

Discussion paper on aggregation in the pharmaceutical supply chain

Purpose

This paper provides guidance on the implementation of aggregation using GS1 standards, with the goal of underpinning interoperability between distinct implementations, in turn reducing their complexity and cost.

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

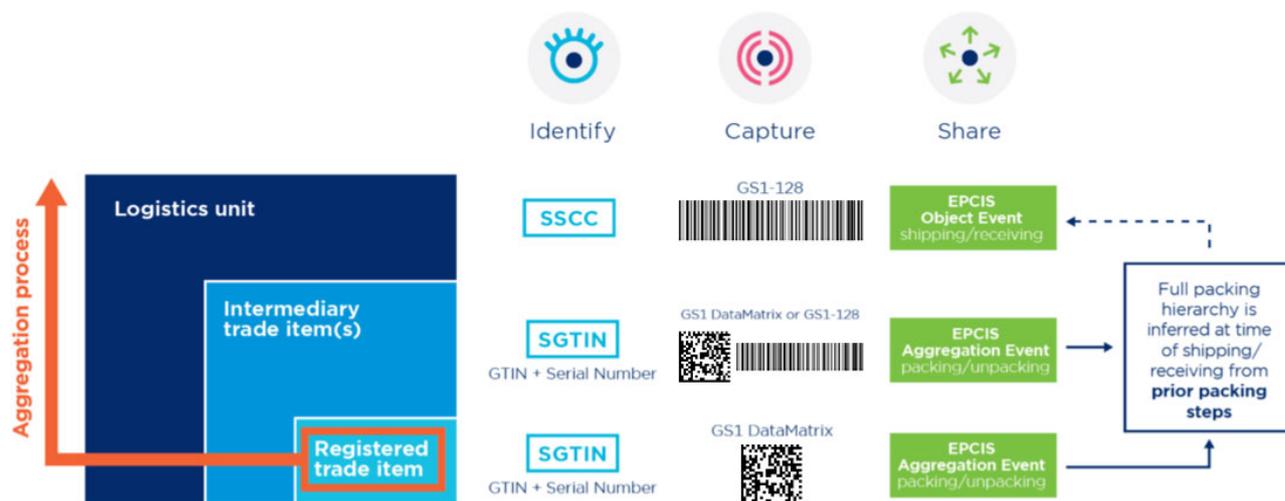
Audience

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

Scope

This paper focuses on regulated pharmaceutical products worldwide. In this context, **aggregation** is understood to begin with the serialised, **registered trade item**. In the pharmaceutical sector, this is currently the lowest regulated, serialised level of packaging. *This paper does not consider levels of packaging hierarchy lower than the registered pack size (i.e. 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 (serialisation) of the parent. In pharmaceutical supply chain practice, **each aggregated child is uniquely serialised** mainly because of regulatory requirements mandating serialisation of registered trade items.

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 **GTIN**—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 **logistics unit** is an item of any composition—uniquely identified by **SSCC**—established for transport and/or storage that needs to be managed through the supply chain. Logistics units take many forms (e.g., a single box containing a limited number of products, a pallet of multiple products or an intermodal container containing multiple pallets).

Any **bundles** included in the aggregation process can be optionally identified by either **GTIN** or **SSCC**. The choice of GTIN 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.

Aggregation guidelines

Levels	Each child is one or more... (n to 1)	Parent is one...
Trade item to trade item	<p>registered trade item (lowest registered level)</p> <p>uniquely identified by: GTIN – AI(01) Serial Number – AI(21)</p> <p>ID supplemented by: Lot/Batch – AI(10) Expiry – AI (17)</p> 	<p>trade item (next level above secondary pack)</p> <p>uniquely identified by: GTIN – AI(01) Serial Number – AI(21)</p> <p>ID supplemented by: Lot/Batch – AI(10) Expiry – AI(17)</p> 
Trade item to logistics unit	<p>registered trade item (lowest registered level)</p> <p>uniquely identified by: GTIN – AI(01) Serial Number – AI(21)</p> <p>ID supplemented by: Lot/Batch – AI(10) Expiry – AI(17)</p> 	<p>logistics unit (created for transport/storage)</p> <p>uniquely identified by: SSCC – AI(00)</p> 
	<p>registered trade item (level above secondary pack)</p> <p>uniquely identified by: GTIN – AI(01) Serial Number – AI(21)</p> <p>ID supplemented by: Lot/Batch – AI(10) Expiry – AI(17)</p> 	<p>logistics unit (created for transport/storage)</p> <p>uniquely identified by: SSCC – AI(00)</p> 
Logistics unit to logistics unit	<p>logistics unit (created for transport/storage)</p> <p>uniquely identified by: SSCC – AI(00)</p> 	<p>logistics unit (created for transport/storage)</p> <p>uniquely identified by: SSCC – AI(00)</p> 

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.

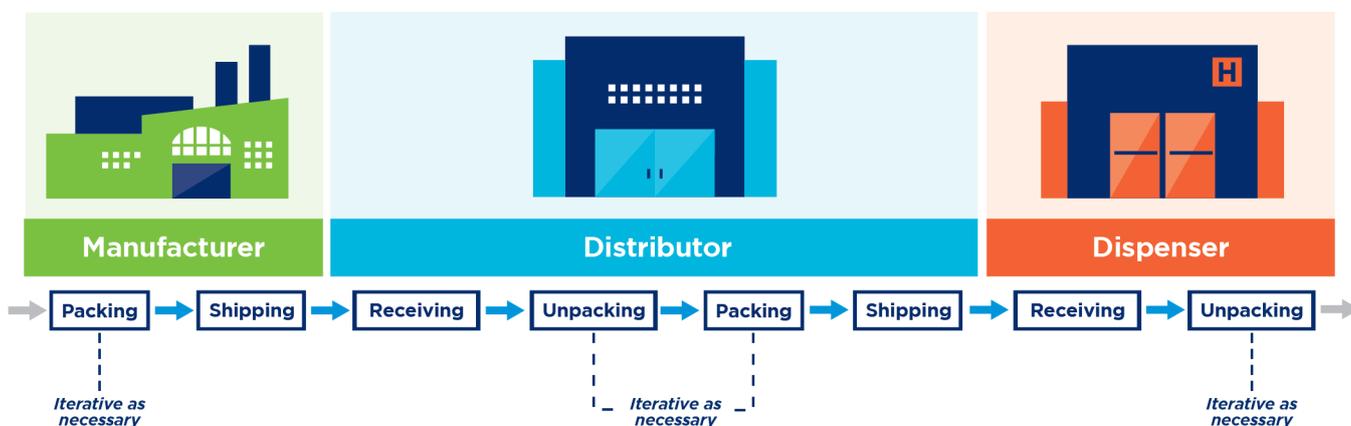
Although aggregation can be done without using EPCIS, an increasing number of manufacturers and re-packagers are leveraging the **EPCIS Aggregation Event** to capture the creation of hierarchies such as those illustrated in the table above, as they actually occur in the physical supply chain.

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.

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 Logistics Label Guideline

https://www.gs1.org/docs/tl/GS1_Logistic_Label_Guideline.pdf

ISO/TS 16791:2014—Health informatics—Requirements for international machine-readable coding of medicinal product package identifiers

<https://www.iso.org/standard/57776.html>

