The Global Language of Business

How to start implementing traceability in a country

Ask the expert

Grant Courtney

April 2016

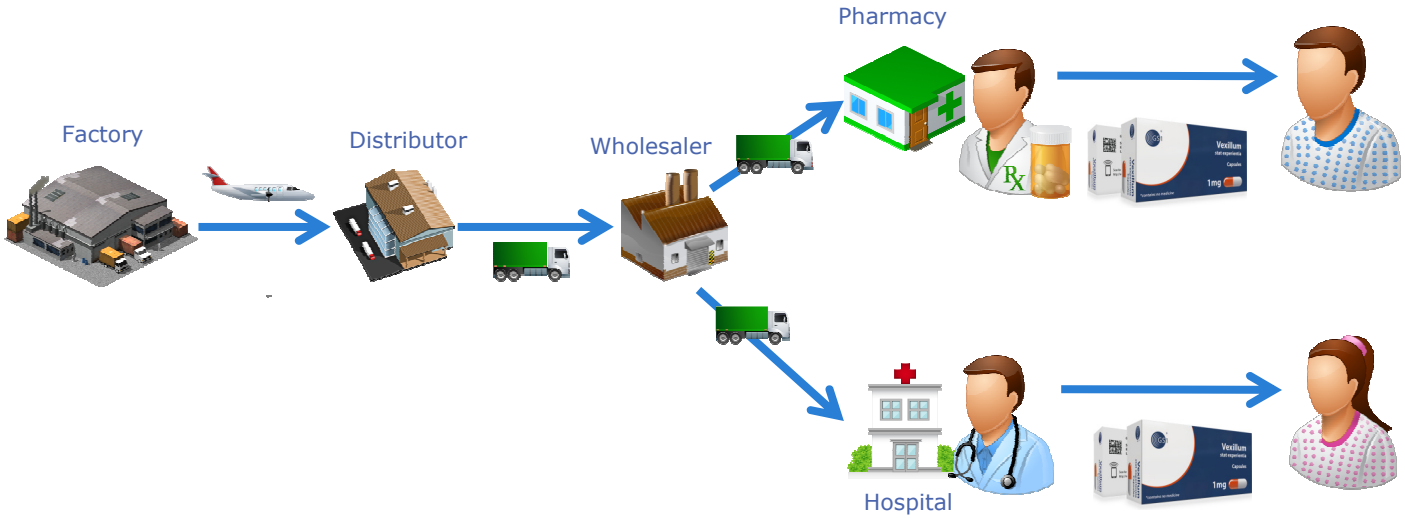
Introduction – Grant Courtney

- Member of GS1 Healthcare Leadership Team
- 21 Years experience in Healthcare - GSK
- 10 Years in Traceability

The purpose of today's session

How to start implementing **traceability** in a **country**

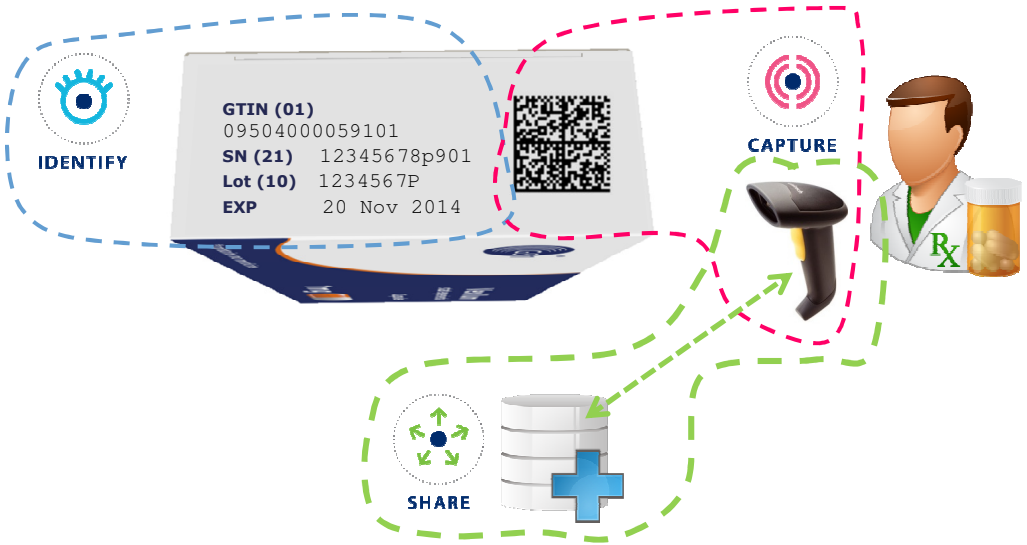
Simple supply chain – physical flow



Do you want to know a secret ?

