a single item

One primary package

One or more primary packages

Group of primary packages containing a single item

In-scope commodities can have more than one level of secondary packaging, such as an inner pack (bundles) and intermediate packs (inner case). Identification and marking of inner and intermediate secondary packaging levels is required. Examples of inner or intermediary secondary packaging include, but are not limited to:

3.3 Primary Packaging

Primary packaging is the first level of packaging that is in direct contact with the trade item. This packaging level is marked with a GS1 Data Matrix, either on the packaging itself or on a label affixed to the packaging.

Identification and labelling of trade items at this level is a preferred characteristic unless the supplier is providing items in "carton less packaging", i.e., without a secondary packaging level, in which case it is mandatory. Marking trade items at this level is also recommended where the secondary package will likely be opened or removed before being dispensed to one or several patients (e.g., a display carton is opened, and individual or split blister packs are distributed to patients).

Examples of primary packaging include, but are not limited to:

4.0 REQUIREMENT FOR PHARMACEUTICAL PRODUCT IDENTIFICATION AND LABELLING

This section describes how to implement the product identification and labelling requirements. Refer to the GS1 General Specifications and the GS1 AIDC Healthcare Implementation Guideline, or their GS1 Member Organization for additional information.

4.1 Tertiary Pack Logistic Unit

All tertiary pack logistic units must include a GS1-128 barcode encoded with the following information and printed adjacent to the data carrier in human readable form:

AI	Description	Required by
00	SSCC	No later than 5 years from date of publication of the guidelines

A Serial Shipping Container Code may be re-used after a period of one year, as noted within the GS1 General Specifications.

An example of this in practice:

(00)006141411234567890

Encoded in the data carrier, this example will take on the following format:

FNC Opening Character	AI	SSCC
FNC1	00	006141411234567890

Read via AIDC technology, this example will take on the following format:

]c1000061414112345678 90

4.2 Tertiary Pack Trade Item

All tertiary pack trade item packages must include a GS1-128 barcode or a GS1 Data Matrix encoded with the following information and printed adjacent to the data carrier in Human Readable form:

AI	Description	Required by
01	GTIN	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guidelines
10	Batch or Lot	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guidelines
17	Expiration Date	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guidelines
21	Serial Number	No later than 5 years from date of publication of the guidelines

An example of this in practice:

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

(01)10857674002017(17)251231(10)NYFUL01(21)192A837H7

Encoded in the data carrier, these examples will take on the following format:

FNC Opening Character	AI	GTIN	AI	Expiration Date	AI	Batch/ Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

Read via AIDC technology, this example will take on the following format:

]d2011085767400201717251231 10NYFUL01<GS>21192A837H7

The character sequence resulting from the combination of the product identifier and the serial number shall be unique to a given pack of a medicine.

The Authority shall not stipulate the order in which data is encoded into the data carrier. However, for the most efficient encoding, it is recommended to have fixed-length data elements precede variable-length elements. In this instance where a tertiary pack trade item is also considered a logistic unit, the SSCC can be applied in lieu of the serialized GTIN.

Stakeholders shall notify the Authority if they need to add information other than the four data elements described above in the unique identifier.

4.3 Secondary Pack Trade Item

All secondary trade item packaging must include a GS1 Data Matrix encoded with the following information and printed adjacent to the data carrier in human readable form:

AI	Description	Required by
01	GTIN	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guideline
17	Expiration Date	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guideline
10	Batch or Lot	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guideline
21	Serial Number	No later than 5 years from date of publication of the guideline

An example of this in practice:

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

Encoded in the data carrier, this example will take on the following format:

FNC Opening Character	AI	GTIN	AI	Expiration Date	AI	Batch/Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

Read via AIDC technology, this example will take on the following format:

]d201108576740020171725123110NYFUL01<GS>21192A837H7

The character sequence resulting from the combination of the product identifier and the serial number shall be unique to a given pack of a medicine.

