

UNIQUE DEVICE IDENTIFICATION

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Structure of the presentation

- I. Introduction
- II. The GHTF Ad hoc Working Group
- III. Future actions at the EC level
- IV. Conclusions

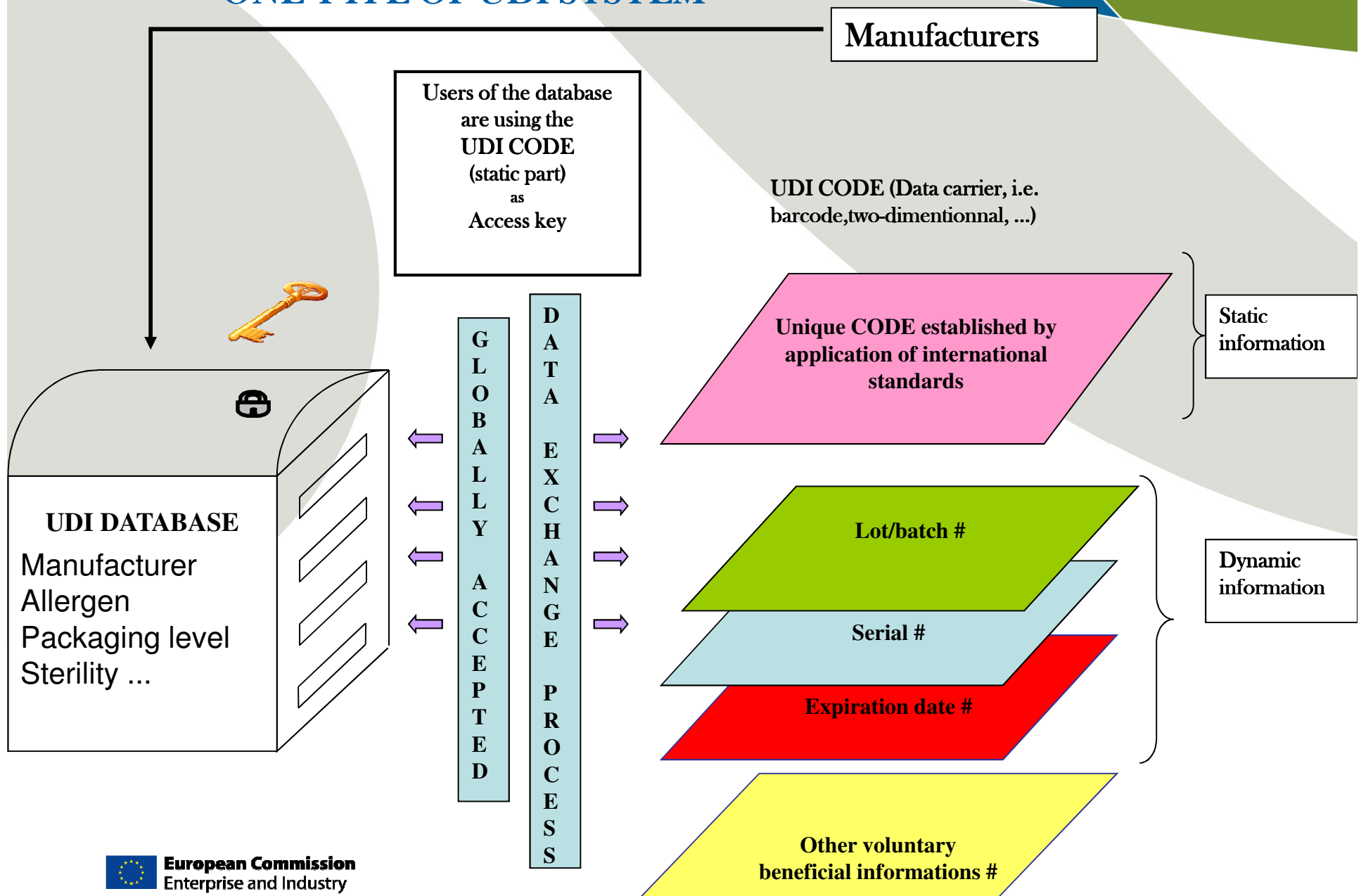
I. INTRODUCTION

- Where do we stand at the EC level?
 - What are we talking about?
- Why are we talking about UDI, now?
- What are we doing on this topic?

