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TRACEABILITY OF MEDICAL DEVICES

Unique Device Identification (UDI)

Part I

The Global Approach and the European Perspective

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DHoU SANCO B2 "Cosmetics and Medical Devices"

GS1 - Amsterdam 04.10.2011

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Content of the presentation

I. GHTF developed a draft guidance for a global UDI

II. Rationale / Purpose

III. Definitions

IV. A Global framework for a worldwide UDI

V. European Development of UDI
A. European Database
B. Data elements

VI. Other issues
A. Risk based approach
B. Dynamic data
C. Future developments

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Global Harmonisation Task Force

European Union

United States

Canada

Australia

Japan

- Conceived in 1992, rotation of Chairmanship every 3 years

- Purpose: international harmonization in MD regulations for safety, effectiveness, performance adequacy/quality of MDs

- Publication of harmonized guidance docs on regulatory practices.

- Guidance docs for adoption by Regulatory Authorities.

- GHTF cooperates with Asian Harmonisation Working Party (AHWP)

- GHTF : Mission accomplished… Next : A new « Regulators Forum »

UDI in GHTF…

- **October 2008**
  In Ottawa, GHTF Steering Committee sets Ad Hoc WG on 'UDI', Chair by EC representative.

- **July 2009**
  In Uppsala, EU Competent Authorities' meeting supports Commission's suggestion to reflect on "traceability - UDI" .

- **February 2010**
  Commission under Spanish Presidency chairs workshop in Madrid with 10 MS.

- **31 March 2010**
  End of public consultation launched by Ad Hoc WG. ca 45 contributions received.

- **5 November 2010**
  UDI draft Guidance accepted by GHTF Steering Committee:
  Posted on GHTF website for public comment by April 30, 2011

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GHTF UDI Ad Hoc WG

Balance between Regulators - Industry

Laurent Sellès (Chair), Rodolphe Muñoz (EU Com)

Matthias Neumann (DE)

Christine Tarrajat (EDMA)

Mike Kreuzer, Volker Zeinar (EUCOMED)

Jay Crowley, Terrie Reed (FDA)

Jeff Secunda, Jackie Elkin (Advamed)

Christopher Rose (Health/Santé Canada)

Tom Werthwine (HCSUS)

Hiroshi Ishikawa (JFMDA)

Liang Yan (Shanghai SFDA)

Lindsay Tao (AHWP Secretariat) **+ Interest expressed by Russia**

Aims of GHTF UDI guidance

UDI can be used for various purposes.

- **The objectives of the GHTF UDI ad hoc group were:**
  - To increase patient safety
    - Facilitating traceability of medical devices
    - Improving the identification of devices in adverse events
    - Facilitating field service corrective actions

- **The objectives of the ad hoc group were not:**
  - To find a solution to counterfeit devices
  - To enable better control of purchasing and distribution

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UDI Principles

- **The marking of the device with its UDI shall be an additional labelling requirement (UDI is not an alternative to existing labelling requirements).**

- **UDI allows the unambiguous identification of a specific product on the market.**

UDI Structure

UDI SYSTEM

UDI CARRIER

- Machine readable
- Human readable
- Bar code
- 2D bar code
- Data matrix,…

UDI DATA BASE (Elements)

- Device identifier
- manufacturer name
- address, contact
- nomenclature term
- device model number
- packaging, size,
- storage conditions
- sterility
- restrictions of use
- URL…

UDI CONTENT

Device Identifier (static part)
(Access key)

Production Identifier (dynamic part)
- Serial number
- Batch/lot
- Expiry date

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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
…

