EU Regulatory Framework on Vigilance for Medical Devices

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Health and Consumers

Conflict of interest: **nothing to disclose**

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Q & A

A: Does Vigilance means the control of Manufacturers activities done by Competences Authorities and Notified Bodies?

B: Does Vigilance cover all types of incidents?

C: Is reporting by health professionals voluntary?

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Place of Vigilance within Medical Device Surveillance System

► **Market Surveillance**
- Competent Authorities responsibility
- Managed at national / regional level

► **Post Market Clinical Follow Up**
- Manufacturer's responsibility
- Quality, performance and safety aspects

►**Vigilance**
- Manufacturers and national CAs responsibility
- Reporting of serious incidents and corrective actions

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Main aspects of current EU Vigilance System

- Mandatory reporting by Manufacturer (MFR) to the Competent Authorities (CAs) when a serious incident(s) occurs
- Responsibility of CAs for assessment of all notified incidents and for the validation of Field Safety Corrective Actions
- National Competent Authorities Reports (NCARs) to inform other CAs and the Commission of incidents when corrective actions have been taken or are contemplated
- Reporting by Health Professionals according to national rules

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Is reporting by health professionals mandatory or voluntary?

MANDATORY	VOLUNTARY
Italy, Norway	Luxembourg
Belgium, Portugal	Cyprus
Lithuania, Denmark	Ireland
Sweden, Poland	
Finland, Latvia	
United Kingdom	
Germany	

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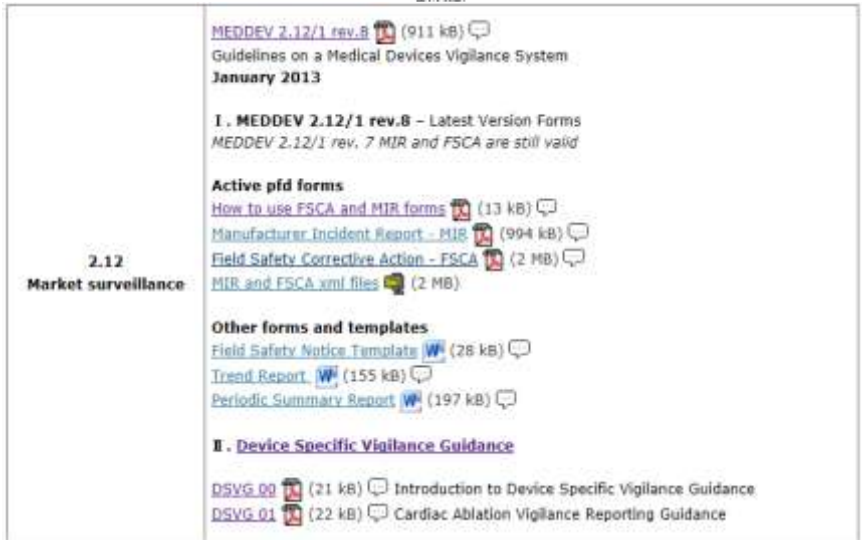
Main aspects of current EU Vigilance System

- Development of European guidelines (MEDDEV) by the EU Vigilance WG (National Competent Authorities, industry and health professionals' organisations)
- To harmonize the scope for reporting, definitions related to Vigilance and implementation by MFRs and CAs
- To standardize reporting forms (available on DG GROW Europa Website) http://ec.europa.eu/growth/sectors/medical-devices/documents/guidelines/index_en.htm



2.12 **Market surveillance**	MEDDEV 2.12/1 rev.8 (911 kB) Guidelines on a Medical Devices Vigilance System **January 2013** **I. MEDDEV 2.12/1 rev.8** – Latest Version Forms *MEDDEV 2.12/1 rev. 7 MIR and FSCA are still valid* **Active pfd forms** How to use FSCA and MIR forms (13 kB) Manufacturer Incident Report - MIR (994 kB) Field Safety Corrective Action - FSCA (2 MB) MIR and FSCA xml files (2 MB) **Other forms and templates** Field Safety Notice Template (28 kB) Trend Report (155 kB) Periodic Summary Report (197 kB) **II. Device Specific Vigilance Guidance** DSVG 00 (21 kB) Introduction to Device Specific Vigilance Guidance DSVG 01 (22 kB) Cardiac Ablation Vigilance Reporting Guidance

