



# GTIN Allocation Team

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## Guideline Document

### Worldwide Standard

- Built on GS1 GTIN rules
- **OTC, Pharma, and Medical Devices**

### Country Specific?

- Regulatory
- Would require a living document??



## Introduction to GTIN in Healthcare

### Definition

- OTC
- Rx
- Medical Device

### Allocation of GTIN

### Regulators

### GTIN Examples/Guidelines

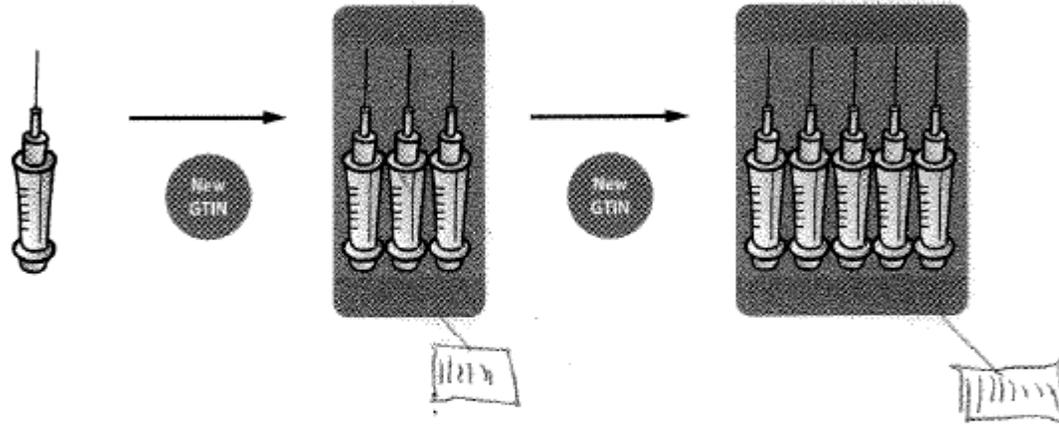
- OTC
- Pharma
- Medical Devices

## DIFFERENT QUANTITIES

### Type of Change to Trade Item

Grouping of the same item containing different quantities

Example: A single item- loose syringe, a multi-pack of 3 blister syringes, and also a 5 blister syringes.



GTIN for Standard Trade Item Grouping  
(Picture of case with New GTIN bug)

### Rationale

Different GTIN necessary to distinguish between the different pack sizes.

### Consequence if Rule Not Applied

The GTIN identifies all aspects of the standard trade item grouping for ordering, stocking or billing systems. Using the same GTIN for the standard trade item grouping containing different quantities invalidates these systems.

### Notes:

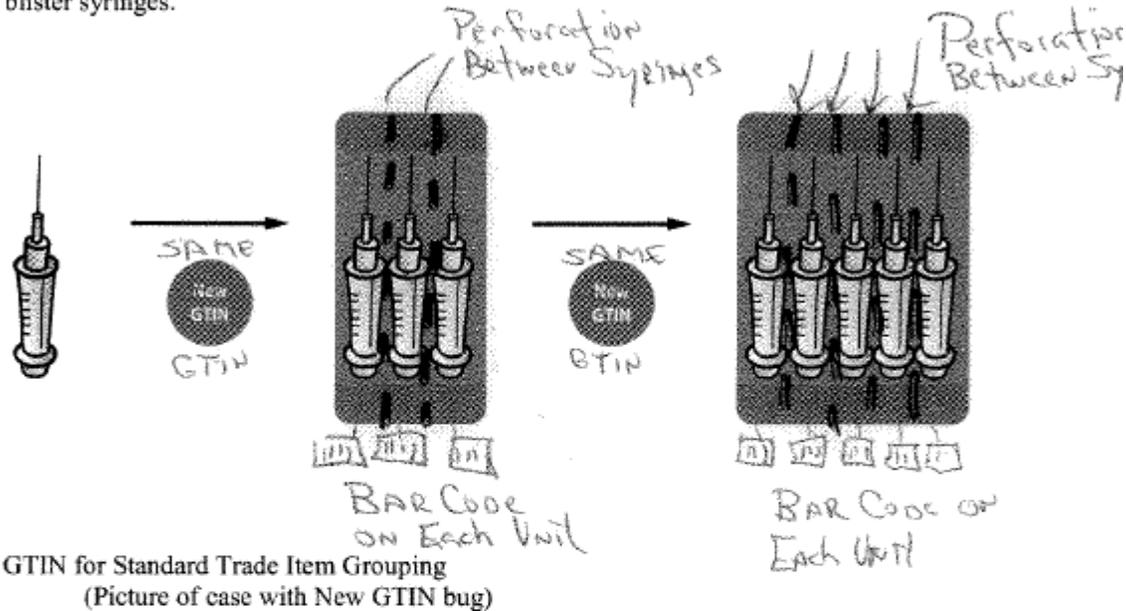
- In this situation the blister does not have perforations separating each individual unit in the multi unit. (See .....)
- The GTIN on the individual syringes remains the same in all packs

## DIFFERENT QUANTITIES / Perforated Blister/GTIN on Each Blister Cell

### Type of Change to Trade Item

Grouping of the same item containing different quantities

Example: A single item- loose syringe, a multi-pack of 3 blister syringes, and also a 5 blister syringes.



