The Global Language of Business

Traceability: How to choose a traceability model? Learnings from the APEC toolkit

African GS1 Healthcare Conference 2018
Breakout Panel II @ 16:15 – 17:30hrs - Tuesday 09 May 2018
Addis Ababa, Ethiopia

Your Panelists

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GS1 Global Office

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Serialisation and End-to-end traceability leader EMEA, Johnson & Johnson, Belgium

The Global Language of Business

Traceability models

Ulrike Kreysa - Senior Vice-President Healthcare - GS1 Global Office

Traceability in Healthcare

A key driver in the Healthcare sector for

- Patient Safety
- Preventing counterfeiting
- Enabling correct patient records
- Enabling effective product recalls
- Traceability down to the patient
- Enabling regulatory compliance
- Enhancing business processes (e.g. inventory management, optimized supply chain efficiency, eProcurement)

APEC Roadmap for Global Medical Product Integrity and Supply Chain Security

- 5 year project (Jan. 2013 - Dec. 2017)
- APEC sponsors:
  - APEC Life Sciences Innovation Forum
  - APEC Regulatory Harmonization Steering Committee
- Objective:
  - examine current practices and regulatory requirements
  - develop recommendations to regulators
  - develop training programs which will be made publically available through the APEC website
- Track & Trace Work Group (TTWG) with 10 work streams
- Published by APEC Harmonization Center at http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf

TTWG - members

Lilly
Johnson & Johnson
ANMAT
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica
Roche
abbvie
GE Healthcare
AHRMM
Association for Healthcare Resource & Materials Management
Advancing the Healthcare Supply Chain
AstraZeneca
AmerisourceBergen
Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios
Abbott
Pfizer
GS1
edqm
European Directorate for the Quality of Medicines & HealthCare
Bristol-Myers Squibb
FDA
食品藥物管理署
Food and Drug Administration
MERCK
Be well
NOVARTIS
FDA

Traceability – definition

- Traceability is the ability to identify and trace the history, distribution, location, and use of products. **A traceability system records and follows the trail as products come from suppliers and are processed and ultimately distributed / dispensed as final products**.

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

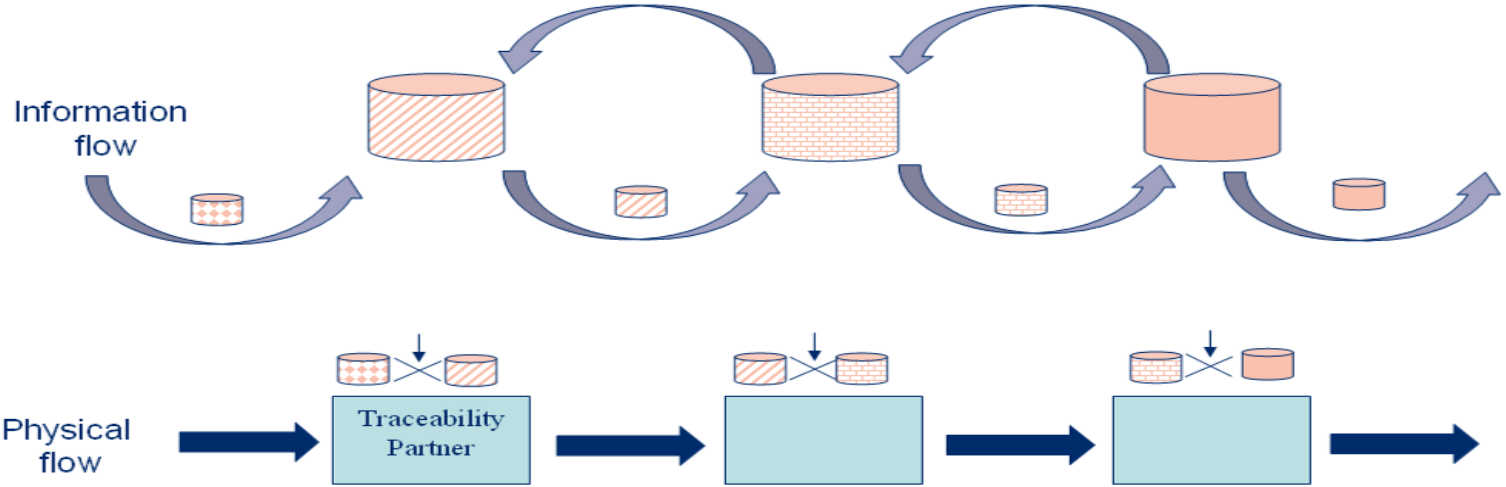
- Throughout the entire supply chain:
  - There is Internal and External Traceability
  - Inputs (e.g. receipt) must be linked to outputs (e.g. shipments / dispensing)
  - Stakeholders can have varying roles

The traceability system – important decisions

- Where to collect and hold the data from the traceability system?
- Where physically hosted?
- Traceability data are critical, important and sensitive
- Data security
- Access to data? Patients?
- Efficiency of the system
- Dependencies on solution provider?
- End-to-end verification or full traceability?

One up, one down

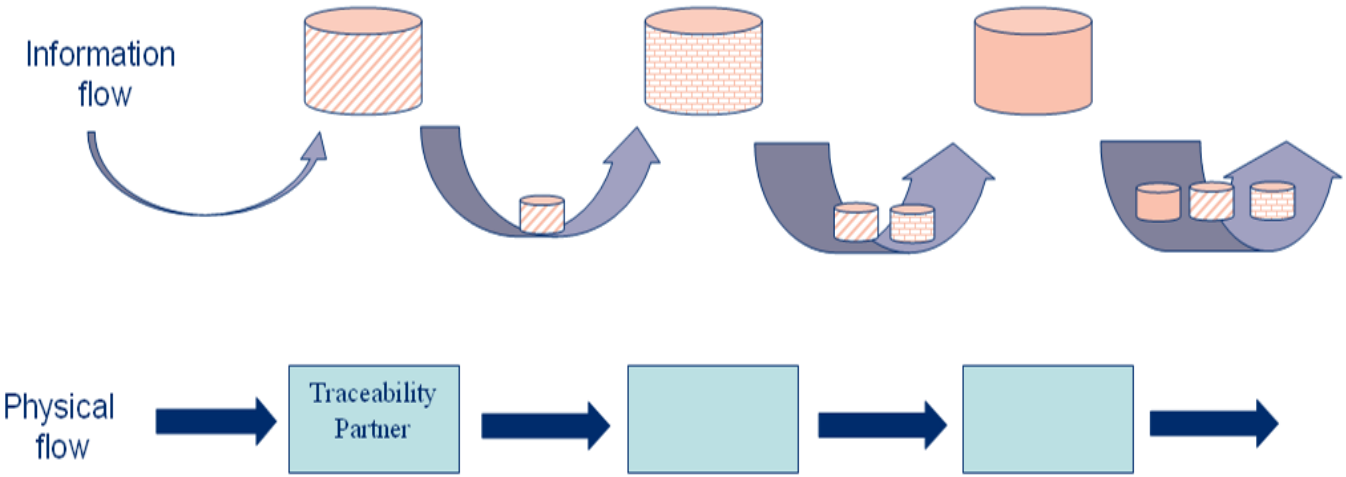
- Point-to-point information sharing for day to day operations
- Other data on request when necessary to previous actor
- The « traditional » concept - simple, but disadvantages



