

Global Location Number (GLN) Allocation Guideline



ETHIOPIAN FOOD AND DRUG AUTHORITY

Global Location Number (GLN) Allocation Guideline

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Global Location Number (GLN) Allocation Guideline

Foreword

Ensuring safety, quality and efficacy of pharmaceuticals are challenges at global level. There is also a tremendous need for supply chain stakeholders to share information regarding pharmaceutical products and locations. Currently, it is difficult to uniquely identify the location of supply chain stakeholders, as the location information is not shared to the Ethiopian Food and Drug Authority (EFDA).

Many supply chain stakeholders are developing their own solutions without following basic principles and globally accepted standards that would enable them to track and trace products movement through the supply chain from the source to the patient and back. This non-standardized, uncoordinated and fragmented approach makes the supply chain system inefficient and the data exchange inaccurate. It also creates confusion in the healthcare industry which threatens the quality of care and patient safety.

It has become crucial to develop global standards to provide simplicity and consistency by promoting universal applicability and optimal functionality across the globe for the healthcare industry. These standards will enable the Authority to identify the specific locations where a product originated from, its distribution status and ensure that it has arrived at the intended location. Considering this, the Authority is committed to enforce the use of standardized location information.

The Global Location Number (GLN) allocation Guideline will serve as a useful guide to supply chain stakeholders to assign and share party or location information. It gives me great pleasure to introduce this edition to all beneficiaries, which is the fruit of the 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 Traceability Steering Committee and Technical Working Group members and other participants from different governmental and private sectors for their valuable contribution and comments during the preparation of the guideline.

Global Location Number (GLN) Allocation 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 and to all the experts who have directly or indirectly extended their helping hands 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 or +251-115523206, e-mail:

contact_efda@efda.gov.et or traceability@efda.gov.et.

HERAN GERBA

Director General, EFDA

Global Location Number (GLN) Allocation Guideline

Abbreviations and Acronyms

AI	Application Identifier
DHA	Digital Health Activity
EFDA	Ethiopian Food and Drug Authority
GLN	Global Location Number
MO	Member organization
RFID	Radio-frequency identification
USAID	United States Agency for International Development

Global Location Number (GLN) Allocation Guideline

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The Ethiopian Food and Drug Authority (EFDA) would like to acknowledge and express its appreciation to the USAID/DHA for the financial and technical support provided in the preparation of the GLN allocation Guideline.

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Global Location Number (GLN) Allocation Guideline

Table of Contents

Foreword.....	i
Abbreviations and Acronyms.....	iii
Acknowledgements	iv
1. Introduction	1
1.1. Guiding Principles	2
1.2. Scope.....	2
1.3. Objective.....	2
2. Definition.....	2
3. Users of this Guideline.....	3
4. Use and Data Structure of GLN.....	3
5. Who Allocates the GLN.....	5
6. GLN Allocation Rules	5
7. GLNs and data carrier.....	8
8. GS1 Application Identifiers (AIs) for GLNs	9
9. Sharing party or location information.....	9
10. GS1 Member Organization (MO).....	9
Reference:.....	10

Global Location Number (GLN) Allocation Guideline

1. Introduction

The Ethiopian Food and Drug Authority (EFDA) is mandated to ensure the safety, quality and efficacy of pharmaceutical products. All healthcare facilities and pharmaceutical establishments are required to obtain a license before they become operational.

The infiltration of falsified and substandard pharmaceuticals to the supply chain and lack of end-to-end supply chain visibility are challenges in ensuring patient safety and supply chain efficiency. Inability to identify specific locations where a product originated from, distributed to and arrived at the intended location is also a challenge. Additionally, the use of non-standardized location information in the healthcare supply chain leads to errors and inefficiencies, and has implications to patient safety.

Noting this, the use of a common language and globally-accepted standards are essential. The GLN is the GS1 Identification key used for any party or location that needs to be identified for use in the supply chain. The GLN is a unique number assigned to parties or locations to enable them to be identified uniquely worldwide. Hence, organizations must use the GS1 system of standards to help improve supply chain efficiency, visibility and overall patient safety.

