The Global Language of Business

Traceability: How to get started? Learnings form the APEC toolkit

African GS1 Healthcare Conference 2018
Breakout Panel II @ 14:30 – 15:45hrs - Tuesday 09 May 2018
Addis Ababa, Ethiopia

Your Panelists

Ulrike Kreysa
Senior Vice-President Healthcare
GS1 Global Office

Francoise Hirth
Serialisation Coordinator for Europe and EEMEA, Roche, Switzerland

Dirk Van Den Wouwer
Serialisation and End-to-end traceability leader EMEA, Johnson & Johnson, Belgium

The Global Language of Business

Traceability - the basics

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)

Driven by many regulations worldwide

- From Turkey to Argentina, South Korea, USA, Europe, Saudi-Arabia and many other MEMA countries
- Different data base models, but all with the basic data elements

- Product Identifier (GTIN)
- Serial Number
- Expiry date
- Lot/Batch number

APEC Roadmap for Global Medical Product Integrity and Supply Chain Security

- 5 year project (Jan. 2013 - Dec. 2018)
- 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
AmerisourceBergen
AstraZeneca
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

TTWG – Six recommendations

- All three overarching Recommendations apply irrespective of the geography, economy or regulatory issue being addressed :
  - 1st Recommendation: define clear objective to be achieved
  - 2nd Recommendation: collaborate with stakeholders
  - 3rd Recommendation: recommend the use global data standards (GDS)
- All three secondary-Recommendations apply over time as traceability systems are incrementally implemented:
  - Identify
  - Capture
  - Share

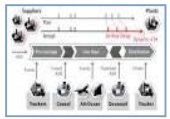
First Recommendation

Define clear objectives to be achieved

The solution required by a regulation should be based on the regulatory objective to be achieved

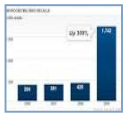
What issue is being addressed?

Drivers



Supply Chain Visibility

Product Protection



Recall Improvement

Returns, Shipment accuracy and efficiency

Reimbursement

The dilemma created by lack of clear objectives

- Strategic alignment of stakeholders may not occur – differing interpretations and implementation
- Missed opportunity to leverage global learnings
- Unclear what the solution is addressing and if it will work – too onerous / costly? not addressing the issue?
- Processes become complex
- Timelines may extend
- Costs can increase

Clear objectives will facilitate the achievement of regulatory needs and costs can be minimized

Defining clear objectives

- Provides stakeholders certainty so able to focus on task rather than being sidetracked by ambiguity
- Supports development of common approaches/standardisation to issue being addressed
- Leverages committed industry stakeholders who possess the skill, creativity, dedication and tenacity to create appropriate solutions to address the issue

Second Recommendation

Collaborate with stakeholders

- *A collaboration of the drug supply chain partners and regulators should define the implementation approach (i.e. timing and phasing) and governance model, including data management and privacy.*

- *Collaboration should be ongoing due to the changing and/or evolving nature of the situation.*

The benefits of collaborating with stakeholders

- Strategic alignment of stakeholders across geographic networks
- Multiple economies facing common challenges moving towards the same approach for a shared supply chain network
- Globally unique/globally interoperable solutions are implemented
- Reduce complexity, timelines and costs

Third Recommendation

Recommend the use of global data standards (GDS)

The use of global data standards would enable global interoperable product identification, capture and sharing of data. This may support efficient and cost effective management of the pharmaceutical supply chain globally. This may also facilitate harmonised implementation of regulatory requirements.

The dilemma created by lack of Global Data Standards

- Multiple economies facing common challenges create different approaches for identification and data exchange
- Disparate and proprietary solutions are implemented and expensive to maintain
- Internal applications that serve several geographic networks require complex logic
- External systems can not be shared across regional boundaries
- Processes become very complex
- Costs increase

Without Global Data Standards, health care costs rise and time to deliver product to the market increases

Global Data Standards

- **GS1 standards enable traceability**
- **The result:** Prevent counterfeit drugs entering the market, gain efficiency, have the right product in the right place at the right time, more effective recalls and more…

Traceability Matrix

What is the Traceability Matrix?

