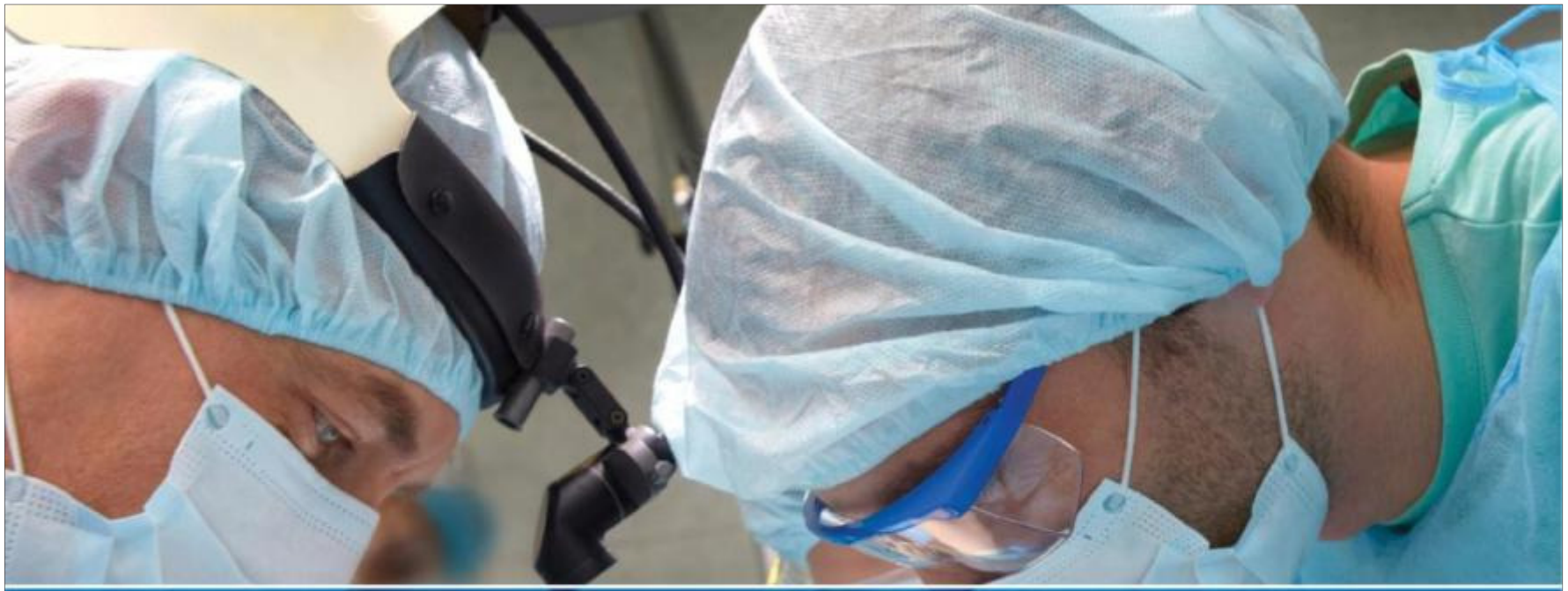
Eucomed
Medical Technology

www.eucomed.org



Eucomed and UDI

GS1 Lisbon Conference – October 2012

Mike Kreuzer - Regulatory Affairs Director ABHI - Chair Eucomed ETF

Eucomed

Represents the medical technology industry in Europe.

- Its mission is to make modern, innovative and reliable medical technology available to more people.

Facts & figures about medical technology industry in Europe:

- Annual sales of €95 billion – 8% ploughed back into research and development each year
  - 1/3 of global medical technology market
  - Second largest market behind the US
- 22,500 companies – 80% of SMEs
- Nearly 500,000 employees

Eucomed

Objectives

- Promote balanced policy environment (effective, proportional and encourages innovation)
- Promote & drive high standards of ethical behaviour
- Demonstrate value of the medical technology
- Provide membership services (data, training, etc)

Membership includes:

- 26 national industry associations
- 5 associate Members
- 62 direct corporate members

ABHI - Association of British Healthcare Industries

UK MedTech Industry

- 3000 companies 95% SMEs
- 60,000 employees
- Sales £15 BN

ABHI

STRATEGY

Advocating policies that allow members to operate in a favourable business environment

