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A critical stage in the development of EU legislation on UDI

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Eucomed UDISC representing EU MedTech industry

- Work on Automatic identification and data capture (AIDC) started in 2004 with formation of ETF
- Cooperation with GS1 commenced in 2005

- Today UDI and Supply Chain Task Force (UDISC)
  - Develops EU Industry policy on UDI/UDID
  - Represents this to EU Commission and national regulatory bodies
  - Works across industry e.g. with: EDMA, AdvaMed...
  - Works to prevent proliferation of non-standard systems
  - Provides EU industry representation on IMDRF UDI Work Team
  - Raises awareness of best practice in UDI to:
    - Industry
    - Healthcare systems providers

Industry interaction with the Commission and others

- 2007: Commission interest in counterfeiting led to…
- … Commission involvement in IMDRF WG on UDI (late 2008)
- and worked with the FDA to ensure full EU industry awareness of UDI Rule
- EU/US Transatlantic Trade and Investment Partnership - *under negotiation*
  - designed to drive growth, create jobs; aims at removing trade barriers in a wide range of economic sectors
  - MedTech industry (US/EU) included UDI as proposed topic for regulatory convergence (April 2013)

UDI is now firmly 'on the map'

- As a key part of the new MD legislation - this is a notable success.
- Today UDI is widely hailed as the answer to many problems e.g.
  - Patient safety initiatives e.g. Implant traceability & registries in UK
- Widely referenced in Healthcare policy documents
- Eucomed has issued guidance on data base and general implementation
- Eucomed organises workshops with EDMA to raise industry awareness
- Indeed UDI is widely seen as a '**done deal**' only awaiting Delegated Acts

BUT…

Danger of fragmentation

- We are facing a severe threat because some Member States:
  - have databases which seem to be incompatible with the planned EUDAMED
  - and may also be incompatible with global UDI systems.
- Examples are: Andalucia; Italy; Estonia; Portugal; Turkey;
- In spite of Commission Recommendation (April ‘13) which we contributed to
- Unless we act now to eliminate these deviations