The concept of traceability is **simple**

The 3 basics of the GS1 standards



Traceability

IDENTIFY

- **Items** – e.g. A pack of tablets
- **Places** – e.g. A warehouse or a pharmacist
- **People** – e.g. A healthcare professional

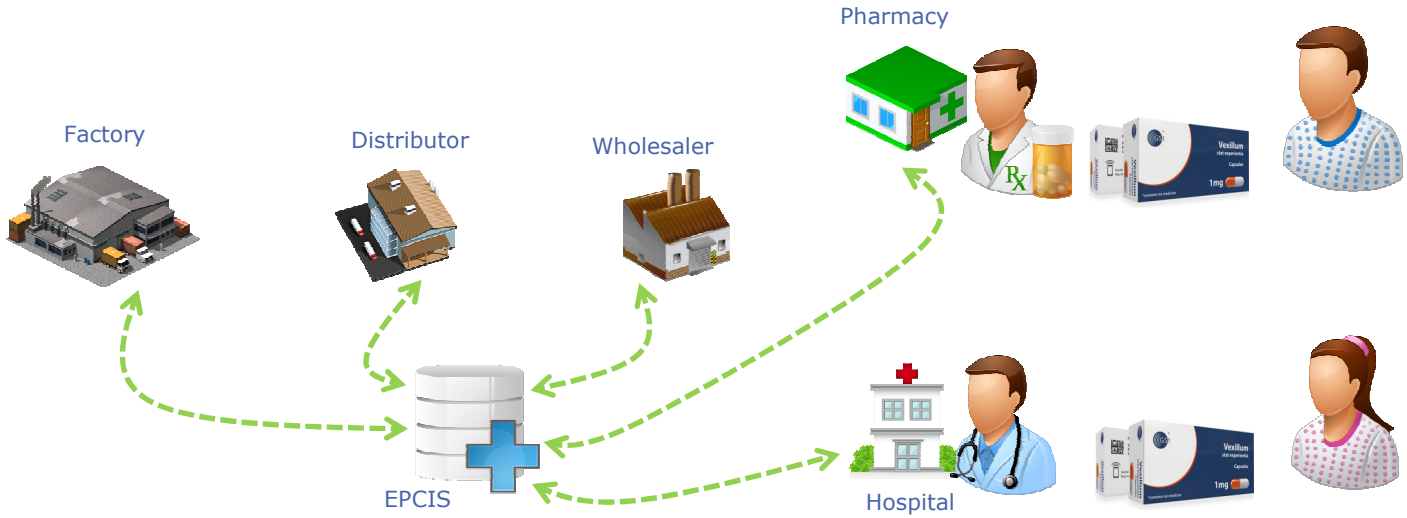
CAPTURE

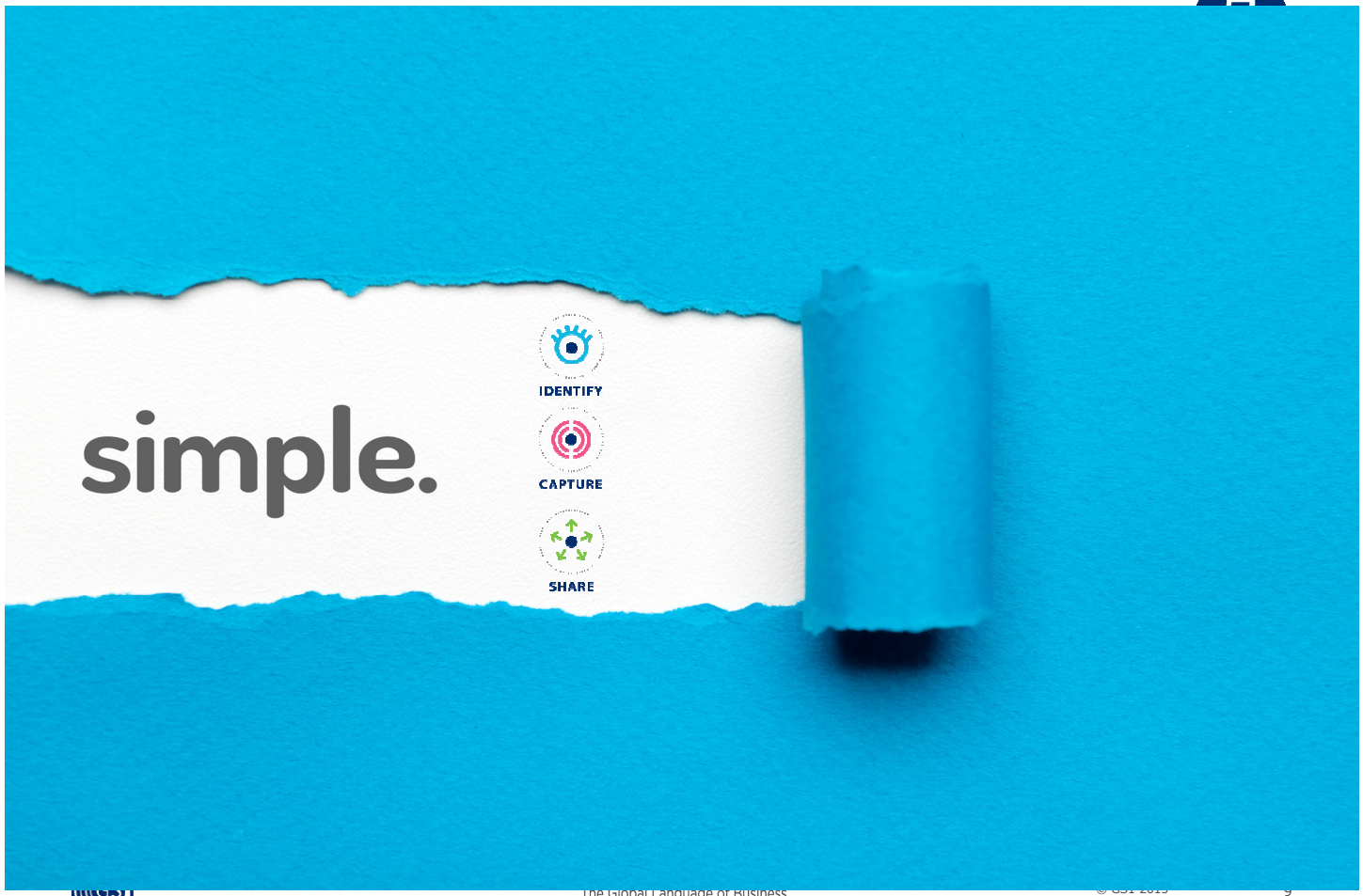
- **Barcodes** – e.g. 1D (linear) or 2D DataMatrix
- **RFID**

SHARE

- **EPCIS –** Electronic Product Code Information Service (IT systems, processes)

Simple supply chain – traceability data flow





The purpose of today's session

How to start implementing traceability in a **country**

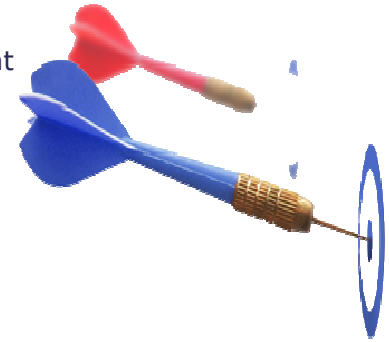
We can learn from many real world cases of traceability deployments and pilots

So here is a list to get you started . . .

- Understand the problem - define clear objectives
- Collaborate with stakeholders
- Identify, then avoid the traps
- Produce detailed requirements
- Set realistic timelines – then monitor them
- Base solutions on global standards
- Pilot, phase deployment & ramp up
- Stabilise, then leverage

Understand the problem - define clear objectives

- What are some of the potential objectives
  - Supply chain visibility & efficiency, Reimbursement & payment management, Product & patient protection, Recall management
- Define the scope
  - Which products to include and exclude e.g. OTC, Herbal, Samples
- Measure before
  - This helps identify the issues to address
  - It also helps you assess if you have made an improvement



Ambiguity will drive systems which do not meet the primary goal and cause confusion among stakeholders

