FOOD AND DRUGS AUTHORITY

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Guidelines on Implementation of Identification and Data Capture for Traceability of Pharmaceutical Products

Draft

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Guidelines on Implementation of Identification and Data Capture for Traceability of Pharmaceutical Products

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The Food and Drugs Authority (FDA) Ghana acknowledges the support of the USAID through the Promoting the Quality of Medicines Plus (PQM+) program implemented by USP Ghana.

The FDA also acknowledges the support of the WHO in the drafting of this document.

Lastly, we acknowledged all players in the pharmaceutical supply chain in Ghana without whose support this document would not have seen the light of day.

Executive summary

This guideline was developed in response to the requirements of WHO Global Benchmarking Market Surveillance and Control function Indicator MC.01.05 which requires an existence of legal provisions and regulations for placing product unique identification number on outer packaging.

The guidelines takes its root from the Ghana National Pharmaceutical Traceability Strategy documents developed by the Ministry of Health (MOH) and the FDA which aims to improve the health status of all citizens of the country by ensuring the availability of quality, safety, and effective medical products as well as their rational use, including the ease of traceability.

This guideline adopts GS1 standards which are universally recognized standards and basic principles that would allow them to track and trace products from the source to the patient and back again through the supply chain system.

This Guideline therefore conforms with global standards and provides simplicity and consistency by promoting universal applicability and optimal functionality across the globe for all industry sectors.

All stakeholders in the pharmaceutical supply chain were duly consulted in the development of these guidelines.

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1. Introduction

Pharmaceutical products (allopathic drugs) play an indispensable role in the provision of health care delivery systems in every country. Ghana as a country has made progress in improving access to safe, quality and efficacious medicines to the public while promoting their rational use.

To further enhance healthcare delivery to its citizenry, the Ministry of Health (MOH) together with the FDA and other stakeholders have developed the Ghana National Pharmaceutical Traceability Strategy. The aim is to ensure the availability, quality, safe and efficacious, as well as the rational use of pharmaceutical products including the ease of traceability to improve the health status of all people living in the country.

Assuring the safety, quality and efficacy of medicines is a global challenge. As a result, there is a surge in demand by healthcare providers and other agencies to exchange information regarding medicine quality and traceability within the supply chain system.

In response, many institutions and healthcare facilities are developing their own solutions without recourse to common basic principles and globally accepted standards that would enable them to track and trace products from the source to the patient and back to the source, through the supply chain system.

This uncoordinated and fragmented approach makes the supply chain system inefficient, and the data collected inaccurate thereby compromising the quality of healthcare and patient safety. This Guideline is therefore crucial as it conforms with global standards and provides simplicity and consistency by promoting universal applicability and optimal functionality across the globe for all industry sectors.

At the core of these Guidelines are to ensure that the objectives outlined below are effectively addressed to enhance the healthcare delivery system generally and pharmaceutical product quality and efficacy in particular.

The objectives of these Guidelines includes the following:

a) To protect the public from expired, recalled, unregistered, unwholesome(falsified, substandard), or otherwise harmful pharmaceutical products.

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

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

d) To provide the measures for assurance of traceability to track and trace the product at every step of the supply chain.

In order to achieve the set objectives, these guidelines further outline implementation requirements for meeting the master data sharing provisions as detailed herein.

Detailed provisions have also been made in ensuring that the identification and labelling provisions as outlined in these Guidelines are adequately met.

Notwithstanding the above, players in the pharmaceutical industry shall comply with all other existing National Statutory Requirements.

These Guidelines are hereby promulgated for information, guidance and strict adherence by all concerned.

1.1. Legal Basis

This guideline is made in exercise of the powers conferred on the Food and Drugs Authority (FDA) by Part Seven, Section 148 (1), (2) (a) (ii), (2) (j), (2) (l), (2) (m), and Section 113 (1) (a) of the Public Health Act, 2012, Act 851.