Cumulative Tracking (e.g. California ePedigree)

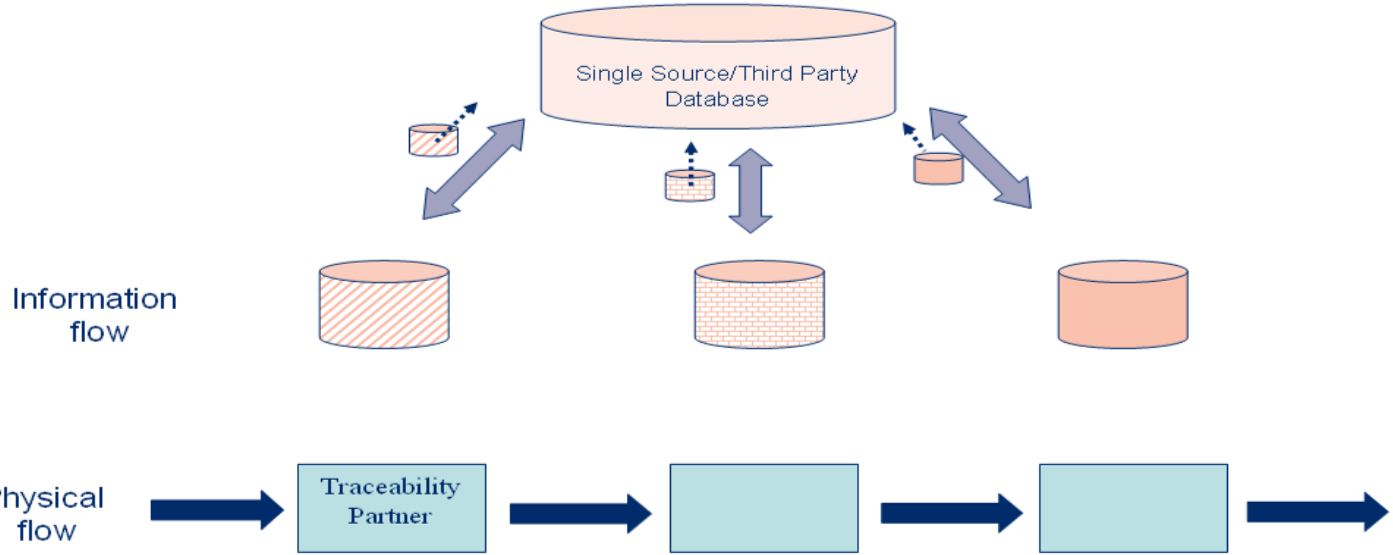
Traceability data received from all previous upstream chain sources **plus** its additional traceability data, available to the next downstream supply partner.

Very “heavy solution” not recommended anymore in “cloud age”



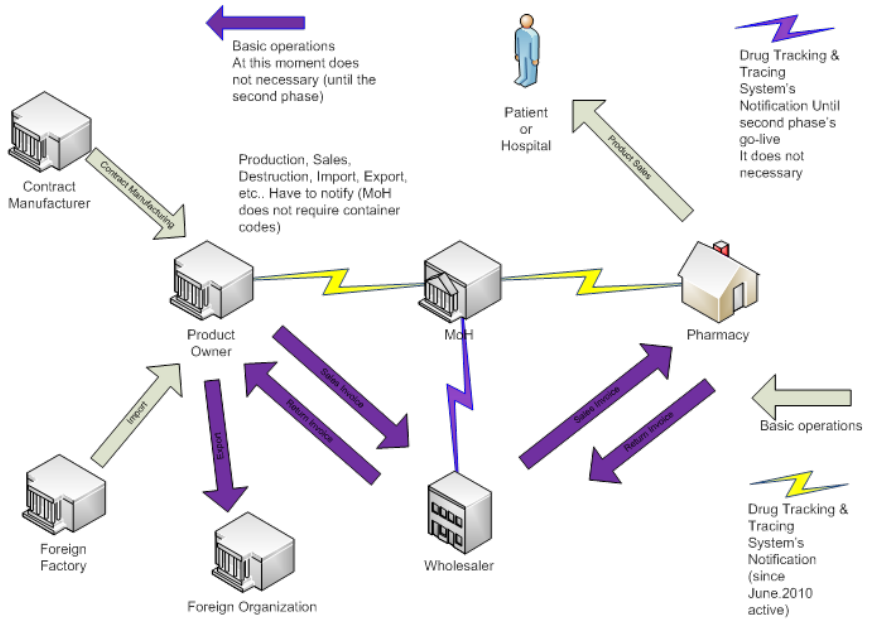
Central Database

The traceable item source makes its traceability data available (e.g. publishes the data) to a central repository/database maintained by a third party/regulatory body.



Centralised model - Example: Turkey

- The first country which implemented full traceability with GS1 standards was Turkey - did overcome all issues
- Government hold database
- Great success beyond expectations
- ROI after only few years
- Full visibility of drug supply chain

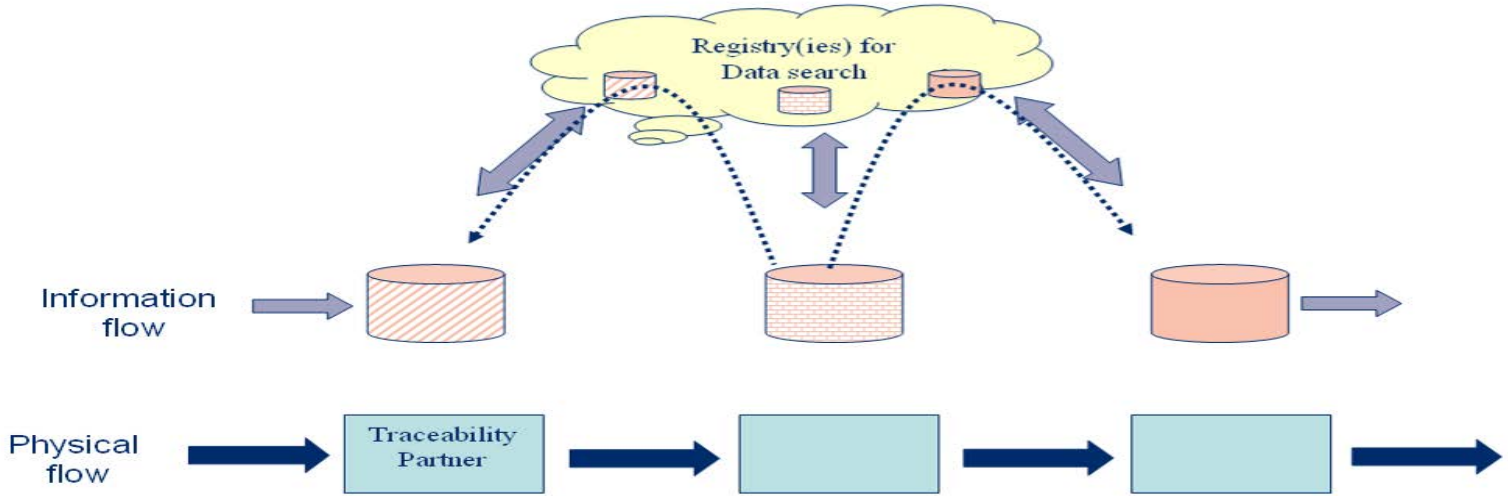


Many achievements and benefits

- Safe medicines, prevents counterfeiting
- Prevents resale of medicine
- Expedites recalling of medicine
- Prevents sale of expired medicine
- Preventing drug shortages
- Quality data for insurances
- Provides statistics to develop policies on Rational Medicine Use
- Enables pharmacovigilance and strategic planning

Distributed Model(s)

Traceability identification keys available in a registry to enable traceability data search - information can be stored anywhere as the registry provides the link and data search mechanism. Semi-distributed, full-distributed…



Distributed Model – cloud enabled

- The stakeholders in the USA would like to see this model implemented for the DSCSA (Drug Supply Chain Security Act)
- Broad agreement to use **GS1 EPCIS** standard – supported by US FDA
- Discussions ongoing – also if and how to use **blockchain**

EPCIS – sharing information on events

WHAT objects are the subject of event?

