GLOBAL STANDARDS TECHNICAL IMPLEMENTATION GUIDELINE FOR GLOBAL HEALTH COMMODITIES

Product and Location Identification, Labeling, and Data Exchange

Version 2.1, March 2019

Stop TB Partnership GLOBAL DRUG FACILITY

The Global Fund

UNFPA

UNDP

Empowered lives. Resilient nations.

USAID FROM THE AMERICAN PEOPLE

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

USAID FROM THE AMERICAN PEOPLE CDC

U.S. President's Malaria Initiative

CONTENTS

REVISION HISTORY

Date	Version no.	Description of change	Author
01 Jan 2018	1.0	Initial USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) document	K. Roche
27 Mar 2019	2.1	Modified USAID GHSC-PSM document to become an implementation road map for International Procurement Agencies (IPAs), including: • Added *Acknowledgments* • Added *Endorsements* • Updated *Section 1* • Updated *Section 2* (replaced timelines with phases) • Updated *Section 3* (replaced timelines with phases) • Updated *Section 4* (new images) • Added to *Annex A: Glossary* definitions to include check digit, concatenation, data synchronization, Global Location Number, and kit • Updated *Annex B: FAQs* sections 1.2.9; 3.3.4; 4.1.1; 4.1.2; 4.1.5; 4.2.1 • Added to *Annex B: FAQs* sections 1.1.6; 1.1.7; 1.5.1; 1.5.2; 3.1.9; 4.1.3; 4.1.6 • Added *Annex C: Agency Uptake Timelines*	K. Roche

ACRONYMS

AI ..... GS1 Application Identifier
AIDC ..... automatic identification and data capture
ASN ..... advanced ship notice
CBV ..... Core Business Vocabulary
EDI ..... electronic data interchange
EPCIS ..... Electronic Product Code Information Services
FAQ ..... frequently asked question
IEC ..... International Electrotechnical Commission
IPA ..... International Procurement Agency
ISG ..... Interagency Supply Chain Group
ISO ..... International Organization for Standards
IT ..... information technology
GCP ..... GS1 Company Prefix
GDF ..... Global Drug Facility
GDSN ..... Global Data Synchronization Network
GHSC-PSM ..... Global Health Supply Chain Program-Procurement and Supply Management
GLN ..... Global Location Number
GTIN ..... Global Trade Item Number
HRI ..... human readable interpretation
MO ..... GS1 Member Organization
NRA ..... National Regulatory Authority
RFID ..... radio frequency identification
RHGTAG ..... Reproductive Health Global Traceability Advisory Group
SSCC ..... serial shipping container code
TB ..... tuberculosis
UNDP ..... United Nations Development Programme
UNFPA ..... United Nations Population Fund
UNICEF ..... United Nations International Children's Emergency Fund
USAID ..... United States Agency for International Development
VPPAG ..... Vaccines Presentation and Packaging Advisory Group
WHO ..... World Health Organization

ACKNOWLEDGEMENTS

The authors thank the members of the Inter-Agency Supply Chain Group (ISG), the GS1 Healthcare Team, and the following individuals for their technical contributions and support in facilitating the development of this document:

Name	Organization
Chris Wright	Gavi
Dorothy Amony	GDF / Stop TB Partnership
Magali Babaley	GDF / Stop TB Partnership
Nigorsultan Muzafarova	GDF / Stop TB Partnership
Mouna Jarmouni	The Global Fund
Sophie Logez	The Global Fund
Hitesh Hurkchand	ISG
Cécile Macé	UNDP
Benoit Marquet	UNDP
Zafar Yuldashev	UNDP
Udara Bandara	UNFPA
Roberto Mena	UNFPA
Thinlay (Nono) Wangchuk	UNFPA
Lindabeth Doby	USAID
Ramy Guirguis	USAID
Clerisse Lemke	USAID
Geoffrey Soybel	USAID
Kaitlyn Roche	USAID GHSC-PSM
Rachel Smith	USAID GHSC-PSM
Hayley Traeger	USAID GHSC-PSM

ENDORSEMENTS

This *Global Standards Technical Implementation Guideline for Global Health Commodities* has been formally endorsed by the following organizations:

Stop TB Partnership
GLOBAL DRUG FACILITY

The Global Fund

UNFPA

UNDP
Empowered lives.
Resilient nations.

USAID
FROM THE AMERICAN PEOPLE

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

USAID
FROM THE AMERICAN PEOPLE
CDC
U.S. President's Malaria Initiative

SECTION NO. 1

INTRODUCTION

BACKGROUND

Managing and implementing a global health supply chain requires alignment between supply and demand, as well as the orchestration of three flows of commerce: the movement of products, data, and funding. At implementation levels, current supply chain management practices in global and national healthcare supply chains may be inhibiting optimal performance through use of proprietary identification numbers, inconsistent product labelling, and highly manual and ad hoc data exchange practices, which hinder efficiency and prohibit interoperability.