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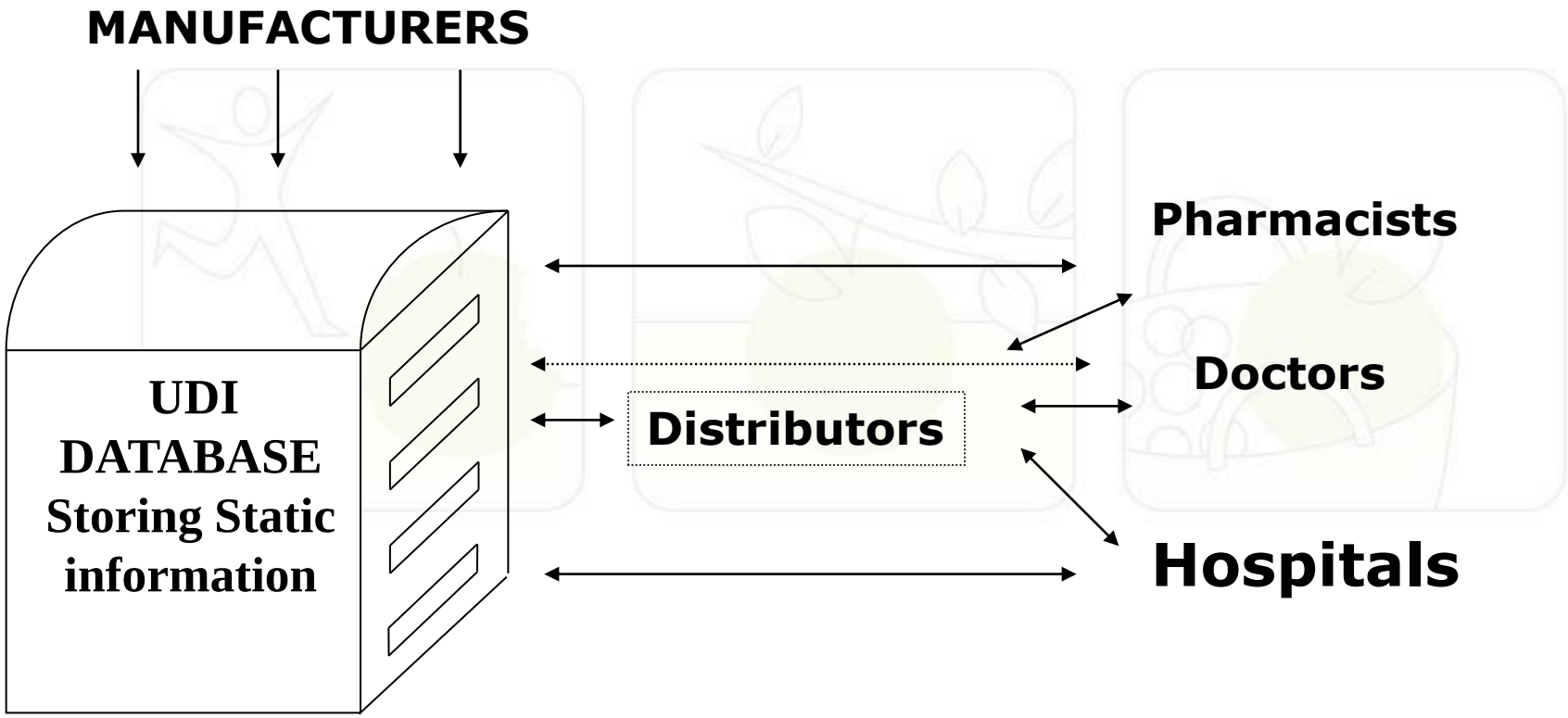
What is necessary to achieve...



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European Development of UDI

- **Revision of MD Directives Q2/2012**
- **Obligation for Traceability in every future legislation (Decision 678/2008/EC)**

