# Product Identification and Labelling for Pharmaceutical Product Guidance and Template

**Version 1: September 2020**

USAID FROM THE AMERICAN PEOPLE

PEPFAR U.S. President's Emergency Plan for AIDS Relief

USAID FROM THE AMERICAN PEOPLE CDC

U.S. President's Malaria Initiative

# How to Use the Document

The Product Identification and Labelling for Pharmaceutical Products Guidance and Template document includes two sections: guidance and template. The guidance section provides key considerations that a country should use as decision points to aid in applying the template to the country context.

The template section is not intended to be prescriptive, but rather to serve as a guide for drafting identification and labeling requirements for pharmaceutical products. It is designed to provide trading partners with further information on how to implement existing regulations on labelling pharmaceutical products and medicines to be distributed on the country market. This section includes numerous provisions that must be tailored specifically to the country context. These provisions are noted in [blue brackets].

# Background

The Product Identification and Labelling for Pharmaceutical Products Guidance and Template document is intended for use by national drug regulatory authorities (NDRAs) alongside the Guidance Model Directive for Traceability Regulation Development (model directive) in developing pharmaceutical labelling and packaging requirements to advance supply chain security. The model directive helps countries think through in-country regulation and includes guidance in how to identify gaps and recognize areas of enhancement in line with the traceability implementation process. This document is intended to specify how to implement that regulation in accordance with good global practices that leverage GS1 standards.

Product identification and labelling requirements should reference existing regulations and statutory instruments such as ministerial orders on medicines control and packaging/labelling of the medicines in the country. Where such instruments do not exist, the NDRA should decide on the applicable country framework to regulate guidelines specified in this document.

# Key Considerations

| Focus Area | Key Consideration | Reference |
|---|---|---|
| Introduction | a. In this section, the NDRA should outline the goals that have been identified in the country's National Traceability Strategy that will be achieved through implementing global standards and traceability. | Section 1 |
| Description of Packaging Levels | a. Readers of the document should consult the *GS1 General Specifications* and the *GS1 AIDC Healthcare Implementation Guideline*, or their GS1 Member Organization for more information. | Sections 5 and 7 |
| Product Identification and Labelling Requirement for Pharmaceuticals | a. NDRAs should refer to existing regulation on whether or not 1) serialization is in scope for traceability implementation and 2) guidance on the type of barcode on packaging types should be updated to align with the regulation. | Section 6.1 |
| | b. In-scope and exempt commodities should align with those described in the statuary instrument. | Section 6 |
| | c. Dates for compliance with labelling and packaging requirements must align with those mandated in the statutory instrument. | Sections 6.1, 6.2, and 6.3 |
| | d. The NDRA may mandate the order in which data are encoded into the data carrier. Where there is no such mandate, it is recommended that fixed-length data elements precede variable-length elements. | Sections 6.1, 6.2, and 6.3 |
| Overview of Relevant Global Standards | a. This document is based on the use of the *GS1 General Specifications* as the primary reference document for technical specifications to implement in accordance with GS1 global standards. *GS1 General Specifications* should be considered as a reference, as specifications are subject to regular updates. | Section 7 |

# Product Identification and Labelling Requirements

## Government of [Country]

**Reference Regulation: No. …. of ……. /…. /2020**

**Governing the Implementation of Global Standards and Traceability for Pharmaceutical Products**



**For Comments:** [INSERT CONTACT INFORMATION]

For the latest updates, please visit the [REGULATORY AUTHORITY] website: [INSERT WEBSITE]

# Revision History

| Version | Author | Date | Comments |
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# Contents

# 1. Introduction

The Identification and Labelling Requirements for Pharmaceutical Products document outlines implementation requirements for those stakeholders in scope for meeting the identification and labelling provisions outlined in the [NAME OF STATUATORY INSTRUMENT].

[NAME OF COUNTRY STATUTORY INSTRUMENT] is established under the [ACT] whose main mandate: *[for example; is to ensure that all medicines and allied substances being made available to the country citizens consistently meet the set standards of quality, safety and efficacy].* With this mandate comes a need to provide guidelines for leveraging global standards to provide simplicity and consistency for product identification and labelling. These guidelines 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.

# 2. Rationale

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

# 3. Purpose

This document is intended to provide trading partners with further information on how to implement [COUNTRY REGULATORY AUTHORITY] Regulations on labelling pharmaceutical products and medicines to be distributed on the [COUNTRY] market. The information in this document is informed by existing good practices and GS1 global standards for labelling and packaging.

# 4. Scope

This document applies to all products that fall within the definition of pharmaceutical products [NAME OF COUNTRY STATUTORY INSTRUMENT].

# 5. Description of Packaging Levels[1]

## 5.1 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[2]
- A case that contains (one or usually) several items in the items' primary or secondary packaging[3]

[1] 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
[2] For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.4, Case/Shipper and Pallet.
[3] ibid.

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 Human Readable Interpretation (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.

#### 5.1.1 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. Often, the tertiary package logistic unit is a pallet but may also be an export carton.

The logistic unit is identified using the serial shipping container code (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.

#### 5.1.2 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.

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

### 5.2 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.[4] 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:

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 are required.**

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

### 5.3 Primary packaging

Primary packaging is the first level of packaging that is in direct contact with the item.[5] This packaging level is marked with a GS1 DataMatrix, either on the packaging itself or on a label affixed to the packaging.