This guideline is therefore developed to provide guidance for the use of the GS1 GLN in healthcare. It reflects the allocation and use of GLN across the entire healthcare value chain.

Global Location Number (GLN) Allocation Guideline

1.1. Guiding Principles

The following guiding principles should be considered during GLN allocation or when introducing changes to an existing party or location:

- Does the stakeholder (e.g., manufacturers, importers, wholesalers, hospitals, health centers, specialty centers, clinics, drug retail outlets, consumers, patients, etc.) need to distinguish the changed or new party or location from the previous/current party or location.
- Is there a regulatory/liability disclosure requirement by the stakeholder?
- Is there a substantial impact to the supply chain (e.g., where (or to/from whom) the product is shipped, stored, and/or received).

1.2. Scope

This guideline applies to allocation of GLN to the party or location of healthcare facilities (e.g. hospitals, centers, clinics) and pharmaceutical establishments (e.g. manufacturers, importers, wholesalers, drug retail outlets).

1.3. Objective

The objective of this guideline is to set requirements and guide supply chain stakeholders on GLN allocation rules; and sharing information among the supply chain stakeholders.

2. Definition

1. "**Authority**" means Ethiopian Food and Drug Authority.
2. "**Global Location Number (GLN)**" means the GS1 identification key used to identify physical locations or parties.
3. "**GS1 Application Identifier**" means the field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
4. "**New party or location**" means an addition of a new entity to what already exists *and* has been allocated a new GLN.
5. "**Change**" means an update to information associated with a pre-existing party or location

Global Location Number (GLN) Allocation Guideline

that is already identified by a GLN.

6. **“Discontinue use”** means when a party or location no longer needs to be actively used, the associated GLN will be discontinued.
7. **“Party” means** an entity that needs to be represented in a business-related transaction.
8. **“Merger”** means when two or more parties/locations are combined into a single party/location.
9. **“Physical location”** means a tangible place that may be represented by an address, coordinates, or other means.

3. Users of this Guideline

The main users of this guideline are supply chain stakeholders including concerned government offices, EFDA, pharmaceutical manufacturers, importers, wholesalers, drug retail outlets, hospitals, health centers, specialty centers, clinics, health posts. This guideline will be used in conjunction with national laws and the GS1 standards.

4. Use and Data Structure of GLN

There are a variety of parties and locations that can be identified by GLN (Table 1). A single GLN can be used to identify a single party or location or a combination of the two.

Global Location Number (GLN) Allocation Guideline

Table 1: Types of parties and locations that can be identified by GLN

Identification	Type	Definitions and examples
Party identification	Legal entity	Any parent organization or division or department that has standing in the eyes of the law and has the capacity to enter into agreements or contracts. E.g.: manufacturers, Importers, wholesalers, hospitals, etc.
	Function	A function or subdivision or department within
	within legal entity	an organization that is most commonly segmented based on the specific tasks being performed. E.g.: hospital pharmacy, hospital wards, distribution department, etc.
Location identification	Physical location	A tangible place that may be represented by an address, coordinates, or other means. E.g.: manufacturer, warehouse, distribution center, hospital, hospital departments, nursing station.

Global Location Number (GLN) Allocation Guideline

GLN is a 13-digit numbers composed of three basic segments:

- **GS1 Company Prefix:** The globally unique number issued by GS1 member organizations to a specific subscriber.
- **Location Reference:** A number that uniquely identifies a specific location which is assigned by the holder of the GS1 company prefix. The location reference varies in length as a function of the GS1 company prefix length.
- **Check Digit:** A calculated one-digit number used to ensure the integrity of the data. It is calculated from the first twelve digits.

Note: combined length of GS1 company prefix & location reference is always 12 digits.

Figure 3: Data format of a GLN

GS1 Company prefixes							Location reference					Check digit
N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	N11	N12	N1

Eg.: Company prefixes = 5012346, location reference = 12343, check digit = 8.

Company prefixes = 50561234, location reference = 0123, check digit = 9.

5. Who Allocates the GLN

The GLN and associated data must be managed at the source by the organization itself and allocated by the party that defined the location.

6. GLN Allocation Rules

As a general rule, a separate, unique GLN is required whenever an organization needs to distinguish between one party or location from another.

