Pharmaceutical Products Barcoding Guideline

December, 2021

Addis Ababa, Ethiopia

Foreword

Nowadays, pharmaceutical products are manufactured and distributed in complex supply chains. Due to this, the likelihood of infiltration of substandard and falsified pharmaceutical products to the legal supply chain is high. Moreover, end-to-end visibility in the supply chain is weak. Resolving these vulnerabilities will strengthen the integrity and efficiency of the supply chain, and improve patient safety.

A full-fledged traceability system that tracks and traces pharmaceutical products from the manufacture to the point of dispensing is critical. To capture and share near real-time information, reliable barcodes are a vital part of the supply chain. The Ethiopian Food and Drug Authority (EFDA) requires the manufacturers to place GS1 DataMatrix and other supply chain stakeholders to utilize GS1 compliant barcodes.

The Authority developed pharmaceutical products barcoding guideline that will serve as a guidance to supply chain stakeholders. It gives me great pleasure to introduce this edition to all beneficiaries, which is the fruit of joint effort of the EFDA and partners.

EFDA would like to thank all development partners and individuals who have been involved in the preparation of this valuable document. I would also like to thank the National Traceability Steering Committee and Technical Working Group members and other participants from different governmental, nongovernmental and privates for their valuable contribution and comments during the preparation of the guideline.

Finally, I would like to take this opportunity to acknowledge and express my appreciation to the United States Agency for International Development (USAID)/Digital Health Activity (DHA) for the financial and technical support in the preparation of this guideline. I call upon health professionals and interested parties to continue their usual support in reviewing the guideline by forwarding comments and suggestions to the EFDA using P.O.box 5681, Telephone: +251-115524122, e-mail: contactefda@efda.gov.et or traceability@efda.gov.et

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Acknowledgements

The Ethiopian Food and Drug Authority would like to acknowledge and express its appreciation to the USAID/DHA for the financial and technical support provided in preparing the Barcode Guideline.

The Authority would also like to thank the members of the National Steering Committee and Technical Working Group for their commitment and contribution in developing this guideline. Last but not least, the Authority would like to give special acknowledgments to those who were involved in the preparation of the guideline, for their invaluable contributions in scrutinizing and seeing it through to completion.

Abbreviations and Acronyms

AI	Application Identifier
AIDC	Automatic Identification and Data Capture
API	Active Pharmaceutical Ingredient
DHA	Digital Health Activity
EAN	European Article Number
EFDA	Ethiopian Food and Drug Authority
FNC1	Function 1 Symbol Character
GLN	Global Location Number
GSMP	Global Standards Management Process
GTIN	Global Trade Item Number
HRI	Human Readable Interpretation
MO	Member organization
PSM	Procurement and Supply Management
RFID	Radio Frequency Identification
SSCC	Serial Shipping Container Code
UI	Unique Identifier
USAID	United States Agency for International Development

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1. Introduction

The Ethiopian pharmaceutical supply chain system faces many challenges including substandard and falsified products, ineffective system for product recalls, medication errors and supply chain inefficiencies. Furthermore, end-to-end visibility in the pharmaceutical supply chain system is a critical challenge.

To improve patient safety, it is necessary to introduce a versatile regulatory system coupled with a traceability system of pharmaceutical products. This will make sure that patients are not exposed to falsified, substandard, expired, recalled or otherwise harmful pharmaceuticals. It will also improve the supply chain system efficiency by ensuring the visibility of pharmaceutical products.

In the healthcare system, unified global standards for Automatic Identification and Data Capture (AIDC) can make Ethiopia's pharmaceutical supply chain system safer. The unique identification of pharmaceutical products for track and trace purposes - from the point of manufacture to the point of dispense - is a key objective of traceability systems around the world. The EFDA requires the use of unique identifiers encoded in machine-readable forms. The use of GS1 DataMatrix barcodes helps to reduce or detect potential medication errors in health care settings by enabling health care professionals to verify that the right medication, in the right dose and right route of administration, is being given to the right patient at the right time.