A tool to assist you in selecting the appropriate system (process & model) for traceability to meet the objective(s) defined earlier in the decision making process (1st Recommendation)

Driver / Objective	Issue	TRACEABILITY (aka track and trace) PROCESS APPROACH				Applicable IT System choreography models
		Chain of Ownership (Finished Goods)	Chain of Custody (Finished Goods)	Point of Dispense Verification	End consumer/ patient verification	
Improve Patient Safety	Counterfeit or stolen product detected in the legitimate supply chain	✓	✓	✓		Centralised, Semi-Centralised, Distributed
	Counterfeit or stolen product obtained/consumed by the patient	✓	✓	✓	✓	Centralised, Semi-Centralised, Distributed
	Inefficient reverse logistics processes (e.g. returns, recalls)	✓	✓			Centralised, Semi-Centralised, Distributed
	Lack of visibility of status of product (e.g. expired, recalled)	✓	✓	✓	✓	Centralised, Semi-Centralised, Distributed
Improve payment monitoring	Inefficient payment and payment monitoring processes	✓		✓		Centralised
	Reimbursement fraud	✓	✓	✓		Centralised
Improve supply chain efficiency	Lack of knowledge of where the product is across the supply chain	✓	✓			Centralised, Semi-Centralised, Distributed
	Inefficient inventory management	✓	✓	✓		Centralised, Semi-Centralised, Distributed
	Inefficient reverse logistics processes (e.g. returns, recalls)	✓	✓			Centralised, Semi-Centralised, Distributed
	Lack of harmonised trade/ customs clearance procedure	✓	✓			Centralised, Semi-Centralised, Distributed

Note: the objectives are not presented by order of importance or preference.

THIS TRACEABILITY MATRIX IS AN INTEGRAL PART OF THE APEC TRACK & TRACE WORK GROUP TOOL KIT
IT SHOULD ONLY BE READ OR USED AS A PART OF THAT TOOL KIT
IT SHOULD NOT BE READ OR USED SEPARATELY OR INDEPENDENTLY OF THAT TOOL KIT

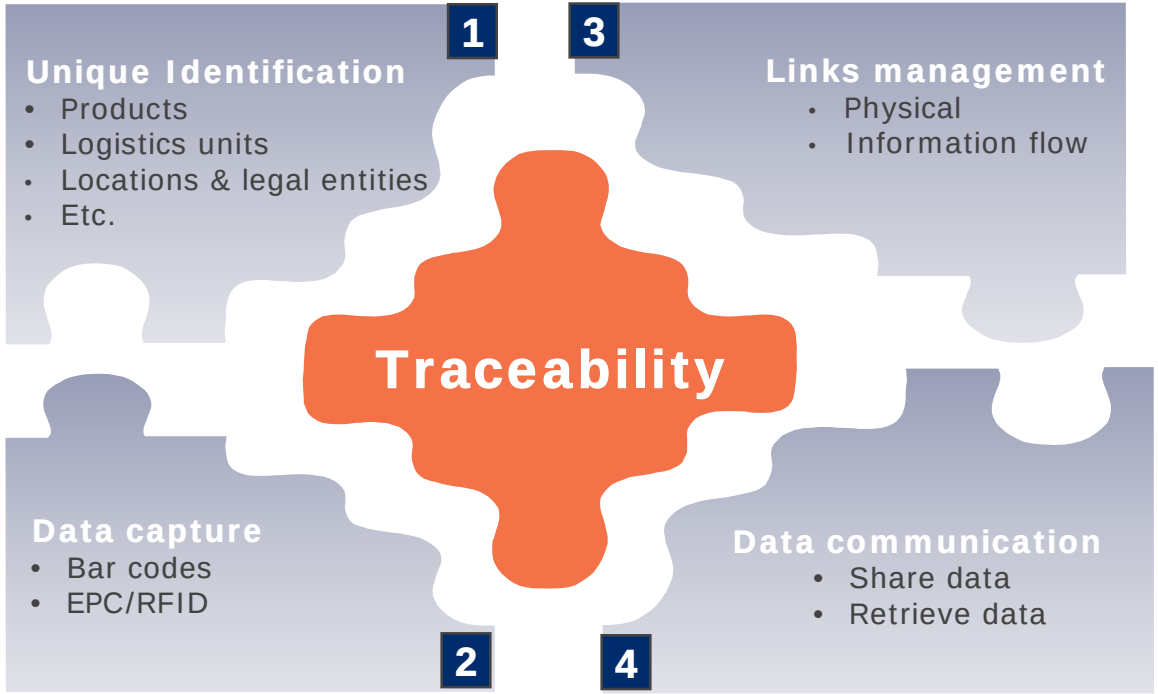
Traceability – definition

- 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 “building blocks”



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Traceability: How to get started

Francoise Hirth, Roche

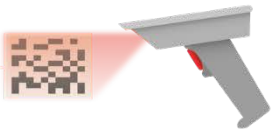
Traceability: how to get started?

