Eucomed and UDI
(Unique Device Identification)

Eucomed ETF (eBusiness Task Force)
May 2010
UDI : History and Players

- 09/2007 : US Congress asked FDA to develop a ‘UDI-System’
- 10/2008 : GHTF (Global Harmonization Task Force) recognized global relevance

GHTF ad-hoc WG
- founded in 10/2008
- regul. bodies + industry trade assoc.
- assess FDA draft / ensure global harmonization
- draft ‘UDI Guidance’ published 11/2009

EUROPE
- EU Commission (L. Selles, R. Munoz)
- MoH DE (M. Neumann)
- Eucomed (V. Zeinar - B. Braun)
- EDMA (C. Tarrajat)

USA
- FDA (J. Crowley)
- AdvaMed (J. Secunda, T. Werthwine)

ASIA
- China Shanghai FDA (L. Yan)
- JFMDA Japan (H. Ishikawa - Toshiba)
- AHWP (L. Tao, AHWP - J&J)

partnership between regulatory authorities and the regulated industry (founded in 1992)
→ achieve greater uniformity between national medical device regulatory systems

www.ghtf.org
The regulators intention:
Make the usage of auto-ID technology at Medical Devices mandatory!

To
- ... improve patient safety
- ... enhance vigilance & market surveillance
- ... facilitate traceability
- ... support processes

Machine-readable Marking (AIDC) packaging and/or product + Database(s)
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The 3 main parts of the UDI system

1. UDI Code
   - device ID
   - production ID
   - static data
   - variable data
     - expiration date
     - lot/serial no.

2. UDI Carrier
   - linear bar code
   - DataMatrix
   - Rfid
   - technology neutral
   - ... and others

3. UDI database (network)
   - product identification and marking based on global standards (GS1 or HIBC)
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What is Unique Device Identification?

UDI (alone) is not Serialisation!

► UDI (GTIN Static Data)...

Will distinguish one type of device from one manufacturer with differing product or packaging characteristics

GTIN = AI(01)35019315050804

GTIN = AI(01)3501931508695

GTIN = AI(01)35019315050804

GTIN = AI(01)3501931508695

at the beginning confusion about the term ‘unique’
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What is Unique Device Identification?

**UDI** (alone) is not Serialisation!

- **UDI (GTIN Static Data) + Batch/Lot Number (Production Data)…**
  - Will distinguish a device from a manufacturer with *identical* characteristics but manufactured in *different batches*

GTIN + AI(10)12345

GTIN + AI(10)67891

GTIN + AI(10)65439
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What is Unique Device Identification?

Serialisation is:

- **UDI** *(Static Data) + Serial Number (Production Data)*...

  Will distinguish *individual* devices from a manufacturer with *identical* characteristics

![Image of medical devices with GTIN + AI(21) numbers]
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The latest definition of the main goals

Improve patient safety by:

► enhancing the identification of devices in case of adverse events
► facilitating traceability of devices in the event of a field safety correction

It is anticipated the UDI may facilitate the reduction of medical errors.

The former definition:

• reducing device related medical errors
• enhancing the identification of devices in case of adverse events
• facilitating traceability
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UDI is the foundation, leading to improved process for...

UDI creates transparency, improves processes, increases efficiency and makes isolated systems interoperable
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UDI regulations/requests from around the world → not all are following a globally harmonized approach!

Europe / Mid.East
- England
- Spain (Andalusia)
- Turkey
- Italy
- EU Com
- Saudi Arabia

North America
- US (FDA)
- Canada

Latin America
- Chile
- Brazil

Asia Pacific
- Japan
- India
- Australia
- China
- Hong Kong
- Korea
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**Milestones**

- **US Congress mandates FDA to develop a UDI guidance**
- **US FDA 1. pilot UDI-DB**
- **US FDA publishes UDI guidance (draft)**
- **EU Commission going to consider UDI at MDD recast**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept 2007</td>
<td>GHTF SC established UDI ad-hoc WG goal = ‘global harmonization’</td>
</tr>
<tr>
<td>Oct 2008</td>
<td>GHTF SC published 1. UDI discussion paper</td>
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<tr>
<td>Sept 2009</td>
<td>GHTF SC end of public comments period</td>
</tr>
<tr>
<td>Nov 2009</td>
<td>Comments review by the GHTF ad-hoc WG</td>
</tr>
<tr>
<td>Mar 2010</td>
<td>Comments from: Eucomed, AdvaMed, JFMDA, EDMA, COCIR, GS1, .... (40+)</td>
</tr>
<tr>
<td>May 2010</td>
<td>GHTF ad-hoc WG presents 2. UDI discussion paper to GHTF SC</td>
</tr>
<tr>
<td>Q3 2010</td>
<td>GHTF SC decision on how to move forward</td>
</tr>
<tr>
<td>Q1 2011</td>
<td></td>
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</tbody>
</table>
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Implementation Schedule (expected)

US:
- UDI guidance becomes a law
- Implementation deadline for Class 3 products
- Implementation deadline for Class 2 products
- Implementation deadline for Class 1 products

EU:
- MDD recast UDI legislation
- 2 years legislation process (2011-2013)
- at least 3 years transition period for implementation on national level (2013 – 2016)

Other regions worldwide ???
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- EU Com organised a meeting of Competent Authorities (17)
  - Madrid, March 2010
  - representatives from 17 member states
  - 1st introduction to UDI → great success

- Agreement between Industry + EU Com about the way forward
  - some MSs diverge
  - ‘realistic/practical’ approach versus ‘high-end’ approach incl. traceability

- The EU MedTech industry is working through the various medical device trade associations to put together a joint industry response

The EU MedTech industry is speaking with one voice!
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UDI - Industry Key Messages (1):

