

Guideline for Identification and Labelling of Pharmaceutical Products

Template and Guidance

Version 2.0, January 2025



The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership.

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The views expressed in this publication do not necessarily reflect the views of the U.S. Agency for International Development or the U.S. government.

Introduction

The *Guideline for Identification and Labelling of Pharmaceutical Products Template and Guidance* document is intended for use by ministries of health (MoHs) and/or national drug regulatory authorities (NDRAs). It is designed to support implementation of existing regulation and statutory instruments such as ministerial orders on medicines control and packaging/labelling of medicines in the country. A guideline for identification and labelling of pharmaceutical products should provide those trading partners subject to an overarching regulation the information required to effectively comply. Where such instruments do not exist, the NDRA should decide on the applicable country framework to enforce this document.

This resource may be used alongside the *Model Directive for Traceability Regulation Template and Guidance*.¹ The model directive helps countries develop regulation and includes guidance on how to identify gaps and recognize areas of enhancement to support the traceability implementation process.

How to Use this Document

The document includes two sections: guidance and template. The guidance section provides key considerations that authorities should use as decision points to aid in applying the template to the local context.

The template provides a structure and illustrative text that can be adapted and adopted to define and convey product and identification guidelines, as they relate to GS1 global standards, for pharmaceutical manufacturers and suppliers, and other stakeholders, such as marketing authorization holders, donors, and care providers. The user will need to change the structure and content of the template to reflect context-specific requirements. If the language is adopted as is, the fields denoted in blue will need to be updated to reflect context-specific information. Also, where illustrative objectives are included, you will need to adapt these to reflect context-specific objectives. In the template, these objectives and organizations are depicted in *blue italics*.

This template and guidance document is intended for use by MoHs and/or NDRAs in implementing pharmaceutical traceability and/or standards adoption strategies. Each regulator must assess the current status and readiness of its market in meeting the described requirements to inform a) the extent to which requirements are already being met by the market b) market readiness to comply with the requirements detailed in the guideline, and c) any gaps that may exist in certain market segments (e.g., domestic manufacturing, specialized goods) that may require alternative implementation timelines.

¹ Available: <https://www.ghsupplychain.org/index.php/TraceabilityModelDirectivehttps://www.ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities>

Key Considerations

| Focus Area | Considerations | Template Section |
|---|---|------------------|
| Introduction | <ul style="list-style-type: none"> – Outline the goals that have been identified in the country’s National Traceability Strategy that will be achieved through the product identification and labelling guideline. – Ensure the purpose of the document is aligned with the country’s intention. – Ensure the scope of products affected by the guideline is aligned with the scope described in the regulation. | Section 1 |
| Product Identification and Labelling Requirement for Pharmaceuticals | <ul style="list-style-type: none"> – Refer to existing regulation to determine whether serialization is in scope for product identification and labelling. – Ensure dates for compliance with labelling and packaging requirements align with those mandated in the regulation. – Incorporate additional guidance or nuances that are described in the regulation but not included in this document. – Does not include primary packaging because identification and labelling of primary packaging is generally not regulated at this time, due to technical challenges with implementation. | Section 2 |
| Description of Packaging Levels | <ul style="list-style-type: none"> – This section is generic and should largely be applicable to any country implementation. – Primary packaging is included to define and differentiate from other levels of packaging, though is generally not recommended to be regulated at this time due to implementation feasibility. – If more information is required, consult the <i>GS1 General Specifications</i> and the <i>GS1 AIDC Healthcare Implementation Guideline</i>, or their GS1 Member Organization for more information. | Sections 3 |
| Overview of Relevant Global Standards | <ul style="list-style-type: none"> – This section is generic and should largely be applicable to any country implementation. – If more information is required, consult the <i>GS1 General Specifications</i> and the <i>GS1 AIDC Healthcare Implementation Guideline</i>, or their GS1 Member Organization for more information. | Section 4 |
| Additional Resources | <ul style="list-style-type: none"> – This section is generic and should largely be applicable to any country implementation. Confirm that resources reflect the latest version of reference documents, as these are periodically updated before publishing as part of the guideline. – Consider whether to add any additional national references that may support implementation | Section 5 |
| Glossary of Terms | <ul style="list-style-type: none"> – This section is generic and should largely be applicable to any country implementation. – Consider whether to add or adjust any additional definitions based on the relevant regulation | Annex A |

Guideline for Identification and Labelling of Pharmaceutical Products

Government of [Country]

Reference Regulation: No. of /.... /2021

For Inquiries: [INSERT CONTACT INFORMATION]

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

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Acronyms

| | |
|------|---|
| 2D | two-dimensional |
| AI | application identifier |
| AIDC | automatic identification and data capture |
| FNC1 | Function 1 Symbol Character |
| MO | GS1 Member Organization |
| GTIN | Global Trade Item Number |
| HRI | human readable interpretation |
| SSCC | Serial Shipping Container Code |

Template

Revision History

| Version | Author | Date | Comments |
|---------|--------|------|----------|
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Template

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 [NAME OF STATUTORY INSTRUMENT].

[NAME OF STATUTORY INSTRUMENT] is established under the [ACT] whose main mandate is to: *[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 guidance for complying with this [ACT], 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 [NDRA] seeks 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] with further information on how to implement [NDRA] regulations on labelling pharmaceutical products to be distributed in the [COUNTRY] market. The information in this document is informed by existing good practices and GS1 global standards for identification and data capture.