Individual objects (SGTIN) or groupings (GTIN + Lot/batch)

WHEN did this event take place?

Date, time, time zone

WHERE did this event take place?

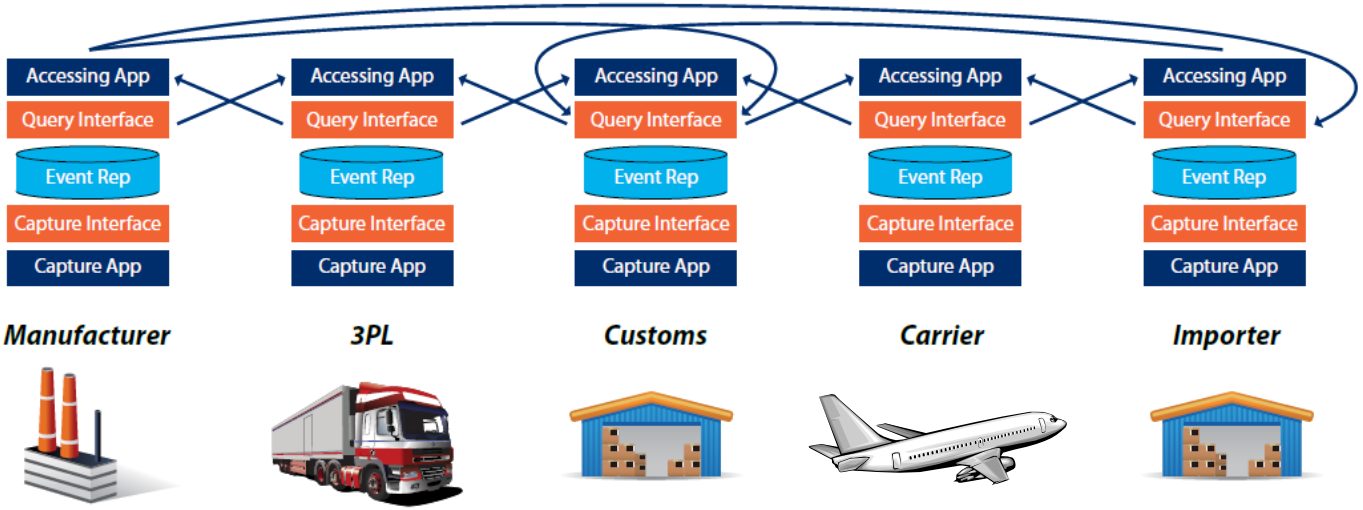
GLN of physical location & object's subsequent whereabouts

WHY did this event take place?

Business step, Disposition, Source/Destination info

All captured in an EPCIS repository

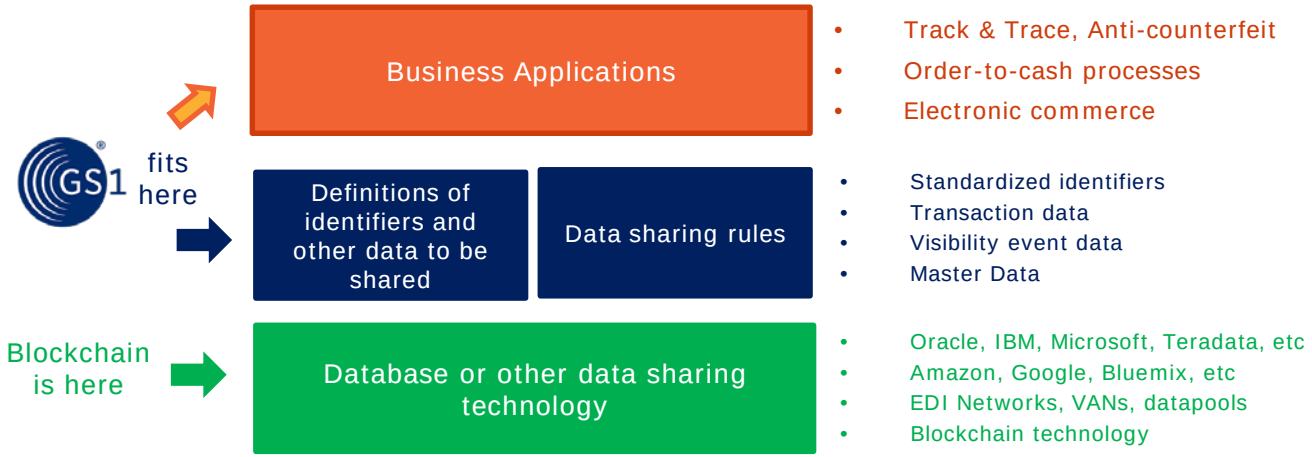
EPCIS end-to-end Visibility



EPCIS enables tracking and tracing AND easy sharing of event data in real-time among trading partners up and downstream

https://www.youtube.com/watch?v=2aIAV88U6F4

Blockchain and GS1



Blockchain is a shared, secure, distributed ledger;
GS1 facilitates standards for data and some business applications

GS1 Standards are more important in Blockchain than ever before!
(Jeff Denton, AmerisourceBergen)

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Traceability: How to choose a traceability model

Francoise Hirth, Roche

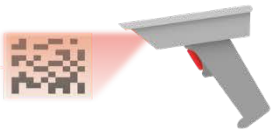
Traceability: how to choose a model?

Françoise Hirth

F.Hoffmann-La Roche ltd

Serialization Coordinator EU & EEMEA



Roche's objectives with Supply Chain Safety Measures

Patients

Improve patient care and safety

- Ensure drugs are authentic
- Reduce medication errors

Safety

Trading partners

- Improve collaboration
- Enhance activities and processes

Reliability

Roche

- Increase supply chain efficiency, thus reducing costs
- Support introduction of and comply with non-negotiable regulations for supply chain standardization
- Protect and improve brand position

Reputation

Deploy
Serialization & Traceability

Different measures for different purposes

PRIMARY

SECONDARY

TERTIARY

GTIN + required variable data

GTIN + required variable data

GTIN + Serial Nr + required variable data

SSCC

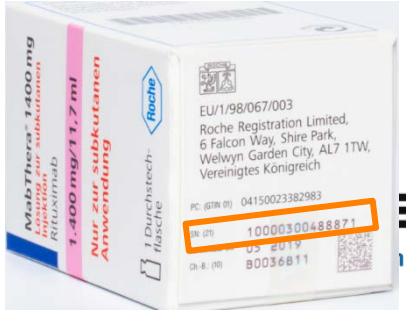
Serial Shipping Container Code

SSCC

1. Codification

2. Serialization

3. Aggregation



eploy
n & Traceability

Which measures when ?

