Structure of the presentation

I. Introduction

II. The GHTF Ad hoc Working Group

III. Future actions at the EC level
INTRODUCTION

• Where do we stand?

• What are we talking about?

• Why are we talking about UDI, now?

• What are we doing on this topic?
State of play regarding UDI at the EC level

• At the moment Nothing
  - Has been developed
  - Has been officially decided
ONE TYPE OF UDI SYSTEM

Manufacturers

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

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

Unique CODE established by application of international standards

Static information

Dynamic information

UDI DATABASE
Manufacturer
Allergen
Packaging level
Sterility ...

GLOBALLY ACCEPTED

DATA EXCHANGE PROCESS

Lot/batch #
Serial #
Expiration date #
Other voluntary beneficial informations #
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
- The US is developing a UDI mechanism and other States will follow
What is necessary to avoid

MANUFACTURERS

UDI DATABASE
State A

UDI DATABASE
State B

UDI DATABASE
State D

UDI DATABASE
State G

UDI DATABASE
State F

UDI DATABASE
State C
The US UDI work plan

• Adoption by the Congress: the 27th of September 2007

• The FDA is currently writing regulations

• Provisional timetable
Where to act?

- At the international level
  GHTF – Global Harmonisation Task Force

- At the EC level
  - Start reflexion
  - Start brainstorming
II. WORK AT THE GHTF LEVEL

• The establishment of the Ad hoc WG

• The results achieved

• The results to come
The Ad hoc WG

• The 8th of October 2008 establishment of an Ad hoc WG

  - Regulators / Industry

  - US/Japan/Europe
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
Work achieved by the Ad hoc Working Group

- Two meetings took place
- The release of a questionnaire
ANALYSIS OF THE CURRENT OUTCOME

- A learning process
- The content of questionnaire
The discussion

- The most important thing is to confront:
  - The different approaches
  - The different definitions
The 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
Next steps …

- Analysis of the answers
- Meetings to draw conclusions
- Developments of a general document to address the issue at the GHTF level
- Presentation of the work at the next GHTF conference in May 2009
III. THE WORK AT THE EUROPEAN LEVEL

- We are just starting
- We need to act
- How to act: the legislator dilemma
- Mainly opened questions
We are starting

• **The idea is**
  - To avoid the multiplication of national systems at the EC level
  - To develop an international approach
The dilemma of the legislator

- **FACTS:**
  - It is a useful instrument
  - then it will develop globally in the years to come

- **But** it cannot lead to an excessive increase of costs for producers

- **Therefore:**
  Choices have to be made …
Balance

• **A balance has to be found between:**
  - The potentialities of UDI
  - The feasibility of UDI
Open questions ...

- To which medical devices
- To which purposes
- Data protection issues
- Spare parts
- Parallel imports
Conclusion: Actions

• **Short term**
  The work of the GHTF Ad hoc WG

• **Medium term**
  Policy actions / Distribution channel studies

• **Long term**
  Recast
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