International procurement agencies (IPAs) that procure and distribute pharmaceuticals, vaccines, medical devices, sterile kits, laboratory reagents and other global health commodities (hereinafter referred to collectively as "health commodities") for developing markets are committed to incorporating lessons learned over the last decade of health supply chain management to enable more secure and efficient supply chains. Implementation and use of global supply chain data standards for product and location identification, data capture (e.g., barcoding), and data exchange as the foundation for business communications across global, regional, and national trading partners is agreed to be central to achieving those objectives

Since 2014, actors within this community of IPAs have promoted the concept of global data standards for health commodities to provide a harmonised framework for facilitating supply chain visibility, strengthening anti-counterfeiting measures, and sharing of data between parties. The IPAs endorsing this *Global Standards Technical Implementation Guideline for Global Health Commodities* have developed this document in an effort to:

- Enable end-to-end data visibility through globally unique item and location identification and increasingly mature master data management practices, which create opportunities for improved systems interoperability;
- Identify and implement supply chain efficiencies through use of automatic identification and data capture (AIDC) (e.g., barcode) technology across donors, procurement agencies, and donor-supported country supply chains;
- Ensure supply chain security through chain-of-ownership or chain-of-custody product management that identifies risk and incident of product loss, expiry, and diversion; and
- Increase patient safety through use of serialization to enable improved controls against substandard and counterfeit medicines.

Separate from this document, the World Health Organization (WHO) is developing a policy position regarding the use of data standards in supply chains for health commodities. This will advise WHO Member States on a number of related issues, including regulatory oversight of track and trace technologies, the use of established and harmonized standards in the supply chain and lifecycle management of health commodities, governance of information technology (IT) systems and other areas of data management and governance.

SCOPE

This document is intended for use by endorsing IPAs and their suppliers of health commodities, acknowledging that other IPAs and wholesale suppliers may opt to use it at their discretion. Compliance with this document is voluntary for IPAs and it is the responsibility of any IPA to indicate what portions, if any, it will invoke in its procurement transactions. This document may be used as a general reference, and certain sections of this document may be specified in international procurement tenders as a requirement. Suppliers are recommended to use the *GS1 General Specifications* as the primary reference document for technical specifications referenced within.

The product and location identification, data capture, and data exchange standards covered in this document does not include guidance for creating the complete enabling environment required to implement verification, traceability of health commodities from manufacture to dispense, costing, data governance, regulatory affairs, monitoring, and enforcement. A complete analysis of the implications of implementing similar approaches to the whole supply chain remains pending.

DISCLAIMER

This document makes reference to the data standard known as GS1. This is a global data standard developed for healthcare supply chains that is already in use by several IPAs. The document provides information on how to use that standard in the context of international tenders for health commodities procured; however, it should not be interpreted as an endorsement for the use of specific data standards for countries that receive any health commodities, regardless of whether or not their procurement is executed by the IPAs, and also does not intend to endorse a specific standards agency.

Contact the IPA with which you have a contractual relationship to determine if this requirement is applicable to the trade items your company supplies. In any document that speaks to packaging guidelines, each company is also individually responsible for meeting all statutory and/or regulatory requirements for the company and its products. It does not intend to supersede any regulatory requirements, including but not limited to those of national regulatory agencies (NRAs) for health commodities. Consult with your company's legal counsel or regulatory and quality compliance teams for more specific information about statutory and regulatory requirements on a country-by-country basis.

SECTION NO. 2

OVERVIEW OF THE ROADMAP FOR PHARMACEUTICALS[1] AND VACCINES[2]

This section lays out an implementation roadmap for trade item and location identification, data capture, and data exchange for pharmaceuticals and vaccines at various levels of the packaging hierarchy. This includes a phased approach, where capabilities are implemented over time. Specific timelines associated with each phase may vary by IPA and are included where defined by endorsing IPAs in Annex C.

The following **minimum** use of GS1 identification keys and data carriers are recommended for pharmaceuticals and vaccines at various packaging levels:

IDENTIFY		
Entity	**Requirement**	**Phase**
Trade items	Assign and provide[3] Global Trade Item Numbers (GTINs) for all levels of the packaging hierarchy including each, inner packs, intermediate packs, case, and pallet (if trade item)	Phase 1
Locations and/or legal entities	Assign and provide[4] Global Location Numbers (GLNs) for sold-from, manufacture-from, ship-from, and data synchronization	Phase 1

CAPTURE				
Packaging level	**Packaging type**	**Requirement**	**Human readable interpretation (HRI)**	**Phase**
Tertiary: logistic unit		GS1 DataMatrix or GS1-128 barcode symbology encoded with: • Serial shipping container code (SSCC)	Information printed in human readable interpretation: • SSCC	Phase 3

[1] This guideline is aligned with the Identification Recommendations for Reproductive Health Pharmaceutical Products, developed and published by the Reproductive Health Global Traceability Advisory group. Available: https://www.ghsupplychain.org/media/305.

[2] This guideline is inclusive of, but may also exceed, the guidance developed in the Generic Preferred Product Profile for Vaccines, developed and published by the WHO's Vaccine Presentation and Packaging Advisory Group (VPPAG). Available: www.who.int/immunization/policy/committees/VPPAG_Generic_PPP_and_Workplan.pdf.

[3] Identifiers can be submitted to IPAs through the GTIN/GLN submission form, available: https://www.ghsupplychain.org/global-standards/gtinglnsubmissionform

[4] ibid.