1.2. Scope

These Guidelines shall apply to all pharmaceutical products,vaccines and biologicals that are registered in Ghana , with the exception of :

a) Personalized prescriptions
b) Products submitted for quality analysis.
c) Blood or blood components.
d) Nutraceuticals (food supplements)
e) Extemporaneous preparations.
f) Investigational Drugs
g) Any other product the Authority may determine

2. Definitions and Abbreviations

For the purposes of these Guidelines, the following definitions shall apply:

a) **"Allopathic drug"** means any product or substance other than a medical device, which is to be administered to one or more human beings or animals on its own, or as an ingredient in the preparation of a substance, for a medicinal purpose.
b) **"Authority"** means Food and Drugs Authority, Ghana.
c) **"Barcode"** means a symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars, and pale spaces.

d) **"Batch/Lot number"** means a designation in numbers and/or letters to identify and trace a set of identical products that shares certain characteristics of production, including production time, production date, or other similar characteristics.

e) **"Brand owner"** is the organization that is responsible for allocating the unique identifier to the product which may be same as the Marketing Authorization Holder.

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

g) **"EAN-13 barcode**" means barcode of the EAN/UPC/GTIN symbology that encodes a Global Trade Item Number (GTIN) for retail purposes. **"Expiration date"** The date placed on the container or labels of a medical product designating the time during which it is expected to remain within established shelf-life specifications if stored under defined conditions, and after which it should not be used**.**

h) **"Global Location Number (GLN)"** means the GS1 identification key used to identify physical locations (operational or legal) that needs to be identified in the supply chain. The key comprises a GS1 company prefix, location reference, and check digit.

i) **"GS1-128"** means a subset of Code 128 that is used exclusively for GS1 system data structures.

j) **"Global Trade Item Number (GTIN)"** means The GS1 identification key used to identify trade items.

k) **"Human Readable Interpretation (HRI)"** 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.

l) **"Investigational Drugs"** means products intended to be used in Clinical Trials/ Clinical research.

m) **"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 pharmaceutical product.

n) **"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.

o) **"Manufacturer"** means a company that carries out operations such as production, packaging, repackaging, labelling and relabelling of medical products.

p) **"Marketing authorization holder (MAH)/ Applicant"** means any legal entity that holds a marketing authorization issued by the FDA to distribute and sell its pharmaceutical products in Ghana. May also be responsible for allocating the

unique identifier to the product.

q) **"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.

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

s) **"Patient"** means the end user of the pharmaceutical product.

t) **"Pharmaceutical"** means any product or substance other than a medical device, which is to be administered to one or more human beings or animals on its own, or as an ingredient in the preparation of a substance, for a medicinal purpose.

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

v) **"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.

w) **"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.

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

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

z) **"Supply chain entity"** means any person in the supply chain who manufactures, imports, distributes, transports, stores, or dispenses pharmaceuticals or is involved in related activities.

aa) **"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.

bb) **"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.

cc) **"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.

dd) **"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.

ee) **"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 repackager.

[These Guidelines have to be read in conjunction with Annex 1 of this document]

3. Technical Specifications of the Unique Identifier

3.1. General requirements for unique identification

a) All pharmaceutical trade items and/or logistic units that are distributed in Ghana shall be identified with a unique identifier.

b) The manufacturer shall maintain records about each such unique identifier up to 5 years after the expiry of a trade item to which the unique identifier is affixed or imprinted and provide those records to the FDA upon request.

c) The unique identifier for a trade item shall be assigned and labelled, at the latest, when the trade item is physically created by the manufacturer of the product.

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

e) 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.

3.2. Composition of the Unique Identifier

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

b) The unique identifier shall be a sequence of numeric or alphanumeric characters that is unique to a given primary packaged trade item, secondary packaged trade item, tertiary packaged trade item, or logistic unit.

c) 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 (Global Trade Item Number)

   ii) Batch/lot number

   iii) Expiration date

   iv) Manufacturing date

   v) Serial number

d) Notwithstanding section 4.2(c), the brand owner/ MAH shall notify the Authority of any other information it intends to add to the unique identifier.

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

f) When the logistic unit is an orderable trade item, the logistic unit shall be identified with an SSCC and a GTIN.

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

4. Technical Specifications of Data Carriers

4.1. General requirements for data carriers

a) 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.

b) The unique identifier of the primary package where necessary, shall be encoded in a GS1 DataMatrix.

c) The unique identifier of the secondary package shall be encoded in a GS1 DataMatrix.

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

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

f) It is not allowed to use multiple two-dimensional barcodes on a single packaging of an allopathic drug product to identify and verify its authenticity.

