Implementation Reality - Traceability

GS1 Healthcare Global Conference

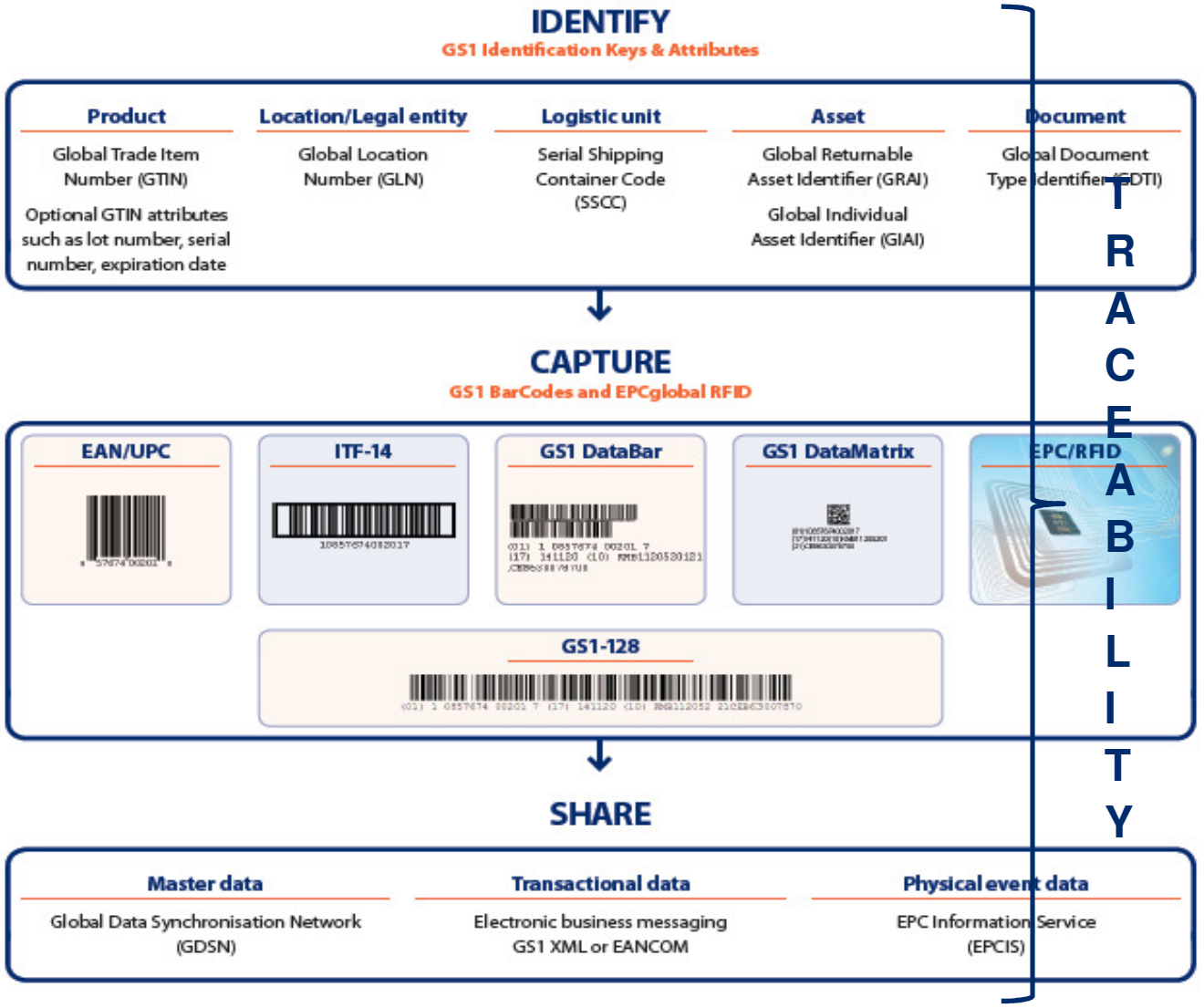
San Francisco, California, USA

Wednesday 2nd October 2013

Agenda

- Introduction — Janice Kite, GS1 Global Office
- Case Studies
  - Country View:Turkey — YELİZ GERİŞ, GS1 Turkey
  - Manufacturer — Jenny Gough, Molynlycke Healthcare
  - Hospital — Frederique Fremont, CHI Ballanger, France
- 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]