The Authority believes that a standardized identification system from manufacture to the point of dispense is imperative to comply with the increasing demands for product traceability. To this end, as per article 53 (5) of the Food and Medicine Administration Proclamation No. 1112/2019, the Authority requires placement of a GS1 DataMatrix barcode on the label of pharmaceutical products. Considering this, the Authority urges all pharmaceutical manufacturers to adopt the barcoding standards.

Therefore, this guideline is developed to set requirements and provide guidance to the development, use and management of GS1 DataMatrix. The guideline describes the barcode requirements related with encoding, placement, printing, quality, reading and

proper use of the GS1 DataMatrix barcode, and roles and responsibilities of the supply chain stakeholders.

2. Objectives

2.1. General Objective

To provide guidance to supply chain actors to comply with the pharmaceutical products barcoding requirements in order to ensure patient safety, improve supply chain efficiency and end-to-end visibility.

2.2. Specific objectives

- To set barcoding specifications and guide supply chain stakeholders on barcoding system;
- To improve patient safety by reducing medication errors;
- To improve inventory management and minimize associated costs;
- To enable the tracking of each unit of pharmaceutical products in the supply chain;
- To improve detection of falsified products, improve recall effectiveness and ensure end-to-end visibility;
- To ensure accurate and real-time information movement among stakeholders.

3. Scope

The guideline applies to pharmaceutical products and it does not include medical devices.

4. Users of this guideline

The main users of this guideline includes pharmaceutical manufacturers, importers, wholesalers, drug retail outlets, health care facilities (e.g. hospitals, health centers, specialty centers, clinics etc.), and other pharmaceutical supply chain stakeholders.

This guideline will be used in conjunction with national medicine laws, GS1 system of standards and the relevant ISO standards.

5. Definitions

In this guideline, the following terms and definitions applies:

1. **“Aggregation**”: the documented parent/child relationships between uniquely identified items and the uniquely identified outer container that they are contained within for the purposes of improving the efficiency of serialization business processes involving data exchange and/or regulatory requirements.
2. “**Alphanumeric”:** a set of characters that contains alphabetic characters (letters), numeric digits (numbers), and other characters, such as punctuation marks.
3. “**Attribute”:** an element string that provides additional information about an entity identified with GS1 identification key, such as a batch number associated with a Global Trade Item Number (GTIN).
4. **“Authority”:** The Ethiopian Food and Drug Authority.
5. **“Barcoding”:** printing of data read by the barcode reader by using an appropriate barcode symbology and printing method on a specified surface.
6. **“Barcode Symbology”:** a method that will be applied in the coding and decoding of information on the barcode.
7. **“Carton/Case”**: a number of secondary packaging packed in a carton or case. It could be of the same drug or a mix of different drugs.
8. **“Data carrier”:** a technology used to encode and present product identification data on a product package. There are many specific types of data carriers but those used in pharmaceutical supply chains generally fall into linear barcodes, two-dimensional barcodes and radio frequency identification tags.
9. **“Element string”**: the combination of a GS1 Application Identifier and GS1 Application Identifier data field.
10. **“Human readable interpretation (HRI)”**: 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.
11. **“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).

12. **“GS1-128”**: a subset of Code 128 that is utilized exclusively for GS1 system data structures.
13. **“GS1 AIDC data carrier”**: a resource to represent data in a machine readable form; used to enable automatic reading of the element strings as specified for use by GS1.
14. **“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.
15. **“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 brand owners make correct use of the GS1 System of standards, have access to education, training, promotion and implementation support and have access to play an active role in Global Standards Management Process (GSMP).
16. **“Pallet”**: a number of cartoons/cases in a pallet used for shipments. It could be of the same drug or a mix of different drugs.
17. **“Packaging level”**: the hierarchy of product packaging. Each level includes a specific way of protecting and identifying the product during different types of handling. Recognized levels include “primary”, “secondary” and “tertiary”.
18. **“Primary pack”**: the innermost layer of packaging, i.e. the layer closest to the product (pill, implant, etc.) or the package that has immediate contact with the product i.e. a blister pack, an ampoule, a vial.
19. **"Non-HRI text”**: characters such as letters and number that can be read by persons and may or may not be encoded in a GS1 data carrier and are not confined to a structure and format based on GS1 standards (e.g., a date expressed in a national format, brand owner name, manufacturing date).
20. **“Secondary pack”**: the layer of packaging surrounding the primary package.
21. **“Supply chain actor”**: any person in the supply chain to manufacture, import, distribute, transport, store or dispense pharmaceutical products or is involved in related activities. in this guideline supply chain actor and supply chain stakeholder can be used interchangeably.
22. **“Tertiary pack”**: a third level of packaging or higher, usually including logistic units like shippers, cases and pallets.

