The Global Language of Business

Panel – Improving patient care with single unit identification

34th GS1 Global Healthcare Conference
Bangkok, Thailand

The Global Language of Business

Sebastien Langlois-Berthelot, Pharma Global Technical Operations Supply Chain Project Management, F. Hoffmann-La Roche Ltd, Switzerland

Vicki Ibrahim, Senior Clinical Reference Lead, Clinical Strategy, Clinical & Consumer Engagement & Clinical Governance, Australian Digital Health Agency, Australia

Dr. Guadalupe Fernández Porto, Pharmaceutical Director at the IADT - Argentine Institute of Diagnosis and Treatment, Argentina

Pascal Aulagnet, Senior Manager, Business Technology, Pfizer Inc., France

October 30, 2018

Improving patient care with single unit identification

Vicki Ibrahim
Consultant Pharmacist

30 October 2018
Bangkok, Thailand

Global Patient Safety Challenge

Medication errors occur when weak medication systems and/or human factors such as fatigue, poor environmental conditions or staff shortages affect prescribing, transcribing, dispensing, administration and monitoring practices, which can then result in severe harm, disability and even death.

Unsafe medication practices and medication errors are a leading cause of avoidable harm in health care systems across the world

Worldwide, medication errors cost an estimated US$42 billion annually

This is 0.7% of the total global health expenditure

Errors occur most frequently during administration, however there are risks at different stages of the medication process.

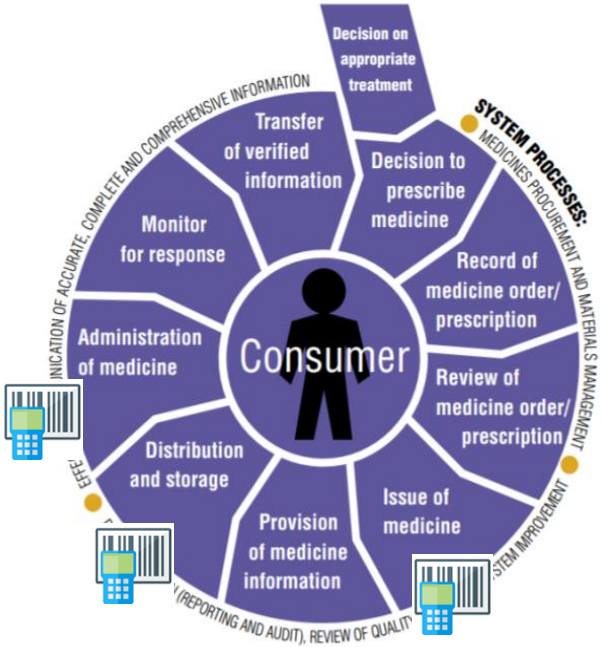
MEDICATION WITHOUT HARM
Global Patient Safety Challenge

KNOW
CHECK
ASK

World Health Organization

Medication Errors

Figure 1: Medication management process



Source: APAC 2005[2]

Of **serious** medication errors, about :
1/3 occur at the ordering stage
1/3 occur during the transcription and dispensing stages,
1/3 occur during medication administration

Medication errors resulting in preventable adverse drug events (ADEs) occurred most often at the stages of prescribing (56%) and administration (34%)

One study identified 6.5 adverse events relating to medication use per 100 inpatient admissions; more than 25% of these events were the result of errors and were thought to be preventable

Bainbridge M, Askew D. Barcoding and other scanning technologies to improve medication safety in hospitals. Sydney: ACSQHC; 2017

Technology Enabled Medication Identification

Last Line of Defence

Nearly 50% of medication errors originating from prescriber's orders are intercepted before they reach the patient; however only 2% of nursing medication errors are preventable

Technological Safety Net

Technology enabled patient and medication identification can decrease the frequency of medication administration errors

Safer Medication Management

Can be used from medication ordering to dispensing and administration to address the 'five rights' of medication safety

Workflow Integration

Facilitates error reduction by introducing workflow blocks

Scanning Technology in Closed-Loop Medication Management

1. **Pharmacy stock control and dispensing**

Prerequisite:

Barcode on package

Prevents selection of wrong medication

2. **Medication administration**

Prerequisites:

Barcode on package

Patient ID on wristband

Unit dose dispensing & administration

Mitigates:

- Wrong patient
- Wrong medication
- Wrong time

3. **Closed-loop medication management**

Prerequisites:

Barcode on package

Patient ID on wristband

Unit dose dispensing & administration

CPOE

Automation

Mitigates:

- Wrong patient
- Wrong medication
- Wrong time
- Wrong dose

Technology Enabled Medication Identification: Literature Review

Effect of BCMA on Medication Errors

Medication Error Type and Study	Error Rate: Before Implementation	Error Rate: After Implementation	RRR (%)	*p* Value
Administration errors: timing				
Poon et al.[10]	16.7% (1126/6723)	12.2% (891/7318)	−27.3	0.001
Administration errors: nontiming				
Poon et al.[10]	11.5% (776/6723)	6.8% (495/7318)	−41.4	< 0.001
Franklin et al.[12*]	7.0% (103/1473)	4.3% (49/1149)	−39.0	0.005
Helmons et al.[11] (medical and surgical units)	8.0% (71/888)	3.4% (24/697)	−56.9	< 0.0001
Helmons et al.[11](ICU)	11.0% (41/374)	9.9% (39/394)	−10.0	NSS
Transcription errors				
Poon et al.[10]	6.1% (110/1799)	0 (completely eliminated)	−100	Not calculated[†]
All types of medication errors				
Richardson et al.[14]	2.89 errors per 10 000 doses (% not reported)	1.48 errors per 10 000 doses (% not reported)	−48.8	Not calculated

BCMA led to decreased time on medication administration and increased time on direct patient care in ICU

