



Eudamed

WG meeting
Brussels, 14th November 2012

Future Eudamed
Presentation of the new draft
regulations



Future EUDAMED: *Draft provisions*

26 September 2012

CHAPTER III

(Identification and traceability of devices, registration of devices and economic operators, summary of safety and clinical performance, Eudamed)

of the

Proposal for a Regulation on **MD**

(**Article 27** – European databank)

&

Proposal for a Regulation on **IVD MD**

(**Article 25** – European databank)



Future EUDAMED:

Main objectives

Addressing the main shortcomings of the current system:

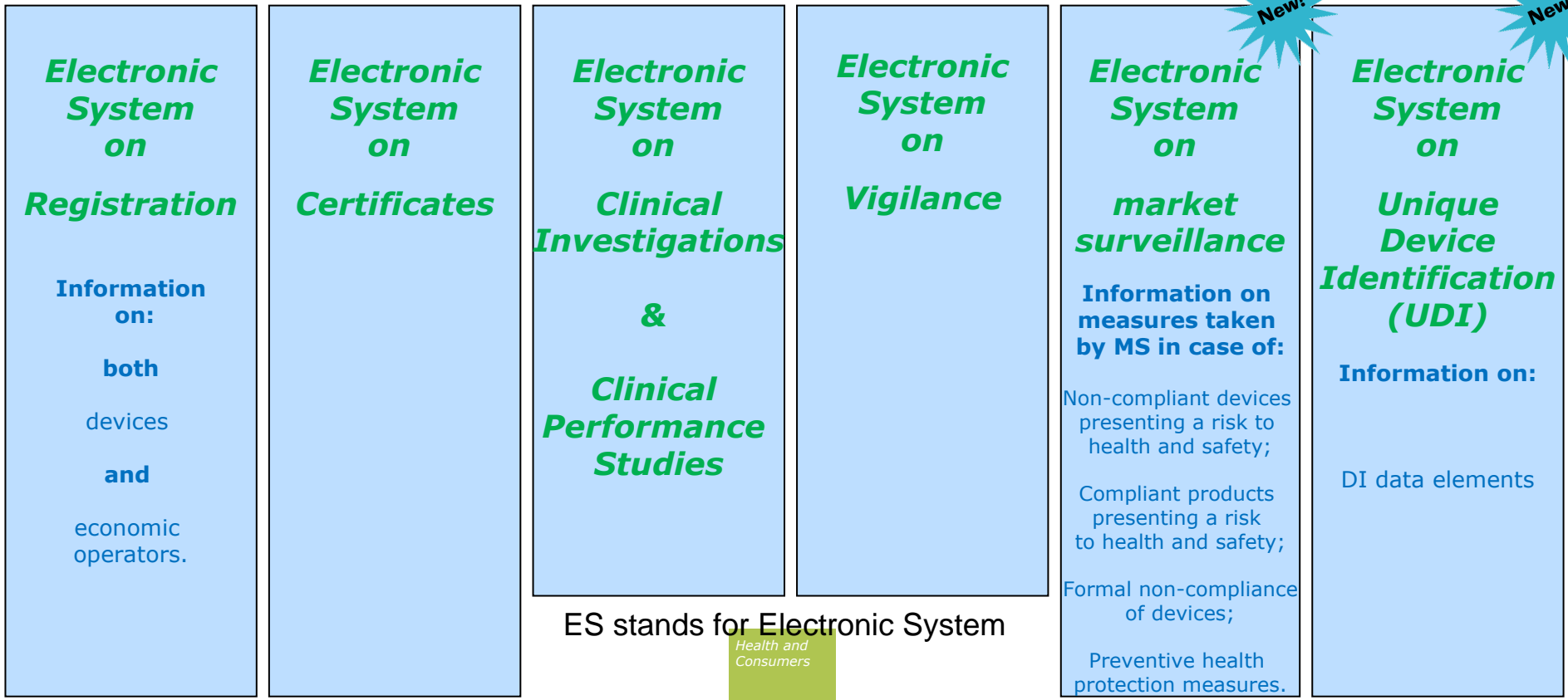
1. **LACK OF TRANSPARENCY**
2. **INCOMPLETENESS OF INFORMATION ON ACTORS & DEVICES**
3. **DIVERGENCES BETWEEN NATIONAL REGISTRATION REQUIREMENTS**



European Commission

EUDAMED 3

(Data stored in the future European MD databank)



ES stands for Electronic System

Health and Consumers



Future EUDAMED: Main function of the Electronic Systems

1. ES on registration → Publicly accessible

Enabling the public to be adequately informed on DVC & economic operators on the market.

2. ES on certificates → Publicly accessible

Enabling the public to be adequately informed on Certificates on the market.

3. ES on clinical investigations → Publicly accessible (subject to confidentiality restrictions)

Enabling sponsor single application for CIVs in more MS & ensuring cooperation between MS.



Future EUDAMED: Main function of the Electronic Systems

4. **ES on vigilance → Accessible to MS, COM & NB** (partly accessible to the public and HC professionals)

Enabling manufacturers' reporting of serious incidents and other events & supporting coordination of their assessment by NCAs.

5. **ES on market surveillance → Accessible to MS & COM**



Ensuring the exchange of information between NCAs.

6. **ES on UDI → Publicly accessible**



Identification and traceability of MD.



Future EUDAMED:

Access to stored information

Fully accessible to the:

- National Competent Authorities,**
- Commission.**

Accessible to (to the extent necessary to comply with their obligations):

- Notified Bodies,**
- Economic operators.**

Partly accessible to the:

- Public.**



Future EUDAMED: *Data entering*

Data will be directly entered into Eudamed by:

- 1. National Competent Authorities,**
- 2. Notified Bodies,**
- 3. Economic operators.**



THANK YOU FOR YOUR ATTENTION!