- **Codification** ; allows to identify the product; GTIN + lot no. + Expiry date
  - First step to go towards traceability (Jordan, Qatar)

- **Serialization** ; allows to capture and share data: GTIN + lot no. + Expiry date + Serial Number
  - End to End verification system in Europe

- **Aggregation**; allows traceability, only possible when all stakeholders come to common solution
  - Turkey implementation

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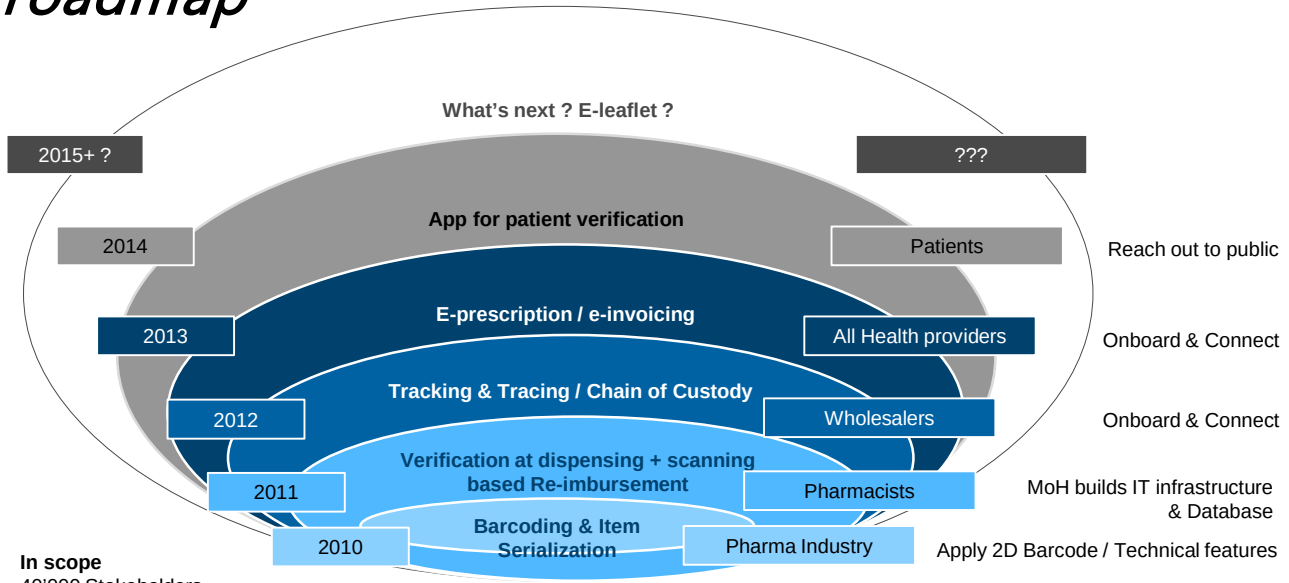
Serialization & Traceability

Onboarding of HC Actors by Continuous Scope Extension

See the example of Turkey's implementation roadmap



In scope
40'000 Stakeholders

- Hospitals
- Health Centers
- Family Physician Centers
- Pharmacies and Pharmacy Warehouses
- Manufacturers
- Importers
- Reimbursement Institutions

Figures & Facts today
Number of drug types in İTS: 18 900
Number of drug unıts in İTS: 7 000 000 000
Number of daily operations in İTS: 45 000 000
Number of operations per second in İTS: 520
Response time of system: < 1 sec
ROI in ONE YEAR!

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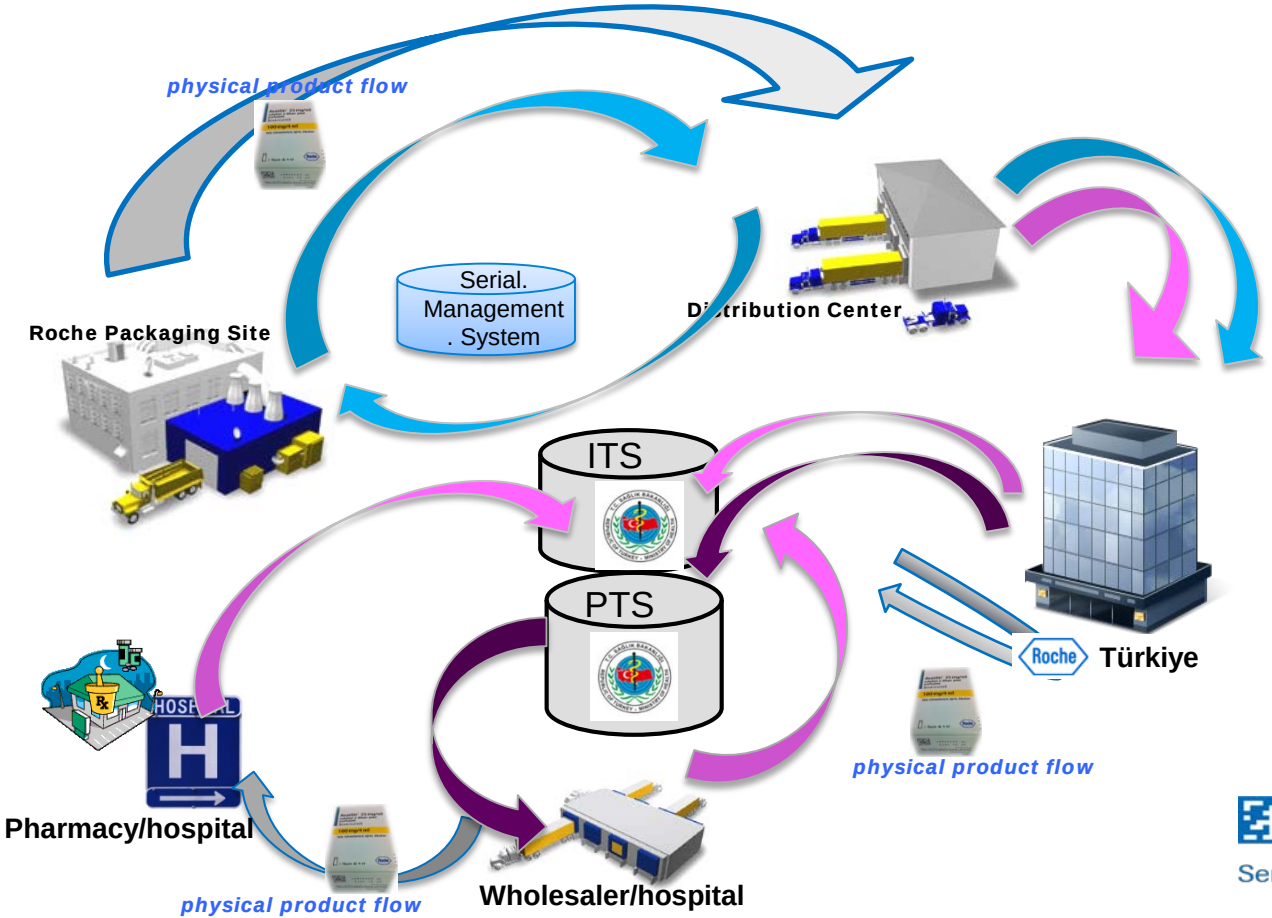
Serialization & Traceability

