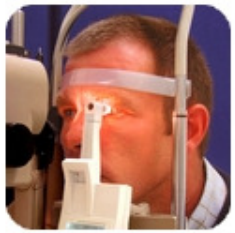
The Eucomed E-Business and Supply Chain Task Force (ETF)

Why it is Important for the Healthcare Industry to reach a Global Standard for Unique Device Identification now

Mike Kreuzer, ABHI
Wolfgang Gross, AUSTROMED
Joël Guillou, SNITEM

GS1 Healthcare Conference, Vienna, 17 March 2009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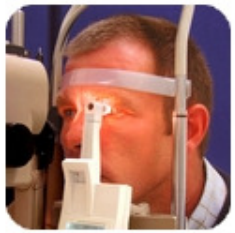
An overview

Mike Kreuzer
Chairman ETF
Technical & Regulatory Director ABHI


E-Business and Supply Chain Task Force

- Group set up circa 8 years ago
  - Distribution
  - Bar Coding
  - Other Supply Chain Issues
- Soon started to focus on AIDC and Patient Safety
- Co-operation with GS1 Healthcare started in 2005
- Reciprocal membership Eucomed / GS1 Healthcare

ETF Output

- Workshops in 2003 and 2004
- Position Paper on Bar Coding
- 'Backgrounder' on AIDC
- Revision to Eucomed Guidelines on GDP (WIP)
- Survey of members
- Major seminar at MedTech Forum October 2008
- Presentation to senior management January 2009

UDI is moving to centre stage

- GHTF AHWG established – EU Commission chairing
- The EU Commission is developing policy
- Good Distribution Practice/Market Surveillance
- BUT fragmentation is increasing

Country-Specific Requirements?

- Country-specific requirements on UDI (e.g. numbering systems) would have major impact on multiple country device configurations!
  - **supply chain inefficiencies**
  - **higher costs**
  - **could impact patient safety**

Need for risk-based approach

Extreme diversity in size, materials, processing, use and criticality

- needs to be considered for any identification rules!
- some differences on UDI needed, at least on required information

Examples*:

- pacemakers, hip replacements : device ID + serial no. + lot no.
- catheters, needles : device ID + lot no.
- syringes, stopcocks : device ID
- Single use commodity devices : no UDI

**Examples vary on specific devices, usage, packaging levels,....*

ETF Priorities for 2009

- Communicate with European industry & authorities
- Understand industry's views and needs
- Develop risk-based approach
- Monitor and influence policy
- UDI – with FDA & EU Commission (GHTF Ad Hoc WG)
- GDP and market surveillance

What do we need from an industry perspective?

The industry needs a **Global** Standards system

Only global and open standards enable the realisation of all healthcare and economic benefits related to UDI

