

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

PROCUREMENT AND SUPPLY MANAGEMENT

GLOBAL STANDARDS TECHNICAL IMPLEMENTATION GUIDELINE

**Product and Location Identification, Labeling, and Data
Exchange**

Version 1.0, January 2018



U.S. President's Malaria Initiative

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DISCLAIMER

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

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ACRONYMS

AI	GSI Application Identifier
AIDC	 automatic identification and data capture
ASAP	as soon as possible
ASN	 advanced ship notice
CBV	 Core Business Vocabulary
EDI	 electronic data interchange
EPCIS	 Electronic Product Code Information Services
ERP	enterprise resource planning
FAQ	 frequently asked question
IEC	 International Electrotechnical Commission
ISO	 International Standards Organization
IT	information technology
GDSN	 Global Data Synchronization Network
GHSC	Global Health Supply Chain
GLN	 Global Location Number
GSMP	 Global Standards Management Process
GTIN	Global Trade Item Number
HRI	 human readable interpretation
MIS	management information system
MO	 GSI Member Organization
NLT	no later than
PSM	Procurement and Supply Management
RDC	 regional distribution center
RFID	radio frequency identification device
SSCC	serial shipping container code
SDP	 service delivery point
SKU	stock keeping unit
TDM	 technical direction memorandum
USAID	U.S. Agency for International Development

REVISION HISTORY

Date	Version no.	Description of change	Author
Jan 1, 2018	1.0	Initial document	K. Roche

INTRODUCTION

Chemonics is acting on behalf of the U.S. Agency for International Development (USAID) to implement the Global Health Supply Chain-Procurement and Supply Management (GHSC-PSM) project. The purpose of the project is to:

- Serve as the primary vehicle through which USAID will procure and provide health commodities for all USAID health programs, including but not limited to HIV/AIDS, Malaria, Reproductive Health, and Maternal and Child Health
- Provide systems strengthening technical assistance to improve supply chain management and commodity security in partner countries

Through the project, lifesaving health commodities will be delivered to many of the world's most vulnerable people.

USAID TECHNICAL DIRECTION

For many years, USAID has been investigating the use of global standards to improve the management of health commodity procurements. Through a technical direction memorandum (TDM) issued on April 25, 2017, USAID has instructed GHSC-PSM to:

- Develop a contract requirement for implementing global standards for product identification, labeling, and data exchange
- Seek to harmonize requirements and implementation timelines with other global stakeholders
- Design its management information system to support and exchange data leveraging global standards
- Support country governments in regulating global standards, product authentication, and track-and-trace solutions

ABOUT THE GHSC-PSM REQUIREMENT

In response to the TDM, on May 15, 2017, GHSC-PSM issued a notice to suppliers announcing the implementation of global standards for product identification, labeling, and data exchange.¹ Under this new requirement, all pharmaceuticals, medical devices, sterile test kits, and reagents should be identified and labeled at various packaging levels using the GS1 system of standards.

GHSC-PSM developed this requirement to address challenges in supply chain data visibility, supply chain efficiency, and supply chain security in the GHSC-PSM global supply chain and the national supply chains of USAID-supported country programs. Implementing global standards will enable these stakeholders to develop automation, authentication, and track-and-trace solutions to address these issues, which will

¹ *Announcement of Intention to Implement Global Standards for Product Identification, Labeling, and Data Exchange.*
https://www.ghsupplychain.org/sites/default/files/2017-05/PSM_Announcement%20of%20Global%20Standards%20Contract%20Requirements_FINAL.pdf

benefit stakeholders across the supply chain, from manufacturers to patients, including procurement agencies, wholesalers, distributors, importers, and healthcare providers. Adopting globally harmonized standards for product identification and data exchange is a critical step in addressing these issues.

The requirement mandates the use of product serialization for pharmaceuticals at the trade packaging level, both secondary and tertiary. Serialization enables implementation of a comprehensive system to track and trace the movement of drugs through the entire supply chain. By identifying every product with a globally unique product number (Global Trade Item Number® (GTIN®)), and by capturing information on its expiration date, batch/lot number, and unique serial number (where applicable), the product's lifecycle can be tracked from production to distribution across borders, all the way to its dispensation to patients at a hospital, clinic, pharmacy, or other service delivery point.

In addition to the identification and labeling requirements outlined in the specifications, manufacturers/brand owners/responsible entities will submit product master data to GHSC-PSM through the GS1 Global Data Synchronization Network™ (GDSN®).

ABOUT THIS DOCUMENT

The GHSC-PSM Global Standards Technical Implementation Guideline is a resource developed for GHSC-PSM trading partners to inform the implementation of contract requirements for product and location identification, labeling, and data exchange. GHSC-PSM recommends using the GS1 General Specification as the primary reference document for technical specifications to meet the requirement in accordance with GS1 global standards.

DISCLAIMER

In any document that speaks to procurement requirements, each company is also individually responsible for meeting all statutory and/or regulatory requirements for the company and its products. Consult with your company's legal counsel or compliance team (regulatory or quality) for more specific information about statutory and regulatory requirements on a country-by-country basis beyond those detailed in this document.

OVERVIEW OF THE REQUIREMENT FOR PHARMACEUTICALS

The requirements specify the following **minimum** use of GS1 identification keys and data carriers labeled on pharmaceutical products at various packaging levels:

Packaging level	Packaging type	Requirement	Human readable interpretation (HRI)	Timeline
Tertiary: logistic unit		GS1-128 barcode ² symbology encoded with: Serial shipping container code (SSCC)	Information printed in human readable format: SSCC	As soon as possible (ASAP) but no later than (NLT) June 30, 2022
Tertiary: trade item	Homogenous	GS1 DataMatrix or GS1-128 barcode symbology encoded with: - GTIN - Batch/lot - Expiration date - Serial number	Information printed in human readable format: - GTIN - Batch/lot - Expiration date - Serial number	For GTIN, batch/lot, and Expiration date, ASAP but NLT December 30, 2018 For serial number, NLT June 30, 2022
	Mixed or partial	GS1-128 barcode ³ symbology encoded with: SSCC	Information printed in human readable format: SSCC	ASAP but NLT June 30, 2022
Secondary: trade item		GS1 DataMatrix symbology encoded with: - GTIN - Batch/lot - Expiration date - Serial number	Information printed in human readable format: - GTIN - Batch/lot - Expiration date - Serial number	For GTIN, batch/lot, and Expiration date, ASAP but NLT June 30, 2020 For serial number, ASAP but NLT June 30, 2022
Primary: trade item Optional; Required only when the product is supplied in carton-less packaging.		GS1 DataMatrix symbology encoded with: - GTIN - Batch/lot - Expiration date - Serial number	Information printed in human readable format: - GTIN - Batch/lot - Expiration date - Serial number	Optional

² If and when the GS1 DataMatrix is recommended for use on the logistic unit in the GS1 General Specification, suppliers are permitted to use that data carrier to meet the GHSC-PSM logistic unit labeling requirement.

