



The Global Language of Business

Panel II: The basics of global data standards and data sharing for traceability

Addis Ababa, Ethiopia

9 May 2018

Panelists



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GS1 Global Office



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leader EMEA
Johnson & Johnson



Master Data

Addis Ababa, Ethiopia

Pete Alvarez

Senior Director, Identification and Data Strategy, Healthcare

GS1

9 May 2018



The Master Data problem



Every company has a **database** filled with master data about the products they **make, sell, or buy**

But when one company **changes** any bit of information in their database or **adds a new item**, another database becomes **outdated!**



What happened to master data over the years



- Systems have evolved in **silos** over the last 40+ years
- The link between “process” and data was **broken**, and *remains so in many cases*
- Master data is *found* **throughout** the enterprise, structured & unstructured
- **Lack of understanding** of the intended purpose of the data (i.e. procurement, logistics, pharmacy, regulation)
- **Data quality starts at the source** and needs to be maintained throughout the information supply chain!

The Challenge – for manufacturers



Where do we start???



What are customers looking for???

How do we define success???

What data do I have and what do I need to start collecting???

Are we in compliance???

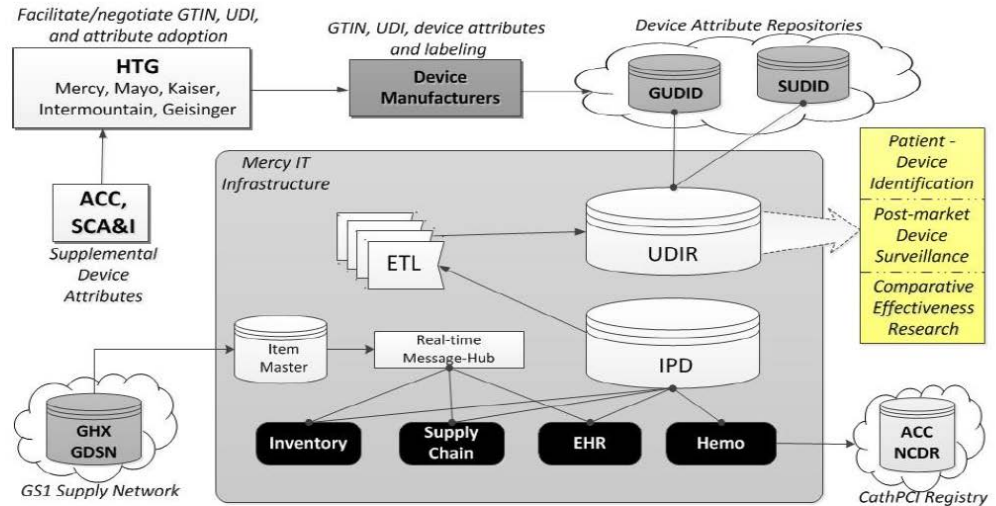
The challenge – for hospitals



How hospitals get data:

- Printed catalog
- Price quote
- PDF data
- Excel tables
- Text data
- Link to website

UDI Demonstration Project High Level Architecture



Glossary: UDIR = UDI Research database GUDID = Global UDI Attributes SUDID = Supplemental UDI Attributes
IPD = Integrated Patient Datamart ETL = Extract/Transform/Load of data

The challenge – for regulators



- U.S. Department of Defence* discovered that :
 - product catalogues had problems matching the correct manufacturer name for 30% of the medical devices and 20-25% lack the product brand name
 - the part number '8630' in the product catalogue of a leading GPO was linked to 9 different numbers from different distributors
- *“Different manufacturers use different standards in different ways if they use anything at all. Distributors apply their own. Hospitals apply their own. And we just sort of cascade into this series of events which means that we can't find devices.”*

Jay Crowley, US FDA, FDA UDI Public Workshop, Feb. 2009

- In the US from 2005 through 2009, firms initiated 3,510 medical device recalls, an average of just over 700 per year.

Regulators need to ensure highest levels of market surveillance, to efficiently manage adverse event reports and to quickly recall products, not only in their country but also across borders

Managing master data: Preferred state



Supplier = data source

Needs single point-of-entry

- One database to load new item data and update data on existing items

Needs security

- Authorisation access by supply chain partners

Standards-based

- Standard identification keys
- Predefined (set of) product attributes

Hospital & Regulators = data recipient

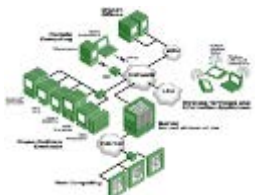
Need single point-of-truth

- One source for up-to-date, accurate data
- Continuous synchronisation

Standards-based

- Standard identification keys
- Consistently formatted information
- Complete information

Master Data Management (MDM)



Data Governance

Roles and Responsibilities

Enterprise wide Data Management

Data Quality

The quality of the data is reflection on the quality of the product

Information lifecycle: Data chain of custody



1. Create, Import or Receive

- *Collect, Create, Receive & Capture*

2. Enrich/Validate

- *Data Quality*

3. Activate

- *Push to users*

4. Audit/Evaluate

- *Routine Monitoring*

5. Update/Maintain

- *Maintain, Protect & Preserve*

6. Inactivate/Archive

- *Remove from active use*

7. Purge

- *Delete from system*



Manufacturers

The quality of the data is a direct reflection on the quality of the product

- Take steps to improve the quality of data at the source
- Establish MDM & Governance processes, executive sponsorship, including roles and responsibilities
- Enterprise-wide information life-cycle process for all master data
- Establish Data Quality measures and KPIs to ensure “data is fit for the intended purpose”

Distributors

Critical link between the manufacturer and the customer

- Establish MDM & Governance processes, including executive sponsorship, roles and responsibilities
- Integrate and maintain integrity of master data provided by the data source across all internal systems
- Develop an enterprise-wide information life-cycle process for all product master data
- Establish Data Quality measures and KPIs to ensure “data is fit for the intended purpose”

Solution & Service Providers

Partners involved in improving data quality

- Establish MDM & Governance processes, including executive sponsorship, roles and responsibilities
- Maintain integrity of master data provided by the data source across all internal systems and to customer
- Support the use of GS1 Keys, standards and Data Quality practices

