



The Global Language of Business

The FMD Pack Coding, Sharing and Transition

Ask the expert

Joan Cahill & Grant Courtney

April 2017



Introduction – Joan Cahill



- Director, Pfizer Packaging & Delivery Systems
- Member EFPIA Supply Chain Working Group
- 7 years FMD Experience



Introduction – Grant Courtney



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





Key topics covered

- Pack Coding
- Pack Sharing
- Pack Transition

The purpose of today's session



Not to give you the answers . . .

. . . it is to **share** information and make you **aware** of the things to **consider** when preparing for the FMD



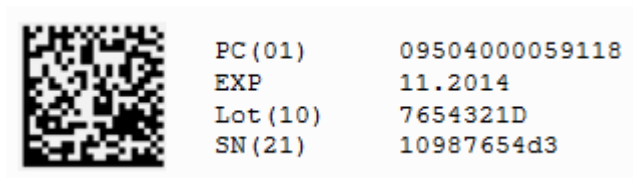
The Global Language of Business

FMD Requirements

FMD Requirements



- In summary we have to comply with ISO/IEC standards
- GS1 standards meet these standards
- National coding in barcodes will have to transition to the use of an ISO/IEC standard



Article 5

Carrier of the unique identifier

1. Manufacturers shall encode the unique identifier in a two-dimensional barcode.
2. The barcode shall be a machine-readable Data Matrix and have error detection and correction equivalent to or higher than those of the Data Matrix ECC200. Barcodes conforming to the International Organization for Standardisation/International Electrotechnical Commission standard (ISO/IEC) 16022:2006 shall be presumed to fulfil the requirements set out in this paragraph.
3. Manufacturers shall print the barcode on the packaging on a smooth, uniform, low-reflecting surface.
4. When encoded in a Data Matrix, the structure of the unique identifier shall follow an internationally-recognised, standardised data syntax and semantics ('coding scheme') which allows the identification and accurate decoding of each data element of which the unique identifier is composed, using common scanning equipment. The coding scheme shall include data identifiers or application identifiers or other character sequences identifying the beginning and the end of the sequence of each individual data element of the unique identifier and defining the information contained in those data elements. Unique identifiers having a coding scheme conforming to ISO/IEC 15418:2009 shall be presumed to fulfil the requirements set out in this paragraph.
5. When encoded in a Data Matrix as data element of a unique identifier, the product code shall follow a coding scheme and begin with characters specific to the coding scheme used. It shall also contain characters or character sequences identifying the product as a medicinal product. The resulting code shall be less than 50 characters and be globally unique. Product codes which conform to the ISO/IEC 15459-3:2014 and ISO/IEC 15459-4:2014 shall be presumed to fulfil the requirements set out in this paragraph.
6. Where necessary, different coding schemes may be used within the same unique identifier provided that the decoding of the unique identifier is not hindered. In that case, the unique identifier shall contain standardised characters permitting the identification of the beginning and the end of the unique identifier as well as the beginning and the end of each coding scheme. Where containing multiple coding schemes, unique identifiers which conform to ISO/IEC 15434:2006 shall be presumed to fulfil the requirements set out in this paragraph.



Definitions

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

GTINs and NTINs are all from the same GS1 number Pool



0000000000000010



04150000000010
↓
04150999999990

05054626000010
↓
05054626999990



99999999999999999

Market	NTIN formation rules
Austria	908888 + PZN + check digit
France	3400 + CIP/ACL Code + check digit
Germany	4150 + 8-digit PZN + check digit
Spain	847000 +Codigo Nacional
Sweden, Finland, Denmark, Iceland, Norway	704626 + Nordic Drug Code issued by Nordic Number office + check digit
Switzerland	7680 + Code assigned by Swissmedic (consists of 5 digits Product License number + 3 digits Pack Size indicator) + check digit

