



The Global Language of Business

Panel I – Impact and issues around implementation of barcodes

ONE barcode, one product with two different GTIN, multiple barcodes, barcode quality, etc.

Tuesday, 26 March 2019

Noordwijk, Netherlands



ADENTS



The Global Language of Business



Connect to the Wi-Fi

The Global Language of Business

Network: GS1

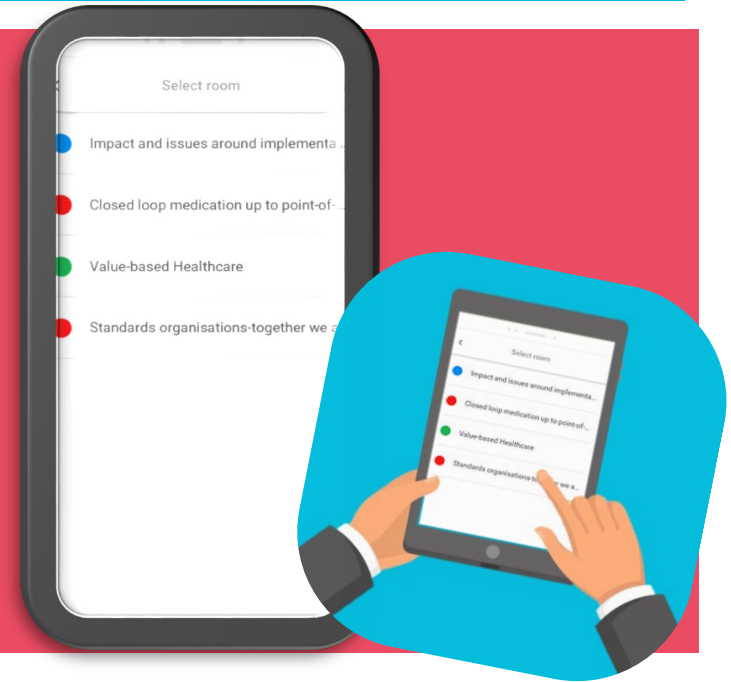
Password: Healthcare2019



You have a question ?



1. Go to [slido.com](https://www.slido.com)
 2. Enter **#GS1HCNoordwijk**
 3. Select the panel session you are in
 4. Go to "Questions"
 5. Enter your **FULL NAME**
- *if the questions you've raised are not selected, the GS1 team will follow up with you you!*
6. Post your questions



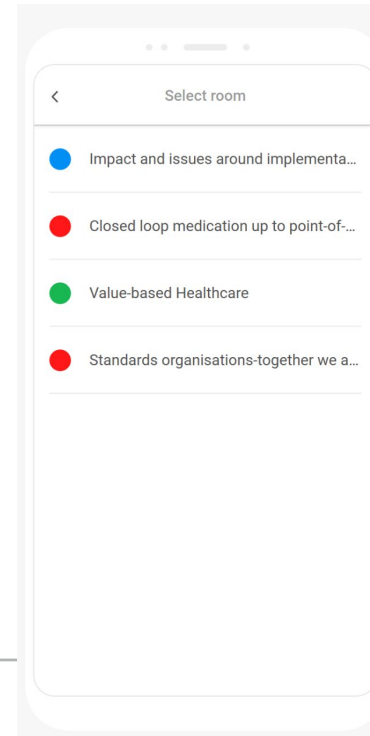
On your smartphone browser, type slido



Enter event number:
#GS1HCNoordwijk



Select the panel session you are in



Insert your contact




☰ Standards organisations-to... 👤

QUESTIONS POLLS

Ask the speaker

✓ Type your question




There are no questions asked yet.
Ask the first one!

sli.do Ask



← My profile

Basic info



👤 Your name

🏢 Your company

✉ Your email

SAVE

Privacy Preferences



Panelists



Greg Magrane,
eCommerce
Project Manager,
St. James's
Hospital, Dublin,
Ireland



Charity Hovey,
Regulatory
Affairs
Manager, 3M,
US



Tatjana Pathare,
Global Supply Chain
Management Team,
F. Hoffmann La
Roche Ltd,
Switzerland

St James's Hospital



- 60 Acre Campus, 52 separate buildings
- €440m annual spend
- 1,050 beds
- 25,000 IP Discharges
- 48,000 Day Cases
- 280,000 OPD
- Largest Academic Teaching Hospital in Ireland
- Focus on innovative projects
- Robotic Dispensers installed in Pharmacy 2017
- Electronic Patient Record (Go Live Oct 2018)



Evolution Of a Medical Campus, “Shared Vision”



MISA



Mercers Institute for Successful Ageing

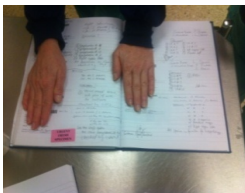


NCH

National Children's Hospital



Evolution of Supply Chain & Procurement at St. James's Hospital



1985 - 1995

- Manual Paper Purchase Orders.
- Price Takers
- Reactive practices
- Poor Quality information
- Pre-PC era
- Move to purpose built Warehouse



1995 – 2003

- Hospital wide computerisation project
- Supplies Department computerised in 1995
- Mainly purchasing and stock control
- Coding and classification system based on NSV



2004 - 2014

- Implementation of SAP, 2004.
- Standard business processes adopted
- Internal Supply Chain integration
- Wireless Kanban
- Supply Chain Management viewed as a strategic support .
- High outputs of reliable, accurate data.
- Started to incorporate GTIN Identifiers
- EDI Messaging



2016 – 2020

GS1 Standards Enabler for:

- Standardised Coding for all supply chain partners
- Full E-Procurement (EDI)
- Full track and Trace to Patient Episode

