European regulations...make compliance easier with GS1

Ulrike Kreysa, VP Healthcare, GS1 Global Office

Lisbon, 20th October 2016
Agenda

• Why standards in Healthcare
• GS1 Healthcare
• The EU Falsified Medicines Directive
• UDI – also in Europe
• Imagine…
Counterfeiting - The Impact

According to Interpol more than **one million people** die each year from counterfeit drugs!

In some areas of Asia, Africa and Latin America counterfeit medical goods can form up to 30% of the market.
Increasing Healthcare costs

Costs for Healthcare are increasing quicker than GDP – could be in 2050 25% of France’s GDP, 35% of the US’s according to OECD Health statistic (2013, Institute for Health Metrics and Evaluation,)

Some good reasons
Medical errors are third leading cause of death in United States after Heart disease and cancer - claiming 251,000 lives every year – more than strokes, accidents, diabetes, Alzheimer...

Source: BMJ 2016;353:i2139
Recalls

Recall based on GTIN in the UK

Product recalls in Healthcare are painful for all stakeholders

Metal-on-metal (MoM) hip replacements - guidance on implantation and patient management

From: Medicines and Healthcare products Regulatory Agency
Published: 25 June 2015
Issued: 25 June 2015
Alert type: Medical device alert
Medical specialism: General practice, General surgery, Haematology and oncology, Orthopaedics, Pathology, Physiotherapy and occupational therapy, Radiology, and Theatre practitioners

(Smith & Nephew Orthopaedics) Birmingham Hip™ Resurfacing (BHR) system - higher than expected revision rate for certain patient groups (MDA/2015/024)
Actions

A lot of regulatory bodies have decided to take action and chosen GS1 standards for implementation of traceability!
Working with many regulatory bodies across the world

And many more…
To lead the healthcare sector to the successful development and implementation of **global standards** by bringing together **experts** in healthcare to enhance **patient safety** and **supply chain efficiencies**.
Our vision

The vision of GS1 Healthcare is to be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders seeking input and direction for global standards in healthcare for

- patient safety
- supply chain security & efficiency
- traceability
- product data
GS1 Healthcare: an expanding, committed community of globally engaged stakeholders...

...and there are many more companies working with GS1 at a local level
Cooperating with global organisations...

Joint Initiative Council

International Organisation for Standardisation
European Committee for Standardization
Health Level 7 International
International Health Terminology SDO
Clinical Data Interchange Standards Consortium
Integrating the Healthcare Enterprise
Digital Imaging and Communications in Medicine

World Health Organization
World Customs Organization
International Hospital Federation
International Council for Commonality in Blood Banking Automation
International Society for Quality in Healthcare
European Federation of Pharmaceutical Industries and Associations
European Federation of Pharmaceutical Industries and Associations
European Medical Devices Industry Association

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Regulatory requirements in Europe
Delegated Regulation (EU) 2016/161 of the EU Falsified Medicine Directive

- a. Technical characteristics of the **unique identifier (UI)**, an unique sequence carried by a **2D barcode** allowing the identification and authentication of the individual pack on which it is printed

- b. Verification of the Safety Features

- c. Repositories system for the UI

- d. Lists of exceptions from bearing/not bearing the safety features

**NOT** specifying the ATD – anti-tampering device – left to the discretion of manufacturer – CEN standard EN 16679:2014 to consider
The Unique Identifier in the DA

The UI - Composition

- The UI will contain:
  - **Product code**: ISO-compliant (ISO 15459); < 50 characters; globally unique; issued by ISO-compliant coding agencies;
  - **Serial number** (max 20 characters; randomised)
  - A **national reimbursement or identification number** (optional)
  - **Batch number**
  - **Expiry date**

- UI also ISO-compliant (ISO 15418; ISO 15434).

(01)09876543210982(21)12345AZRQF1234567890(10)A1C2E3G4I5(17)180531

*Illustrative example – not binding.*
European Federation of Pharmaceutical Industries and Associations (EFPIA): Recommendation for Coding of Pharmaceutical Products in Europe

Data Matrix – Coding proposal derived from GS1 standards (EAN 128 syntax with Application Identifiers; DataMatrix ECC200)

Manufacturer Product Code (GTIN or NTIN): 14 digits
Unique Serial Number (randomized): up to 20 alpha-numeric characters
Expiry Date: 6 digits (YYMMDD)
Batch Number: up to 20 alpha-numeric characters

+ minimum requirements on quality of randomisation

Example:

<table>
<thead>
<tr>
<th>GTIN</th>
<th>(01) 07046261398572</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch</td>
<td>(10) TEST5632</td>
</tr>
<tr>
<td>Expiry</td>
<td>(17) 130331</td>
</tr>
<tr>
<td>S/N</td>
<td>(21) 19067811811</td>
</tr>
</tbody>
</table>

Specifications provided in EFPIA’s: “European Pack Coding Guidelines”
The coding situation in Europe today

19 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, Hungary)

6 countries use a NTIN (2) (EAN 13 compatible code) 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, Slovenia, Spain)

7 countries allow NTIN AND GTIN
(DK, Finland, Iceland, Norway, Poland, Sweden, Switzerland)

4 countries use their own non-GS1 compatible solution
(Belgium, Germany, Italy, Portugal)