Both are held in AI 01, are the same format and from the same number pool

Getting numbers in the Data Matrix



GTIN + NHRN



GTIN & NHRN

Product Code 09504000059118
National Number 10389358

NTIN



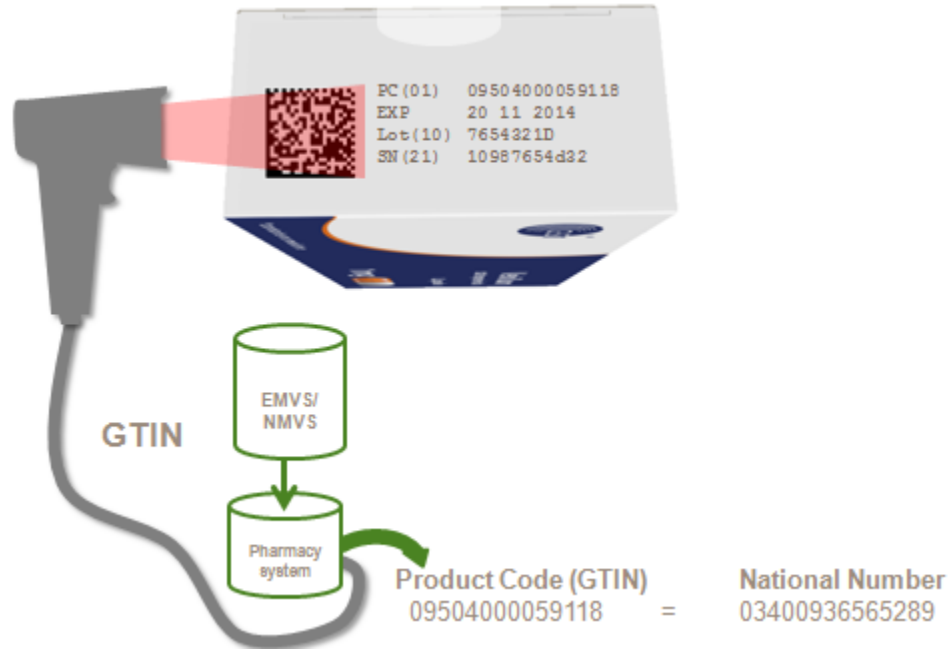
NTIN

Product Code 04150103893583

10389358 National Number

However, the preferred solution is to look up the national number on a database, where required