Passive

Independent

Supportive

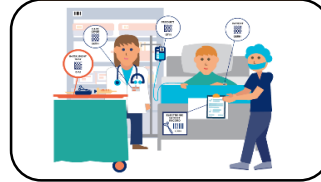
Integrative

Standardisation = Interoperability



On-Going GS1 Projects

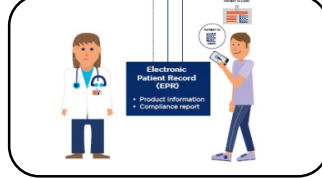
Instrument T&T



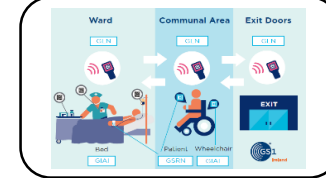
Scan4Surgery



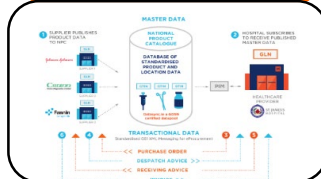
Haemophilia T&T



Automatic tracking (RFID)



eProcurement



SJH Healthcare Campus



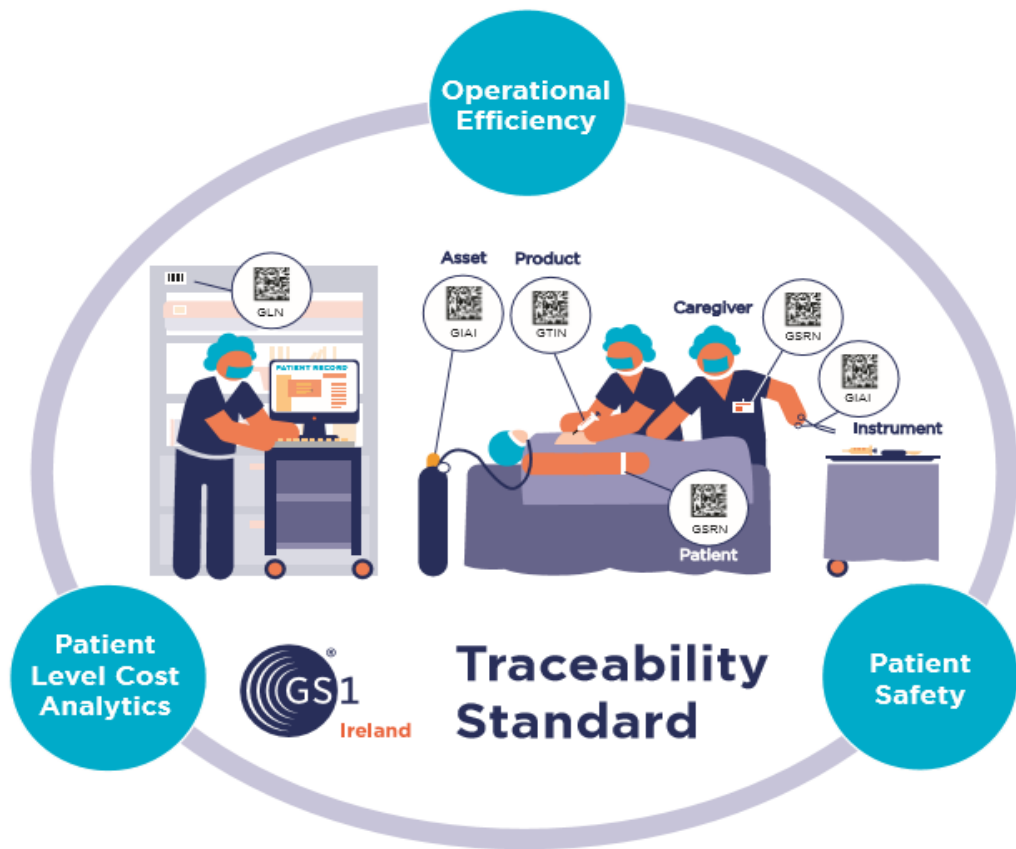
Others...



...implementing GS1 standards across the hospital campus
Supported by Regulation for medical devices and pharma

SCAN FOR SURGERY

Project Overview



Operational Efficiency

- Automation of supply chain processes for nursing
- Make additional time available to spend with patients
- Managed minimum inventory levels

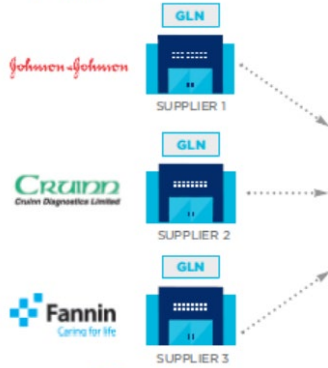
Patient Safety

- Product Traceability to individual patients
- Product Expiry Identification

Patient Level Cost Analytics

- Increased visibility of patient costs
- Improved data analytics for decision making

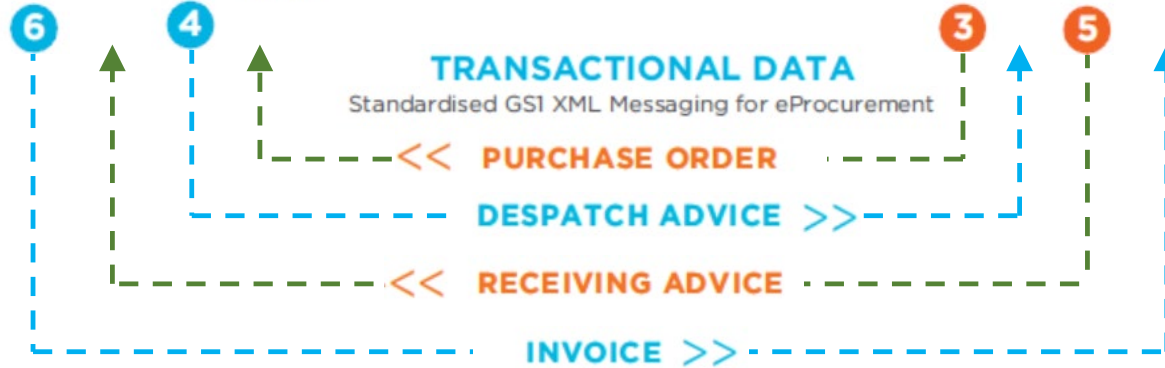
1 SUPPLIER PUBLISHES
PRODUCT DATA
TO NPC



MASTER DATA



2 HOSPITAL SUBSCRIBES
TO RECEIVE PUBLISHED
MASTER DATA



Electronic Purchase Order
to Invoice process
To: Supplier X - GLN
From: Hospital A - GLN
10 x Product Code - GTIN

SJH plans to send All Purchase Orders to Supplies via E-Procurement



Drivers for Standardisation

Obstacle

- Lack of standardised product identification (and unit of measure)
- Lack of standardised location identification
- Multiple product catalogues
- Inaccurate and inefficient procurement practices

