



UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

GS1 Barcoding of CONVENTIONAL MEDICINES

An Introduction and Reference Guide
Version 1.0



Document Control

Version	Date	Author(s)	Comments
0.1	14 February 2021	Ministry of Health and Prevention	First Draft
1.0	10 August 2021	Ministry of Health and Prevention	Final Version



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Introduction

The Ministry of Health and Prevention, UAE, launched the Tatmeen Project, a platform for tracking and tracing serialized pharmaceutical products to fortify and secure the country's healthcare supply chains. The initiative strengthens the UAE's position with leading countries with advanced pharmaceutical safety solutions.

Protecting public health, contributing to increased population happiness and sustainability, and ensuring reliable, safe, effective, and easily accessible health care requires creating best in class solutions through digital technologies and simple processes that connect the entire stakeholder community in close cooperation.

The Ministry of Health and Protection's commitment to the public has been emphasized through this new project, which is a powerful serialized drug track and trace system that will benefit from the latest technological developments. The drug tracking system will allow the identification and tracking drugs sold in the UAE from a central command center using the unique GS1 standard serialized bar codes. Inspectors will be able to scan bar codes in stores, pharmacies, and hospitals, identify counterfeit and illegal drugs and service providers. The public will be able to validate their medications using customized mobility solutions. The system will also enable supply chain stakeholders to track the movement of medicines.

This solution puts the UAE at the forefront of the healthcare system with its unique features of full integration with a single central command center and will be a platform that will set an industry benchmark for controlling counterfeit and substandard medicines.

This document provides further information regarding the GS1 System of Standards, its benefits for all stakeholders in the UAE pharmaceutical supply chain, and how stakeholders can become compliant with the UAE's serialization requirements.

The guide is available on the Tatmeen website (www.tatmeen.ae)



1. Definitions

Term	Definition
GS1-128 Barcode	The GS1-128 barcode is a subset of the Code 128 barcode symbology. Its use is exclusively licensed to GS1. This extremely flexible symbology encodes element strings using GS1 Application Identifiers.
Global Trade Item Number (GTIN)	The Global Trade Item Number (GTIN) is the GS1 identification key that uniquely identifies products worldwide. It can be encoded in various types of data carriers, including GS1 DataMatrix. The GTIN can be used to identify types of products at any packaging level (e.g., consumer unit, inner pack, case, pallet).
Global Location Number (GLN)	The Global Location Number (GLN) is a globally unique GS1 identification number that can identify any location in the supply chain that needs to be uniquely identified. The GLN may be used to identify both physical locations and legal entities.
Serial Shipping Container Code (SSCC)	The Serial Shipping Container Code (SSCC) is the GS1 identification key used to identify logistics units, which can be any combination of trade items packaged together for storage and/or transport purposes; for example, a case, a pallet.
Serial Number	The serial number is used to identify each product unit of product identified by GTIN. The serial number used for a product cannot be used again for the same product. The serial number can be up to 20 alphanumeric characters in length.
GS1 Application Identifier (AI)	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
Human Readable Interpretation (HRI)	Human Readable Interpretation (HRI) refers to the characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC (Automatic Identification Data Capture) data carriers confined to a GS1 standard structure and format.
Batch/Lot Number	Associates an item with information the manufacturer considers relevant for traceability of the trade item. The batch number can be up to 20 alphanumeric characters in length.
Data Carriers	Data carriers include different kinds of barcodes that can hold GS1 Identification keys and Application Identifiers. Examples include GS1 DataMatrix, GS1-128 and EAN/UPC barcodes.
Expiry Date	An expiration date or expiry date is a date after which a product should no longer be used, either by law or by exceeding the anticipated shelf life for perishable goods.
Label	A label refers to all labels and other written, printed, or graphic material that is affixed to pharmaceutical products.
Logistic Unit	A logistic unit is an item of any composition that is uniquely identified by a Serial Shipping Container Code (SSCC) established for transport and/or storage that needs to be managed through the supply chain. Logistic units take many forms (e.g., a single box containing a limited number of items, a