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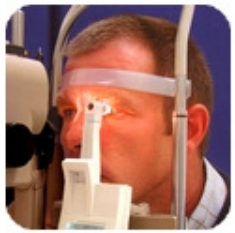
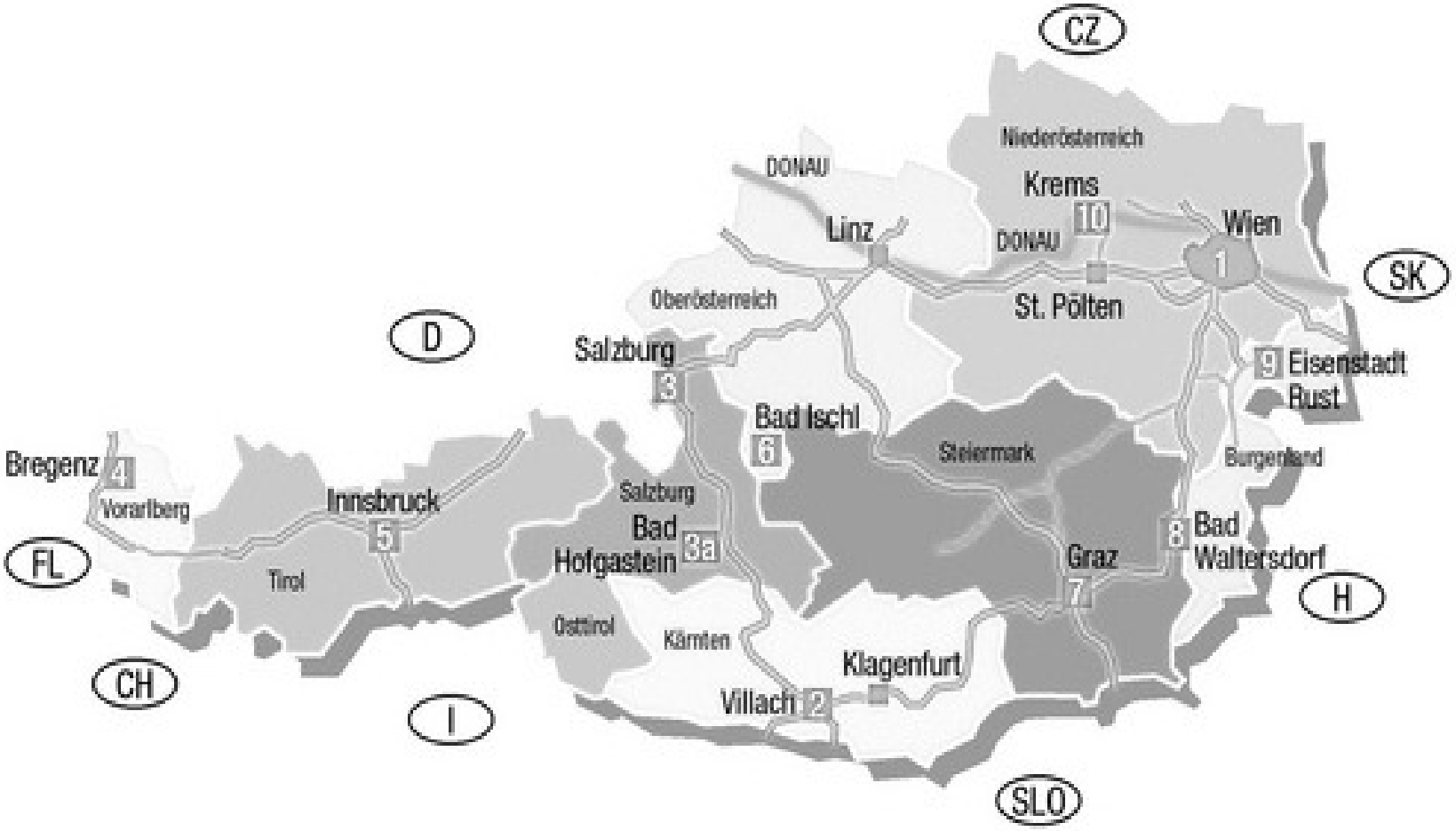
Medical device industry in Austria

Wolfgang Gross
General Manager AUSTROMED
Member ETF



Austria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Key figures

- Population: 8.3 Mio
- GDP (real / 2006): 233,15 bn €
- Hospitals: 264
- Beds: 64,556
- Doctors / hospital: 19,295 & Doctors / extern: 30,102
- Nurses: 75,989
- Expenditure in Health Care (OECD 2005): 25,08 bn €
- Expenditure / GDP: 10.2 %
- Turnover Medical Device Companies: ~ 2 - 2.2 bn € (estimated value)
- Domestic Market: ~ 1.4 – 1.6 bn €

Legal perspective

- Medical device law since 1996 (MPG - based on directives)
- No concrete, general measures for traceability
- In case of incident / near incident: responsibility to trace products
- Special ordinance foreseen for high – risk products (i.e § 73b MPG)
- No specific requirements like Turkey, Spain, Italy……

