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Directorate-General for Health & Consumers

A European UDI

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Aims of this presentation

- To show the developments at the EU level of a UDI mechanism
- To have your comments

Important element

The Recast elements, which will be presented, concern only the traceability aspects

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Content of the presentation

I. Introduction

II. The European Approach

III. The UDI System

A. Rationale
B. Definitions
C. One type of UDI
D. Database

IV. Other aspects

A. Risk based approach
B. Dynamic data
C. Additional questions

V. Conclusion

Introduction

- **Historic developments**

- US FDA
- GHTF (Ad Hoc WG on UDI)
- European Member States

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The EU Approach

- Current status
- Why a UDI now?
- Recast and traceability

Traceability for MDs at EU

- **Current Status**

- No traceability requirements at the EU level
- However, it is imposed at the Member States level
- And it is ensured by manufacturers

Develop a EU UDI: Why now?

- **Different reasons**

- Safety and Internal market
- Recast of MD Directives First quarter 2012
- Obligation for Traceability in every future legislation (Decision 768/2008/EC)
- Work developed at the US and GHTF level

Recast

- **Current status**

- The last discussion with stakeholders and member States took place last week

- Political choices are mainly done

Recast

- **More “technical” work**

- Impact Assessment
- Writing of the Directives
- Internal consultation

Recast

- **Next steps**

- COM Final
- Co-decision procedure (Parliament / Council)
- Adoption
- Transposition period
- Adoption of Delegated Acts

Recast

- **Potential problems?**

- Time
- Member States will develop their own national systems
- No traceability will be available
- Free movement will be hindered

European Ad Hoc WG

- **First aims of this group**

- Discuss GHTF documents
- Inform member States
- Take note of member States positions
- Present national systems

- **Additional aim**

- Discuss the development of a Commission's Recommendation

A Recommendation what for?

Adoption of the Recommendation

↓

Recast January 2012: Traceability obligations

↓

Decision making procedure

↓

Adoption of the Directive

↓

Adoption of detailed traceability requirements

The content of the Recommendation

- GHTF Ad Hoc WG

- Main aspects

- Rationale
- Definitions
- « The » UDI System
- Database

Rationale

- **Main purposes: Patient safety**

- Improving tracking and tracing of devices
- Improving device recalls
- Improving adverse event reporting and surveillance
- Reducing medical errors
- Improving query in different database
- Fighting Counterfeits

- **Other purposes**

- Better control of purchasing and distribution
- Stock management

Definitions

- **UDI**
  - UDI system
  - Static information
  - Dynamic information

- **UDI Carrier / Placement**

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Manufacturers

Users of the database are using the UDI CODE (static part) as Access key

UDI CODE (Data carrier, i.e. barcode,two-dimentionnal, ...)

UDI DATABASE
Manufacturer
Allergen
GMDN
Packaging level
Sterility ...

