Implementation Reality – Traceability

How to enable/implement traceability?

2nd April 2014, Seoul/Korea

Round 1 (13:30 – 15:00)

- <u>Moderator</u>
  - Grant Courtney, Business Lead, Fingerprint Serialisation, Global Manufacturing & Supply GSK

- <u>Panelists</u>
  - Peggy Staver, Pfizer
  - Scott Mooney, McKesson
  - Lloyd Mager, AbbVie
  - Christian Riediger, Bayer

Agenda

- Introduction: Traceability and the GS1 standards as base for it - the different models for traceability across the world

- What does serialisation mean for a manufacturer (Peggy Staver, Pfizer)

- Traceability – everybody needs to be involved – the wholesaler view (Scott Mooney, McKesson)

- Traceability pilot in the US – experiences and learnings (Lloyd Mager, AbbVie)

- Experiences in Europe/Pilot in Germany (Christian Riediger, Bayer)
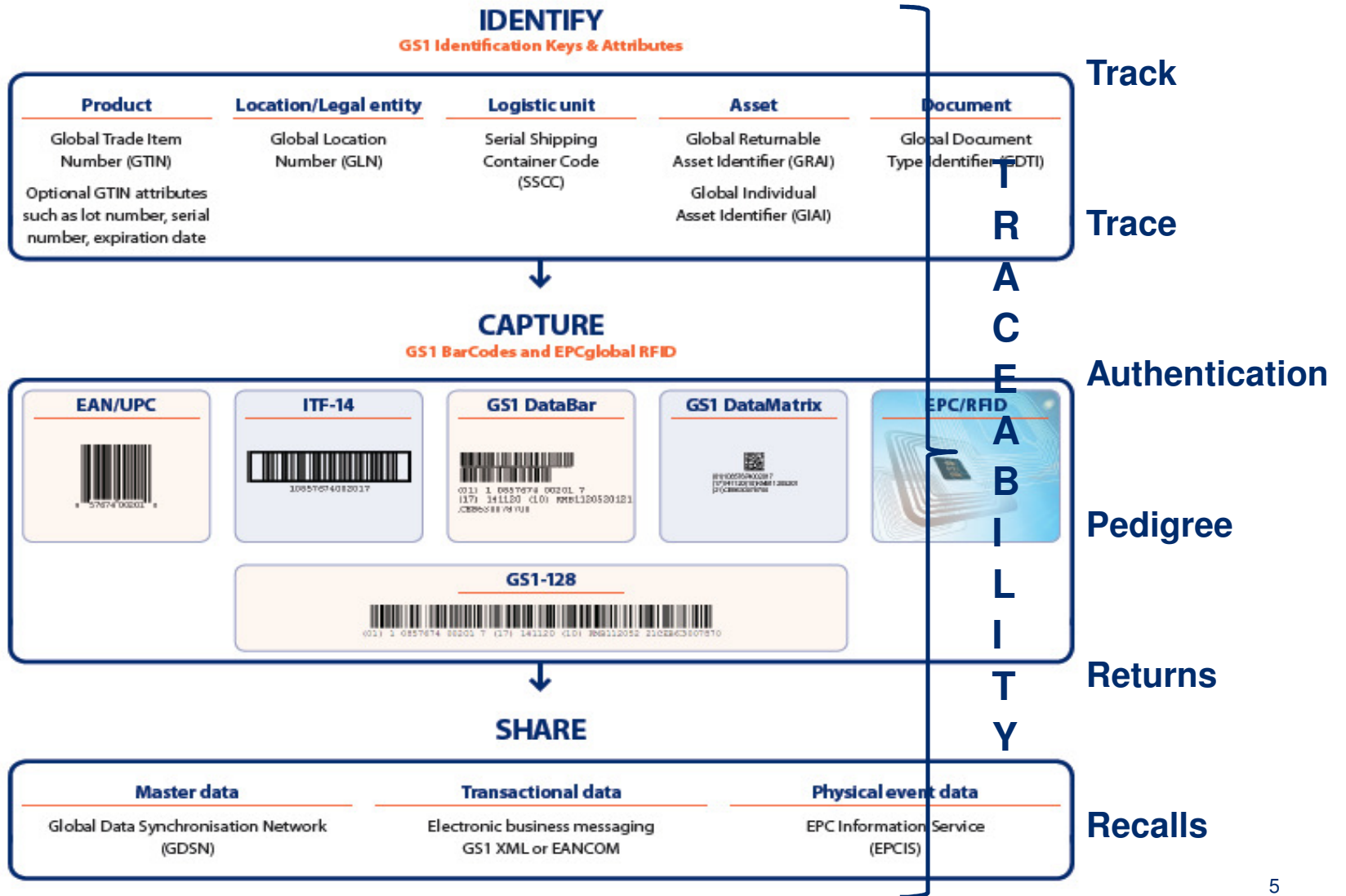
- Panel discussion