► UDI is a key development for the Medical Technology Industry

► A Unique Device Identification system must first be defined
   - for e-health systems to work (patient records, traceability, reimbursement, registration, etc.)
   - to provide an identifier (‘passport’) for each MedDev

► UDI identifiers must be globally unique → key success factor!
   - Med Tech is a global industry
   - NO local or national deviation → unacceptable fragmentation

► Step-wise implementation is essential
   - vast undertaking for the healthcare industry
   - at least 3 years is needed by manufacturers for 1. step
   - starting with the highest risk class first
   - based on a globally harmonised risk classification system
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### UDI - Industry Key Messages

- A risk-based approach is essential (AIDC);
  - not all MedDev need the same information at all packaging levels

- Industry recommendation (AIDC)

<table>
<thead>
<tr>
<th>Unit (consumption) Pack or Product itself (direct part marking)</th>
<th>Shelf Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory</td>
<td>Optional(^{(2)})</td>
</tr>
<tr>
<td>Class I</td>
<td>GTIN(^{(3)})</td>
</tr>
<tr>
<td>Class IIa</td>
<td>GTIN</td>
</tr>
<tr>
<td>Class IIb</td>
<td>GTIN</td>
</tr>
<tr>
<td>Class III</td>
<td>GTIN + Production Data</td>
</tr>
</tbody>
</table>

**Note:**

1. Technical feasibility prerequisite (space, substrate etc.)
2. At the manufacturer’s discretion (e.g. for internal processes), but not to be used for regulatory purposes
3. GTIN = Global Trade Item Number (GS1 terminology) = UDI code, static data
4. Production Data = Expiry Date + Lot Number or Serial Number

*Does not exclude the use of production data, which is at the manufacturer’s discretion*

*It is at the manufacturer’s decision whether the product is ‘Lot Number’ or ‘Serial Number’ controlled*
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**UDI - Industry Key Messages (3):**

- UDID (UDI Database) should be the single global database for Core Product Identification Attributes
  - probably a network of DB’s
  - can be used for other purposes (e.g. migration to, integration with or replacement of other currently un-harmonised databases)

- The Core Attributes from Eucomed’s perspective
  - 8 attributes focusing on identification and should be mandatory

  - UDI code (static data)
  - Manufacturer name
  - Manufacturer contact information
  - Nomenclature (e.g. GMDN)

  - Device name (generic name)
  - Trade name (brand name)
  - Device model number (REF number)
  - Regional authorised representatives (if applicable)

- all other attributes should be optional
  (not clear how e.g. ‘storage conditions’ can improve patient safety)
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#### List of Attributes within the GHTF Paper

<table>
<thead>
<tr>
<th>Attribute (GHTF draft)</th>
<th>Reducing Errors</th>
<th>Enhancing Identification</th>
<th>Facilitating Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 UDI code (static part) = KEY</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2 Manufacturer name</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3 Manufacturer contact information</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>4 Nomenclature (e.g. GMDN)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>5 Device name (generic name)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>6 Trade name (brand name)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>7 Device model number (Ref no.)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>8 Controlled by serial/lot no - manuf./expiry date</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>9 Quantity and packaging level</td>
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<td>No</td>
<td>No</td>
</tr>
<tr>
<td>10 Size incl. units of measure</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>11 Storage conditions</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>12 Sterility (and sustainability)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>13 Labeled as single use</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>14 Need to be sterilized before use</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>15 Restricted number of use</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>16 Labeled as containing allergens/materials of concern</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>17 Regional authorized representatives</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>18 URL for additional information</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>19 Special instructions for use</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

- **Main purpose of the UDI system**

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[www.eucomed.org](http://www.eucomed.org)
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What do we need first?

Clear definition of the purpose of the UDI-database!

Know what the use cases will be!

Know what the expectations of the SC stakeholders are!

otherwise it’s hardly possible to create a system!
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UDI - Industry Key Messages (4):

► Legislations directed at the manufacturer only!

► Authorities must ensure that healthcare providers are under an equivalent obligation
  - to achieve the public health objective
  - otherwise whole exercise + vast cost to industry will have been largely wasted

► A thorough Impact Assessment must be carried out
  - essential because the costs (investment and implementation) will be significant for both industry + healthcare systems
  - only way to assess the full effect and to achieve the full benefit of UDI
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UDI - Industry Key Messages (5):

► How to handle space constraints or other physical limitations?

► Increasing requirement, in the EU, for more languages, more symbols for material content (e.g. DEHP, LATEX...), addresses, human readable information etc.
  - what can be omitted from the labelling to meet the mandated UDI requirements for high risk devices, if there is insufficient space to include all this information?

► For very small packs/products there might not be sufficient space to include UDI; therefore it will have to be omitted from labelling until technology can provide a solution
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The risk of technical neutrality = ‘AIDC Babylon’

- Bar Code (linear, 2D), Rfid
- GS1 : EAN-13, GS1-128, DataMatrix, DataBar, composite, ..., Rfid
- HIBC : Code39, Code128, Codablock, DataMatrix, QR, ..., Rfid
- concatenated, non-concatenated, stacked, ...
  → all versions would fulfill UDI
  → but could be a nightmare for HC providers !?
  → will this enhance adoption on HC prov. side?
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In Summary

UDI will bring great benefits for:

✓ PATIENT SAFETY
✓ IMPROVED VIGILANCE & MARKET SURVEILLANCE
✓ GLOBAL TRADE

BUT it is essential that

✓ A pragmatic (risk-based) approach is adopted
✓ Healthcare providers are fully resourced to respond
✓ Regional authorities co-operate to ensure a truly **GLOBAL** and **HARMONISED UDI** approach
Thank you very much for your attention!

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