European Commission

Eudamed

WG meeting
Brussels, 14th November 2012

2012 Eudamed evaluation
Internal analysis and survey results

Health and Consumers

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EUDAMED Evaluation: Legal basis

Article 14a(4) of Directive 93/42/EEC

Obligation for the Commission to:

- **Implement** Eudamed no later than 5 September 2012;

- **Evaluate** the operational functioning and the added value of the databank no later than 11 October 2012;

- **Present proposals** to the EP and the Council or **measures**.

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EUDAMED Evaluation: Structure

Internal Analysis

- Technical issues
- Information on data
- Information on users

Survey

- Operational functioning
- Added value

EUDAMED Evaluation: Internal Analysis

Technical issues: most significant upgrades

- Changes to **business rules**, including clarification on mandatory data,
- New business rules for certificates, IVD and CIV,
- New **xml** validation rules,
- A better **identification of IVD** devices,
- Significant improvements in the **CIVs module**,

EUDAMED Evaluation: Internal analysis

- **New non mandatory fields** in the CIVs and NCAR modules,
- Improvement of the **e-mail notifications**,
- A review of the user **interface**,
- The alignment between the user interface and the XML Scheme
- Addressing identified **inconsistencies** in the database,
- The resolution of **issues raised by the users**,
- **User guide update**.

EUDAMED Evaluation: Internal analysis

Information on users

- Number of users: 334

(covering EU MS, EEA countries and Turkey)

- Access to Eudamed: 48 CAs

- Number of users per CA:

From 1 to 5 (most CAs),
From 5 to 10,
More than 10 (few CAs),
Up to 100 (Only 1 CA).

EUDAMED Evaluation: Internal analysis

Information on users

- Number of users receiving e-mails notifications for NCARs:

44% of users from **32** countries

- Number of users receiving e-mails notifications for CIVs:

33% of users from **28** countries

EUDAMED Evaluation: Internal analysis

Information on data

- **Before 1 May 2011:** data entry **voluntary**,

- **2003: Actors** & **Devices** modules,

- **2004: Vigilance NCARs** & **Certificates** modules,

- **2011: CIV** module.

EUDAMED Evaluation: Internal analysis

Information on data

- **Actors:** data from 28 countries,

- **Devices:** data from 26 countries,

- **Certificates:** data from 19 countries,

- **NCARs:** data from 15 countries,

- **CIVs:** data from 14 countries.

EUDAMED Evaluation: Internal analysis

Statistics on data quality analysis

The statistics was based on selected samples

Criteria for the **samples selection**:

1. Data entered after the 1st May 2011;
2. Minimum one data set of each active CA.

Criteria for the **data quality analysis**:

1. The consistency of data;
2. The completion of mandatory fields;
3. The use of optional fields;
4. The use of the attachments possibility.

EUDAMED Evaluation: Internal analysis

Conclusions of data quality analysis

- Data contained in Eudamed is **reliable;**

- All countries entering data **comply with the Eudamed Decision**;

- There is still **room for improvement** since the Eudamed ambition is to collate 100% of consistent and reliable data.

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EUDAMED Evaluation: Survey to CAs

Operational functioning

The overall opinion is generally positive

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EUDAMED Evaluation: Survey to CAs

Added value: main results

- Eudamed is overall perceived as an important tool for **transparency** and **market surveillance enhancement**,
- In the **market surveillance** area Eudamed is not yet fully satisfactory,
- Eudamed is more widely used in the follow up of Notified bodies activities,
- Data on **Actors** and **Devices** is entered/uploaded with higher frequency,
- Eudamed reporting and searching functions are overall satisfactory.

EUDAMED Evaluation: Structural problems

Main shortcomings

- Eudamed does not provide a **complete overview** of actors and devices on the EU market;

- Eudamed does not yet lead to full **transparency**;

- The current **ownership rules** lead to multiple data entries.

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EUDAMED Evaluation: Proposed changes

Improvements of the Regulations' proposals

- **Central registration databank,**

- **Part of the information publicly available.**

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EUDAMED Evaluation: Conclusions

The current Eudamed:

Meets legislative requirements,

Brings a clear added value for the participating countries,

Is not fully able to meet today's expectations in terms of completeness, data quality, interlinkage and transparency.

The Future Eudamed aims to:

Overcome the existing shortcomings,

Develop Eudamed into a comprehensive and transparent information system on medical devices.

THANK YOU FOR YOUR ATTENTION!

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