23. **“Trace”**: the ability to know where a product has been within a supply chain prior to its current location.
24. **“Track”**: the ability to know where a product is right now.
25. **"Unique identifier”**: the safety feature enabling the verification of the authenticity and the identification of an individual pack of a pharmaceutical product.
26. **“Verification”**: the process of determining that the unique identifier on a product is valid.

6. Data carrier

Data carrier is a means of representing data in a machine-readable form. There are different types of data carriers (i.e. barcodes and Radio Frequency Identification (RFID)) that are supported by the GS1 system of standards **(Figure 1).** For more information refer to Use of GS1 2D Matrix Data Carriers in Healthcare.

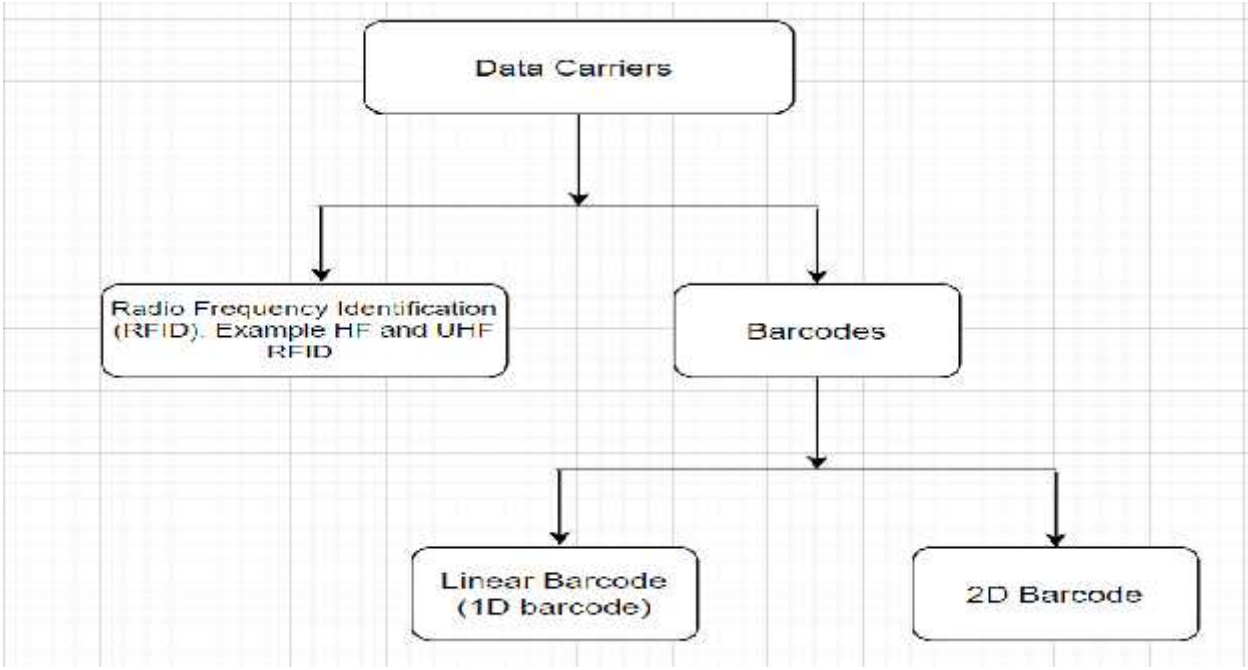


Figure 1: Pictorial representation that describes the classification of data carriers.

7. Barcoding requirements

One of the key components of pharmaceutical regulation is uniquely identifying products from the point of manufacture to the point of dispensing and use. The EFDA requires the use of unique identifiers to be encoded into machine-readable forms (also called data carriers). The Authority requires manufacturers to use the GS1DataMatrix barcode symbol as a data carrier for pharmaceutical products. All supply chain stakeholders shall ensure the placement of GS1 DataMatrix in the products before they procure and supply to the market.