Françoise Hirth

F.Hoffmann-La Roche ltd

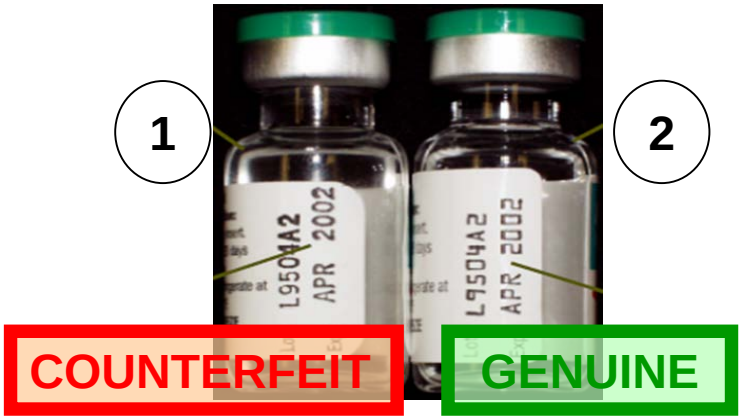
Serialization Coordinator EU & EEMEA



What does Roche want to achieve with serialization/traceability? (1/2)

- Fight against counterfeits

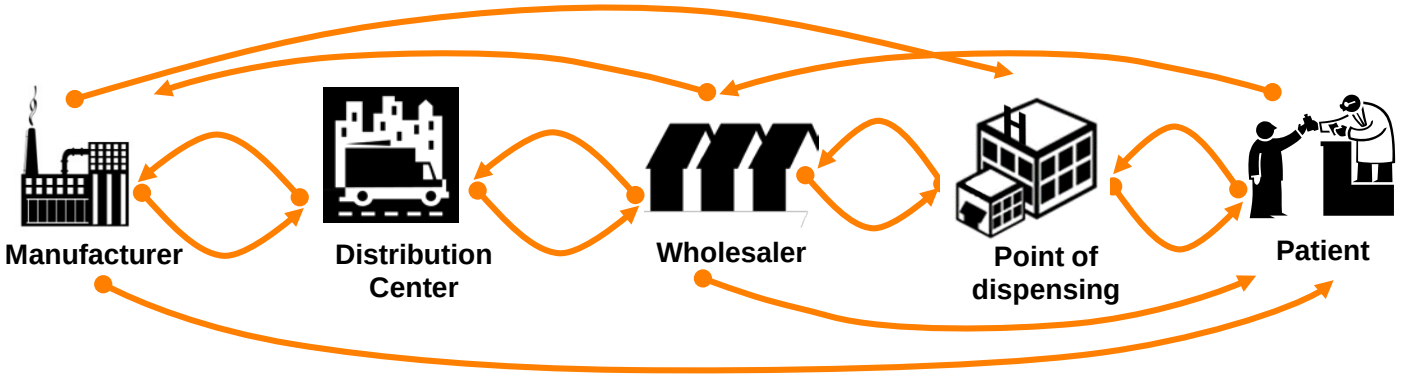


Counterfeiting

- endangers the lives of patients;
- undermines confidence in healthcare systems and health professionals;
- damages public confidence in authentic pharmaceutical products
- is a threat to the reputation of the legitimate healthcare business

What does Roche want to achieve with serialization/traceability? (2/2)