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(1) GTIN: Global Trade Item Number
(2) NTIN: National Trade Item Number
The move towards harmonisation and GS1 standards in Europe
England – NHS

Objectives:
• Deliver efficiency and productivity gains
• Improve data, information and transparency
• Re-think clinical engagement in procurement
• Improve trust capabilities in procurement

Actions:
• Mandate through contracts GS1 standards GTIN, GLN and GDSN
• Create a single NHS GS1 data pool
• Define standards for eProcurement
• Establish standards for datasets/classification
• Put implementation support in place
UDI = Unique Device Identification

...is enabled by GS1 Standards!!
US FDA UDI rule

GS1 was accredited as first issuing agency by the FDA

Accredited Issuing Agencies

An issuing agency is an FDA-accredited organization that operates a system for assignment of UDI: final rule permits multiple issuing agencies and provides a process through which an applicant would issuing agency.

Applicants seeking initial FDA accreditation as an issuing agency shall notify the FDA via email at udi@fda.hhs.gov.

FDA has accredited the agencies listed below:

1. Firm Name: GS1
   Address: Princeton Pike Corporate Center, 1009 Lenox Drive, Suite 202, Lawrenceville, NJ
   Contact Person: Siobhan O’Bara, Senior Vice President - Industry Engagement
   Phone: (609) 620-8046
   Email: sobara@gs1us.org
   Web Site: http://www.gs1.org
   Date of Initial Accreditation: December 17, 2013
   Initial Accreditation Granted through: December 17, 2016
   • Application
   • Approval Letter
More than 90% of products in US FDA GUDID carry GS1 as UDI primary device identifier.
UDI system...similar in the US FDA and the EU, some differences in the details!

UDI/UDID - System

UDI
- DI
  * Device Identifier (static data)
- PI
  * Production Identifier (dynamic data)

UDID (database)
- Static Data Elements
  - DI = primary access key
  - ...
  - ...

AIDC
- Machine – readable Data Carrier
  - Linear Bar Code
  - 2D Bar Code
  - RFID
  - ...

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# UDI & the GS1 system...

## UDI in GS1 identification (identify) terms...

<table>
<thead>
<tr>
<th>UDI</th>
<th>GS1 Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique Device Identification</td>
<td>Product Identification</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DI</th>
<th>GTIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier (DI)</td>
<td>Global Trade Item Number</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PI</th>
<th>AI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Identifier (PI)</td>
<td>Application Identifier (AI)</td>
</tr>
<tr>
<td>(if applicable)</td>
<td>- Expiration Date AI(17) - e.g. 141120</td>
</tr>
<tr>
<td></td>
<td>- Lot/Batch AI(10) - e.g. 1234AB</td>
</tr>
<tr>
<td></td>
<td>- Serial Number AI(21) - e.g. 12345XYZ</td>
</tr>
</tbody>
</table>

*Production Identifier data will vary by medical device type and manufacturer current practice.*

\[
DI + PI = UDI \\
GTIN or GTIN + Al(s) = UDI
\]
Manufacturers are able to provide data to any UDI database and their customers (hospitals, distributors, wholesalers, GPOs), with a single connection.
UDI: the EU roadmap

- **2012** EC proposals MD & IVD Regulations
- **2013** EC Recommendation to MS
- **Q1 2017** EU Regulations published (tbc)
- **2020**
  - EU Regulations applicable: deadline for UDI assignment and data submission in EUDAMED (tbc)
- **2021**
  - UDI labelling for Class III (tbc)
- **2023**
  - UDI labelling for Class II (tbc)
- **2025**
  - UDI labelling for Class I (tbc)

... development of EUDAMED (UDI-D) ...
GS1 Healthcare aims for harmonization of regulatory requirements across the world

- A global standardized system is needed for “unique” identification numbers to ensure world-wide supply chain compatibility and traceability.

- **The result:** Prevent counterfeit drugs entering the market, gain efficiency, have the right product in the right place at the right time, more effective recalls and more...
The value of AIDC

“The use of identification and data capture technology will continue to be foundational, allowing the healthcare sector to move products through every organisation as necessary, while ensuring patient wellbeing. These products are required in short timeframes and shipped across long distances. Many of the products look or sound alike or are the same chemical in different strengths, making visual identification of them difficult. When administering the product to the patient, caregivers need absolute certainty that the right product is being used — there is no margin for error. Identification and data capture helps to automate processes and ensure accuracy in a very important and rewarding, but complex environment.”

Scott Mooney, Vice President, Distribution Operations, McKesson
“Take care of the patient and everything else will follow.”

Dr. Thomas Frist Sr.
Founder of the Hospital Corporation of America

EVERYBODY in the supply chain needs to implement to derive true benefits – for EVERYBODY
And the next big development...

- Identification on primary packaging level – blister, ampoule etc.
- The European Association of Hospital Pharmacists is requesting this for patient safety – requirements from AMGROS and others moved the industry
- Hospitals do not want to re-package, but use bedside scanning
Imagine a world...

... where bedside scanning confirms that the patient gets the right product in the right dosage at the right time and the patient records captures all the details.

... where hospitals and pharmacies know the exact location of short-supply medical devices and drugs and when they can be delivered.

... where regulators can recall products with accuracy and speed from every point in the supply chain and there is no possibility of receiving a counterfeit product.
Ultimately it is all about...

PATIENT SAFETY!
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