In addition to the machine-readable data elements, the manufacturer shall add associated HRI and non-HRI texts - non-machine readable data elements. Placement of non-HRI text forms in the package as a label is dictated by the national medicine laws (i.e. proclamations, regulations and directives) of the country.

7.1. GS1 DataMatrix Barcode

All pharmaceutical products imported to and manufactured in Ethiopia shall have GS1 DataMatrix barcode. It is mandatory to place the GS1 DataMatrix barcode in the secondary packages. GS1 DataMatrix barcodes can also be placed in the primary packages when required. In the tertiary packages, the GS1 DataMatrix or GS1-128 is the recommended barcode symbol. The GS1 identification keys, AI and HRI are the same for both GS1 DataMatrix and GS1-128 barcodes on the label.

Figure 2: GS1 DataMatrix symbol adopted from GS1 General Specification

7.2. Shape and size of the barcode

GS1 DataMatrix may be printed in a square or rectangular format. The data elements encoded in both the square or rectangular shape DataMatrix barcode shall be the same. EFDA highly recommends the square shape of the DataMatrix and developers of the barcode shall use the GS1 system of standards and relevant ISO standards.

The size of the GS1DataMatrix symbol varies depending on the amount of encoded data, the symbol specified, where the symbol will be used, and how the symbol will be printed.

7.3. Number of symbols

The presence of more than one barcode symbol on the same package or label is prohibited. Multiple barcode symbols on a single item can lead to quality issues of the symbol and potentially dangerous confusion for the user. This can also lead to scanning and reading performance challenges as the user might find it difficult to identify which barcode should be or has been scanned for the purpose of identification and verification of authenticity of pharmaceuticals.

7.4. Placement of the GS1 DataMatrix

Consistency of symbol placement is critical to successful scanning. The GS1 DataMatrix barcode must be printed on one side of the packaging, which may be either the face, side or end panel - preferably on a flat surface. To facilitate the reading process, it shall be placed on the same side where possible. Manufacturers shall print the barcode on the packaging on a smooth, uniform, and low-reflecting surface.

The exact location of a GS1 DataMatrix symbol is determined by the manufacturer and shall consider:

- The available space on the package;
- The type of product and printing substrate (packaging material);
- Other packaging constraints that affect the reading of the symbol. For example folds or seams in the packaging, curvature (e.g., blister packs), etc can impact scanning and should be considered when selecting the most appropriate symbol location; and

- The size of GS1 DataMatrix symbols.

The following general principles for barcode placement shall be considered for any package type, whether it is scanned at the point-of-sale or elsewhere in the supply chain **(Table 1).**

Table 1: Placement guidelines for specific package types

S.N	Package type	Packaging Level	Placement of the DataMatrix
1.	Blister packs	Primary package	Secondary pack **
2.	Ampoules	Primary package	Secondary pack **
3.	Vials	Primary package	Secondary pack **
4.	LDPE & HDPE bottles	Primary package	Secondary pack **
5.	Bottles and jars	Primary package	Primary pack
6.	Boxes	Secondary package	Secondary pack **
7.	Thins	Primary package	Primary pack
8.	Tubes	Primary package	Secondary pack**
9.	Injection trays	Secondary package	Secondary pack**
10.	Cartons	Secondary Package	Secondary pack**
11.	Sachet	Primary Package	Primary Pack
12.	Aluminum foil	Primary Package	Secondary pack**
13.	IV containers/bag	Primary Package	Primary pack
14.	Prefilled syringes	Primary Package	Secondary pack**
15.	Shipping containers (e.g. ice bag, cases, carton, etc.)	Secondary Package	Secondary pack**

** *A manufacturer who wants to place a DataMatrix barcode on the primary packaging is encouraged.*

7.5. DataMatrix readability

The GS1 system of standards describes the quality that the data carrier should have in order to be scannable. The symbol shall be easy to read and indelible. It is important to follow the GS1 standards to comply with the specific quality requirements, including:

- Nominal dimensions of characters

- Symbol height,
- Quiet zone,
- Symbol length,
- Positioning of the add-on symbol,
- Reference decode algorithm,
- Human readable interpretation, and
- Colour contrasting

7.6. Encoding Data

When encoding data elements in a GS1 DataMatrix barcode, the structure of the unique identifier and other data elements shall follow the GS1 standards. In terms of encoding data elements, the application standard shall specify the following:

- The Data Matrix syntax and encoding rules (refer to the current version of GS1 standards and relevant ISO standards);
- Which Application Identifiers (AIs) to use (i.e. mandatory and optional data elements);
- Location and format of Human Readable Interpretation;
- If necessary, symbol placement is determined by the area of application.