⇨ Potential for disastrous results which could take years to sort out

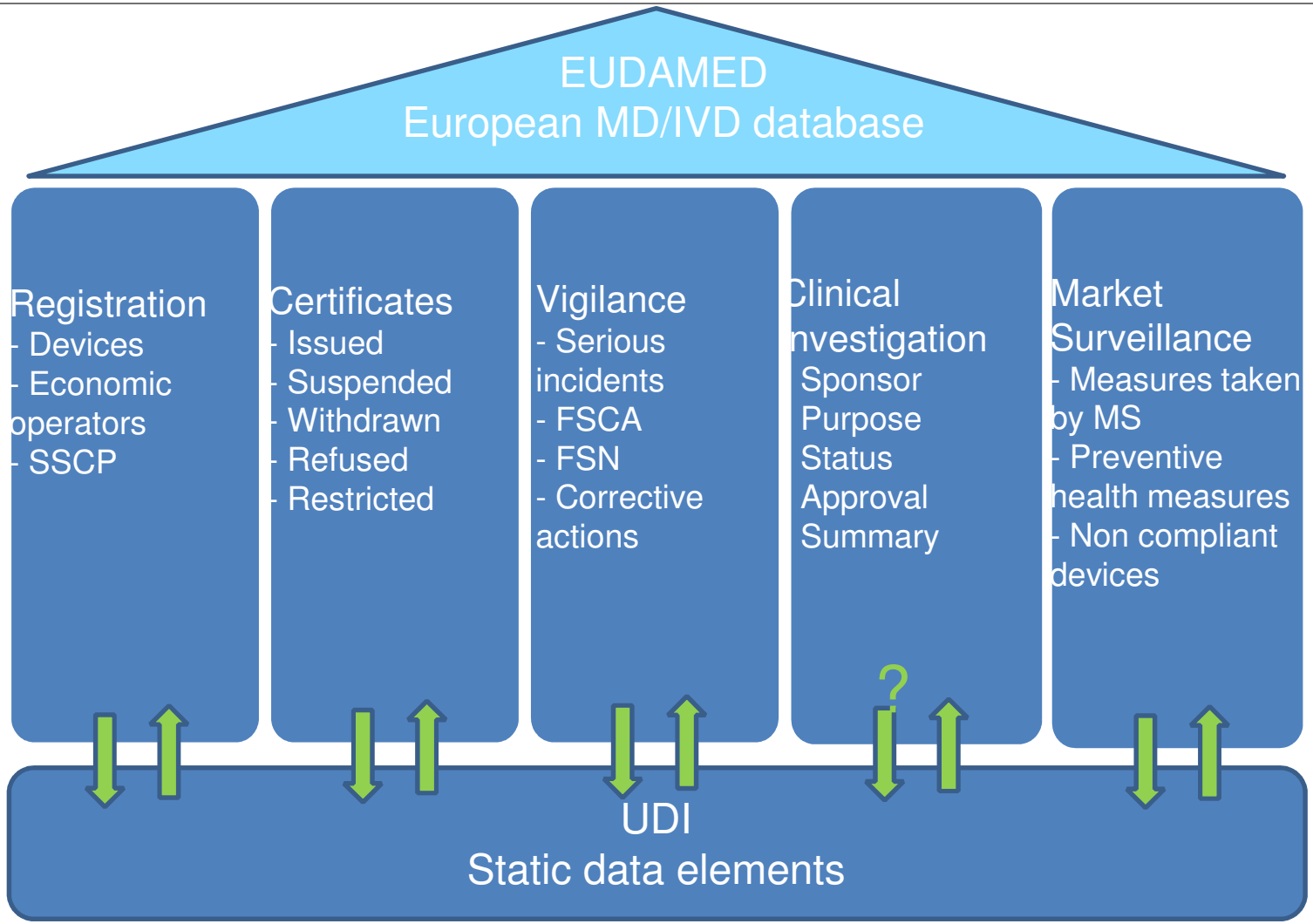
Action needed

- UDI and the database to support the MDR are inextricably linked
- The Commission cannot proceed due to lack of a 'legal basis'

⇨ Reconvene WG with MSs, Industry, Patient Groups, HC systems reps

- Industry will attempt to do this but this is focused on UDI
- We need to include the need for a single centralised database in this dialogue
- A new Industry Task Force needed on EUDAMED (for which UDI is an enabler)

What is Eudamed III?



Eucomed position on EUDAMED

- Eucomed welcomes and fully supports the creation of Eudamed, which aims at addressing e.g. traceability, transparency, lack of coordination, improving safety.
- Shall ensure transparency while protecting confidential information, like personal data, and commercially sensitive information
- Should be a single central database managed by an independent body (e.g. the European Commission), with a central regulatory submission point in a single language easily understandable by users, economic operators and Competent Authorities, limiting the burden of translations and allowing for international cooperation
- Network of national databases should be avoided as it is highly unlikely to answer to the need for centralization:
  - lead to inefficiency (updating the information)
  - increasing red tape (duplication of submissions)
  - unlikely to guarantee a user-friendly setting

Issues from Industry

- Databases
  - 33 members of the European economic area = up to 33 databases
  - Different attribute requirements
  - Different languages
  - Different methods for uploading data
  - Different rules around changes etc
- Ideally ONE Global Database but we recognise that.....
- Realistically a limited number of Regional Databases (NAFTA, EU, ASEAN, Mercosur)
  - One point of entry for manufacturers core data in one language

Eucomed UDISC objectives going forward

- Ensure that the work of the IMDRF on UDI is better coordinated
- Continue to monitor content of legislation
- Be involved in the process of introducing UDI & UDID at EU and Member State level
- Increase communication outreach on what UDI Systems will mean for business
- Work with healthcare systems (particularly in the EU) to ensure they adapt and respond to UDI
- Support the work of the database task force

Eucomed key messages on UDI

UDI will bring great benefits for:

- Patient safety
- Improved vigilance and 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