UNIQUE DEVICE IDENTIFICATION

Situation in the International Medical Device Regulators Forum (IMDRF)

and in the European Union

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CONTENT OF THE PRESENTATION

1. UDI: an IMDRF Work Item

2. Achievement: the IMDRF Guidance on UDI

3. Extension work on UDI Databases (UDIDs)

4. EU activities on UDI and Traceability

5. Outlook for the future
Aspiration to convergence

IMDRF

Deployment fora

Health and Consumers

AHWP

OBS.
International Medical Device Regulators' Forum (IMDRF)

Australia, Therapeutic Goods Administration
Brazil, National Health Surveillance Agency (ANVISA)
Canada, Health Canada
China, China Food and Drug Administration
European Union, European Commission DG Health and Consumers
Japan, Ministry of Health, Labour and Welfare with Pharmaceuticals and Medical Devices Agency
Russian Federation, Russian Ministry of Health
United States of America, US Food and Drug Administration

+ Observers (WHO) , Affiliates (AHWP, APEC)
INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM

MANAGEMENT COMMITTEE
- Regulators (rotating chair)
  AUS, BZ, CAN, EU, JAP, US (CN, IND, RU)
- Official Observers by Invitation

MANAGEMENT LEVEL:
Decision Making, strategic direction, workplan monitoring

SECRETARIAT
- Administrative Tasks
  Edition, maintenance of website
- ‘BRANDING’: Benefit of ‘Global’ image, Promotion of Global Regulatory Model

OPERATIONAL LEVEL:
Technical document development (Regulators, industry, other stakeholders)

Affiliate Organizations

Sub-committees

Regulators + Industry + Other Stakeholders

Working Group

Working Group

Working Group

Working Group

Working Group
UDI Work Group

US-FDA

CHINA CFDA

EU DG SANCO

JAPAN PMDA

ADVAMED

EUCOMED/EDMA

DITTA

HEALTH CANADA

JFMDA/JIRA

AHWP

ANVISA

...With some invited observers.
Bar-coding for every Medical Device

UDI SYSTEM

UDID Database
For DI part Only

DI
- Company Name
- Address
- Product Name
- GMDN code
- term
- etc

PI
- Production Information
- Life
- Serial or Lot Information

DI
- Device Information
- Company
- Product ID
The IMDRF UDI Guidance was adopted as a final document (IMDRF/WG/N7:2013) by the Management Committee on 15 November 2013.
# Summary table- UDI - AIDC Marking / Placing Rules

<table>
<thead>
<tr>
<th>Category</th>
<th>Unpacked UoU</th>
<th>Base Package</th>
<th>Bulk Package (higher pack. config)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single-use MDs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• IMDRF class A (low-risk)</td>
<td>-</td>
<td>-</td>
<td>DI + PI*</td>
<td>*PI not required by the US FDA</td>
</tr>
<tr>
<td>• IMDRF class B (medium-r.)</td>
<td>-</td>
<td>-</td>
<td>DI + PI</td>
<td></td>
</tr>
<tr>
<td>• IMDRF classes C+D (high-r.)</td>
<td>-</td>
<td>DI + PI</td>
<td>DI + PI</td>
<td></td>
</tr>
<tr>
<td><strong>Re-usable MDs</strong></td>
<td></td>
<td></td>
<td></td>
<td>Require reprocessing between uses</td>
</tr>
<tr>
<td>• all risk-classes</td>
<td>DI + PI</td>
<td>DI + PI</td>
<td>DI + PI</td>
<td></td>
</tr>
<tr>
<td>• not all package levels necessarily exist</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• surgical instruments, IV pumps, etc</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Implantable MDs</strong></td>
<td></td>
<td></td>
<td></td>
<td>PI = serial number for active implants</td>
</tr>
<tr>
<td>• sterile</td>
<td>-</td>
<td>DI + PI</td>
<td>DI + PI</td>
<td>* usually single packed (1 piece)</td>
</tr>
<tr>
<td>• non-sterile</td>
<td>must be identifiable</td>
<td>DI + PI</td>
<td>DI + PI</td>
<td>* often multiple packed (,n’ pieces)</td>
</tr>
<tr>
<td>• non-sterile</td>
<td>must be identifiable</td>
<td>DI + PI</td>
<td>DI + PI</td>
<td>* not necessarily DPM, other tech. options allowed to identify the unpacked MD</td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Kits (IVD / non-IVD)</td>
<td>-</td>
<td>DI + PI</td>
<td>DI + PI</td>
<td>* concerns the kit package itself</td>
</tr>
<tr>
<td>• Standalone Software</td>
<td>DI + PI</td>
<td>DI + PI</td>
<td>-</td>
<td>* must not necessarily be packed</td>
</tr>
<tr>
<td>• config. MD Systems</td>
<td>DI + PI</td>
<td>-</td>
<td></td>
<td>* AIDC carrier to be placed on a ,main part’ (primary mode of action)</td>
</tr>
<tr>
<td>• OTC exclusively</td>
<td>-</td>
<td>-</td>
<td>DI (linear bar code)</td>
<td>* Point-of-Sale scanners can’t work with PI</td>
</tr>
<tr>
<td>• OTC + other channels</td>
<td>-</td>
<td>-</td>
<td>DI + PI (non-concatenated)</td>
<td>* PI should be presented in a separate AIDC carrier due to Point-of-Sale scanners</td>
</tr>
</tbody>
</table>
DIVERGENCES BETWEEN THE FDA UDI RULE AND THE IMDRF UDI DRAFT GUIDANCE...?