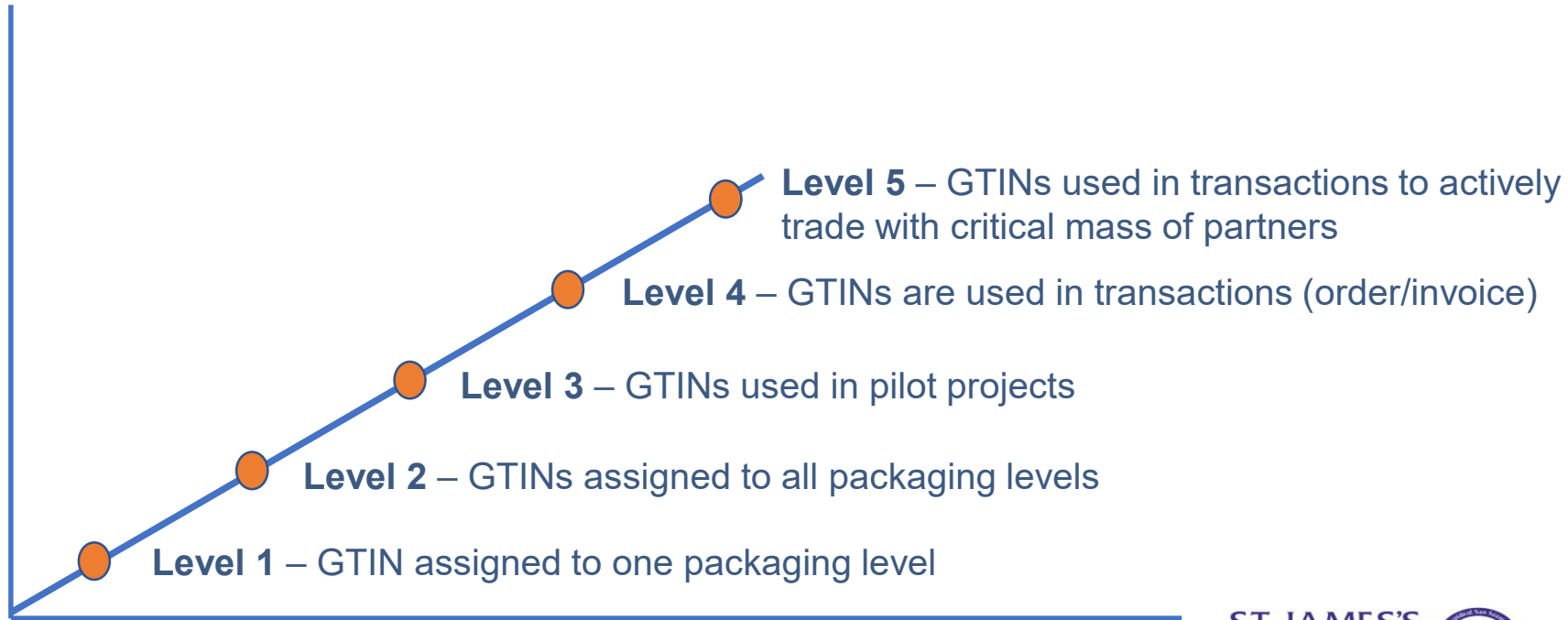


Solution

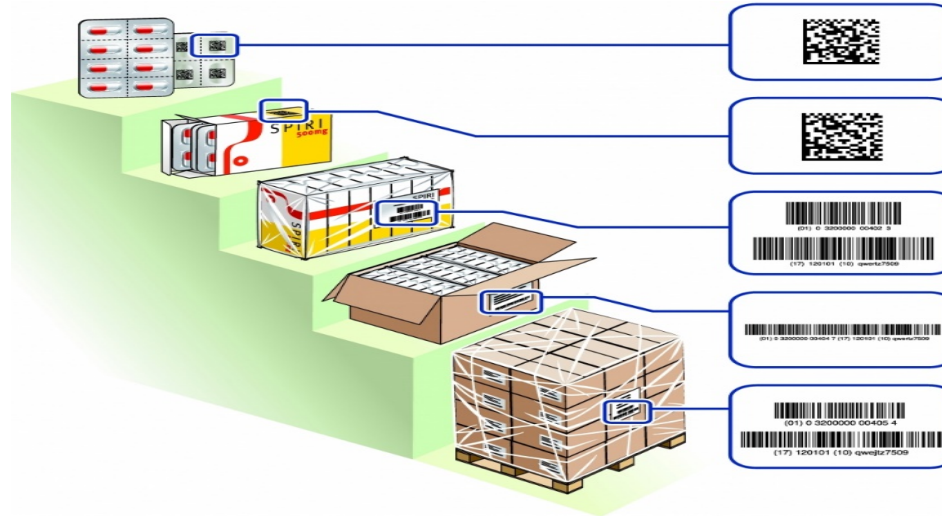
- Use GS1 Global Trade Identifier **GTIN**
- Use GS1 Global Location number **GLN**
 - Who we are, Who you are, Where to deliver
- Single Product Catalogue **NPC**
- Automated messaging using EDI that incorporate standard identifiers **GTIN, GLN**
 - **Purchase Order (Starting point)**
 - Advance Shipping Notice
 - Receiving Advice Notice
 - Invoice



GTIN Implementation Maturity



The Correct Association of the UOM is Crucial



The GTIN changes for each packaging level



Each

GTIN 1



Box/Case

GTIN 2

GTIN (01) 05391234560008
Expiry (17) 151231
Batch (10) 987654321ABCD
Serial (21) ABCD1234

All levels of packaging from the individual unit to the case should be regardless of whether it is sold commercially

The Reality of Healthcare

- If a Hospital was a supermarket your product would not appear on the shelves if it did not have the following
 - A GTIN
 - Traceability data
 - Pricing file as at the day of sale



First barcode to be
scanned in Retail in 1974



Il Buono, Il Brutto, Il Cattivo



The Good



Case/Cartron GTIN: (01)
04054596148703

4 boxes in a case, 50 eachs in a box



Box/Outer GTIN: (01) 04054596115422

Each/Inner GTIN: (01) 04054596059214

The Good



- Description is in 26 Languages
- GTIN is in 1 language (the universal language printed only once and can be scanned in every country.... and every Hospital)

The Not So Good

No barcode at any level



Barcode on outer, none on inner



The Very Confusing



- 5 Instances of same product
- 4 different GTINs

If retail can do it at the humblest level why can't we ?