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 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:

# 6. Product Identification and Labelling Requirements for Pharmaceuticals

Per [STATUTORY INSTRUMENT], the following pharmaceutical products are in scope for labelling and packaging requirements detailed in this section:

a. [in scope products]
b. [in scope products]
c. [in scope products]
……..

Per [STATUTORY INSTRUMENT] the following pharmaceutical products are exempt from the identification and labelling requirements detailed in this section: An example of this is as follows:

a. [exempted products]
b. [exempted products]
c. [exempted products]

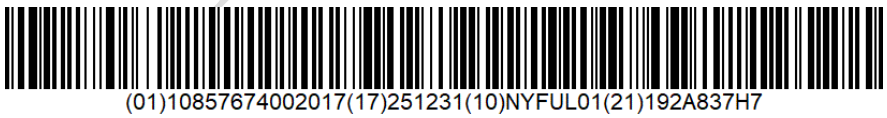
### 6.1 Tertiary pack trade item

All tertiary pack trade item packages must include a GS1-128 Linear Barcode or a GS1 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:

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




[4] For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.3, Secondary Package.
[5] For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.2, Primary Package.

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:

]d2011085767400201717251231 10NYFUL01<GS>21192A837H7

It is recommended to have fixed-length data elements precede variable-length elements. When a tertiary pack trade item is also considered a logistic unit, the SSCC can be applied in lieu of the serial number.

### 6.2 Tertiary pack logistic unit

All tertiary pack logistic units must include a GS1-128 Linear Barcode[6] encoded with the following information and printed adjacent to the data carrier in HRI:

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

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:

]c1000061414112345678 90



[6] 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.

### 6.3 Secondary pack trade item

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

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

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

]d201108576740020171725123110NYFUL01<GS>21192A837H7

It is recommended to have fixed-length data elements precede variable-length elements.

# 7. Overview of Relevant Global Standards[7]

## 7.1. Identify

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

***AI (00) Serial Shipping Container Code (SSCC)[8]***
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

***AI (01) Global Trade Item Number® (GTIN®)[9]***
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 of the item and are used to identify items as they move through the global supply chain to the hospital or ultimate end user.



[7] 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
[8] For more information, see *GS1 General Specifications*, Section 3.3.1, Identification of a logistic unit (SSCC): AI (00).
[9] For more information, see *GS1 General Specifications*, Section 3.3.2, Identification of a trade item (GTIN): AI (01).

The GTIN can be 8, 12, 13, or 14 digits in length. 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 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

***AI (10) batch/lot***[10]
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 → $X_{20}$ |

***AI (17) expiration date***[11]
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



[10] For more information, see *GS1 General Specifications*, Section 3.4.1, Batch or Lot Number: AI (10).
[11] 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 | $N_1$ | $N_2$ | $N_3$ | $N_4$ | $N_5$ | $N_6$ |

***AI (21) serial number***[12]
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 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 → $X_{20}$ |

## 5.2 Capture

All tertiary and secondary packages are recommended to be labelled in accordance with the specified barcode requirement, encoded with relevant GS1 Application Identifiers, and printed in their human readable form.[13]

All barcode symbols should meet print-quality "Grade C" (1.5 or above).[14] 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.

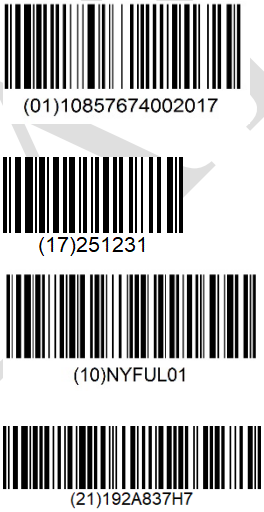
***GS1-128 barcode***[15]
A GS1-128 barcode is a linear barcode symbology using bars and spaces in one dimension that leverage a subset of Code 128 that is used exclusively for GS1 system data structures. A linear barcode can be concatenated (i.e., represent all elements of a data string in a single barcode) or non-concatenated (i.e., represent individual elements of a data string over two or more barcodes).

*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)




***GS1 DataMatrix***[16]

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

*Example of a GS1 DataMatrix for a logistic unit*

(00) 0 0614141 123456789 0



[12] For more information, see *GS1 General Specifications*, Section 3.5.2, Serial Number: AI (21).
[13] For more information, see *Ten Steps to GS1 Barcode Implementation User Manual*.
[14] For more information, see *GS1 General Specifications,* Section 5.5, Barcode Production and Quality Assessment.
[15] For more information, see *GS1 General Specifications,* Section 5.4, Linear Barcodes—GS1-128 Symbology Specifications.
[16] For more information, see *GS1 General Specifications,* Section 5.7, Two-dimensional barcodes—GS1 DataMatrix symbology.

*Example of a GS1 DataMatrix for a trade item*

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

## 8. Supporting Resources

***Find a GS1 Member Organization***
Provides a resource for finding a GS1 Member Organization 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

***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

## Annex A. 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 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) | A separator used as a barrier in between different data entry components 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 that is used exclusively for GS1 system data structures. |
| 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 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:<br>a) Is used in the diagnosis, treatment, mitigation, or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof<br>b) Is used in restoring, correcting, or beneficial modification of organic or mental functions in humans<br>c) Is articles other than food, intended to affect the structure or any function of the body of humans<br>d) 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. |
| 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. |
| 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. |