Medicines Barcoding and Serialization Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Introduction

The National Health Regulatory Authority (NHRA) believes that global standards for automatic identification provide an opportunity to make the healthcare supply chain in the Kingdom of Bahrain safer as well as more efficient and accurate. NHRA has realized that a global, standardized identification system from product manufacture to patient treatment is imperative to comply with the increasing need for product traceability around the world.

Therefore, and because the GS1 system of standards, which the global healthcare community has endorsed, is one of the most widely used trade item identification systems worldwide, NHRA urges all international drug manufacturers exporting to the Kingdom of Bahrain to adopt GS1 supply-chain standards.

The National Health Regulatory Authority (NHRA) is now adopting and mandating the use of GS1 DataMatrix on the packaging of pharmaceutical products. All products must be compliant with this new regulation by 31st December 2019, as per the requirements detailed within this guideline.

This document provides further information regarding the GS1 system of standards, the benefits of its use for key stakeholders (manufacturers, distributors, importers, pharmacies and hospitals) and how stakeholders can become compliant with the Supreme Council of Health resolution no. (41) for the year 2017 - Issuing the System for Tracking and Tracing Medicine Provision and Supply Chain inside the Kingdom of Bahrain.

It is important to note that this document represents a summary of the core information that stakeholders should be aware of in relation to the GS1 system of standards. For further detailed reading on the practical and technical elements of this system, please refer to the GS1 General Specifications.

Definitions

- **GS1 DataMatrix 2-D Barcode**

  The GS1 DataMatrix barcode is a graphic representation of digital data in a two-dimensional format with high information-decoding capacity.

- **Global Trade Item Number (GTIN)**

  The GS1 Global Trade Item Number (GTIN) is an identification key that uniquely identifies products worldwide. It can be encoded in various types of data carriers, including GS1 DataMatrix.

- **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.

- **GS1 Company Prefix (GCP)**

  A GS1 Company Prefix (GCP) allows companies to uniquely identify products, logistic units, locations, and assets globally. The GCP is used to construct GS1 identification keys such as GTINs, GLNs and SSCCs (Serial Shipping Container Code).

- **Serial Number (SN)**

  The serialization number (SN) is used to identify each product unit of product identified by GTIN. The SN used for a product cannot be used again for the same product. The SN can be up to 20 alphanumeric characters in length.

- **Application Identifier (AI)**

  The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.

- **Attribute**

  An element string that provides additional information about an entity identified with a GS1 identification key, such as batch number associated with a Global Trade Item Number (GTIN).

- **Batch Number**

  The batch or lot number associates an item with information 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.

- **Data Carriers**

  Different kinds of media that can hold GS1 Identification keys and application identifiers.

- **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.

- **Primary Packaging**

  The first level of packaging for the product marked with an automatic identification and data carrier (AIDC) either on the packaging or on a label affixed to the packaging.

- **Secondary Packaging**

  A level of packaging marked with an automatic identification and data carrier (AIDC) that may contain one or more primary packages or a group of primary packages containing a single item.

- **Scanner**

  An electronic device to read barcode and convert them into electrical signals understandable by a computer device.

Objectives

- Increase patient safety.
- Reduce medication errors.
- Detect counterfeits.
- Ensure traceability and fast product recalls and withdrawals.
- Ensure accurate, real-time information flow among stakeholders.

Identification of Medicinal Products for NHRA

The following new requirements must be applied by drug manufacturers on all human drugs. Please refer to related circular announced by the Supreme Council of Health regarding implementation dates.

A. Main Required Attributes

I. **The GS1 Global Trade Item Number (GTIN) – AI (01):** is an identification key that uniquely identifies products worldwide. It can be encoded in various types of data carriers, including GS1 DataMatrix. A company receives a GS1 Company Prefix by joining a GS1 Member Organization. This gives the company the ability to create GTINs and access to the GS1 standards. Note: Refer to the GS1 General Specifications and GS1 Healthcare GTIN Allocation Rules for the GTIN Structure.

II. **Expiration Date – AI (17):** If you require additional data to identify an Expiration Date the GS1 Application Identifier (17) (often referred to as expiry date, use by date or maximum durability date) is used. This indicates the limit of consumption or use of a product (e.g., for pharmaceutical products it can indicate the possibility of an indirect health risk resulting from the ineffectiveness of the product after the date). It is expressed as year, month and day (YYMMDD). Note: The Expiration Date data string can only specify dates within a certain range. Please refer to the GS1 General Specifications for additional information on structure and range

III. **Serial Number – AI (21):** If Healthcare products are to be individually tracked and traced using a Serial Number, Application Identifier (21) can be used. This additional data is alphanumeric with a variable length of up to 20 characters. The SN determined by the pharmaceutical company does not need for a third party to get the SN. The GS1 application identifier used to identify the SN is 21.