- Conclusions

Introduction

The GS1 System

IDENTIFY
GS1 Identification Keys & Attributes

Product	Location/Legal entity	Logistic unit	Asset	Document
Global Trade Item Number (GTIN)	Global Location Number (GLN)	Serial Shipping Container Code (SSCC)	Global Returnable Asset Identifier (GRAI)	Global Document Type Identifier (GDTI)
Optional GTIN attributes such as lot number, serial number, expiration date			Global Individual Asset Identifier (GIAI)	

CAPTURE
GS1 BarCodes and EPCglobal RFID

EAN/UPC	ITF-14	GS1 DataBar	GS1 DataMatrix	EPC/RFID

GS1-128

SHARE

Master data	Transactional data	Physical event data
Global Data Synchronisation Network (GDSN)	Electronic business messaging GS1 XML or EANCOM	EPC Information Service (EPCIS)

TRACEABILITY

- Track
- Trace
- Authentication
- Pedigree
- Returns
- Recalls

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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_Health care.pdf
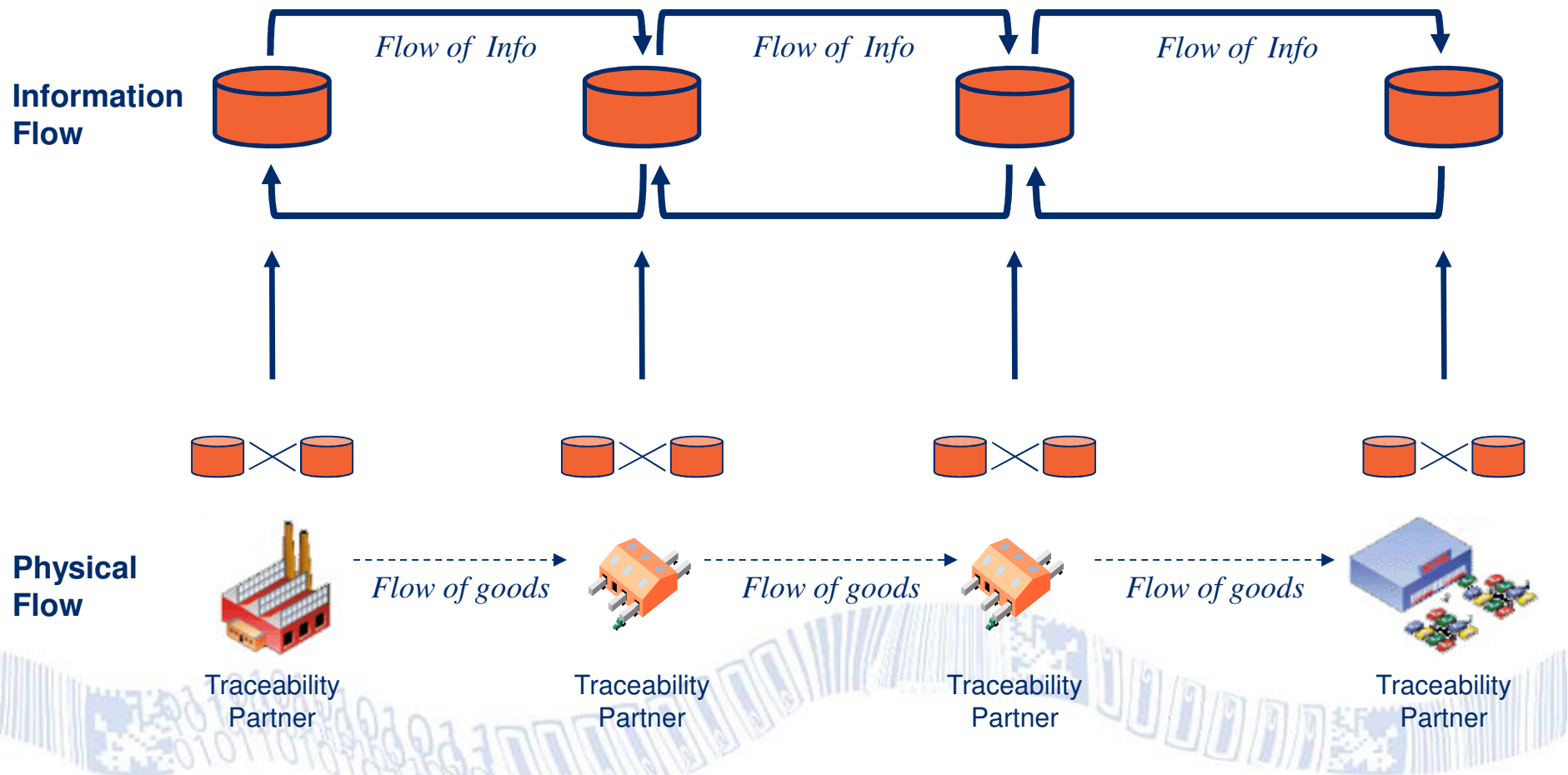
Common themes