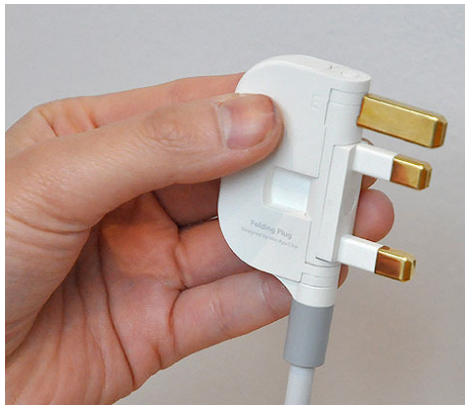
Collaborate with stakeholders

- Solution providers, supply chain partners, industry bodies, standard agencies, etc
- Traceability only works if all stakeholders are working together

Identify, then avoid the traps

- Be clear about data, access, ownership, etc
- Be clear on cost models
- Be careful about being driven by vendor specific solutions
- Decide early on who with establish the IT system(s)
- Being to restrictive
- What to do about product already in the supply chain
- Use the standards . . . Unaltered !

Don’t alter the standards . . . !



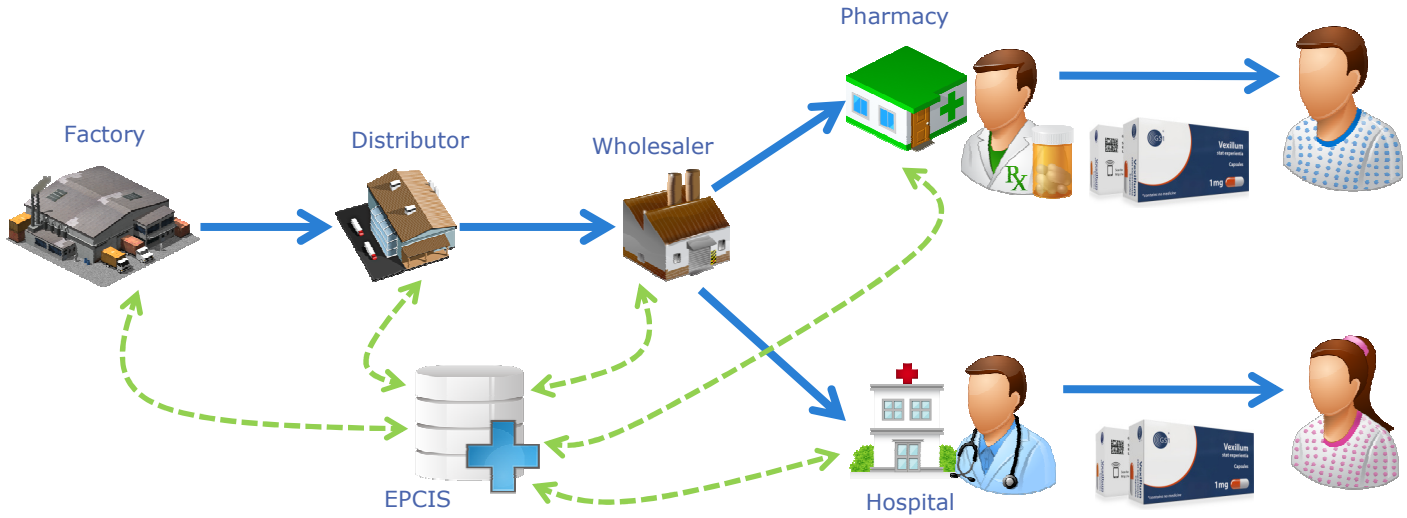
But you can requested that they are updated/ improved

Produce detailed requirements

- Be prepared to break this task down
- Reference the standards, not duplicate them
- Test requirements before publishing them – take feedback
- Don’t alter the standards – if you do then they are not “the standards”
- Resist the temptation to focus on the barcode – remember the data/ systems/ processes . . .

Vague & incomplete requirements drive resistance and slow progress

There is much more than just a barcode !



Set realistic timelines – then monitor to them

- It can take years from the initial ideas through to being in place
  - It can take over 12 months to upgrade a production line and 18 – 36 months for IT
  - IT systems are GxP
  - Packaging artwork needs to be updated
  - Processes need to be designed and piloted
  - There is limited resources to implement
- Be prepared to work with the stakeholders to modify timelines if required

Nothing drives resistance more than short timelines

Base solutions on global standards

- Traceability across a supply chain is simply not possible unless every stakeholder is working to a common set of processes built on common standards

- Using Global Standards will:
  - Decrease costs to deploy and maintain
  - Speed implementation
  - Prevent solutions being proprietary
  - Increase knowledge and experience

Pilot, phase deployment & ramp up

- Processes and IT systems need to be set up and tested
- Don't try and do everything at once start with a few products
- Scale up the requirements, perhaps start with identification of products first
- Ramp up over time, fixing issues early
- Focus on the objectives

Stabilise, then leverage

- Once the systems go live there will be “Snags”
  - Unforeseen things will happen
- Keep stakeholders involved, work through issues
- Measure
  - Remember you need to see that the issues have been resolved
- Now start to leverage the system for some of the other goals

Let’s recap . . .