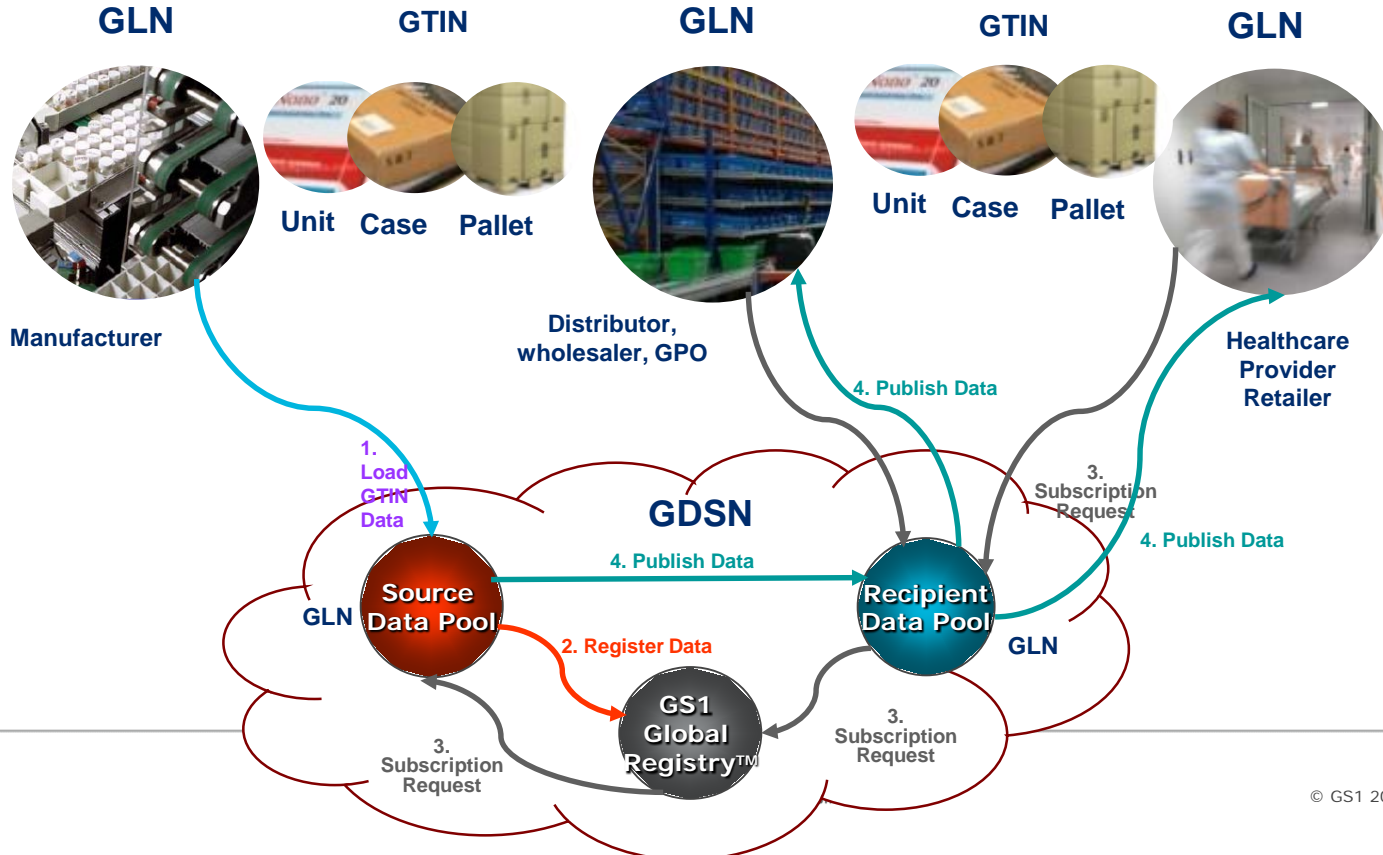
Data Recipients

Data sources need to understand the intended purpose of the data, hospitals and regulators

- Hospitals need to transact with GS1 Keys and integrate data into internal systems
- Establish MDM & Governance processes
- Ensure internal systems are capable of supporting GS1 standards
- Integrate and maintain integrity of master data provided by the data source across all internal systems



The GDSN in action

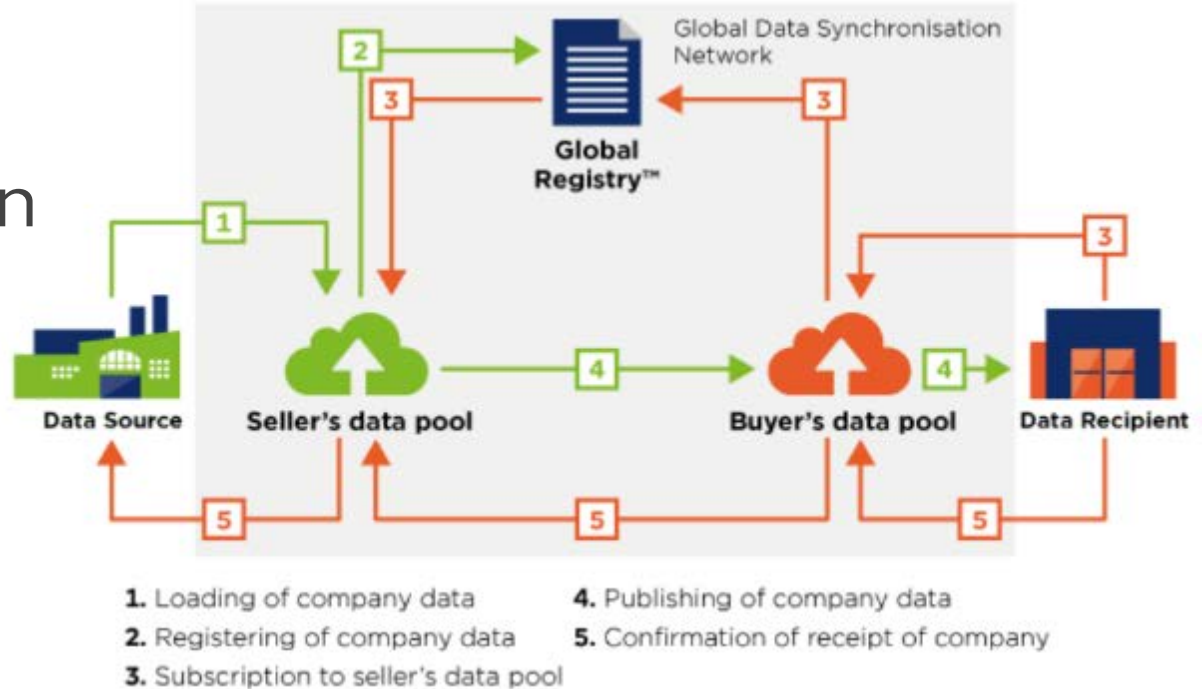


Sharing master data



Global Data Synchronisation Network:

A one to many connection





Event-Based Visibility with EPCIS

Addis Ababa, Ethiopia

Craig Alan Repec

Senior Manager, Supply Chain Visibility, EPCIS & RFID

GS1

9 May 2018



EPCIS, a GS1 and ISO open standard



- GS1 Keys identify the “what” & “where” of visibility events
- Works ideally with GS1 DataMatrix
- Helps **share visibility data** across & **between enterprises**
- Enabler for traceability solutions & services

Serialisation & event-based visibility will fundamentally change supply chain precision... EPCIS will support this!

EPCIS enables supply chain visibility



- **Tracking**

Where are the products we shipped?

- **Tracing**

Where did this batch of products come from?

