The FMD
Pack Coding, Sharing and Transition

Ask the expert

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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
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 Standardization/International Electrotechnical Commission standard (ISO/IEC 16022:2006) shall be presumed to fulfill 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 fulfill 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 fulfill the requirements set out in this paragraph.

6. When 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 15414-2:2006 shall be presumed to fulfill 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

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

Both are held in AI 01, are the same format and from the same number pool
Getting numbers in the Data Matrix

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

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(1) GTIN: Global Trade Item Number  
(2) NTIN: National Trade Item Number
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

<table>
<thead>
<tr>
<th>Existing pack</th>
<th>Take the worst colour</th>
<th>What to use in the Data Matrix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mkt 1</td>
<td>Mkt 2</td>
<td>Mkt 3</td>
</tr>
<tr>
<td>GTIN</td>
<td>GTIN</td>
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<td>NTIN</td>
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<tr>
<td>NTIN</td>
<td>NTIN</td>
<td>GTIN</td>
</tr>
</tbody>
</table>

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 is 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

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

<table>
<thead>
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<th></th>
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<tbody>
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<td>Italy</td>
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</tr>
</tbody>
</table>

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

• 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

Challenge
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

**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!*

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**GTIN only pack** (preferred but needs system functionality)

**GTIN and NTIN pack** (not preferred but may be required for a short period during transition)
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
How do the systems in the pharmacy deal with this variation and only collect the data it needs?

9504000059118
010950400005911817141100107654321D
010950400005911817141100107654321D2110987654d3
0109504000059118171411002110987654d3107654321D
010950400005911817141100107654321D2110987654d3271313123456789137121234567
010950400005911817141120107654321D2110987654d3271313123456789138200http://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
Finally