DATA EXCHANGE PROCESS GLOBALLY ACCEPTED

Unique CODE established by application of international standards

Static information

Lot/batch #

Serial #

Expiration date #

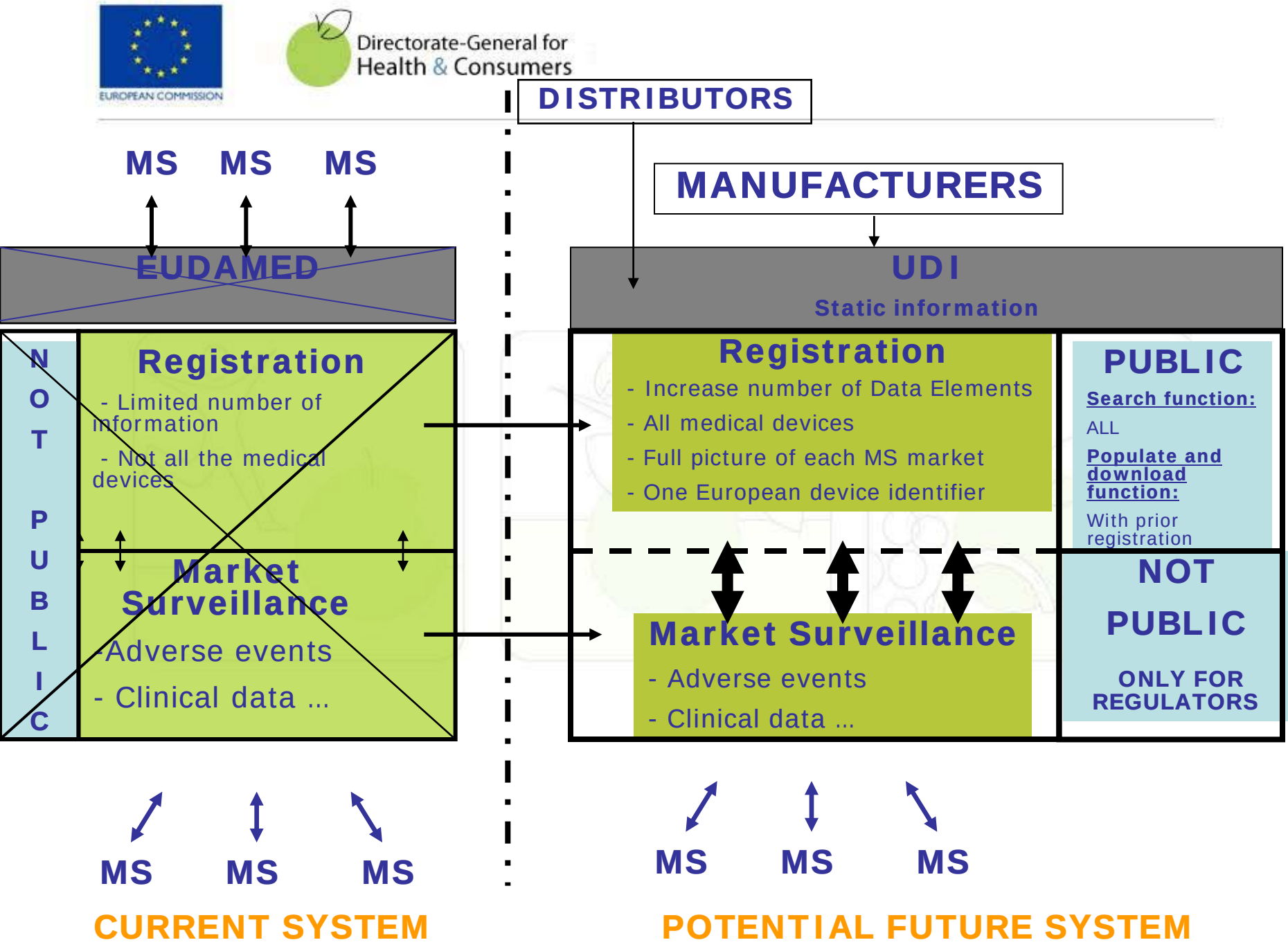
Dynamic information

DATA TRANSFER

Regulators
Distributors
Hospital
Pharmacy
Patient
…

European database

- Internationally compatible
- Merger with Eudamed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DISTRIBUTORS
MS MS MS
MANUFACTURERS
EUDAMED
UDI
Static information
NOT PUBLIC
Registration
- Limited number of information
- Not all the medical devices
Market Surveillance
-Adverse events
- Clinical data ...
Registration
- Increase number of Data Elements
- All medical devices
- Full picture of each MS market
- One European device identifier
Market Surveillance
- Adverse events
- Clinical data ...
PUBLIC
Search function:
ALL
Populate and download function:
With prior registration
NOT PUBLIC
ONLY FOR REGULATORS
MS MS MS
MS MS MS
CURRENT SYSTEM
POTENTIAL FUTURE SYSTEM

Database attributes

- Boolean choices
- Numerical data
- No free text as possible

Database elements

- Vocabulary
  - If applicable
  - Optional

1. **Device Identifier**
2. **Manufacturer Name (as represented on the label and/or instruction for use)**
3. **Manufacturer address structure**
4. **Contact Information (if different from manufacturer)**
5. **Nomenclature**
6. **Nomenclature term**
7. **Trade Name** (Brand Name) **if applicable**
8. **Device model number** (or reference or catalogue number) **if applicable**
9. **Controlled by: check all that apply**
10. **The Device Identifier can be found on (...)**
11. **In case of different levels of packaging, parent/child relationship shall be provided**
12. **Other alternative Device Identifiers (if applicable)**
13. **Size, Volume, Length, Gauge, Diameter** (**if applicable)**

14. Additional product Description (optional) 15. Storage and handling conditions (as labelled on the product and / or in the IFU)
16. Labelled as single use
17. Sterility
18. Restricted number of reuses (if applicable)
19. Labelled as Containing Latex
20. Authorised Representatives (list of countries) (if required by the local / regional regulatory authority)
21. License or marketing authorization or registration number / code (if required by the local regulatory authority)
22. URL for additional information – Web address (optional)
23. Critical Warnings or Contraindication (if applicable)

Data attributes

- **Questions**

- The number of attributes
- The definition of attributes
- The necessary specificities

- **However the main question is:**
  Why do we want a database?

Data attributes

- **Consequences of "too much" data attributes**

- Burdensome
- Costly
- ...