Medication errors ↓58%, but timing errors did not change significantly

Journal of Health Care Quality sites

> Transcription errors ↓ from 6.1 errors/100 orders to 0 errors/100 orders

> Wrong medication ↓ 57.4%

> Wrong dose ↓41.9%

> Improper documentation ↓ 80.3%

NEJM 2010

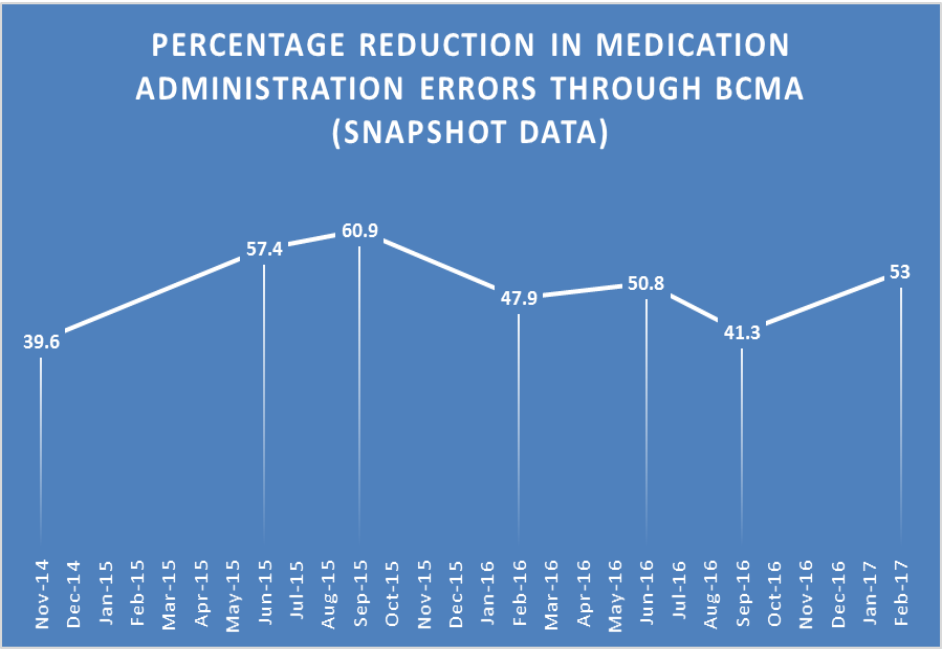
12,459 medication errors avoided per month

4 serious ADEs per 1,000 errors prevented

Sentara Health System (HIMMS Stage 7)

Shah, K., Lo, C., Babich, M., Tsao, N. W., & Bansback, N. J. (2016). Bar Code Medication Administration Technology: A Systematic Review of Impact on Patient Safety When Used with Computerized Prescriber Order Entry and Automated Dispensing Devices. *The Canadian Journal of Hospital Pharmacy*, *69*(5), 394–402.

Australia: St Stephen's Hervey Bay Hospital



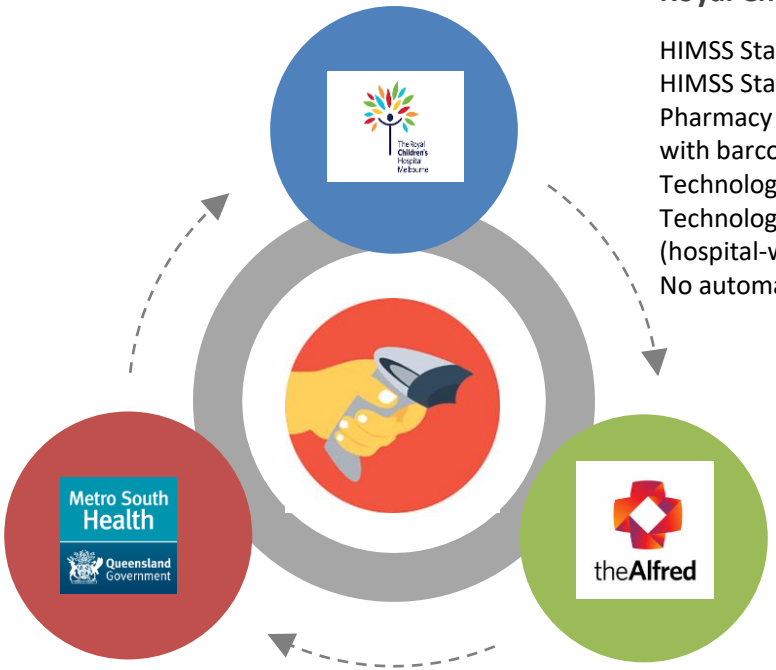
HIMSS EMRAM Stage 6 , Dec 2014
HIMSS EMRAM Stage 7, Nov 2018

Near Miss/Medication Error	(n=38) Number (%)	Examples
Wrong Drug/Wrong Patient	24 (63%)	• Patient prescribed Sinemet 250/25mg tabs – Madopar Rapid 50/12.5mg scanned • Patient prescribed candesartan 8mg tabs – candesartan/hydrochlorothiazide 16/12.5mg tabs scanned • Patient prescribed Panadol Osteo – Panadeine scanned • Patient prescribed Ostelin D with Calcium – Ostelin D scanned • Patient prescribed temazepam 10mg – diazepam 2mg scanned • Warfarin scanned – patient not prescribed
Wrong Strength	8 (21%)	• Seretide 250/25 MDI prescribed – Seretide 250/50 Accuhaler scanned • Symbicort Rapihaler 100/3 prescribed – Symbicort 400/12 Turbuhaler scanned • Magnesium 500mg tabs prescribed – Magnesium 750mg scanned
Wrong Time	4 (11%)	• Patient received paracetamol dose 2hrs prior • Venlafaxine due in the morning – scanned in the evening • Celecoxib order scanned – preop order only
Wrong Route	1 (3%)	• Patient prescribed metoclopramide 10mg PO – IV amp scanned
Duplicate Dose	1 (3%)	• Patient received dinner dose of metformin-saxagliptin – medication scanned again on evening round

Australia: Early Adopters

MONASHHEART
MonashHealth

A new, art of state hospital to open in 2022
Plan to implement Close Loop Medication Management Model supported by automation



Royal Children Hospital, Melbourne

HIMSS Stage 6 EMRAM & Outpatient, May 2017
HIMSS Stag 7, EMRAM Outpatient
Pharmacy manually barcoding medications, i.e. labels with barcodes are generated on dispensing
Technology enabled patient identification 100%
Technology enabled medications identification 57.5% (hospital-wide)
No automation

Princess Alexandra Hospital, Brisbane

HIMSS EMRAM Stage 6, May 2017
Technology enabled patient identification >90%
Technology enabled medication identification <1%
No automation
Pharmacy workflows do not support medication barcoding

The Alfred Hospital, Melbourne

Go Live October 2018
CareaAware backwards scanning
NPC and GTINs- ongoing maintenance
Use of commercially available barcodes on imprest medications (approx. 80%)
Pharmacy manually barcoding medications dispensed to patients (approx. 20%)
Pockets of automation

Unit Dosage Packaging in Australia

- Medications packaged in unit dose format are NOT readily available for use in Australia
- Not all commercially available medicines can be packaged in unit doses
- Limitations of unit dosage packaging equipment available in Australia
- Outsourcing to packaging facilities is cost-prohibitive
- Regulatory considerations

Assumed benefits

01

Inventory Management

Reduced wastage of medications

02

Inventory Management

Reduced pharmaceutical imprest expenditure

03

Medication Safety

Medication dose remains identifiable
Minimises reliance on product selection by package presentation (colour/size etc.).

Considerations for Implementation of Unit Dose

1. Standardisation, terminology and interoperability
2. Hardware, software, wireless network
3. Clinician engagement
4. Workflows considerations
5. Repackaging: hospital based vs industry/wholesaler
6. One dimensional or two-dimensional barcodes

This barcode is actually a hyperlink to a medication information leaflet!