Product and Data Flow



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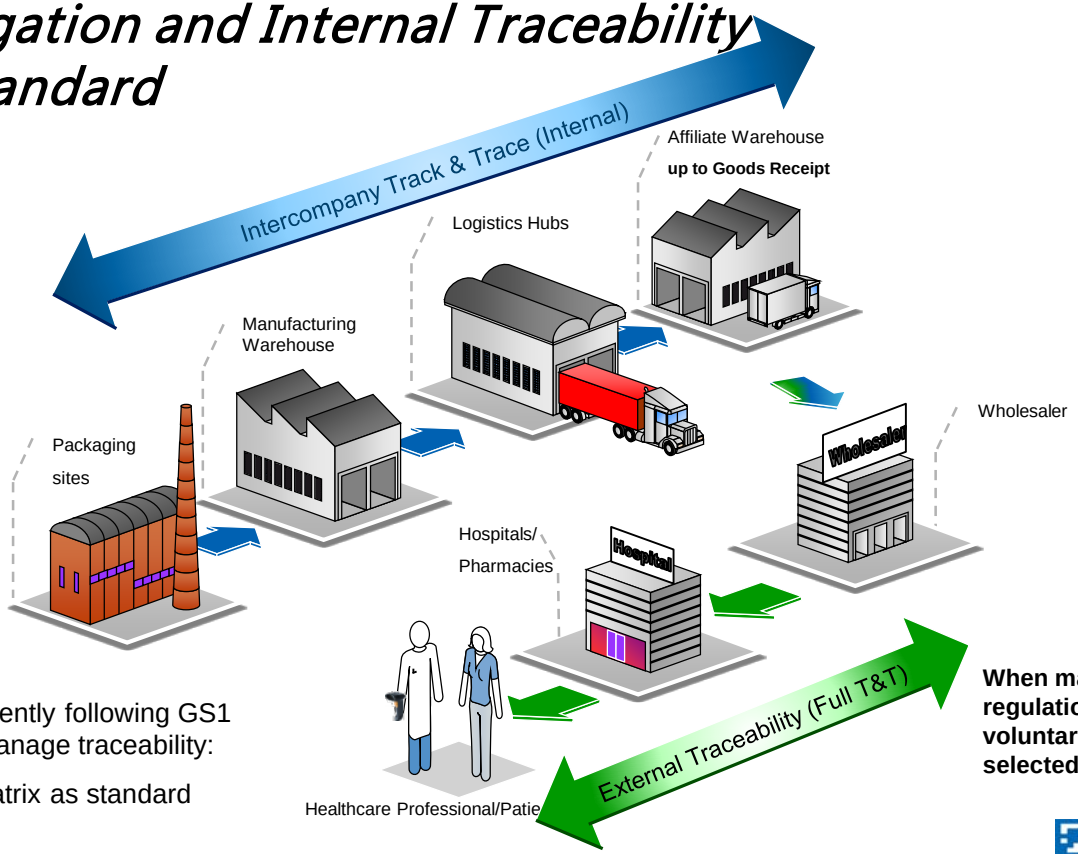
Serialization & Traceability

Proactive measures

- Based on our strategy to fight against counterfeits and to ensure a safe supply chain, we proactively implement safety measures:
  - **Codification in Africa**
    - Ensure product identification
  - **Aggregation in Europe** whereas only serialization is required
    - Ensures a better visibility of the supply chain
  - **Serialization in Ecuador, Australia** whereas there is no Health Authority requirement
    - Known counterfeits cases

Traceability Model at Roche

Aggregation and Internal Traceability as a Standard



We use consistently following GS1 standards to manage traceability:

- ❑ GS1 DataMatrix as standard data carrier
- ❑ EPCIS as traceability data standard

When mandated by regulations or as voluntary project in selected countries

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Serialization & Traceability

Doing now what patients need next

Deploy
Serialization & Traceability

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Implementing Falsified Medicines Directive (EU) Deployment in a global company

Dirk Van Den Wouwer, Johnson & Johnson

Implementing Falsified Medicines Directive (EU)

Deployment in a global company

Dirk Van den Wouwer
EMEA Serialization & Traceability Leader
Johnson & Johnson Supply Chain

Regional GS1 Healthcare Conference, Addis Ababa, Ethiopia
May 2018

Johnson & Johnson

- Global science & technology company focused solely on healthcare
- More than 275 operating companies in 60 Countries
- Selling products in more than 175 Countries
- Approximately 130,000 employees worldwide


Our Credo
We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.
We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognize their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfill their family responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management, and their actions must be just and ethical.
We are responeible to the communities in which we live and work and to the world community as well. We must be good citizens — support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.
Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.
Johnson & Johnson
Unser Credo
我們的信條
Наше Кредо
uestro Credo
Nosso Credo

Johnson & Johnson Portfolio

Consumer

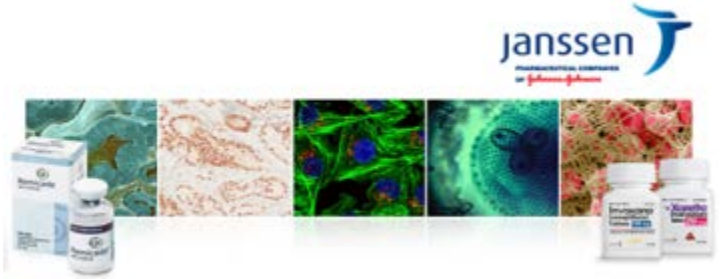
Baby Care • Body Care • Facial Skin Care • Sun Care • Feminine Personal Care • Allergy Care • Compromised Skin Care • Cough and Cold Care • Digestive Health • Oral Care • Pain Care

Medical Devices

Wound Closure & Surgical Devices • Minimally Invasive Surgery • Joint Replacement • Sterilization • Eye Health • Diabetes Care

Pharmaceuticals

Oncology • Infectious Diseases & Vaccines • Immunology • Cardiovascular & Metabolism • Neuroscience & Pain • Pulmonary Hypertension