Therefore the rule shall be as a regulator before imposing one "data attribute": Why I need this attribute for?

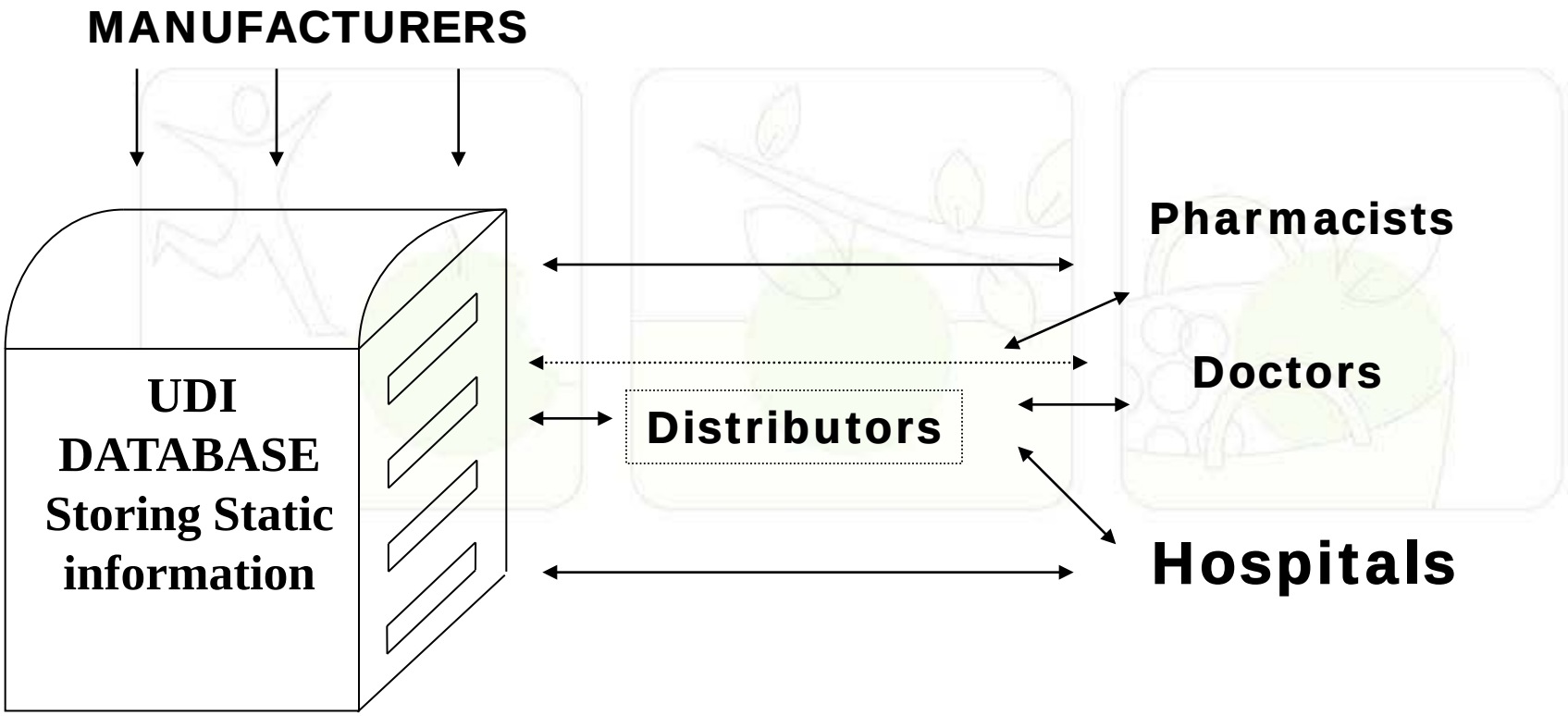
Data attributes

- **Consequence of "not enough" attributes**

- Necessity for regulators to request more attributes
- Obligation for manufacturers to fill out several databases

Therefore, it will be a useless database

What is necessary to achieve…



How to achieve the « ideal database »

- **Involvement of every actors**

- Regulators
- Manufacturers
- Distributors
- Hospital
- Doctors

Other issues

- Risk based approach
- Dynamic information
- Others aspects

Risk based approach

- **All medical devices shall have:**

- A static identifier
- A dynamic identifier

- **The difference will be:**

- The type of dynamic data
- The placing of the UDI
- The time left to implement UDI obligations

Dynamic information

- **Legal obligation for all the supply chain**

- Manufacturers
- Distributors
- Authorised representatives
- ...

Conclusion

- **Next steps**

- Written comments (End April 2011)

- GHTF ad Hoc UDI meeting (May 2011)

- Drafting of the Recommendation

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Thank you for your attention …