Outlook

Adoption of the Recommendation

Revision proposal Q2/2012: Traceability obligations

Decision making procedure

Adoption of the New REGULATION

Adoption of detailed traceability requirements

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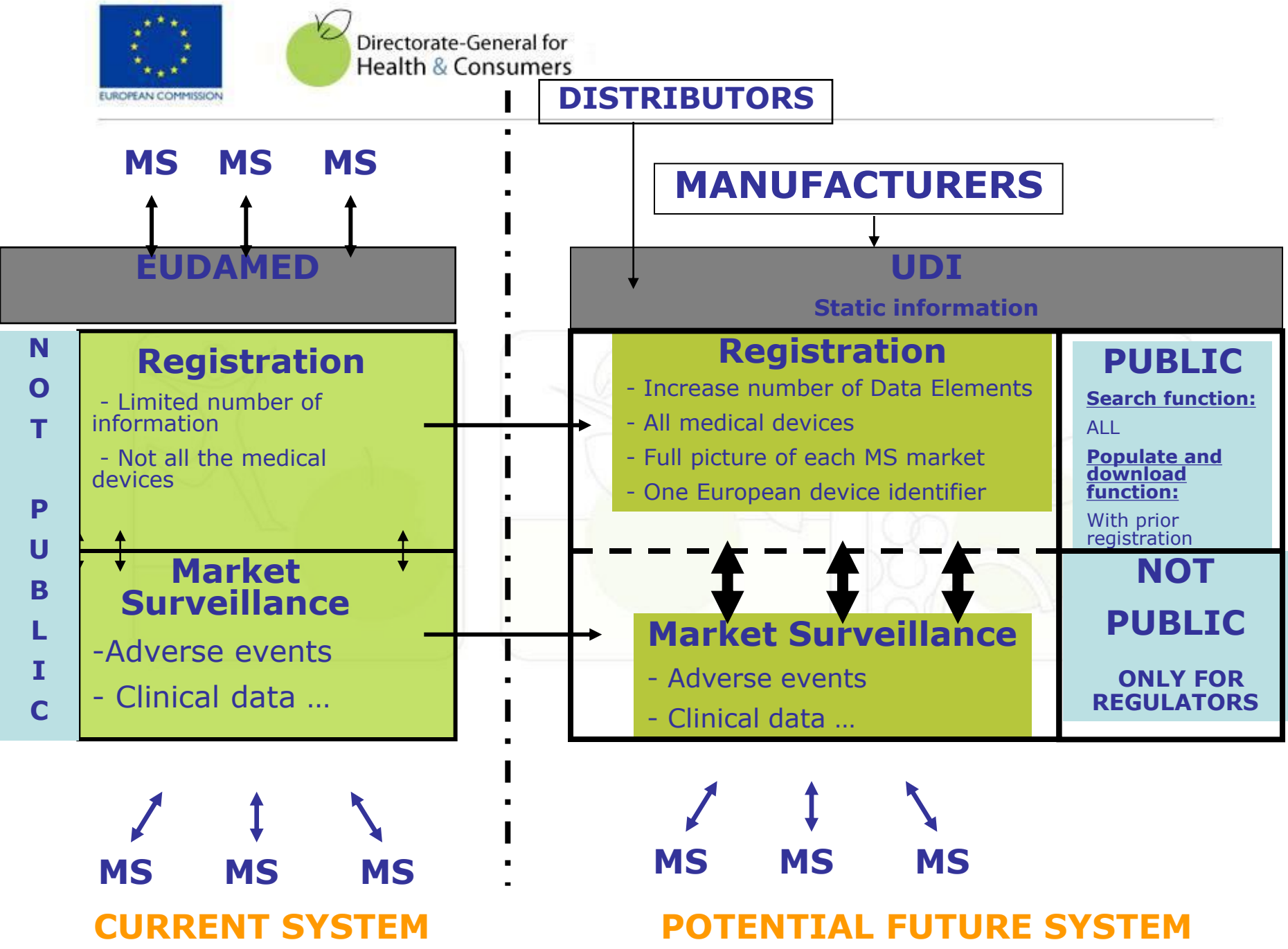
European database

- **Internationally compatible**
- **Merger with Eudamed**
  - **Registration of manufacturers/devices**
  - **Accessible by Competent Authorities**
  - **Certificates issued by Notified bodies**
  - **Clinical trials**
  - **Vigilance procedures**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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

Risk based approach

- **All medical device shall have:**

- A static identifier
- A dynamic identifier

- **The difference will be:**

- The type of dynamic data
- The placing of the UDI

Dynamic information

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

- Manufacturers
- Distributors
- Authorised representatives
- …

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Conclusion

A long and winding road…

- Unvoidable (traceability needs)

- Global Goodwill (understanding the unicity of the identification)

- In the EU: Drafting the Recommendation

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Thank you for your attention!

European Commission

Health and Consumer Protection Directorate-General

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http://ec.europa.eu/health/medical-devices/index_en.htm