	pallet of multiple items or an intermodal container containing multiple pallets).
Trade Item	Any item (product or service) from 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.
Pharmaceutical Supply Chain	Pharmaceutical supply chain is the flow from the origin to the consumption of pharmaceutical products covering the manufacturing, import, distribution, transportation, storage, and dispensing stages, as well as other types of flows.
Recall	Recall is a process for removing a pharmaceutical product from the pharmaceutical supply chain because of a proven defect in quality, safety or efficacy, a falsified label, or any other similar defect.
Primary Packaging	The innermost layer of packaging, i.e., the layer closest to the pharmaceutical product (pill, liquid, instrument, etc.).
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 regulated packaging level is the lowest serialized saleable pack in the supply chain.
Scanner	An optical electronic device used to read a barcode, thus decoding the graphic image and transmitting the encoded data to a computer system.
Traceability	Traceability is the capability to trace something. In some cases, it is interpreted as the ability to verify the history, location, or application of an item by means of documented recorded identification.
Aggregation	Aggregation is the creation of a hierarchical, parent-child relationship between a containing object (i.e., parent) and one or more objects (i.e., children) that are contained in it. Aggregation requires unique identification of the parent: i.e., GTIN + serialization (SGTIN) if the parent is a trade item, or SSCC (Serial Shipping Container Code) if the parent is a logistic item.



2. Objectives



PRODUCT SECURITY

- Detect counterfeits and falsified medicines
- Avoid reimbursement fraud
- Ensure traceability and fast product recalls and withdrawals



PATIENT SAFETY

- Avoid medication errors



SUPPLY CHAIN VISIBILITY

- Forecasting shortages
- Recall effectiveness
- Ensure accurate, real-time information flow among stakeholders



3. The GS1 System of Standards



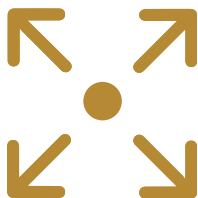
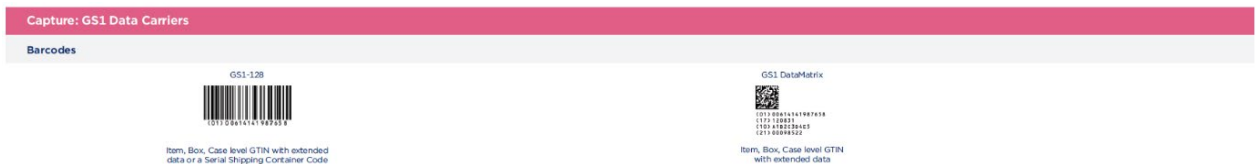
Identify

GS1 identification numbers make it possible to assign globally recognized unique identification for products and locations.



Capture

GS1 data carriers, typically barcodes, provide an array of choices for product and package type.



Share

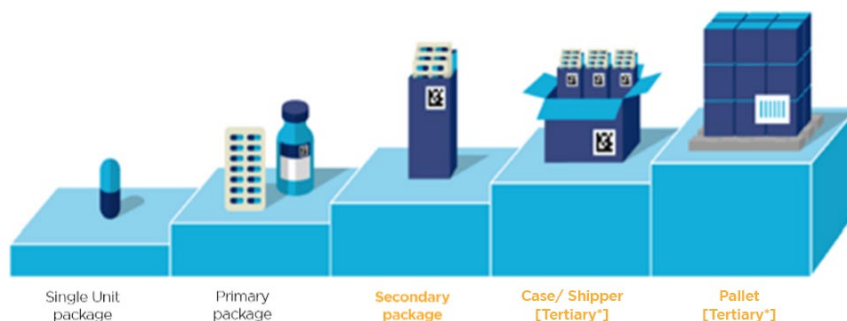
GS1 standards enable the efficient sharing of information from trusted and authentic sources.