Preferred solution to obtain a national number



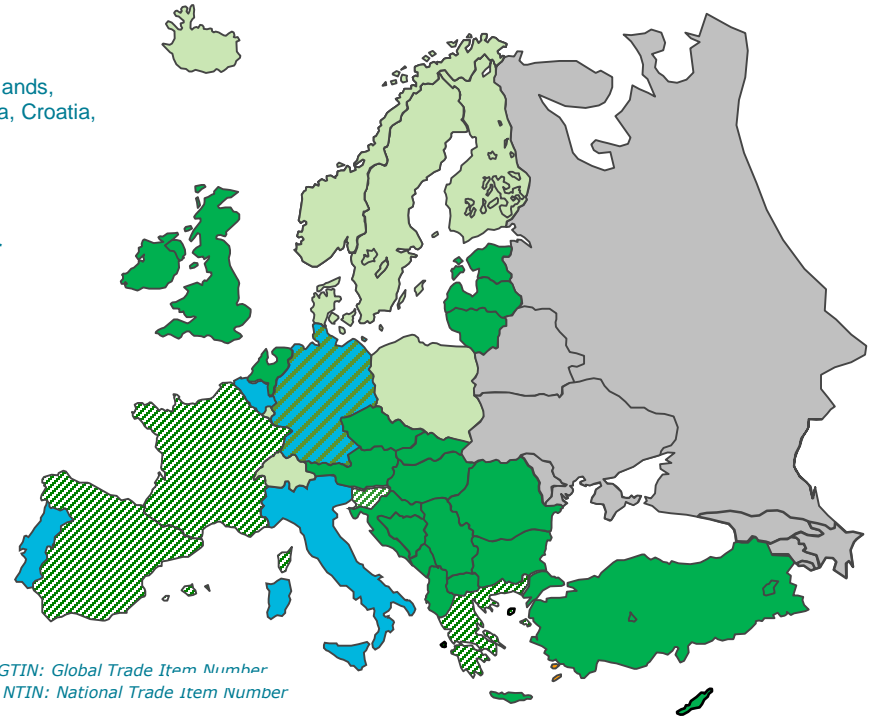


Coding Requirements

The coding situation in Europe today



-  20 countries have a **full GS1 GTIN⁽¹⁾ code structure**
(UK, Ireland, Czech Republic, Slovakia, Latvia, Lithuania, Estonia, Malta, Netherlands, Turkey, Romania, Bulgaria, Serbia, Albania, Bosnia and Herzegovina, Macedonia, Croatia, Cyprus, Slovenia, Hungary) + Germany for shared packs
-  5 countries use a **GS1 NTIN⁽²⁾** with product identification number allocated by a number bank or an external agency for the coding of pharmaceuticals embedded in GS1 data structure
(Austria, France, Germany, Greece, Spain)
-  7 countries allow **GS1 GTIN AND GS1 NTIN**
(Denmark, Finland, Iceland, Norway, Poland, Sweden, Switzerland)
-  3 countries use their own **non-GS1 compatible solution**
(Belgium, Italy, Portugal) + Germany if using a PPN



Key issues



- ❑ Countries which have not yet confirmed coding requirements
- ❑ How countries transition from NTIN to GTIN
- ❑ How countries transition from existing serialised systems to the FMD



Shared Packs

Multiple markets taking a pack



- Any number of GTIN markets can be in a shared pack group*
- Only 1 NTIN market can be in a shared pack group

**Subject to labelling requirements and space on the packaging*

Existing pack				
Mkt 1	Mkt 2	Mkt 3	Take the worst colour	What to use in the Data Matrix
GTIN	GTIN	GTIN	Pack Group can be retained	Hopefully all 3 GTINs are the same on the shared pack
NTIN	GTIN	GTIN	Pack Group can be retained	Use the NTIN
NTIN	NTIN	GTIN	2 NTINs - group must be split	Pack can no longer be shared

Other considerations

- If an NHRN is also used there may be technical constraints on how many lines of data can be encoded in the Data Matrix
- NTIN + NHRN in the Data Matrix is not supported by the standards
- Once a PPN is used in the barcode no other GS1 standard using market can share that pack as they are not compatible within the same barcode

Most market combinations work



	Market	Bulgaria	Croatia	Estonia	Germany	Hungary	Ireland	Latvia	Lithuania	Malta	Netherlands	Romania	Slovakia	Slovenia	UK	Cyprus	Czech Republic	Denmark	Finland	Iceland	Norway	Poland	Sweden	Belgium	France	Liechtenstein	Switzerland	Austria	Greece	Spain	Luxembourg	Portugal	Italy	
Market	Country Code	GTIN	GTIN	GTIN	GTIN / NTIN or PPN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN or NTIN	GTIN or NTIN	GTIN or NTIN	GTIN or NTIN	GTIN or NTIN	GTIN or NTIN	National -> GTIN	NTIN	NTIN	NTIN	NTIN	NTIN	NTIN	Mix ?	National	National	
Bulgaria	BG	BG																																
Croatia	HR	HR	HR																															
Estonia	EE		EE	EE																														
Germany	DE			DE	DE																													
Hungary	HU					HU																												
Ireland	IE						IE																											
Latvia	LV							LV																										
Lithuania	LT								LT																									
Malta	MT									MT																								
Netherlands	NL										NL																							
Romania	RO											RO																						
Slovakia	SK												SK																					
Slovenia	SI													SI																				
UK	UK														UK																			
Cyprus	CY															CY																		
Czech Republic	CZ																CZ																	
Denmark	DK																	DK																
Finland	FI																		FI															
Iceland	IS																			IS														
Norway	NO																				NO													
Poland	PL																						PL											
Sweden	SE																							SE										
Belgium	BE																								BE									
France	FR																									FR								
Liechtenstein	LI																										LI							
Switzerland	CH																											CH						
Austria	AT																												AT					
Greece	GR																													GR				
Spain	ES																														ES			
Luxembourg	LU																															LU		
Portugal	PT																																PT	
Italy	IT																																	IT

