Pharmaceutical Products Traceability Global Trade Item Number (GTIN) Allocation Guideline

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Foreword

Pharmaceutical products are key components of healthcare. Infiltration of ineffective, poor quality and harmful pharmaceuticals into the supply chain affects lives of individuals and the community as well as the healthcare system. Furthermore, lack of supply chain inefficiencies and end-to-end visibility are also important challenges. This drives the need to use global standards.

Traceability systems established according to the global systems of standards can ensure the integrity and improve the efficiency of the supply chain. To successfully trace and track pharmaceutical products, it is necessary to have a robust system, governance and data management. The uses of global unique identification keys to products are foundational. Global Trade Item Number (GTIN) is the globally unique GS1 identification key used to identify pharmaceutical products as well as their different level packaging configurations.

Therefore, It gives me great pleasure to introduce the Pharmaceutical Products Global Trade Item Number Allocation Guideline. I hope that the guideline will serve as a useful guide to manufacturers to manage and allocate GTINs to their pharmaceutical products.

EFDA would like to appreciate and thank all development partners and individuals who have extended their helping hands in the preparation of this valuable document. I also would like to thank the National Traceability Steering Committee and Technical Working Group members and other participants from different governmental and private sectors for their valuable contribution 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 and forwarding feedback to the Authority.

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Acknowledgements

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 preparing the GTIN allocation Guideline.

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Abbreviations and Acronyms

AI	Application Identifier
DHA	Digital Health Activity
EFDA	Ethiopian Food and Drug Authority
GTIN	Global Trade Item Number
MO	Member organization
SSCC	Serial Shipping Container Code
SF	Substandard and falsified
USAID	United States Agency for International Development

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1. Introduction

Ensuring the safety, quality and efficacy of pharmaceutical products is a challenging issue at global level. Ethiopia is not immune from these challenges. Substandard and Falsified (SF) pharmaceuticals are common problems and negatively impact patient safety. In addition, lack of end-to-end visibility in product movement among stakeholders and within organizations highlight supply chain inefficiencies. In response, implementation of global standards for pharmaceutical products identification and data exchange is crucial.

Real-time information and appropriate data access can provide visibility of products and can expedite regulatory responses to safeguard patients and the supply chain, including: Ensuring only authorized, registered or approved products circulate in the legal supply chain; Preventing the distribution and/or dispensing of falsified, expired, prohibited or recalled products; Facilitating efficient and fast market recalls; Enabling efficient inventory management at all levels; and Identifying shortages and monitoring the reasons for shortages and stockouts.

Unique identification of pharmaceuticals is critical in maintaining operational efficiencies that business partners rely on to exchange information in consistent ways; as well as; for ensuring the smooth operations of global supply chains and complying with various regulations. Furthermore, the unique identification and the communication of unique identification between supply chain stakeholders is essential to ensure the right product is made available and moving across the supply chain.

The GTIN is one of the GS1 unique identification systems that uniquely identify a pharmaceutical product up on which there is a need to retrieve predefined information and that may be priced, or ordered, or invoiced at any point in the supply chain. The key principle of GTIN allocation is that GTIN uniquely identifies a product and its packaging configuration. Therefore, the GTIN allocation guideline is developed in accordance with the GS1 system of standards.

1.1. Guiding Principles

The following guiding principles shall be considered when developing GTIN assignment for a new pharmaceutical product and introducing changes to an existing one.

a) Is the supply chain stakeholder and/or consumer expected to distinguish the changed or new product from previous/current products?
b) Is there a regulatory or liability requirement to disclose to change to the supply chain stakeholders and/or consumers?
c) Is there a substantial change impacting the supply chain (e.g., how the product is shipped, stored, received or handled)?

1.2. Scope

The guideline applies to pharmaceutical products and provides requirements for the allocation of the GTIN.

1.3. Objective

The guideline aims at providing guidance to supply chain stakeholders to comply with requirements of the GTIN allocation to the pharmaceutical products in order to improve supply chain efficiency and ensure patient safety, and end-to-end visibility.

2. Users of this guideline

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

3. Definitions

In this guideline, the following terms and definitions applies:

1. **"Authority"** means Ethiopian Food and Drug Authority.
2. **"Base unit"** means the retail consumer trade item level or unit of use. The term refers to the lowest traded packaging level. This level might contain more than one single unit/unit of use.