CAPTURE Cont.				
Packaging level	**Packaging type**	**Requirement**	**Human readable interpretation (HRI)**	**Phase**
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 interpretation: • GTIN • Batch/lot • Expiration date • Serial number	Phase 1 for GTIN, batch/lot, and expiration date Phase 4 for serial number
Tertiary: trade item	Mixed or partial	GS1 DataMatrix or GS1-128 barcode symbology encoded with: SSCC	Information printed in human readable interpretation: SSCC	Phase 4
Secondary: trade item		GS1 DataMatrix symbology encoded with: • GTIN • Batch/lot • Expiration date • Serial number	Information printed in human readable interpretation: • GTIN • Batch/lot • Expiration date • Serial number	Phase 3 for GTIN, batch/lot, and expiration date Phase 4 for serial number
Primary: trade item *Optional; required only when the item is supplied in cartonless packaging.*		GS1 DataMatrix symbology encoded with: • GTIN • Batch/lot • Expiration date • Serial number	Information printed in human readable interpretation: • GTIN • Batch/lot • Expiration date • Serial number	If required: Phase 3 for GTIN, batch/lot, and expiration date Phase 4 for serial number

SHARE			
Data type	**Scope**	**Requirement**	**Phase**
Master data	Trade items	Provide mandatory and required attribute data via the GDSN	Phase 2

SECTION NO. 3

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

This section lays out an implementation roadmap for trade item and location identification, data capture, and data exchange for medical devices, sterile kits, and laboratory reagents at their various levels of the packaging hierarchy. This includes a phased approach, where capabilities are implemented over time. Specific timelines associated with each phase may vary by IPA and are included where defined by endorsing IPAs in Annex C.

The following **minimum** use of GS1 identification keys and data carriers are recommended for medical devices, sterile kits, and laboratory reagents at various packaging levels:

IDENTIFY		
Entity	**Requirement**	**Phase**
Trade items	Assign and provide[5] GTINs for all levels of the packaging hierarchy including each, inner packs, intermediate packs, case, and pallet (if trade item)	Phase 1
Locations and/or legal entities	Assign and provide[6] GLNs for sold-from, manufacture-from, ship-from, and data synchronization	Phase 1

CAPTURE				
Packaging level	**Packaging type**	**Requirement**	**Human readable interpretation (HRI)**	**Phase**
Tertiary: logistic unit		GS1 DataMatrix or GS1-128 barcode symbology encoded with: • SSCC	Information printed in human readable interpretation • SSCC	Phase 4
Tertiary: trade item	Homogenous	GS1 DataMatrix or GS1-128 barcode symbology encoded with: • GTIN And when applicable: • Batch/lot • Expiration date	Information printed in human readable interpretation: • GTIN And when applicable: • Batch/lot • Expiration date	Phase 1

[5] Identifiers can be submitted to IPAs through the GTIN/GLN submission form, available: https://www.ghsupplychain.org/global-standards/gtinglnsubmissionform

[6] ibid.

CAPTURE Cont.				
Packaging level	**Packaging type**	**Requirement**	**Human readable interpretation (HRI)**	**Phase**
Tertiary: trade item	Mixed or partial	GS1 DataMatrix or GS1-128 barcode symbology encoded with: SSCC	Information printed in human readable interpretation: SSCC	Phase 3
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 interpretation: • GTIN And when applicable: • Batch/lot • Expiration date	Phase 3
Primary: trade Item *Optional; required only when the item is supplied in cartonless packaging.*		GS1 DataMatrix or GS1-128 barcode symbology encoded with: • GTIN And when applicable: • Batch/lot • Expiration date	Information printed in human readable interpretation: • GTIN And when applicable: • Batch/lot • Expiration date	If required: Phase 3

SHARE			
Data type	**Scope**	**Requirement**	**Phase**
Master data	Trade items	Provide mandatory and required attribute data via the GDSN	Phase 2

SECTION NO. 4

DESCRIPTION OF PACKAGING LEVELS[7]

This section includes summary descriptions and examples[8] of each level of the packaging hierarchy referenced in Sections 2 and 3. Suppliers should consult the *GS1 General Specifications* and the *GS1 AIDC Healthcare Implementation Guideline* for more information. It is further recommended that suppliers consult relevant IPA contacts provided in Section 7 or their GS1 Member Organization (MO) for supplier- or item-specific guidance as needed.

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[9]
- A case that contains (one or usually) several items in the items' primary or secondary packaging[10]

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).

It is recommended that labels containing the barcode symbols, with associated human readable interpretation (HRI), be positioned on two faces of the tertiary packaging to enable ready access for scanning when the item is stored, stocked on shelves, or handled.

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 the relevant IPA. In many instances, the tertiary package logistic unit is a pallet but may also be an export carton.

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

[7] For more information, see GS1 General Specifications, Section 8.1 GS1 Glossary of Terms and Definitions.
[8] Image credits: GS1 AISBL, 2019.
[9] For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.4, Case / Shipper and Pallet.
[10] ibid.

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 Global Trade Item Number (GTIN), batch/lot number, expiration date, and serial number. A mixed or partial pack trade item is identified with an SSCC. This packaging level can be marked with a GS1-128 linear barcode or a GS1 DataMatrix, with a strong preference for a GS1 DataMatrix, either on the packaging itself or on a label affixed to the packaging.