4.2. Data carrier specifications

a) .

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

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

4.3. Quality and Readability

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

b)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.

c)The manufacturer shall ensure consistent printing quality across packages.

d) The manufacturer shall verify through testing that the data carrier can stand moisture, abrasion, and other external factors possibly influencing the data carrier quality.

4.4. Placing of the data carrier on the label

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

5. Human Readable Interpretation (HRI)

5.1. General requirements for HRI

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

5.2. Master Data Sharing

General requirements for master data sharing

a) The manufacturer shall share product master data with the Authority for all trade items within the scope of this Guideline:
    i) At the time that an application for marketing authorization is submitted
    ii) Upon request by the Authority at any other time
b) The manufacturer shall ensure that product master data are maintained for all trade items and notify the Authority within 30 days of any effective change.
c) A unique identification number in the form of a Global Location Number (GLN) must be assigned and shared with the Authority to identify the following legal entities or locations associated with a trade item:
    i) the brand owner/MAH 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 Ghana

6. Traceability Reporting

6.1. General requirements for traceability reporting

a) All actors in 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.
b) All actors in the pharmaceutical supply chain shall record and communicate traceability data to the national traceability system.
c) Proven impossibility of complying with the requirements of capturing and sharing traceability data shall be communicated to the Authority within 2 working days.

7. Administrative Provisions

7.1. Notifications of Authority

Any supply chain entity that encounters trade items or logistic units within the specific scope without required unique identification captured in the required data carrier or non-scannable data carrier shall inform FDA within 24 hours.

7.2. Duty to Cooperate

The concerned governmental bodies and pharmaceutical supply chain actors shall have the duty to cooperate with all appropriate agencies to execute their responsibility given in these Guidelines.

7.3. Administrative Sanctions

Any person who violates or contravenes these Guidelines is liable to sanctions as outlined in the Public Health Act, 2012 (Act 851) and any other legislation as applicable.

7.4. Enforcement of the Guideline

No guideline, practice, or circular letter shall, in so far as it is inconsistent with these Guidelines, be applicable with respect to issues provided under these Guidelines.

7.5. Transitional measures

The following transitional measures apply:

a) Any pharmaceutical product manufactured, imported, distributed, and dispensed without the unique identifier before the effective date of these Guidelines, and that is not repackaged or re-labelled thereafter, may be placed on the market until its expiry date.

b) Within Two (2) years of the effective date of these Guidelines (4 years for local manufacturers), master data for all listed pharmaceutical trade items, their packaging levels, and their associated locations and legal entities and pharmaceutical products shall be shared with the Authority.

c) Within Two (2) years of the effective date of these Guidelines, listed pharmaceutical trade items in primary packages (where possible), secondary packages and higher packaging levels shall be identified with a GTIN, batch/lot number, manufacturing date and expiration date encoded in the specified data carrier.

d) Within three (3) years of the effective date of these Guidelines, listed pharmaceutical trade items in primary packages (where possible) secondary packages and higher packaging levels shall be identified with a GTIN, batch/lot number, expiration date, and serial number encoded in the specified data carrier.

e) Within three (3) years of the effective date of these Guideline, logistic units containing listed pharmaceutical trade items shall be identified with a SSCC encoded in the specified data carrier.

FOOD AND DRUGS AUTHORITY

Guidelines on Implementation of Identification and Data Capture for Traceability of Pharmaceutical Products

ANNEX 1: GUIDANCE FOR IDENTIFICATION AND LABELLING OF PHARMACEUTICAL PRODUCTS

Annex 1: **Guidance for Identification and Labelling of Pharmaceutical Products**

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Annex 1: **Guidance for Identification and Labelling of Pharmaceutical Products**

Acronyms

2D	Two-Dimensional
AI	Application Identifier
AIDC	Automatic Identification and Data Capture
FNC1	Function 1 Symbol Character
GTIN	Global Trade Item Number
HRI	Human Readable Interpretation
SSCC	Serial Shipping Container Code

Revision History

Version	Author	Date	Comments

Annex 1: **Guidance for Identification and Labelling of Pharmaceutical Products**

1. Introduction

The Guideline for Identification and Labelling of Pharmaceutical Products document outlines implementation requirements for those stakeholders in scope for meeting the identification and labelling provisions outlined in the Guideline on Implementation of Identification, Data Capture and Data Sharing for Traceability of Pharmaceutical Products.