- This table is a snapshot and will change over time
- There are choices of coding scheme in some markets

GTIN:GTIN - allowed

NTIN:GTIN – allowed*

NTIN:NTIN – not allowed

National:Any – not allowed**

* Is acceptable from a legal and standards perspective

**National codes do not meet the ISO standards so will have to change





Pack Transition

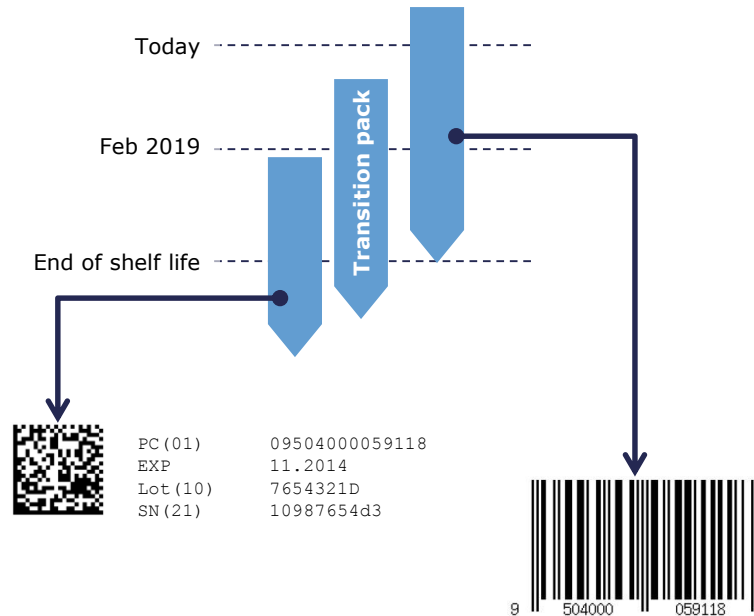
Pack Transition



Issues

- ❑ Pack design prior to Feb 2019
- ❑ NTIN to GTIN Transition
- ❑ Ability to scan and collect data from the Data Matrix

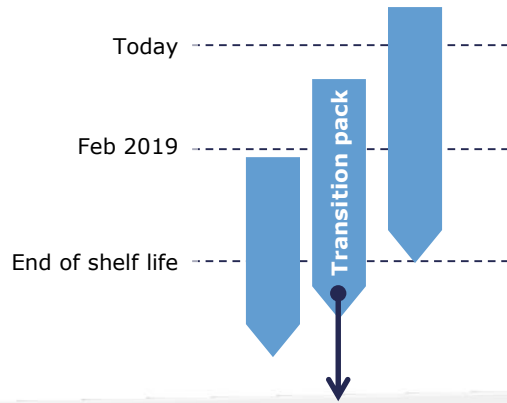
What do we mean by transition management



Challenge

- What do packs look like which are serialised and put on the market before Feb 2019 ?
- There will be guidance from authorities which we need to be aware of
- The best way to monitor this is to participate in the GS1 Public Policy EU FMD Implementation work group

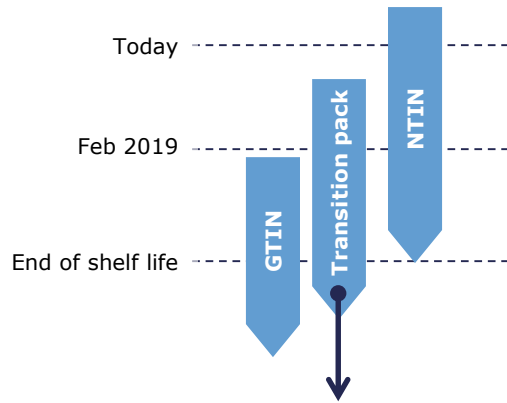
Pack Design Prior to 2019



GTIN

- Applying a GTIN in both the linear and Data Matrix could be a simple solution to enable products to be used before and after Feb 2019