3. **“Brand owner”** means the organization that owns the specifications of a trade item (i.e. the manufacturer or license holder), regardless of where and by whom it is manufactured.
4. **"Identification key”** means a unique identifier for a class of objects (e.g., a trade item) or an instance of an object (e.g., a logistic unit).
5. **“GS1 Application identifier (AI)”** means the field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
6. “**Global Trade Item Number”** means the GS1 identification key used to identify trade items.
7. **“Pallet”** means a number of cartoons/cases in a pallet used for shipments. It could be of the same or a mix of different pharmaceuticals.
8. **“Packaging level”** means 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”.
9. **“Trade item”** means any pharmaceutical product that may be priced, or ordered, or invoiced at any point in any supply chain. Trade items include individual items as well as all other packaging configurations offered for sale (e.g., two-pack; case; pallet; etc.).
10. **“Primary package”** means 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.
11. **“Product”** means pharmaceutical products or trade items to which GTINs are assigned.
12. **“Secondary package**” means the layer of packaging surrounding the primary package.
13. **"Unique identifier”** means the feature that enables the verification of the authenticity and the identification of an individual pack of a pharmaceutical product.

4. GTIN Structure

GTIN-14 is a 14 digit numerical string used to identify a trade item and is more common in healthcare. The key composed of distinct a segment which includes:

- **Indicator Digit:** The indicator digit identifies packaging level in order to define packaging hierarchy of a product with the same Item Reference. The field consists of a numeric value from 1 to 9 and is only used in GTIN-14.
- **GS1 Company Prefix:** A globally unique number issued to a company by a GS1 Member Organization (MO) to serve as the foundation for generating GS1 identifiers (e.g., GTINs). GS1 Company Prefixes are assigned in varying lengths depending on the company's needs.
- **Item Reference:** A number assigned by the user to identify a trade item. The Item Reference varies in length as a function of the GS1 Company Prefix length.
- **Check Digit:** A one-digit number calculated from the preceding digits of the GTIN used to assure data integrity.

5. General rule: GTIN assignment and non-reuse

1. A new GTIN shall always be assigned to a new product to accurately distinguish the new product from those currently available in the marketplace or previously existing product that has been discontinued.
2. A separate, unique new GTIN is required when a change to any of the pre-defined characteristics or attributes of an existing pharmaceutical product changes or is different in any way that is relevant to the trading process.
3. Each packaging level shall be identified by a unique GTIN.
4. GTINs are assigned by the brand owner of the pharmaceutical product.
5. An allocated GTIN shall not be reallocated to another pharmaceutical product and shall never be reused.

Exception: pharmaceutical products withdrawn from the market and are reintroduced may use the original GTIN if they are reintroduced without any modifications or changes as specified by this guideline.

For further detail related to GTIN management and allocation rules please refer to www.gs1.org/1/gtinrules/en.

6. Levels of Packaging

A unique GTIN is required for every level of packaging. There shall be a unique GTIN identifying the consumer unit, case or pallet where applicable. Where a higher level of packaging (e.g. pallet) is considered as a trade item, it needs a GTIN.

7. GTIN Allocation Rules

GTIN allocation rules are designed to help the healthcare industry to make consistent decisions about the unique identification of the pharmaceutical products. GTIN shall be assigned to a new product or changed for a replacement product. Changes to existing products are considered as replacement products. The following rules are described to indicate at what level(s) the GTIN must be changed and assigned.

7.1. New product introduction

Introducing a new pharmaceutical product into the supply chain system requires the assignment of a new GTIN. New pharmaceutical product is a product that does not currently exist or has not been available for sale and is an addition to the brand owner's portfolio.

7.2. Declared formulation or functionality

A change to the formulation or functionality that affects the legally required declared information on the packaging of a product requires the assignment of a new GTIN. A new GTIN shall be assigned when any of the key properties of the base product changes.

For example a new GTIN is required when there is change to:

- an active ingredient
- an excipient
- an indication, as the case may be.

Note: *"Functionality" is defined as the particular use or set of uses for which something is designed; and "Formulation" is defined as a list of the ingredients used to create a trade item.*

7.3. Declared net content/pack size

Any change (increase or decrease) to the legally authorized pack size or net content that is printed on the pack, requires assignment of a new GTIN. All impacted levels of hierarchy where the net content change occurs shall have a new GTIN.

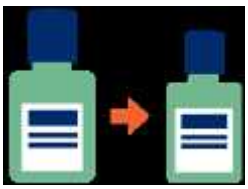
For example 10 tables per blister changed to 14 tablets, number of cartons per case, number of cases in a pallet needs a new GTIN.

