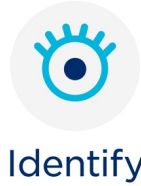# Exchanging Traceability Data with EPCIS

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Senior Manager, Supply Chain Visibility, EPCIS & RFID

GS1

GS1 Healthcare Conference

Bangkok, 31 October 2018

EPCIS: a GS1 "Share" standard

Identify

Capture

Share

GS1 Standards for Identification

Company & Location
- Global Location Number (GLN)

Product
- Global Trade Item Number (GTIN)
- Serialised Global Trade Item Number (SGTIN)

Logistics & Shipping
- Serial Shipping Container Code (SSCC)
- Global Shipment Identification Number (GSIN)
- Global Identification Number for Consignment (GINC)

Assets
- Global Individual Asset Identifier (GIAI)
- Global Returnable Asset Identifier (GRAI)

Services & More
- Global Service Relation Number (GSRN)
- Global Document Type Identifier (GDTI)
- Global Coupon Number (GCN)

GS1 Standards for Barcodes & E.../RFID

GS1 Barcodes

EAN/UPC

9 501101 021037

GS1-128

(00) 3 9501100 00000100

ITF-14

00501101021037

GS1 DataBar

(01) 0 9501101 02103 7

GS1 DataMatrix

GS1 QR Code

GS1 Composite Barcode

GS1 EPC/RFID

Electronic Product Code (EPC) RFID

EPC HF Gen 2

EPC UHF Gen 2

GS1 Standards for Data Exchange

Master Data
- Global Data Synchronisation Network (GDSN)

Transactional Data
- eCom (EDI): EANCOM, GS1 XML

Event Data
- EPC Information Services (EPCIS)

EPCIS

CBV

The Global Language o...

GS1

EPCIS, a GS1 and ISO open standard

- defines interfaces for capturing & sharing data

- defines a framework data model for event data

- helps **share visibility data** across enterprises

- enables services & solutions for supply chain visibility

- GS1 Keys identify the "what" & "where" of visibility events…
  - …encoded as data-carrier neutral EPCs
  - …even when used with GS1 barcodes (instead of RFID)

- published as ISO/IEC 19987

Core Business Vocabulary (CBV)

- companion standard to EPCIS

- defines specific data values to populate EPCIS data model

- ensures a common understanding of data semantics

- anchors EPCIS events to business process context

- **critical to interoperability of EPCIS implementations**

- published as ISO/IEC 19988 **ISO**

EPCIS enables supply chain visibility
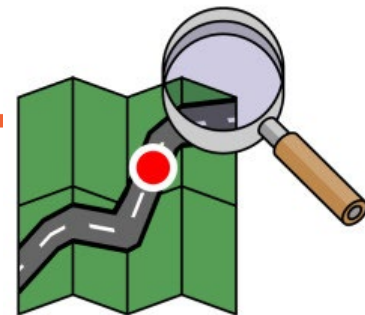
- **Tracking**

  Where are the products we shipped?

- **Tracing**

  Where did this batch of products come from?

- **Chain of Custody (CoC) / Chain of Ownership (CoO)**

  Which parties had custody or ownership of these products?

- **Inventory Management / Inventory Maintenance**

 *How many units are in stock? When does my available inventory expire?*

- **Recall**

  Find all Product XYZ shipped from facility 4711 on 8 October 2018...

The 4 data dimensions of an EPCIS event

- **What** objects are the subject of event?
  Individual objects (GTIN + Serial Number = SGTIN)

- **When** did this event take place?
  Date, time, time zone

- **Where** did this occur and where are the objects thereafter?
  GLN of physical location

- **Why** did this event take place?
  Business step (e.g. "Shipping") and Disposition (e.g "in transit")
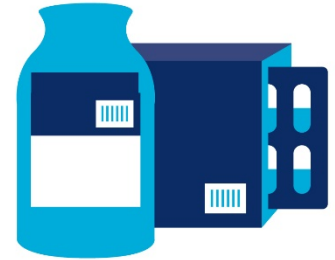
Egypt
Requirements to be released