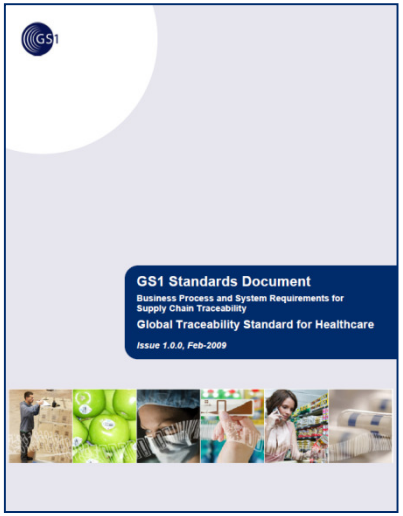
SO THAT:

- 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

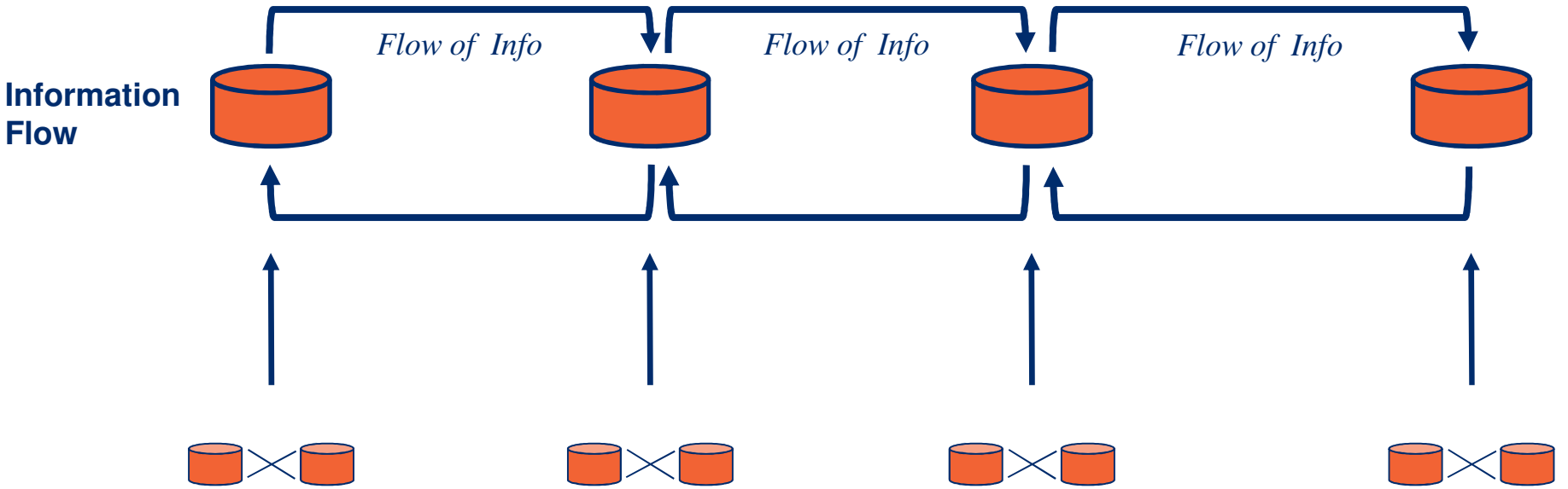
Common themes

- 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

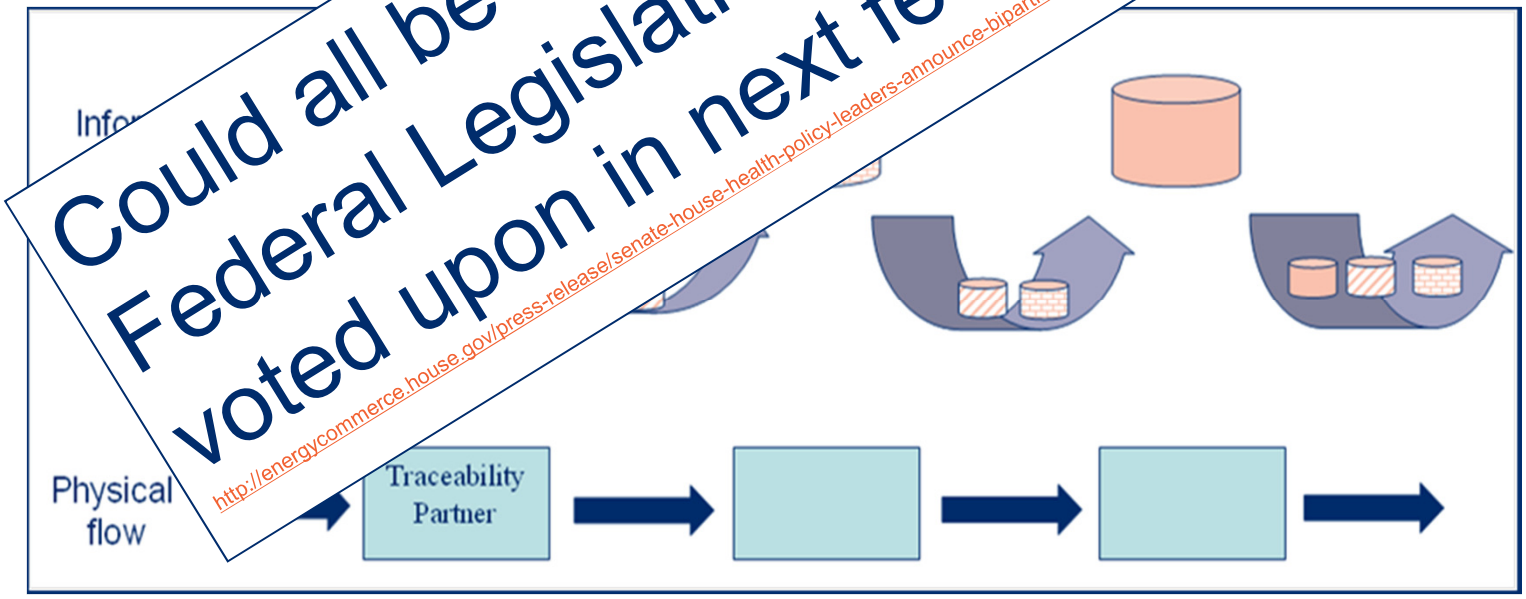
Emerging Models