POVIDONE-IODINE 7.5% (15mL) MOUTHWASH (BETADINE SORE THROAT GARGLE) 1 0xRpt
Dilute 1mL to 20mL with water using the measure provided and gargle for 30 seconds. Gargle SIX hourly.

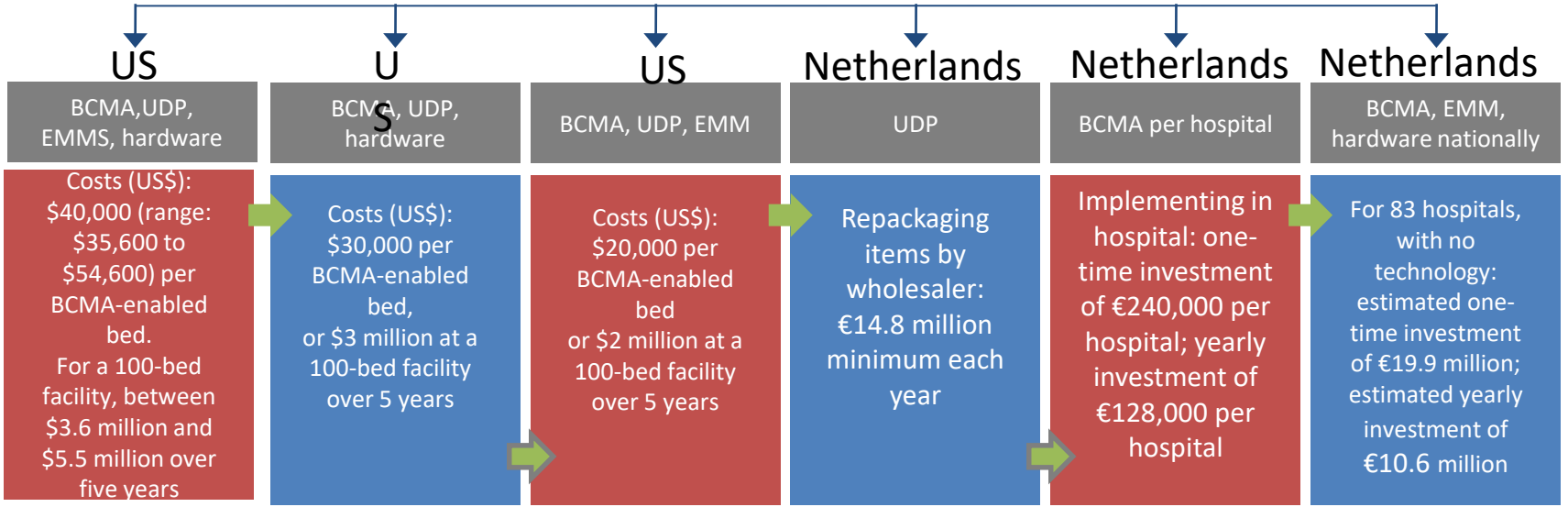
KEEP OUT OF REACH OF CHILDREN ERI
ST STEPHEN'S HERVEY BAY HOSPITAL
1 MEDICAL PLACE, URRAWEEN 4655. TEL: (07) 4120 6140
A Uniting Care Health Pharmacy

This barcode is only for use within Pharmacy. It will NOT read correctly at the bedside!

Scan here

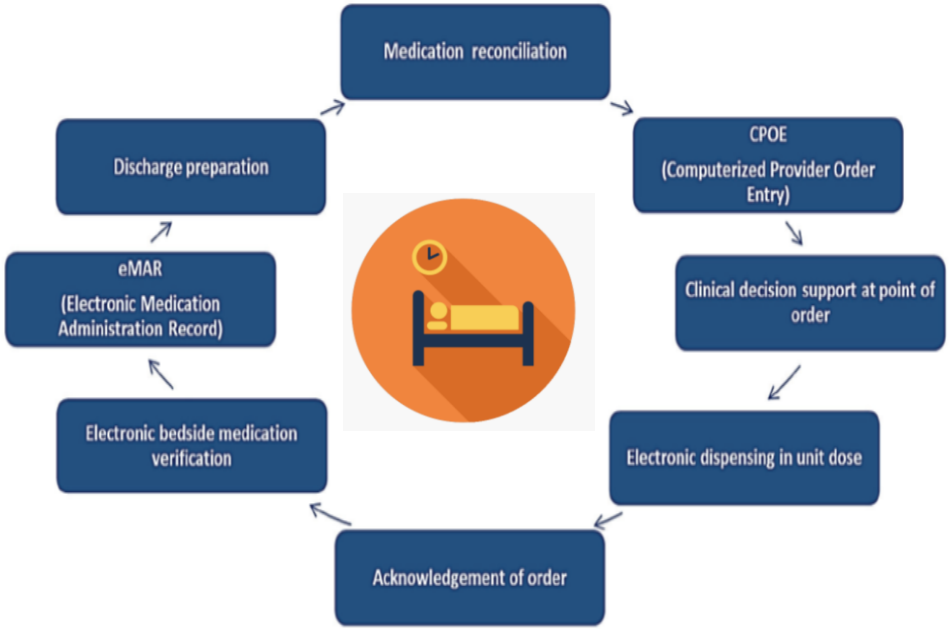
Do **NOT** scan here
Cover this barcode with your thumb

Unit Dose Packaging: Cost vs Benefit



A positive financial return on investment for the hospital:
the net benefit after five years was US$3.49 million, and the break-even point occurred within one year of the system becoming fully operational (Maviglia et al, 2007)

Improving Patient Safety with Technology Solutions



Investment vs Opportunity

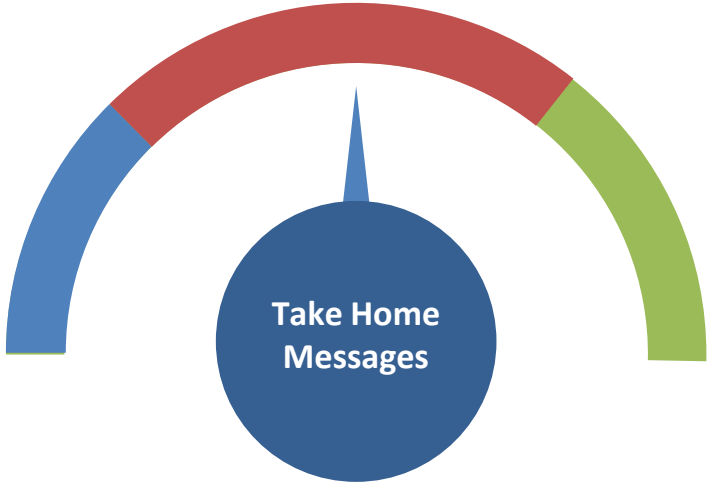
Significant investment for health services yet it also presents a major opportunity to improve the quality, safety and efficiency of patient care

- the effectiveness of the system in preventing medication errors could have a large effect on the cost-effectiveness
- the opportunity to prevent errors depends on the number and type of medication doses administered, and the potential for harm if an error does
- commercial availability of unit dose identification will facilitate implementation and adoption

In Summary

Advocacy for global standards that uniquely identify patients, processes, healthcare providers, administered products, medications, blood, human milk

Medications save lives but they can also cause harm



BCMA prevents medication errors but implementation can be challenging

The Global Language of Business

IMPROVING PATIENT CARE WITH SINGLE DOSE UNIT IDENTIFICATION

HOSPITAL PHARMACY PERSPECTIVE

Dra. Guadalupe Fernández Porto, IADT – Buenos Aires, Argentina.