³ If and when the GS1 DataMatrix is recommended for use on the logistic unit in the GS1 General Specification, suppliers are permitted to use that data carrier to meet the GHSC-PSM logistic unit labeling requirement.

OVERVIEW OF THE REQUIREMENT FOR MEDICAL DEVICES, STERILE KITS, AND LABORATORY REAGENTS

The requirements specify the following **minimum** use of GS1 identification keys and data carriers labeled on medical devices, sterile kits, and laboratory reagents at various packaging levels:

Packaging level	Packaging type	Requirement	HRI	Timeline
Tertiary: logistic unit		GS1-128 barcode ⁴ symbology encoded with: • SSCC	Information printed in human readable format • SSCC	ASAP but NLT June 30, 2022
Tertiary: trade item	Homogenous	GS1 DataMatrix or GS1-128 barcode symbology encoded with: • GTIN And when applicable: • Batch/ILot • Expiration date	Information printed in human readable format: • GTIN And when applicable: • Batch/lot • Expiration date	ASAP but NLT December 30, 2018
	Mixed or partial	GS1-128 barcode ⁵ symbology encoded with: • SSCC	Information printed in human readable format: • SSCC	ASAP but NLT June 30, 2022
Secondary: trade item		GS1 DataMatrix or GS1-128 barcode symbology encoded with: • GTIN And when applicable: • Batch/lot • Expiration date	Information printed in human readable format: • GTIN And when applicable: • Batch/lot • Expiration date	ASAP but NLT June 30, 2020
Primary: Trade Item Optional; required only when the product is supplied in carton-less packaging.		GS1 DataMatrix or GS1-128 barcode symbology encoded with: • GTIN And when applicable: • Batch/lot • Expiration date	Information printed in human readable format: • GTIN And when applicable: • Batch/lot • Expiration date	Optional

⁴ If and when the GS1 DataMatrix is recommended for use on the logistic unit in the GS1 General Specification, suppliers are permitted to use that data carrier to meet the GHSC-PSM logistic unit labeling requirement.

⁵ If and when the GS1 DataMatrix is recommended for use on the logistic unit in the GS1 General Specification, suppliers are permitted to use that data carrier to meet the GHSC-PSM logistic unit labeling requirement.

DESCRIPTION OF PACKAGING LEVELS⁶

This section includes summary descriptions and examples of each level of the packaging hierarchy as it relates to the GHSC-PSM implementation requirement. Levels are defined and should be referenced in the GS1 General Specification.

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
- A case that contains (one or usually) several items in their primary or secondary packaging

Tertiary packaging may be used as either a logistic unit or as a trade item. Tertiary packages can be homogenous (i.e., consisting entirely of the same trade item, batch/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).

Labels containing the barcode symbols, with their associated HRI, should be positioned on two faces of the tertiary packaging to enable ready access for scanning when the product is stored, stocked on shelves, or handled.

Logistic Unit

A logistic unit is an item of any composition established for transport and/or storage that needs to be managed through the supply chain. In this instance, the tertiary package logistic unit refers to the logistic units issued by the supplier to GHSC-PSM. In most instances, the tertiary package logistic unit will be the pallet, but may also be an export carton.

The logistic unit is identified using the SSCC. This packaging level is marked with a GS1-128 linear barcode.⁷

Trade Item

Trade items are products and services upon 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 Global Trade Item Number (GTIN), batch/lot number, expiration date, and serial number. A mixed or partial pack trade item is identified with an

⁶ For more information, see GS1 General Specifications – Section 8.1 GS1 Glossary of Terms and Definitions

⁷ If and when the GS1 DataMatrix is recommended for use on the logistic unit in the GS1 General Specification, suppliers are permitted to use that data carrier to meet the GHSC-PSM logistic unit labeling requirement.

SSCC. This packaging level can be marked with a GS1-I28 linear barcode or a GS1 DataMatrix, with a strong preference for a GS1 DataMatrix.

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



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. This packaging level is marked with a GS1 DataMatrix, either on the packaging or on a label affixed to the packaging.

Pharmaceutical products and medical devices 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 for GHSC-PSM.**

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

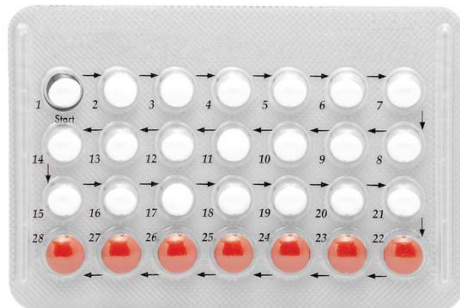
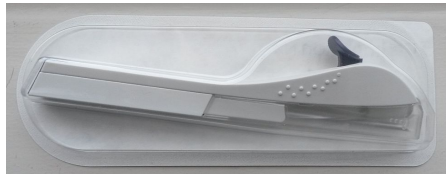


PRIMARY PACKAGING

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

Marking products at this level is optional, unless the supplier is providing items in “carton-less packaging,” i.e., without a secondary packaging level.

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



OVERVIEW OF GS1 STANDARDS USED

Current supply chain management practices in global health supply chains inhibit optimization of information technology (IT) systems and drain supply chain business processes. GHSC-PSM is committed to incorporating lessons learned over the last decade of global health supply chain management and exploring industry innovations that will lead to a better, more efficient supply chain. Adoption of global standards is a central part of that effort as a strategic enabler for supply chain efficiency, effectiveness, and innovation for numerous industries across the globe. Therefore, to reduce costs, enhance efficiency, and improve the availability of health commodities worldwide, GHSC-PSM is committed to implementing and using the global standards detailed below to identify, capture, and share.

IDENTIFY

GHSC-PSM will leverage the GS1 Application Identifiers (AIs) referenced in this section 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	SSCC (Serial Shipping Container Code)																	
	Extension digit	GS1 Company Prefix →										Serial reference ←						
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 Specification and the following resources:

- <http://www.gs1.org/barcodes/technical/idkeys/sscca>
- 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., products that may be priced, ordered, or

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)

invoiced). GTINs are assigned by the brand owner of the product and are used to identify products as they move through the global supply chain to the hospital or ultimate end user.

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					
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 Specification and the following resources:

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

AI (10) Batch/lot¹⁰

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

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 date¹¹

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

The format of the expiration date is as follows:

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)

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 number¹²

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 medicinal product 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

Global Location Number (GLN)¹³

The GLN is the GS1 standards-based, globally unique identifier for supply chain parties and locations. It enables supply chain partners to use the same standards-based identifier to identify parties and locations in a standardized data format. Supply chain partners use GLNs to identify parties and locations in all supply chain transactions, supply chain communications, and internal systems.