IV. **Batch Number (or Lot Number) – AI (10):** If you require additional data to identify Batch or Lot Number, the GS1 Application Identifier (10) is used and typically assigned at the point of manufacture. This additional data is alphanumeric with a variable length of up to 20 characters.

Please note that the above attributes are not standalone attributes and must be associated with a GTIN and encoded within the same Data Carrier.

B. 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.

Healthcare products often encounter regulatory, space, and technical constraints, so some specific rules are outlined within the GS1 General Specifications for these products. The GS1 General; Specifications allow label designers to minimize space requirements through merging HRI and non-HRI text when meeting the GS1 recommended format is not practical. Doing so enables the manufacturer to display product safety information such as the batch / lot and expiry date, without the need to display it both as HRI and in a standard label structure.

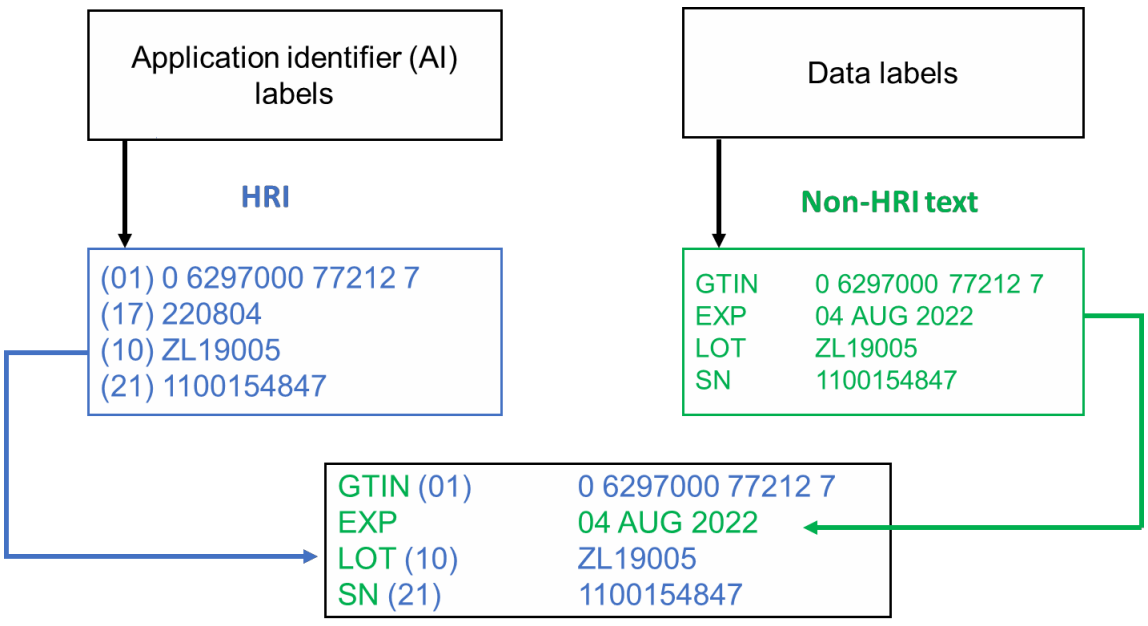
The figure below illustrates just one application of this approach, combining data labels (e.g. GTIN, SN, and LOT, etc.) with application identifier (AI) labels (01, 17, 10, 21). This approach enables the label designer to simultaneously meet the HRI labelling requirements without having to print this information in two locations. Since the application identifier label is displayed next to each attribute, the data printed must follow the HRI rules, matching the data encoded in the barcode symbol.

Figure 4: Example of HRI labelling

Figure 4

When the data format required to be displayed matches the HRI format, the AI may be used. However, when it does not match, the AI must be omitted, but the data label should be used to identify the attribute (refer to the GS1 General Specifications for more detail). This applies to all encoded attributes that may appear on a healthcare product label. This is illustrated in Figure 5 below. In this example, the date shown in HRI is 220804, while in non-HRI, it is represented as 04 Aug 2022. Since these formats do not match, the non-HRI format may be used, but the application identifier label, (17), is omitted. The label formats used in the following examples are not intended to be descriptive or recommendations for meeting the requirements of the standards or local regulations.