34th Global GS1 Healthcare Conference – Bangkok 2018

AT THE SUPERMARKET

EAN13

2 012345 012349

AT THE HOSPITAL PHARMACY

DIFFERENT CODES

EAN13

2 012345 012349

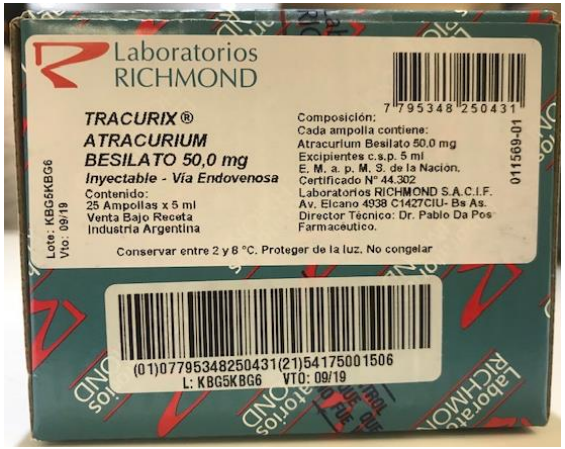
GS1 DataMatrix

GS1-128

(00) 3 9501100 000001001 9

NO CODE

DIFFERENT CODE HAVE DIFFERENT ENCODED INFORMATION



😐

EAN 13: GTIN

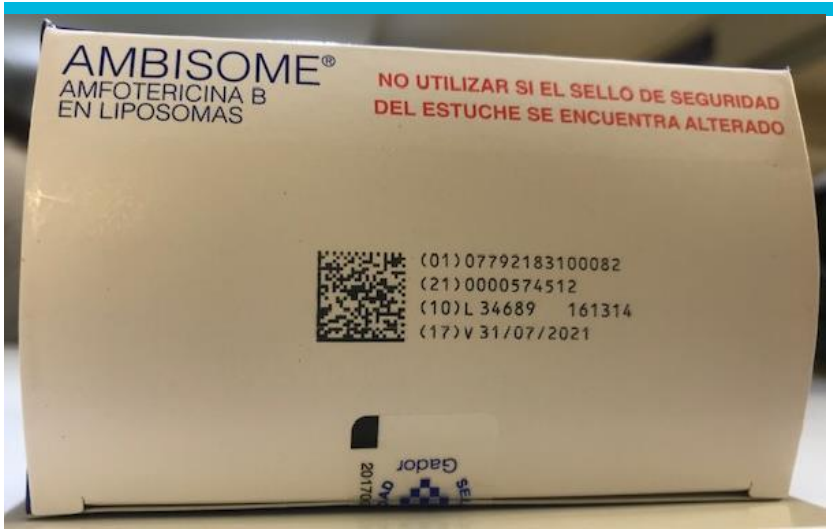
Additional info must be added to the system manually

😐

GS1 128: GTIN + SN

Additional info must also be added to the system manually

DIFFERENT CODES HAVE DIFFERENT ENCODED INFORMATION



ALL THE INFORMATION ADDED TO THE SYSTEM BY SCANNING.

GS1 DATAMATRIX

- GTIN 14
- SERIAL NUMBER (OPTIONAL)
- EXPIRATION DATE
- BATCH NUMBER

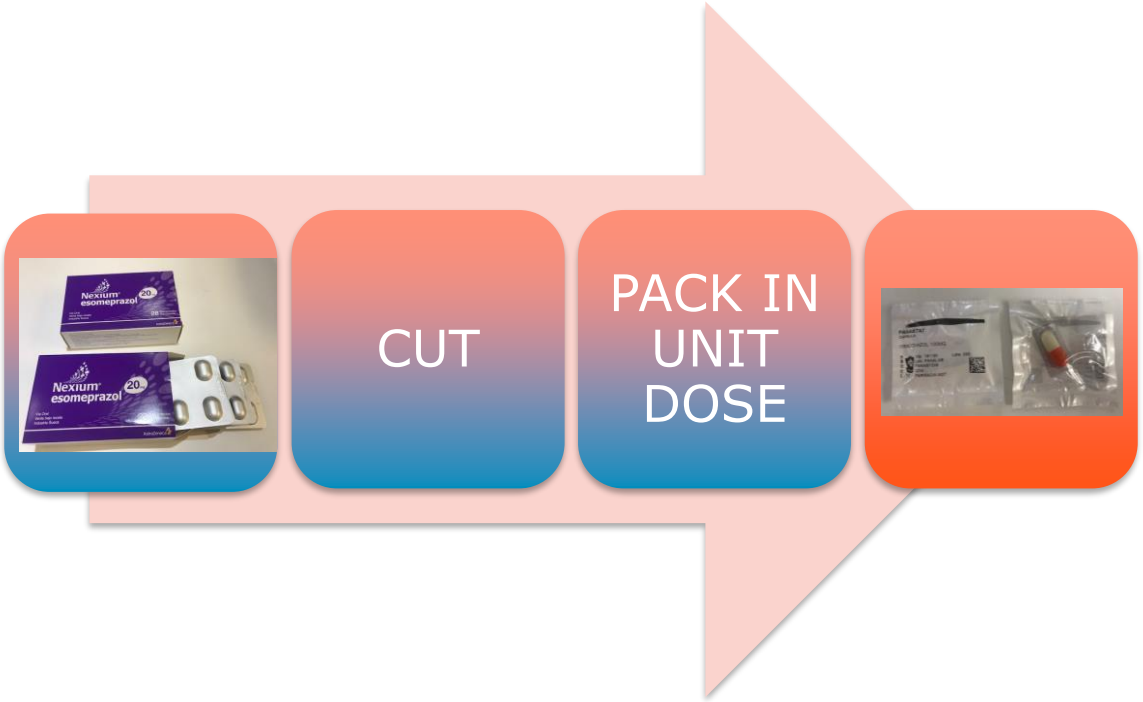
FILLING THE GAP USING THE UNIT-DOSE PACKAGING

EQUIPMENT

- 2600 PACKAGING UNITS / HOUR
- TABLETS, PILLS
- IN < 20ML VIALS THE PROCESS IS AUTOMATIC
- IN > 20ML VIALS THE PROCESS REQUIRES ADDITIONAL MANUAL WORK
- U$S 5000 PER MONTH IN SUPPLIES

ADD GS1 DATAMATRIX TO PACKAGE!