Status: <u>Decree on national track and trace system</u> & <u>Decision 29-2016</u> (18 April 2016)

Scope: only products registered as pharmaceuticals

Requirements as applicable:

POSTPONED deadline of 1 June 2018

New deadlines: by end 2018 T&T of at least one product and implementation plan (ie. detailed implementation timeline for printing two-dimensional barcodes on the rest of their products) for the rest

Data Portal: GS1 Egypt database on master data will be included in the MoH Database

Open points/next developments:

Updated version for Egypt Track & Trace Project Guidelines. It will be reviewed & discussed by industry prior to health agency announcement and implementation.

Data sharing or registration methods: EPCIS required

PP Database Dossier #: 606EGPH101004

Malaysia
Draft full T&T system

Status: draft requirements - announced on 5 October

Scope: pharmaceutical products

Planned Requirements:

• Phased implementation: starts in 2020 with scheduled poison products and the rest will be implemented in phases

• Primary level serialization is not required in the initial phases but will be required after full track and trace is implemented

• As of 2023: full implementation

Data Submission Portal: Centralised model will be used

Open point(s)/upcoming dev.:

•   They will follow GS1 standards and follow globally harmonized approach

•   They want to model their system based on Turkey since they believe that Turkey is the most successful implementation thus far

Data sharing or registration methods:

– **EPCIS** will be used for reporting to the central database

PP Database Dossier #: 458MYSPH181008

USA – DSCSA
2015 to 2023

Scope: Pharmaceuticals (prescription drugs)

Requirements as applicable:

- Packaging level: saleable units and homogeneous cases
- Data elements: NTIN, Expiry date, lot/batch number, serial number
- Data carrier: 2D DataMatrix
- Serialisation : Nov. 2018

Traceability Model: full track & trace

Data sharing: US FDA points to **EPCIS** : **GS1 US Implementation Guideline:**

Updates:

- Product Identifiers (final):
  https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf
- Product Identifier Qs and As (for comment purposes):
  https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM621044.pdf
- Guidance for Verification Systems requirements for drugs as part of US DSCSA.
  https://www.federalregister.gov/documents/2018/10/25/2018-23306/verification-systems-under-the-drug-supply-chain-security-act-for-certain-prescription-drugs-draft

PP Database Dossier #: **738USAPH140430**

GS1 Standards for DSCSA & Traceability
GS1 US Rx Guideline   www.GS1US.org/RxGuideline

- Describes how GS1 Standards can best be applied to pharmaceutical supply chain business processes to support traceability

- Supports collaborative supply chain traceability solutions

- Participation from over 50 pharmaceutical supply chain organisations

- Updated as neccessary per requirements & industry feedback
  - V 1.0 (2012): satisfy California Pedigree regulations
  - V 1.1 (2014): align with DCSCA lot-level requirements
 - **V 1.2 (2016)**: align with DSCSA **item-level** requirements

EPCIS for Serialized Item-Level Traceability

- Events are captured at instance-level (GTIN + Serial, SSCC)

- ***Commissioning*** events enable validation of serial numbers

- ***Packing*** & ***Unpacking*** events record packaging hierarchy
  - **Aggregation** of item -> case -> pallet

- DSCSA CoO transaction info integrated in ***Shipping*** event

- ***Receiving***, ***Dispensing***, ***Decommissioning*** events
  - record product lifecycle beyond DSCSA compliance
  - These events comprise Transaction Information (TI) & Transaction History (TH)
  - Transaction Statement (TS) is included in the EPCIS header
  - Single XML document containing all DSCSA-required information

Aggregation
Leveraging the EPCIS Aggregation Event
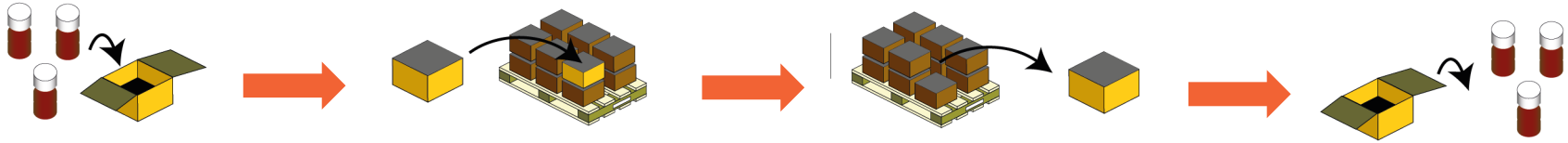

Aggregation of items into a case　　**Aggregation of cases onto a pallet**　　**Disaggregation of cases from a pallet**　　**Disaggregation of items from a case**

- Parent-Child logistical hierarchy
- Applied to a containing object and a set of contained objects
- Enables the practice of **inference**
- ADD an Aggregation (children aggregated to parent)
- OBSERVE an Aggregation (may be incomplete)
- DELETE an Aggregation (removal of subset or all children)

EPCIS events captured and shared by . . .
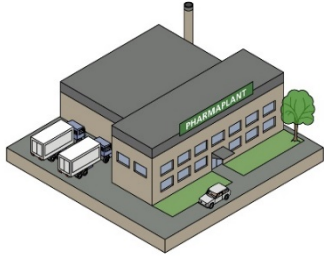
Party at beginning of the supply chain (e.g., manufacturer)

- Commissioning
- **Packing**
- Shipping

Intermediate parties (e.g., distributor)
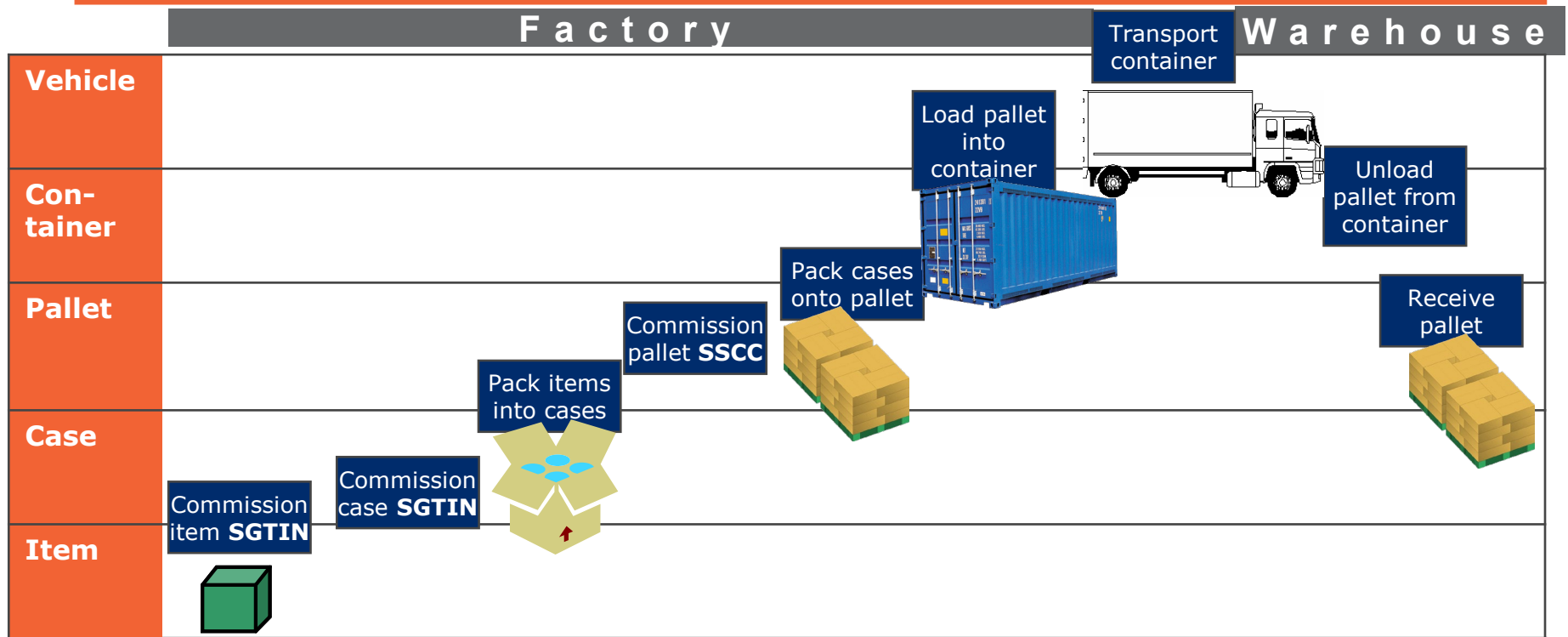
- Receiving
- **Unpacking**
- **Packing**
- Shipping

Party at end of chain (e.g., pharmacy)

- Receiving
- **Unpacking**
- Dispensing
- Decommissioning

Process Flow Example
Designing a Visibility System using EPCIS

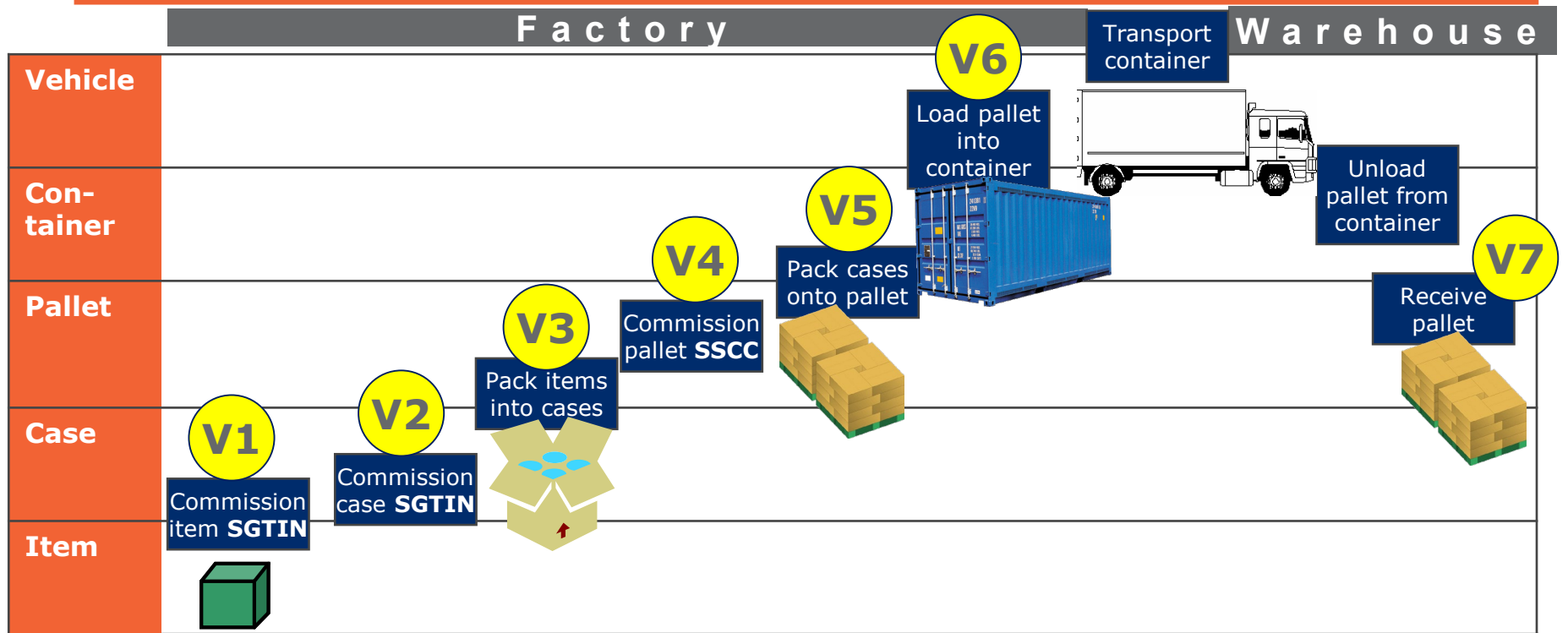# Designing a visibility system using EPCIS