Requested Key	
Code	GTIN
Value	05391519221655
GS1 Key Licensee	
Party Name	Cafe Sol Ltd
Address	
Company Name	Cafe Sol Ltd
Street Address	Head Office
Street Address 2	46 Lower Baggot Street
City	Dublin 2
Country Code	IE
County Code	Dublin 2



Key Learnings and Experiences

- Healthcare way behind retail
- Cross-Learning from experiences
- Development work – the first few steps are the hardest and take the most time
- GS1 partnership
- Co-Operation with other hospitals and healthcare organisations especially in UK (NHS and Trusts Demonstrator Sites Scan4Safety)
- Patience - it takes time to get connected to the right people in the Supplier organisations and to create awareness
- FDA/EU UDI regulation



Our request to you

- Make the commitment
- Assess Procure-to-Pay capabilities
- Commit resources
- Engage with the SJH project team
- Join GS1 if not already a member
- Publish product data (at all levels !)

Panel I: Implementation of barcodes

Charity Hovey

March 2019

3M at a glance*

- Sales in ~200 countries
- \$32.8 billion in sales
- Five business groups
- 93,000 3M employees globally
- \$1.8 billion invested in R&D
- 109,000+ patents
- >100 straight years of dividends
- One of 30 companies on the Dow Jones Industrial Index

*2018
figures

The 3M Carlton Science Center



3M vision

3M Technology Advancing Every Company

3M Products Enhancing Every Home

3M Innovation Improving Every Life

3M Health Care strategic intent

“Care pathway innovation for improved and cost effective health outcomes”



All external facing data needs
to match for customer &
regulatory requirements

- Label (all levels)
- IFU or Insert
- License, registration & DoC
- Website
- EDI transactions
- Sales orders/invoices
- Customs declarations
- Bill of Lading
- Customer syndication
- Regulatory data syndication

Business impact of mis-matched data



Delay at Customs



Customer Perception of Falsification



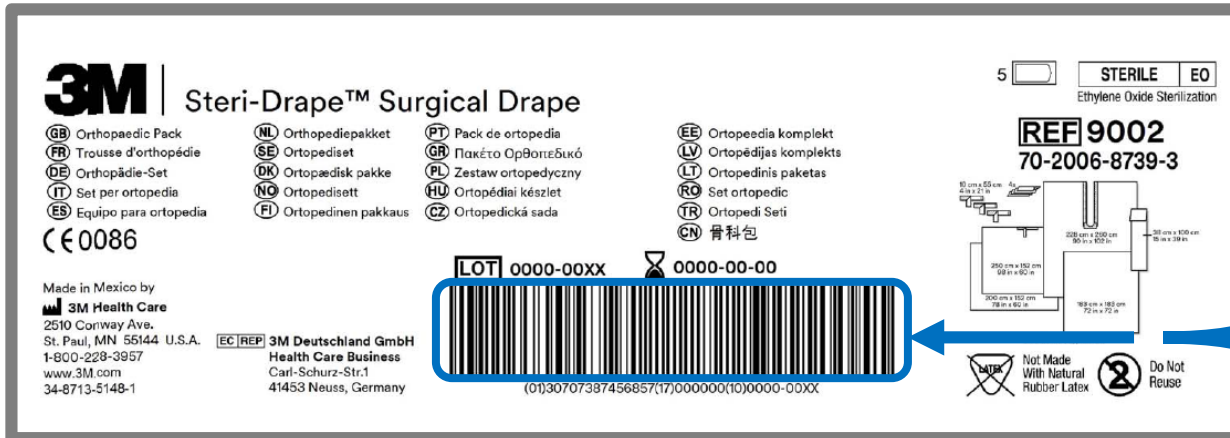
Delay in Getting Paid



Forced workaround at distributors & customers

Unique device identification (UDI)

UDI enables all of this data at customers' fingertips



Scan barcode

- Global trade item number
- Lot
- Expiration date
- Serial number
- Date of manufacture

Customers who pull UDI from GUDID, UTS, Eudamed, etc.

- Catalog
- Description
- Brand owner
- Single use only
- Latex
- Supplied sterile
- Customer sterilization method
- Clinically relevant sizes

Scan barcode at:

- Receiving to add inventory
- Surgical supply to allocate materials
- Bedside to access product safety data – **UDI databases**
- Bedside to enter data into electronic health record
- Central supply to access sterilization method – **Digital bridge**
- Central supply to return to inventory

Customers with 3M GDSN

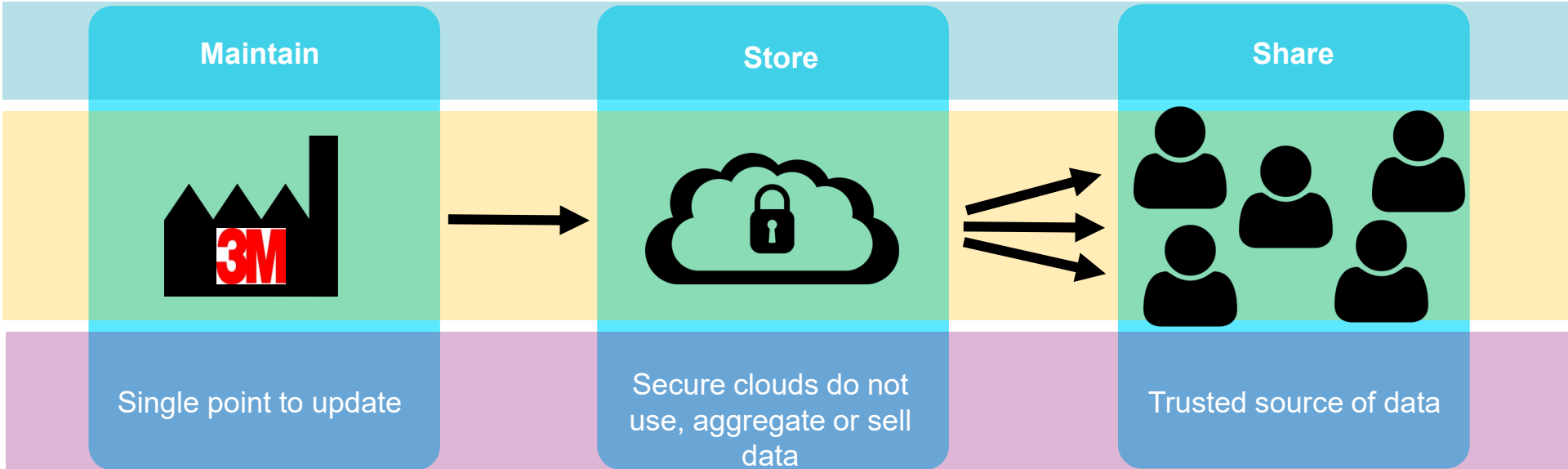
- Warnings
- Chemicals of concern
- Country of origin
- Length, width, depth, weight
- Minimum order quantity
- Lead time
- Truck load quantity
- Waste classification
- Post-consumer recycled content