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

SECONDARY PACKAGING

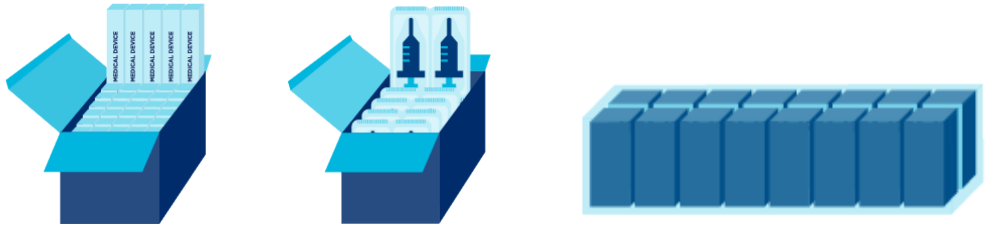
Secondary packaging is a level of packaging that may contain one or more primary packages, or a group of primary packages containing a single item.[11] The secondary pack is always a trade item. This packaging level is marked with a GS1 DataMatrix, either on the packaging itself or on a label affixed to the packaging.

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

In-scope commodities can have more than one level of secondary packaging, such as an inner pack (bundles) and intermediate packs (inner case). **Identification and marking of inner and**

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

intermediate secondary packaging levels are considered to be required. Examples of inner or intermediary secondary packaging include, but are not limited to:

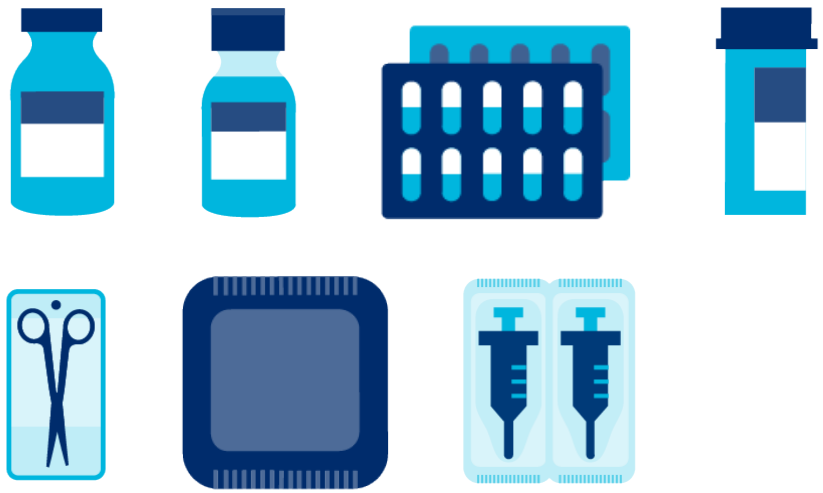


PRIMARY PACKAGING

Primary packaging is the first level of packaging that is in direct contact with the item.[12] This packaging level is marked with a GS1 DataMatrix, either on the packaging itself or on a label affixed to the packaging.

Marking items at this level is optional unless the supplier is providing items in "cartonless packaging", i.e., without a secondary packaging level. Marking items at this level is also recommended where the secondary package will likely be opened or removed before being dispensed to one or several patients (e.g., a display carton is opened, and individual or split blister packs are distributed to patients).

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



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

SECTION NO. 5

OVERVIEW OF GS1 STANDARDS USED

A summary of the GS1 standards relevant to this procurement requirement are described in this section. This document is based on the use of the *GS1 General Specifications* as the primary reference document for technical specifications to implement in accordance with GS1 global standards.

IDENTIFY

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

AI (00) Serial Shipping Container Code (SSCC)[13]

The GS1 AI (00) indicates that the data field contains an SSCC. The SSCC is used to uniquely identify a logistic unit. The SSCC must remain unique and not be reallocated for a minimum of one year from the shipment date of the logistic unit from the SSCC assignor to the trading partner, in accordance with *GS1 General Specifications*.

The SSCC format is as follows:

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

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

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

AI (01) Global Trade Item Number® (GTIN®)[14]

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.

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

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

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

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

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

AI (10) Batch/lot[15]

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

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

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

AI (17) Expiration date[16]

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

[15] For more information, see GS1 General Specifications, Section 3.4.1, Batch or Lot Number: AI (10).
[16] For more information, see GS1 General Specifications, Section 3.4.7, Expiration Date: AI (17).

The format of the expiration date is as follows:

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

AI (21) Serial number[17]

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

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

The format of the serial number is as follows:

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

Global Location Number (GLN)[18]

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 identifier to identify parties and locations in a globally standardised data format. Supply chain partners use GLNs to identify parties and locations in all supply chain transactions, supply chain communications, and internal systems.

The GLN does not need to be encoded in a data carrier or labelled on trade item or logistic unit packaging. GLNs will be utilised to identify legal entities and locations in the data exchange process.

[17] For more information, see GS1 General Specifications, Section 3.5.2, Serial Number: AI (21).
[18] For more information, see GS1 General Specifications, Section 4.6, GLN Rules.

Responding suppliers are expected to assign and provide GLNs for the following entities at a minimum:

- Data synchronization
- Sold-from entity/location
- Manufacture-from entity/location
- Ship-from entity/location

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

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

IPAs will be using the following GLNs in transactions:

Agency	Global Location Number	
	Bill-to/Invoice-to	Data Synchronization
USAID GHSC-PSM	0858939007009	0858939007009

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.[19]

All barcode symbols should meet print-quality "Grade C" (1.5 or above).[20] 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 MOs provide comprehensive barcode verification services to ensure companies are implementing barcode labelling requirements to specification based on optical and data structure requirements.