GHSC-PSM does not require the GLN to be labeled on packaging, but will leverage GLNs in the data exchange process. Chemonics' GLN is **0858939007009** and will be used by the GHSC-PSM as the identifier for AI (410) Bill to — Invoice to in procurement transactions.

GHSC-PSM expects suppliers to assign and provide GLNs for the following entities at a minimum:

- GLN for data sync
- AI (414) GLN for identification of a physical location, to be provided for the location a product will ship from¹⁴
- AI (415) GLN of the invoicing party¹⁵
- AI (416) GLN of the production or service location¹⁶

¹² For more information, see GS1 General Specifications, Section 3.5.2, Serial Number: AI (21)

¹³ For more information, see GS1 General Specifications, Section 4.6, GLN Rules

¹⁴ For more information, see GS1 General Specifications, Section 3.7.9, Identification of a physical location — Global Location Number: AI (414)

¹⁵ For more information, see GS1 General Specifications, Section 3.7.10, Global Location Number of the invoicing party: AI (415)

¹⁶ For more information, see GS1 General Specifications, Section 3.7.11, GLN of the production or service location: AI (416)

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

- <https://www.gs1.org/gln>
- https://www.gs1.org/docs/healthcare/GLN_Healthcare_Imp_Guide.pdf

CAPTURE

Per GHSC-PSM requirements, all tertiary and secondary packages should be labeled in accordance with the specified barcode requirement, encoded with relevant GS1 Application Identifiers, and printed in their human readable form.

All barcode symbols should meet print-quality “Grade C” (1.5 or above).¹⁷ 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 (MOs) provide comprehensive barcode verification services to ensure companies are implementing barcode labeling requirements to specification based on optical and data structure requirements.

GS1-128 Barcode¹⁸

A GS1-128 barcode is 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 tertiary package: logistic unit



Example of a GS1-128 barcode for a tertiary package: trade item

Concatenated (preferred)

¹⁷ For more information, see GS1 General Specifications — Section 5.5, Barcode Production and Quality Assessment.

¹⁸ For more information, see GS1 General Specifications, Section 5.4, Linear Barcodes — GS1-128 Symbology Specifications.



(01)10857674002017(17)141120(10)NYFUL01(21)192837

Non-concatenated (only if necessary)



(01)10857674002017



(17)141120



(10)NYFUL01



(21)192837

GS1 DataMatrix¹⁹

A GS1 DataMatrix is a standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. DataMatrix symbols are read by two-dimensional imaging scanners or vision systems.

The GS1 DataMatrix is the preferred barcode symbology for trade items. If and when the GS1 DataMatrix is recommended for use on the logistic unit in the GS1 General Specification, suppliers are permitted to use that data carrier to meet the GHSC-PSM logistic unit labeling requirement.

Example of a GS1 DataMatrix for a tertiary package — trade item or secondary package

¹⁹ For more information, see GS1 General Specifications, Section 5.7, Two-dimensional barcodes — GS1 DataMatrix symbology



(01)10857674002017
(17)141120
(10)NYFUL01
(21)192837

SHARE

Master Data

GHSC-PSM has adopted and implemented the GS1 Global Data Synchronization Network™ (GDSN®) to receive item attribute information as the basis of our product catalog, and seeks the benefits of synchronizing product data with trading partners for new and existing items. Using the GDSN process will help improve supply chain data quality and management for all of our trading partners. It will provide USAID-supported countries with the information they need to optimize decision-making for GHSC-PSM order planning, procurement, shipping, and receiving. Master data received from synchronization will allow countries to make the best purchasing decisions when ordering life-saving commodities for global health programs across the world.

All suppliers of pharmaceuticals, medical devices, sterile kits, and laboratory reagents are expected to register with the GDSN and complete data sync with GHSC-PSM by December 30, 2019. The GHSC-PSM Data Sync Implementation Guide and GHSC-PSM Data Attribute Guide (on our landing page at www.1worldsync.com/customer-page/ghsc-psm) includes instructions for registering with a GDSN data pool provider and initial priority attributes expected to be provided as relevant on products supplied to GHSC-PSM.

Transaction Data

At the point when the supplier implements the product identification and labeling requirements, the primary identification number on all transaction documentation provided to GHSC-PSM — including but not limited to the packing list, commercial invoice, and advanced ship notice (ASN) — must reflect the GTIN for the products included within. The packing list must also include SSCCs for logistic units once applied to the logistic unit label.

Event Data

GHSC-PSM does not currently have a requirement to share event data.

IMPLEMENTATION PROCEDURES

To meet the GHSC-PSM requirement, all suppliers will be required to register their products and locations with GS1. The following steps are illustrative and can be used as a guide based on experience with other implementations.

REGISTER WITH A GS1 MEMBER ORGANIZATION TO OBTAIN A GS1 COMPANY PREFIX

- Contact information for GS1 MOs can be found here: <https://www.gs1.org/contact/overview>
- More information on how to obtain a GS1 Company Prefix can be found here: <https://www.gs1.org/company-prefix>

UNDERGO TRAINING AND EDUCATION

GS1 and certified solution providers can assist companies in training and education to support implementation and compliance with the GHSC-PSM requirement.

ASSIGN GLOBALLY UNIQUE IDENTIFICATION NUMBERS TO ITEMS AND LOCATIONS

Allocate a unique GTIN to each item and GLN to each business entity that transacts with GHSC-PSM. For more information on how to generate and maintain GTINs and GLNs, please contact your GS1 MO and refer to the to the GS1 General Specification. The following resources are also available:

- <http://www.gs1.org/gtin>
- <https://www.gs1.org/gln>

INTEGRATE PRODUCT AND LOCATION IDENTIFICATION INFORMATION INTO INTERNAL SOFTWARE APPLICATIONS

Suppliers will have to capture the GTINs, GLNs, and other related attributes like name, description, content, etc. in enterprise resource planning (ERP) applications or other internal software applications. Parent-child relationships for product GTINs should be maintained in the database that links the primary, secondary, and tertiary GTINs of each product and its variants.

IDENTIFY A GDSN-CERTIFIED DATA POOL AND SHARE PRODUCT MASTER DATA WITH GHSC-PSM

A list of GDSN-certified data pool providers can be found on the GS1 website: <https://www.gs1.org/services/gdsn/certified-data-pools>.

The GHSC-PSM Data Sync Implementation Guide and GHSC-PSM Data Attribute Guides include instructions for registering with a GDSN data pool provider and initial priority attributes expected to be provided as relevant for products supplied to GHSC-PSM. Those resources and additional information can be found on GHSC-PSM's GDSN landing page: www.1worldsync.com/customer-page/ghsc-psm

IMPLEMENT LABELING

Evaluate printing software and hardware

When choosing or using existing printer software, check the capability to properly format/encode, and print GS1 symbol(s) in accordance with the coding and marking guidelines provided in this document and the GS1 General Specifications.