Data sharing & data continuity

Syndication is the current business standard

Global Data Synchronization Network (GDSN) is the tool of choice



Customers and governments require data to be shared electronically and maintained current at all times

3M Data attributes requested

Supply Chain/eCommerce

- Stock keeping unit (3M SKU)
- Catalog
- Description
- GTIN/UPC
- Quantity
- Weight
- Length/width/depth
- Out of package dimensions
- Minimum order quantity
- Lead time
- Storage/handling temperature
- Brand owner
- Model/version
- Saleable unit, orderable unit, shippable unit
- UNSPSC
- Marketing features & benefits
- URL
- Product image or image link
- Equivalent product – GTIN/UPC

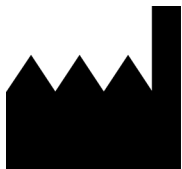
UDI Fields

- UDI issuing agency
- Product hierarchy
- Manufacturer per label
- HCBG address (GLN)
- Rx vs. over the counter
- Clinically relevant sizes
- Sterility status
- Sterilization method
- Single use only
- MRI compatibility
- Latex warning on label
- Global medical device nomenclature (GMDN)
- Product classification by country
- License/registration number
- Production controls – lot/serialization, date of manufacture, expiration date
- Human cells or tissues
- Drug reimbursement code
- European representative

Extended Attributes

- Materials of concern
 - Animal derived material
 - DEHP/phthalates
 - Latex containing
 - Carcinogen, mutagen, reproductive toxicant, endocrine disruptor
 - Bisphenol A & derivatives
 - Halogenated flame retardants
 - Nanomaterials
 - Ionizing radiation
 - PVC
- Sustainability
 - Post-consumer recycled content
 - Packaging recyclable
- Expanded regulatory attributes
 - Reprocessed, single use only
 - Limited number of reuse
 - Basic UDI-DI (family designation)
 - Critical warnings/contraindications
 - Country of origin
 - Shelf life
 - Calibration or maintenance required
 - Contains software
 - Contains batteries

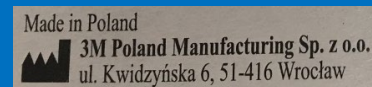
Why would a manufacturer ever have multiple GTINs for the same product?



Large multi-national companies make the same products at multiple locations

REF 9002
70-2006-8739-3

- May have same catalog code, but different company identifiers for different target markets
- Government or military contracts may require a certain country of origin
- Some products may be needed for emergency response and global supply pool is critical
- De-centralized companies have different legal entities for different locations



The data syndicated needs to match the product received

- A GTIN hierarchy can only have 1 legal manufacturer
- A GTIN hierarchy can only have 1 country of origin
- Not all business partners understand or have a place to store the “equivalent product” data provided

National Code considerations

NTIN requirements: May cause significant localization activities and delay critical medical treatments. Also, safety responsibility would transfer from legal manufacturer to local importer depending on the level of marking needed

Example - change to re-usable instruments

- Importer will need to obtain QMS certification as a manufacturer
- Importer will have to unpack sterile goods
- Add equipment at local re-packaging sites to laser etch, re-print or attach labels and tags
- Re-package
- Re-sterilize
- Over-label all other packaging
- Data syndication would be highly customized and may not be submitted by OEM due to changes in manufacturing responsibility



In 3M experience- over-labelled packaging can be perceived as counterfeit or less desirable by the customer

The background is a complex, abstract pattern of overlapping triangles and polygons in various shades of blue, ranging from light cyan to deep navy. The shapes are irregular and create a sense of depth and movement.

How do you manage all this data and these rules?

What is Data Governance?

Textbook Definition:

“Formalizing behavior around the **definition, production, and usage** of data to **manage risk** and **improve quality and usability** of data.”

Data Quality

- Quality Data is **trusted** and **reliable**.

- 1) Data Quality Rule Creation: **Declarative** statements the resolve to **True/False**, Pass/Fail

All dogs must be classified as Canines.

- 2) Data Quality can be **measured** and **repeated**.
- 3) Accessible to consumers in the form of a **scorecard** that is **accessible** and easy to **understand**.

Data Quality Maturity Curve



What it takes to build better data

3M UDI experience 2014-2018

- **Resources**

- Initiate: 1 project manager, 1 syndication associate, 3 person data collection & cleanse team, 129 participants from other functions (Master Data, R&D, Regulatory, Quality, Marketing, Packaging & Labeling, Microbiology, etc.)
- Maintain: 3 syndication associates, 1 health care governance team, 1 corporate governance team, and the entire company to maintain quality

- **Time**

- 6 months of project & data architecture planning, 2+ years of system development & enhancement
- 38 months of data collection & cleanse for 104 initial fields of approximately 17,000 SKUs
- Currently managing over 2 million attribute fields across several systems, to multiple governments/customers/websites/registries/distributors

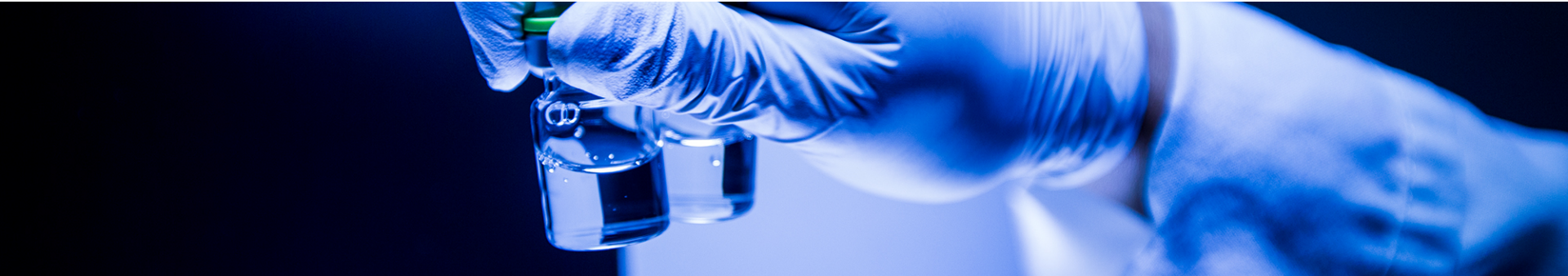
- **Change management + new attributes**

- Each new attribute takes between 3-6 months to: Set governance, collect & cleanse initial values, identify data partners, and syndicate
- Communication plan in place for eCommerce, regulatory and customer syndication, because many local 3M sites use the data beyond UDI now
- Every product & data change has to go through regulatory review for impact to syndicated data.