➢ Keeping the supply chain safe for the patients

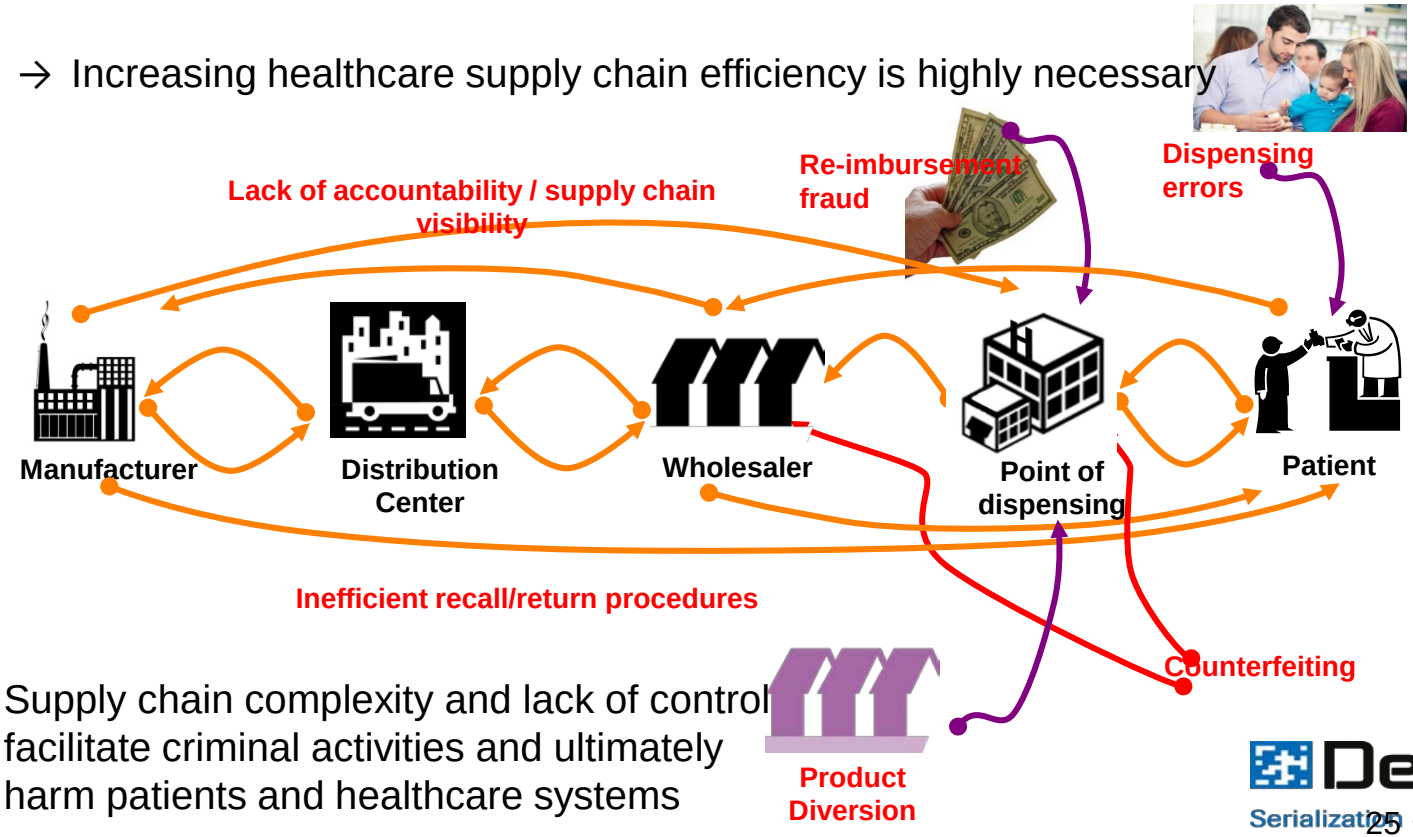


Back and forth route due to:

- → Obsolete stocks
- → Returns
- → Loses
- → Incorrect deliveries
- → Payment issues, etc.

What does Roche want to achieve with serialization/traceability? (2/2)

→ Increasing healthcare supply chain efficiency is highly necessary



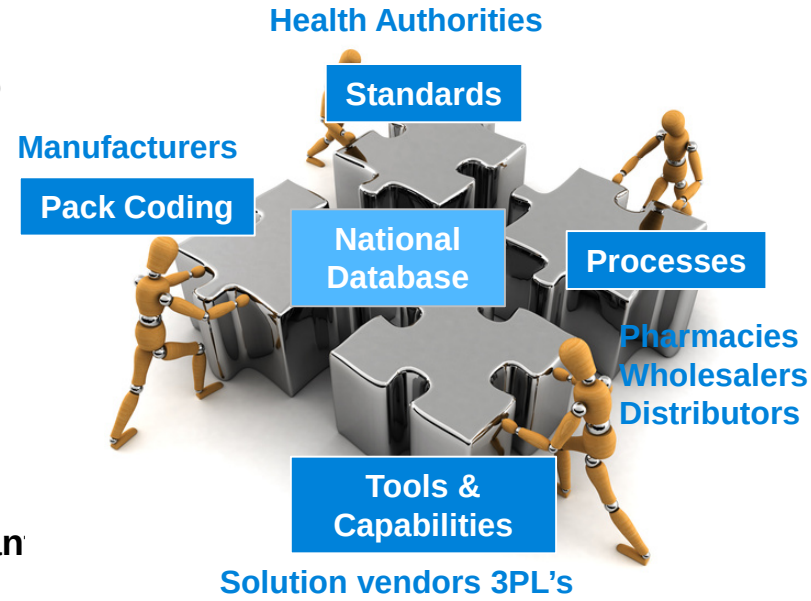
Supply chain complexity and lack of control facilitate criminal activities and ultimately harm patients and healthcare systems

Work Together with All Stakeholders to Co-develop the National Verification / Traceability

What needs to be DEFINED

- **Standard** Data Carrier
- **Standard** Data Construct
- Access to Data
- Reporting needs
- National database
- Implementation Timelines