- 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"

Information Flow

Flow of Info *Flow of Info* *Flow of Info*

Physical Flow

Flow of goods *Flow of goods* *Flow of goods*

Traceability Partner Traceability Partner Traceability Partner Traceability Partner

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Healthcare Traceability
Emerging Models

Pharma – Different emerging models... Turkey

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

Ownership: Government developed and controlled, Centralised Track & Trace system (iTS)

- Enforcement date 2010
  - 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...

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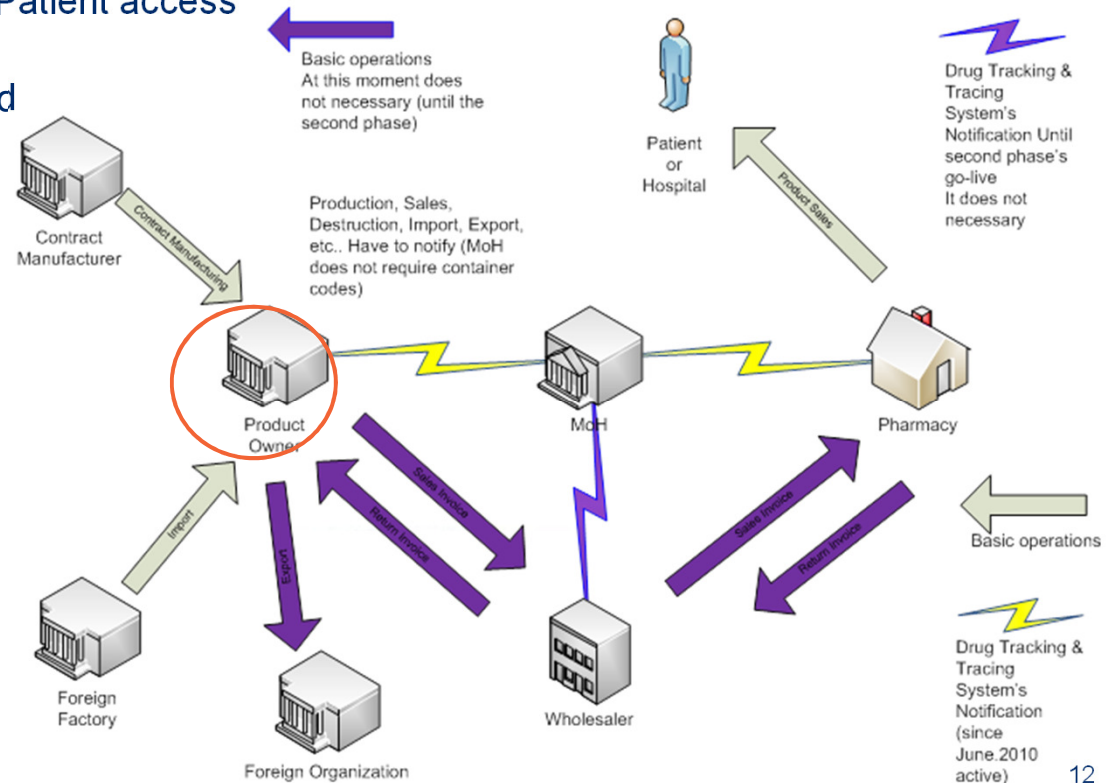
Pharma – Different emerging models... Europe