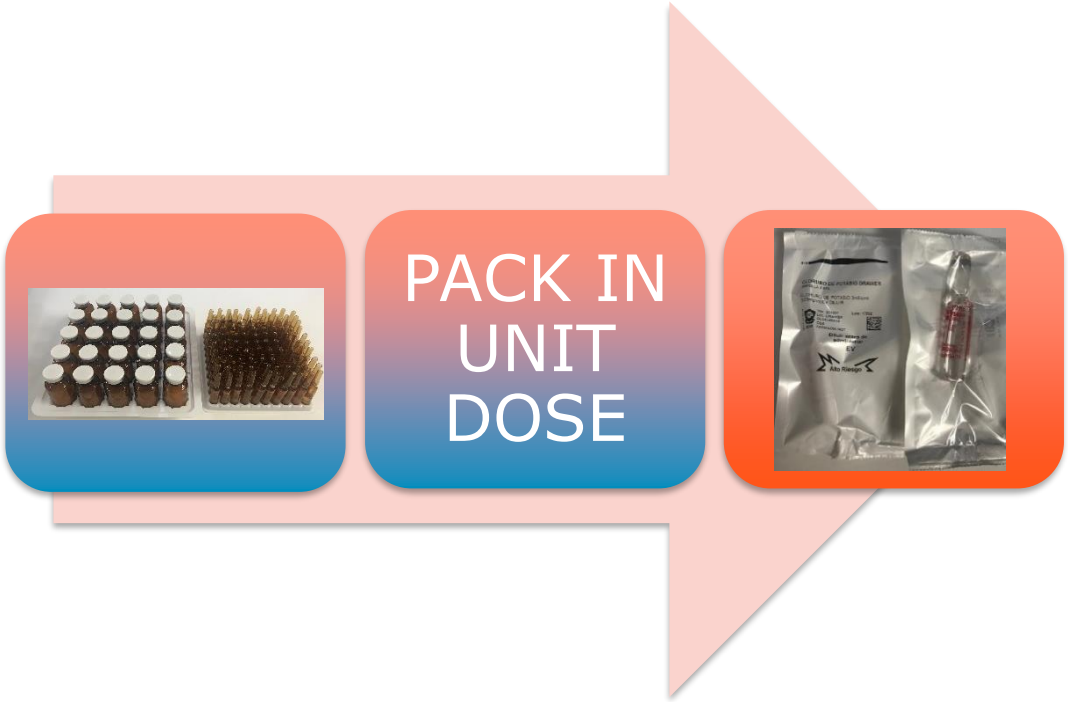
UNIT-DOSE IDENTIFICATION



SOLID FORMS

- 30.000 PACKED UNITS PER MONTH
- 50HS CUTTING PILLS PER MONTH
- 83HS COMPLETE PROCESS TILL PACKAGING
- TOTAL PROCESS TIME: **5,5 DAYS PER MONTH**

UNIT-DOSE IDENTIFICATION



VIAL FORMS

- 55.000 PACKED UNITS PER MONTH
- 156HS COMPLETE PROCESS TILL PACKAGING
- TOTAL PROCESS TIME: **6,5 DAYS PER MONTH**

CHEMOTERAPY BAGS

OPPORTUNITY OF IMPROVING

Working with our supplier…

- Add GS1 datamatrix
- Standardize encoded information
- Our goal: bedside scanning

NUTRITION IV BAGS

OPPORTUNITY OF IMPROVING

Working with our supplier…

- Change bar code or Add GS1 datamatrix
- Standardize encoded information
  Our goal: bedside scanning

THANK YOU!

Improving patient care with single unit identification

Pfizer Global Supply – Manufacturing and Quality Solutions

GS1 Global Healthcare Conference - Bangkok

Pascal Aulagnet, Senior Manager Business Technology, **Pfizer Inc**

30th of October 2018 – Bangkok

Disclaimer: *This presentation outlines a general technology direction. Pfizer Inc. has no obligation to pursue any approaches outlined in this presentation or to develop or use any functionality mentioned in this presentation. The technology strategy and possible future developments are subject to change and may be changed at any time for any reason without notice.*

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Customer Requirements

Increase patient safety and compliance by introducing technologies to allow bedside scanning

- Medication errors are recognized as an important failure point in care processes
- Identification of primary packages such as vials, pre-filled syringes or solid forms in blister cavity is an important prerequisite for successful point of care verification and registration in electronic health records

The Right Approach of Implementation

Multi-phased implementation to be considered

- Extend Primary package label information with **static data** (Product code / GTIN) encoded in a 2D DataMatrix barcode

Mid term objective

Long term objective

- Provide product information and **variable batch related data** encoded in the DataMatrix (Batch #, Expiration date)