At a minimum but not limited to, the GS1 DataMatrix barcode must carry the following mandatory data elements:

a) GS1 Global Trade Item Number (GTIN): The GS1 application identifier for identifying the GTIN is 01. GTIN must be the first data element encoded in the Data Matrix Code.

Application Identifier (AI)	GTIN
01	06280000000000

b) Expiration date: The GS1 application identifier for identifying the expiration date is 17. YYMMDD format in 6 digits as follows:

YY	MM	DD
Last two digits of the year (Example: 2021 written	The month (Example:	The day (Example: eleventh day of a

as 21)	January, written as 01)	month written as 11)

Example: 25 February 2021 is represented as follows:

Application Identifier (AI)	Expiration Date		
17	21	02	25

c) Batch/lot number: is variable in length up to 20 alphanumeric characters. The GS1 AI that identifies the batch/lot number is 10. Example:

Application Identifier (AI)	Batch/Lot Number
10	AD34245678

d) Serial number (SN): is variable in length up to 20 alphanumeric characters. The GS1 AI for identifying the serial number is 21. Example:

Application Identifier (AI)	Serial Number (SN)
21	Y12345678FMHACA

GTIN must be the first data element encoded in the DataMatrix code. The sequence of the other elements should be as shown in table 2.

7.7. Application Identifier (AI)

GS1 Application Identifiers (AIs) are prefixes used in barcodes to define the meaning and format of data attributes. It is an introductory code of two or more digits used to distinguish every entry from other data elements in the DataMatrix contents by setting specific introductory numbers for each data element encoded in the DataMatrix barcode. Example, AI for GTIN is written at the start of a GTIN to identify that the number is a GTIN and not a serial number. all AI should be separated using parenthesis. Regardless of the entry that follows an application identifier, it does not affect its character count.

Table 2: application identifiers

Data elements	**Application Identifier (AI)**	**Character requirements**
GTIN	(01)	14 numeric digits
Batch/lot number	(10)	up to 20 alphanumeric

Expiration date	(17)	6 numeric digits
Serial number (SN)	(21)	up to 20 alphanumeric

7.8. Printing Instructions

Anything that will obscure or damage a barcode will reduce scanning performance and shall be avoided. At least the following printing instructions shall be considered:

- Ensure that the surface to be marked is suitable for printing. Never place barcodes, including quiet zones, on perforations, die-cuts, seams, ridges, edges, tight curves, folds, flaps, overlaps, and rough textures.
- Verify through testing that rubbing does not damage the marking.
- Test the legibility of barcode markings in certain moist conditions.
- Ensure consistent printing quality across packages for information redundancy.
- Ensure the color contrast with the surface area of the packaging.
- Never put staples through a barcode or its quiet zones.
- Never fold a symbol around a corner.
- Never place a symbol under a package flap.

7.9. Aggregation

Aggregation defines the relationship between the parent and child packs allowing the receiver of the product to scan one code and understand exactly what is in the whole shipment - every case, bundle, or individual carton.

It is mandatory that manufacturers do the aggregation for packaging stages or packaging levels of the supply chain according to GS1 standards. This makes it easier for the distributors down to the supply chain system to track the products and share data to EFDA on each unit of drug movement without having to scan the individual boxes.

It will also help warehouses to register and track drugs in their system by just scanning the outer barcode and get all the GTIN, expiry date, batch/lot number and serial number without having to input all the information manually (which may increase the likelihood of errors).