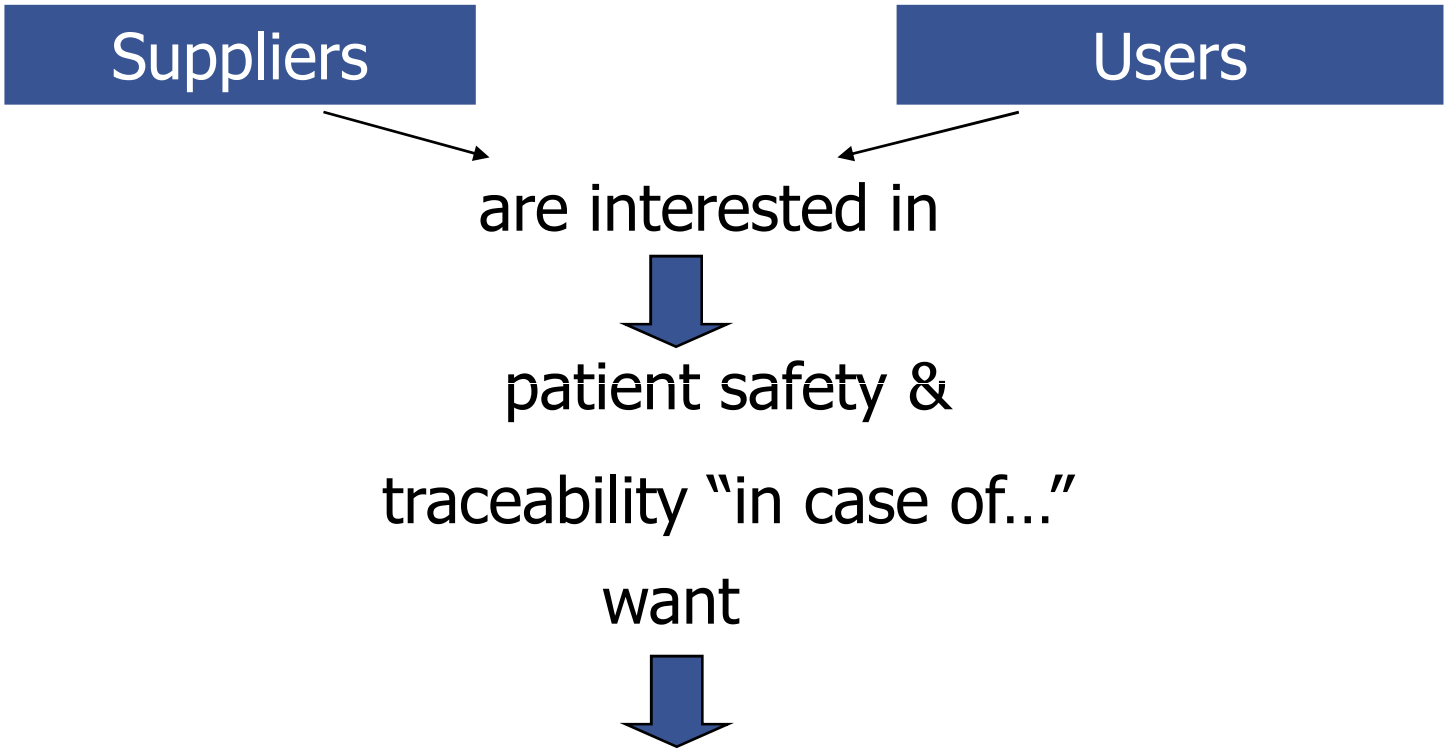
Supplier's situation

- Overwhelming number of companies function as distributors
- Even if multinational branch offices
- Only few manufacturing sites (appr. 10 %)
- SMEs only (70% up to 50 employees)
- In distribution: wide range of products / depending on their suppliers
- Get "ready products"
- Where production takes place: destination = export
- What do they want?

User's situation

- Many of them are changing their EDP environment
- Different systems / approaches
- Focus on processes
- Changing of warehouse-systems
- Pilot projects in linking products with patient's files
- What do they want ?