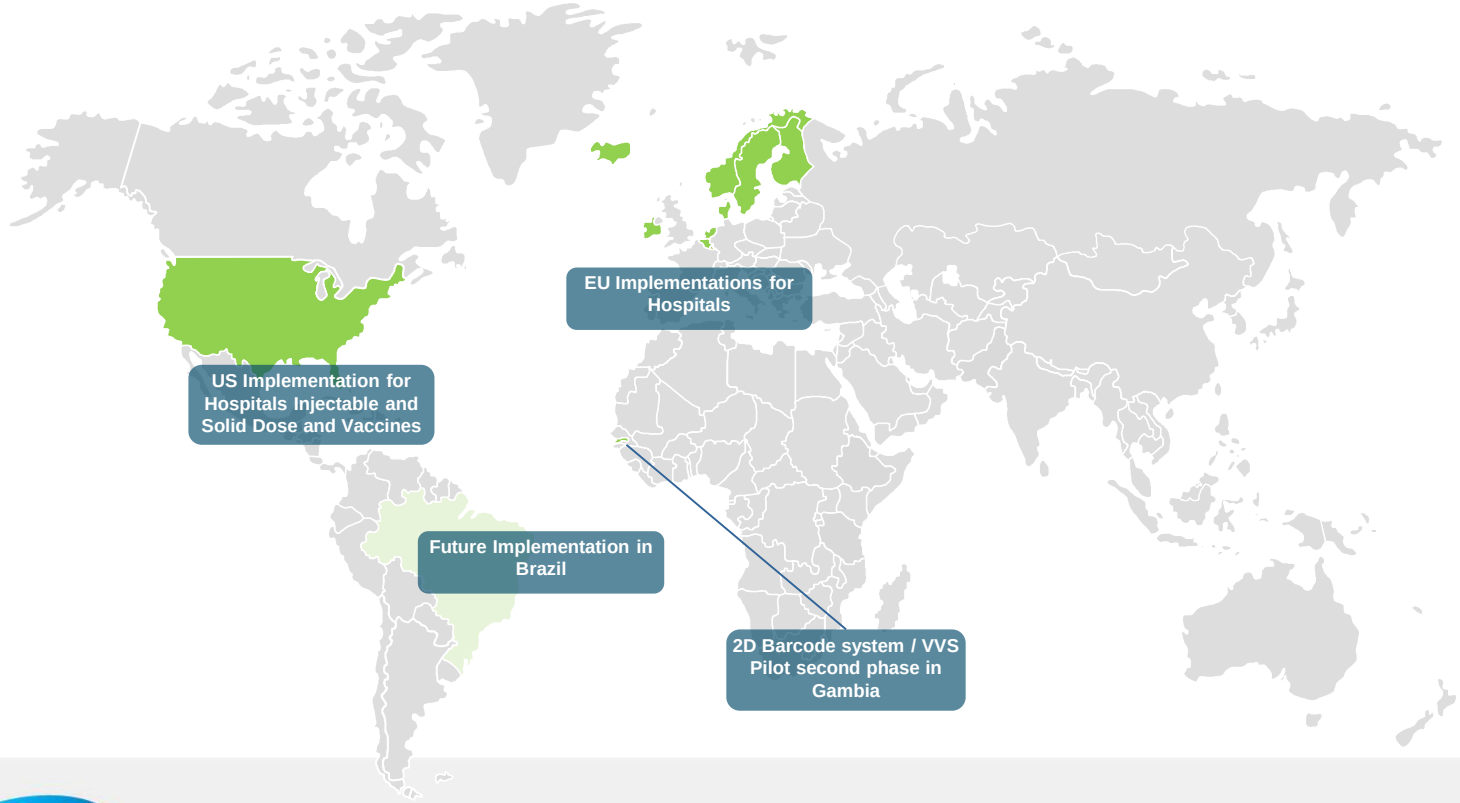
Not considered

Provide **unique identification** of the primary package by introduction of a **serial number** encoded with the other information

PFIZER Approach

Cross Business	Single Unite Coding or HUD (Hospital Unit Dose) as an integral component of the overall hospital strategy
	A pan-European/Worldwide approach for all Markets and Pfizer Global Supply
	Key component of the Vaccine Visibility System

Implementation across the world



Technically Possible

For Solid Form

Blister

Bottle (Plastic, Glass)

Tube (Aluminum, Plastic)

Strip

Technically Possible

For Injectable and Liquid Form

Syringe

Vial (Plastic, Glass)

Ampule

Plastic Bag / Pouch

Challenges and Opportunities

Challenges

- Size of the Container
- Reflecting surface (Aluminum Foil and tube)
- Label space constraint
- GTIN Management

Opportunities

- Right investment to cutting edge technology
- Redesign of label artwork
- GTIN governance and Tool leveraged by serialization mandates
- Provide a way for vaccine traceability and inventory management

In Summary

Utilization of **Standard** is key (GS1) and **Maintenance** of your GTINs is crucial

GS1 Position Paper

Collaboration between all the actors and stakeholders

Phased Approach Implementation

Contact Details

Email : pascal.aulagnet@pfizer.com

LinkedIn : linkedin.com/in/pascal-aulagnet

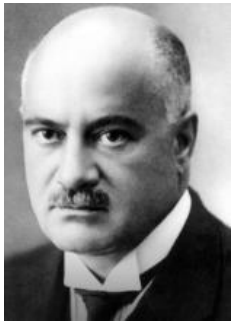
Improving patient care with single unit identification

Roche's experience

Sébastien Langlois-Berthelot

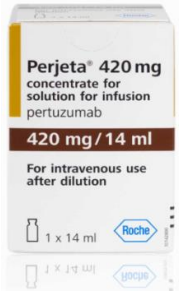
About Roche

A pioneer in Healthcare



- Founded in 1896 by Fritz Hoffmann-La Roche in Basel, Switzerland
- 1897 onwards Roche starts to expand worldwide
- 1968 Roche enters Diagnostics Market

TODAY – ROCHE CREATES INNOVATIVE MEDICINES AND DIAGNOSTIC TEST THAT HELP MILLIONS OF PATIENTS GLOBALLY



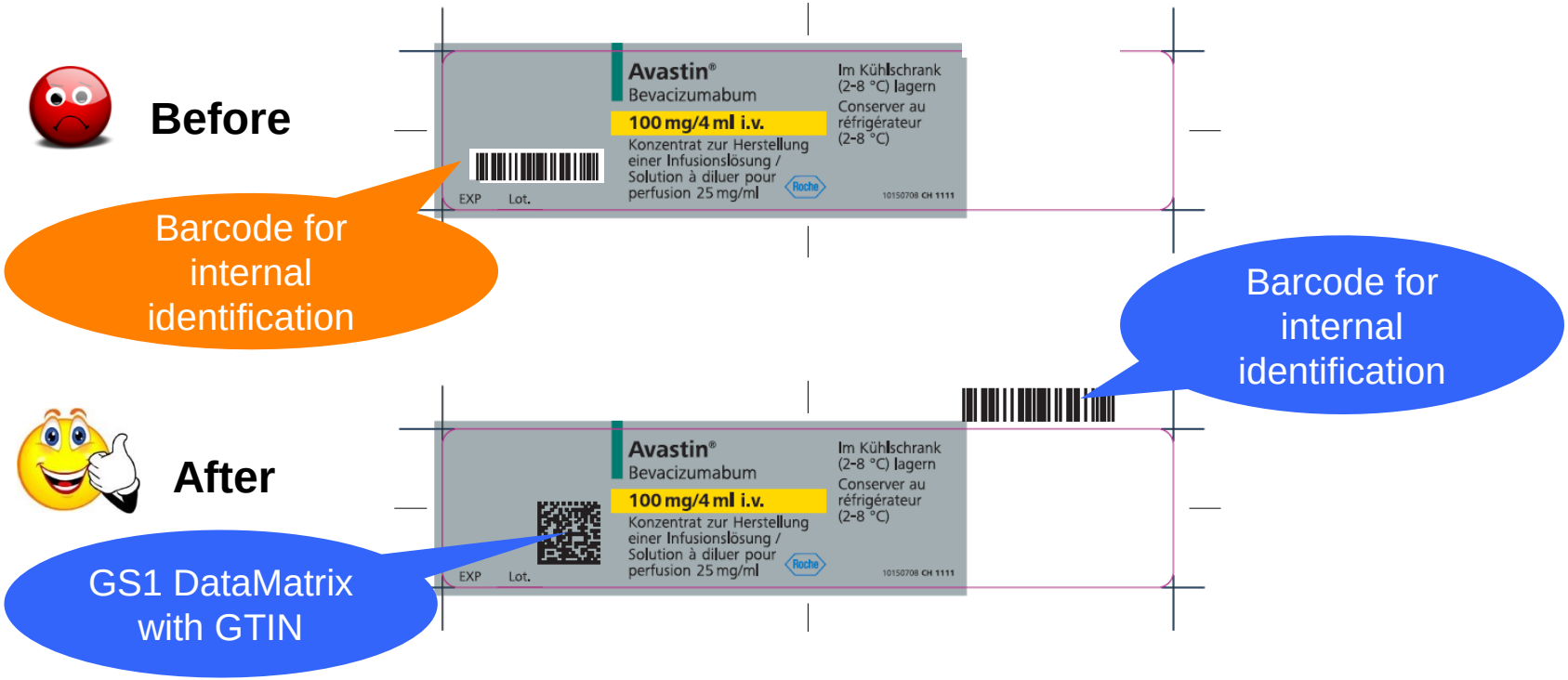
- Largest Biotech Company
- Frontrunner in Personalized Healthcare
- Global leader in Cancer Treatments