Challenges for the Vigilance System

- Disparity of MFRs reporting practices with significant under-reporting
- Need of higher reporting by health professionals to CAs
- Huge increase of total number of MFR incident reports but not optimised usability of collected data for CAs:
  - Mix of reportable (serious incidents) and non reportable events
  - Little data aggregability due to lack of use of international nomenclatures for device identification, device types, event types and root causes, patient harm
  - Difficulty to develop tools for signal detection and trending
- Need of better use of health professional registries for Vigilance purposes

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Main improvements for Vigilance Commission Legislative Proposals

- Direct reporting of all serious incidents and FSCA by MFRs to the EU Portal
- Member States to encourage Health professionals and patients to report serious incidents at national level through harmonised forms
- Increased transparency through differentiated access to vigilance information
- Extended use of standardised nomenclatures enabling aggregation of data and development of statistical tools for signals' detection and trend analysis

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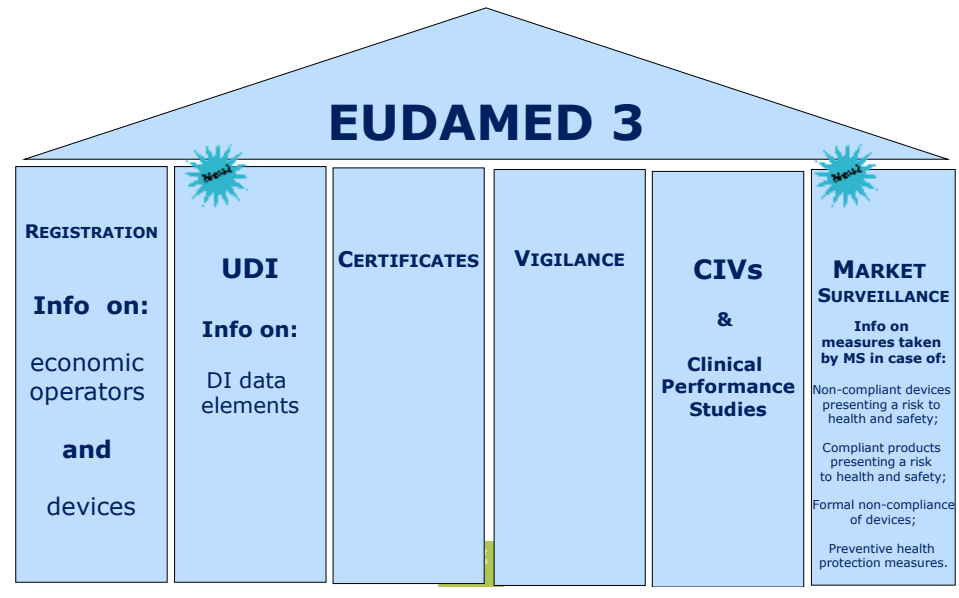
New EU Database for Medical Devices (EUDAMED III)

- An Electronic System with different modules (scheme)
- Modules for:
  - Unique Device Identifiers (UDI)
  - Registration of economic operators and devices on the EU market
  - Certificates
  - Clinical Investigations
  - Vigilance
  - Market Surveillance
- Different access levels for CAs, Manufacturers, Health professionals, Notified Bodies and the public



Q & A

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NO

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B: Does Vigilance cover all types of incidents?

NO

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Q & A

C: Is reporting by health professionals voluntary?

BOTH

Health and Consumers

Q & A

A: NO

B: NO

C: Both

Health and Consumers