I. Identify

4. General Requirements for Product Identification

1. All secondary packaging sold, imported, produced and supplied to the UAE must be serialized. Secondary packaging must have the following data elements on it and encoded in a GS1 DataMatrix:
 - a. Global Trade Item Number (GTIN)
 - b. Randomized Serial Number (1/10,000 randomization)
 - c. Expiry Date
 - d. Batch or Lot Number
2. Logistic Units must be aggregated and identified with an SSCC (Serial Shipping Container Code). Aggregation is to be done by the manufacturer on all applicable packaging levels to ensure ease of downstream reporting. Distributors, wholesalers and health facilities that unpack and re-pack products to deliver to points of dispensing are required to aggregate the Logistic Units using their own SSCC codes. If, in addition to being a Logistic Unit, the item is regarded as a Trade Item by the brand owner, it may additionally be identified with a GTIN.




*Note: There is no globally standardised definition of 'tertiary package'

■ : Mandatory for UAE



Illustration of Packaging Levels



Required Serialization and Aggregation on Different Levels of Packaging

Packaging Unit	Encoded Data	Application Identifier	Mandatory Symbology	Mandatory Optional
- Secondary Packaging 	GTIN Serial Number Expiry Date Batch Number	(01) (21) (17) (10)	GS1 DataMatrix	Mandatory
- Trade Item - Example: Bundle 	GTIN Serial Number Expiry Date Batch Number	(01) (21) (17) (10)	GS1 DataMatrix	Optional
- Trade Item - Example: Shipper Case - Preferred Option for UAE 	GTIN Serial Number Expiry Date Batch Number	(01) (21) (17) (10)	GS1 DataMatrix	Mandatory
- Homogeneous Logistic Unit - Example: Shipper Case 	SSCC	(00)	GS1-128	Mandatory
- Heterogeneous Logistic Unit and/or Partial Logistic Unit 	SSCC	(00)	GS1-128	Mandatory



<p>- Homogeneous Logistic Unit - Example: Pallet</p> 	SSCC	(00)	GS1-128	Mandatory
<p>- Heterogeneous Logistics Unit - Example: Pallet</p> 	SSCC	(00)	GS1-128	Mandatory

Products that require serialization include:

- All conventional medicines sold, distributed, or stored in the UAE.

Products that are exempt from serialization include:

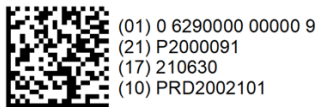
- Free samples of pharmaceutical products.
- Pharmaceutical products imported for personal use only.
- Medical Devices and Supplies.
- GSL Products.



II. Capture

5. General Requirements

All secondary packaging must be barcoded with a GS1 DataMatrix. The GS1 DataMatrix must be encoded with the following Application Identifiers:



*the above illustration is the preferred encoding order of the Application Identifiers in the GS1 DataMatrix.

Application Identifier(AI)	Data Element	AI Type	Format
01	GTIN	Fixed in Length	14 Digits
10	Batch or Lot Number	Variable in Length	X_1-X_{20} Alpha-Numeric Characters
17	Expiry Date	Fixed in Length	6 Digits
21	Serial Number	Variable in Length	X_1-X_{20} Alpha-Numeric Character







The above are not standalone data elements and must be associated with a GTIN and encoded within the same GS1 DataMatrix.

To ensure that no additional risk or inefficiencies are created by having both a linear and a GS1 DataMatrix barcode, MoHAP recommends that all secondary packaging should only have a GS1 DataMatrix barcode. If a linear barcode and a GS1 DataMatrix are present on the secondary packaging, both barcodes need to be encoded with the same GTIN.