EU Falsified Medicines Directive

Serialization is only one part of the directive

Product Safety Features

Authenticity

Pack Identity

Tamper Evidence

Feb 9, 2019

Good Distribution

Wholesalers & Brokers

GDP

2014-Q1

Active Substances

GMP for Excipients

Jan 2, 2013

Registration API Activities

July 2, 2013

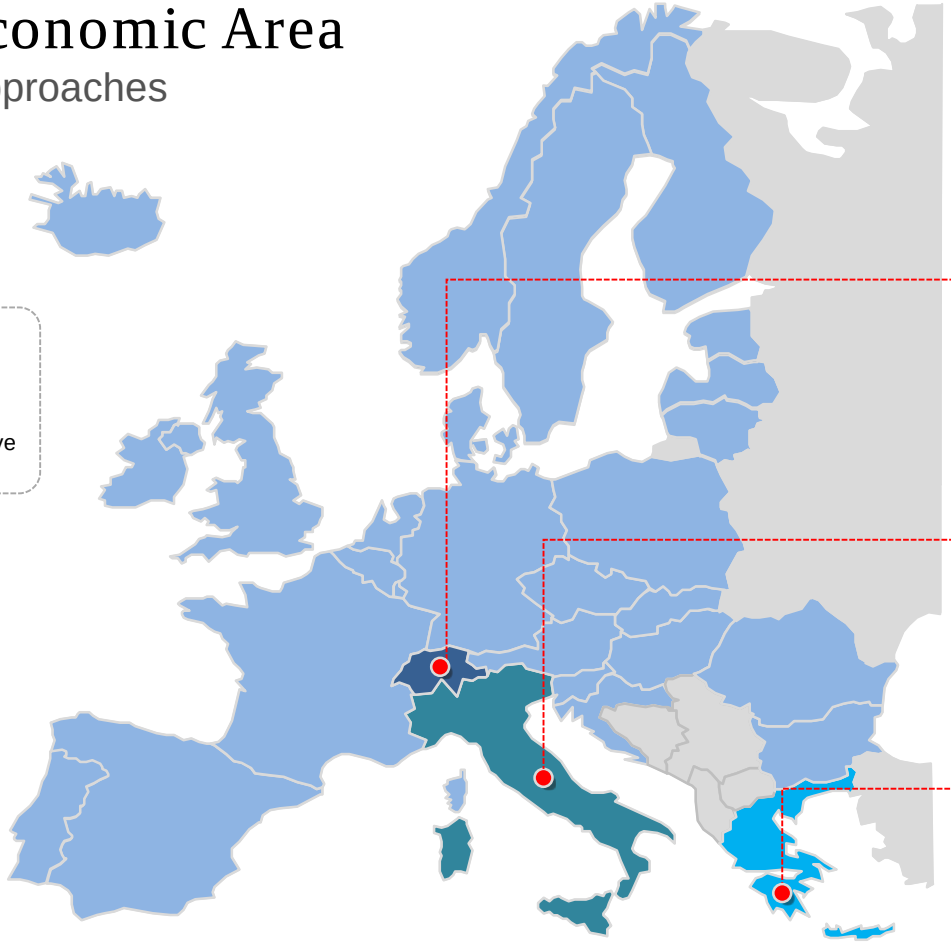
Internet Sales

Community Logo

2015

European Economic Area

Diverse country approaches



Confirmed RA Requirements

Pending RA Requirements

European Economic Area

- **Feb 9 2019:**
  - Serialization
  - Falsified Medicines Directive
  - All countries except…

Switzerland

- **Voluntary Adoption:**
  - Serialization
  - Falsified Medicines Directive

Italy

- **Feb 9 2025:**
  - Serialization
  - Falsified Medicines Directive

Greece

- **Feb 9 2025:**
  - Serialization
  - Falsified Medicines Directive

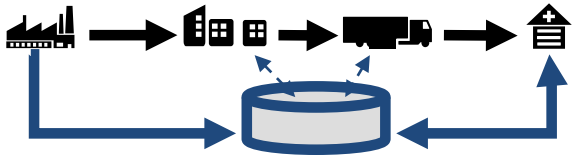
Delegated Act Mandates Rules for End-to-End Verification

Key pillars of serialization and verification

Serialization by manufacturer

+

Verification at point of dispense



Unique identifier

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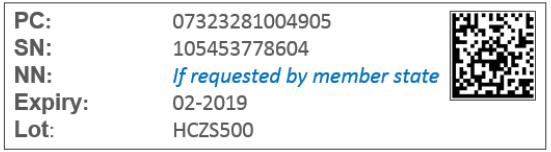
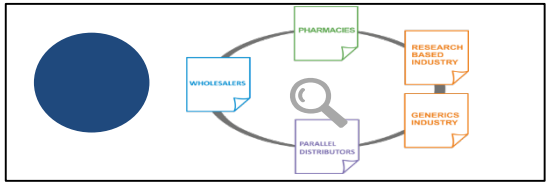
Tamper evidence

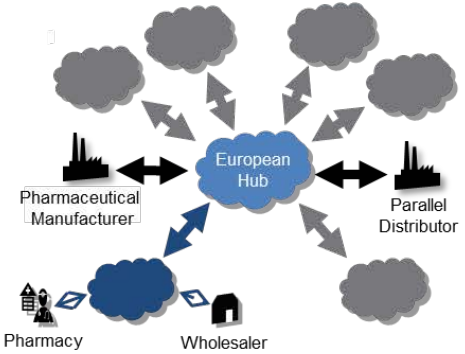


System set up and governed by stakeholders under supervision of local authorities



Manufacturers pay for the system

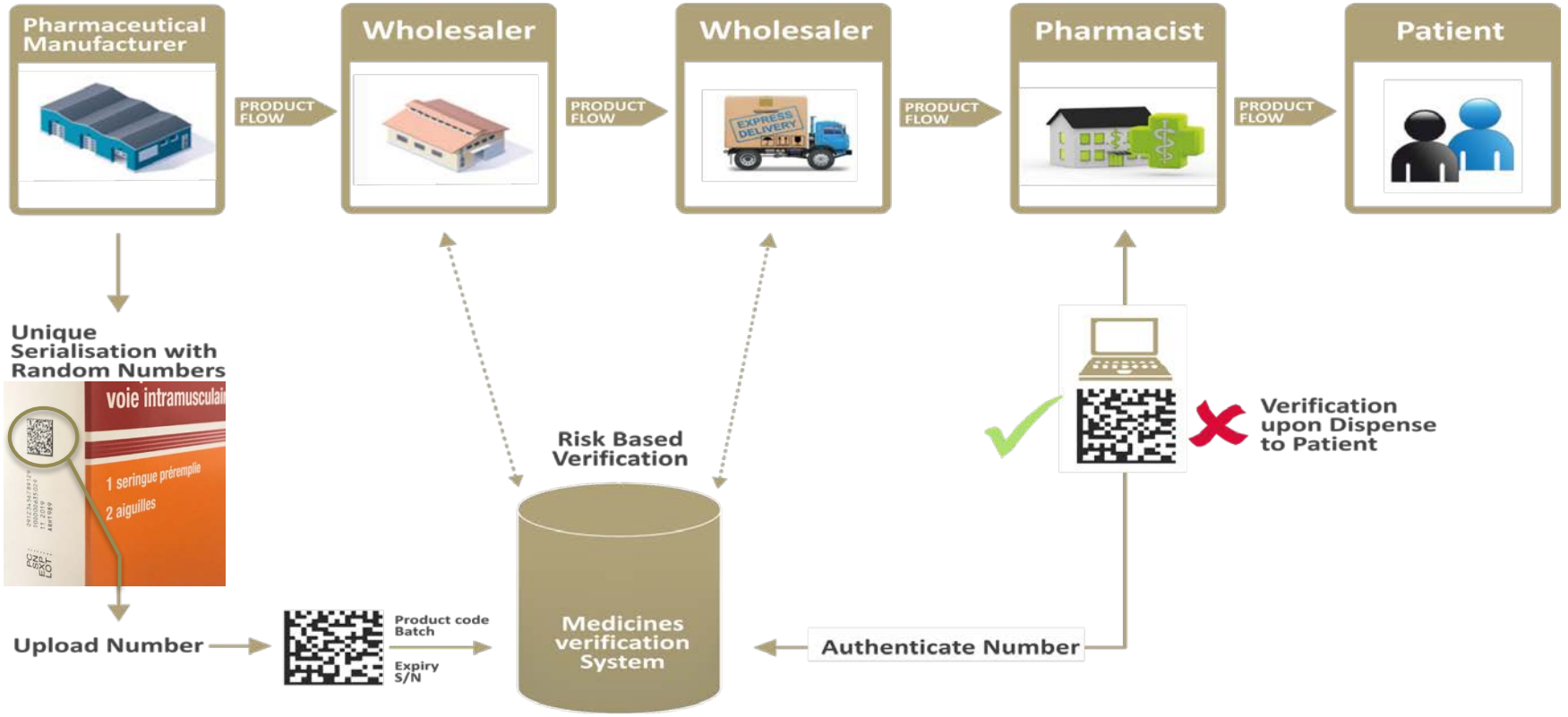
Who Will Have to Pay?