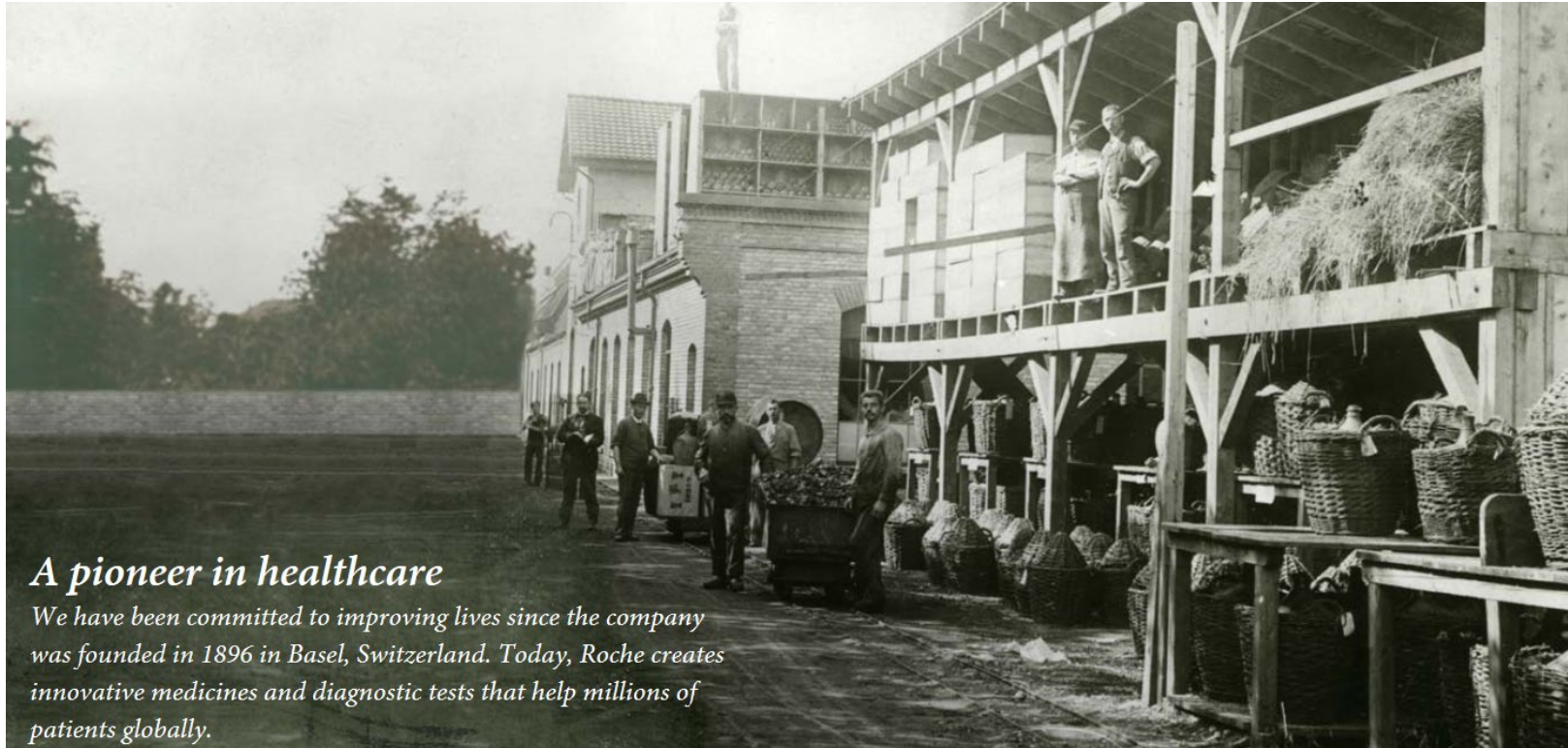
Impact and Issues around Implementation of Barcodes

Noordwijk/Amsterdam March 26, 2019

Tatjana Pathare



About F. Hoffmann-La Roche



A pioneer in healthcare

We have been committed to improving lives since the company was founded in 1896 in Basel, Switzerland. Today, Roche creates innovative medicines and diagnostic tests that help millions of patients globally.

About F. Hoffmann-La Roche

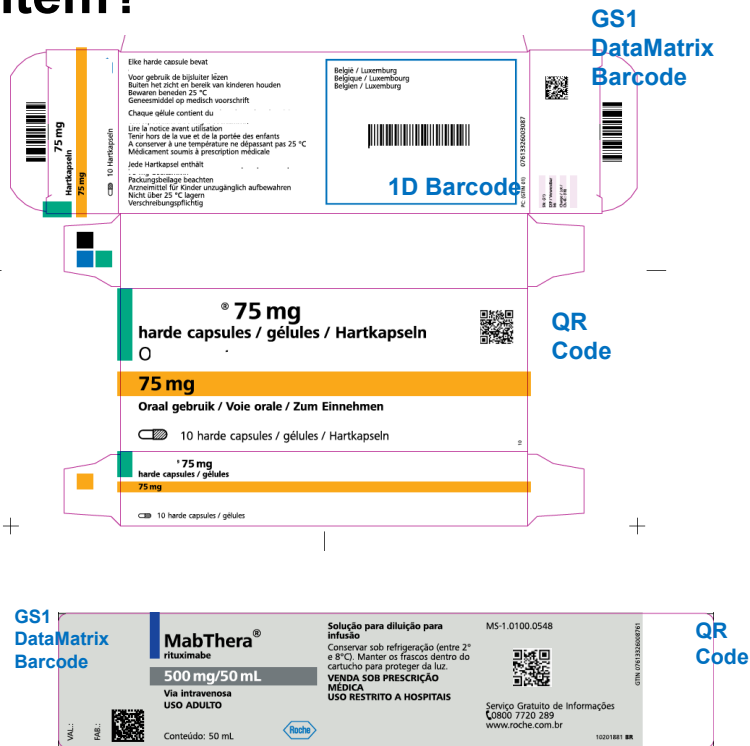


- Company headquarters are located in Basel, Switzerland
- In 1934, it became the first company to mass-produce synthetic Vitamin C, under the brand name Redoxon
- In 1957 it introduced the class of tranquilizers known as benzodiazepines – brand names Valium and Rohypnol
- To present date we manufacture several cancer drugs
- Today Roche ranks among the world's leading healthcare companies and has two strong core businesses: Diagnostics and Pharmaceuticals
- Frontrunner in personalised healthcare -With our combined strength in pharmaceuticals and diagnostics, we are better equipped than any other company to further drive personalised healthcare