Where do we stand at the EC level

- **At the moment Nothing**
 - Has been developed
 - Has been officially decided

ONE TYPE OF UDI SYSTEM



Why to act?

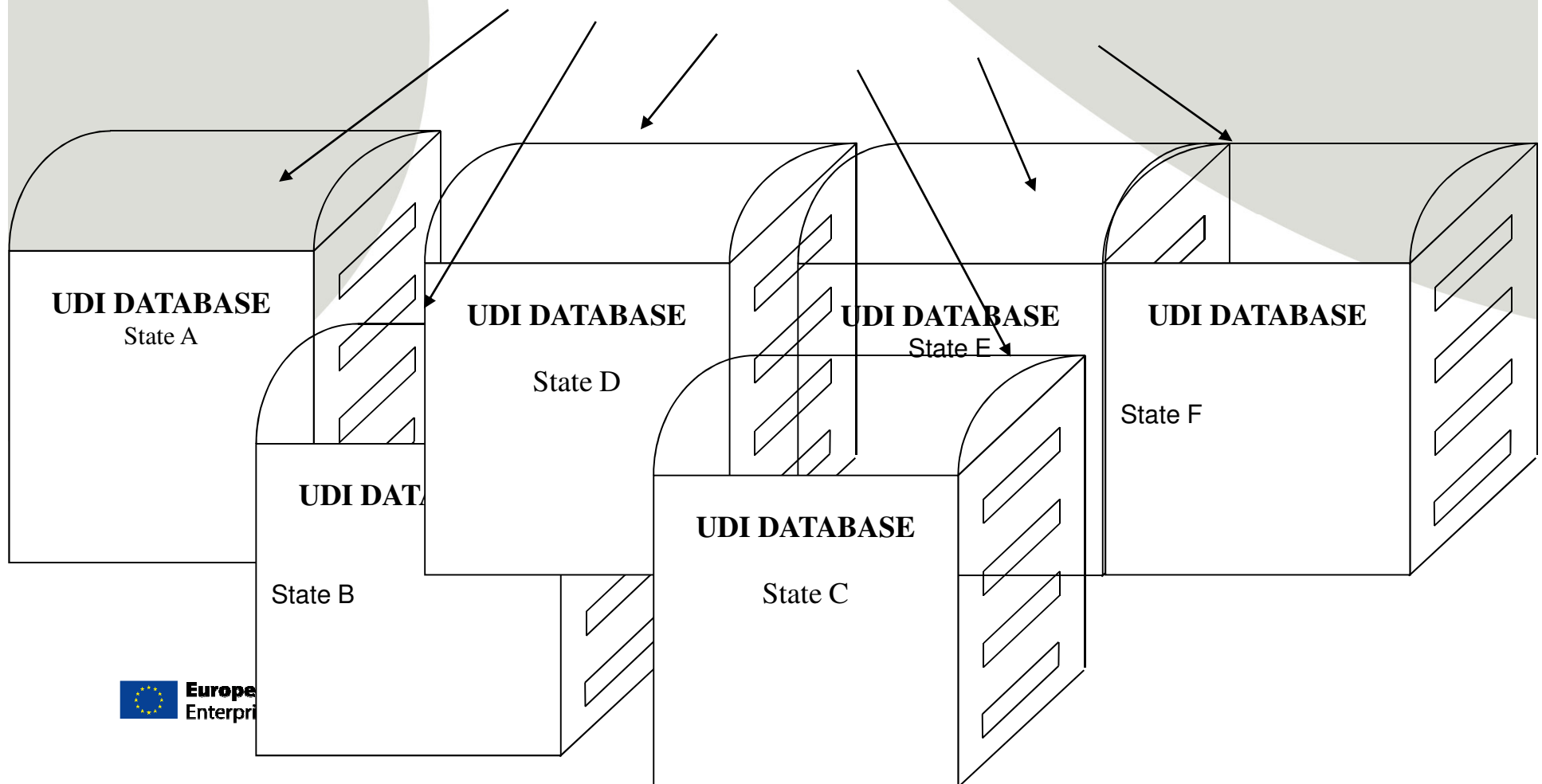
- **Mainly because developing a UDI will have positive consequences:**
 - Patient safety
 - Market surveillance
 - Data management for hospitals
 - ...