Installations for pack coding	Installations for pack verification	Repository system (Hub & national systems)
		
Marketing Authorisation Holders	**Pharmacists, wholesalers, …**	**Marketing Authorisation Holders**

MAHs selling products in a Member State pay for respective national system and a share of the European Hub

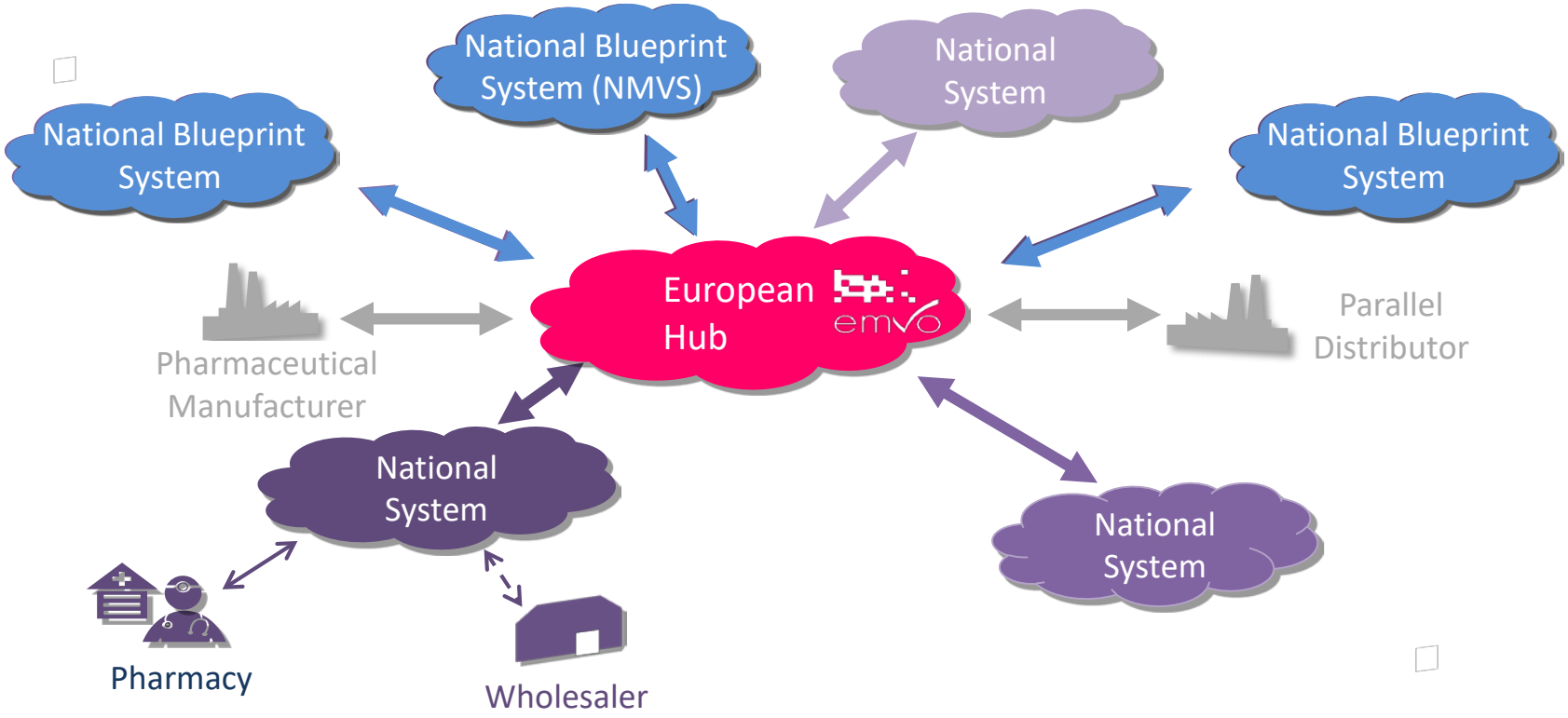
Point of Dispense Verification

All parties verify against one central system



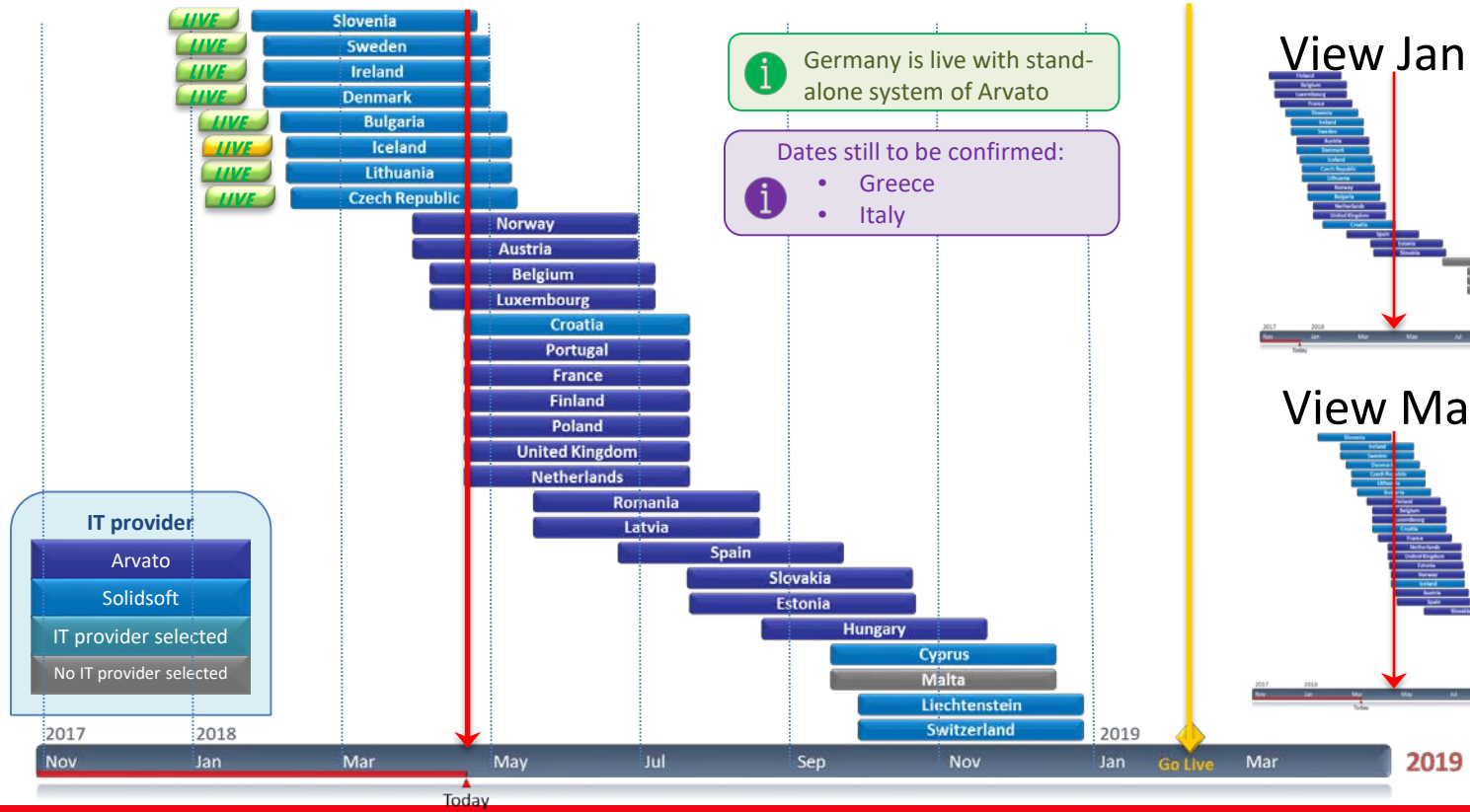
Repositories Systems

Enable systematical point of dispense verification

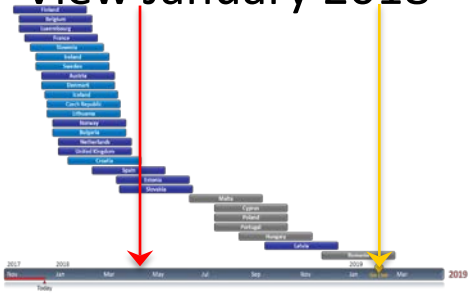


Implementation National Systems - View 2 May ‘18

More go lives expected!



View January 2018



View March 2018

Constant Focus Required on Different Areas

Good progress made, but time is ticking…

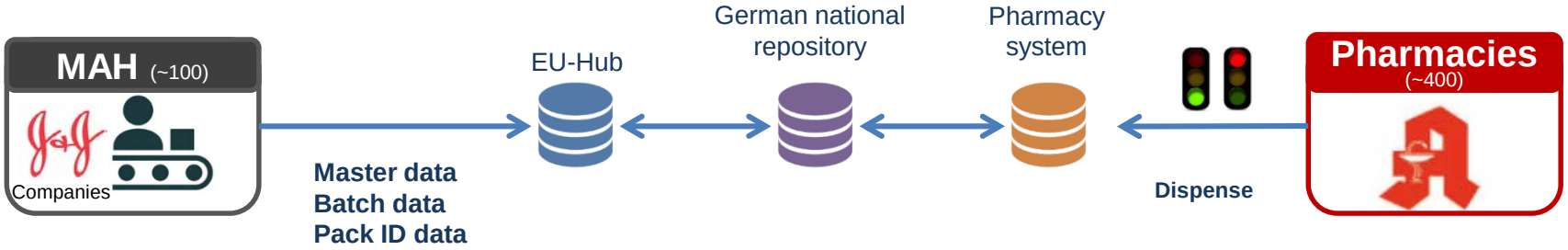
Artwork started

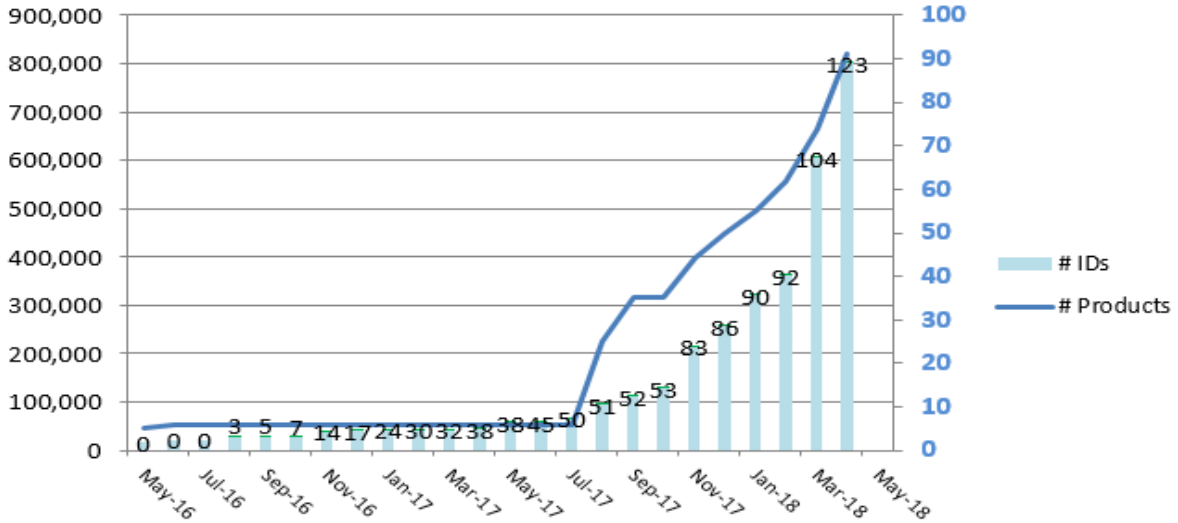
Artwork Finished

First Production

Piloting the German National System

Proven technology but quite some learning by doing



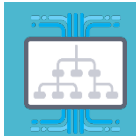


End-April 2018

- 800K+ packs
- ~400 batches
- ~100 SKUs / products
- 123 dispenses

Key Attention Points

Build on experience gained in other countries



Game Changer

- Full end-to-end process