Which barcode should I scan to get the relevant information on a single item?

Folding box

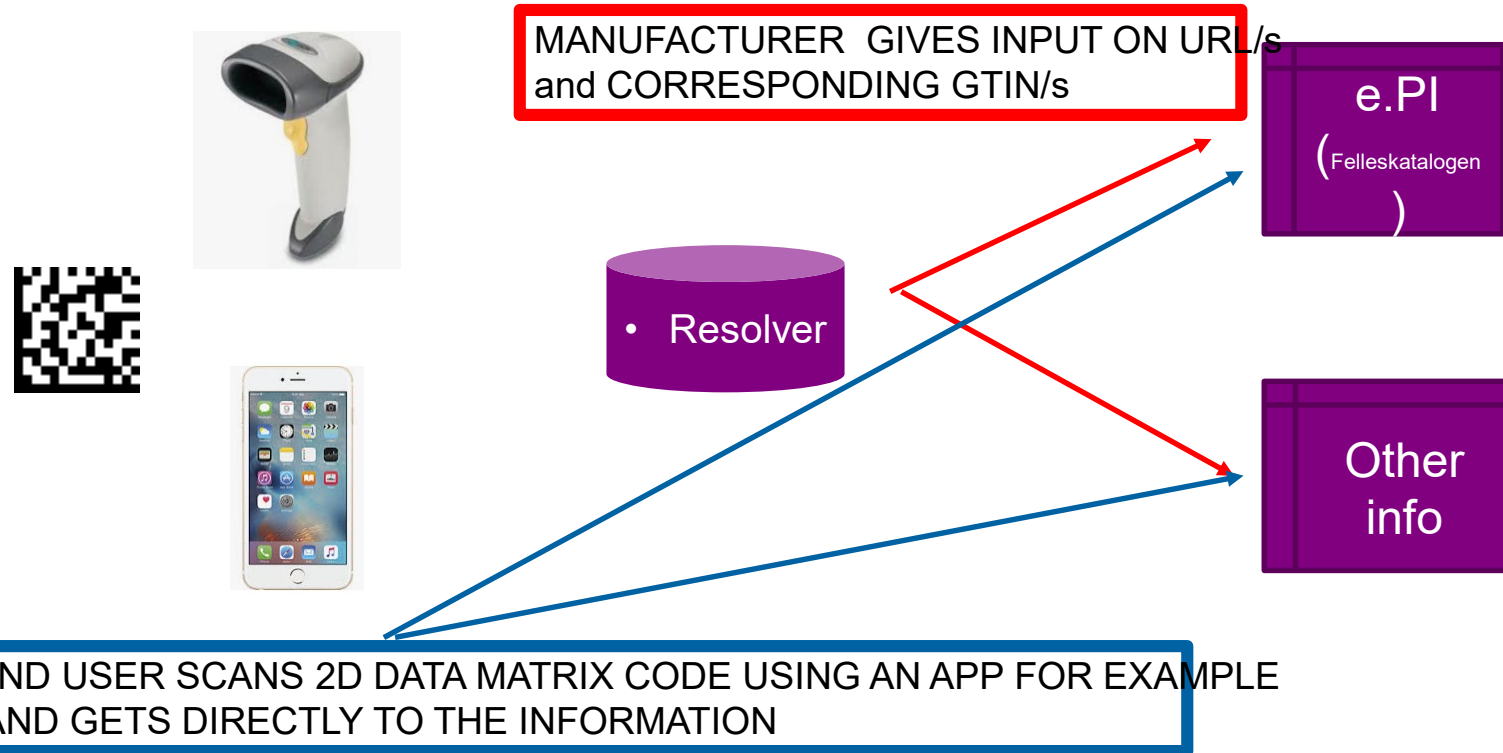


Vial label

Use the Digital Link !

GSI Healthcare has come up with a solution by providing a **Digital Link standard** to connect the **existing** GS1 DataMatrix barcode for more information **WITHOUT** adding a URL/URI in the barcode

Digital Link standard - How does it work?



The prototype GS1 resolver (id.gs1.org)

Item Description: ESBRIET FILM COATED TABLETS 267 MG 21

Resolver

Reference <https://id.gs1.org/> Global Trade Item Number / 07613326003872

URI:

Add Consumer Product Variant

Add Batch or Lot identifier

Add GTIN Serial Number

Resolver Destination Attributes for language ==> no - Norwegian (Norsk)

Attribute Name

Alternative Attribute Name

Response Destination URL

(gtin) <https://gs1.org/voc/bijsluiters>

Felleskatalogen

<https://www.felleskatalogen.no/medisin/pasienter/pil-esbriet-roche-640925>



WE need to address this now

As Regulators are already moving

EU – EC (European commission), EMA (European Medicines Agency) and HMA (Heads of Medicines Agencies) joint press release in January 2016 : a 6 –month public consultation on draft *‘Key Principles for the Electronic Product Information of EU medicines’*

Singapore - Singapore HAS (Health Science Authority) is working with SAPI (Singapore Association of Pharmaceutical Industries) on a draft guidance on e-labelling

Taiwan – Taiwan FDA 2019 prioritizing objectives, one of them being e-labeling

Patients and Healthcare providers asking for trusted electronic information

We should strive for a standard solution

What are we planning to do with the Digital Link standard ?