- Understand the problem - define clear objectives
- Collaborate with stakeholders
- Identify, then avoid the traps
- Produce detailed requirements
- Set realistic timelines – then monitor to them
- Base solutions on global standards
- Pilot, phase deployment & ramp up
- Stabilise, then leverage

Use this conference and GS1 to connect and learn more

Questions

Where can I get more information ?

- Contact Information – Ulrike Kreysa

GS1 Global Office
Avenue Louise 326, bte 10
B-1050 Brussels, Belgium
T + 32 2 788 78 00
W www.gs1.org

Finally

The Global Language of Business

Identification and marking of multi-country packs & Human Readable Interpretation

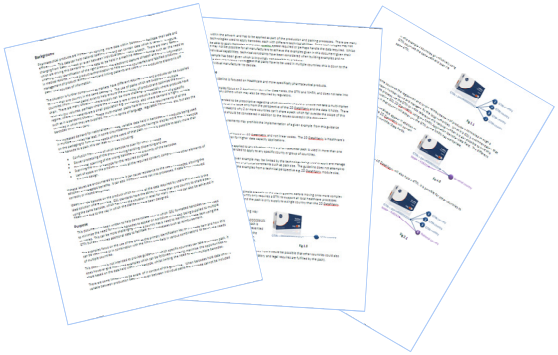
Ask the expert

Grant Courtney

October 2015, GS1 Healthcare Conference, Budapest

This session covers 2 separate topics

Topic 1
Identification and marking of multi-country packs



Topic 2
Human Readable Interpretation

Introduction – Grant Courtney

- Member of GS1 Healthcare Leadership Team
- 20 Years experience in healthcare
  - Co-author of the GS1 discussion paper on Multi-market packs
  - Member of WR 10-303

Topic 1

Identification and marking of multi-country packs

Lets start with some basics . . .

- What is a multi-market pack
  - A product which is designed to be supplied and used in more than one country

- What are the key terms I need to understand
  - GTIN – The GS1 Identification Key used to identify trade items. The key comprises a GS1 Company Prefix, an Item Reference and Check Digit
  - NTIN – A coding scheme, administered in the Healthcare sector by a national organisation for which a GS1 Prefix has been issued to permit its uniqueness within the GTIN pool but without assurance of full compatibility with GTIN functionality.
  - NHRN – National and/or regional identification numbers for product registration purposes and/or for the management of Healthcare provider reimbursement

Why do we need a discussion document ?

GTIN =
09504000059101

1 GTIN country
2 GTIN country
3 GTIN country
4 GTIN country

NTIN country
National country
National country

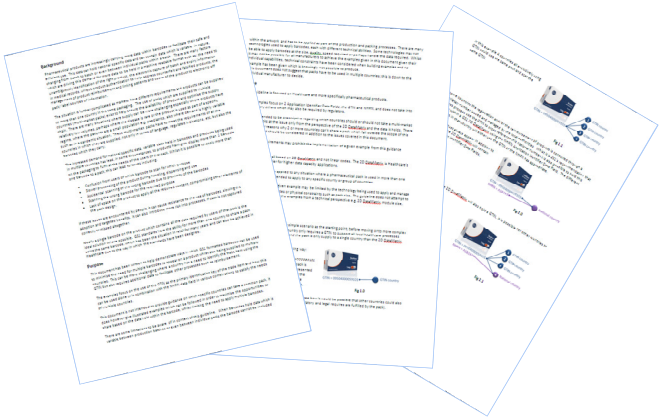
We will look at this in some of our scenarios

- If all countries identify the product using a GTIN then its easy
  - One Multi-Market pack
  - One barcode
  - One GTIN
  - Many countries
- But what if they don't use GTIN or also use other identifiers ?