But why to act now?

- The evolution of the technology
- Developments of different types of “UDI” in different countries
 - US
 - China
 - ...

What is necessary to avoid

MANUFACTURERS



Where are we doing on this topic?

- **At the international level**

GHTF – Global Harmonisation Task Force

- **At the EC level**

- Start reflexion
- Start brainstorming

II. WORK AT THE GHTF LEVEL

- The Ad hoc WG
- The results achieved
- The next steps

The Ad hoc WG

- **The 8th of October 2008 establishment of an Ad hoc WG**
 - Regulators / Industry
 - US/Japan/Europe
 - Recently China has been joined the Ad Hoc WG

The discussion

- **The most important thing is to confront:**
 - The different approaches
 - The different definitions

Terms of reference (I)

- Establish co-operation with all stakeholders
- Insure global compatibility
- Define a minimum dataset needed for an effective global market surveillance

Terms of references (II)

- Address compatibility with the US FDA UDI mechanism and with other regional regulatory frameworks.
- Propose implementation of the UDI system into the GHTF-Model

THE QUESTIONNAIRE

- A learning process
- The content of questionnaire
 - Complex
 - Lengthy

The questionnaire: 3 parts

- **First part**
The label and the code on the product
- **Second part**
Potential additional information to be provided by the manufacturer
- **Third part**
The implementation of the UDI into the GHTF model

First part

- **AIDC (Automatic Identification and Data Capture) system**
 - Type
 - Standards
 - Evolution
- **Coding system**
 - Type of coding system
 - Information readable with only the UDI
- **To which products UDI should be applied**
 - All medical devices
 - Different level of traceability
- **Privacy issues**

Second part

- Information to be provided by the manufacturer
- Standards for data exchange
- Management of the database

Third part

- Link with the GHTF-model
- Link with the GHTF guidance on medical device registration system

The results achieved ...

- Analysis of the answers
- Developments of a general document to address the issue at the GHTF level
- Presentation of the work at the GHTF conference of Toronto

Content of the work

- Definitions
- Recommendations (still at a **draft** stage)
- Database attributes (still at a **draft** stage)

Definitions

- **1. UDI system**
- **2. UDI code**
 - **2.1 UDI-CODE static part (product identifier)**
 - **2.2 UDI-CODE dynamique part (production identifier)**
- **3. UDI Coding system**
- **4. "UDI Label"**
- **5. Data Carrier**
- **6. UDI software**
- **7. UDI-Database**

DRAFT RECOMMENDATIONS

- General aspects
- UDI label
- UDI Database

General aspects (I)

- ❖ The UDI shall be **an additional labeling requirement** (...)
- ❖ **Currently available globally accepted device auto-identification standards** shall be used to create the UDI code. (...)
- ❖ **The manufacturer** (as defined by GHTF) is the one (and only one) whose UDI is on the device. (...)

General aspects (II)

- ❖ **No particularly form of automatic identification** technology can be required; (...)
- ❖ The manufacturer is responsible for maintaining the **uniqueness of the UDI** for a device during its whole lifetime.
- ❖ **The UDI system should be implemented according to the risk of the device (...)** Further, that **the introduction of UDI allows sufficient implementation time frames** to allow manufacturers to comply with the requirements.
- ❖ **The use of UDI should be promoted among all stakeholders**, including regulatory agencies, medical device manufacturers, distributors, hospitals, and medical professionals.