GS1-128 barcode[21]

A GS1-128 barcode is a linear barcode symbology using bars and spaces in one dimension that leverage a subset of Code 128 that is used exclusively for GS1 system data structures. A linear barcode can be concatenated (i.e., represent all elements of a data string in a single

[19] For more information, see Ten Steps to GS1 Barcode Implementation User Manual.
[20] For more information, see GS1 General Specifications, Section 5.5, Barcode Production and Quality Assessment.
[21] For more information, see GS1 General Specifications, Section 5.4, Linear Barcodes — GS1-128 Symbology Specifications.

barcode) or non-concatenated (i.e., represent individual elements of a data string over two or more barcodes).

Example of a GS1-128 barcode for a logistic unit

Example of a GS1-128 barcode for a trade item

Concatenated (preferred)

Non-concatenated (only if necessary)

GS1 DataMatrix[22]

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

Example of a GS1 DataMatrix for a logistic unit

(00) 0 0614141 123452

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

Example of a GS1 DataMatrix for a trade item

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

SHARE

Master data

A number of IPAs are implementing the GS1 Global Data Synchronization Network™ (GDSN) to synchronise product master data with trading partners to use as the basis of product catalogues. Using the GDSN process will help improve supply chain data quality and management for trading partners.

Suppliers of pharmaceuticals, vaccines, medical devices, sterile kits, and laboratory reagents may be expected to register with a GDSN-certified data pool and synchronise master data. For more information on IPA-specific GDSN implementation guidance and attribute guides, please reach out to your relevant IPA contacts identified in Section 7.

Transaction data

When the responding supplier implements the item identification and data capture requirements, the primary identification number on all transaction documentation provided to the relevant IPA — including but not limited to the packing list, commercial invoice, and advanced ship notice where relevant — is recommended to include the GTIN(s) for the item(s) being referenced in the transaction.

Event data

IPAs do not currently share event data but may consider it in the future.

SECTION NO. 6

IMPLEMENTATION PROCEDURES

Suppliers subject to this guideline must register their trade items and locations with GS1. The following steps are illustrative and can be used as a guide based on experience with other implementations.

Step 1: Register with a GS1 MO 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

Step 2: Undergo training and education

GS1 and certified solution providers can assist companies in training and education to support implementation and adherence to this guideline.

Step 3: Assign globally unique identifiers to items and locations

Allocate a unique GTIN to each item and GLN to each relevant business entity (e.g. data synchronization entity, sold-from entity/location, manufacture-from entity/location, ship from entity/location). For more information on how to generate and maintain GTINs and GLNs, please contact your GS1 MO and refer to the *GS1 General Specifications*. The following resources are also available:

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

Step 4: Integrate item 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 applications or other internal software applications. Parent-child relationships for item GTINs should be maintained in the database that links the primary, secondary, and tertiary GTINs of each item and its variants.

Step 5: Implement labelling[23]

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, marking, and quality guidelines provided in this document and the *GS1 General Specifications*.

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

The position of the barcode on the packaging should be checked to ensure that it meets the use case and any requirements within this document and the *GS1 General Specifications*.[24] Any final labelling or wrapping should also be examined to ensure that the barcodes remain visible and easy to scan.

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.

Step 6: Identify a GDSN-certified data pool and share trade item master data
A list of GDSN-certified data pool providers can be found on the GS1 website: https://www.gs1.org/services/gdsn/certified-data-pools.

Information regarding specific IPA GDSN implementations can be found below.

Agency	GDSN Data Pool	Landing Page
USAID GHSC-PSM	1WorldSync	http://www.1worldsync.com/customer-page/ghsc-psm/

For more information on agency-specific GDSN implementation guidance and attribute guides, please reach out to your relevant IPA contacts in Section 7.

[24] For more information, see GS1 General Specifications, Section 6, Symbol Placement Guidelines.

SECTION NO. 7

RESOURCES

TRANSITION GUIDANCE

As suppliers transition to the new identification and data capture requirement, GTINs and relevant item master data must be provided in the method of the IPAs choosing until data synchronization through the GDSN is compulsory. Once the relevant IPA confirms receipt of the required master data, shipments will be accepted with the global standards data capture requirement.

IPA CONTACTS

You can contact the following resources for questions on IPA-specific implementation:

Agency	Contact	
	Global Standards	Data Synchronization
GDF / Stop TB Partnership	Nigorsultan Muzafarova Lead QA Officer nigorsultanm@stoptb.org	Dorothy Amony Product Quality Officer dorothya@stoptb.org
UNDP	Zafar Yuldashev Procurement Specialist zafar.yuldashev@undp.org	Zafar Yuldashev Procurement Specialist zafar.yuldashev@undp.org
UNFPA	Thinlay (Nono) Wangchuk ICT Specialist wangchuk@unfpa.org	Thinlay (Nono) Wangchuk ICT Specialist wangchuk@unfpa.org
USAID GHSC-PSM	Kaitlyn Roche Manager, Global Standards globalstandards@ghsc-psm.org	Samuel Oh Product Catalogue Manager datasync@ghsc-psm.org

GS1 RESOURCES

More than 110 GS1 MOs are available globally to support registration, training and education, and implementation. Information on how to contact GS1 MOs is available here: https://www.gs1.org/contact/overview

GDSN RESOURCES

Many 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.