Guideline on Implementation of Identification, Data Capture and Data Sharing for Traceability of Pharmaceutical Products is established under the Public Health Act, 2012 (Act 851) whose main mandate is to provide and enforce standards for the sale of food, herbal medicinal products, cosmetics, drugs, medical devices and household chemical substances. With this mandate comes a need to provide guidance for complying with this Act 851, leveraging global standards to provide simplicity and consistency for product identification and labelling. This guideline will enable 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 trading partner.

1.1. Rationale

By leveraging existing global standards for labelling and packaging of pharmaceutical products FDA hopes to create efficiencies in the public and private health supply chains through standardized identification, automated data capture, and decreased cost in gaining compliance.

1.2. Purpose

This document is intended to provide trading partners subject to Act 851 with further information on how to implement FDA regulations on labelling pharmaceutical products and medicines to be distributed in the Ghana market. The information in this document is informed by existing good practices and GS1 global standards for labelling and packaging.

1.3. Scope

This document applies to all products that fall within the definition of pharmaceutical products per Guideline on Implementation of Identification, Data Capture and Data Sharing for Traceability of Pharmaceutical Products.

2. *Product Identification and Labelling Requirements for Pharmaceuticals*

This section describes how to implement the product identification and labelling requirements as mandated in the referenced guideline. Readers should consult the GS1 General Specifications[1] and the GS1 Automatic Identification and Data Capture (AIDC) Healthcare Implementation Guideline,[2] or their GS1 Member Organization, for additional information.

2.1. Tertiary Pack Trade Item

All tertiary pack trade item packages must include a GS1-128 Linear Barcode or a GS1 two- dimensional (2D) DataMatrix barcode encoded with the following information and printed adjacent to the data carrier in Human Readable Interpretation HRI):

AI	Description	Required by
01	GTIN	No later than [DDMonthYY]
10	Batch/Lot	No later than [DDMonthYY]
17	Expiration Date	No later than [DDMonthYY]
21	Serial Number	No later than [DDMonthYY]

An example of this in practice on a 2D DataMatrix:

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

Annex 1: **Guidance for Identification and Labelling of Pharmaceutical Products**

An example of this in practice on a GS1-128 Linear Barcode:

[1] For more information, see https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications
[2] For more information, see https://www.gs1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf

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

]d201108576740020171725123110NYFUL01<GS>21192A837H7

The probability that the serial number can be guessed will be negligible and, in any case, lower than one in ten thousand. The character sequence resulting from the combination of the product identifier and the serial number will be unique to a given pack of a medicinal product.

This guideline does not mandate the order in which data are encoded into the data carrier. However, for the most efficient encoding, it is recommended that fixed-length data elements precede variable-length elements. In this instance where a tertiary pack trade item is also considered a logistic unit, the Serial Shipping Container Code (SSCC) can be applied in lieu of a serial number.

2.2. Tertiary pack logistic unit

All tertiary pack logistic units must include a GS1-128 Linear Barcode[3] encoded with the following information and printed adjacent to the data carrier in HRI:

[3] Per the *GS1 General Specifications* (Release 19.1), trading partners have the option to include a GS1 2D DataMatrix in addition to the GS1-128 Linear Barcode on the logistic unit.

AI	Description	Required by
00	SSCC	No later than [DDMonthYY]

A SSCC may be re-used after a period of one year of the shipment date, as noted within the GS1 General Specifications.[4]

An example of this in practice:

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

FNC Opening Character	AI	SSCC
FNC1	00	006141411234567890

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

]c10006141411234567890

2.3. Secondary Pack Trade Item

All secondary trade item packaging, including inner and intermediate secondary packaging levels, must include a GS1 2D DataMatrix barcode encoded with the following information and printed adjacent to the data carrier in HRI:

[4] For more information, see GS1 General Specifications, Section 2.2.1, Individual Logistic Units – Application Description

AI	Description	Required by
01	GTIN	No later than [DDMonthYY]
17	Expiration Date	No later than [DDMonthYY]
10	Batch/Lot	No later than [DDMonthYY]
11	Manufacturing Date	
21	Serial Number	No later than [DDMonthYY]