Patient safety & Traceability



Single / harmonised standard to link with <u>their</u> system!

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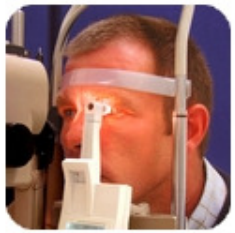
Traceability of medical devices in France

Joël Guillou
Director Regulation Reimbursement SNITEM
Member ETF



SNITEM

- A Professional Organisation created in 1987
- First trade association in France representing companies from the Medical Technologies sector (more than 240 member companies and 80 % of the turnover of the sector), SNITEM is the reference and choice interlocutor of the French Authorities
- At European level, SNITEM participates in the numerous working groups of the following organisations:
  - EUCOMED
  - COCIR (Committee for co-ordination of the Radiological and Electro-medical Industries)
  - Eurom VI (European federation of the optics and precision mechanics industry, group 6: medical-surgical equipment

(1) French Health Products Agency
(2) Commission for MD evaluation in the frame of reimbursement

SNITEM Mission

- **TO ORGANISE** the Medical Technologies (or Medical Devices) Industry Profession at the national level.
- **TO REPRESENT** this Profession in dealings with the various parties involved in the Healthcare System, in France, in Europe and internationally.
- **TO STUDY** any subject of an economic, technical or professional nature relating to the Medical Technologies (or Medical Devices) Industry.
- **TO INFORM** its members about issues relating to the Industry, as well as the Healthcare System and its development.
- **TO DEFEND** the economic and industrial interests of its members.
- **TO PROMOTE** the Profession and its image, both in France and abroad.
- **TO DEVELOP and MAINTAIN**, among its members, respect for the general interest of the Profession and professional ethics.

Traceability of medical devices in France

- As the French Healthcare Institutions are required to ensure Patient Safety and Quality of Healthcare, related to any medical act, the reduction of adverse events is a priority
- Since January 1st, 2009, the particular rules of the Vigilance exerted on Implantable Medical Devices (IMD), taken in application to French public health code aimed to identify quickly :
  - in which patients Medical Devices of a specific lot were used
  - which Medical Devices were applied with certain patients

Identification & bar coding of medical devices in France

- Identification should take into account the harmonization of this coding with at least :
  - The name and reference of the product
  - The name or reference of the manufacturer or distributor
  - The lot or serial number of the product
- To place at the disposal of users, with the MD, a set of labels, detachable, self-adhesive and comprising the above listed information
- To use barcodes (1 or 2 dimensions) as a system of symbolization which has to appear on the unit packaging
- In order to avoid errors all the necessary information should be gathered in only one barcode, easily identifiable and comprehensible

Traceability & public health

Traceability of medical devices is essential for Public Health but also for:

- Epidemiology (clinical studies, pharmacoeconomic data)
- Economic applications (T2A, e.g. French DRGs, Bar-coding is required for the reimbursement of certain MD)
- Organisational aspects such as dematerialization of the data and interworking)
- Counterfeiting : the risk of increase in counterfeit products force users and regulators to consider product serialisation and traceability at unit level, …

… Promotion of DataMatrix as harmonised data carrier (ECC200): as of 2011, France will migrate to high-density coding **DataMatrix** for drugs and is probably to migrate to DataMatrix for MD over the next 5 years

SNITEM e-Commerce Task Force

- While taking into account the diverse legislative and regulatory requirements
- Ensuring that the business needs of the industry are fulfilled
- By organizing and/or participating to several work groups at International, European and French levels (Eucomed, GS1, ACL, Europharmat …), **SNITEM aims at facilitating the development by its members of**:
  - A Unique harmonized classification (such as CLADIMED)
  - Global Traceability Standards for Medical Devices : the 2008 Snitem member survey indicated more than 80 % of barcodes (60 % for IMD) used for traceability with a sustained trend to GS1 standards
  - Good Distribution Practice

Eucomed
Medical Technology

Thank you !