The position of the barcode on the packaging will need to be checked to ensure that it meets the use case and any requirements within the GS1 General Specifications.²⁰ Any final labeling or wrapping should also be examined to ensure that the barcodes remain visible and easy to scan.

Identify solution providers

For barcoding and printing solutions, companies can approach solution providers registered with GS1 for various barcoding, hardware/software, consumables, and other services. Details on solution providers are available at <https://www.gs1.org/spfinder>.

²⁰ For more information, see GS1 General Specifications, Section 6, Symbol Placement Guidelines.

RESOURCES

TRANSITION GUIDANCE

Until the supplier can comply with the trade item tertiary pack labeling requirement identified in Sections 1 and 2 (except serialization), trade item tertiary packs must be labeled with the GHSC-PSM stock-keeping unit (SKU), batch/lot, expiration date, and quantity in human readable form at a minimum.

Once a supplier is ready to transition to the new requirement, GTINs and relevant product master data must be provided to GHSC-PSM through the GDSN, or the GHSC-PSM Product Master Form until the point at which data synchronization through the GDSN is compulsory. Once GHSC-PSM confirms receipt of the master data, shipments will be accepted with the GTIN labeling requirement.

GHSC-PSM RESOURCES

GHSC-PSM's primary contact for global standards is:

Kaitlyn Roche
Manager, Global Standards
+1 (202) 558-5890
globalstandards@ghsc-psm.org

GHSC-PSM's primary contact for master data synchronization is:

Samuel Oh
Product Catalog Manager
+1 (202) 558-5772
datasync@ghsc-psm.org

GS1 RESOURCES

A total 112 GS1 MOs are globally available to support registration, training and education, and implementation. Information on how to contact GS1 is available here:

<https://www.gs1.org/contact/overview>

GDSN RESOURCES

A total 39 GSDN-certified data pools are available to support registration, training and education, and implementation. Information on those organizations is available here: <https://www.gs1.org/gdsn/certified-data-pools>. More information on syncing data with GHSC-PSM can be found on our GDSN landing page: www.1worldsync.com/customer-page/ghsc-psm

ANNEX A: GLOSSARY OF TERMS

A glossary of key terms is provided below. GHSC-PSM recommends that suppliers consult the GS1 General Specification and use references and terms therein whenever available.

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 dark bars and pale spaces.
barcode verification*	The assessment of the printed quality of a barcode based on International Standards Organization (ISO)/International Electrotechnical Commission (IEC) standards using ISO/IEC-compliant bar code verifiers.
batch/lot*	The batch or lot number associates an item with production information that the manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained in it.
brand owner*	The organization that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is normally responsible for managing the GTIN.
DataMatrix*	A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern.
Global Trade Item Number	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 standards in the world.
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.
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 AISBL. *GS1 General Specification*. Release 17.1, Ratified July 2017.

GS1 Company Prefix*	A globally unique string of four to twelve digits assigned to an entity and used to issue GS1 identification keys. The first digits are a valid GS1 prefix and the length must be at least one longer than the length of the GS1 prefix. The GS1 Company Prefix is issued by a GS1 Member Organization. As the GS1 Company Prefix varies in length, the issuance of a GS1 Company Prefix excludes all longer strings that start with the same digits from being issued as GS1 Company Prefixes.
GS1 DataMatrix*	GS1 implementation specification for use of the DataMatrix.
GS1 Healthcare	A global, voluntary user group that develops standards to advance global harmonization. GS1 Healthcare consists of manufacturers, wholesalers, distributors, hospitals, and pharmacy retailers and maintains close contacts with regulatory agencies and trade organizations worldwide. It drives the development of GS1 standards and solutions to meet the needs of the global healthcare industry and promotes the effective use and implementation of global standards for the industry.
GS1 Identification Key*	A unique identifier for a class of objects (e.g., a trade item) or an instance of an object (e.g., a logistic unit).
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 the Global Standards Management Process.
healthcare 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 nonsterile packaging, the first level of packaging can be the packaging 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.
healthcare 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*	Characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The human readable interpretation is a one-to-one illustration of the encoded data. However, start, stop, shift, and function characters, as well as the symbol check character, are not shown in the human readable interpretation.
logistic unit*	An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with an SSCC.

manufacturer	An entity that makes or produces drugs, pharmaceutical, or medical devices through a process involving raw materials, components, or assemblies, usually on a large scale.
medical device*	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for any medical purpose.
serial number*	A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined GTIN and serial number.
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.
solution provider	A vendor that provides technical or service support to a company. It offers companies hardware, software, guidance, resources, and tools in a variety of areas. Examples are barcode services, including labels, printing, designing, and verifying; barcode hardware, including printers, readers, and scanners; and barcode software.
supplier	An entity with which GHSC-PSM has a contractual relationship for providing one or more trade items. The supplier is involved or plays a role in the buying, selling, or production of the pharmaceutical or medical device and can be a manufacturer, brand owner, wholesaler, or distributor.
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, or ordered, or invoiced at any point in any supply chain.

ANNEX B: FREQUENTLY ASKED QUESTIONS

This document provides answers to frequently asked questions (FAQs) by the industry. It has been created to aid trading partners across the global supply chain in applying GS1 Standards to GHSC-PSM requirements.

The questions in this document are organized into four main sections:

- Section 1, IDENTIFY: Questions about GS1 identification numbers, including the identification of trade items (products), logistic units, parties, and locations
- Section 2, CAPTURE: Questions about data carriers
- Section 3, SHARE: Questions about GS1 data sharing standards Global Data Synchronization Network
- Section 4: Additional questions beyond the above three topics

SECTION 1: IDENTIFY

The questions in this section address identifying things — assigning a GS1 identification number to items and locations so that it can be unambiguously referenced in data that is captured within an organization and shared with other organizations.

1.1 Questions about the GTIN²¹

The questions in this section address identifying trade items (products) using the GTIN.

1.1.1 What is a GTIN?⁺

The GTIN is the globally unique GS1 identification number used to identify “trade items” (i.e., products and services that may be priced, ordered, or invoiced at any point in the supply chain). It is assigned by the brand owner of the product and is used to identify products as they move through the global supply chain to the hospital or consumer/patient. The GTIN is used to uniquely identify a product at each packaging level (a bottle of 30 tablets, a case of 100 bottles of tablets, etc.).

1.1.2 What happens when my case quantity changes? Do I need another GTIN?⁺

Yes. You need a new GTIN to identify a case containing a different number of trade items or to identify a predefined pallet configuration containing a different quantity of cases.