7.9.1. Level of aggregation

The distributed pharmaceutical products in the supply chain including healthcare facilities and drug retail outlets may have different barcode symbols in the different packaging hierarchies. Manufacturers may decide the use of GS1 DataMatrix or GS1-128 on higher packages (such as carton, cases or pallet). However, it is mandatory to use only GS1 DataMatrix for both the primary and secondary packages. For more information refer to EFDA's Pharmaceutical Products Global Trade Item Number (GTIN) Allocation Guideline, GS1 Healthcare GTIN Allocation Rules and the GS1 General Specifications.

Table 3: level of aggregation and barcoding requirements

Packaging Level	**Barcoding Requirement**	**Human Readable Format**	**Requirement level**
Primary packaging	GS1 DataMatrix barcode symbol encoded with: ● GTIN ● Expiry date ● Batch/lot number ● Serial number	Optional	See table 1
Secondary packaging	GS1 DataMatrix barcode symbol encoded with: ● GTIN ● Expiry date ● Batch/lot number ● Serial number	Required: ● GTIN ● Expiry date ● Batch number ● Serial number	Required
Tertiary packaging - trade item	GS1-128 or GS1 DataMatrix barcode symbol encoded with: ● GTIN ● Expiry date ● Batch/lot number ● Serial number	Required: ● GTIN ● Expiry date ● Batch/lot number ● Serial Number	Required
Tertiary packaging - logistics unit	GS1-128 barcode symbol encoded with SSCC	Required: ● AI (00) SSCC	Required

7.9.2. Encoding of Serial Shipping Container Code (SSCC)

Serial Shipping Container Code (SSCC) is a unique number, which remains the same for the life of the logistic unit to which it is assigned. The SSCC provides functionality to support the management (tracking, tracing, storage, etc.) of logistic units through the supply chain. To ensure global uniqueness and traceability, the physical builder of the logistic unit or the brand owner of the logistic unit is responsible for the allocation of the SSCC.

Logistic units shall be aggregated or nested into other logistic units for part of the journey to the final destination. The SSCC shall be encoded in a GS1-128 barcode or GS1 DataMatrix using AI (00).

Application Identifier (AI)	SSCC
00	012345678911121314

The identification and symbol marking of logistic units enable a large number of user applications. In principle, the SSCC provides a unique reference number that can be used as key to access information regarding the logistic unit in computer files. However, attributes relating to the logistic unit (e.g., ship to information, logistic weights) are also available as standardized element strings

The SSCC provides a link between the physical logistic unit and information pertaining to the logistic unit that is communicated between trading partners. The SSCC AI is used for the identification of logistic units. Each individual logistic unit is allocated a unique number. When assigning an SSCC, the rule is that an individual SSCC must not be reallocated.

7.10. Human Readable Interpretation (HRI)

HRI refers to the characters such as letters, numbers printed below, beside or above a barcode. It is a one-to-one illustration of the encoded data in the barcode. The Authority requires printing of both the GS1 DataMatrix barcode and the HRI that represents all the information encoded within that barcode. All human readable data elements should be

placed next to the GS1 DataMatrix. For details, refer to the GS1 HRI Implementation Guide.

HRI Rules

The HRI rules enable industries to create consistent packaging designs **(Table 4)**. The HRI shall preferably be placed below the GS1DataMatrix and grouped together wherever physically possible. The HRI shall be legible and indelible.

There are two types of texts that appear on a label (i.e. HRI and non-HRI texts). Non-HRI text is all other texts other than the HRI available on the label or package **(Figure 3).** If the GS1 AIDC data carrier cannot be read or scanned, the HRI should be used as back-up information.

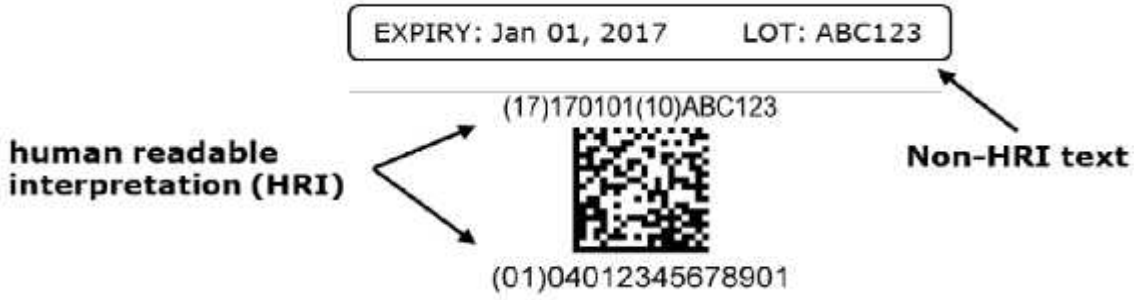
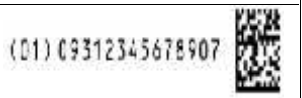


Figure 3: Example of HRI and non-HRI text.