It’s about collaborating and leveraging opportunities
Our Journey to Single Unit Coding

- **2010** - Roche had to redesign its vial labels following technical issues. We took the opportunity to include a **GTIN encoded in a GS1 DataMatrix** where space allowed (65% of vials labels).
- **2011** - Roche collaborated with GS1 Switzerland to implement GTIN in GS1 DataMatrix on the labels of all its **injectables** for the Swiss market.
- **2012** - Roche signed a **joint recommendation** with other Swiss pharmaceutical manufacturers and Swiss hospital associations to providing guidance for the implementation of single unit coding.
- **2012+** - Roche refurbished its packaging lines for the implementation of serialization. At the same time, an **online printing equipment for primary packaging** has been installed on 60% of the lines (90% for labels, 20% for blisters).
- **2016+** - we started with the **implementation of the IT software** to allow printing of GS1 DataMatrix with GTIN and variable data.

How Did Everything Start at Roche?

2011 – Vial Label Adaptation



First Attempts to Meet Hospitals Needs (as of 2011)

Static GS1 DataMatrix with GTIN only

GS1 DataMatrix with **GTIN only**

AMGROS Requirement in Denmark
(except for blisters)

Voluntary implementation for **all injectables in Switzerland**

Voluntary implementation for **infusion solution vials for all EU countries**
(centrally registered products)

Pictures for illustrative purposes only. Do not reflect the actual layout for the specific market.

Next Steps since 2016

Adding Expiry Date and Batch Number to the DataMatrix

GS1 DataMatrix **with GTIN, Expiry Date and Batch Number**

Voluntary implementation of single unit coding for **vials for selected products and markets**

GTIN (01)

Expiry Date (17)

Batch Number (10)

Pictures for illustrative purposes only. Do not reflect the actual layout for the specific market.

Phased Deployment Approach at Roche

Addressing Complexity by Technology – Leverage Global Standards

Labels (bottles, parenterals, syringes)

Blisters (single unit)

1 element (static)

GS1 DataMatrix content

3 elements (variable)

GTIN only ❶	GTIN only (per cavity)
GTIN + Expiry date + Batch number ❷	GTIN + Expiry date + Batch number (per cavity) ❸

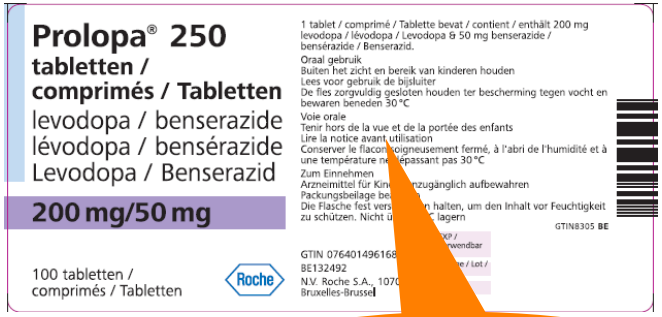
Issues and Challenges

Multiple Constraints Making It Difficult to include a Barcode

- Very small containers

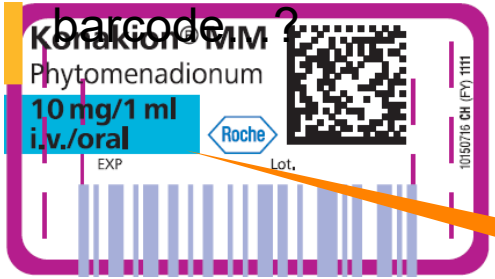
- Reflecting lidding foil of blister

- Amount of text and font



Font size: 5 pt

- What is more important? Text or barcode…?



Font size: 3.25 pt

Issues and Challenges
Manage User Expectations

- Readability of barcode on syringes with safety device

- GTIN on bottle = 50 tablets, not 1 tablet!

- GTIN on on primary should always be different from secondary packaging!

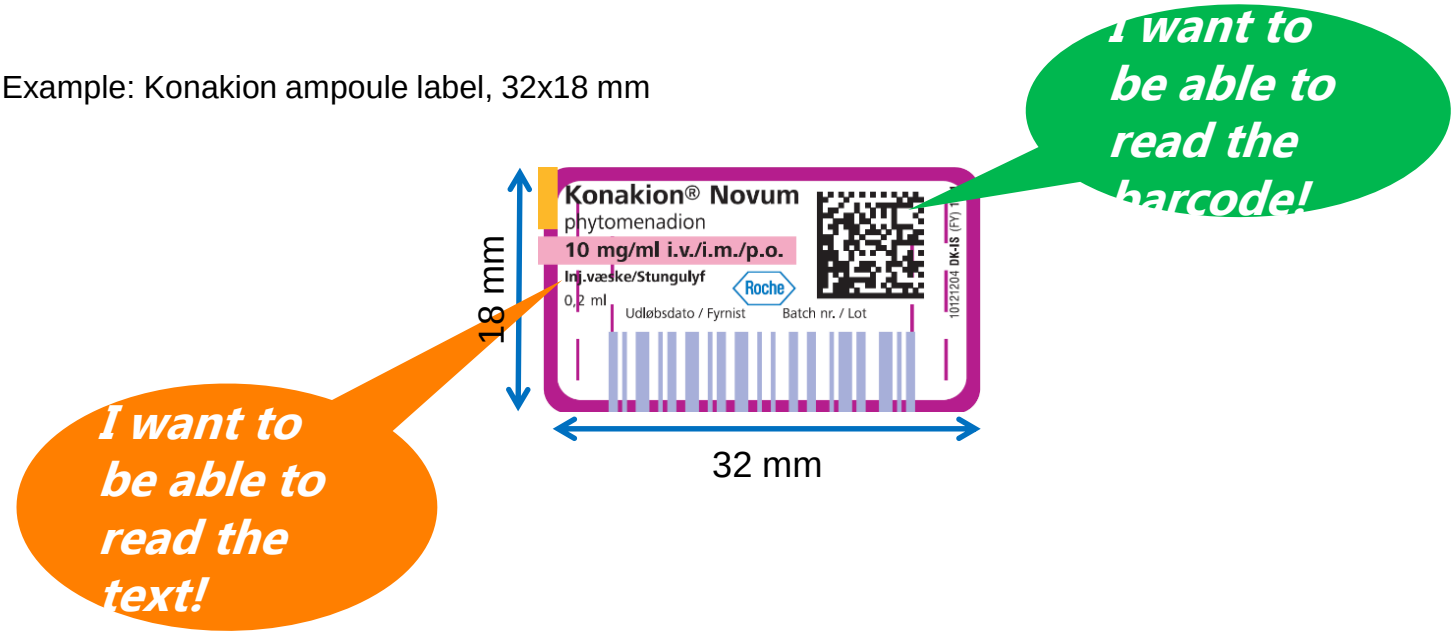
GTIN A: sales unit with 2 vials inside

GTIN B: 1 vial (single unit)

- GTIN on non single-unit blister = 21 capsules, not 1 capsule!