In the planning stage:

- Pilot in Belgium to link to a data base with eLeaflets for some medicines sold in Belgium and Luxembourg
- Pilot in Norway to link to a data base with eLeaflets for some medicines sold in Norway

.....And we can do more

- Add more features – info about recalls, adverse event reporting
- More proof of concept in other countries

**USE ONE BARCODE AND
USE THE DIGITAL LINK
STANDARD**

Discussion and Q&A



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Chain Management
Team, F. Hoffmann
La Roche Ltd,
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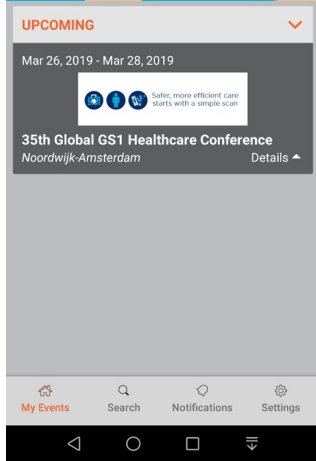


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4. Enter your email address (the same one used for conference registration)
5. Enter the password “GS1events” to log in.

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Safer, more efficient care starts with a simple scan



Activity Feed



My profile



Programme



My programme



Feedback forms



Speakers



Sponsors



Marketplace exhibitors



Practical information



Need any help? Contact us!



Look for the turquoise scarves and ties - we are happy to help you!



Poster Reception tonight



Join us at 17:30 –18:30 in **Bentley Bar**
Explore the world-wide healthcare success stories.





The Global Language of Business

COFFEE BREAK



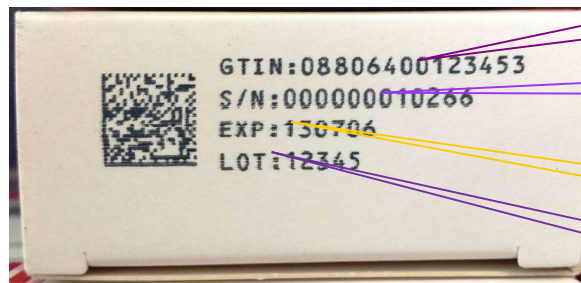
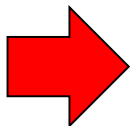
Additional supporting slides follow

*Doing now what patients
need next*

Disadvantages of having too many codes on the pack

- Takes up valuable space package and label space - smaller font size of text on folding box /label/blister foil cavity to fit in the different codes
- Multiple barcode symbols can lead to potentially confusion for the user

OUR AIM – use only **ONE barcode**



**Product Identifier
(GTIN)**

Serial Number

Expiry date

Lot/Batch number

Use the **existing** barcode so that the end users can use this code to get digital information

- **Linking** to verification as protection against counterfeiting
- **Linking** to information about the product (videos, audios, illustrations, texts...)
- **Linking** to electronic health records etc.
- **And more**

Example : Roche data for BE (a URL that directs the user to the product information)

Packaging Level	GTIN	User Language	URL of Target Data Content
Secondary	07613326002912	NL	https://www.e-compendium.be/nl/bijsluiters/patient/1220/1530
Secondary	07613326002912	FR	https://www.e-compendium.be/fr/bijsluiters/patient/1220/1530
Secondary	07613326002912	DE	https://www.e-compendium.be/de/bijsluiters/patient/1220/1530
Secondary	07613326002608	NL	https://www.e-compendium.be/nl/packungsbeilagen/patient/3570/3021
Secondary	07613326002608	FR	https://www.e-compendium.be/fr/packungsbeilagen/patient/3570/3021
Secondary	07613326002608	DE	https://www.e-compendium.be/de/packungsbeilagen/patient/3570/3021
Primary	07640128018216	NL	https://www.e-compendium.be/nl/bijsluiters/patient/1220/1530
Primary	07640128018216	FR	https://www.e-compendium.be/fr/bijsluiters/patient/1220/1530
Primary	07640128018216	DE	https://www.e-compendium.be/de/bijsluiters/patient/1220/1530
Primary	07640149612837	NL	https://www.e-compendium.be/nl/packungsbeilagen/patient/3570/3021
Primary	07640149612837	FR	https://www.e-compendium.be/fr/packungsbeilagen/patient/3570/3021
Primary	07640149612837	DE	https://www.e-compendium.be/de/packungsbeilagen/patient/3570/3021

What do you require?

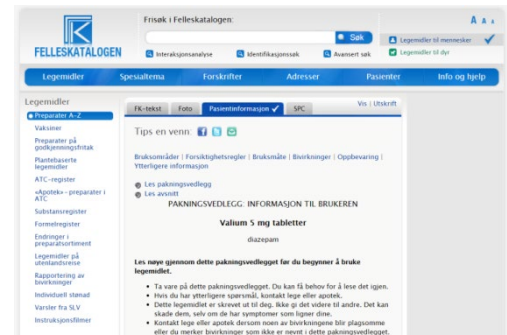
- An app to scan the 2D Data Matrix code (some countries have their own apps / some solution providers)



- GS1 Digital Link standard

- Database containing the information (e.g. e-compendium.be; felleskatalogen.no)

Packaging Level	GTIN	User Language	URL of Target Data Content
Secondary	07613326002912	NL	https://www.e-compendium.be/nl/bijsluiters/patient/1220/1530
Secondary	07613326002912	FR	https://www.e-compendium.be/fr/bijsluiters/patient/1220/1530
Secondary	07613326002912	DE	https://www.e-compendium.be/de/bijsluiters/patient/1220/1530
Secondary	07613326002608	NL	https://www.e-compendium.be/nl/packungsbeilagen/patient/3570/3021
Secondary	07613326002608	FR	https://www.e-compendium.be/fr/packungsbeilagen/patient/3570/3021
Secondary	07613326002608	DE	https://www.e-compendium.be/de/packungsbeilagen/patient/3570/3021
Primary	07640128018216	NL	https://www.e-compendium.be/nl/bijsluiters/patient/1220/1530
Primary	07640128018216	FR	https://www.e-compendium.be/fr/bijsluiters/patient/1220/1530
Primary	07640128018216	DE	https://www.e-compendium.be/de/bijsluiters/patient/1220/1530
Primary	07640149612837	NL	https://www.e-compendium.be/nl/packungsbeilagen/patient/3570/3021
Primary	07640149612837	FR	https://www.e-compendium.be/fr/packungsbeilagen/patient/3570/3021
Primary	07640149612837	DE	https://www.e-compendium.be/de/packungsbeilagen/patient/3570/3021



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need next*



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