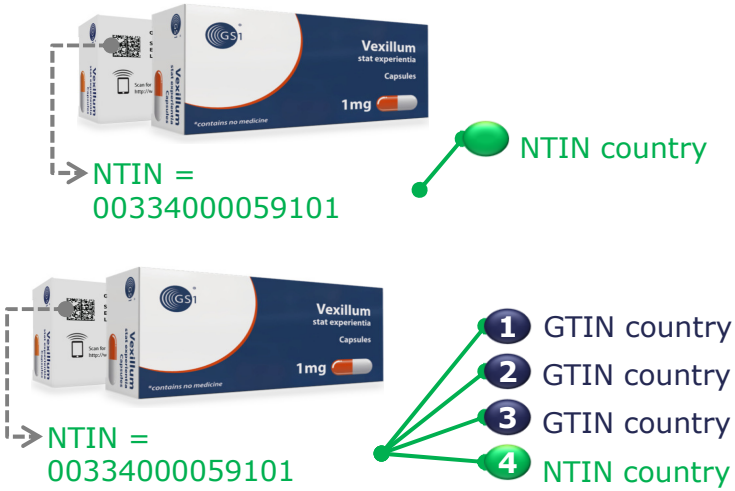
The Discussion Paper

- The discussion paper was written to help demonstrate ways in which GS1 bar codes can be used to minimise the need for multiple bar codes to appear on product packaging while still enabling products to be supplied to multiple countries.

- Including how GTIN, NTIN and NHRNs can be used together



Lets look at the second scenario



- A country uses an NTIN
- Can this pack be shared with other countries ?
- **Yes**, this pack can also be taken (in principle) with other GTIN countries*

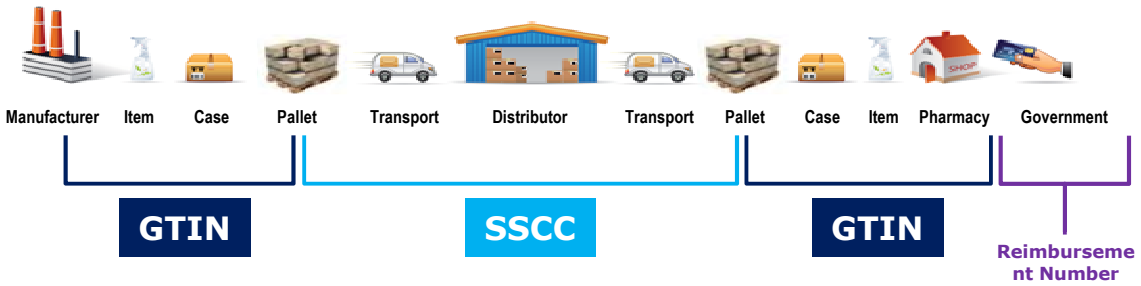
** The government's host system must be configured to use the correct AI*

The document works its way through different scenarios

Fields in GS1 DataMatrix			Market types which can take this pack		
Primary key	Other fields				
(01) Containing a GTIN			GTIN countries		
(01) Containing a GTIN	NHRN 1		GTIN countries	NHRN 1 country	
(01) Containing a GTIN	NHRN 1	NHRN n	GTIN countries	NHRN 1 country	NHRN n country
(01) Containing an NTIN			NTIN country		
(01) Containing an NTIN			GTIN countries	NTIN country	

Lets examine some of the slightly more complex scenarios

Why do other identifiers exist ?



- Processes exist in countries which are controlled by numbers other than GTIN
- Reimbursement is sometimes an example of this

Multi market example

Example of the actual pack

Data encoded in the GS1 DataMatrix

(01) 09504000059101
(17) 141120
(10) 1234567P
(21) 12345678p901
(713) 1312345678913
(8200) http://www.gs1.org/demo/

Countries taking the pack

1. GTIN country
2. GTIN country
3. GTIN country
4. National country

- The reimbursement number can be encoded in the NHRN field as an attribute of the GTIN
- This example also includes a serial number and URL to show how different keys can be combined