1.1.3 How do I communicate my GTINs to GHSC-PSM?

GHSC-PSM is using the GDSN to receive master data from our trading partners. Additional information on syncing data with GHSC-PSM can be found on our GDSN landing page:

<http://www.1worldsync.com/customer-page/ghsc-psm>

²¹ For more information, see GS1 General Specifications, Section 4.3, GTIN Rules

⁺ GS1 US. *Frequently Asked Questions by the Pharmaceutical Industry in Preparing for the U.S. DSCSA*. Release 1.0, May 23, 2017.

1.1.4 What is the difference between a GTIN and a serial number?

Each trade item is assigned a unique GTIN, but each *instance* of a given trade item receives a different serial number. For example, a particular GTIN might be assigned to identify the trade item “30-tablet bottle of drug XYZ.” All 30-tablet bottles of drug XYZ will have the same GTIN, but each individual 30-tablet bottle of drug XYZ will have a different serial number.⁺ The unique combination of GTIN and serial number can be used to track and trace that one individual bottle through the supply chain.

1.1.5 What is the human readable interpretation?*

HRI is the printed representation of the data encoded in a barcode (e.g., GS1 DataMatrix or GS1-128 barcode). HRI text always appears immediately adjacent to the barcode and is subject to formatting rules specified in the *GS1 General Specifications*.²²

A label may also repeat other information found in the barcode, such as the expiration date or lot number, on some part of the label not near the barcode. Such printed information is not considered HRI and is not subject to GS1 formatting rules (although other regulations governing label content may apply).

1.2 Questions about the SSCC²³

The questions in this section address identifying logistic units using the SSCC.

1.2.1 What is a Serial Shipping Container Code?*

The SSCC is the globally unique GS1 identification number used to identify individual logistic units. A “logistic unit” is defined as an item of any composition established for transport and/or storage that needs to be tracked individually and managed through the supply chain.

Common logistic units in the pharmaceutical industry include a pallet of cases picked to order, a mixed case of items picked to order, or a homogeneous case of items that contains fewer than a full case. Unlike a trade item, each logistic unit contains different contents.

1.2.2 What is an SSCC used for?*

The SSCC is assigned for the lifetime of the transport item and is a mandatory element on the GS1 logistic label. SSCCs serve as “license plates” to facilitate simple tracking of goods and reliable look-up of complex load detail. The SSCC enables the logistic unit to be tracked individually, which brings benefits for order and delivery tracking and automated goods receiving. Because the SSCC provides a unique number for the delivery, it can be used as a lookup number to provide detailed information on load contents.

1.2.3 Who generates an SSCC?*

The shipping party creates the SSCC. When building a shipment for the buyer, the shipping party creates an SSCC using the shipper’s GS1 Company Prefix (see Section 2.4) and places a

⁺ GS1 US. *Frequently Asked Questions by the Pharmaceutical Industry in Preparing for the U.S. DSCSA*. Release 1.0, May 23, 2017.

²² For more information, see GS1 General Specifications, Section 4.14 Human Readable Interpretation (HRI) Rules

²³ For more information, see GS1 General Specifications, Section 4.4 SSCC Rules

logistics label containing the SSCC on the shipping unit (e.g., tote, pallet). Suppliers are responsible for assigning (allocating) SSCCs to their logistic units.

1.2.4 Under which circumstances can an SSCC be reused?

When assigning an SSCC, the rule per the GS1 General Specification is that an individual SSCC number must not be reallocated within one year of the shipment date from the SSCC assignor to a trading partner.²⁴

1.2.5 How is an SSCC different from a GTIN?*

SSCCs are distinctly different from GTINs. The SSCC acts as a license plate to track a shipment of logistic units through the supply chain. The GTIN uniquely identifies trade items (products and services).

1.2.6 My company already has a GS1 Company Prefix, which it uses to assign GTINs. Does my company need another GS1 Company Prefix to use SSCCs?*

No. You can use the same GS1 Company Prefix that you already use for GTINs to create SSCCs. If you have more than one GS1 Company Prefix, you can use any or all of them to create SSCCs (and so you will have greater capacity than if you just had one GS1 Company Prefix).

1.2.7 Can I use a SSCC when shipping partial homogeneous cases? What about mixed cases?*

Yes to both. SSCCs should be used to identify partial cases of homogeneous items or mixed cases of different items.

1.2.8 Can I have a GTIN and a SSCC together?

The GTIN and SSCC exist on the same package only when the package is both a logistic unit and a trade item. When the GTIN and SSCC are labeled on the same package, they should be captured in separate data carriers.

If a package is a trade item (e.g., an individual unit of use or a homogeneous case of fixed composition), it will carry a GTIN; if a package is a logistic unit and/or a mixed or partial pack, it will carry an SSCC.

An exception is a homogeneous case of fixed composition that is manufactured and marked with serial number + GTIN, but later that case is shipped *by itself* and so is also a logistic unit for the purpose of that shipment. In that scenario, the case must be given an SSCC as well, at the point in the supply chain where it becomes a logistics unit. For purposes of data reporting, the case serial number + GTIN would be considered as packed inside the logistic unit SSCC (that is, the SSCC just has one serial number + GTIN as its contents), even though they are the same physical package.

²⁴ For more information, see GS1 General Specifications, Section 4.4.1.1, Allocating Serial Shipping Container Codes

* GS1 US. *Frequently Asked Questions by the Pharmaceutical Industry in Preparing for the U.S. DSCSA*. Release 1.0, May 23, 2017.

The following table summarizes the identifiers present for GHSC-PSM compliance for pharmaceuticals:

Scenario	Identifier on secondary pack	Identifier on tertiary pack (trade item)	Identifier on tertiary pack (logistic unit)
Full homogeneous case where there is a GTIN for that case configuration, and the case is packed onto a pallet with other cases	GTIN (based on the item-level GTIN) + serial number	GTIN (based on the case-level GTIN) + serial number	SSCC
Partial/incomplete homogeneous case, and the case is packed onto a pallet with other cases	GTIN (based on the item-level GTIN) + serial number	SSCC	SSCC (different than the case-level SSCC)
Mixed case, and the case is packed onto a pallet with other cases	GTIN (based on various item-level GTINs) + serial number	SSCC	SSCC (different than the case-level SSCC)
Full homogeneous case where there is a GTIN for that case configuration, and the case is shipped by itself as a logistic unit	GTIN (based on the item-level GTIN) + serial number	GTIN (based on the case-level GTIN) + serial number and SSCC	SSCC
Partial/incomplete homogeneous case, and the case is shipped by itself as a logistic unit	GTIN (based on the item-level GTIN) + serial number	SSCC	
Mixed case, and the case is shipped by itself as a logistic unit	GTIN (based on various item-level GTINs) + serial number	SSCC	

The following table summarizes the identifiers present for GHSC-PSM compliance for medical devices, sterile kits, and laboratory reagents:

Scenario	Identifier on secondary pack	Identifier on tertiary pack (trade item)	Identifier on tertiary pack (logistic unit)
Full homogeneous case where there is a GTIN for that case configuration, and the case is packed onto a pallet with other cases	GTIN	GTIN	SSCC
Partial/incomplete homogeneous case, and the case is packed onto a pallet with other cases	GTIN	SSCC	SSCC (different than the case-level SSCC)
Mixed case, and the case is packed onto a pallet with other cases	GTIN	SSCC	SSCC (different than the case-level SSCC)
Full homogeneous case where there is a GTIN for that case configuration, and the case is shipped by itself as a logistic unit	GTIN	GTIN and SSCC	SSCC
Partial/incomplete homogeneous case, and the case is shipped by itself as a logistic unit	GTIN	SSCC	

Mixed case, and the case is shipped by itself as a logistic unit	GTIN	SSCC
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1.2.9 How do I pass SSCCs to GHSC-PSM?