UK MARKET

Policies that support the rapid evaluation, reimbursement and adoption of medical technologies by UK healthcare systems

INTERNATIONAL MARKETS

Policies to provide an effective gateway to foreign markets

REGULATION & STANDARDS

Policies for simple and smart regulation, providing patients with safe, effective, high quality and innovative medical technologies

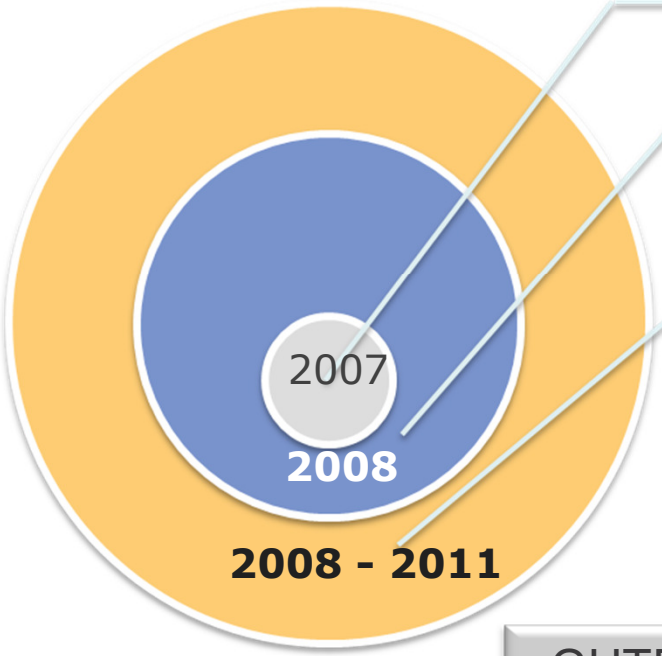
ETHICS & PRINCIPLES

Policies to ensure business is conducted in the right manner

Eucomed ETF representing EU MedTech industry

- Develops EU Industry policy on UDI/UDID and represent this to the Commission and where appropriate national regulatory bodies.
- Works with standards development bodies and GS1 to promote adoption of GS1 Standards as the preferred European and global solution
- Works to prevent deviation from or proliferation of non-standard systems particularly in Europe
- Provides representation on IMDRF UDI Work Team
- Raises awareness of best practice in UDI and Distribution both to industry and to and healthcare systems providers

UDI: History and Players



US Congress mandates FDA

GHTF recognizes global relevance

GHTF ad-hoc WG for guidance preparation
'ensure global harmonization'

www.ghtf.org

GHTF ad-hoc WG

Europe	North America	Asia - Pacific
• EU Commission	• US FDA	• China FDA
• MoH Germany	• Health Canada	• JFMDA
• Eucomed	• AdvaMed	• AHWP
• EDMA		

Where are we today?

- We are today at an inflection point in the development of UDI
- The legislative components are in place but not yet enacted and lacking coordination
- Awareness is often low
- Those who are aware are at risk of moving in the wrong direction - Commission Recommendation

Legislation

- FDA Rule will be law next year
- MDD Revision in EU Co-Decision process
- BUT UDI details subject to Delegated Act - 2014?
- Other legislation / regulation?

Global oversight

- Now under auspices of IMDRF - Great!
- But how much authority / influence does IMDRF have?
- How effectively are UDI matters coordinated within IMDRF?
- Greater industry input needed

Awareness and readiness - industry

- Awareness in industry is patchy BUT cost will be very significant
- Reluctance to engage until details of legislation clear
- Need for enhanced Comms programme
- Industry must lead provider awareness

Awareness - healthcare systems

- This could be our biggest challenge
- The legislation targets industry with no guarantee that healthcare systems will respond
- We need to develop a smart way to work with Member State authorities probably at political level

Awareness at another level

- Commission's 'Immediate Measures' - call for early implementation in response to PIP and MoM

- Traceability initiatives in UK and Belgium

- All good stuff but underlines need for vigilance to ensure no deviation

What we need to do

- Ensure that the work of the IMDRF on UDI is better coordinated
- Continue to monitor the content of the legislation and be involved in the process of introducing UDI & UDID at EU and Member State level
- Communicate better and more widely what UDI Systems will mean for business
- Work with healthcare systems (particularly in the EU) to ensure they adapt and respond to UDI

Eucomed - UDI

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