In cases where the HRI must be printed above, to the left, or to the right of the symbol due to packaging or space constraints, HRI shall always be printed adjacent to the data carrier. It is important that encoding sequencing is the order in which the data is encoded in the data carrier. For example, if the order of the AIs encoded in the barcode is AI (01), (17), (10), and (21) the HRI will appear in the same order.

Table 4: Human readable interpretation (HRI) rules.

S.N	Questions	HRI rules	Example
1.	Where to print the HRI?	The HRI shall be placed below the barcode and grouped together wherever physically possible, while maintaining the HRI legibility and minimum barcode height. The HRI must be grouped	 (01) 0 9501101 53000 3 (17) 150119 (10) AB-123

S.N	Questions	HRI rules	Example
		together under the symbol, but across multiple lines of text.	
2.	What to do if the HRI does not fit under the barcode?	1. Place the HRI above or to the side: the HRI may be printed above, to the left, or to the right of the symbol. 2. Use a combination of top, bottom, and side to place the HRI	
3.	What to do if the HRI line is too long?	A single data element shall not be broken into two lines of HRI, for example the data for a serial number would appear on one line of HRI. The rule also implies that the AI should not be separated from its corresponding data. In cases where space constraints do not permit all HRI to fit on one line, the AI and its corresponding data should be moved to the next line	
4.	Font type and size	A clearly legible font type and character size shall be acceptable provided the interpretation is clearly legible.	
5.	How to represent the GS1 AI in HRI?	The AI values must be represented in parentheses	(17)110931
6.	Do I always need to print the HRI?	HRI shall always appear except in rare circumstances for specific applications where there are extreme space constraints (e.g., direct part marking). If the GS1 AIDC data carrier cannot be read or scanned and the HRI does not appear on the label, package, or item, non-HRI text should be used as backup	

S.N	Questions	HRI rules	Example
		information. This should be approved by the authority on a case by case basis.	
7.	Should I print all data as HRI?	For GS1 DataMatrix, it may not be practical to display all the data in human readable interpretation form. In these instances, some of the data may be omitted from the HRI text. However, primary identification data such as GTIN, batch/lot number, expiry date must always be shown.	
8.	Is it mandatory to place HRI on the GS1 2D symbol on a logistic label while it is presented in GS1-128 symbol?	HRI alongside a GS1 DataMatrix symbol on a logistic label is not required if this is already present with the GS1-128 symbol, or is present as data titles and data content elsewhere on the label	

7.11. Printing process

It is important to realize that the unique identifiers (i.e. GTIN, batch/lot number, expiry date and serial number) contain dynamic information that the barcode cannot be printed using traditional printing presses directly on the package or on a label that is applied to the package beforehand.

Either digital or a combination of digital and traditional printing will be required. It is important to critically analyze the current labeling process and see where it needs adjustment to successfully implement the unique identification requirements.

The technology chosen for a given application should take into account the internal environment including factors such as substrate (the material upon which the GS1DataMatrix will be printed). The symbol marking technologies most suited in printing GS1 DataMatrix are:

- Thermal transfer
- Inkjet
- Laser etch
- Direct part marking (dot-peening, engraving, etc.)

The manufacturer shall follow the relevant GS1 standards on selecting printers and printing steps.

7.12. Barcode verification

The benefits of verification are reassurance and confidence that the barcode will perform as intended throughout the supply chain, produced as per the GS1 specifications and help assess the scanning performance. In addition, it is important to ensure that symbol size, position, colour, etc will not create any difficulty.