The challenges are importan



Success through a **collaborative approach**
Manufacturers, Health Authorities, Associations, Peers, Trading Partners, Solution Vendors…

What Roche's approach towards emerging regulation is in the area of Supply Chain Integrity

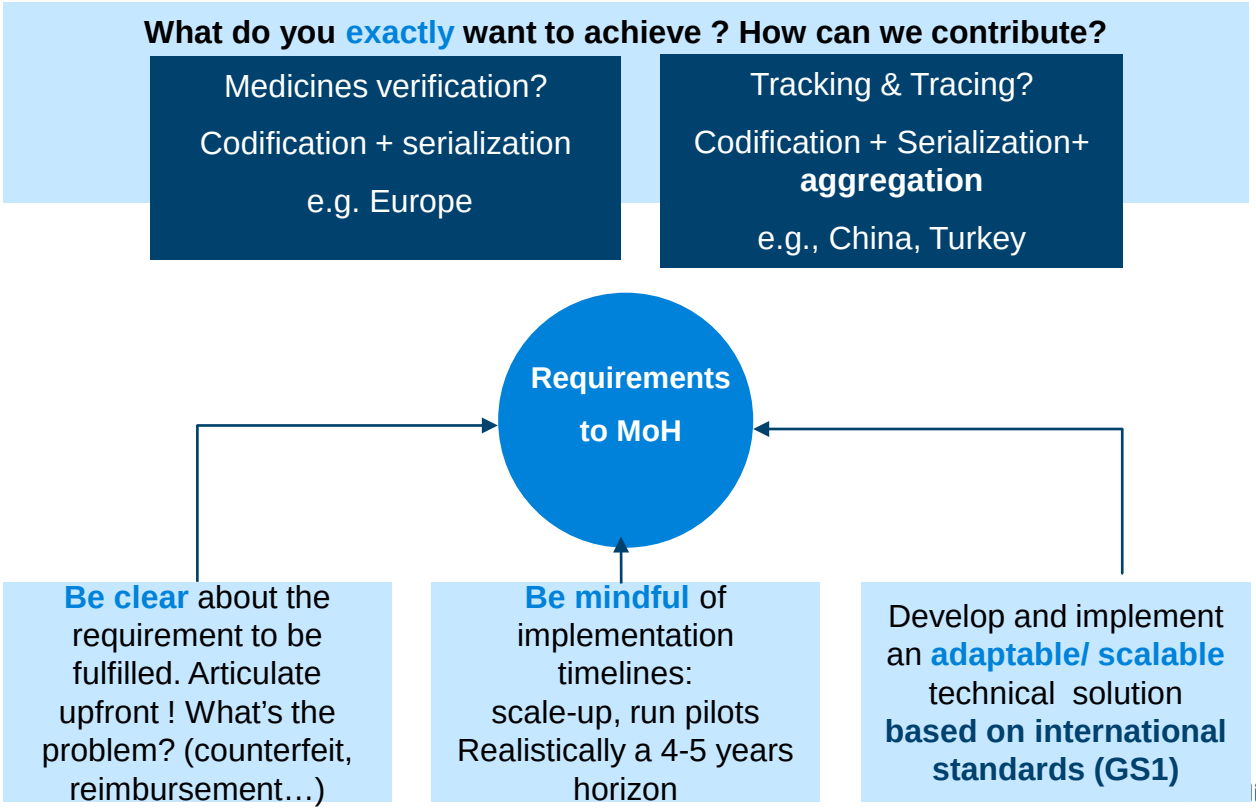
- **We welcome Health Authoritie's efforts** to secure drug supply to the benefit of our patients

- Roche & Industry is **willing to work with Health Authorities** to achieve longer term patient safety goals

It is important that regulators engage key stakeholders in the definition process (of the regulation)