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

Ownership: Stakeholders, access for regulatory bodies

- **European Stakeholder Model (ESM)**
  - A pan-European end-to-end system enabling medicines to be verified at point of dispensing
  - Interoperable across markets and supports standard interfaces
  - Developed and maintained 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
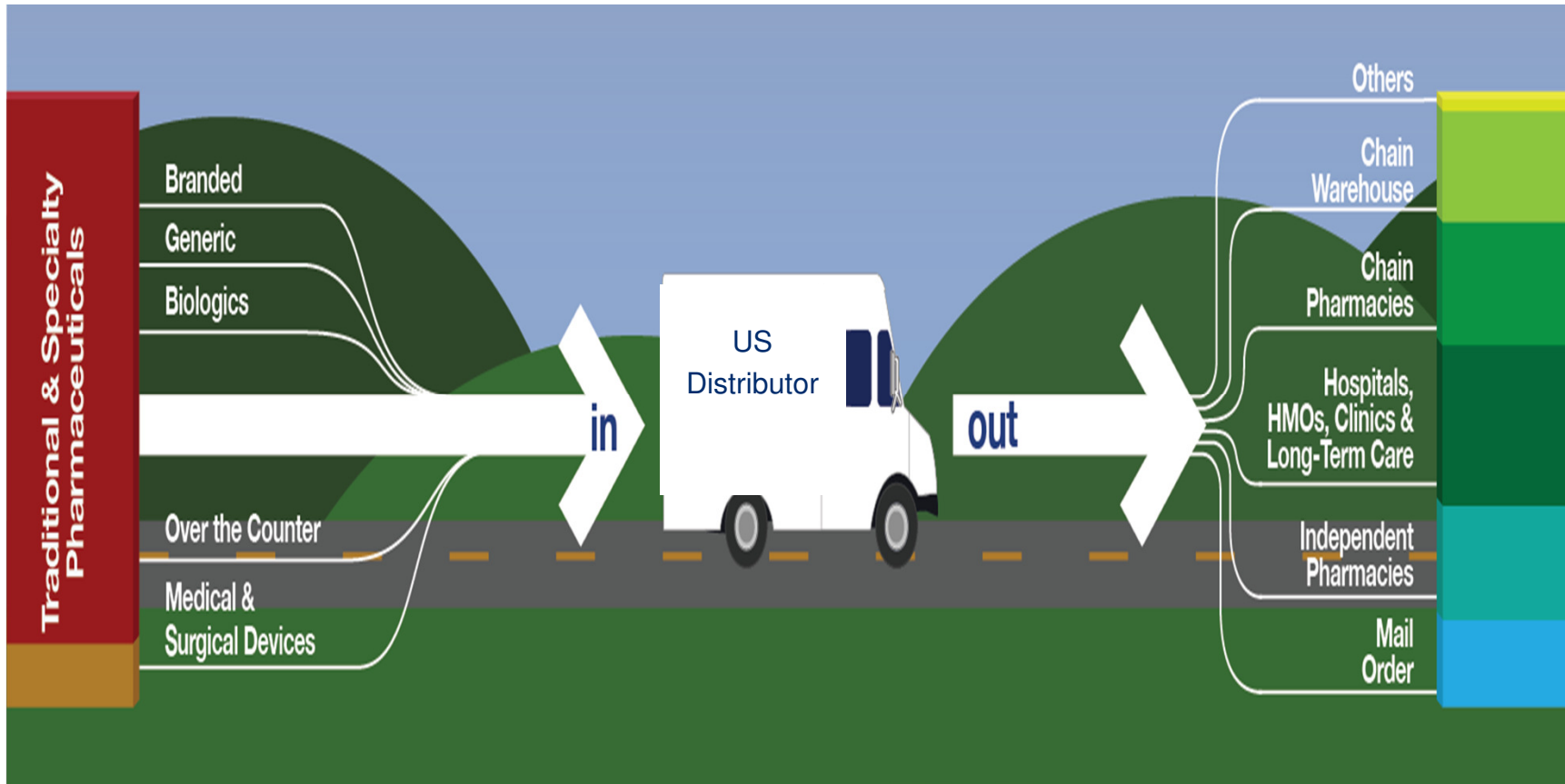 - Effective system expected in 2017
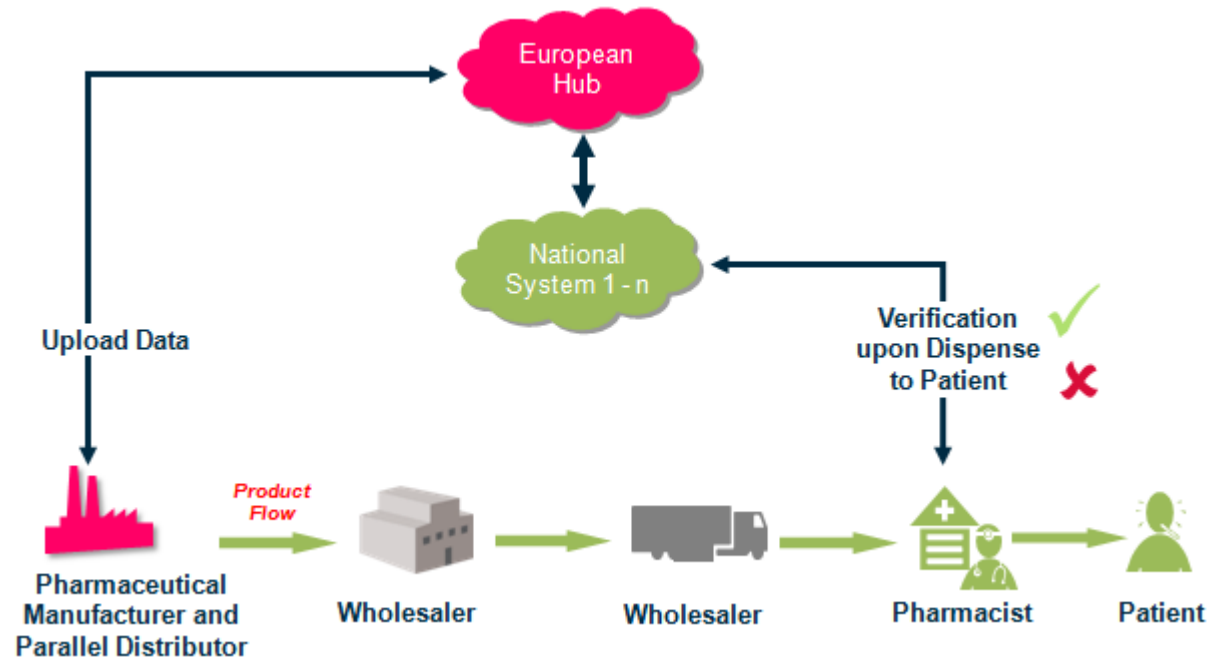
Traceability – everybody needs to be involved – the wholesaler view

Scott Mooney, McKesson

Wholesaler Perspective

Wholesaler Perspective

- Importance of standards

- Processes that support the standards also need to be explored and updated within the industry

- Complexities of operating in the middle of the supply chain
  - 700+ pharmaceutical manufacturers
  - 200,000 + dispensing entities

- Speed of through put – patient demand for pharmaceuticals

- Attention to detail, without losing focus on the big-picture

Wholesaler Perspective

- Data exchange

- Exception management

- Flexibility - patience needed by all with trading partner relationships
  - This is new to the entire pharmaceutical industry

- Continued industry collaboration / knowledge sharing

- ROI will be driven by critical mass and continued development of process to align with standards