More than 1 NHRN can be encoded within a GS1 DataMatrix

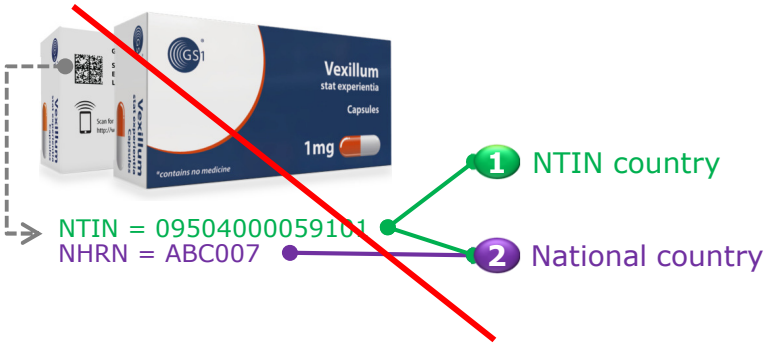
- It is possible to encode multiple NHRN's into the data carrier*
- Several countries with NHRN's can therefore share the same pack

** There may be technical constraints which limit a manufacturers' ability to encode multiple NHRNs, also the government's host system must be configured to use the correct AI*

What if a country does not use GTIN

- If a country uses a national number and this is not encoded as an NHRN then the pack can not be shared or would have to carry multiple data carriers

You can not combine an NTIN and NHRN



- You should not combine an NTIN and NHRN*
- The NHRN is always a GTIN attribute

**As the global usability of an NTIN is not assured it is not advised to use NHRN with NTIN*

Where can I get more information ?

Discussion Paper Product Identification in Healthcare

http://www.gs1.org/docs/healthcare/20140319_Discussion_Pape_%20Multi-Market_Pack_Guideline.pdf

Position Paper (II), Healthcare Provider Advisory Council, Implementation in hospitals hindered by bar code symbol issues

http://www.gs1.org/docs/healthcare/20130725_HPAC_Position_Paper_Bar_Code_Issues.pdf

GS1 General Specifications

http://www.gs1.org/barcodes-epcrfid-id-keys/gs1-general-specifications

Questions

Thank you

- For further information on the discussion paper please contact:

- Public Policy Manager, GS1 Healthcare, Brussels, Belgium +32 2 788 7800

Topic 2

Human Readable Interpretation

Where can I find this information ?

Version 15

What is HRI ?

Human Readable Interpretation

- HRI show a human exactly what's in a barcode
- It's there in case the barcode does not read
- Some HRI rules are **specific to Healthcare** and these have been updated

Whether a GS1 AIDC Data Carrier encodes a GS1 identification Key, GS1 Key Attributes, or a combination of both, the HRI should be placed below the barcode and grouped together wherever physically possible while maintaining the HRI legibility and minimum barcode height.

Why have the HRI rules been updated

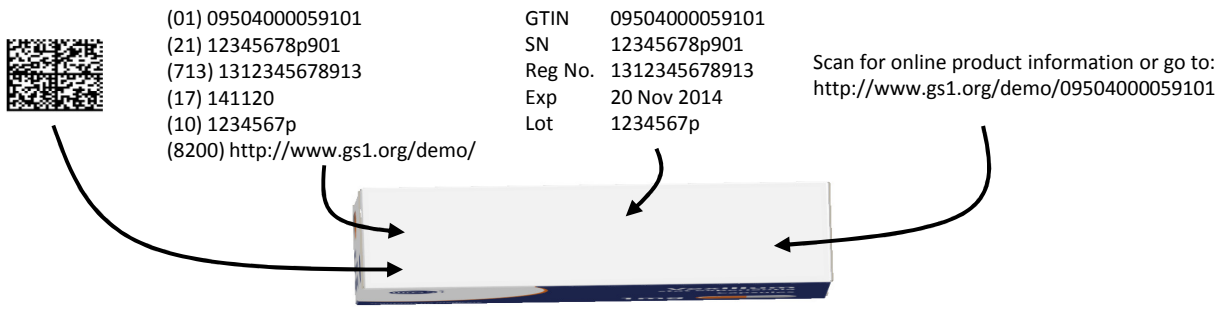
- In retail the barcode usually only contains the GTIN
- This makes adding the HRI simple

- Healthcare is now a lot more complex
- Regulators are driving a more data into the barcodes on products

(01) 09504000059101
(21) 12345678p901
(713) 1312345678913
(17) 141120
(10) 1234567p

Lack of space and technical constraints

- It was not always possible to meet all stakeholders requirements using the pervious HRI standards, especially on smaller packs
- Factors like on line printing, language and local regulations all created issues



So we needed a **Healthcare** solution

- A way of incorporating the HRI and non-HRI text onto a product where regulations, space and technical constraints prevented the application of both