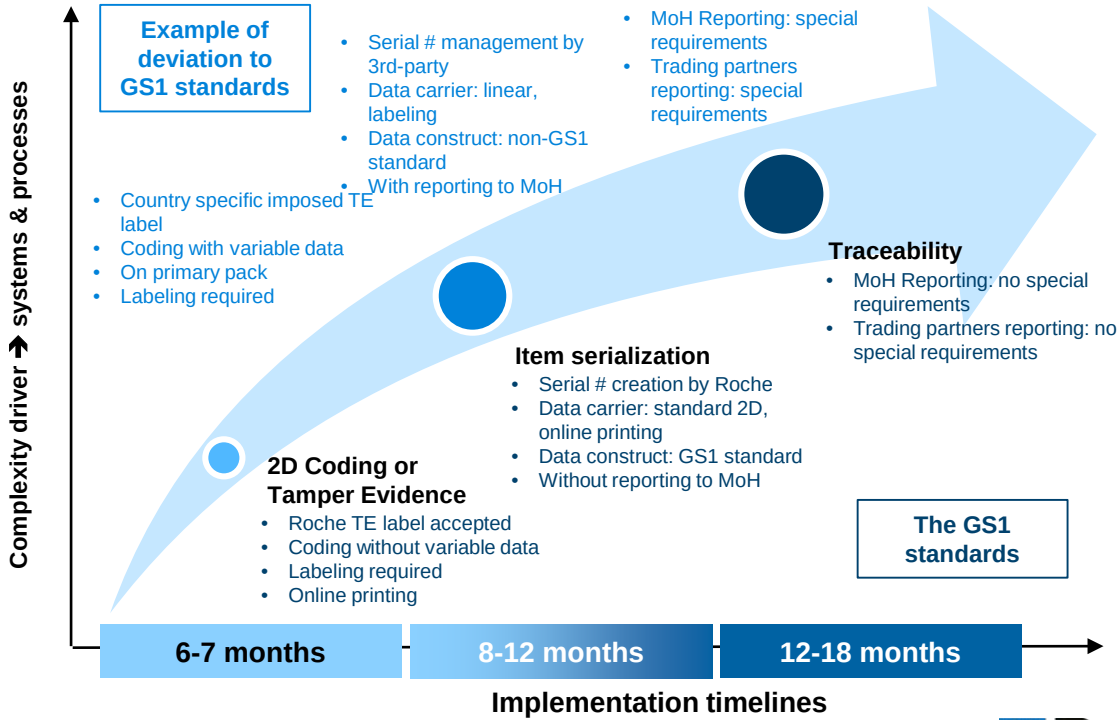
Deploy
Serialization & Traceability

Do or Will you have draft regulations ?
For which problem ?



Deploy
ization & Traceability

Implementation Workload can be More or Less High, Requiring Sufficient Time



an extension in case of deviation to defined standards

Doing now what patients need next

Deploy
Serialization & Traceability

The Global Language of Business

Implementing Serialization and End-to-End Traceability using GS1 Standards

Dirk Van den Wouwer, Johnson & Johnson

Johnson & Johnson SUPPLY CHAIN

Implementing Serialization and End-to-End Traceability using GS1 Standards

A global company perspective

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

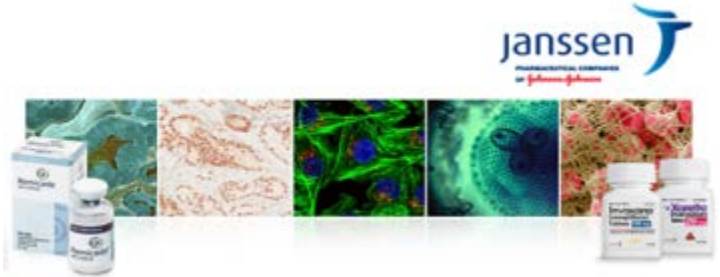
Baby Care • Body Care • Facial Skin Care • Sun Care • Feminine Personal Care • Allergy Care • Compromised Skin Care • Cough and Cold Care • Digestive Health • Oral Care • Pain Care

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



7 Billion Reasons to Care

GS1 Global Standards Will Benefit
Patients and Consumers Everywhere

Benefits of Serialization

- Enables patient safety
- Allows for continued product access
- Creates end-to-end transparency
- Reduces threat of counterfeiting, theft, diversion
- Allows better control of reimbursement
- Minimizes errors
- Improves logistics efficiency and order accuracy

