European Commission

ENTERPRISE DIRECTORATE-GENERAL

Towards global unique device identification
GS1 conference Granada, 12 February 2007

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Elements of unique device identification

Unique

Label

Medical device and production identifier

Distribution chain and use

Meeting organised in the context of the GHTF

Sponsored by current Chair of the Global Harmonisation Task Force: US Food and Drug Administration

Meeting held within that context 29 January at the US Food and Drug Administration, Rockville, United States

Objective: the intention of the FDA to propose a rule relating to UDI for medical devices. Stakeholders have repeatedly indicated that it would be very beneficial to have a global approach for UDI.

Participants: Australia, Canada, European Commission, Germany, Panama, Pan American Health Organization, Mexico and Shanghai FDA

Common definitions needed

What triggers a new UDI?

- Fully refurbishing
- Refurbishing
- Remanufacturing
- Reprocessing
- Reprocessing single-use
- Maintenance/service

OR

- What is a “significant” change?

Human readable code and/or encoded

When should human readable required?

- Home care environment
- Readability: size of packaging and letter size

When should encoded be used?

- Readers can read 1D and 2D but readers for all technology do not exist.
- Not all health care institutions have all the readers needed for every technology

Which technology?

Medical devices very large product group and users group : UDI needs to be technology free. Different technologies can suitable, depends on the medical device and the end user.

Combination products: medicine and medical device or medical device and medicine

- Combination products are coming increasingly prominent in the market
- There is already an identification system for medicines (e.g. NDC)
- Difficulties in determination of the primary mode of action
- Allow identification for “components” or the integral combination product?

other combination products and capital equipment

Issue at stake: medical device consisting of components with different life cycle

e.g.

bed + mattress

wheelchair: chair + wheels

Do they require separate UDIs?

Unapproved/uncertified medical device in clinical trials

Issue at stake is that hospitals indicated that UDI would be beneficial for patient records purpose.

However, the medical device is not considered to be on the market

Yet, it is a patient safety issue.

Clinical investigational drugs are not given a e.g. NDC.

Implementation of UDI

Retroactively applying UDI?

Stocks

After service, maintenance

Refurbishing

Reprocessing

Implementation of UDI

- GMDN
- International database
- Central database
- Connected databases
- Additional national requirements
- Validation of data entered

Global approach in UDI requires

- Common definitions
- Standard global data set
- National elements

European Commission: UDI via a global standard requires CEN standard