• NOTHING SIGNIFICANT... (Examples)

• ALIGNMENT (Fair...)
The UDI Challenge

Manufacturers DBs

FDA UDID
EU UDID
China UDID
Japan UDID

Health and Consumers
Deployment of a small number of regional UDIDs
Extension of the UDI Work Item

UDI Guidance adopted by IMDRF-4 not sufficient?

IMDRF MC Decision: A joint "RPS + UDI" subcommittee to capture regulatory life-cycle aspects.

RPS= Regulated Product Submission, now extended to Common Data Elements for regulatory life-cycle
PROPOSED EXTENSION OF IMDRF UDI Work item in 2014

2013

GUIDANCE
IMDRF/WG/N7FINAL:2013

2014-2015

HARMONIZED DATA SETS (UDI DATABASES)
Part of RPS Extension "Common Data Elements"
Proposed "RPS + UDI" Extension:

DATA FIELDS AND DATA SETS:

CLEAR STANDARDIZED RULES ON RIGHTS TO ACCESS, READ, WRITE OR CORRECT DATA
level of identification, verification, validation of data
same/similar mechanism to keep data in the UDID up-to-date
standardized structures
standardized (secured and legally correct) protocols for data exchange
technical minimum hardware requirements to enable the interaction and communication between UDIDs
standardized field names, etc

(UDIDs challenges ahead)
RPS/UDI extension Work plan approved on 30 June 2014

With strong involvement of IT/database experts

Aiming at ensuring the alignment with the GUDID Data Sets Formats

Open to all IMDRF jurisdictions

With MC consent, constitution of WG in progress
Benefits expected: *Paving the way...*

For the IMDRF "Regulators":

- towards future international traceability.

For Industry:

- towards less burdensome UDID entries
EU political strategy for the globalisation phenomenon.

"The Council of the EU invites the European Commission:

- to take the following considerations into account in the course of its future legislative work (...),

as the medical device sector is a global one, a stronger coordination with international partners is desirable

in order to ensure that medical devices are manufactured according to high safety requirements worldwide" (OJ C202/7 of 8.7.2011).
EU AGENDA 2020

EU Internal Market
EU 'Regulation'

International Trade
Global 'Regulation'

Two sides of the same medal

→ INTERNATIONAL REGULATORY CONVERGENCE!
CHAPTER III: Identification and traceability

(MDs) Article 23, 24, 25 and 27
(IVDs) Article 22, 23, 24 and 26

- Identification within the supply chain

- Unique device identification system

- Electronic system on registration of devices and economic operators

- European databank (EUDAMED)
"Economic operators shall be able to identify:

(a) any economic operator to whom they have supplied a device;
(b) any economic operator who has supplied them with a device;
(c) any health institution or healthcare professional to whom they have supplied a device.

Upon request, they shall inform the competent authorities thereof."
Provisions on the future EU UDI System define:

- The general framework of the System,
- The objectives of the System,
- The powers delegated to the Commission,
- UDI Electronic System Data Elements,
- Accreditation system (UDI issuing entities)
European UDI System

- A system for Unique Device Identification shall be put in place in the EU;

- A UDI system for identification and traceability of devices consisting of:
  
  - (a) production of a UDI (DI+PI),
  - (b) placement of the UDI on the label of the device,
  - (c) storage of UDI by economic operators and the health institutions through electronic means,
  - (d) establishment of an electronic system on UDI.

- Entities designated for the assignment of UDIs according to international standards.

...i.e. IMDRF
UDI System

- The UDI shall be used for reporting serious incidents and field safety corrective actions;

- Economic operators and health institutions shall store and keep both DI and PI;

- The Commission shall be empowered to adopt delegated acts to specify:
  - the devices, categories or groups of devices, whose identification shall be based on the UDI system,
  - the timelines for implementing the system (risk-based approach),
  - the data to be included in the production identifier (risk-based approach),
  - the obligations of economic operators, of health institutions and of professional users
TRANSPARENCY

Publicly available information in EUDAMED regarding:

- Devices on the EU market,
- Summary of Safety and Clinical Performance Data for high risk devices,
- Manufacturers, authorized representatives and importers,
- Certificates issued by notified bodies,
- Clinical investigations / clinical performance studies,
- Field safety notices.
DIFFERENT TYPES OF DATABASES

Manufacturer Databases
- DI - Device Information
  - Company
  - Product ID
- PI - Production Information
  - Life
  - Serial or Lot Information
- Country
- Registration#
- Approved #
- Nomenclature#
- others

UDID Database
- DI - Company Name
- Address
- Product Name
- GMDN - code
- - term
- .
- . etc

GMDN
- GMDN
- code
- - term
IN THE EU: UDI in EUDAMED

EUDAMED

(Possible integration of UDI ES in the future regulatory framework)

ES on Registration

ES on Certificates

ES on Vigilance

ES on CIV

ES on Market Surv.

ES on UDI

DI

PI

UDI

DI = Device Identifier

PI = Production Identifier

Man/Exp Date

Lot/batch nr.

Serial nr.
DEVELOPMENT OF THE EU UDI DATABASE WILL BE KEY

Mō zhe shítou guò hé.

摸着石头过河。

Crossing the river by feeling each stone.
Outlook

**UDI: EU Implementation**

Revision proposals
(26th September 2012)

Recommendation a common UDI System in the EU
(March 2013)

Ordinary legislative procedure
(2 to 3 years)

Adoption of the New REGULATIONS
(2015?)

Preparation of delegated acts (UDI and traceability requirements)
(End 2015 or 2016?)