UDI Label (I)

- The UDI may be established by combining **static information** (the device identifier) and **dynamic information** (the production identifier).
- The **static device identifier** it is an “unintelligent” number that should not be parsed and it has no inherent meaning. It is globally unique and is the primary key used to access information about the device stored in the UDI Database (UDID).

UDI Label (II)

- The **static device identifier** uniquely identifies the specific device (e.g., manufacturer, type of device, including model number, and key characteristics of the device if the same type of device is supplied in several sizes/gauges/lengths, quantities per pack).
- The **production identifier** provides auto-identifiable information on the lot, batch or serial number (or all), and the expiration date if the device's carries one.

UDI Label (III)

- In most cases, the UDI has **to be both human readable and encoded in a form of automatic identification technology** (“auto-id”) that facilitates its use throughout the life of the device. **If there are significant space constraints** limiting the use of both forms, the auto-id should normally be used. Certain use cases, such as home care, may warrant the opposite.
- In most cases, the **human readable information and the auto-id form** should be both placed on the label of the device.

UDI Label (IV)

- **GHTF should develop guidelines for direct part marking of certain devices** (such as reusable surgical instruments, re-processing...).
- **A risk-based approach should determine the level of specificity and granularity of the UDI**

UDI Database (I)

- **The Unique Device Identification Database (UDID)** currently under development by FDA should be established with a global and compatible perspective, so that this UDID can be used globally or a data exchange network to other existing or emerging regional UDI-database can be established.
- **GHTF UDI AHWG should develop global attributes and their definitions for the UDID.** This should parallel that of the standards working in this area.

UDI Database (II)

- **The manufacturer** (or organization otherwise responsible for the device) should be the one responsible for submitting and maintaining the identifying information and other attributes/specifications in the UDID.
- **Most of the information** in the UDID shall be made **publically available**, free of charge. (...)
- A list of **database attributes** should be developed

Database Attributes (I)

- 1. Global Unique Identification Number
- 2. Manufacturer (refurbisher, Reprocessor)
- 3. Device name
- 4. Trade name
- 5. Make, model, size
- 6. Article or catalogue number
- 7. Controlled by serial, lot or batch number
- 8. Storage conditions (e.g. needs to be refrigerated)

Database Attributes (II)

- 9 nomenclature, classification
- 10 generic device type (according to the nomenclature)
- 11 packaging level/number of items
- 12 labelled as single use or re-usable
- 13 sterility
- 14 contains known labelled allergen (e.g. latex)
- (...)

Conclusion : Next steps

- **Short term**

Finalisation of the work (Vancouver 1-4 November 2009)

- **Medium term**

Development of the different aspects (UDID, ...) through GHTF guidelines

- **Long term**

A global UDI ?

III. THE WORK AT THE EUROPEAN LEVEL

- We are just starting
- We need to act
- We have a lot of open questions
- What will be the next developments

We are starting

- **The goals are:**
 - To increase traceability and patient safety
 - To avoid the multiplication of national systems at the EC level
 - To develop an international approach

We need to act but in a balanced way

- A balance has to be found between:
 - The potentialities of UDI
Patient safety / traceability / Recalls
 - The feasibility of UDI
Cost for companies and above all for SMEs / Legal constraints

Open questions ...

- To which medical devices
- To which purposes
- Data protection issues
- Spare parts
- Parallel imports
- Translation
- (...)

Next developments

- **Short term**
Policy actions / Distribution channel studies
- **Medium term**
Recast
- **Long term**
Implementation of the recast

IV. CONCLUSION

- We are at a crossroad
- Importance of a global approach
- Difficulties to develop such a global approach

More info and contact:

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