This section details when a GLN must be allocated as the result of a new party or location being defined or when a change to an existing party or location occurs.

Global Location Number (GLN) Allocation Guideline

Table 2: GLN allocation rules

Party/Location	New GLN	Remarks
6.1. New party or location introduction		
● New legal entity	Yes	When a new legal entity, new function or new location is defined or added, it must be allocated a new GLN.
● New function	Yes	
● New physical location	Yes	
6.2. Party or location split		
● Legal entity split	Yes	When a legal entity, function or physical location splits, the one that does not keep the original GLN will be classified as being new and it must be allocated a new GLN. But, the one that keeps the original GLN does not
● Function split	Yes	
● Physical location split	Yes	
6.3. Party or location merger		
● Legal entities being merged or	No	When a legal entity, function or physical location is merged with another so that they will no longer function independently, one of the existing GLNs may remain in use. All other GLNs merged shall be removed from active use
● Functions being merged	No	
● Physical locations being Merged	No	

Global Location Number (GLN) Allocation Guideline

		party or location merger does not require a new GLN. Discontinuation of
6.4. Change of party or location use or purpose		
• Change to legal framework	Yes	When there is a change to activities, purpose, or functionality of a party or location, it needs allocation of a new
• Change of the function purpose	Yes	
• Change of use of the physical	Yes	
6.5. Change to party or location address		A change to party or location address occurs when the location reference point for interacting with the party or location is modified. This may be a change to an address, coordinates, geofence, or other location references.
• Physical location address change	Yes	Manufacturer A moves from AB main
• Physical location address change	No	Municipality renames street. The
• Relocation of a legal entity or Function	No	Changes to the location(s) associated with a legal entity or function do not require the allocation of a new GLN. The GLN identifying the legal entity or function does not identify the physical location. E.g. A company moves from Addis Ababa to Hawassa.

Global Location Number (GLN) Allocation Guideline

● Party or location name change	No	A change to the legal name of a party or location does not require allocation of a new GLN. For example: a warehouse that was previously called
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		Warehouse A was changed to
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6.6. Contact information change

● Change to contact details of legal entity	No	When the legal entity's contact details changes (e.g. visiting address, postal address, phone number, e-mail address, etc.), it doesn't require allocation of a new GLN.
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● Change of the function contact Details	No	When the function's contact details changes, it does not require a new GLN. example contact person of a department, phone number, e-mail, etc.
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6.7. Financial changes

	No	Changes to the financial information associated with a party or location do not require the allocation of a new GLN. For example changes to tax registration numbers such as value added tax (VAT), account number, etc.
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7. GLNs and data carrier

GLN related data should be stored in a database. Storing GLN data in a database system helps to automatically use data carriers to enable users to share GLN. GLNs can be encoded

Global Location Number (GLN) Allocation Guideline

in GS1 data carriers (i.e. dataMatrix or RFID).

8. GS1 Application Identifiers (AIs) for GLNs

GS1 AIs are numeric prefixes used in barcodes to define the meaning and format of encoded data elements. These GS1 AIs tell the software applications how to handle the information. The GS1 AIs used for GLNs need to follow the GS1 standards. There are different AIs that may be used with GLN. Examples:

AI(410)	indicates the GLN of the location where goods must be delivered
AI(411)	indicates the GLN of the addressee of an invoice
AI(412)	indicates the GLN of the seller in a purchase transaction
AI(413)	indicates the GLN of the final destination of goods being delivered
AI(414)	indicates the GLN that is marked on a physical location

9. Sharing party or location information

The manufacturers, importers, wholesalers, drug retail outlets, healthcare facilities and other supply chain stakeholders shall share their party or location information with the authority and its supply chain actors.

10. GS1 Member Organization (MO)

Since there is no GS1 Office in Ethiopia, Ethiopian manufacturers, suppliers, wholesalers, drug retail outlets, healthcare facilities or other supply chain stakeholders can contact GS1 MO to obtain the company prefix. You will find all GS1 MOs from <https://www.gs1.org/contact>.

Global Location Number (GLN) Allocation Guideline

Reference:

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