- **Chain of Custody (CoC) / Chain of Ownership (CoO)**

Which parties had custody or ownership of these products?

- **Inventory Management**

How many units are in stock? When does my available inventory expire?

- **Recall**

Find all Product Y shipped from facility X on 9 May 2018...

The 4 data dimensions of an EPCIS event



- **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 occur and where are the objects thereafter?

GLN of physical location

- **Why** did this event take place?

Business step, Disposition, Source/Destination info

e.g. Commissioning, Packing, Shipping, Receiving, Dispensing . . .



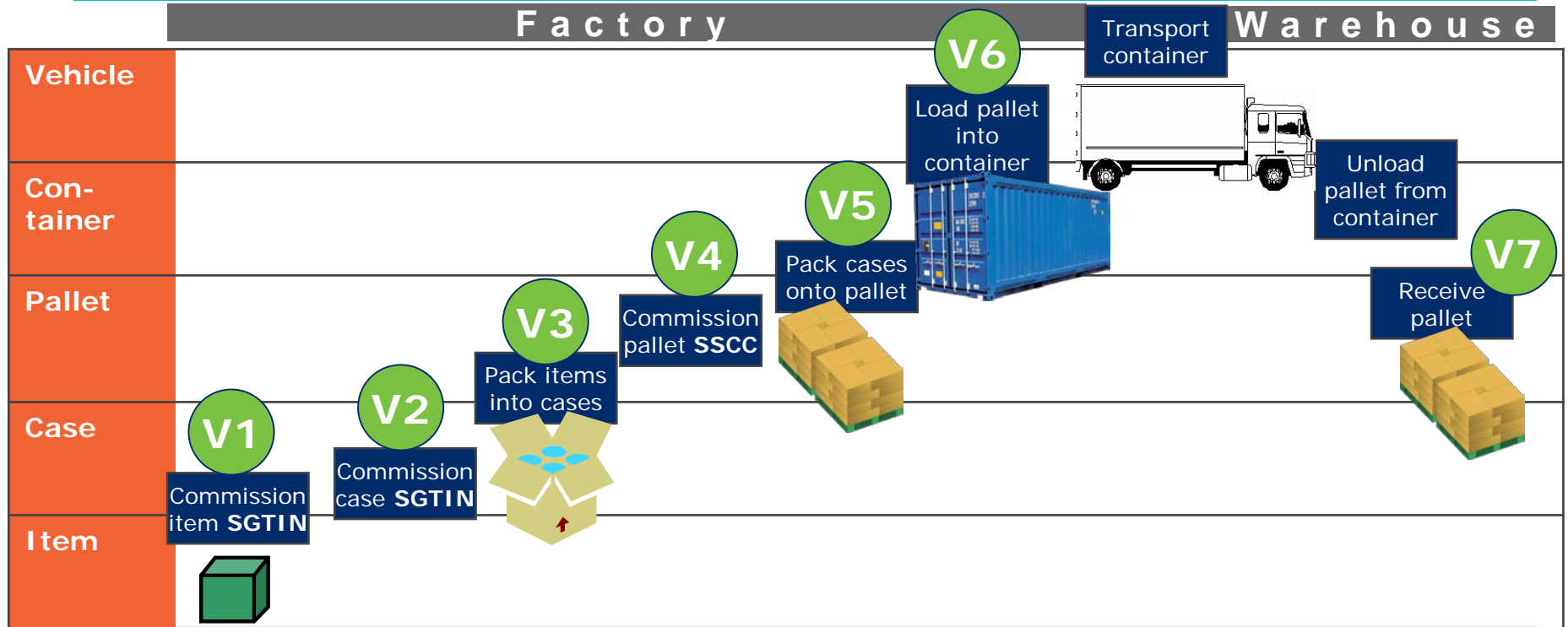
Designing a visibility system using EPCIS

Implementation Guideline http://www.gs1.org/docs/epc/EPCIS_Guideline.pdf

1. Collect visibility goals and requirements
2. Document business process flows
3. Break each process flow into series of discrete steps

Process Flow Example

Designing a Visibility System using EPCIS



Designing a visibility system using EPCIS

Implementation Guideline http://www.gs1.org/docs/epc/EPCIS_Guideline.pdf

1. Collect visibility goals and requirements
2. Document business process flows
3. Break each process flow into series of discrete steps
- 4. Decide which business steps require visibility events**
5. Model completion of each step as a visibility event
- 6. Decide which data to include in the visibility event**
7. Determine vocabularies to populate each data field
8. Document visibility events in a **visibility data matrix**

What info does the business application need?

Visibility Data Matrix

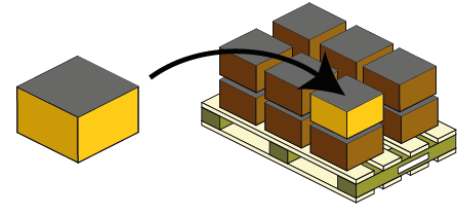
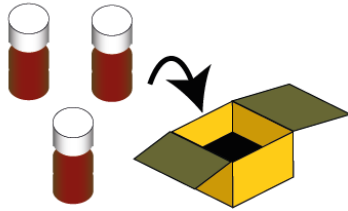
Designing a Visibility System using EPCIS



		Event V1	Event V3	Event V5	Event V6
		Commission items	Pack items into case	Pack cases onto pallet	Ship pallet
What	GS1 Identifiers	GTIN & Serial (SGTIN) of item	SGTINs of items & case	SSCC of Pallet, SGTINs of cases	SSCC of pallet
When	Timestamp	9 May 2018, 12:35 EAT	9 May 2018, 13:04 EAT	10 May 2018, 10:24 EAT	10 May 2018, 11:37 EAT
Where	Location	Packaging line 47	A-frame 21	Plant 1 palletiser	DC 1 dock door
Why	Business Step	Commissioning	Packing	Packing	Shipping

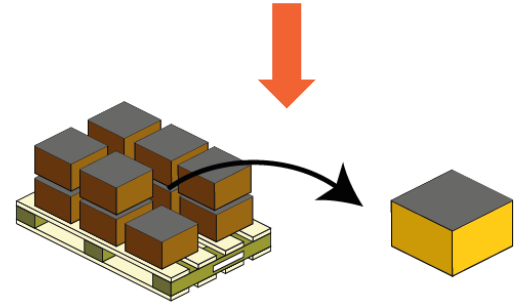
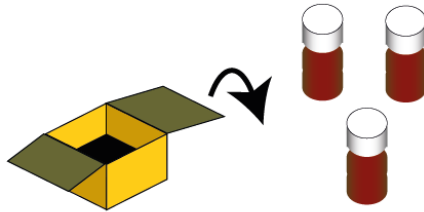
EPCIS Aggregation Event

Parent-Child logistical hierarchy



Aggregation of items into a case

Aggregation of cases onto a pallet



Disaggregation of items from a case

Disaggregation of cases from a pallet

Pharma Traceability Experiences & Learnings



- **Serialisation...**
 - is highly complex, much more than adding line equipment
 - impacts many internal and external stakeholders
 - requires extensive planning and testing
- **Collaboration** with regulators and trading partners is critical
- **Standards**-based solutions and clean master data are essential for **interoperability**
- Shared learnings allow for continuous improvement





ULF SUERIG, ABBOTT ESTABLISHED PHARMACEUTICALS
GLOBAL SUPPLY CHAIN

The Basics of Global Standards and Data Sharing for Traceability



GETTING PEOPLE BACK TO DOING THINGS THEY LOVE



Nutrition



Diagnostics



Medical devices



Medicines

TACKLING CHALLENGING HEALTH NEEDS AROUND THE WORLD

Demand for healthcare rising in growing economies

People living longer

Innovation in personalized medicine

Prevalence of chronic conditions

People taking a more active role in healthcare decisions to live their fullest lives

65%
OF SALES OUTSIDE THE U.S.