The Authority shall not stipulate the order in which data is encoded into the data carrier. However, for the most efficient encoding, it is recommended to have fixed-length data elements precede variable-length elements.

Stakeholders shall notify the Authority if they need to add information other than the four data elements described above in the unique identifier.

4.4 Primary Pack Trade Item

Identification and labelling of trade items at the primary trade item packaging level is a preferred characteristic unless the supplier is providing items in “carton less packaging”, i.e., without a secondary packaging level, in which case it is mandatory.

If implemented, the unique identifier for the primary pack must include a GS1 Data Matrix encoded with the following information and printed adjacent to the data carrier in human readable form:

AI	Description	Required by
01	GTIN	No later than 2 years for imported medicine and 3 years for domestically manufactured medicines from date of publication of the guideline
17	Expiration Date	No later than 2 years for imported medicine and 3 years for domestically manufactured medicines from date of publication of the guideline
10	Batch/ Lot	No later than 2 years for imported medicine and 3 years for domestically manufactured medicines from date of publication of the guideline
21	Serial Number	No later than 5 years from date of publication of the guideline

An example of this in practice:

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

Encoded in the data carrier, this example will take on the following format:

FNC Opening Character	AI	GTIN	AI	Expiration Date	AI	Batch/Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

Read via AIDC technology, this example will take on the following format:

]d2011085767400201717251231 10NYFUL01<GS>21192A837H7

The character sequence resulting from the combination of the product identifier and the serial number shall be unique to a given pack of a medicine.

The Authority shall not stipulate the order in which data is encoded into the data carrier. However, for the most efficient encoding, it is recommended to have fixed-length data elements precede variable-length elements.

Stakeholders shall notify the Authority if they need to add information other than the four data elements described above in the unique identifier.

5.0 REQUIREMENT FOR MEDICINES AND LOCATION MASTER DATA SHARING

This section provides guidance to manufacturers, marketing authorization holders, and/or other supply chain stakeholders on the collection and submission of product and GS1-based trade item master data to the marketing authorization register, National Product Catalogue (NPC)register, including GTINs and relevant Global Location Numbers (GLNs) for medicines procured and supplied to the Zambian market.

5.1 ZAMRA Master Data Attribute Requirements

The Attribute List (see Appendix A) is the primary reference document for Marketing Authorization Holders regarding master data attribute requirements. It includes all initial priority attributes to be provided as relevant on trade items supplied to the Authority. For each attribute, the guide provides the category, attribute name, description, and an example.

Attribute Significance

Attribute Requirement	No. of attributes
Mandatory Attributes that must be populated to share with ZAMRA	13
Optional Attributes that should be populated if available, but not yet mandatory for ZAMRA	52
Total attributes	65

Attribute Groupings

Attribute Grouping	Description
General Item Information	General information about the trade item
Product Description Information	Supplier product descriptions and other descriptive information
Unit Indicators	Supply chain characteristics
Dimensions	Trade item dimensions, weights and measures
Contact/Role Information	Manufacturer, supplier and information provider contact information (name, address and contact method)
Pharmaceutical Information	Information on dosage and route of administration
Hierarchy	Trade item hierarchy (packaging levels) information
Storage, Handling & Shelf Life	Defines the information and processes needed to safely handle the trade item.
Product Classifications	Product classification details
Dangerous & Hazardous Goods Information	Information on dangerous and hazardous goods and waste classification
Referenced Trade Item Identification	These attributes support identification of substitute or alternate trade items from the same brand owner.

