The Global Language of Business

Discussion paper on aggregation in the pharmaceutical supply chain

Purpose

This paper aims at providing **guidance** on the implementation of pharmaceutical aggregation using GS1 standards. It is however important to acknowledge that due to regulatory requirements, trading agreements and/or internal supply chains management processes, industry practices in implementing aggregation may vary from the recommendations below.

This paper does not address implementation of any specific regulatory requirements.

Audience

The main target audience for this paper are trading partners involved in the pharmaceutical supply chain.

Scope

This paper focuses on regulated pharmaceutical products worldwide. In this context, aggregation is understood to begin with the serialisation of the registered trade item i.e. the regulated level of packaging. *This paper does not consider levels of the packaging hierarchy lower than the registered pack size (e.g. primary packaging).*

Executive summary: Aggregation process in the GS1 system

Introduction

Aggregation is the creation of a hierarchical, parent-child relationship between a containing object (i.e., parent) and one or more objects (i.e., children) that are contained.

Aggregation requires unique identification of the parent: i.e. GTIN + serialisation (SGTIN) if the parent is a trade item, or SSCC if the parent is a logistic item.

Aggregation may be created at practically any point in the hierarchy of trade items and logistics units, aggregating...

- trade items (secondary) to a trade item (tertiary)
- trade items (secondary and/or tertiary) to a logistics unit
- logistics units (e.g., shipper case or tote) to a logistics unit (e.g., pallet)

Definitions

A **trade item** is any item—identified by a **Global Trade Item Number (GTIN)**[1] —for which there is a need to retrieve predefined information (i.e. master data) and that may be priced, or ordered, or invoiced at any point in any supply chain.

A **logistic unit** is an item of any composition—uniquely identified by a **Serial Shipping Container Code (SSCC)**[2] — established for transport and/or storage that needs to be managed through the supply chain. Logistic units take many forms (e.g., a single box containing a limited number of items, a pallet of multiple items or an intermodal container containing multiple pallets).

Any **bundles** included in the aggregation process can be optionally uniquely identified by either an **SGTIN** or an **SSCC**. The choice of SGTIN or SSCC will depend on considerations such as a given bundle's role as either a trade item or logistics unit within that particular supply chain, internal identification practices and/or agreements with supply chain partners.

Note: when a trade item is handled as a logistics unit (e.g., shipped out as a case), the trade item assumes the role of - and should be aggregated to - the logistics unit.

- This aggregated case is identified solely by the logistic unit's SSCC, until the logistic unit is received by the recipient.
- Once received, the trade item identifier SGTIN is disaggregated from the logistic unit identifier SSCC. The case reverts to its identity (and SGTIN) as a trade item.

This is illustrated in figure 3 of the **Aggregation Guidelines** diagram on the next page.

[1] *Global Trade Item Numbers (GTINs) uniquely identify items that are traded (Pharmaceuticals, Medical Devices, etc.) in the Supply Chain. Integrity of these numbers throughout the item's lifetime is a key to maintaining uniqueness for manufacturers, wholesalers, distributors, hospitals, regulatory bodies and other Supply Chain stakeholders. A change to one aspect, characteristic, variant or formulation of a trade item may require the allocation of a new GTIN. (Source: GS1 Healthcare GTIN Allocation Rules)*

[2] *An individual 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. When assigning an SSCC, the rule is that an individual SSCC number must not be reallocated within one year of the shipment date from the SSCC assignor to a trading partner. However, prevailing regulatory or industry organisation specific requirements may extend this period. (Source: GS1 General Specifications)*

Aggregation guidelines

Levels	Each child is one or more...	(n to 1)	Parent is one...
1.	**registered trade item** (lowest registered level) uniquely identified by: **GTIN** – AI(01) **Serial Number** – AI(21) ID supplemented by: Lot/Batch – AI(10) Expiry – AI(17) 	→	**trade item** (next higher level) uniquely identified by: **GTIN** – AI(01) **Serial Number** – AI(21) ID supplemented by: Lot/Batch – AI(10) Expiry – AI(17) 
2.	**trade item** (level above secondary pack) uniquely identified by: **GTIN** – AI(01) **Serial Number** – AI(21) ID supplemented by: Lot/Batch – AI(10) Expiry – AI(17) 	→	**logistic unit** (created for transport/storage) uniquely identified by: **SSCC** – AI(00)) 
3.	**trade item** (level above secondary pack) uniquely identified by: **GTIN** – AI(01) **Serial Number** – AI(21) ID supplemented by: Lot/Batch – AI(10) Expiry – AI(17) 	→	***same physical object, but now in the role of a*** **logistic unit** (for transport) uniquely identified by: **SSCC** – AI(00) 
4.	**logistic unit** (created for transport/storage) uniquely identified by: **SSCC** – AI(00) 	→	**logistic unit** (created for transport/storage) uniquely identified by: **SSCC** – AI(00) 
5. Trade item to logistic unit	**Case of mixed registered trade item** (lowest registered level) uniquely identified by: **more than one GTIN** – AI(01) **Serial Number** – AI(21) ID supplemented by: Lot/Batch – AI(10) Expiry – AI(17) 	→	**logistic unit** (created for transport/storage) uniquely identified by: **SSCC** – AI(00) 

Aggregation with EPCIS

EPCIS is a GS1 standard that enables trading partners to capture and share information about the physical movement and status of products as they pass through the supply chain. EPCIS provides the "what, where, when and why" of supply chain visibility to satisfy stakeholder requirements for accurate and detailed product information. Its companion standard, the Core Business Vocabulary (CBV), helps underpin interoperability between EPCIS implementations.