Figure 5: Example of merging HRI and non-HRI text



C. How to Read a GS1 DataMatrix Barcode

The Data Matrix barcode can be read by camera-based barcode scanners but not linear laser barcode scanners. However, camera-based barcode scanners can read all 1D/ linear and 2-D/ Matrix barcodes, including GS1 DataMatrix.

Generally, camera-based scanners have a higher price point than laser scanners, but they offer distinct advantages:

- Flexibility: They can read both 2-D/ Matrix and 1D/ linear barcodes; linear laser scanners can read only linear barcodes.
- Reliability: They have fewer moving parts than laser scanners, meaning a lower total cost of ownership.
- Image-capture support: They can image products, identification cards, and other documents.
- Compactness: Their size allows for integration with other systems (e.g., packaging line verification) and handheld computers.

GS1 Healthcare has published a specific position statement on camera-based scanners which provides further information about the need for these scanners and their advantages. You can read the statement here: www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf

Benefits of Applying GS1 DataMatrix Barcodes

A. For Manufacturers

- Reduce inventory assets: Improve demand forecasting and inventory planning.
- Reduce inventory financing and holding costs:
    - Reduce financing due to low inventory assets.
    - Reduce inventory management costs with more efficient and accurate processes.
- Reduce produce waste due to obsolescence: Improve inventory management to shrink inventory levels and unused product.
- Reduce cost of recalls:
    - Improve execution efficiency (increased supply-chain visibility).
    - Reduce scope of recalls (better targeting).
- Reduce counterfeits and recover lost profits: Reduction in counterfeit supply raises sales volume.
- Protect brands.
- Support product tracking and tracing.

- Reduce errors.
- Support patient and product safety.
- Obtain hospital accreditation.

B. For Distributors and Wholesalers

- Reduce inventory assets: Improve demand forecasting and inventory planning.
- Reduce inventory financing and holding costs:
    - Reduce working capital requirements by lowering inventory assets.
    - Reduce inventory management costs with more efficient and accurate processes.
- Improve recall effectiveness: Distributors capture shipment lot numbers for potential recall processing.
- The distributor would comply with track-and-trace regulations and mitigate the risk of inadvertently accepting counterfeit or diverted products into its supply chain.
- Transaction challenges: Serialization may create efficiencies in the chargeback process for distributors subject to this practice and make returns processing more effective and accurate.

C. For Retail Pharmacies

- Reduce recall processing costs: Minimize manual recall processing by visually inspecting products and contacting all patients potentially affected.
- Reduce data-cleansing costs: Reduce staff needed to cleanse supply-chain data by matching product data with master catalogue and validating accounts receivable and payable data.
- Reduce counterfeit risk: Use the data encoded within the barcode to validate product authenticity upon receipt.
- Reduce obsolescence: Ensure excellent management of nearly expired products.

D. For Hospitals

- Reduce adverse drug events: Reduce preventable medication errors and ADEs through bedside scanning.
- Reduce inventory levels: Improve demand forecasting and inventory control.
- Reduce inventory costs (financing and management): Automate processing for inbound receiving, SKU management, stock audits, and product returns.
- Reduce obsolescence: Improve inventory control and visibility on product expiry.
- Reduce recall processing costs: Minimize time spent searching for information.
- Reduce data-cleansing costs: Automate data management, order processing, and financial transactions.

GS1 DataMatrix Barcoding and Serialization Requirements

A. Products That Require Barcodes:

- Registered medicines with NHRA.
- Non-registered medicines, with valid temporary importation licenses from NHRA.

B. Products That Do Not Require Barcodes:

- Medicines free samples.
- Registered Health Products with NHRA.
- Approved Alternative & Complementary Medicines by NHRA.
- Non-registered Health Products and Alternative & Complementary Medicines, with valid temporary importation licenses from NHRA.
- Nuclear Imaging Agents and Contrast Media used for diagnostic purposes.
- Medicines cleared for secondary packing purposes (for local manufacturers ONLY).

