Eucomed and UDI

(Unique Device Identification)

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GS1 Healthcare Conference - June 2010

Eucomed
Medical Technology

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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

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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
  - Unique Device Identification (UDI): Getting ready - (Press Release 22nd July 2009): www.eucomed.be/Home/portal/press/press_releases/2009/07/20090722pr1509.aspx
  - Eucomed Guidance for Bar Coding Medical Devices - (Position Paper Sept. 2007): www.eucomed.be/press/~/media/C34B6581E25B4AA8BF66A2C826494DD6.ashx

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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!

North America
USA (FDA)
Canada

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

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/45B95BF4CBEB400D94EE229E821D87A8.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)

	Unit (consumption) Pack[1] or Product itself (direct part marking)		Shelf Pack	
	Mandatory	Optional[2]	Mandatory	Optional[2]
Class I		GTIN[3]	GTIN	Production Data
Class IIa	GTIN	Production Data[4]	GTIN + Production Data	
Class IIb	GTIN	Production Data	GTIN + Production Data	
Class III	GTIN + Production Data		GTIN + Production Data	

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

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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

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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!

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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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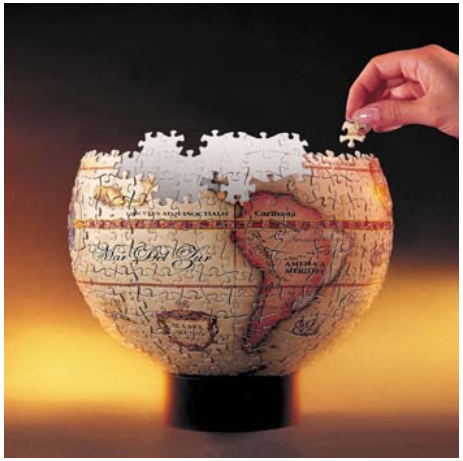
In Summary

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 *U*n*D*I*v*ided attention!

Some Useful Website Links:

www.eucomed.com

www.ghtf.org

http://ec.europa.eu/enterprise/sectors/medical-devices/specific-areas-development/udi/index_en.htm

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)