58%

OF SALES IN
DEVELOPED
MARKETS


42%

OF SALES IN
EMERGING
MARKETS

Emerging Markets

Abbott is the only global company whose pharma business is 100% focused on emerging markets.





What does
Serialization & Traceability
implementation mean to us?

New regulations are changing the information, symbols and data sharing requirements at the saleable unit

Dynamic Coding



Human readable lot and expiry



GS1 DataMatrix with GTIN, lot, expiry

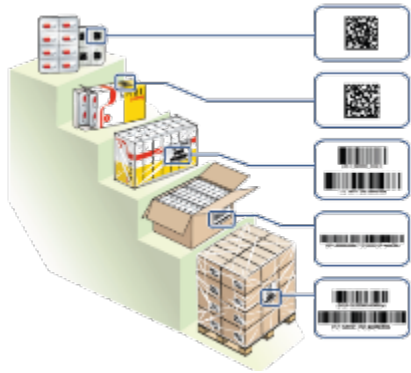
Serialization



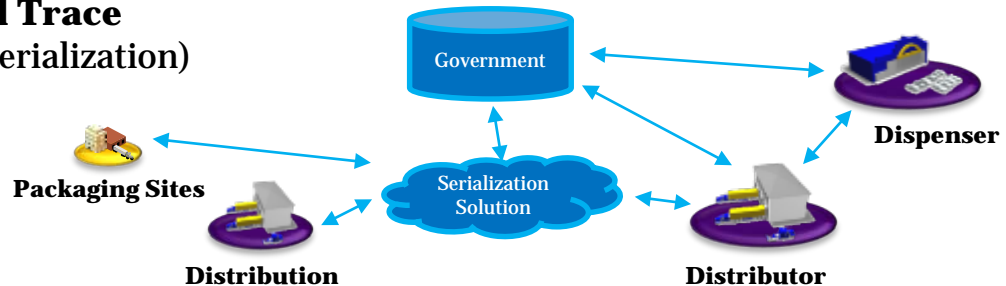
GS1 DataMatrix with GTIN, lot, expiry, SN



China – Code 128 with Chinese Product & Serial Number

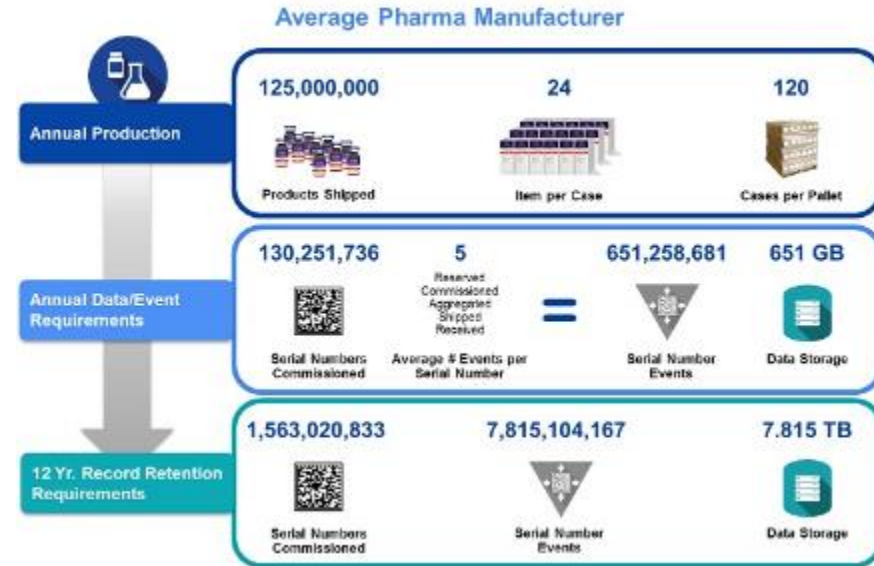


Track and Trace (includes Serialization)



Serialization & Traceability is equal to Complexity and Big Data

- The implementation of Serialization and Traceability will transform the supply of medicines
- The complexity will increase and therefore it is wise to invest in the design of the regulation
 - What are the objectives?
 - What kind of stakeholders are effected by the implementation?
 - What are the benefits of using global standards?
 - What are realistic timelines to implement Identification, Data Capture and Sharing Data?



Example: Turkey

Model: Full Track and Trace
extended to the drugs reimbursement to the patient –
In- and out-bounds are reported

Implementation: Phased - by requirements
Prescription drugs

- Serialization in 2009
- Aggregation and Reporting in 2012

Success: Efficient serialization model
Designed for stopping fraud to reimbursement. The savings granted ROI shortly. The Turkish government is using this system for other purposes, recalls and tax verification-controls

Challenges: Gap in Master Data between national repository and industry's data:
Returns in the first weeks and missing specifications about quality of the barcode led to errors at dispense



Example: China

Model: Full Track and Trace
System controlled by the Authorities
In- and out-bounds are reported

Implementation: Phased - by requirements

- National production in 2011
- EDL imports in 2012
- Remaining products in 2014

Challenges: Coding is not based on GS1 standards
Underestimation of complexity and impact on operations
Linear barcode with Serial numbers generated by a central system
Central system is not owned and governed by the Regulators
Additional cost occurring for the manufacturers and distributors

Outlook: Launching a GS1 pilot in 2018



Example: Pakistan

Model: Full Track and Trace

Implementation: Phased - by requirements

- Dynamic Coding in 2017
- Serialization, Aggregation and Reporting in 2019

Challenges: Coding is not compliant with GS1 standards

- Master data and prices are to be included in the 2D or in the human readable text

Short implementation timelines

Serialization of primary packaging is new to the industry on large scale basis

New, cost efficient solutions are to be developed for this



Challenges for the implementation of different coding systems

- **Equipment is not able to print all codes**

Longer lead times and efforts (verification and testing) driving up the cost

- **Additional information are difficult to print**

Size limitation to read a 2D code are existing as well as the number per lines printable by one print head

- **Upstream complications for external manufacturers**

Same efforts for internal manufacturing needs to be implemented where sourcing is externalized