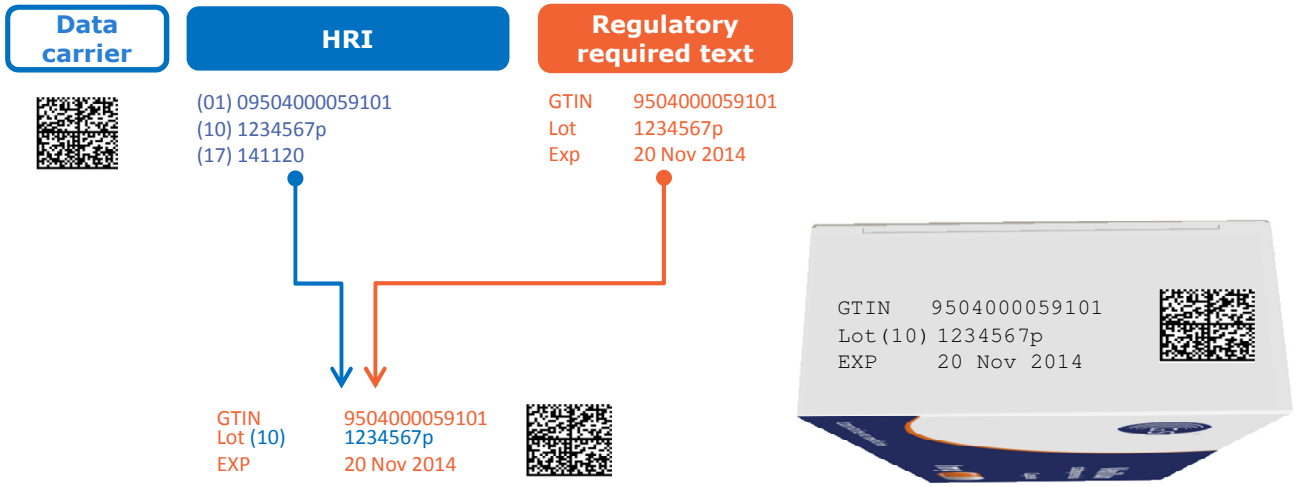
How deviation for Healthcare works . . .

If a deviation from the preferred format is required that results in HRI not being printed, then **a combination of HRI and Non-HRI Text may be used**. When doing so, the following rules apply:

- If the data represented in the Non-HRI Text is exactly as in the HRI, then the appropriate AI shall be printed along with the data title.
- If data represented in the Non-HRI Text does not match the HRI, then only a data title may be used. The AI shall not be printed.
- The selection of data titles may be determined by the manufacturer based on regulatory, local language requirements, relevant standards (e.g. ISO/IEC 15223) or appropriate abbreviations.

Simple example 1

Simple example 2



Complex example

Data carrier

HRI

(01) 09504000059101
(21) 12345678p901
(713) 1312345678913
(17) 141120
(10) 1234567p
(8200) http://www.gs1.org/demo/

Regulatory required text

GTIN 09504000059101
SN 12345678p901
Reg No 1312345678913
Exp 20 Nov 2014
Lot 1234567p

Commercial required text

Scan for online product information or go to:
http://www.gs1.org/demo/09504000059101

GTIN (01) 09504000059101
Reg No (713) 1312345678913
SN (21) 12345678p901
Lot (10) 1234567p
EXP 20 Nov 2014

Scan for online product information or go to:
http://www.gs1.org/demo/09504000059101

Why is this important

- The new Healthcare HRI rules allow us to work in a common way across many markets
- Promoting these standards will help prevent the proliferation of national requirements which drive complexity

Questions

Thank you

- For further information on the HRI rules contact your local GS1 office

The Global Language of Business

Contact Details

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W www.gs1.org

Spare Slides

HRI Situation

- Regulators require data such as GTIN, Batch, Expiry & serial number to be held in a DataMatrix
- Brand owners may want to hold additional information in the same data carrier e.g. URL
- This data is identified differently with the data carrier than in human readable formats e.g.
  - Expiry date format is 141120 in the data carrier and may be displayed as 20 Nov 2014 in the human readable format
  - The data elements in a data carrier are identified using application identifiers (17 = expiry) whilst human readable format may identify expiry using a prefix of Exp
- Different users of the pack will need to access the data through different means
  - e.g. A patient will need to read the expiry date in human readable format whilst a wholesaler may scan the GS1 DataMatrix to access/ capture the expiry date
- There are existing regulations which constrain how content appears on the product packaging