Eucomed and UDI
(Unique Device Identification)

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GS1 Healthcare Conference - June 2010
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► An introduction to Eucomed
► Some facts about the MedTech industry
► Background on Eucomed’s Activities on UDI
► Key messages from industry
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What is Eucomed?

► The Voice of the medical technology industry in Europe
  – Eucomed represents 4,500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability
  – Eucomed members include 26 national trade and pan-European product associations and c.60 internationally active manufacturers of all types of medical technology

► Mission
  – To improve patient and clinician access to modern, innovative and reliable medical technology
What is the MedTech Industry in Europe?

- Products range from bandages to scanners
- **€73bn sector sales**
- Highly innovative but less than 7% of total healthcare expenditure
- NOT a cost driver – device cost inflation well below other costs
- Diverse sector – c. 11,000 businesses of which 80% are SMEs
- Over 445,000 highly skilled workers are employed
- BUT MedTech (Devices) is NOT the Pharma industry
- The regulatory regime is different to that applied to medicines
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What is the Eucomed ETF (e Business & Supply Chain Task Force)?

► Background
  – Focused on AIDC and Unique Device Identification (UDI) since 2002

► Forged 'alliance' with GS1 Healthcare, becoming part of a global 'movement'

► Objectives:
  – to monitor developments in AIDC as a tool for improved PATIENT SAFETY
  – develop policy and industry guidance on UDI,
  – to engage industry, healthcare professionals and the authorities-ensure AWARENESS
  – represent industry to the EU Commission

► Output
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How has the ETF engaged with the Authorities?

Positive engagement

► 2007 UK Department of Health published 'Coding for Success'

► 2007 EU Commission - concerns about counterfeit medical devices

► WHO ‘IMPACT’ group

BUT ....

► Fragmentation in international markets e.g. Turkey, Spanish regions, with potential barriers to trade and threat to global objectives
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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 Commission
- Saudi Arabia

North America
- USA (FDA)
- Canada

Latin America
- Chile
- Brazil

Asia Pacific
- Japan
- India
- Australia
- China
- Hong Kong
- Korea
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Key milestone: 2008 Global Harmonization Task Force (GHTF) recognised the importance of UDI

Main driver: proposed FDA rule

GHTF Working Group established - chaired by EU Commission with ETF participation from Volker Zeinar

New priority for industry: to ensure that regulation is truly global and practical in its application

This led to the development of ‘risk-based’ approach
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The ‘Risk Based’ approach

► In a perfect world all device and/or packaging should carry a unique identifier
► Today a pragmatic approach is needed
► Start with devices where patient safety is the major consideration
► These would be MDD Class III or IIb devices e.g. implants
► Many devices are too small to be marked individually
  - Therefore these devices need to be marked only at an appropriate level of packaging e.g. shelf pack
► Very significant costs to all stakeholders are anticipated
► Proposal: Risk-based implementation of Unique Device Identification (UDI)

► ETF Position Paper June 2009:
  www.eucomed.be/~/media/45B95BF4CBE840D94EE229E821D87A8.ashx
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UDI - Key Messages from Industry (1):

► UDI is a key development for the Medical Technology Industry

► A Unique Device Identification system is needed for:
  – Patient Safety, reimbursement
  – To provide an identifier (‘passport’) for all devices

► UDI identifiers must be globally unique → key success factor!
  – MedTech 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 the first step
  – starting with the highest risk class first
  – based on a globally harmonised risk classification system
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## UDI - Key Messages from Industry (2):

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

- Industry recommendation (AIDC)

<table>
<thead>
<tr>
<th>Class</th>
<th>Unit (consumption) Pack or Product itself (direct part marking)</th>
<th>Shelf Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mandatory</td>
<td>Optional$^{(2)}$</td>
</tr>
<tr>
<td>Class I</td>
<td>GTIN$^{(3)}$</td>
<td>GTIN</td>
</tr>
<tr>
<td>Class IIa</td>
<td>GTIN</td>
<td>Production Data$^{(4)}$</td>
</tr>
<tr>
<td>Class IIb</td>
<td>GTIN</td>
<td>Production Data</td>
</tr>
<tr>
<td>Class III</td>
<td>GTIN + Production Data</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
   
   *Does not exclude the use of production data, which is at the manufacture’s discretion*

4. Production Data = Expiry Date + Lot Number or Serial Number
   
   *It is at the manufacturer’s decision whether the product is ‘Lot Number’ or ‘Serial Number’ controlled*
UDI - Key Messages from Industry (3):

► UDID (UDI Database) should be the single global database for Core Product Identification **Elements** [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

► Clarification is needed for
  - Definition of the UDID purposes
  - Intended use cases
  - Know the expectations of users, particularly Healthcare Providers
  - UDID Governance Model - ownership after GHFT process complete
UDI - Key Messages from Industry (4):

► Legislation directed at the manufacturer only!
  ► FDA Rule
  ► Recast of Medical Devices Directive

► Healthcare providers must be under an equivalent obligation
  – to achieve the public health objective
  – otherwise the whole exercise and vast cost to industry will have been largely wasted

► A thorough Impact Assessment must be carried out
  – Costs 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 - Key Messages from Industry (5):

- How to handle space constraints or other physical limitations?

- Increasing requirement, in the EU, for more languages, more symbols

- For very small packs/products there might not be sufficient space

- 27 EU MSs and other countries’ language requirements in the database?

- Multiple bar codes: additional symbol to identify the UDI bar code?!?

The EU MedTech industry is speaking with one voice and asking for one global system and standard!
What about the Healthcare Providers?
This is the key concern for industry!

► The healthcare community must be able to interface effectively

► This is an even greater task than adoption in industry

► Healthcare establishments must be
  – properly equipped and
  – personnel trained

► Regional authorities (e.g. FDA, EU Commission, MHLW, SFDA…) must also address this
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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
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Thank you for your UnDIvided attention!

Some Useful Website Links:

www.eucomed.com
www.ghtf.org
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers/default.htm
www.gs1.org/healthcare
www.abhi.org.uk
www.youtube.com/user/GS1Healthcare
www.linkedin.com/e/vgh/2410702/

(LinkedIn user name and password required)