ANNEX A: GLOSSARY OF TERMS

A glossary of key terms is provided below. It is recommended that responding suppliers consult the *GS1 General Specifications* 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 Organization for Standardisation (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 the management of the GTIN.
check digit*	A final digit calculated from the other digits of some GS1 identification keys. This digit is used to check that the data has been correctly composed. (See GS1 check digit calculation.)
concatenation*	The representation of several element strings in one barcode.
data synchronization	The process of maintaining the consistency and uniformity of data instances across all consuming applications and storing devices.
Data Matrix*	A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern.
Global Location Number (GLN)*	The GS1 identification key used to identify physical locations or parties. The key comprises a GS1 Company Prefix, location reference, and check digit.
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 AISBL. GS1 General Specifications. Release 18, Ratified January 2019.

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 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 opportunity 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 non-sterile packaging, the first level of packaging can be in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.
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.

*GS1 AISBL. GS1 General Specifications. Release 18, Ratified January 2019.

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.
kit*	A collection of different regulated healthcare items assembled for use in a single therapy.
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, pharmaceuticals, 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 products and/or 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 a procurement agent 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 distributer.
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.

*GS1 AISBL. GS1 General Specifications. Release 18, Ratified January 2019.

tertiary packaging	The highest level of packaging that may include a pallet that contains (one or usually) several cases or a case that contains (one or usually) several items in its primary or secondary packaging. Tertiary packaging may refer to either a logistic unit or a trade item.
tertiary partial pack	A homogenous pack of products that is not to be considered a trade item because it is less than full.
trade item*	Any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in any supply chain.

*GS1 AISBL. GS1 General Specifications. Release 18, Ratified January 2019.

ANNEX B: FREQUENTLY ASKED QUESTIONS

This annex 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 global standards to meet requirements of endorsing IPAs.

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

- **Section 1: IDENTIFY.** Questions about GS1 identification numbers, including the identification of trade items, 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: OTHER.** Additional questions beyond the above three topics

SECTION 1: IDENTIFY

The questions in this section address identification — assigning a GS1 identification number to items and locations so they can be unambiguously referenced in data captured within an Organization and shared with other Organizations.

1.1 Questions about the GTIN[25]

1.1.1 What is a GTIN?[+]

The GTIN is the globally unique GS1 identification number (or "GS1 Key") 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 relevant IPAs?

GTINs and GLNs can be provided through the GTIN/GLN Submission Form available at: https://www.ghsupplychain.org/global-standards/gtinglnsubmissionform

[25] 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)?+

HRI is the printed representation of the data encoded within a barcode (e.g., GS1 DataMatrix or GS1-128 barcodes). HRI text always appears immediately adjacent to the barcode and is subject to the formatting rules specified in the GS1 General Specifications.[26]

A shipping 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. Unless encoded in 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).

1.1.6. Are kits considered homogeneous or mixed trade items?

Kits are collections of non-homogeneous, separable components that are identified, purchased, and supplied as a single trade item for a specific clinical or commercial purpose.[27] Each component of a kit may be considered a trade item, but the kit itself is sellable, identified, and available for trade as a homogenous item.

All kits should be identified with a GTIN. As a best practice, all kit components should be listed on the product label. At a minimum, all kit components should be contained in a product catalogue, database, or similar document that references the kit GTIN.

When one or more kit component is specified (i.e., that item has unique characteristics and is not generically interchangeable with an equivalent item) and that component is substituted, the kit GTIN must be changed as well.

For more information on assigning GTINs to kits or bundles, see Section 5.1.8 of the GS1 Healthcare GTIN Allocation 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 4.14 Human Readable Interpretation (HRI) Rules.

[27] GS1 Healthcare GTIN Allocation Rules, Release 9.0.2, Section 2.2.1.1, Kits.

1.1.7 What is a partial pack trade item and how should it be identified and labeled?

A partial pack is a homogenous pack of items that is not to be considered a trade item because it is "less than full." Partial packs often result from an end-of-batch run. If a partial pack is produced, the carton should be labeled with an SSCC and require an extra label clearly marking the carton as "Partial" or equivalent and the quantity of units included within.

1.2 Questions about the SSCC[28]

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 (i.e. a partial pack). 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 "licence 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 logistics label containing the SSCC on the shipping unit (e.g., tote, carton, pallet). Suppliers are responsible for assigning (allocating) SSCCs to their logistic units.

[28] For more information, see GS1 General Specifications, Section 4.4 SSCC Rules.

1.2.4 Under which circumstances can an SSCC be reused?

When assigning an SSCC, the rule per the *GS1 General Specifications* 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.[29]

1.2.5 How is an SSCC different from a GTIN?[+]

SSCCs are distinctly different from GTINs. The SSCC acts as a licence 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 an 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 labelled 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.