In databases, SSCC fields should be 18 characters in length. The SSCC should be represented in a database as a text field (not numeric), so that leading zeros are not inadvertently dropped.

Suppliers will provide SSCCs for all logistic units to GHSC-PSM on the packing list.

1.3 Questions about the GLN²⁵

The questions in this section address identifying parties and locations using the GLN.

1.3.1 What is a GLN?*

The GLN is the globally unique GS1 identification number used to identify parties and locations. The GLN can be used to identify a legal entity (like a brand owner), a functional entity (like a manufacturing facility), or a physical location (like a warehouse, storage location, or clinic).

1.3.2 Who generates a GLN?*

The GLN for a legal entity is assigned by a GS1 Member Organization (MO) when the legal entity first registers for a GS1 Company Prefix. For other GLNs, such as functional entities within the legal entity or physical locations, the company that owns the functional entity or that owns or occupies the physical location generates the GLN.

1.3.3 Do GLNs need to be encoded in a data carrier?

For the GHSC-PSM requirement, GLNs are not required to be labeled on packaging in a barcode. The purpose of GLNs is to standardize location identification and related information in master and transaction data exchange.

1.4 Questions about the GS1 Company Prefix²⁶

The questions in this section address the GS1 Company Prefix.

1.4.1 What is a GS1 Company Prefix?*

A GS1 Company Prefix is a unique string of 6–11 digits issued to your company by your local GS1 MO. These digits are part of every GS1 identification number that you create (GTIN, SSCC, GLN, etc.). Because your GS1 Company Prefix is different from every other company's GS1 Company Prefix worldwide, the GS1 identification numbers you create are also globally unique.

1.4.2 Does the GS1 Company Prefix uniquely identify my company or brand?*

No. The GS1 Company Prefix is not an identifier. It is a string of digits that is used as a part of GS1 identification numbers. A GS1 Company Prefix does not uniquely identify a company or brand because a given company could have more than one GS1 Company Prefix, and sometimes

²⁵ For more information, see GS1 General Specifications, Section 4.6, GLN Rules

* GS1 US. *Frequently Asked Questions by the Pharmaceutical Industry in Preparing for the U.S. DSCSA*. Release 1.0, May 23, 2017.

²⁶ For more information, see GS1 General Specifications, Section 1.5, GS1 Company Prefix Allocation

a company uses the same GS1 Company Prefix to identify products of several brands. The unique identifier for a company is a corporate GLN.

1.4.3 How do I get a GS1 Company Prefix?

To get a GS1 Company Prefix, suppliers must register with a GS1 MO. Contact information for GS1 MOs globally can be found here: <https://www.gs1.org/contact/overview>. More information on how to obtain a GS1 Company Prefix can be found here: <https://www.gs1.org/company-prefix>.

1.4.4 Our company does business in multiple countries. Do I need a GS1 Company Prefix for each country?*

No. Your GS1 Company Prefix can be used to create GTINs, SSCCs, GLNs, or any other GS1 identification number for use globally. You are encouraged to license your GS1 Company Prefix with the country where you are headquartered and where you will look to receive GS1 support.

1.4.5 If an intermediary supplier (e.g., wholesaler, distributor) is supplying pharmaceuticals or medical devices to GHSC-PSM, then whose GS1 Company Prefix should be used for identification on the GTIN, GLN, and SSCC?

Ideally, the GS1 Company Prefix registered to the brand owner of the product should be used. If the brand owner does not provide its GS1 Company Prefix, then either the actual manufacturer or supplier has to identify the drugs using a GS1 Company Prefix registered to them to comply with the requirements

SECTION 2: CAPTURE

The questions in this section address **capturing** data from physical items using barcode data carriers. GS1 data carriers provide machine-readable representations of GS1 identification keys that facilitate automatic identification and data capture.

2.1 Questions about GS1-128 barcode data carriers²⁷

The questions in this section address the GS1-128 barcode data carrier. For more information, please see the GS1 General Specification.

2.1.1 What is a GS1-128 barcode?*

GS1-128 is a linear barcode used to encode data for logistic units such as cases and pallets. Using this barcode supports fast and accurate data capture and inventory tracking, adding visibility to your supply chain.

The GS1-128 barcode is most commonly used to label a logistic unit with a SSCC.

2.2 Questions about GS1 DataMatrix data carriers²⁸

* GS1 US. *Frequently Asked Questions by the Pharmaceutical Industry in Preparing for the U.S. DSCSA*. Release 1.0, May 23, 2017.

²⁷ For more information, see GS1 General Specifications, Section 5.4, GS1-128 symbology specifications

²⁸ For more information, see GS1 General Specifications, Section 5.7, Two-dimensional barcodes — GS1 DataMatrix symbology

The questions in this section address the GS1 DataMatrix data carrier. For more information, please see the GS1 General Specification.

2.2.1 What is a GS1 DataMatrix?*

The GS1 DataMatrix is a two-dimensional barcode that may be printed as a square or rectangular symbol made up of individual squares. This representation is an ordered grid of dark and light squares bordered by a finder pattern. The finder pattern is partly used to specify the orientation and structure of the symbol. The data is encoded using a series of dark or light squares based on a predetermined size. The size of these squares is known as the X-dimension.

The GS1 DataMatrix is most commonly used to label a trade item with a GTIN and other related information, such as batch/lot, expiration date, and serial number.

2.2.2 What is a QR Code, and how is it different from a GS1 DataMatrix?*

A QR Code is a two-dimensional matrix symbology consisting of square modules arranged in a square pattern. The symbology is characterized by a unique finder pattern located at three corners of the symbol. QR Code version 2005 is the only version that supports GS1 identification numbers, including function 1 symbol character. QR Code symbols are read by two-dimensional imaging scanners or vision systems.

2.2.3 What is the physical difference between a GS1 DataMatrix and a QR Code?*

GS1 DataMatrix and QR Codes can be distinguished by the naked eye by looking at the finder patterns. A GS1 DataMatrix will appear to have a solid black line on two sides of the symbol. A QR Code has a distinctive square “bulls-eye” pattern in three of the four corners.