6. Encoding Options for Secondary Packaging

Below are the 6 options for encoding the Application Identifiers in the GS1 DataMatrix:

1.	 (01) 0 6290000 00000 9 (21) P2000091 (17) 210630 (10) PRD2002101	GTIN Serial Number Expiry Date Batch Number
2.	 (01) 0 6290000 00000 9 (17) 210630 (21) P2000091 (10) PRD2002101	GTIN Expiry Date Serial Number Batch Number
3.	 (01) 0 6290000 00000 9 (17) 210630 (10) PRD2002101 (21) P2000091	GTIN Expiry Date Batch Number Serial Number
4.	 (01) 0 6290000 00000 9 (10) PRD2002101 (17) 210630 (21) P2000091	GTIN Batch Number Expiry Date Serial Number
5.	 (01) 0 6290000 00000 9 (10) PRD2002101 (21) P2000091 (17) 210630	GTIN Batch Number Serial Number Expiry Date
6.	 (01) 0 6290000 00000 9 (21) P2000091 (10) PRD2002101 (17) 210630	GTIN Serial Number Batch Number Expiry Date



7. Serial Shipping Container Code (SSCC)

All Logistic Units must be aggregated and barcoded using a GS1-128 barcode. The SSCC should be encoded in a GS1-128 using AI (00).

For example:

Application Identifier (AI)	SSCC
00	00123456789101123

GS1-128







8. Human Readable Interpretation (HRI)


Human readable interpretation (HRI) is the information below, beside, or above a barcode which is encoded in the barcode and represents the same characters as carried in the barcode. HRI refers to the characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC (Automatic Identification Data Capture) 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 any symbol check character, are not shown in the human readable interpretation.



Printed Information on Secondary Packaging

Options	GS1 DataMatrix	Clarification	Labelling on Secondary Packaging
First Option	 GTIN: 0 6290000 00000 9 SN: P2000091 EXPIRY: 210630 BATCH/ LOT: PRD2002101	GTIN, Serial Number, Batch, and Expiry Date are compulsory in the same format. Expiry date also must be written on the outer pack in a clear format that shows the month and year.	Lot: PRD2002101 Exp: June 2021 Mfg: June 2018
Second Option	 GTIN: 0 6290000 00000 9 SN: P2000091	GTIN and Serial Number can be printed without the Batch Number and Expiry Date, but the Batch Number and Expiry Date should be printed on the outer pack.	Lot: PRD2002101 Exp: June 2021 Mfg: June 2018
Third Option	 GTIN: 0 6290000 00000 9 SN: P2000091 EXPIRY: 210630 BATCH/ LOT: PRD2002101	GTIN, Serial Number, Batch Number, and Expiry Date are compulsory in the same format. Expiry Date must be written on the outer pack in a clear format that shows the month and year.	Exp: June 2021 Mfg: June 2018
Fourth Option	 GTIN: 0 6290000 00000 9 SN: P2000091 BATCH/ LOT: PRD2002101	GTIN, Serial Number, Batch Number can be printed without the Expiry Date, as long as the Expiry Date is printed on the outer pack.	Exp: June 2021 Mfg: June 2018



Fifth Option	 GTIN: 0 6290000 00000 9 SN: P2000091 EXPIRY: 210630 BATCH/ LOT: PRD2002101	GTIN, Serial Number, Batch Number and Expiry Date are compulsory in the same format.	Mfg: June 2018
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9. Quality and Readability General Requirements

The barcodes quality measurement processes and minimum quality levels detailed in the GS1 General Specifications Section 5.12.3 “GS1 Symbol Specification Tables” shall be followed. The manufacturer shall have a procedure in place to control and document the print quality of the barcode and shall be able to provide documentation to the Ministry of Health and Prevention upon request at any time. The manufacturer shall ensure consistent printing quality across packages. The manufacturer shall verify that the barcode can stand moisture, abrasion and other external factors that can possibly influence its quality. The barcode shall be printed on the label of the product in a good, visible manner. The barcode shall be printed on a flat surface. The barcode shall not be covered by anything which prevents its scanning.

10. Scanning Environment

To read a GS1 DataMatrix, scanners must be appropriately programmed to read the GS1 barcodes. Like other 2D barcodes, GS1 DataMatrix symbols require scanners that are based upon camera or 2D imaging technology. It should be noted that 1D Linear barcode scanners cannot read GS1 DataMatrix barcodes; however, imaging-based barcode scanners can read both linear and GS1 DataMatrix barcodes.