---

[29] 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 summarises the appropriate use cases for GTIN and SSCC identifiers for pharmaceuticals and vaccines:

Scenario	Identifier on secondary pack	Identifier on tertiary pack	Identifier on 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 (aggregated "parent" of case-level SSCCs)
Mixed case, and the case is packed onto a pallet with other cases	GTIN (based on various item-level GTINs) + serial number	SSCC	SSCC (aggregated "parent" of case-level SSCCs)
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	SSCC on the case logistic label
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 summarises the appropriate use cases for GTIN and SSCC identifiers for medical devices, sterile kits, and laboratory reagents:

Scenario	Identifier on secondary pack	Identifier on tertiary pack	Identifier on 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 (aggregated "parent" of case-level SSCCs)
Mixed case, and the case is packed onto a pallet with other cases	GTIN	SSCC	SSCC (aggregated "parent" of case-level SSCCs)
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 on the case logistic label

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

1.2.9 How do I pass SSCCs to relevant IPAs?

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 on relevant transactional documentation in the format and exchange mechanism specified by a given IPA.

1.3 Questions about the GLN[30]

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?

When a company joins GS1, the GS1 MO it registers with issues a GS1 Company Prefix (GCP) and assigns a GLN, which identifies the business entity to which the GCP has been issued. GLNs for additional locations and/or business entities can be assigned by the holder of the GCP as necessary.

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

GLNs are not required to be labelled on packaging or encoded in a data carrier. The purpose of GLNs is to standardise location identification and related information in master, transaction and, in the future, event data exchange.

1.4 Questions about the GS1 Company Prefix (GCP)[31]

1.4.1 What is a GCP?[+]

A GCP is a unique string of digits issued to your company by your local GS1 MO. These digits are part of every GS1 identification number that you create (GTIN, SSCC,

[30] 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.

[31] For more information, see GS1 General Specifications, Section 1.5, GS1 Company Prefix Allocation.

GLN, etc.). Because your GCP is different from every other company's GCP worldwide, the GS1 identification numbers you create are also globally unique.

1.4.2 Does the GCP uniquely identify my company or brand?[+]

No. The GCP is not an identifier. It is a string of digits used as a part of GS1 identification numbers. A GCP does not uniquely identify a company or brand because a given company could have more than one GCP, and sometimes a company uses the same GCP to identify products of several brands. The unique identifier for a company is a corporate GLN.

1.4.3 How do I get a GCP?

To get a GCP, 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 GCP can be found here: https://www.gs1.org/company-prefix.

1.4.4 Our company does business in multiple countries. Do I need a GCP for each country?[+]

No. Your GCP can be used to create GTINs, SSCCs, GLNs, or any other GS1 identification number for use globally. You are encouraged to licence your GCP with the country where you are headquartered and where you may choose to solicit support from your GS1 MO.

1.4.5 If an intermediary supplier (e.g., wholesaler, distributer) is supplying pharmaceuticals or medical devices, then whose GCP should be used for identification on the GTIN, GLN, and SSCC?

Ideally, the GCP registered to the brand owner of the product should be used. If the brand owner does not provide its GCP, then either the actual manufacturer or supplier has to identify the commodities using a GCP registered to it to comply with the requirement.

1.5 Questions about the serial number[32]

1.5.1. Are there specifications for the profile of the serial number?

No, there is not a mandated structure or profile of 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

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

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

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. All other technical guidance related to generating and maintaining uniqueness of the serial number should be referenced from the *GS1 General Specifications*.

1.5.2. Is serial number aggregation required?

Serial number aggregation is not a formal requirement. However, in many cases manufacturers will determine aggregation is a business requirement to enable management and exchange of serial number data and associated information.

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 carriers[33]

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 carriers[34]

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.

[33] For more information, see GS1 General Specifications, Section 5.4, GS1-128 symbology specifications.

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

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 characterised 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 the 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?

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.*[35]

2.3 General questions about data carriers

2.3.1 What are GS1 Application Identifiers (AI)?[36] 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.

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 a 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."

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

[35] Interagency Supply Chain Group. Visibility for Health Systems: Adoption of Global Data Standards (GS1). August 2017. Available: https://www.ghsupplychain.org/visibility-health-systems-adoption-global-data-standards.

[36] For more information, see GS1 General Specifications, Section 3, GS1 Application Identifier definitions.

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 to this guideline.

Use case	Data carrier	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 recommended to have fixed-length data elements precede variable-length elements. As an example:

- (01) GTIN
- (17) Expiration date
- (10) Batch/lot
- (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 in this document?

This guideline identifies the minimum GS1 identification keys to be included on product labels. However, additional AIs are permitted at the discretion of the supplier.

While barcode reading applications should work correctly even if additional AIs are present, the use of additional AIs is discouraged, unless necessary, to avoid possible

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

challenges if downstream barcode reading applications are not configured to support additional AIs.

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 should test your barcode(s) for compliance with GS1 Standards using a formal verification process. Testing assesses size, colour, print quality, quiet zones, barcode height, location/placement, and calculation of the check digit.
- Your solution provider should 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

3.1.1 What is master data?

Master data is description attribute information about a product (GTIN) or location (GLN). These data attributes are generally fairly static and will not change on a transaction-by-transaction basis. Examples of product master data include weight, dimensions, shelf-life, quantity, and market authorization information. 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 GS1 Global Data Synchronization Network (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 comprises 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 GDSN is a synchronization method for GS1 standards-based data that are 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 data synchronization being implemented?

IPAs have indicated interest in using the GDSN to receive item information as the basis of our product catalogue. This will enable IPAs to provide donor-supported countries with the information they need to optimise decision-making around order planning, procurement, shipping, and receiving for better data visibility and improved data quality. Synchronised 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 synchronizing 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, pack, case, and pallet levels
- Provides accurate, standards-based, synchronised 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.