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665 An example of this in practice:

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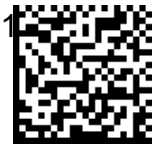
667 (01) 10857674002017
668 (17) 251231
669 (10) NYFUL01
670 (21) 192A837H7



671

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

673

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

674

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

676

677]d2011085767400201717251231 10NYFUL01<GS>21192A837H7

678

679 The probability that the serial number can be guessed will be negligible and, in any case,
680 lower than one in ten thousand. The character sequence resulting from the combination of
681 the product identifier and the serial number will be unique to a given pack of a medicinal
682 product.

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684 *Annex 1:* **Guidance for Identification and Labelling of Pharmaceutical Products**

685 This guideline does not mandate the order in which data are encoded into the data carrier.
686 However, for the most efficient encoding, it is recommended that fixed-length data
687 elements precede variable-length elements.

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3. *Description of Packaging Levels*[5]

This section includes descriptions of each level of the packaging hierarchy. Readers should consult the GS1 General Specifications[6] and the GS1 AIDC Healthcare Implementation Guideline,[7] 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 usually) several cases[8]
- A case that contains (one or usually) several items in the items' primary or secondary packaging[9]

Tertiary packaging may be used as either a logistics unit or a trade item. Tertiary packages can be homogenous (i.e., consisting entirely of the same trade item, batch/lot, and expiry), 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 HRI, be positioned on two faces of the tertiary packaging to enable ready access for scanning when the item is stored, stocked on shelves, or handled.

3.1.1. Tertiary Package 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. Often, the tertiary package logistic unit is a pallet but may also be an export carton.

The logistic unit is identified using the SSCC. This packaging level is marked with a GS1 DataMatrix or a GS1-128 linear barcode, either on the packaging itself or on a label affixed to the packaging.

[5] Annex A is referenced directly from the Global Standards Technical Implementation Guideline for Global Health Commodities. Available at: http://ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21

[6] For more information, see https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications

[7] For more information, see https://www.gs1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf

[8] For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.4, Case/Shipper and Pallet.

[9] ibid.

A GS1 DataMatrix or GS1 QR Code symbol MAY be included in addition to the GS1- 128 symbol. When used, the GS1 2D symbol SHALL include all element strings included in the GS1-128 symbol(s), and MAY include additional element strings. If a logistic unit does not have at least one surface area greater than an A6 or 4" x 6" logistic label, a GS1 DataMatrix or GS1 QR Code MAY be used by itself on a logistic label, though a GS1-128 containing a SSCC is still recommended. If a logistic label is used with only a GS1 DataMatrix or GS1 QR Code, care must be taken to ensure trading partners are able to scan this barcode.

Example of a GS1-128 barcode for a logistic unit

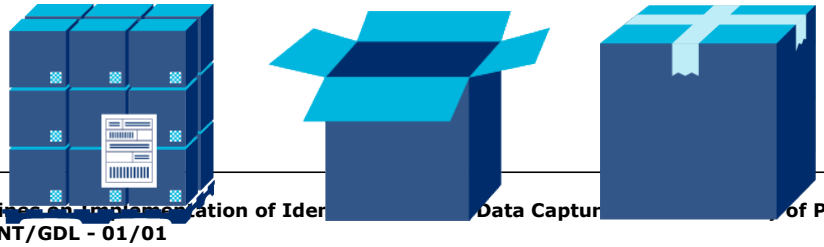
3.1.2. Tertiary Package Trade Item

Trade items are products and services for which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in the supply chain. 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/lot number, expiration date, and serial number. A mixed or partial pack trade item is identified with an SSCC. When a trade item is a logistic unit, it is not identified with a SSCC. This packaging level can be marked with a GS1-128 linear barcode or a GS1 DataMatrix, with a strong preference for a GS1 DataMatrix, either on the packaging itself or on a label affixed to the packaging.