Solving the Barcode vs. Text Dilemma

Example: Konakion ampoule label, 32x18 mm



Internal Challenges
Removing Roadblocks

Solve Technical Issues

- Technical challenges requiring new label formats and enhanced lidding foil non-reflective material require **substantial investments** to be solved.

Implement Processes and Systems

- Line equipement alone is not sufficient to allow single unit coding. All **surrounding processes and systems** must be in place (IT, master data, label change management)

Prioritize Project Internally

- Single Unit Coding projects at manufacturers are **competing** with other regulatory-driven projects and might get de-prioritized in case they do not directly impact regulatory compliance.

Take Home Messages

- Advocate for the use of **GS1 standards** and refer to **ISO 16791**, which mentions primary pack identification.

- Make use of the **GS1 Position Paper on the Identification of the Primary Package Level of Drugs**, which has been endorsed by EFPIA (European Association of Pharmaceutical Manufacturers) and EAHP (European Association of Hospital Pharmacists) as a basis for requirements

- Need to **engage with health authorities** to increase awareness on the importance of point of care scanning and help us solving the dilemma between barcode, text and font size on labels and blisters

- More and more leading hospitals worldwide introduce barcode requirements for **tender orders**. This is a strong incentive for manufacturers, provided requirements are consistent and harmonized

Link to the Position Paper: http://www.gs1.org/sites/default/files/docs/healthcare/position-papers/single_unit_position_paper_final300617.pdf

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…and there are many more companies working with GS1 at a local level

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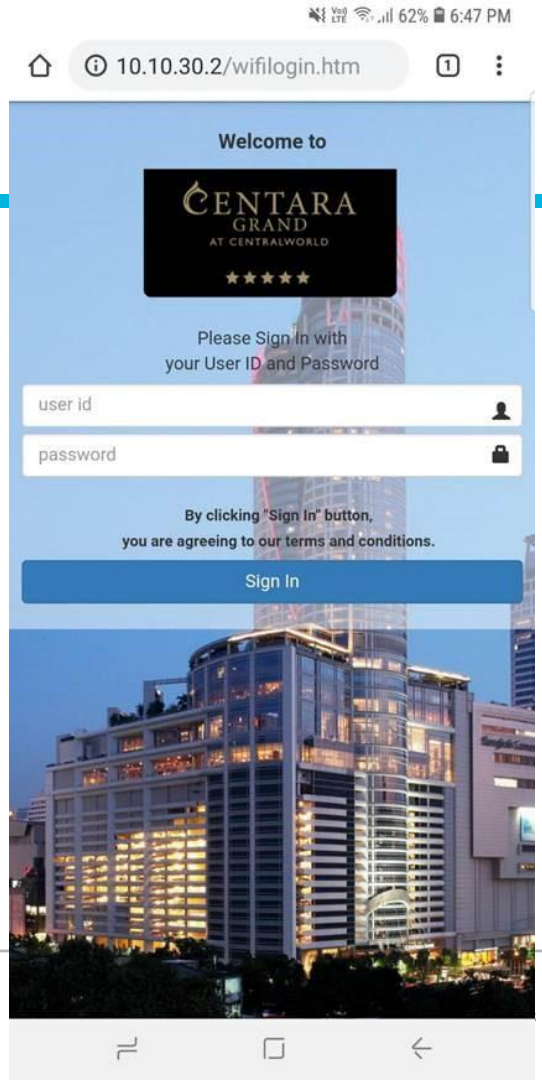

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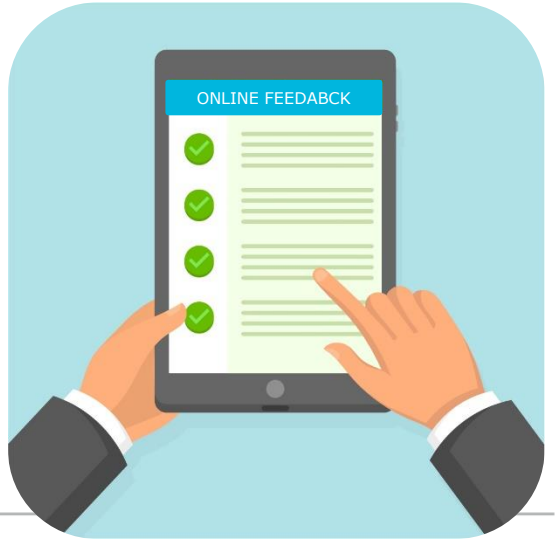
For every day you attend, be sure to complete the short **feedback form** on the event application.



Conference Charity
Baan Fuengfah - Home for Disabled Babies

For every feedback form completed, GS1 will donate USD $5 to the charity.

Your feedback can make a real difference!

Need any help? Contact us!

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

The Global Language of Business

COFFEE BREAK

Poster Reception Tonight

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

Networking Dinner on Wednesday, 19:00

Riverside Terrace

Anantara Riverside Bangkok Resort

257/1-3 Charoennakorn Road,

Thonburi, Bangkok,

Thailand

PLEASE WEAR YOUR EVENT BADGE ☺

Bus departure: **meet in the main lobby** at 6:00 pm

Bus return: beginning at 09:30pm and will run on a loop with a last shuttle leaving at 11:00pm.

Dress code: business casual.

Afternoon at a glance

	TUESDAY, 30. OCTOBER	
13:00 – 14:00	NETWORKING LUNCH	
14:00 – 15:30	**PANEL I** Value based Healthcare	**PANEL II** Public policy: Pharmaceuticals
15:30 – 16:00	COFFEE BREAK	
16:00 – 17:30	**PANEL I** Improving patient care with single unit identification	**PANEL II** Hospital transformation using GS1 Standards
17:30 – 18:30	POSTER RECEPTION	

Afternoon at a glance

	WEDNESDAY, 31. OCTOBER		
13:00 – 14:00	NETWORKING LUNCH		
14:00 – 15:30	Ask the expert sessions 6 topics length 45 minutes		
15:30 – 16:00	COFFEE BREAK		
16:00 – 17:15	**PANEL I** Big data, master data, data quality, regulation and GDSN	**PANEL II** Public policy: Medical Devices	**PANEL II** GS1 standards to move products through the supply chain – the view of wholesaler and + logistic provider
19:00 – 22:00	NETWORKING EVENT		

Thank you