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… ain 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

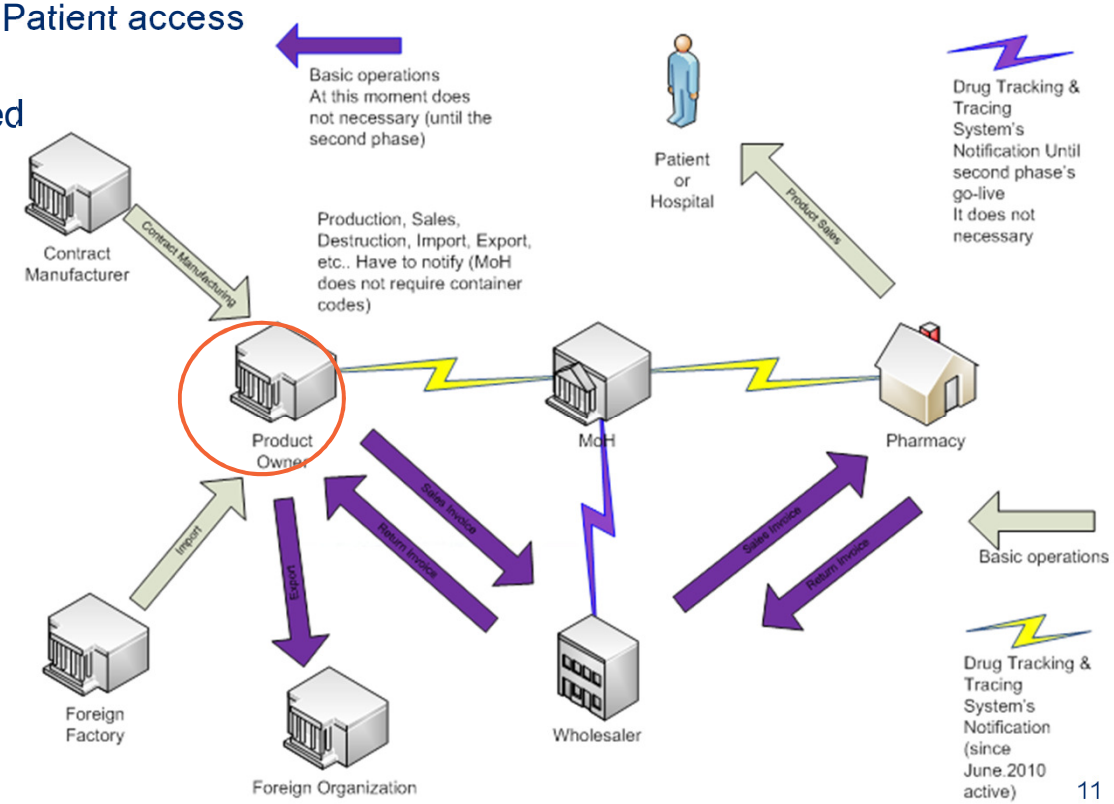
http://energycommerce.house.gov/press-release/senate-house-health-policy-leaders-announce-bipartisan-bicameral-legislation-Address