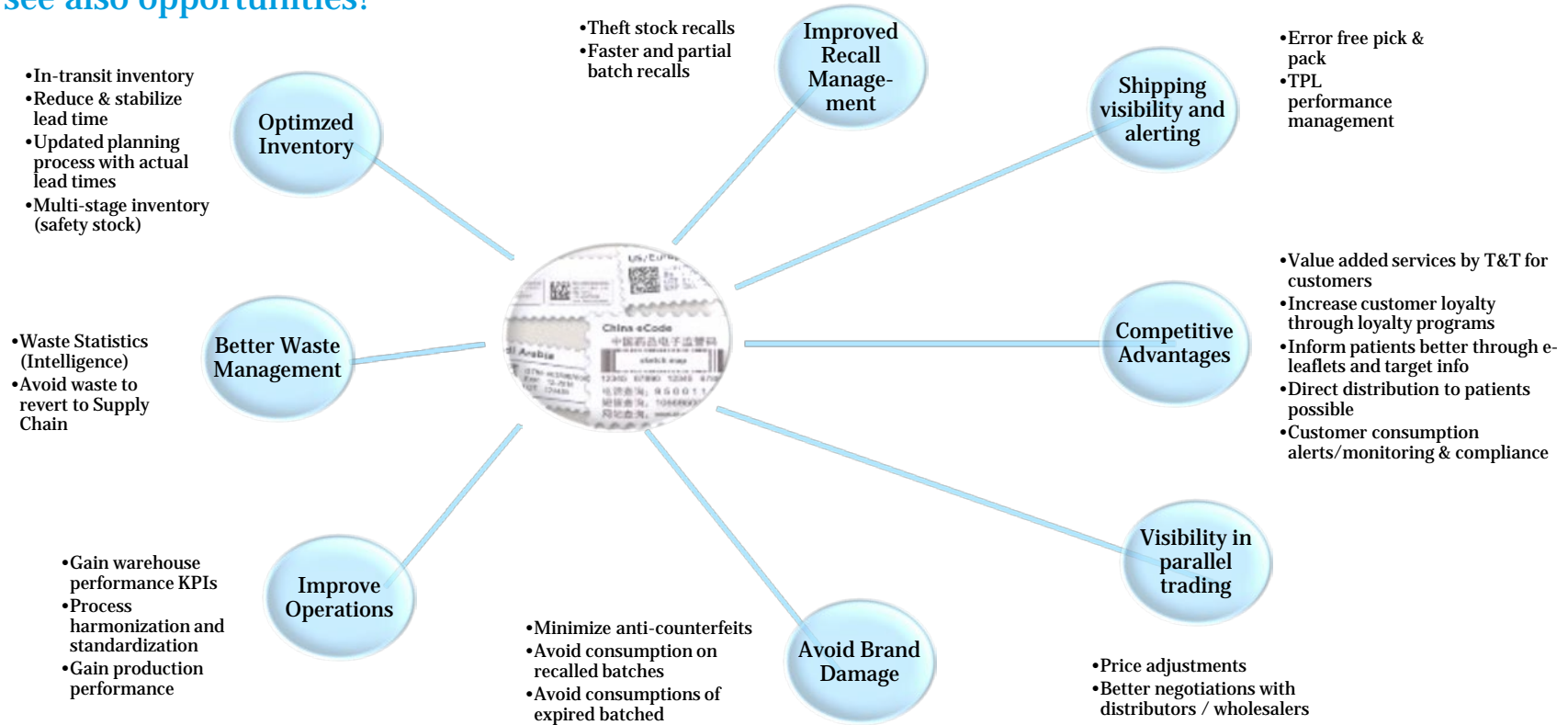
- **Centralized distribution of serial numbers**

The more we have non-standardized codes and centrally maintained serial numbers the higher the risk is for failures or data breaches

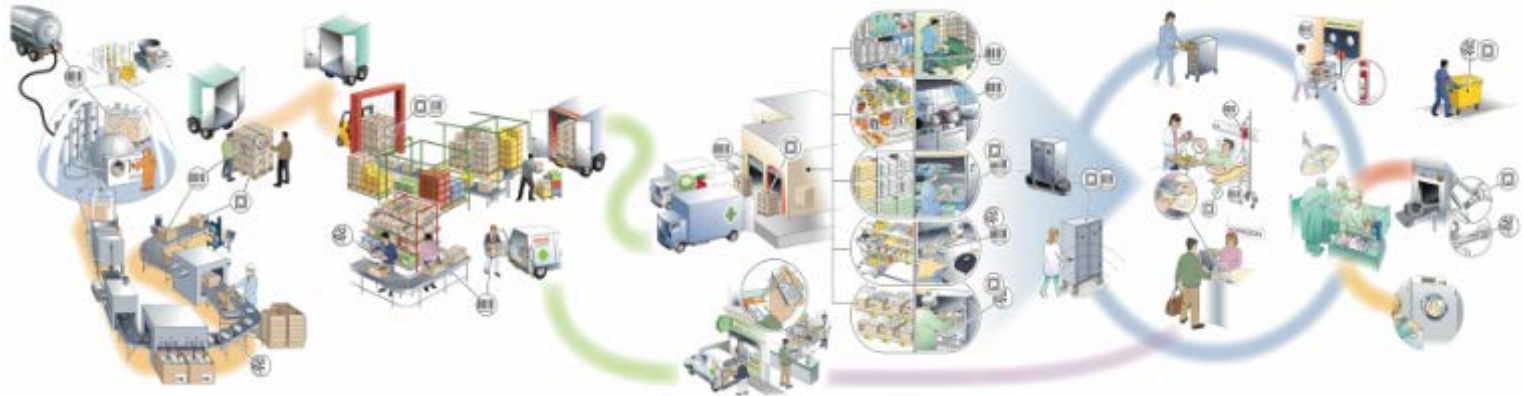


Serialization beyond Compliance –

We see also opportunities!