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 What data pool is being used?

IPAs may choose to use different data pools. Because all GDSN-certified data pools are capable of exchanging data with one another, the choice of data pool by the recipient IPA and the supplier are inconsequential to participation and data synchronization.

3.2 Questions about transaction data

This section is informational; currently, IPAs are not implementing the GS1 standard for exchanging transaction data.

3.2.1 What is transaction data?

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

3.2.2 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.

3.2.3 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, such as purchase orders and invoices, to be communicated electronically instead through a standard format.

3.2.4. Will there be a guideline for the use of EDI for the exchange of transaction data?

The use of EDI is being evaluated by different IPAs. Details on the use of EDI for transaction data exchange with suppliers, and additional information will be provided is and when guidelines are developed. In the interim, if a supplier is interested in piloting GS1 EDI standards for transaction data exchange with a relevant IPA, please reach out to that IPA counterpart.

3.3 Questions about event data

This section is informational; currently, there are no requirements 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 EPCIS be used for exchange of event data?

Relevant IPAs are assessing processes and systems to determine the appropriateness and applicability of leveraging EPCIS in our supply chains in the future.

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

SECTION 4: ADDITIONAL QUESTIONS

4.1 Questions about the guideline

4.1.1 For which products does this guideline apply?

Many IPAs are moving toward requirements for the identification and labelling of pharmaceuticals and vaccines. USAID GHSC-PSM also has a procurement requirement for medical devices, laboratory reagents, and sterile kits. However, IPAs may adopt this guideline on a voluntary basis for procurements where they consider relevant, necessary and/or beneficial. Item identification and labelling in adherence to this guideline is optional for all other product categories at this time. IPAs may apply this guideline to all or subsets of products under these on a case-by-case basis at their discretion.

4.1.2 Is there a transition period to the new guideline?

No. Previous labelling requirements, where they existed, were often proprietary and used largely for internal purposes such as logistics and inventory control. IPAs are enabling their systems to leverage GTINs and GLNs as the functional identifiers. The primary dependency for their use is the availability of master data associated with the GTIN and GLN for implementation.

4.1.3 What do the dates against each phase signify in Annex C?

The dates in Annex C are the IPA-specific timelines adopted for phased implementation for each commodity group. Contact the relevant IPAs for specific details.

4.1.4 Are there circumstances in which suppliers can request an exemption from the guideline?

Endorsing IPAs will determine the applicability of this guideline, but in general, moving towards compliance will likely become increasingly mandatory.

4.1.5 Are there circumstances in which suppliers can request an exception from the guideline?

Endorsing IPAs will determine the applicability of this guideline, but in general, moving towards compliance will likely become increasingly mandatory.

Exceptions for adherence will be considered on a case-by-case basis for serialization, labelling, and master data exchange, when the supplier can demonstrate either:

a. a reasonable effort to implement within the required timeframe and a plan for full implementation in an alternate proposed timeline, or

b. an importing country has mandated a specific requirement identification and data capture that does not allow for this guideline to be implemented in addition to those requirements.

To request an exception to this guideline, please reach out to relevant IPA contacts identified in Section 7.

4.1.6. What does the date associated with each phase signify?

Any in-scope items manufactured after the date specified for each phase should have the stated capability in place to be compliant.

4.2 Questions about country programs supported by IPAs

The questions in this section address the applicability of this guideline to support country programs.

4.2.1 Which guidelines need to be adhered to if the importing country has specific requirements?

If the importing country NRA has mandated its own specific requirements for identification and data capture that do not also allow for this guideline to be fulfilled, the supplier can request an exception to the data capture requirement at various levels of packaging. However, an instance in which the guideline will not be applied needs to first be confirmed as an exception with relevant IPA contacts identified in Section 7 and relevant NRAs.

ANNEX C: AGENCY UPTAKE TIMELINES

Implementation timelines for vaccines and pharmaceuticals
The following timelines have been developed by IPA for supplier compliance with the specifications outlined in Section 2. These timelines will be formalised in the contracts developed for procurement of each in-scope item as defined by the IPA at its discretion.

Agency	Phase 1	Phase 2	Phase 3	Phase 4
GDF / Stop TB Partnership	30 Dec 2019	30 Dec 2019	30 Jun 2020	30 Jun 2022
The Global Fund	30 Dec 2019	30 Dec 2019	30 Jun 2020	30 Jun 2022
UNDP	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred
UNFPA	30 Dec 2019	30 Dec 2020	Voluntary but preferred	Voluntary but preferred
USAID GHSC-PSM	30 Dec 2018	30 Dec 2019	30 Jun 2020	30 Jun 2022

Implementation timelines for medical devices, sterile kits, and laboratory reagents
The following timelines have been developed by IPA for supplier compliance with the specifications outlined in Section 3. These timelines will be formalised in the contracts developed for procurement of each in-scope item as defined by the IPA at its discretion.

Agency	Phase 1	Phase 2	Phase 3	Phase 4
GDF / Stop TB Partnership	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred
The Global Fund	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred
UNDP	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred
UNFPA	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred
USAID GHSC-PSM	30 Dec 2018	30 Dec 2019	30 Jun 2020	30 Jun 2022