C. To Comply with the Serialization Requirements:

- All companies participating in the exchange of serialization data in the Kingdom of Bahrain will need to have a GCP and a Global Location Number (GLN).
- To license a GCP please contact the GS1 office nearest to your location, or by visiting www.gs1.org.
- This includes all Invoicing Companies, Distributors/Agents and Dispensers.
- This information is used to sign up in the NHRA-MVC Traceability Hub

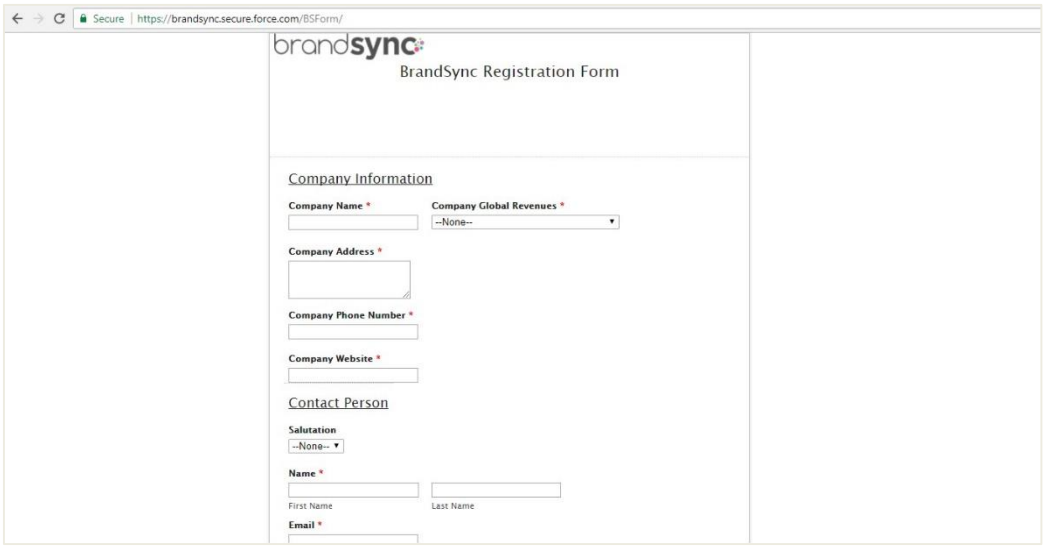
D. Registering of Product Master Data via BrandSync:

The provision of master data is an essential requirement for the successful implementation of this project. Accurate master data enables the unique identification of all products in the supply chain and will increase patient safety by reducing medication errors. Furthermore, accurate and standardized master data reduces costs, resulting in a more efficient supply chain. The NHRA will rely on the accurate and standardized data received from GS1 UAE's Portal (known as BrandSync) for all existing and new products supplied to the NHRA. BrandSync will be the single source of information for all product master data supplied to the NHRA.

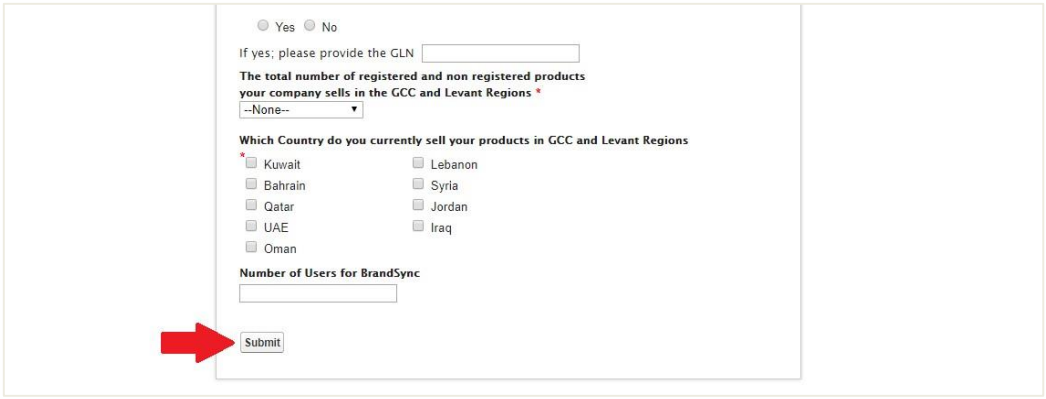
Through BrandSync, product master data can be uploaded, synchronized, and shared between brands and recipients (such as pharmacies, hospitals, and distributors). To become a user of BrandSync, companies must first register via the BrandSync portal and can do so by following these simple steps:

Visit the registration link: https://quote.brand-sync.com

1. Fill out the form to register your company:



2. Ensure completion of all required fields, these are indicated with an asterisk (*).
3. After completing all the required fields, click “Submit” found at the bottom of the form.