Global Standards are a Key Success Factor for Serialization and Traceability





Abbott

Global Standards and Data Sharing

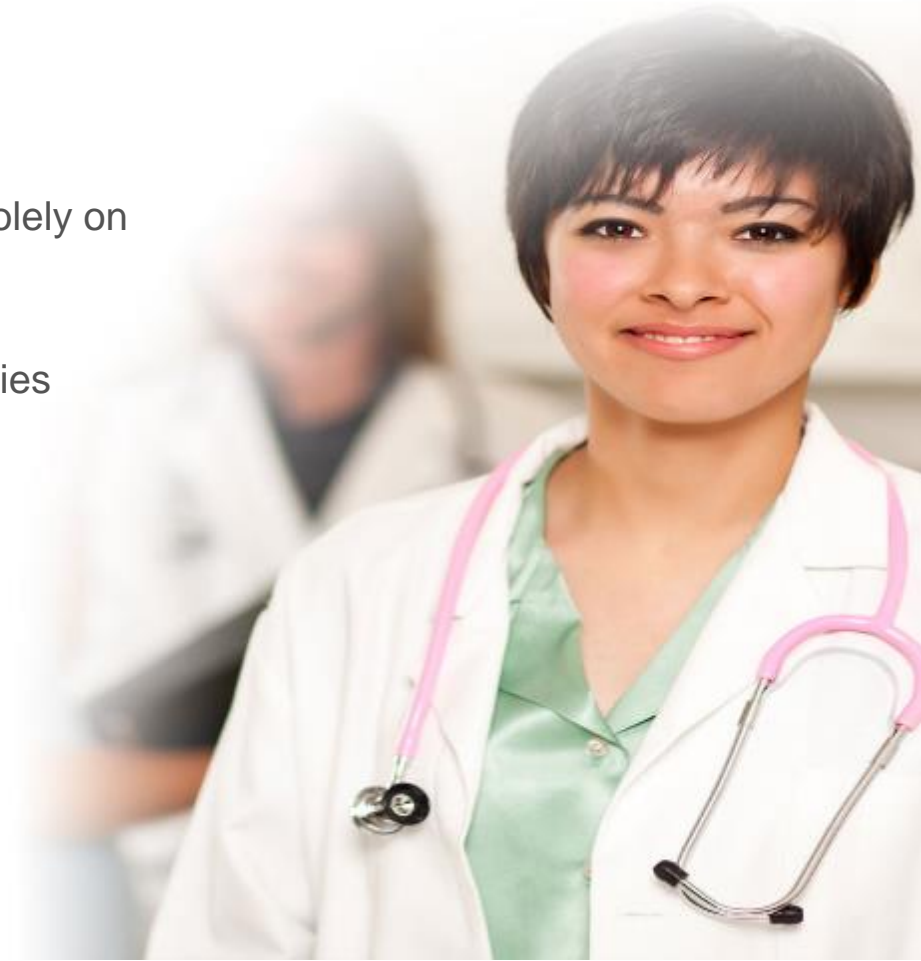
Implementing traceability using a global company perspective

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



我們的信條

我們相信我們對大眾的責任，是為病人、醫生、藥劑師、護士、母親和父親以及所有使用我們產品和服務的人。為了滿足他們的需求，我們必須不斷地提高我們的產品和服務質量。我們的目標是為他們提供最優質的醫療服務。我們必須不斷地提高我們的產品和服務質量。我們的目標是為他們提供最優質的醫療服務。

我們對員工的責任是確保他們在一個安全、健康、公平和尊嚴的環境中工作。我們必須尊重他們的權利和利益。我們必須提供公平的薪酬和福利。我們必須提供培訓和發展機會。我們必須提供一個安全的工作環境。我們必須尊重他們的權利和利益。我們必須提供公平的薪酬和福利。我們必須提供培訓和發展機會。我們必須提供一個安全的工作環境。

我們對社區的責任是成為一個負責任的公民。我們必須支持社區的發展和進步。我們必須遵守法律法規。我們必須保護環境。我們必須尊重社區的權利和利益。我們必須提供公平的薪酬和福利。我們必須提供培訓和發展機會。我們必須提供一個安全的工作環境。

最後，我們的責任是為股東創造價值。我們必須提高我們的盈利能力和增長潛力。我們必須提高我們的生產效率和競爭力。我們必須提高我們的產品和服務質量。我們必須提供公平的薪酬和福利。我們必須提供培訓和發展機會。我們必須提供一個安全的工作環境。

Unser Credo

Wir glauben an die Verantwortung gegenüber den Ärzten, den Krankenschwestern und den Patienten, den Müttern und Vätern und allen anderen, die unsere Produkte und Dienstleistungen nutzen. Um ihren Bedürfnissen gerecht zu werden, müssen wir die Qualität unserer Produkte und Dienstleistungen ständig verbessern. Unser Ziel ist es, ihnen die bestmögliche medizinische Versorgung zu bieten.

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 fulfil 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 responsible 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

Noosso Credo

Наше Кредо

Наша основная ответственность — врачам, медсестрам и пациентам, матерям и отцам и всем другим, кто использует наши продукты и услуги. Чтобы удовлетворить их потребности, мы должны постоянно улучшать качество наших продуктов и услуг. Наша цель — обеспечить им наилучшую медицинскую помощь. Мы должны постоянно стремиться к снижению затрат, чтобы поддерживать разумные цены. Заказы клиентов должны выполняться быстро и точно. Наши поставщики и дистрибуторы должны иметь возможность получить справедливую прибыль.

uestro Credo

Creemos que nuestra primera responsabilidad es con los médicos, enfermeras y padres y madres y todos los demás usuarios de nuestros productos y servicios. Para responder a sus necesidades, todo lo que hacemos debe ser de primera calidad. Nuestro objetivo es brindarles la mejor atención médica posible. Debemos constantemente reducir nuestros costos y mantener precios razonables. Los pedidos de los clientes deben ser atendidos rápidamente y con precisión. Nuestros proveedores deben obtener la oportunidad de conseguir una

razonable. Nuestros empleados de todo el mundo y sus familias deben sentirse seguros en sus trabajos. Cada uno de ellos debe tener un sentido de seguridad en su trabajo. Deben sentirse libres de hacer sugerencias y quejas. Deben haber igualdad de oportunidades para el empleo, desarrollo y avance para los calificados. Debemos proporcionar una gestión competente y sus acciones deben ser justas y éticas.