III. Share

11. Master Data Management

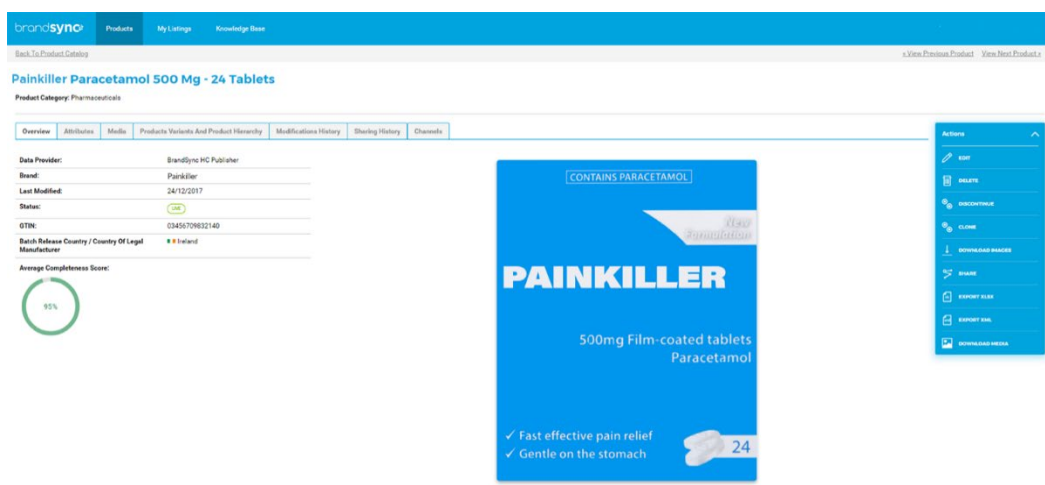
WHAT IS MASTER DATA?

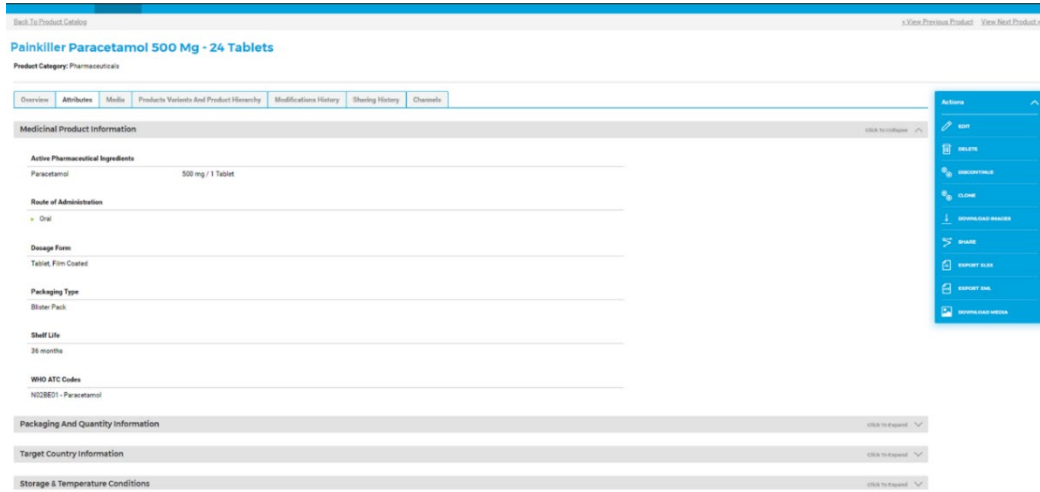
Master data is what is created when identification data and reference data are linked across multiple systems into a single, consistent point of reference. That single point of reference could be an item (GTIN) or location (GLN) identification number. A business application typically needs additional descriptive information associated with each identifier. For example, descriptive information for a GTIN might include the name of the product, the brand name, the packaging type, and so on. Descriptive information for a GLN might include the street address of the location and its geocoordinates. Such descriptive information is called master data.