1.3. Scope

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

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 regulations. Readers should consult the *GS1 General Specifications*² and the *GS1 Automatic Identification and Data Capture (AIDC) Healthcare Implementation Guideline*,³ or their GS1 Member Organization,⁴ 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 [DDMMYY] |
| 10 | Batch/Lot | No later than [DDMMYY] |
| 17 | Expiration Date | No later than [DDMMYY] |
| 21 | Serial Number | No later than [DDMMYY] |

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

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



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



(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 |

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

² For more information, see <https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications>

³ For more information, see https://www.gs1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf

⁴ For more information, see <https://www.gs1.org/contact/overview>

]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 Barcode⁵ encoded with the following information and printed adjacent to the data carrier in HRI:

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

A SSCC may be re-used after a period of one year of the shipment date, as noted within the GS1 General Specifications.⁶

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:

]c10000614141123456789

2.3. Secondary pack trade item

⁵ 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 For more information, see *GS1 General Specifications*, Section 2.2.1, Individual Logistic Units – Application Description

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:

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

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

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.

3. Description of Packaging Levels⁷

This section includes descriptions of each level of the packaging hierarchy. Readers should consult the *GS1 General Specifications*⁸ and the *GS1 AIDC Healthcare Implementation Guideline*,⁹ 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 cases¹⁰
- A case that contains (one or usually) several items in the items' primary or secondary packaging¹¹

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 data carriers 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 unpalletized shipper box or export carton in some circumstances.

A homogenous logistic unit contains entirely of the same trade item, with the same batch/lot and expiration date. A heterogeneous logistic unit may contain different trade items, or the same trade item with mixed batches and/or expiration dates (e.g., a partial or mixed pack).

The logistic unit is identified using the SSCC. This packaging level is marked with a GS1-128 linear barcode with the option to also include a GS1 DataMatrix,¹² either on the packaging itself or on a label affixed to the packaging.

⁷ 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>

⁸ For more information, see <https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications>

⁹ For more information, see https://www.gs1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf

¹⁰ For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.4, Case/Shipper and Pallet.

¹¹ *ibid.*

¹² For more information, see GS1 General Specifications, Section 2.2.1, Individual 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. 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. A mixed or partial pack trade item is identified with an SSCC.

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.¹³ 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:

¹³ 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.¹⁴ 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 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:



¹⁴ For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.2, Primary Package.

4. Overview of Relevant Global Standards¹⁵

A summary of the GS1 standards relevant to [NAME OF STATUTORY INSTRUMENT] are described in this section. This document is based on the use of the *GS1 General Specifications*¹⁶ as the primary reference document for technical specifications to implement in accordance with GS1 global standards. Since changes are regular, the latest version of the *GS1 General Specifications* should always be considered.

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 Code¹⁷

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

4.1.2. AI (01) Global Trade Item Number¹⁸

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. Reuse of a GTIN is not permitted.

¹⁵ 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>

¹⁶ For more information, <https://www.gs1.org/standards/barcodes-epc/efid-id-keys/gs1-general-specifications>

¹⁷ For more information, see *GS1 General Specifications*, Section 3.3.1, Identification of a logistic unit (SSCC): AI (00).

¹⁸ 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>

4.1.3. AI (10) batch/lot¹⁹

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 date²⁰

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 mandatory

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 |

¹⁹ For more information, see *GS1 General Specifications*, Section 3.4.1, Batch or Lot Number: AI (10).

²⁰ For more information, see *GS1 General Specifications*, Section 3.4.7, Expiration Date: AI (17).

4.1.5. AI (21) serial number²¹

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 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, and printed in their human readable form.²²

All barcode symbols should meet print-quality "Grade C" (1.5 or above).²³ 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 (MO) 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 barcode²⁴

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). It is strongly preferred that trading partners implement concatenated barcodes wherever possible to facilitate scanning operations throughout the value chain.

Example of a GS1-128 barcode for a logistic unit

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

²² For more information, see *Ten Steps to GS1 Barcode Implementation User Manual*.

²³ For more information, see *GS1 General Specifications*, Section 5.5, Barcode Production and Quality Assessment.

²⁴ For more information, see *GS1 General Specifications*, Section 5.4, Linear Barcodes—GS1-128 Symbology Specifications.



Example of a GS1-128 barcode for a trade item

Concatenated (preferred)



Non-concatenated (only if necessary)



4.2.2. GS1 DataMatrix²⁵

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.

Example of a GS1 DataMatrix for a logistic unit



Example of a GS1 DataMatrix for a trade item

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



²⁵ For more information, see *GS1 General Specifications*, Section 5.7, Two-dimensional barcodes—GS1 DataMatrix symbology.

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>

GS1 GTIN Healthcare Allocation Rules

Provides the rules for assigning GTINs to trade items in the health sector.

https://www.GS1.org/docs/gsmf/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.

<https://www.ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities>

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 |
|--|---|
| 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 or square dark bars; and pale spaces. |
| batch/lot | 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. |
| DataMatrix | A standalone, 2D matrix symbology that is made up of square modules arranged within a perimeter finder pattern. |
| 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 access to play an active role in 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. |
| health care secondary packaging | A level of packaging marked with a data carrier that may contain one or more primary packages each of which may contain a single item or multiple items. |
| Human Readable Interpretation (HRI) | 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. |
| logistic unit | An item of any composition established for transport and/or storage of pharmaceuticals that needs to be managed through the supply chain. |

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| 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 substances, manufactured, sold, or presented as capable of preventing and treating human or animal diseases and any other substance intended for administration to a human being or an animal to diagnose diseases, restore, correct, or carry out modification of organic or mental functions. It does not include medical devices or their components, parts, or accessories. |
| serial number | A code, numeric or alphanumeric, assigned to an individual instance of an item for its lifetime. |
| Serial Shipping Container Code (SSCC) | The GS1 identification key used to identify logistic 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 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. |