Pharma – Different emerging models… Turkey

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

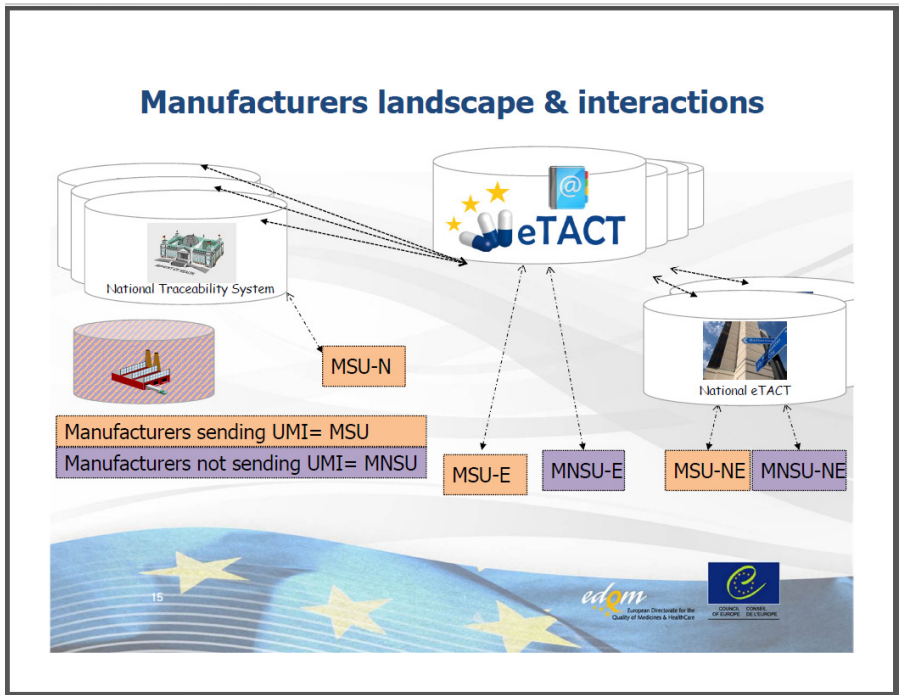
- Government developed and controlled, Centralised Track & Trace system (iTS)
- Enforcement date 2010, live 2+ years (the only live system globally!)
  - Phase 1: Manufacturers published data to MoH central database (2010)
  - Phase 2: Distributors (2012)
  - Future phases: ePrescriptions, Patient access
- 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