GS1 UAE'S PLATFORM

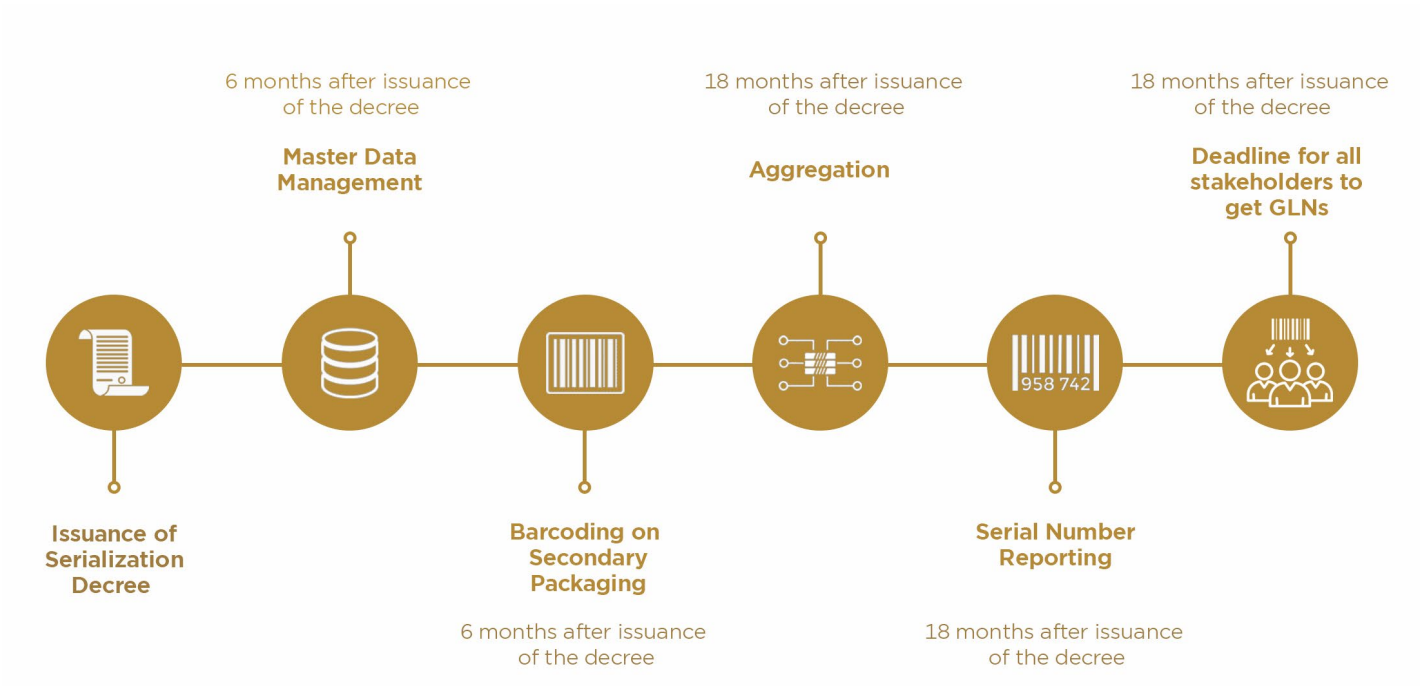
The marketing authorization holder, brand owner, manufacturer, or their subsidiaries shall register and upload the required product master data on GS1 UAE's platform (BrandSync). Registration on BrandSync can be done via this [registration link](#). All supply chain actors located in the UAE must obtain a GLN (Global Location Number) from GS1 UAE to identify their organization, location, and other required information.

Sample of a pharmaceutical product registration





12. Implementation Roadmap





13. References

Ministry of Health and Prevention

<https://www.mohap.gov.ae/>

Tatmeen

<http://www.tatmeen.ae>

GS1 UAE

<https://www.gs1ae.org/>

GS1 General Specifications

<https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications>

GS1 DataMatrix Guideline

<https://www.gs1.org/standards/gs1-datamatrix-guideline/25>

GS1 GLN Allocation Rules

<https://www.gs1.org/1/glnrules/en/>