Note: *"Net content" is defined as the amount of the consumable product of the trade item contained in a package, as declared on the label, which may include net weight, volume, count, units.*

7.4. Dimensional or gross weight change

A change of over 20% to a physical dimension, on any axis, or gross weight, requires assignment of a new GTIN. Changes below 20% may require a new GTIN at the discretion of the brand owner.

The GTIN assignment occurs at the trade item or base unit level. A unique GTIN is assigned at every existing level of the packaging hierarchy above the trade item/base unit level.



7.5. Add or remove certification mark

A certification mark is a symbol, logo or wording on a product that declares conformance to a regulated set of criteria (e.g., logo of the manufacturer). A change to packaging to add a new or remove an existing certification mark requires assignment of a new GTIN.

A unique GTIN is assigned at every existing level of the packaging hierarchy above the base unit level.

7.6. Primary brand

A change to the primary brand that appears on the trade item or at every existing level of the packaging hierarchy above the trade item or base unit level requires assignment of a new GTIN.

Note: *the primary brand is the brand most recognizable by the consumer, as determined by the brand owner, and can be expressed as a logo and/or words.*

For example: The company's primary brand name changed from "ABC Company" to "XYZ".

When there is a co-branding or distributed by party, the responsibility of GTIN allocation remains with the original brand owner. But, no new GTIN is necessary when the distributed by party identification is added to the label. The 'Distributed by' party identification must be made in plain text only.

7.7. Promotional products

A change to a product that is being promoted (including packaging changes) for a specific event or date, impacting the required handling in the supply chain to ensure the trade item is available for sale during a specified time period, requires assignment of a new GTIN.

For promotional products, the GTIN for the trade item/base unit level does not need to be changed, but higher levels of packaging above the base unit need to be uniquely identified. Any promotion impacting the content of the product, or requiring a new regulatory filing, is considered a major change and a new GTIN must be assigned.

Note: Promotions are short-term modifications to the way the item is presented. Any promotion shall be aligned to the national laws.

7.8. Pack/case quantity

A change to the number of trade items in a pack or case or a change to the quantity of cases in a pre-defined pallet configuration requires assignment of a new GTIN.

A unique GTIN is assigned at every existing level of the hierarchy including and above the lowest level that is changed.

Pallets require a GTIN only when they are considered as a trade item (i.e. priced, ordered, or invoiced). But, when it is considered as a logistics unit (e.g., shipment, transport, storage) it shall be identified with a Serial Shipping Container Code (SSCC).

For example: A change to case from containing 10 products to containing 12, the case needs to be assigned a new GTIN.

A change in pallet from containing 16 cases to containing 24 cases, the pallet needs to be assigned a new GTIN.

7.9. Pre-defined assortment

A change, addition or replacement of one or more trade items included in a pre-defined assortment, requires assignment of a new GTIN.

***Note**: A pre-defined assortment is defined as a pack of two or more different trade items that are combined and sold together as a single trade item (may also be referred to as a bundle or kit).*

The creator of the kit or kitter is responsible for allocating the GTIN. The GTIN change occurs at the kit and all levels above. The following GTIN change rules apply:

- All individual component of a kit needs GTIN
- Adding a new component to a kit requires a new GTIN

- Removing a component from a kit requires a new GTIN.
- When kit components are identified by GTIN and/or brand owner item number, and that kit component is substituted, the kit GTIN shall be changed.

7.10. Price on pack

Price on pack is defined as when the brand owner includes pre-pricing as part of the package graphics. This does not include prices marked on a price ticket, sticker, hangtag or anything that could be removed from the package or product. Any addition, change or removal of a price marked directly on the product package, requires assignment of a new GTIN.

The GTIN change occurs at the base unit level. A unique GTIN is assigned at every existing level of the packaging hierarchy above the base unit level.

7.11. Different language

Any change to language (i.e. removal or addition) that impacts where a product can be sold or how supply chain stakeholders and end users interact with it, requires the assignment of a new GTIN. This includes the language printed on the package itself and inserts that are considered as part of the pharmaceutical product. A unique GTIN is assigned at every hierarchy level where the language is listed.

However, when a language is removed from a multilingual package, a new GTIN shall be assigned. When a language is added to an existing package, a new GTIN is not required.

8. Contact a 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.

9. Transition for Implementation

This guideline shall enter into force on the date of approval by the Authority.

References

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- GS1 Healthcare GTIN Allocation Rules. https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf
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