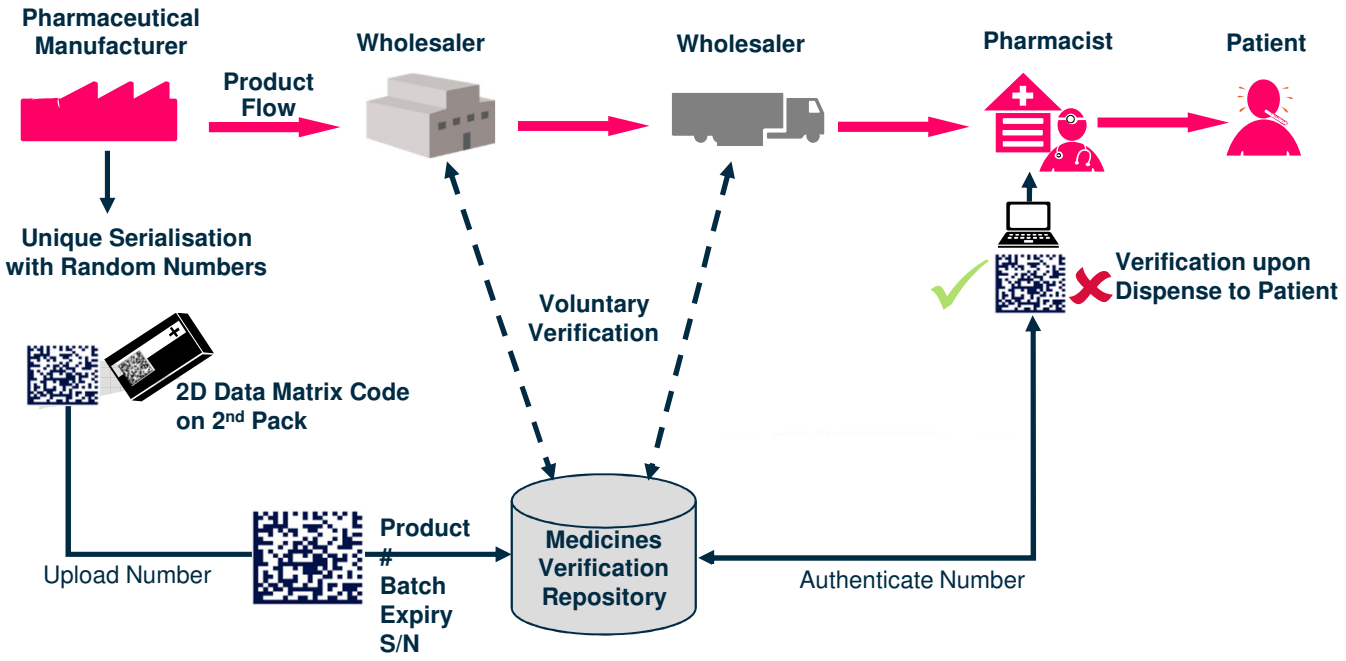


http://www.gs1.org/docs/healthcare/news_events/231012/wed/Wed_04_EDQM_GS1_Healthcare.pdf