### Rationale

GTIN for a single unit should be the same if it is for a single pack or a multi pack.

### Consequence if Rule Not Applied

The GTIN identifies all aspects of the standard trade item grouping for ordering, stocking or billing systems. The GTIN for a single unit should not

### Notes:

- In this situation the blister has perforations separating each individual unit in the multi unit. So the individual blister units will all have the same GTIN
- The GTIN on the individual syringes would be the same as the individual perforated blisters



## Listing of OTC Slides

- New Language - New language on a package sold in one Market/Country- NEW GTIN REQUIRED
- Additional Language on the packaging sold in several markets-SAME GTIN
- Language group cluster substitution- ex an item in English, Spanish and Portuguese that will now appear in English, French and Italian-NEW GTIN
- *GTIN Standard Trade Item Grouping*- NEW GTIN Minor changes which are not relevant to trading partners or consumers (example- neither the consumer nor the ordering, billing, prescribing, stocking, dispensing information is impacted- SAME GTIN
- Minor artwork changes- example- change to reflect a new Marketing “look”-SAME GTIN
- Changes to weight, count volume-New GTIN
- Changes in dosage – NEW GTIN
- Changes in usage – NEW GTIN
- Changes in packaging materials- example- glass to plastic package-SAME GTIN
- Change in weight of declared units- examples- 100 to 125 tablets- NEW GTIN
- Change to a new form- example Aspirin tablet to Aspirin gel cap- NEW GTIN
- Change that affects the trade item name or brand- example Joe’s Aspirin to Paul’s Aspirin- New GTIN
- New/additional pallet layouts to the co-exist permanently with the original layout- example aspirin is sold standard pallet loads but Market pressure requires additional pallet configurations to be made- New GTIN



## Listing of Rx Pages

Groupings of same item containing different quantities- ex. one syringe pack, 3 pack and 5 pack- NEW GTIN

- NOTE: GTIN for each individual syringe will remain the same
- *GTIN Standard Trade Item Grouping- NEW GTIN*

Unit of Use packaging

- One each five pack blister (no perforations) in a carton- THE ONE GTIN PRINTED ON THE CARTON AND THE BLISTER WOULD BE THE SAME
- Two of more five pack blisters (no perforations) in a carton- THE ONE GTIN PRINTED ON THE CARTON AND THE BLISTER WOULD BE different



## Listing of Medical Device Pages

### KITS:

Surgical Stapler and staples

ECG Electrodes single or set

Generator and electrodes

Stutures, multiple types per kit for fixed surgical procedure

Breathing kits

Vascular access systems

Nebulisation kit

Introduction kit for transurethral catheter



# Medical Device

Mark Hoyle



# Areas of Concerns and Resolution

- Number of GTINs for Medical Devices
  - Software
    - Upgraded Versions
  - Voltage
  - Country
  - Language
    - Ex. UK and US
- Countries not Using Systems coding systems not compatible with GTIN- Two codes on the package one GTIN and another country required.
  - i.e. Germany, Austria, Italy
  - UPC and Data Matrix
- Assigning GTINs to lowest level
  - Unit of use
- Best practice in health care is never to reuse GTINs.



# Breakout Groups

- General Review of Process
- Review definitions of OTC, Rx and Medical Devices
- Review listing OTC, Rx and Medical Device Situations to make sure all options are covered.
  - Group 1 OTC/Rx
  - Group 2 Medical Devices



## Contact Details

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    - 2.2.2. Prescription (Rx)
    - 2.2.3. Medical devices (classification I, II, III plus their subset and the 4 subject levels- non-invasive, invasive, active, special rules)
3. Allocating the Numbers



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#### 3.4.3. Pallet

#### 3.4.4. GTIN

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#### 3.6.1. Data Alignment Best Practice



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#### 4.1.1. Over the counter

#### 4.1.2. RX

#### 4.1.3. Medical Devices

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#### 4.2.1. Over the counter

#### 4.2.2. RX

#### 4.2.3. Medical Devices