



# GTIN Allocation Team Breakout Group OTC/RX

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# 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



# Comments

## Package Level Indicator

- Include two methods
  - Follow the IFAH guidelines

## Definitions

- **OTC/Rx Medical Devices**

## Issues

- Bottle of 100
  - Two tablets.
  - What GTIN of one tablet?
    - Manufacturer is only concerned with lowest package level
    - Hospital applies GTIN at lower levels
    - Hospital is responsible for GTIN assigned for smaller unit
      - Dispensing Trolleys
      - Repackaging
- Issues
  - Easier to understand
  - Images for each situation
  - Country dependent changes.
  - Kits



## Contact Details

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1. Scope and Background
2. Introduction to Global Trade Item Number in Healthcare
  - 2.1. Definition of a GTIN
  - 2.2. Healthcare Items (definitions)
    - 2.2.1. Over The Counter (OTC)
    - 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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- 3.1. General rule
- 3.2. Responsibility
  - 3.2.1. Branded and Non-Branded items
- 3.3. Guidelines for Allocating Global Trade Item Numbers
  - 3.3.1. Pre-defined characteristics
  - 3.3.2. Lead time in re-using a GTIN
  - 3.3.3. Prepriced merchandise
  - 3.3.4. Trade item changes



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## Assigning GTIN to Groupings

### 3.4. What are groupings (hierarchies)

#### 3.4.1. Unit of Use Package (i.e., individual blister)

#### 3.4.2. Shipper or Case

#### 3.4.3. Pallet

#### 3.4.4. GTIN

#### 3.4.5. Expiry Date

#### 3.4.6. Batch

#### 3.4.7. Serial Number

### 3.5. Acquisitions and Mergers

#### 3.5.1. Partial Purchase

#### 3.5.2. Split or Spin-Off

### 3.6. Data alignment

#### 3.6.1. Data Alignment Best Practice



## 4. Regulators

### 4.1. Changes not requiring new GTIN

#### 4.1.1. Over the counter

#### 4.1.2. RX

#### 4.1.3. Medical Devices

### 4.2. When a new GTIN is required

#### 4.2.1. Over the counter

#### 4.2.2. RX

#### 4.2.3. Medical Devices