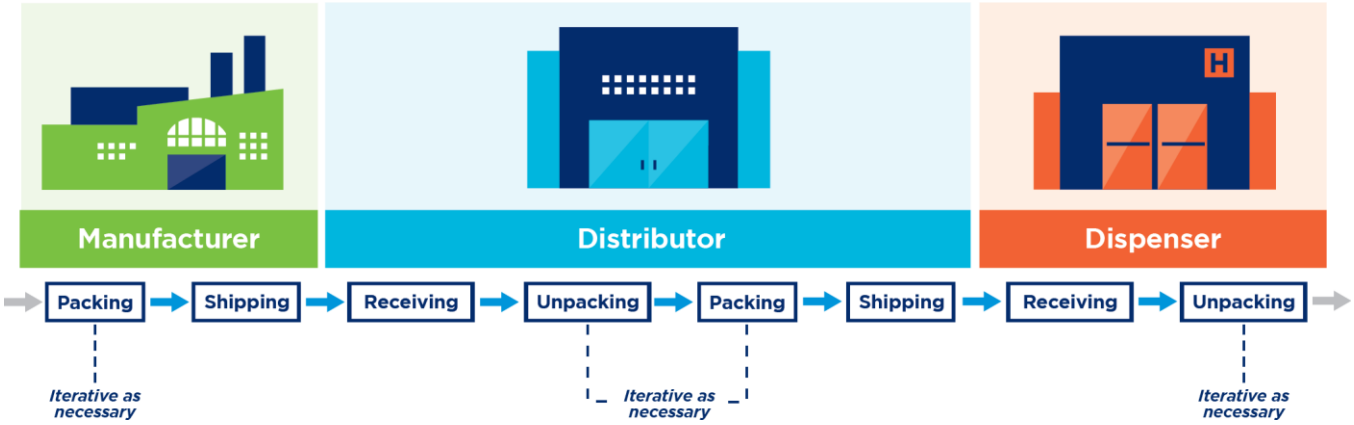
Although aggregation can be done without using EPCIS, an increasing number of manufacturers and re-packagers are leveraging the **EPCIS Aggregation Event** to capture the creation of hierarchies such as those illustrated in the table above, as they actually occur in the physical supply chain.

In an EPCIS Aggregation Event, the "**packing**" business step reflects the process of putting one or more child objects (e.g., secondary packs, cases, etc.) into a larger, parent container (e.g., cases, totes, pallets, etc.) for the purposes of storing or shipping.

Suppliers share their Aggregation Events with the intended recipient(s) of those objects. This allows downstream partners to practice inference, by which the recipient only needs to verify the identifiers of the highest-level objects in the packaging hierarchy. The full packing hierarchy (including all levels of aggregated children) from prior packing steps is inferred to be intact.

The "**unpacking**" business step reflects the reverse process of removing the child objects from their parent, for the purposes of storing or forward processing in the supply chain. This is undertaken by a downstream party, disaggregating the aggregation relationship created by a specific, earlier "packing" step.

The following process flow diagram highlights the packing steps in the supply chain, each of which is captured as a new aggregation in an EPCIS Aggregation Event, along with the unpacking steps, each of which is captured as a disaggregation in an EPCIS Aggregation Event.



This diagram is intentionally simplified and does not include the beginning/end of life Commissioning and Decommissioning steps which are critical to ensuring the end-to-end traceability of each serialised product. This diagram also does not take into account internal manufacturers' supply chain management processes where logistic service providers can execute the same steps as the distributor.

References and links

EPCIS and CBV Implementation Guideline
https://www.gs1.org/docs/epc/EPCIS_Guideline.pdf
GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability
www.gs1us.org/RxGuideline
GS1 Identification Keys in Transport & Logistics
https://www.gs1.org/docs/tl/T_L_Keys_Implementation_Guideline.pdf
GS1 Healthcare GTIN Allocation Rules
https://www.gs1.org/1/gtinrules/en/healthcare

GS1 Logistics Label Guideline
https://www.gs1.org/docs/tl/GS1_Logistic_Label_Guideline.pdf
GS1 Logistic Label Tool
http://www.gs1-labelview.at/front.php
ISO/TS 16791:2014—Health informatics—Requirements for international machine-readable coding of medicinal product package identifiers
https://www.iso.org/standard/57776.html