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



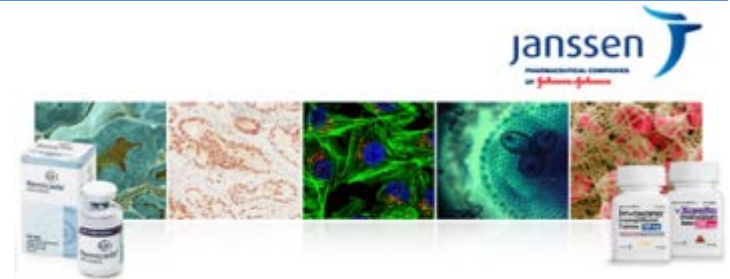
Medical Devices

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



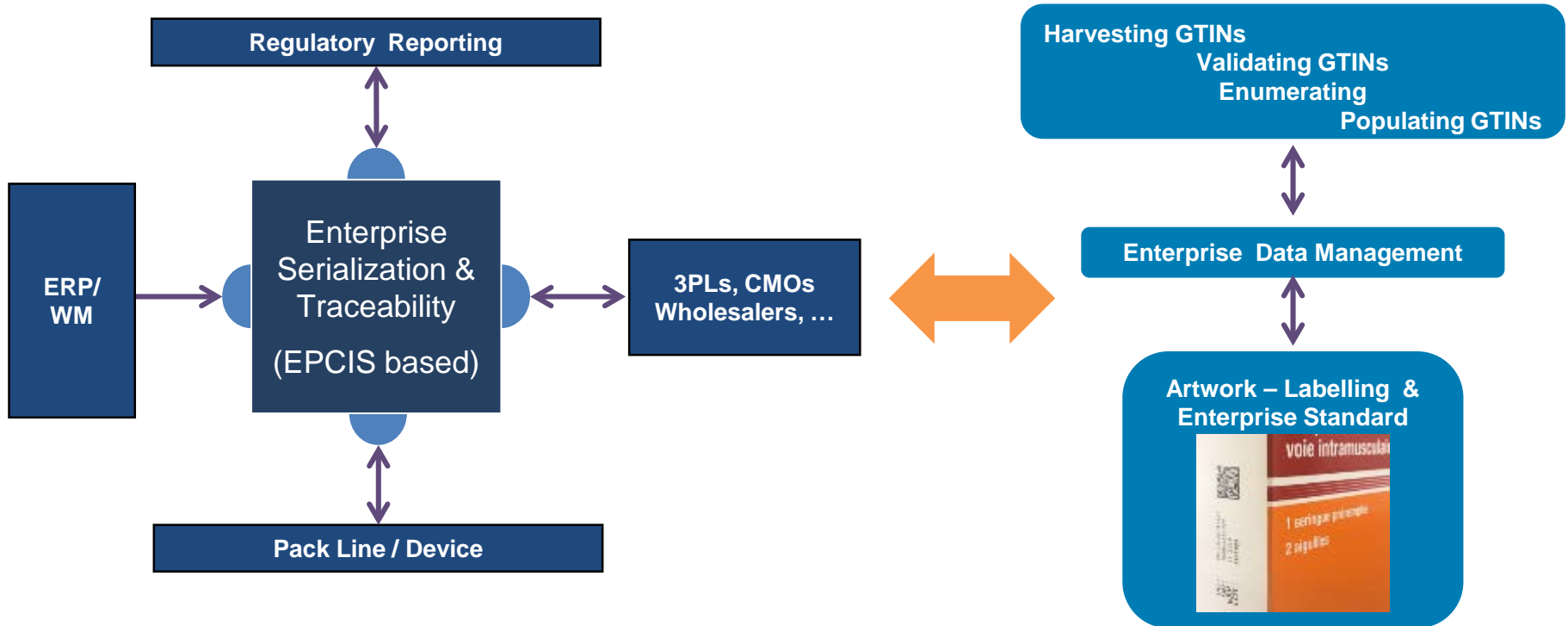
Pharmaceuticals

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



Traceability Entails an Integrated Systems & Processes Approach

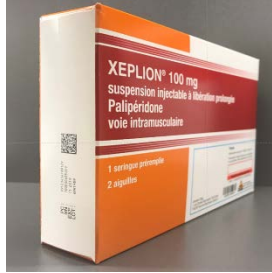
Enabled by GS1 Global Standards (GTIN, GLN, SSCC, EPCIS,...)



Using GS1 Standards to Uniquely Identify and Trace Products

Each product in the supply chain is assigned a globally unique identification number

GTIN A



GTIN B / SSCC



SSCC



12 serialized boxes in a case

261 cases to a pallet

complete

incomplete

GTIN	00359676562016
S/N	123456789012
EXP	12-2015
LOT	123456



PRODUCT INFORMATION

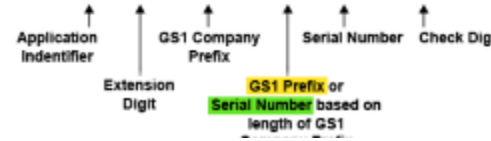
EXP: 11.2015 LOT: ABCDEFG QTY: 0012

(17) 151211 (10) ABCDEFG

(01) 10300123000015 (21) 123456789012



(00) 0 0123456 000000001 8



The **DataMatrix** shall contain the following information:

- (01) GTIN*: 14 characters, numeric
- (21) S/N: 12 characters, numeric, randomized
- (17) EXP*: 6 characters, numeric
- (10) LOT: max. 20 characters, alphanumeric

Different Patterns in Regulations Create a Patchwork

Result - extra complexity, development costs, implementation time and risk



Turning EC FMD Regulation into European Industry Standard

EFPIA recommendation for coding of pharmaceutical products in Europe

DataMatrix – Coding proposal derived from GS1 standards

Manufacturer Product Code (GTIN or NTIN): 14 digits

Unique Serial Number (randomized): up to 20 alpha-numeric characters

Expiry Date: 6 digits (YYMMDD)

Batch Number: up to 20 alpha-numeric characters

+ Minimum requirements on quality of randomisation



EEA License Plate Example:

PC: 012345667891283

SN: 123456789012

EXP: 12-2018

LOT 123456



(01) 012345667891283

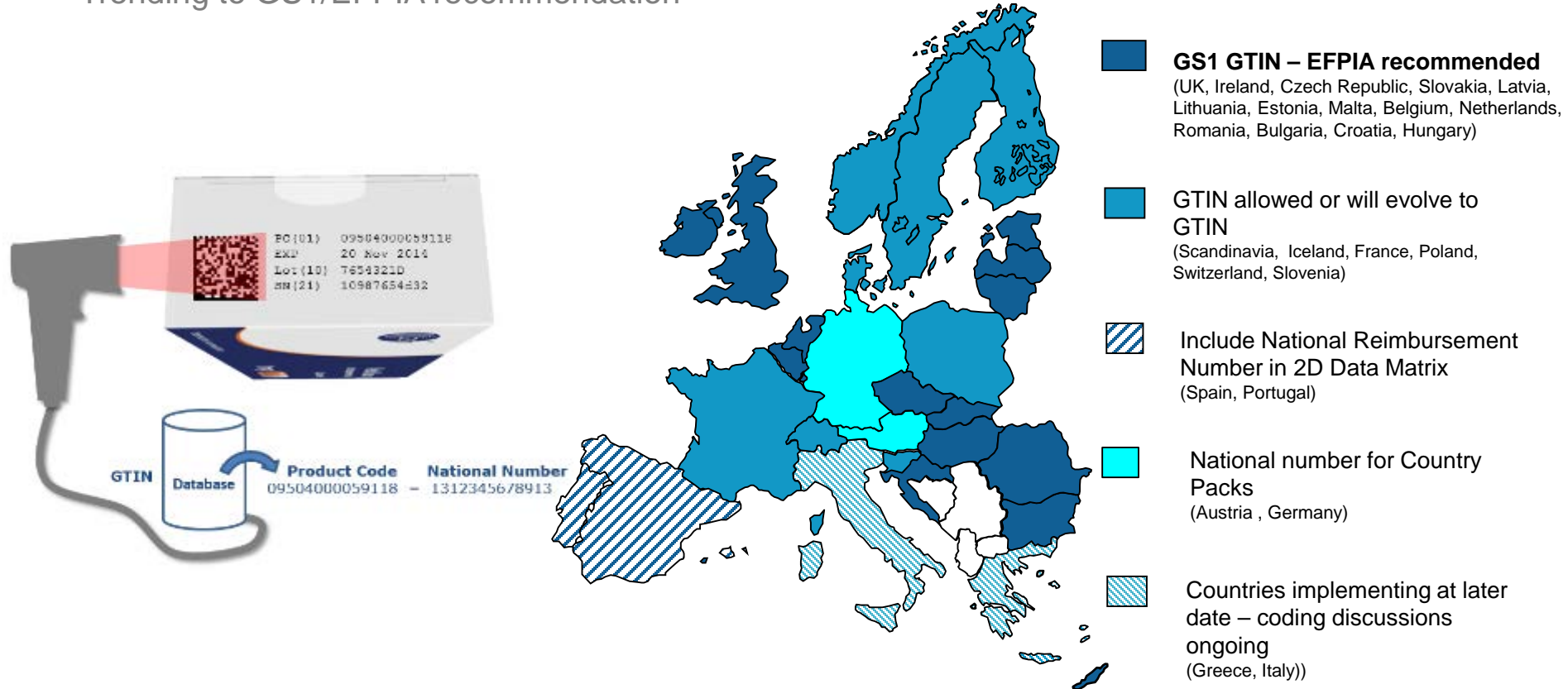
(21) 123456789012

(17) 122018

(10) 123456

Harmonizing Unique Identifier in European Economic Area

Trending to GS1/EFPIA recommendation



Standards for Improved IT Systems Communication

Opportunity connecting European verification system to SPOR (IDMP)



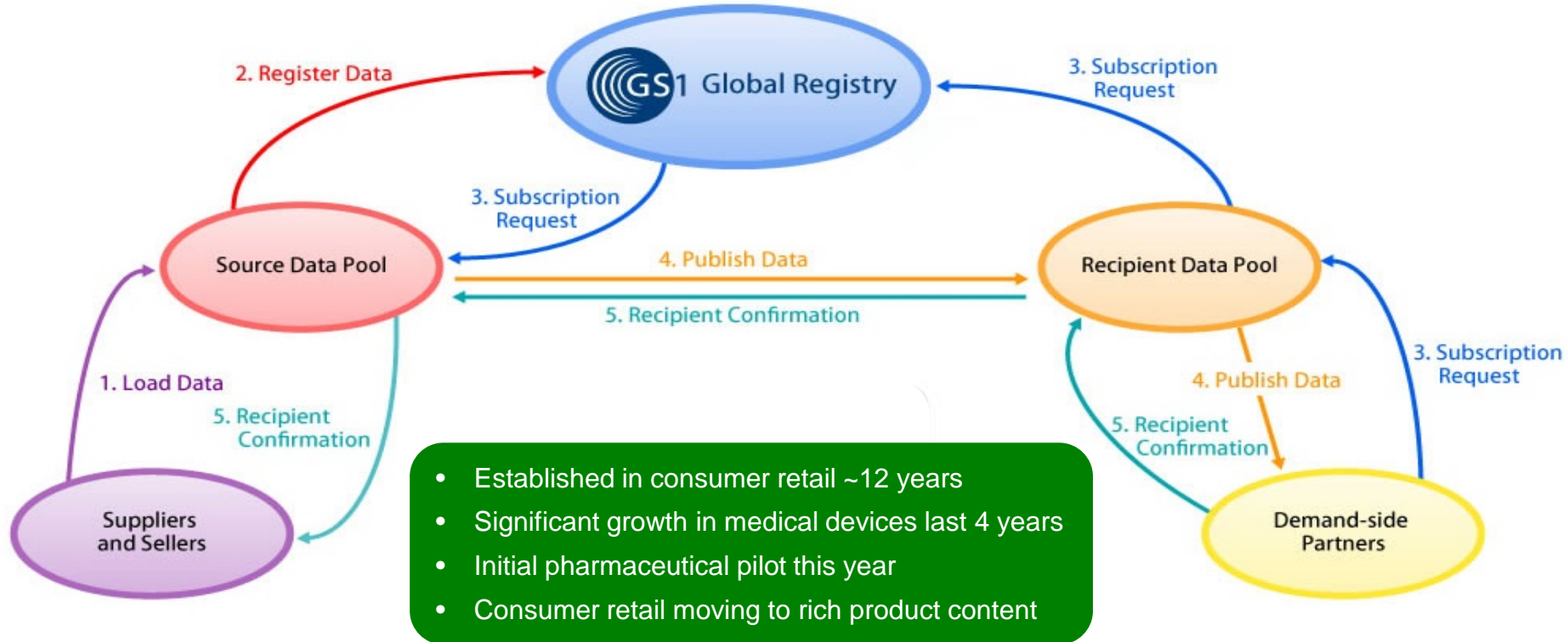
**GTIN =
Unique
Product
Identifier**



EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

Global Data Synchronization Network (GDSN)

Improving OTC and supply chain efficiencies by sharing our product content with our customers



GDSN - A Strength in Global Content Strategy

Collaboration between J&J and customers critical for getting data aligned & improving accuracy

- Treat product data as a highly-valued digital asset as we treat our products
- Publish and maintain accurate product data for customers across the globe – via GDSN
- Leverage standardized language of GS1
- Ensure conversion of physical data to electronic data
- Grow best practices across regions and segments
- Enabler of end-to-end connected visibility



Extend Learnings to Medical Devices and Pharmaceuticals

Involvement of stakeholders is the critical success factor

Supporting Medical Devices

- Several thousand GTINs
- Now in 25 countries – Significant growth in last few years

Preparing for Pharmaceuticals

- Working with GS1 Global and new Use Cases
- Current analysis to prepare Pharmaceutical data
- Pilots initiated in US and EU

Lessons Learned

- Collaboration with each hospital necessary
- Accurate data is imperative
- Continue to improve quality
- Understand business needs
- Start small and share learnings in quick cycles



Importance of Standards

The world is a global village, let's speak the same language



Internal Communication

- Multiple sectors
- Multiple regions
- Different ERP systems



External Communication

- Regulatory instances
- External manufacturers, distributors, 3 PLS
- Trade organisations, wholesalers, pharmacies



Avoiding Operational Complexity

- Manufacturing & distribution for different regulations
- External manufacturers producing for different Marketing Authorisation Holders



Mergers, Acquisitions & Divestitures

- Decrease transition complexity when adhering to standards



Interoperability

- One networked company IT system environment
- One IT development for each deviation
- Linking product codes reduces complexity

7 Billion Reasons to Care



GS1 Global Standards Will Benefit Patients and Consumers Everywhere

Discussion



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Additional information



Welcome to GS1
The Global Language of Business

Our standards in action

Improve call attendance

Reducing costs

Steering data

Bringing transparency

Regulatory information

Standards

Conferences & events

Support

Solution Provider

Healthcare

Retail

www.gs1.org/gdsn

www.gs1.org/healthcare



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