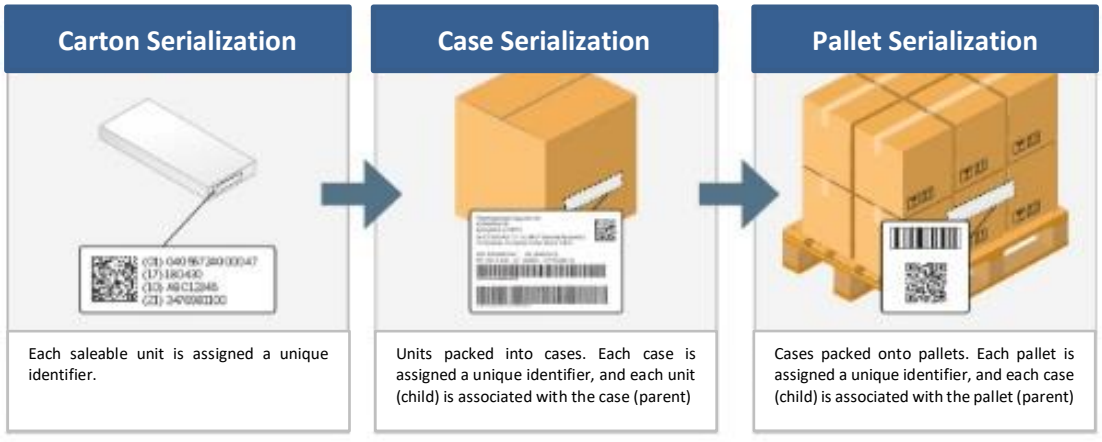


4. After your company details have been reviewed, you will receive a quotation.
5. Once received, you must approve the quotation by sending an email to accounts@brand-sync.com, confirming your approval of the quotation.
6. You will then be sent the Terms & Conditions via email, to be signed by your authorized signatory.

Once you have provided the signed Terms & Conditions and payment, you will receive an email containing your account details. You may then start using the BrandSync portal. Should you have any questions or queries when using the portal, you may contact hello@brand-sync.com or healthcare@gs1ae.org for further assistance.

Aggregation

Aggregation defines the relationship between the parent and child barcodes allowing the receiver of the product to scan one code and understand exactly what is in the whole shipment — every case or individual carton. NHRA requires both the case/shipper and the pallet tertiary packaging aggregation barcodes & serialization.



Timelines for Implementation

Manufacturers should note the following key dates for implementation of the mandatory requirements:

Action	Deadline
Allocating GTINs for medicines supplied in the Kingdom of	November 2017 – April 2018
Reporting of master data by manufacturers	November 2017 – April 2018
Deadline to comply with the barcoding and serialization requirements	December 31, 2019
Deadline to begin reporting serialized information the NHRA-MVC Traceability Hub	October 01, 2021
Deadline to comply with the aggregation of shipments and reporting requirements	May 01, 2022

Appendix: Table of Attributes

The following table outlines the product attributes to be uploaded into BrandSync.

Attribute	Mandatory: M Optional: O Conditional: C
Active Pharmaceutical Ingredients	M
Route of Administration	M
Dosage Form	M
Packaging Type	M
Shelf Life	M
Generic Name	M
Product Packaging Level	M
Is the product intended to be a Consumer Unit or a Tender Unit	O
Net Content	M
WHO ATC Codes	M
Marketing Authorization Holder	M
Manufacturer Internal Reference	O
Health Regulatory Authority Name	M
Is the product registered with the Health Authority	M
Health Regulatory Authority Product Registration Number	M
Registered Distributor or Agent Name	M
Storage and Temperature Conditions	M
Patient Information Leaflet	M
Image	M
GTIN	M
Product Description	M
Brand Name	M
Barcode Type	M
Target Markets	M
Batch Release Country	M

References

1. GS1 General Specifications:
   https://www.gs1.org/sites/default/files/docs/barcodes/GS1_General_Specifications.pdf

2. GS1 Healthcare GTIN Allocation Rules:
   https://www.gs1.org/1/gtinrules/en/

3. Saudi Drug Code (SDC) and Drug Barcoding Specifications:
   https://www.sfda.gov.sa/ar/drug/resources/DocLib2/Drug-resources-562.pdf

4. Bahrain's Supreme Council of Health Resolution.
   Supreme Council of Health resolution no. (41) for the year 2017 - Issuing the System for Tracking and Tracing Medicine Provision and Supply Chain inside the Kingdom of Bahrain.

5. Position Statement - GS1 Healthcare recommends investing in Camera-Based bar code scanners to address specific needs for Automatic Identification in Healthcare:
   https://www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf

6. GS1 DataMatrix Guideline:
   https://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf