Implementation Reality - Traceability

GS1 Healthcare Global Conference

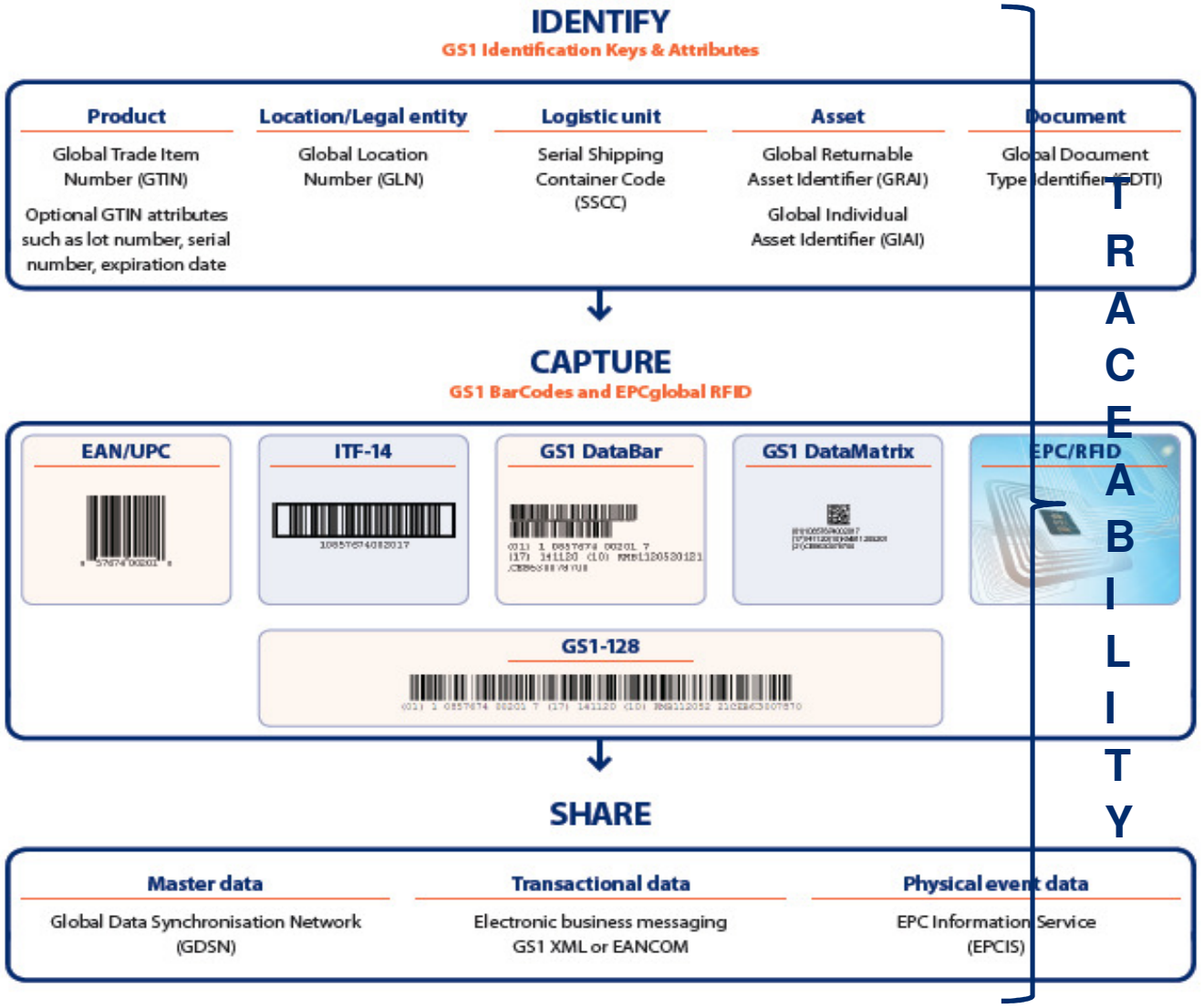
San Francisco, California, USA

Wednesday 2nd October 2013

Agenda

- Introduction — Janice Kite, GS1 Global Office
- Case Studies
  - Manufacturer — Cyndi Poetker, Abbott
  - Distributor — Heather Zenk, AmerisourceBergen
  - Hospital — Feargal McGroarty, St James's, Ireland
- Panel & Q&A Discussion

The GS1 System



GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production[1] to Point of Use[2]

- All authentic **items** are identified with the appropriate **GS1 Identification Keys** (e.g. GTIN) and appropriate **Application Identifier** (AI, e.g. Serial No. AI(21)), if applicable, at point of production
- Supply chain identifiers are associated with the patient and remain with/on items throughout their intended useful life
- All **physical locations** are identified with the appropriate **GS1 Identification Key** (e.g. GLN) across the entire supply chain
- All **patients and care givers**, when in a care giving environment, are identified with the appropriate **GS1 identification Keys** (e.g. AI 8017; AI 8018)
- Agreed **master data** is captured and shared (e.g. via GDSN) amongst trading partners
- Agreed **transactional data** is captured and shared (e.g. via business-to-business messaging) amongst trading partners
- Agreed **event data** is captured and shared (e.g. via EPCIS) amongst trusted traceability stakeholders, based on data sharing/security policies

SO THAT:

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed

GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production[1] to Point of Use[2]

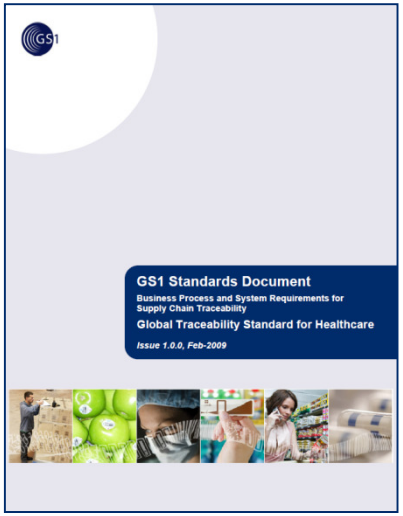
SO THAT:

- Items can be **tracked** (forward / downstream) across the entire supply chain (production to use) in real time
- Items can be **traced** (backward / upstream) across the entire supply chain (from current location back to the producer) in real time
- Item identification is available for use at patient bedside to ensure the Patient Rights[3] are achievable
- Patients Electronic Health Records (EHRs) are updated with agreed traceability information, including Care Giver identification
- Counterfeit products are detected when entering the legitimate supply chain
- A **product recall** would be fast, efficient and effective

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed
3. Pharmaceuticals (5): Right patient, right drug, right dose, right route, right time. Medical Devices (8): right device, right location, right time, right condition, right procedure, right anatomic site, right patient, right user

Traceability in Healthcare Phase I (TH-I)

DELIVERED:



Global Traceability Standard for Healthcare (GTSH)

PUBLISHED 27th February 2009

http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf

GTSH Implementation Guideline

PUBLISHED 24th April 2009

http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Implementation_Healthcare.pdf

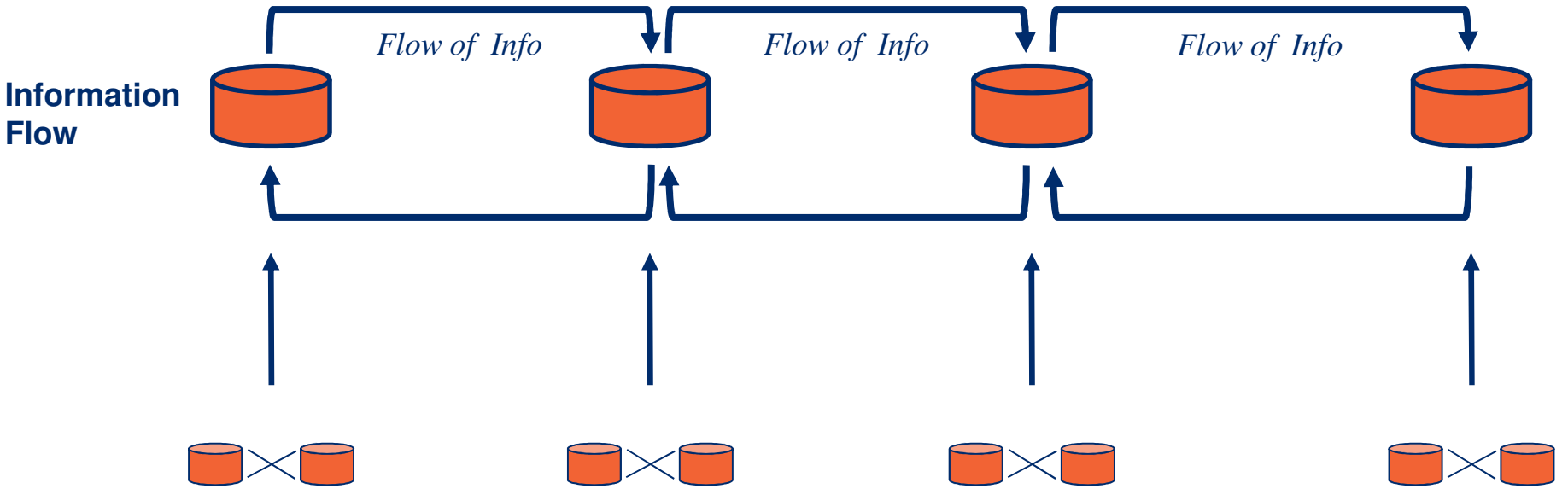
Common themes

- Global Traceability Standard for Healthcare (GTSH) is a PROCESS Standard
- Definition of Traceability: both track & trace (downstream/upstream; forwards/backwards)
- Establishes the minimum model for traceability:

  "One up, One Down"

- In parallel with the flow of product there **has to be** a flow of information about the product

GTSH "One up, One down"



Healthcare Traceability

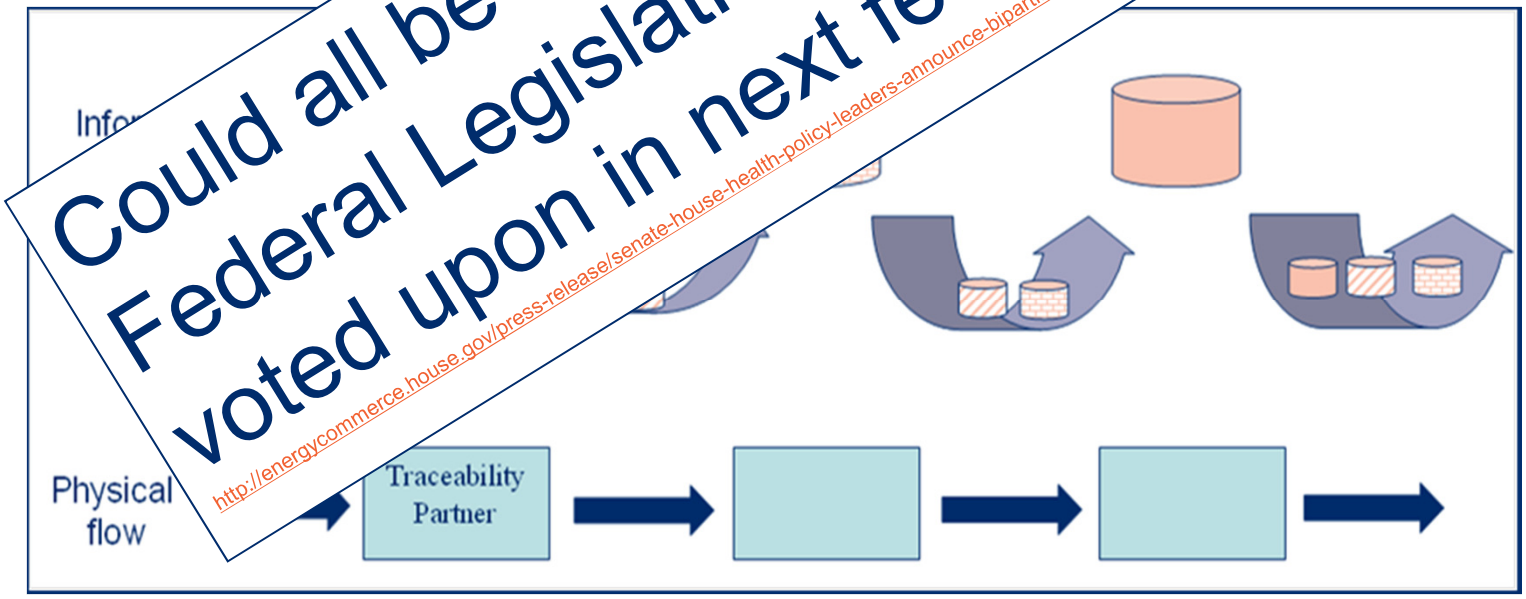
Emerging Models

Pharma – Different emerging models… US

- **Driver:** To address counterfeiting: many actors in the s… …timate/illegal blurred
- (background? Read: Dangerous Doses, Katherine …
- Numerous US States have enacted la…
- California most 'notorious' becaus… …hain of Custody/Chain of Ownership)
- Desire to identify and pr…
- Enforcement date c… …15

Could all be superseded by Federal Legislations due to be voted upon in next few weeks

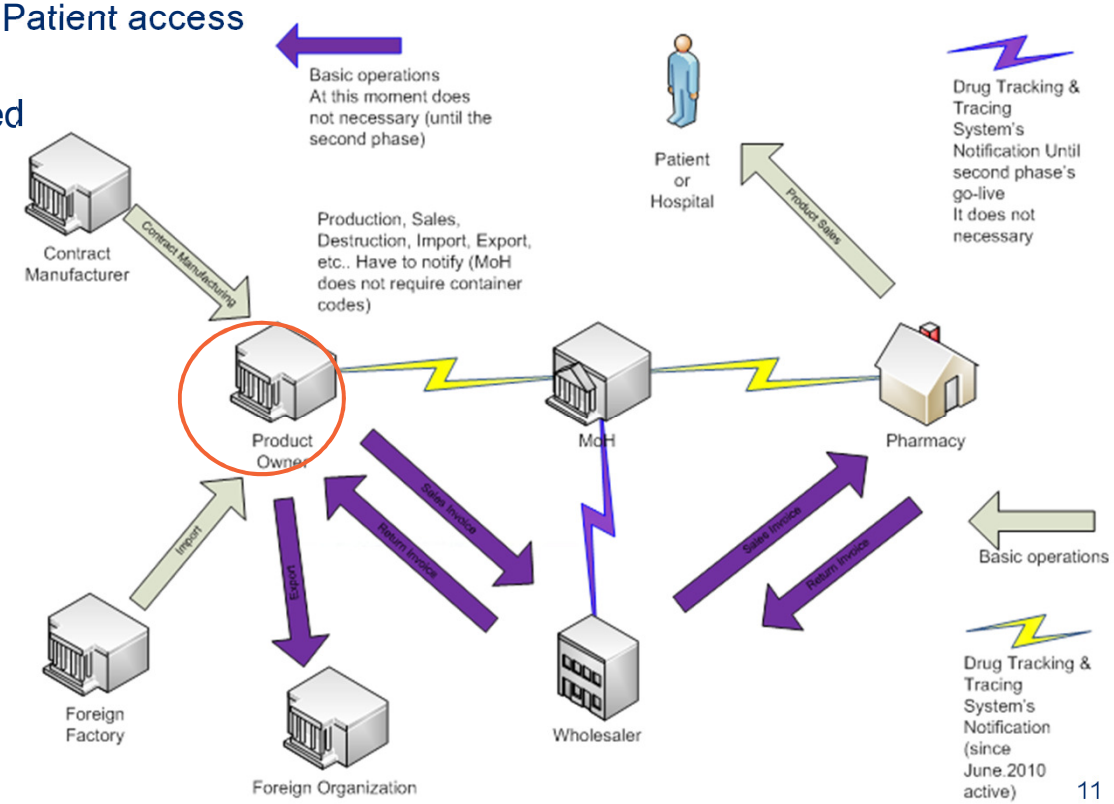
http://energycommerce.house.gov/press-release/senate-house-health-policy-leaders-announce-bipartisan-bicameral-legislation-Address



Pharma – Different emerging models… Turkey

Driver: Reimbursement Fraud; pharmacists claiming more than once for dispensed product

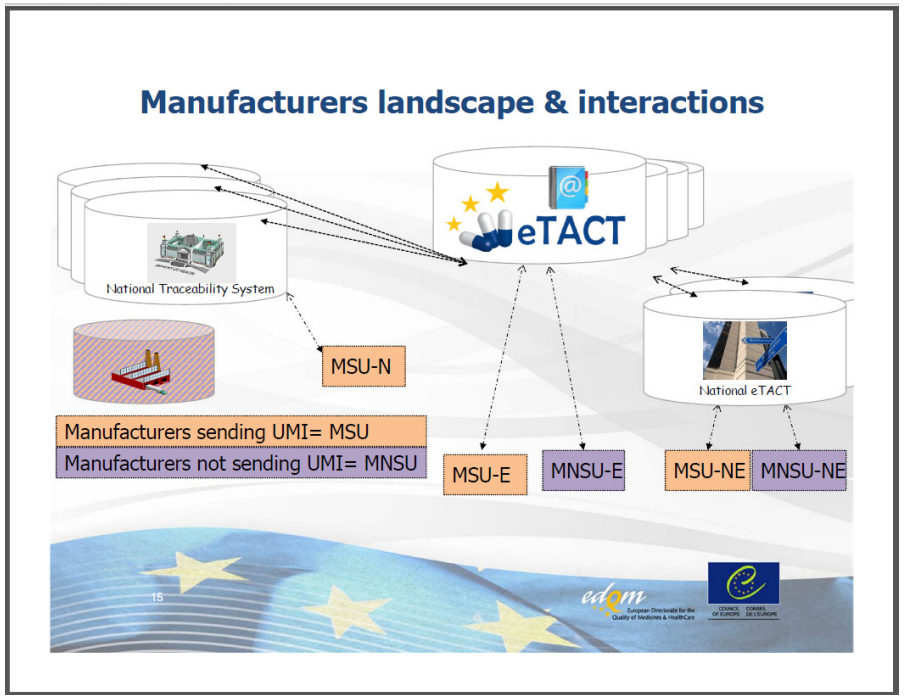
- Government developed and controlled, Centralised Track & Trace system (iTS)
- Enforcement date 2010, live 2+ years (the only live system globally!)
  - Phase 1: Manufacturers published data to MoH central database (2010)
  - Phase 2: Distributors (2012)
  - Future phases: ePrescriptions, Patient access
- ROI in ONE YEAR!
  - Reimbursement fraud eliminated
  - Examples of counterfeits being detected entering legitimate supply chain
  - Prosecutions…



Pharma – Different emerging models…Europe (1)

Driver: To address counterfeiting (falsified medicines), prevent them reaching the patient

- Two emerging (competing?) models: EDQM & EFPIA:
- European Directorate for the Quality of Medicines & HealthCare **(EDQM) eTACT**
  - Part of the Council of Europe; EDQM members 37 European countries, bigger than EU
  - Traceability from manufacture to the patient, ultimately given patients access to authenticate product
  - Developed and paid for by EDQM using GS1 EPCIS
  - Centralised for 37 member countries

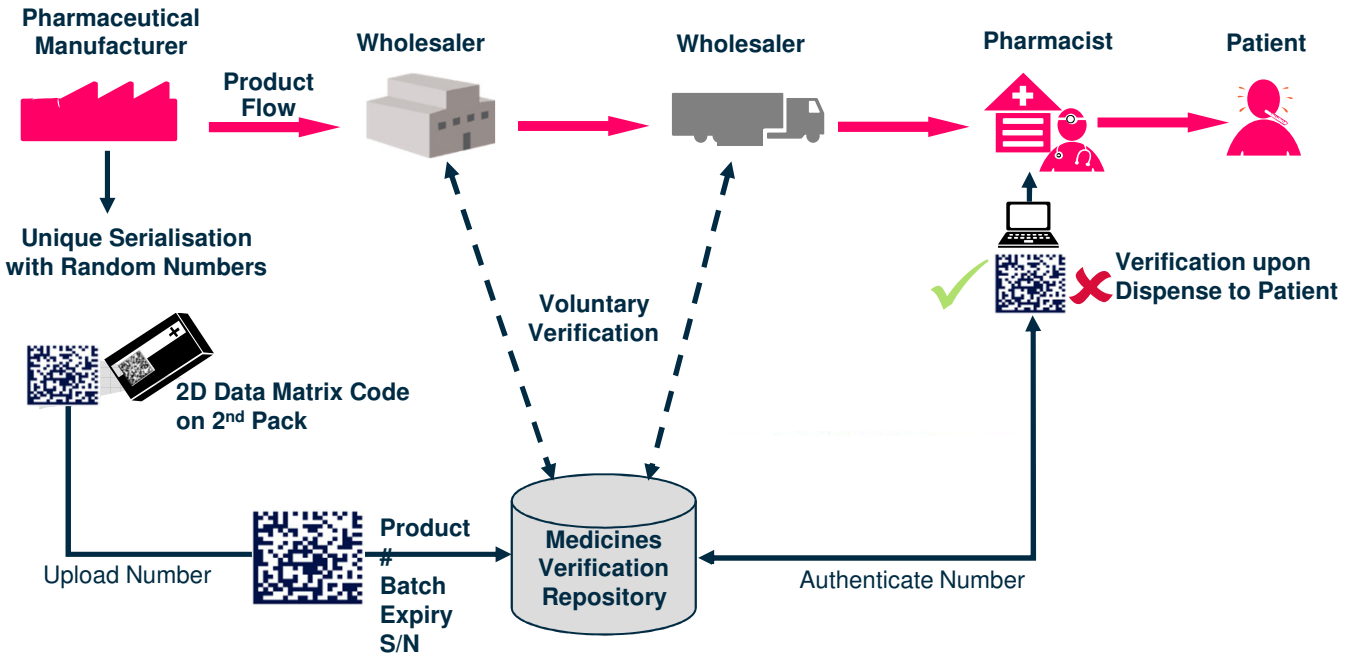


http://www.gs1.org/docs/healthcare/news_events/231012/wed/Wed_04_EDQM_GS1_Healthcare.pdf

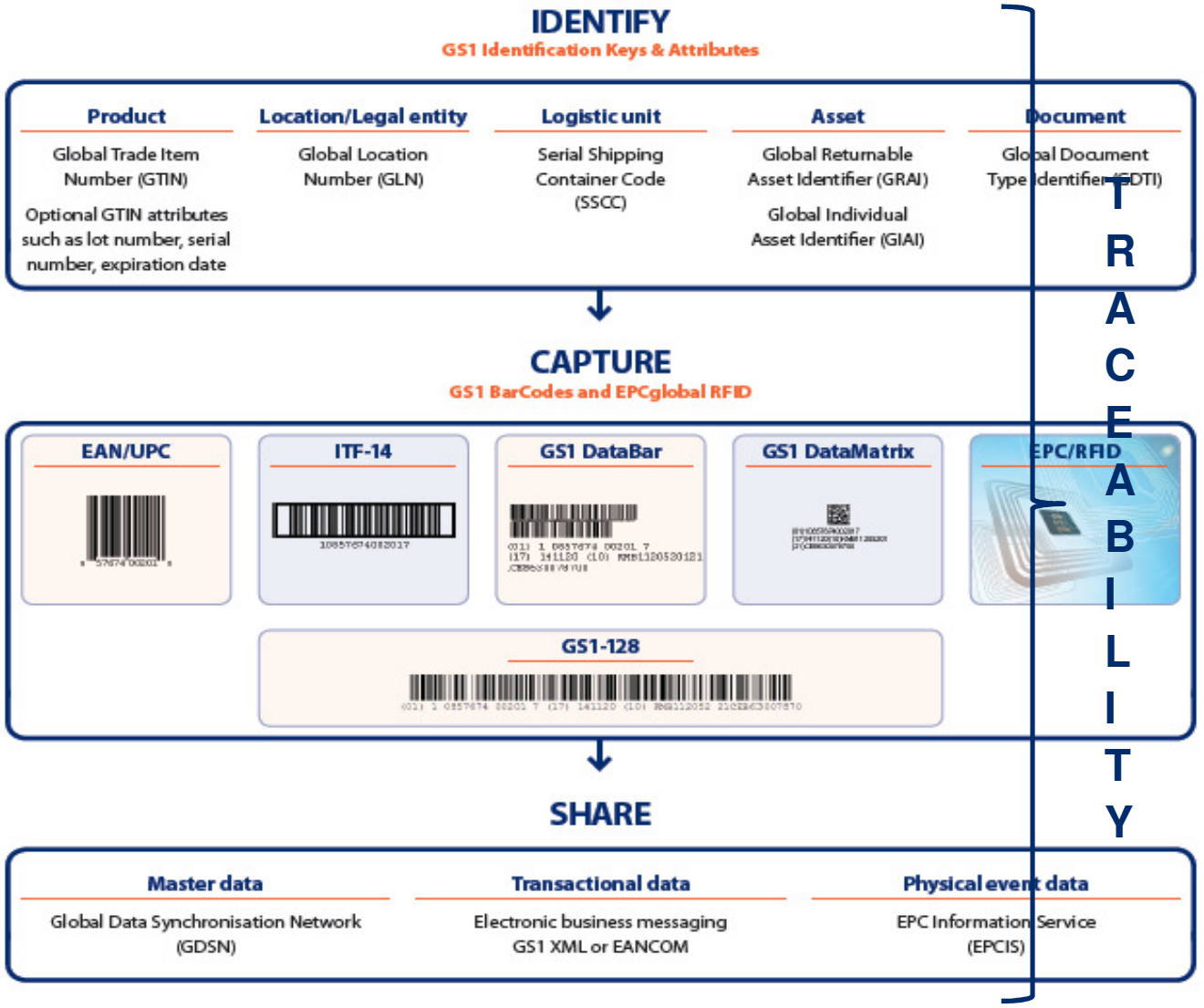
Pharma – Different emerging models…Europe (2)

Driver: To address counterfeiting (falsified medicines), prevent them reaching the patient

- Two emerging (competing?) models: EDQM & EFPIA:
- Euro. Federation Pharma. Industries & Associations **(EFPIA) European Stakeholder Model (ESM)**
  - A pan-European end-to-end system enabling medicines to be verified at point of dispensing
  - Developed by the stakeholders who will use it on a day-to-day basis
  - Run on a non-profit basis; Costs to be borne by Manufacturing Authorisation Holders
  - Effective system expected in 2017



The GS1 System



3 Case Studies

- High level summaries
- Different points of supply chain
- Common themes
  - Implementation from receipt to patient takes time (YEARS)
  - Multi-project work programme
  - Involves all parties across the supply chain (inc. GS1 MOs)
  - Focus on solving key issues
  - All efforts have lead to improved patient safety
  - One size does NOT fit all!

http://www.gs1.org/docs/healthcare/GS1_Healthcare_Reference_Book_2009-2010.pdf
http://www.gs1.org/docs/healthcare/GS1_Healthcare_Reference_Book_2010-2011.pdf
http://www.gs1.org/docs/healthcare/GS1_Healthcare_Reference_Book_2011-2012.pdf
http://www.gs1.org/docs/healthcare/GS1_Healthcare_Reference_Book_2012-2013.pdf
http://www.gs1.org/sites/default/files/docs/healthcare/13_GS1_HC_RefBook2013_All.pdf

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AmerisourceBergen Corporation Case Study

AmerisourceBergen Corporation

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AmerisourceBergen Corporation

AmerisourceBergen Corporation

- Publically traded $80B company
- Headquartered in Chesterbrook, PA
- 32 distribution centers throughout the US
- 25,000 SKU per distribution center with up to 75,000 SKU's active our network
- 750 – 1,000 manufacturer trading partners
- 60,000: pharmacy customers serviced
  - Retail, hospital, long term care, mail order, etc.
  - Next day delivery and same day delivery in some sites

Why we began implementing GS1 Standards

Drivers:

- Regulatory compliance with the state of California
- Regulatory compliance with the impending US Federal regulation
- Efficiency of doing business with our trading partners
- Data harmonization across multiple business units

What was your organisations trying to achieve?

Goal: Compliance with the California requirement (Complex data exchange is a component of this requirement)

We have been working on the public policy side since 2004, and this is on-going

Future projects are planned, e.g.

- Exception management
- Demonstrate data exchange capabilities using EPCIS
- Data harmonization

Where did you start? What benefits were realised?

We started with development and support of solution with our Executive Leadership

We are in the process of building multi business unit master data (using GTIN and GLN)

Initial effort is 85% technology based

To date we are too early on in our project to assess any benefits

What did you learn? Recommendations for others?

Executive support is critical:

- Leadership must be aligned with goals, cost of project and pain points of the project
- Maintaining business focus across multiple business units

Internal Project Structure:

- Clearly define roles and responsibilities must be outlined for success

Continuous communication with trading partners is critical:

- One cannot function in a vacuum

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Case Study:
The use of Serialised barcodes on Medication Packaging

Feargal Mc Groarty, Project Manager,
National Centre for Hereditary Coagulation Disorders, St James's Hospital, Ireland

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St James's Hospital, Dublin, Ireland

- St. James's hospital is an academic teaching hospital
- 1000 Beds
- National Specialties/Services, including
  - Haemophilia Services
- Supra-Regional Specialties/Services
- Regional Specialties/Services
- Catchment Specialties/Services
- The Hospital also focuses on 4 major cross-specialty programmes

Why we began implementing GS1 Standards

Catastrophic Event

Failure of Supply Chain- Haemophilia medication

Infection of patients with Hepatitis C and HIV due to contaminated blood products. Infected medication remained in the supply chain after recall - leading to subsequent infection

Over 70 people died in Ireland alone

What was your organisations trying to achieve?

Goal: Realtime track and trace including electronic recall of Haemophilia medication used for self treatment of patients at home

Improve patient medication recording compliance (budget of €50m for 200 patients)

The project was initially started in 2005

Where did you start?

Adopt the Retail Track and Trace Model based on GS1 Standards

- Unique identification (barcode) of patient – PMGSRN
- Unique identification (barcode) of medication - Serialised GTIN
- Unique identification (barcode) of locations (Hospital/Home/Pharmacy/Transport) - GLN

What benefits were realised?

Validated Cold Chain delivery Service using Datamatrix Bar coding on medication packaging

- Since Cold Chain delivery started all products verifiably delivered between 2^0-5^0 Celsius
- Documentation errors reduced from 12 to zero in the year immediately post service implementation
- € 5 Million worth of medication stock has been removed from the supply chain
- Stock rotation (based on barcoding) in 2011 saved €600,000 worth of stock
- Mock Recall identified location of all (100%) Medication within 10 minutes along with quantities of alternate stock available
- Patient smartphone App incorporating barcode scanning improves medication recording compliance and saves money

What did you learn? Recommendations for others?

- Measures need to be implemented to ensure patient safety
- Measures need to be implemented to improve Supply Chain efficiency
- Barcodes work!
- Standardised bar-coding on packaging is the key
- Using the serialised GTIN, EPC and advanced shipping notice would dramatically improve supply chain efficiency and increase patient safety
- Technology already exists to help improve patient safety and reduce supply chain costs
- Identify a quick win (HPAC slidedeck)
- Don't reinvent the wheel!! Engage with GS1/HPAC community – Healthcare issues are local but also global!

Contact Details

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