Annex 1: **Guidance for Identification and Labelling of Pharmaceutical Products**

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



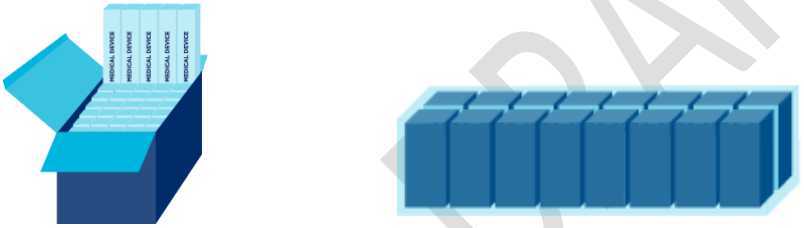
3.2. Secondary packaging

Secondary packaging is a level of packaging that may contain one or more primary packages, or a group of primary packages..[10] The secondary pack is always a trade item. This packaging level is marked with a GS1 DataMatrix, either on the packaging itself or on a label affixed to the packaging.

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

Trade items subject to the requirements 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 are required.**

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



Example of a GS1 DataMatrix for a trade item on Secondary Packaging

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

[10] For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.3, Secondary Package.

3.3. Primary packaging

Primary packaging is the first level of packaging that is in direct contact with the item.[11] This packaging level is marked with a GS1 DataMatrix, embossed on the packaging itself.

Identification and labeling of trade items at this level is **optional unless the supplier is providing items in "cartonless packaging," i.e., without a secondary packaging level.** Marking trade items at this level is preferred 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:

Example of a GS1 DataMatrix for a trade item on Primary Packaging

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

4. *Overview of Relevant Global Standards*[12]

A summary of the GS1 standards relevant to *Guideline for Identification and Labelling of Pharmaceutical Products* are described in this section. This document is based on the use of the *GS1 General Specifications*[13] as the primary reference document for technical specifications to implement in accordance with GS1 global standards. The latest version of the *GS1 General Specifications* should always be considered.

[11] For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.2, Primary Package.

[12] Annex C is referenced directly from the Global Standards Technical Implementation Guideline for Global Health Commodities. Available: http://ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21

[13] For more information,https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications

4.1. Identify

The GS1 application identifiers (AIs) referenced in this section are used for identifying items and locations.

4.1.1. AI (00) Serial Shipping Container Code[14]

The GS1 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 from the SSCC assignor to the trading partner, 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 more 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

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4.1.2. AI (01) Global Trade Item Number[15]

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 (i.e., items that may be priced, ordered, or invoiced). GTINs are assigned by the brand owner/marketing authorization holder of the item and are used to identify items as they move through the global supply chain to the hospital or ultimate end user. Reuse of a GTIN for another trade item is not permitted.

The GTIN can be 8, 12, 13, or 14 digits in length. The format of the GTIN-14 is as follows:

[14] For more information, see *GS1 General Specifications*, Section 3.3.1, Identification of a logistic unit (SSCC): AI (00).

[15] For more information, see *GS1 General Specifications*, Section 3.3.2, Identification of a trade item (GTIN): AI (01).

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 more 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

4.1.3. AI (10) batch/lot[16]

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

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

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

4.1.4. AI (17) expiration date[17]

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) if it is not necessary to specify the day, the field must be filled with two zeros[18]

[16] For more information, see *GS1 General Specifications*, Section 3.4.1, Batch or Lot Number: AI (10).

[17] For more information, see *GS1 General Specifications*, Section 3.4.7, Expiration Date: AI (17).

[18] A General Specification Change Notification (GSCN) has been issued that will change the structure of the Expiration date for Healthcare in the next release of the GS1 General Specification. This GSCN will state: "Note: How the day of the month is expressed for regulated healthcare products will change starting 1 January 2025. As of that date, the day of the month SHALL NOT be expressed as two zeros. A valid day of the month (e.g., last day of July = 31) SHALL be include. For more information, see GS1 General Specifications, Section 3.4.7, Expiration Date: AI(17).

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

4.1.5. AI (21) serial number[19]

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 who assigns the GTIN determines the serial number.

The serial number field is alphanumeric. The probability that the serial number can be guessed shall be negligible and, in any case, lower than one in ten thousand. The character sequence resulting from the combination of the GTIN and the serial number will be unique to a given pack of a health commodity until 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}

4.2. Capture

All tertiary and secondary packages are recommended to be labelled in accordance with the specified barcode requirement, encoded with relevant GS1 Application Identifiers encoded and printed in their Human Readable Interpretation (HRI).[20]

[19] For more information, see *GS1 General Specifications*, Section 3.5.2, Serial Number: AI (21)

[20] For more information, see Ten Steps to GS1 Barcode Implementation User Manual.