- Impacting all business units, partners, systems & platforms

Multi-Country Packs

- Refrain from using NTIN
- Alignment on National Reimbursement number

Special Flows

- Marketing Authorization Holder
- Producer
- Distributor

Regulatory Reporting

- Clear specifications needed upfront
- Alignment to industry standards

Know How

- Reuse experience build by stakeholders
- Cost & timings of implementation decreases as capabilities are being deployed

7 Billion Reasons to Care

GS1 Global Standards Will Benefit
Patients and Consumers Everywhere

Audience Q&A time…

...and THIS WEEK do not miss...

...the “Q&A with the Experts” panels related to Traceability:

Thursday – 10 May

- 14:00 to 15:00 hrs

  Getting started with traceability – Geraldine Lissalde-Bonnet, Director Public Policy, GS1 GO/Dirk Van Den Wouwer, Johnson & Johnson

  Choosing a traceability model – Ulrike Kreysa, SVP Healthcare, GS1 Global Office, Pascal Aulagnet, Pfizer

- 15:00 to 16:00 hrs

  GS1 standards for sharing traceability information – Craig Alan Repec, Senior Manager, Supply Chain Visibility, EPCIS &RFID, GS1 GO, Dirk Van Den Wouwer, Johnson & Johnson

  Traceability implementation in the hospital – Tania Snioch, Director Healthcare, GS1 GO/Feargal McGroarty, St. James’s Hospital, Ireland