2.2.4 Why are QR codes not being used by GHSC-PSM?

QR Codes are not recommended for use in regulated healthcare environments. For more information, please refer to the *GS1 Healthcare discussion paper on the use of GS1 DataMatrix in Healthcare and a comparison to the GS1 QR Code*.²⁹

2.3 General questions about data carriers

The questions in this section address general information on data carriers. For more information, please see the GS1 General Specification.

2.3.1 What are GS1 Application Identifiers?³⁰ How are AIs manifested in the barcode and/or human readable information?*

GS1 AIs are used in barcodes that are capable of holding more than one data element, such as the GS1 DataMatrix. In such barcodes, each data element is prefixed with a GS1 AI, indicating the meaning of that data element. Each AI is a two-, three-, or four-digit numeric code. When rendered in human readable form, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode-encoded data.

* GS1 US. *Frequently Asked Questions by the Pharmaceutical Industry in Preparing for the U.S. DSCSA*. Release 1.0, May 23, 2017.

²⁹ https://www.gs1.org/sites/default/files/docs/healthcare/GS1%20QR%20DM%20discussion%20paper_20140113_FINAL.pdf

³⁰ For more information, see GS1 General Specifications, Section 3, GS1 Application Identifier definitions

For example, the AI for GTIN is 01. Thus, when “01” appears in the encoded content of a barcode that uses AIs, it means the next 14 digits are a GTIN. The AI for serial number is 21. Thus, when “21” appears in the barcode, it means that the next characters are a serial number.

The combination of a single AI and the following data is called a “GS1 element string.” A series of GS1 element strings in a single barcode is called a “concatenated element string.”

2.3.2 How are AIs used in a data carrier?

Each GS1 identification number (GTIN, SSCC, etc.) has an AI. Also, there are AIs for various types of secondary information to enable supply chain partners to communicate item-specific information wherever the barcode is scanned (expiration date, lot number, batch number, etc.).⁺

The following table lists the AIs that are relevant for GHSC-PSM.

Use case	Typical barcode type	Data element	AI	Characters following the AI
Trade item	GS1 DataMatrix	GTIN	01	14 digits
		Expiration date	17	6 digits
		Batch/lot number	10	1–20 alphanumeric characters
		Serial number	21	1–20 alphanumeric characters
Logistic unit	GS1-128	SSCC	00	18 digits

2.3.3 Is there a specific order in which AIs must be encoded in the barcode?

No. AIs may be encoded in any order. However, for the most efficient encoding, it is best to have fixed-length data elements precede variable-length elements. As an example:

- (01) GTIN
- (17) Expiration date
- (10) Batch
- (21) Serial number

Systems that read barcodes must *not* rely on AIs being arranged in any particular order. They must be prepared to process the data regardless of the ordering of AIs.

2.3.4 Can additional AIs be encoded in the barcode, other than those specified by GHSC-PSM?

The GHSC-PSM requirement identifies the minimum GS1 identification keys to be included on product labels. However, additional AIs are permitted at the discretion of the supplier, particularly in producing multimarket packs.

⁺ GS1 US. *Frequently Asked Questions by the Pharmaceutical Industry in Preparing for the U.S. DSCSA*. Release 1.0, May 23, 2017.

While barcode reading applications should work correctly even if additional AIs are present, the use of additional AIs is discouraged to avoid possible problems if downstream barcode reading applications are not implemented correctly.

2.3.5 How do I know if my barcode is correct?*

Many GS1 MOs and other companies provide fee-based barcode verification services. Verification services typically work like this:

- You submit samples of your barcoded item(s) in their final packaged form. If you are submitting a barcode that is located directly on an irregularly shaped unit, the item in its entirety is needed for review. Artwork samples (e.g., laser prints, bromides, mock-ups, and proofs) can be tested to provide an interim report on barcode size and quiet zones. However, final samples of actual packaging are needed to provide a complete verification report.
- Your solution provider will test your barcode(s) for compliance with GS1 Standards using a formal verification process. Testing assesses size, color, print quality, quiet zones, barcode height, location/placement, and calculation of the check digit.
- Your solution provider will deliver a detailed report showing how your barcode(s) performed.

SECTION 3: SHARE

The questions in this section address sharing data between trading partners using GS1 data-sharing standards.

3.1 Questions about master data

These questions provide descriptive information about GS1 identification numbers, such as GTINs and GLNs.

3.1.1 What is master data?

Master data is description attribute information about a product (GTIN) or location (GLN). Examples of product master data include weight, dimensions, shelf-life, and quantity. Examples of location master data include delivery points/addresses, individual locations of an entity (e.g., manufacturing facility, warehouse, headquarters), contact information, or bank account information.

3.1.2 What is the GS1 standard for sharing master data?

The GS1 standard for sharing master data for trade items is called the GDSN. GS1 does not currently have a standard for sharing master data for parties or locations.

3.1.3 What is the GDSN?

The GDSN is an automated, standards-based global environment that enables secure and continuous data synchronization of product information. This allows all trading partners to have consistent item data in their systems at the same time, ensuring that all parties in the supply chain are working with the same data. The GDSN helps to save time and money for all organizations by eliminating steps to correct inaccurate data. The GDSN is comprised of the GS1 Global Registry® and a network of interoperable, certified data pools that enable data synchronization aligned with the GS1 system of standards.

More information on the GDSN can be found here: <https://www.gs1.org/gdsn>

3.1.4 What is data synchronization?

Data synchronization is the electronic transfer of product information between trading partners and the continuous synchronization of that data over time. The GS1 GDSN is a synchronization method for GS1-standards based data that is exchanged through a central global repository known as the GS1 Global Registry®. The registry serves a “traffic director” in the publication and subscription process. It is not a database that an individual or entity can access directly outside of the data sync process.

Product information is referred to as “attributes” in the GDSN. Attributes are defined by the supplier (e.g., GTIN, size, weight, height, brand). More than 3,000 item attributes are available in the GDSN.

3.1.5 Why is GHSC-PSM implementing data synchronization?

GHSC-PSM will be using the GDSN to receive item information as the basis of our product catalog. This will enable GHSC-PSM to provide USAID-supported countries with the information they need to optimize decision-making around order planning, procurement, shipping, and receiving through GHSC-PSM for better data visibility and improved data quality. Synchronized data will allow countries to make the best purchasing decisions when ordering life-saving commodities for health programs across the globe.

3.1.6 What are the benefits of syncing data through the GDSN?

Data synchronization offers several benefits, including:

- Reduces data errors between trading partners
- Allows for real-time item attribute maintenance and updates
- Ensures logistics information, including size, dimensions, and weight, is accurate and received at the each, case, warehouse pack, and pallet levels
- Provides accurate, standards-based, synchronized data that reduces supply chain inefficiencies
- Enables accurate data exchange from many data sources to many recipient parties with a single entry

3.1.7 What is a data pool? What is a GDSN-certified data pool?

A data pool is an entity that provides data synchronization services and a single point of entry to the GDSN. Data pools must be certified by GS1 to operate within the GDSN. Data pools interoperate with the GS1 Global Registry and each other. 1WorldSync is an example of a GDSN-certified data pool.