Regulations Deployed Globally

Protect patient safety and product integrity

DataMatrix
GTIN with Lot Number and Expiry Date

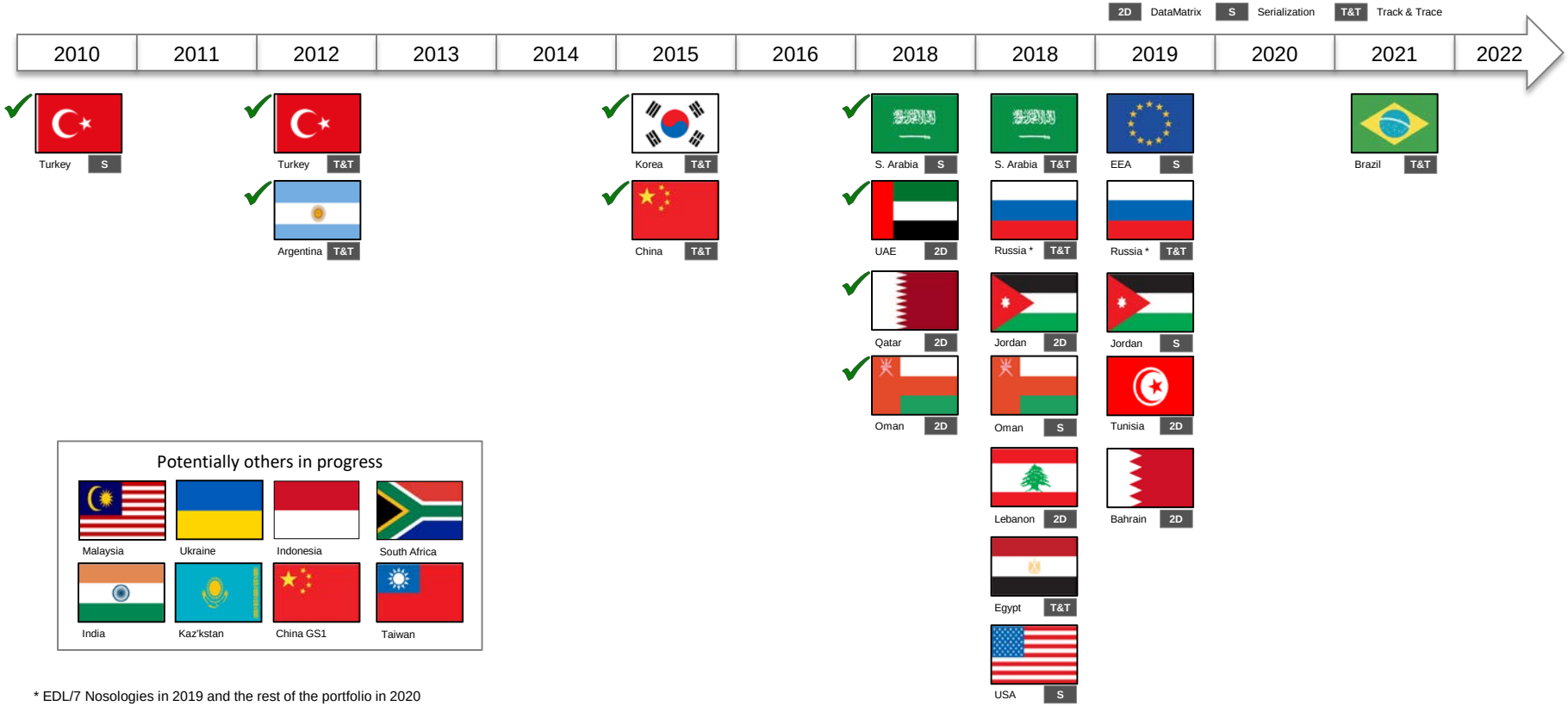
Serialization
Item level serialization using GS1 standards

Track & Trace
Traceability through aggregation & reporting

* Some regulations require anti-tampering solutions as part of the regulations

Over 45 Countries Have Legislated Serialization/Track & Trace

Number of countries increasing and time window for deployments reducing



* EDL/7 Nosologies in 2019 and the rest of the portfolio in 2020

End-to-end Impact

Assessment required over different parts of the business

Internal Manufacturing

External Manufacturing

DataMatrix

Artwork Review

PC 01234567890128
SN 123456789012
EXP 12-2015
LOT 123456
MFG (Optional)