Verification assists the symbol producer and receiver in setting an agreed quality level for acceptance. This provides benefit to Member Organizations, Consumers, Supply Chain Stakeholders

GS1 Specifications provides symbol quality specifications depending on the symbol type, the application, and the identification key the symbol is carrying. for detail, refer to GS1 2D Barcode Verification Process Implementation Guideline.

The manufacturer placing the safety features shall verify that the two-dimensional barcode carrying the unique identifier complies with required laws is readable and contains the correct information.

8. Barcode Scanners/Readers

Camera-based barcode scanners can read both linear and GS1DataMatrix barcodes and are required to be used in healthcare.

9. Products that do not require GS1 DataMatrix barcodes

The Authority may exempt GS1 DataMatrix barcode from the following products:

- Pharmaceutical products imported for personal use only.
- Pharmaceutical products for pre-market quality analysis
- Free samples of pharmaceutical products

- Traditional medicine
- Extemporaneous preparations.
- Donated pharmaceutical products imported for emergency cases.
- Bulk pharmaceutical products.

10. GS1 Member Organization (MO)

In order for a company to ensure alignment with global standards, it is important to contact a GS1 MO. You will find all GS1 MOs from https://www.gs1.org/contact.

11. Roles and Responsibilities

Table 5: Roles and responsibilities of supply chain stakeholders

S.N	Name of stakeholders	Role and Responsibility
1.	EFDA	a. Define and develop requirements of barcoding for the Ethiopian Market. b. Enforce the implementation of the use of GS1 DataMatrix as part of the label across all supply chain stakeholders. c. Develop a centralized repository that syncs data after scanning. d. Provide capacity building on barcoding. e. Ensure the quality of barcodes. f. Update the Barcode Guideline as necessary to accommodate changes.
2.	Manufacturers	a. Comply with the requirements of this guideline. b. Develop the barcode and place in the proper place of the pack as per the national laws, guidelines and relevant international standards. c. Establish a system that enables them to capture data after scanning; d. Develop a procedure for data capturing. e. Contact the GS1 Member Organisation and obtain a GS1 Company Prefix license.

S.N	Name of stakeholders	Role and Responsibility
		f. Submit any changes to the barcodes to the Authority.
3.	Importer, wholesaler, retail outlet and healthcare facilities	a. Develop a procedure for data capturing. b. Create a system to capture data and avail appropriate scanners. c. Do not hold/accept pharmaceutical products having problems related to barcode. d. Report any quality problems of barcodes such as damage, non-scan-able, inappropriate placement, etc to the Authority.
4.	Ministry of Health (MOH)	a. Support healthcare service providers and the drug retailers in the implementation of this guideline. b. Provide resources to the regulatory sector to appropriately enforce the barcoding system. c. Oversee and support implementation of this guideline at national level.
5.	GS1	Provides education, relevant implementation and technical support on the use of GS1 standards.
6.	Partners	Provide technical and financial support on the barcode implementation, as appropriate.

12. Transition for Implementation

This guideline shall enter into force after three months of its approval. The following transitions will be considered during implementation:

- Manufacturers should not scrap packaging labels that have been printed before the endorsement of this guideline. When packaging is redesigned, the requirements in this guideline shall be observed. .
- The timelines for the inclusion of all the mandatory data elements (GTIN, expiry date, batch/lot number and serial number) in the barcode shall follow the Pharmaceutical Products Traceability Directive No. 43/2019. But, it is acceptable by the Authority to combine and include all the data elements in the barcode before the timeline stated in the directive.

13. References

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- Ten steps to GS1 Barcode Implementation. https://www.gs1.org/sites/default/files/ten_steps_to_barcode_implementation.pdf
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- GS1 DataMatrix Guideline: Overview and technical introduction to the use of GS1. 2018. https://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf
- GS1 General Specifications: The GS1 Standard that describes how GS1 barcodes and identification keys should be used. https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications
- GS1 Identification Keys: One page summaries for each of the GS1 Identification Keys. http://www.gs1.org/id-keys.
- GS1 Barcodes: One page summaries of all GS1 barcodes, including an overview of printing methods and scanning environments. http://www.gs1.org/barcodes.
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- ISO/IEC 16022 Information technology – Data Matrix barcode symbology specification.
- ISO/IEC 15415 Barcode print quality test specification –Two-dimensional symbols.