For questions on how to choose the right data pool for your organization, please refer to the GS1 website: <https://www.gs1.org/gdsn>

3.1.8 Where can I find a list of GDSN-certified data pools?

The GS1 website has a list of GDSN-certified data pools with contact information, which can be found here: <http://www.gs1.org/gdsn/certified-data-pools>

3.1.9 Who is 1WorldSync?

1WorldSync is a GDSN-certified data pool and works closely with GHSC-PSM in implementing its data synchronization initiative. A subsidiary of GS1 US and GS1 Germany, 1WorldSync supports and works with more than 16,000 companies of all sizes. GHSC-PSM uses the 1WorldSync Data Pool Solution for its GDSN services.

To learn more about 1WorldSync and its services:

- Visit <http://www.1worldsync.com/>
- Call +1 (866) 280-4013, Option 1

3.1.10 Do I have to sign up with 1WorldSync?

You need to select a GDSN-certified data pool to synchronize your company's data through the GDSN. GHSC-PSM uses 1WorldSync as a GDSN-certified data pool, but your company can choose any of the GDSN-certified data pools for synchronization.

The GS1 website has a list of GDSN-certified data pools with contact information, which can be found here: <http://www.gs1.org/gdsn/certified-data-pools>

3.1.11 Where do I start?

The steps to get started are:

- Visit the GHSC-PSM GDSN landing page at www.1worldsync.com/customer-page/ghsc-psm
- Complete the GHSC-PSM Trading Partner Form.
- Review the GHSC-PSM Data Synchronization Implementation Guide, which will walk you through the implementation process.
- Review the GHSC-PSM Attribute Guide, which will inform you of the data GHSC-PSM seeks to collect through the GDSN.

3.2 Questions about transaction data

The questions in this section address the GS1 standard for sharing transaction data with GHSC-PSM.

3.3.1 What is transaction data?

Transaction data is information about production, purchasing, selling, and other transactions that occur through the supply chain.

3.3.2 What is the GS1 standard for sharing transaction data?

The GS1 standard for sharing transaction data is electronic data interchange (EDI). The EDI standards promoted by the GS1 system (i.e., EANCOM, GS1 XML) make full use of GLNs to simplify business messaging automation.

3.3.3 What is EDI?

EDI is a form of peer-to-peer data exchange in a standard electronic format between business partners. EDI allows information that has traditionally been exchanged by paper, for example, purchase orders and invoices, to be communicated electronically instead through a standard format.

3.3.4. Will GHSC-PSM use EDI for the exchange of transaction data?

GHSC-PSM is evaluating the use of EDI for transaction data exchange with suppliers, and additional information will be provided once requirements have been developed. In the interim, if a supplier is interested in piloting EDI for transaction data exchange with GHSC-PSM, please email globalstandards@ghsc-psm.org.

3.3 Questions about event data

The questions in this section address the GS1 standard for sharing visibility event data. This section is informational; currently, GHSC-PSM does not have a requirement to share visibility event data.

3.3.1 What is event data?

Event data is information about the physical movement and status of products as they move through the supply chain.

3.3.2 What is the GS1 standard for sharing event data?

The GS1 standard for sharing transaction data is Electronic Product Code Information Services (EPCIS). EPCIS is intended to be used in conjunction with the GS1 Core Business Vocabulary (CBV) standard.

3.3.3 What is the EPCIS standard?*

This standard defines a data model and a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain. EPCIS breaks down supply chain business processes into individual steps, such as commissioning, packing, shipping, and receiving, and provides a standard language in which a party carrying out one of these steps can communicate the essential business information about that step to trading partners who need to know the *what*, *when*, *where*, and *why* of each step. Each such step is called an “event,” and the term “EPCIS event” refers to the data record that describes an event using the standard EPCIS language.

3.3.4 Will GHSC-PSM use EPCIS for exchange of event data?

GHSC-PSM is assessing our processes and systems, in addition to those in the countries we support, to determine the appropriateness and applicability of leveraging EPCIS in our supply chain in the future.

SECTION 4: ADDITIONAL QUESTIONS

4.1 Questions about the GHSC-PSM requirement

The questions in this section address the GHSC-PSM requirement.

4.1.1 For which products does the GHSC-PSM requirement apply?

GHSC-PSM has a requirement for pharmaceuticals, medical devices, laboratory reagents, and sterile kits. Identification and labeling in adherence to this requirement are optional for other products at this time.

4.1.2 Does GHSC-PSM require a transition period to the new requirement?

No. The previous labeling requirement, using the GHSC-PSM SKU on the logistic unit, is used only in the GHSC-PSM regional distribution centers for logistics and inventory control. GHSC-PSM’s systems were developed to use the GTIN as the primary identifier, the only dependency being availability of master data associated with the GTIN for implementation.

4.1.3 Are there circumstances in which suppliers can request an exemption from the requirement?

* GS1 US. *Frequently Asked Questions by the Pharmaceutical Industry in Preparing for the U.S. DSCSA*. Release 1.0, May 23, 2017.

No. Suppliers of products referenced in 4.1.1 will not be exempted from the GHSC-PSM requirement.

4.1.4 Are there circumstances in which suppliers can request an exception from the requirement?

Exceptions to adherence will not be granted for product identification. All suppliers are expected to obtain a GS1 Company Prefix and assign GTINs to items and GLNs to parties or locations.

Exceptions for adherence will be considered on a case-by-case basis **ONLY for the labeling and master data exchange requirement**, when the supplier can demonstrate a reasonable effort to implement within the required timeframe.

To request an exception to the GHSC-PSM requirement, please email globalstandards@ghsc-psm.org.

4.2 Questions about GHSC-PSM-supported country programs

The questions in this section address the applicability of the GHSC-PSM requirement to supported country programs.

4.2.1 Which guidelines need to be adhered to in the case that the importing country has specific requirements?

If the importing country regulatory authority has mandated its own specific requirements for barcoding, the supplier need not comply with the GHSC-PSM requirements for identifying and labeling various levels of packaging. However, an instance in which the GHSC-PSM requirement will not be applied needs to be confirmed with GHSC-PSM and relevant authorities.

4.2.2. Is GHSC-PSM supporting countries to leverage the standardized barcodes in their supply chains?

Yes. GHSC-PSM has issued guidance to country programs to implement GS1 global standards within their supply chains. GHSC-PSM is providing technical assistance to select countries to support regulatory, procurement, supply chain operations, and systems deployment activities as they relate to global standards and in support of verification or track-and-trace initiatives.

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