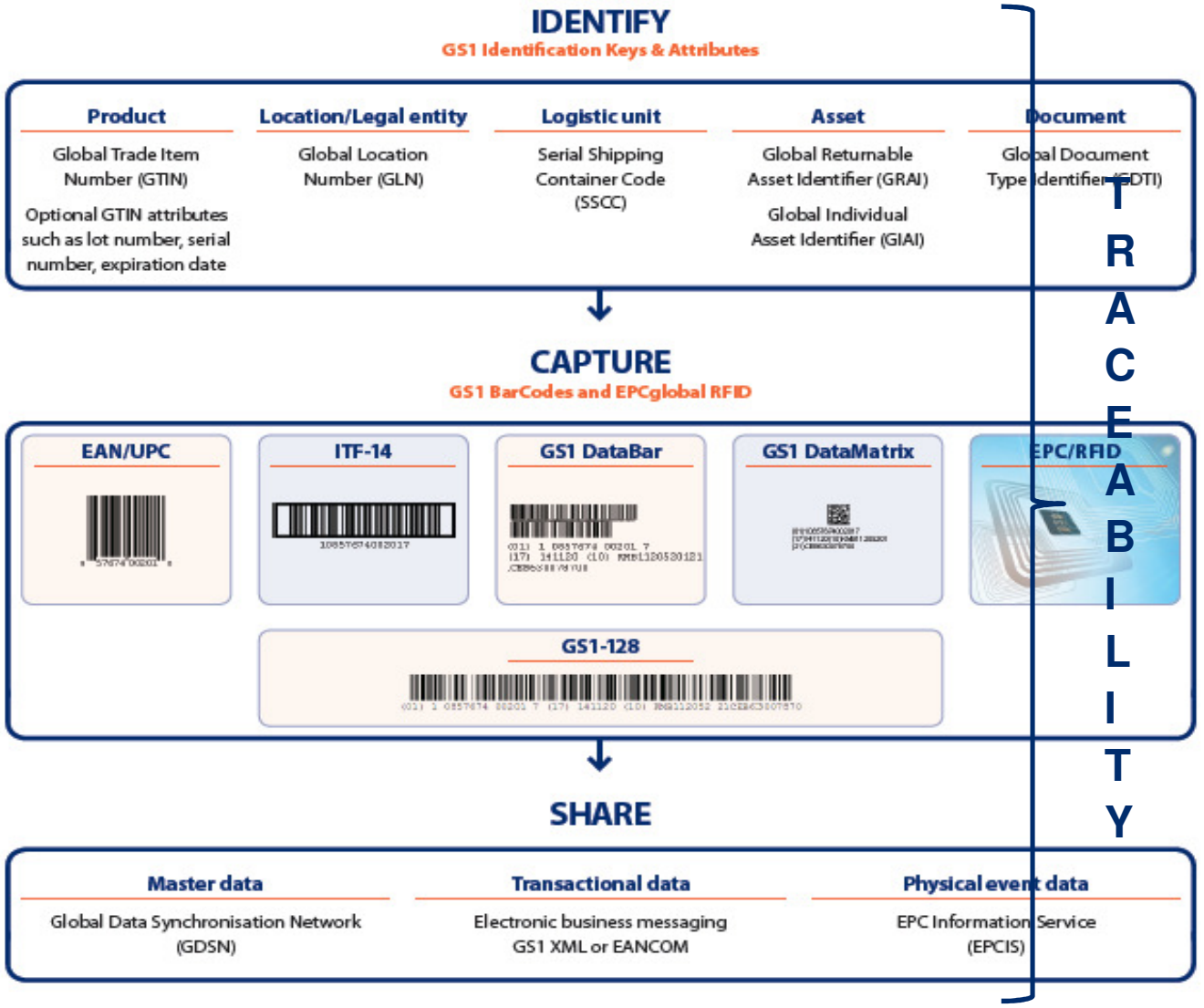
Pharma – Different emerging models…Europe (2)

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

Country View:Turkey

YELİZ GERİŞ, GS1 Turkey

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Turkey -Case Study

Yeliz Geriş, GS1 Turkey

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İTS-Pharmaceutical Track & Trace System - Initiators

- Major Stakeholders:

- Ministry of Health of Turkey –owner of the Project
- SGK –Reimbursement Agency

İTS –Pharmaceutical Track & Trace System

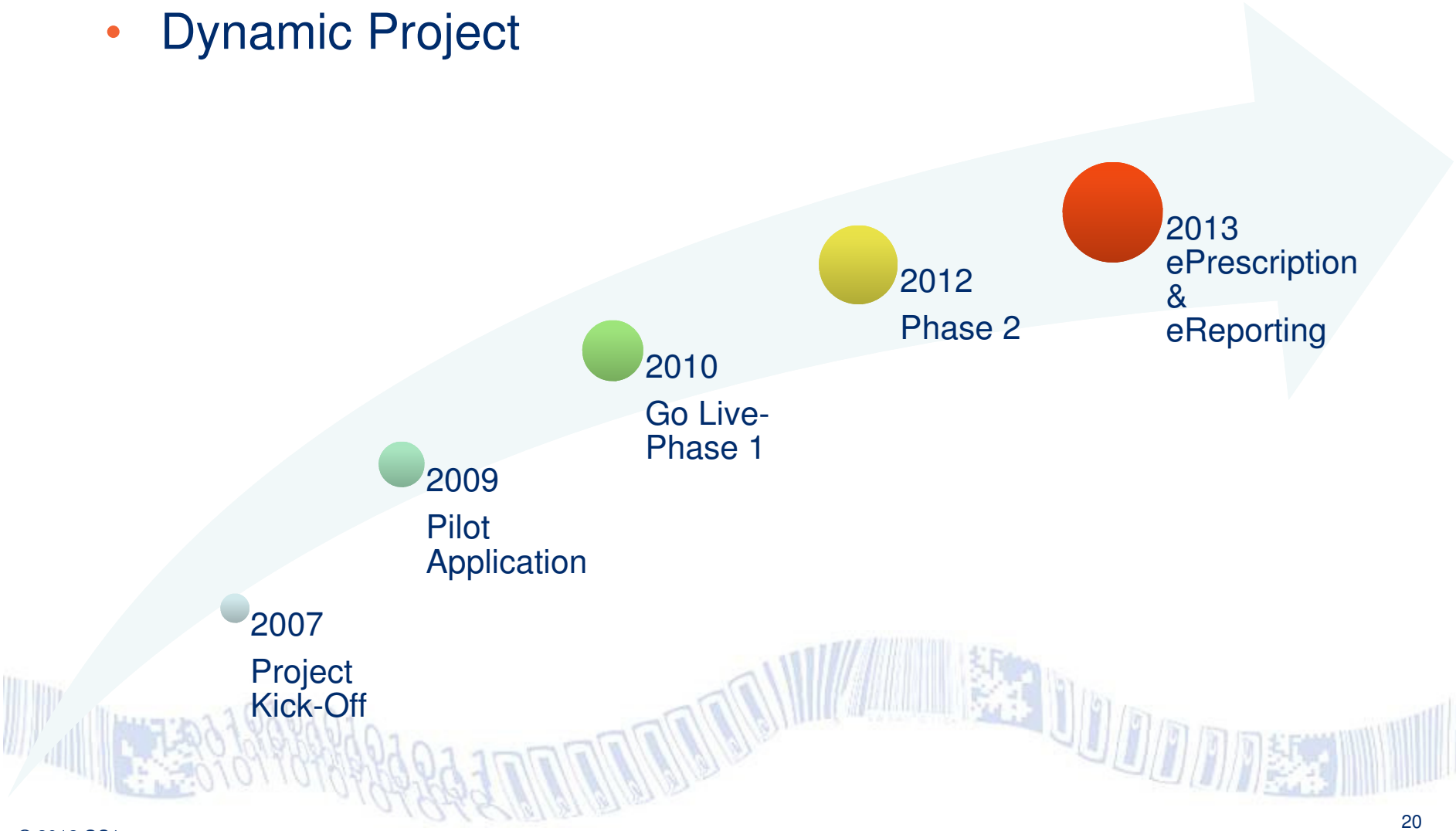
- *Key drivers for implementing the GS1 Standards*

- Overall Goal: Patient safety –reliable supply of drugs
- **to track and trace all units belonging to each pharmaceutical product in Turkey.**

- Regulation –Full traceability
- Prevent counterfeiting/ fraud/smuggling and illegal sale of drugs
- Ensure efficient product recalls
- Prevent barcode and package scams
- Prevent double payments by reimbursment agencies & tax frauds
- Support rational drug use
- Supply data to control market

Implementation Timeline

- Dynamic Project



Scope

- Products:
- 1st. Drugs & 2nd. Medical Nutritional Products

- Stakeholders:
- All parties in the supply/distribution chain + reimbursement agencies

- Unique identification of products & locations
  - GTINs & GLNs

What benefits were realised?

- is 100% safe in fighting against corruption
- prevents the sale of counterfeit drugs
- prevents the sale of smuggled drugs
- controls sale of narcotic drugs
- prevents barcode scams
- prevents the repackaging of drugs in unknown places
- provides safe and original drugs for patients
- supports the process of rational drug use
- prevents the resale of the drugs –double payments & tax frauds
- ensures efficient product recalls
- paves the way for effective market control
- enables data mining & reporting

Recommendations for others?

- Main challenges/opportunities

- Gathering all parties together/working in collaboration with the stakeholders
- All parties to be consulted
- Learning curve
- System problems along the way
- Educating the stakeholders –GS1 (GTIN & GLN)
- Solution provider

Going Forward

- Medical Devices
- TITUBB Data base -92% medical devices registered with GS1 keys (GTIN13-GTIN14-UPC12 etc.)
- TITUBB, Track and Trace Spectacles and Lenses –DataMatrix used similar to İTS

- Cosmetics
- How to implement traceability for cosmetics ?
  - Distribution channel
  - Diversity
  - Price range

Contact Details

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Implementation Reality – Traceability

Jenny Gough
Mölnlycke Health Care Case Study

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Mölnlycke Health Care

M – u – r – n – l – i – c – k – e - r

7,400 employees globally

Sales offices in 32 countries

Selling in over 90 countries

Manufacturing sites in 8 countries (3 continents)