All barcode symbols should meet print-quality "Grade C" (1.5 or above).[21] As part of the regular manufacturing/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.

4.2.1. GS1-128 barcode[22]

A GS1-128 barcode is a linear barcode symbology using bars and spaces in one dimension. It is a subset of the Code 128 barcode symbology; its use is exclusively licenced to GS1. 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).

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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)

[21] For more information, see *GS1 General Specifications,* Section 5.6, Barcode Production and Quality Assessment.

[22] For more information, see *GS1 General Specifications,* Section 5.4, Linear Barcodes—GS1-128 Symbology Specifications

4.2.2. GS1 DataMatrix[23]

A GS1 DataMatrix is a 2D matrix symbology made up of square modules arranged within a perimeter finder pattern. Two-dimensional imaging scanners or vision systems read DataMatrix symbols.

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Example of a GS1 DataMatrix for a logistic unit

(00) 0 0614141 123452

Example of a GS1 DataMatrix for a trade item

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

5. *Supporting Resources*

Find a GS1 MO

Provides a resource for finding a GS1 MO to register your company. https://www.GS1.org/contact/overview

GS1 General Specifications

Serves as the primary document detailing the foundational GS1 standards that define 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

Provides a step-by-step instruction for implementing AIDC in your products. http://www.GS1.org/barcodes/implementation

[23] For more information, see *GS1 General Specifications,* Section 5.7, Two-dimensional barcodes—GS1 DataMatrix symbology

GS1 GTIN Healthcare Allocation Rules

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

Provides information on the more technical aspects of implementing AIDC for health care on various levels of packaging. https://www.GS1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf

Global Standards Technical Implementation Guideline for Global Health Commodities

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 trading partners in their implementation. http://ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21

Strength in Unity: The Promise of Global Standards in Health Care

Summarizes the opportunity for global standards to drive patient safety and supply chain efficiencies in health care. https://www.GS1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf

Glossary of Terms

Term	Definition
Aggregation	Defines the 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)	A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics, and radio frequency identification devices.
Barcode*	A symbol that encodes data into a machine-readable pattern of adjacent, varying width; parallel, rectangular dark bars; and pale spaces.
Batch/lot*	The batch or lot number that associates an item with production information that the manufacturer considers relevant for traceability of the trade item. The data may refer

Term	Definition
	to the trade item itself or to items contained in it.
DataMatrix	A standalone, 2D matrix symbology that is made up of square modules arranged within a perimeter finder pattern. DataMatrix symbols are read by 2D imaging scanners or vision systems.
Expiration date	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)	When used as the first character, a Function 1 Symbol Character (FNC1) indicates that the barcode follows the GS1 standard allowing the scanner to properly decode it. It is also used as a separator in between specific 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)	The GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference, and check digit.
GS1	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	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
GS1 Member Organization	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 an opportunity to play an active role in the Global Standards Management Process.
GS1-128 linear barcode	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
Health care primary packaging	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.
Health care secondary packaging	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.
Human Readable Interpretation (HRI)	Characters, such as letters and numbers, that can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The HRI 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

Term	Definition
	HRI.
Logistic unit	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.
Package	Any article that may be used for filling, inserting, or wrapping or packing regulated products and includes the immediate container and other wrapping materials.
Pharmaceutical	Any substance or mixture of substance that: a) Is used in the diagnosis, treatment, mitigation, or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof b) Is used in restoring, correcting, or beneficial modification of organic or mental functions in humans c) Is articles other than food, intended to affect the structure or any function of the body of humans Includes articles intended for use as a component of any articles specified in clause a), b), or c)
Serial number	A numeric or alphanumeric sequence of a maximum of 20 characters, generated by a deterministic or a non-deterministic randomization algorithm.
Serial Shipping Container Code (SSCC)	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	A tertiary pack that consists entirely of the same trade item with the same batch number and expiration date.
Tertiary mixed pack	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	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	A homogenous pack of products that is not to be considered a trade item because it is less than full.
Trade item	Any item (product or service) 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.

Term	Definition
Unique identifier	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.

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