Implementation Guideline http://www.gs1.org/docs/epc/EPCIS_Guideline.pdf

1. Collect visibility goals and requirements

2. Document business process flows

3. Break each process flow into series of discrete steps

Process Flow Example
Designing a Visibility System using EPCIS

Factory — **Warehouse**

Vehicle		
Con-tainer		
Pallet		
Case		
Item		

V1 — Commission item **SGTIN**

V2 — Commission case **SGTIN**

V3 — Pack items into cases

V4 — Commission pallet **SSCC**

V5 — Pack cases onto pallet

V6 — Load pallet into container

Transport container

Unload pallet from container

V7 — Receive pallet

Designing a visibility system using EPCIS

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1. Collect visibility goals and requirements

2. Document business process flows

3. Break each process flow into series of discrete steps

4. Decide which business steps require visibility events

5. **Model completion of each step as a visibility event**

6. **Decide which data to include in the visibility event**

What info does the business application need?

Designing a visibility system using EPCIS
Implementation Guideline   http://www.gs1.org/docs/epc/EPCIS_Guideline.pdf

1. Collect visibility goals and requirements

2. Document business process flows

3. Break each process flow into series of discrete steps

4. Decide which business steps require visibility events

5. Model completion of each step as a visibility event

6. Decide which data to include in the visibility event

7. Determine vocabularies to populate each data field

8. **Document visibility events in a visibility matrix**

Visibility Data Matrix
Designing a Visibility System using EPCIS

		Event **V1**	Event **V3**	Event **V5**	Event **V6**
		Commission items	Pack items into case	Pack cases onto pallet	Ship pallet
What	**Identifiers**	GTIN & Serial (**SGTIN**) of item	**SGTINs** of items into **SGTIN** of case	**SGTINs** of cases into **SSCC** of pallet	**SSCC** of pallet
When	**Timestamp**	24 Sept 2018, 11:27 CEST	24 Sept 2018, 14:09 CEST	25 Sept 2018, 10:24 CEST	25 Sept 2018, 15:19 CEST
Where	**Location**	packaging line 47	A-frame 21	palletiser 2	dock door 11
Why	**Business Step**	**Commissioning**	**Packing**	**Packing**	**Shipping**

Why align with EPCIS?

- EPCIS provides a standardised way of exchanging and requesting traceability event data in a way that enables the business context to be communicated

- EPCIS is an open standard supported by an increasing number of implementations and software products

- EPCIS and its companion Core Business Vocabulary (CBV) are designed to be applicable across multiple industry sectors

- EPCIS and CBV are recognized as ISO/IEC standards
  - EPCIS = ISO/IEC 19987
  - CBV = ISO/IEC 19988

What is EPCIS ?

EPCIS <u>is</u> . . .

- an open GS1 & ISO technical standard
- an enabler for traceability solutions & services
- data-carrier-neutral, suited to GS1 DataMatrix

EPCIS is <u>not</u> . . .

- an out-of the box solution
- a standalone answer to visibility issues

Serialization & event-based visibility will fundamentally change supply chain precision... **EPCIS will support this!**

Resources: GS1 Standards & Guidelines

- EPCIS & CBV
  www.gs1.org/epcis

- EPCIS & CBV Implementation Guideline
  www.gs1.org/docs/epc/EPCIS_Guideline.pdf

- EPC Tag Data Standard (TDS)
  www.gs1.org/epc/tag-data-standard

- GS1 US DSCSA Guideline
  www.gs1us.org/RxGuideline

For further info on EPCIS…

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