Pack Design Prior to 2019



GTIN only pack (preferred but needs system functionality)

GTIN and NTIN pack (not preferred but may be required for a short period during transition)

NTIN to GTIN Transition

- The same product will be in the supply chain identified with a NTIN or a GTIN depending on what pack is used
- The pharmacy systems must be able to start to scan the FMD pack before Feb 2019 and manage any reimbursement etc using either the old NTIN or new GTIN pack for the same product
- Can you wait for system functionality (e.g. Reimbursement or other similar), and move to GTIN only pack ?

The move to GTIN may not be mandated for existing packs, however if you serialised using NTIN they must be unique !

Ability to scan and collect data from the Data Matrix

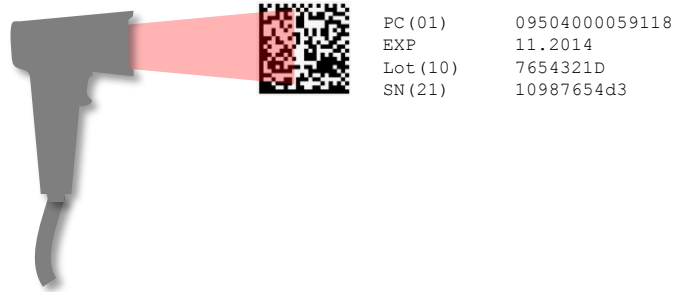
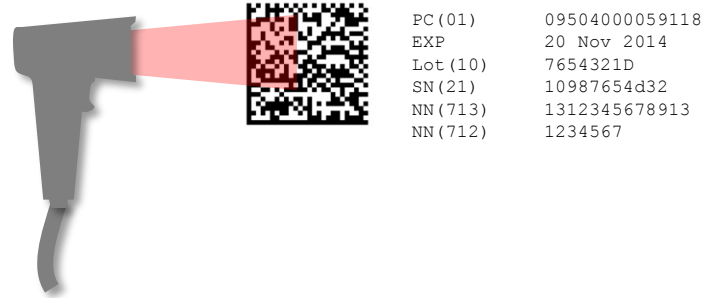
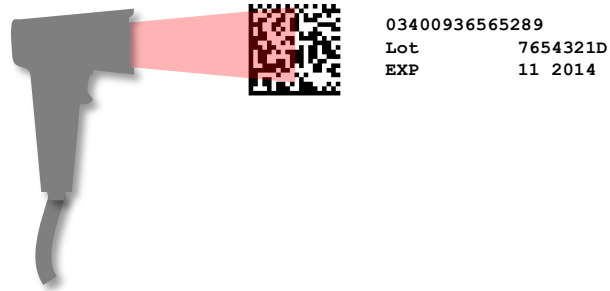


The transition from linear

- Getting data from the data carrier to the system was simple when only the GTIN was encoded
- We need camera based scanners to scan a Data Matrix code
- Now multiple data items will be contained in a Data Matrix, the systems need to be able to make sense of these data strings

Example data strings have been simplified e.g. They do not show group separators or the data carrier identifier

There will be different content encoded



<http://www.gs1.org/demo/09504000059118>

How do the systems in the pharmacy deal with this variation and only collect the data it needs



9504000059118

010950400005911817141100107654321D

010950400005911817141100107654321D2110987654d3

0109504000059118171411002110987654d3107654321D

010950400005911817141100107654321D2110987654d3271313123456789137121234567

010950400005911817141120107654321D2110987654d3271313123456789138200<http://www.gs1.org/demo/>

- Due to pack sharing and movement of goods any one of the above examples needs to be able to be scanned

How to process the data from a Data Matrix is covered within the GS1 General Specification

Questions



Where can I get more information ?



- GS1 Public Policy EU FMD Implementation work group
- GS1 Global Office
Avenue Louise 326, bte 10
B-1050 Brussels, Belgium
T + 32 2 788 78 00
W www.gs1.org
- Or find Grant or Joan at the conference