5.2 Steps for Sharing Product and Location Master Data with ZAMRA

To synchronize data with ZAMRA, Marketing Authorisation Holders are advised to undertake the following actions:

1. Assign a GLN for each of the relevant locations or legal entities, including Marketing Authorisation Holder and manufacturing site.
2. Assign a GTIN to each level of the trade item packaging hierarchy (e.g., each, inner, case, pallet).[2] An example of a trade item packaging hierarchy in the healthcare context is:

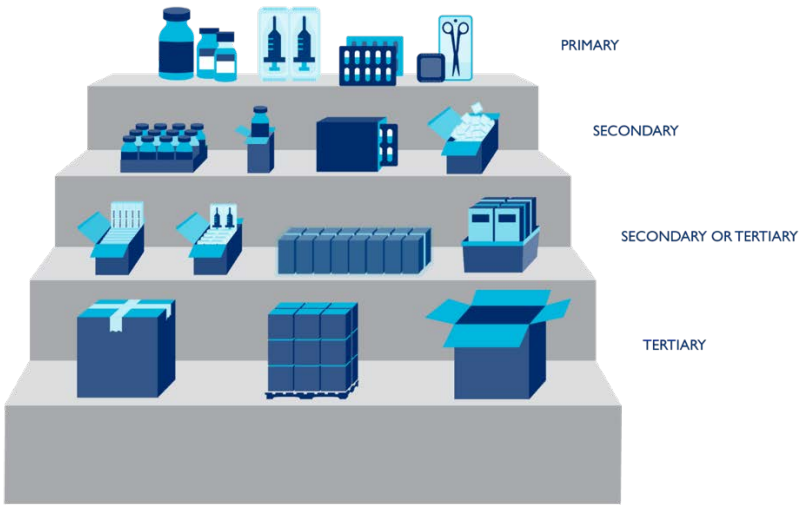


Figure 1. Identification at healthcare levels of packaging

3. Gather the product and location attribute data on each trade item packaging hierarchy level, per the ZAMRA Product and Location Master Data Attribute Guide (Appendix A). Note that these attributes are based on the GS1 Global Data Synchronization Network (GDSN) standard.
4. Populate the ZAMRA Product and Location Master Data Submission Form (Appendix A) in Excel format and submit with the marketing authorization application. If submitting an ad hoc request for master data from the ZAMRA or providing an update to data submitted through the marketing authorization process, email your form to pharmacy@zamra.co.zm.
5. MAHs are expected to ensure that the master data provided for registered products is maintained and updated as necessary. If there are any changes to the master data provided on your products or relevant locations, send an updated template to the Authority within 30 days of implementing the change.

Please note that the Authority seeks to enable direct submission of product and location master data to the NPC over time, either via direct entry or a form of electronic data exchange (e.g. GDSN). This guideline will be updated as those capabilities are developed, tested, and deployed.

6.0 SUPPORTING RESOURCES

Find a GS1 Member Organization

Use this resource to find a GS1 Member Organization to register your company.
https://www.gs1.org/contact/overview

GS1 General Specification

This resource is the primary document that details the foundational GS1 standards that defines how identification keys, data attributes and barcodes must be used in business applications.
https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

10 Steps to Barcode Your Product

This resource provides a step-by-step instruction for implementing AIDC on your products.
http://www.gs1.org/barcodes/implementation

GS1 GTIN Healthcare Allocation Rules

This resource provides the rules for assigning GTINs to trade items in the health sector.
https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

AIDC Healthcare Implementation Guideline

This resource provides information on the more technical aspects of implementing AIDC for healthcare on various levels of packaging.
https://www.gs1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf

GS1 Global Data Dictionary

The GS1 Global Data Dictionary (GDD) is a repository of the data elements defined across all GS1 Standards. Attributes in the GDD are described using data types, some of which may contain code lists. Each GS1 Standard is represented in the GDD, sorted by the type of data exchange standard including Global Data Synchronization Network (GDSN).
http://apps.gs1.org/GDD/SitePages/Home.aspx

Global Standards Technical Implementation Guideline for Global Health Commodities

This resource was developed by a set of international procurement agents in the global health community to support suppliers in meeting their AIDC requirements. It includes a number of technical references and a Frequently Asked Questions section that may be useful to Marketing Authorisation Holders in their implementation.
http://ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21

Appendix A. ZAMRA Product and Location Master Data Attribute Guide and Submission Form