License Plate

Regulations & Timelines

Aggregation

Packaging Lines

Track & Trace

Distribution

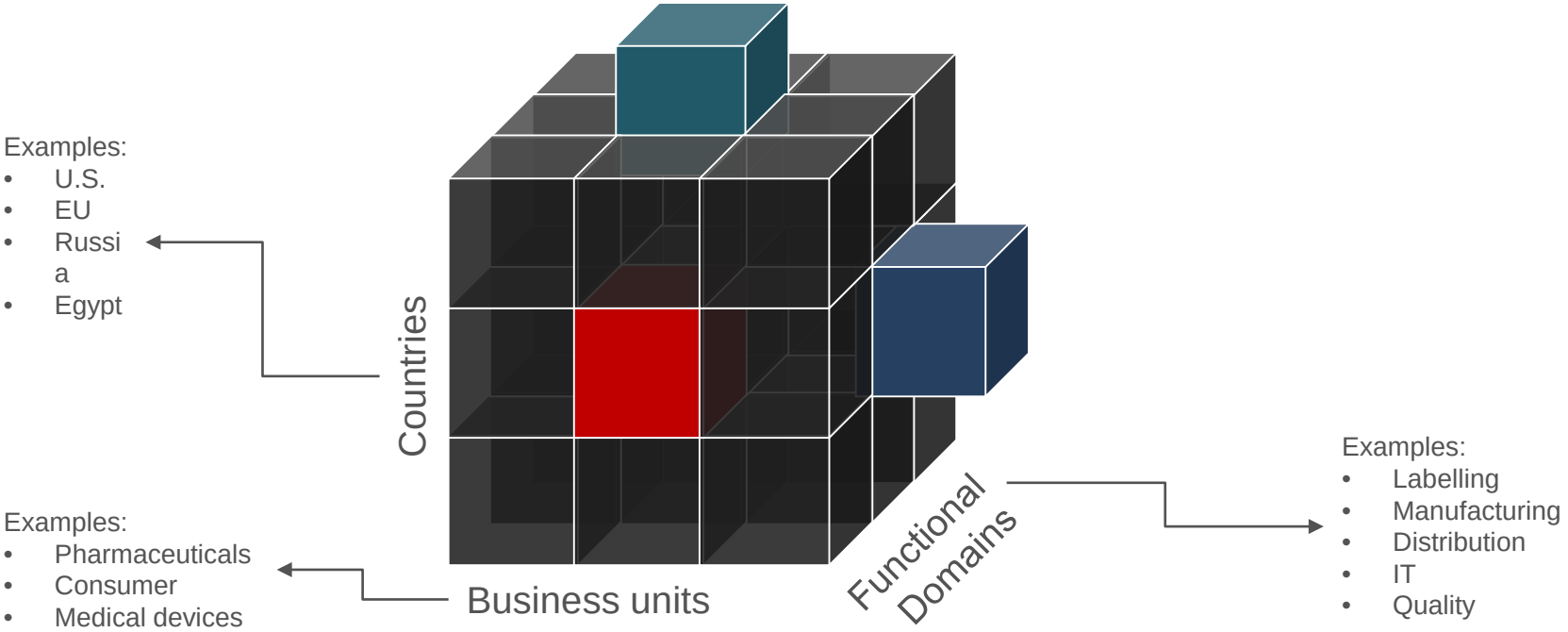
Cost Control Value Beyond

Enterprise IT Architecture

Way of Working

Deploying for Regulations Requires Managing Through Complex Organizational Structures

Organizing in a global, end-to-end, cross-functional context



Key Deliverables in Getting Started

Getting started for the implementation

Initial Communication

Asses Legislation ● Identify Project Leads ● Asses Need for Pilot

Landscape

Draft SKU List & Volumes ● Assess Site & Packaging Line Impact ● Map Distribution Flow

License Plate

Propose License Plate and Shipper/ Pallet Label

End-to-End Process Mapping

Complete Initial High Level Use Cases and Types of Reporting

Kick Off Preparation and Presentation

Draft Project Brief ● Define Project Case ●
Assess Project Team Recourses ● Draft Project Plan

Assessments

Assess Process / Impact / Systems ● Finalize Cost Estimates ● Refine Project Plan

Obtain Capital Resources

Complete Package & Obtain Funding

Health Authorities

Drive Appropriate Communications and Engagement

Streamlined audiences, messages and lots of communication!

Define the right teams
Steering Co., Core team…

Re-do communications
Granularity, frequency…

Drive understanding
Feel engaged by choice

Change Assessment Survey
Well in adoption phase

Industry Workgroups
Streamline Regulations

Stakeholder Engagement

Set-up expert groups that pilot each phase

Leverage Existing Standards & Expertise

Phased approach with realistic timings is recommended

GTIN 01234567890128

EXP 12-2018
LOT 123456
MFG (Optional)

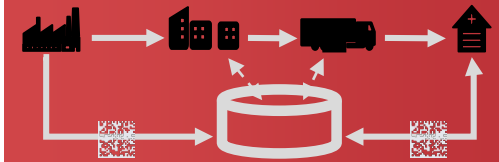
Phase 1: Product Identification

- DataMatrix including GTIN, Batch #, Expiry date
- Suggested Timing: ~6 to 12 months as of publication

PC 01234567890128
SN 123456789012
EXP 12-2018
LOT 123456
MFG (Optional)

Phase 2: Unique Identification of Secondary Pack

- Include serial number in DataMatrix
- Suggested Timing: ~6 to 18 months as of publication

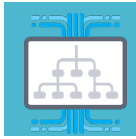


Phase 3: End-to-End Traceability / Verification

- Including reporting to Health Authorities
- Suggested Timing: ~24 to 36 months as of publication

Key Attention Points

Build on the toolkit & 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 local product codes
- 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

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