25+ contract manufacturers globally

MölnIycke Health Care

- Small range of pharmaceutical and biocide products
  - Antiseptics
- Medical Devices (single use, mainly Class I, Class IIa, Class IIb and a small amount of Class III)
  - Drapes & gowns
  - Surgical gloves
  - Procedure trays
  - Dressings
  - Skin care
  - Retention therapy
  - Biological wound treatment
  - Negative pressure wound therapy
  - Electro-stimulation wound therapy

Why we began implementing GS1 Standards

- The key drivers for implementing GS1 Standards:
  - Unique Device Identification – upcoming legislation and the GHTF guidelines
  - Already sold products in the retail sector
  - Customer requests (tender documents)
  - Warehouse efficiencies
  - Traceability and product recalls

What was your organisations trying to achieve?

- Initially a one off project for GS1 compliant product marking set over two years from October 2010:
  - First year analysis of what we were currently doing and what needed to be done to become compliant – budgeting!
  - Second year planning and implementing necessary changes
  - Reality – we are still awaiting the final amends to filter through to warehouses

What was your organisations trying to achieve?

- Further projects planned:
  - Warehouse scanning
    - Commenced early 2011 as part of a larger warehouse consolidation project
    - Still a mixture of scanning and manual entries
  - Traceability
    - System issues (dual sourced products, interfaces with markets, etc)
    - How to use the data being scanned in
    - Pre-study complete, project about to commence

Where did you start? What benefits were realised?

- The pre-study was conducted with a selection of products stored and intended for use in the European market.
- The project covered products produced within all Mölnlycke Health Care manufacturing sites and third party suppliers apart from one factory in Hungary
- We commenced with GTIN application to GS1 specifications

What did you learn? Recommendations for others?

- Don’t put rigid systems in place
- Keep in touch with developing legislation
- Listen to customers and trading partners but do what is best for your company
- Get buy in from Senior Management
- Look at your whole Supply Chain instead departmental silos
- Involve IT
- Don’t underestimate the amount of time you need!

Contact Details

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Implementation Reality
Medical Devices Traceability and scanning Case Study

Frédérique Frémont
C.H.I Robert Ballanger

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Hospital: C.H.I Robert Ballanger, Paris, France

- Intercity hospital serving a population of 400,000 persons
- 670 beds
  - 450 beds in acute care (medical, chirurgical and maternity)
  - 50 beds physical medicine and rehabilitation
  - 170 psychiatry
- Outpatient clinic and pharmacy inside Villepinte detention center located at Charles de Gaulle (CDG) airport hospital, Paris

Why we began implementing GS1 Standards

- Surgical Instruments
- Due to Creutzfeldt-Jakob risk, the last 5 patients on which the instruments have been used must be known
- Applies to hospital owned or loaned instruments

- Implants and high value Medical Devices
- Implants : traceability is mandatory
- Itemized billing to the patient (not included in the hospital bundled payment)

What was your organisations trying to achieve?

- **Goal:** Full traceability of surgical instruments and implantable medical devices
- *(it is mandatory and French Pharmacists are personally liable for Drugs and Sterile Medical Devices)*

- We began in 2009 and finished end of 2012 (3 years)

- Future projects are planned, e.g.
- Tracing the implants and manage the operating theater stock with the WMS we have now implemented in a new Medical Devices warehouse
- Link with automated dispensing cabinets in the operating rooms through GS1 Datamatrix or bar code reading

Where did you start?

- We started with GTINs in GS1 DataMatrix
- for the instruments – laser etch
- then for all the transport containers

What benefits were realised?

- **Patient security:**
- Instrument and process traceability
- **Supply chain efficiency:**
- The surgical boxes prepared sterilization operators working for the 2 hospitals
- Traceability of instrument localization : sterilization unit, O.R, repair contractor, loan to other hospitals
- **Cost reduction:** ROI around 24 weeks
- Decrease in non-conformance and decrease of cost per box per surgical procedure
- Decrease in the number of Operating Theatre nurses needed : 2 as team leaders and referents

What did you learn? Recommendations for others?

- At first, only one engraving supplier (second entered the market in 2012)
- Scanners are one of the biggest challenge in instrument engraving (reading of very small data matrix, 2mm x 2mm or 1.3mm x 2.8mm)
- Interoperability with IT process traceability

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