The New Regulation on UDI in Korea

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Current Status
Overview of UDI Regulation History
UDI Regulation for Medical Devices
IMDIS(Integrated Medical Device Information System)
RDR(Reporting Distribution Records)
MDIIC(Medical Device Information Integration Center)
Next Step
58% of MD manufacturers are using barcodes

60% of barcode-using MD manufacturers are using GS1

34% of barcode-using MD manufacturers’ barcodes are not international standards

More than 90% of MD subject to tracking* are assigned barcodes

* Source: Medical Device Information Integration Center, 2018

- Medical devices subject to tracking:
  1. Devices implanted in human body more than a year
  2. Devices for the life-sustaining purpose at places other than medical institutions
Overview of UDI Regulation History

UDI Regulations

- **Dec, 2016**
  - Developed the UDI concept
  - Introduced IMDIS*  
    * Integrated Medical Device Information System
  - Included RDR* requirement  
    * Reporting Distribution Records

- **Aug, 2017**
  - Assigned NIDS* as MDIIC*  
    * National Institute of MD Safety Information
    * Medical Device Integration Center

- **Nov, 2017~**
  - Planning to establish GIMP*  
    * Good Information Management Practice

- **May, 2017~**
  - Planning to set forth RDR elements

- **July, 2018~**
  - Planning to develop requirements of UDI placement and management

- **Oct, 2018~**
  - Planning to set forth submission elements for Integrated medical device information

- **2019~**
  - Planning to establish good MDIIC management practice
Definition of UDI
- Numbers and bar codes indicated on the container and the package, etc. of devices according to standardized system to identify medical devices and to manage them thoroughly and effectively
- UDI consists of UDI-DI and UDI-PI

Scope of UDI-DI and PI
- UDI-DI : A numeric or alphanumeric code specific to a model name or a package unit of medical devices
- UDI-PI : A numeric or alphanumeric code that identifies the unit of device production. It should include any one of the following information:
  ○ Manufacturing number(lot number or serial number)
  ○ Manufacturing date or expiration date
  ○ Software version information(only applicable to SaMD)
UDI Regulation for Medical Devices

**UDI labeling Requirement**
- To be on the container, package or outside all the devices (including barcodes)
- EAN-13, GS1-128 and GS1-DataMatrix should be used among the GS1 system when barcodes are displayed on a medical device
- SGTIN-96 or SGTIN-198 should be used with the bar code on it when placing RFID TAG
* GS1 system is generally used and international standards (HIBCC, ICCBBA) are acceptable

<table>
<thead>
<tr>
<th>Class</th>
<th>Available Barcode (GS1)</th>
<th>Type</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>EAN-13</td>
<td>DI Only</td>
</tr>
<tr>
<td></td>
<td>GS1-128</td>
<td>DI + PI</td>
</tr>
<tr>
<td></td>
<td>GS1-DataMatrix</td>
<td>DI + PI</td>
</tr>
<tr>
<td>II - IV</td>
<td>GS1-128</td>
<td>DI + PI</td>
</tr>
<tr>
<td></td>
<td>GS1-DataMatrix</td>
<td>DI + PI</td>
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Registering/managing medical device information integration based on UDI

- integrated management of MD-related information with the IMDIS (Integrated Medical Device Information System)

* UDI data (UDI-DI), info on manufacturers and products (similar to the IMDRF standard) + “Health insurance claiming codes (10% of MD)”

Good Information Management Practice (GIMP)

+ Submitting UDI data to the IMDIS after approval prior to releasing, and store/maintain related records in their companies

+ Be updated (modify within 10 days in case of changes), have persons in charge of managing MD consolidated information
**IMDIS (Integrated Medical Device Information System)**

**IMDIS (UDI DB + RDR DB)**
- Electronic data storing & processing system for effectively maintaining information on MD from its approval, production, import, sales to its use (TPLC)

1. Direct marking (handwritten input)
2. Uploading files (such as excel files)
3. API (Application Programming Interface) (partially)
4. ESB (Enterprise Service bus) (future)

Internal system:
- Approval info system
- Tracking system
- AE monitoring system

External system:
- Health insurance management system
- Customs clearance system for MD
- Certain entities

External systems:
- HIRA
- KCS
- NPA
**RDR (Reporting Distribution Records) for Devices**

**Reporting Distribution Records (distribution history) based on UDI**

- RDR to the IMDIS in case the medical devices are delivered to medical institutions, vendors, and renters by manufacturers, importers, vendors, and renters (including used MD).

* UDI data (UDI-DI), place to distribute, distributed volume, info on products (year and date manufactured, lot number or serial number, etc.)

Diagram:
- Manufacturers
- Wholesalers
- Retailers
- Medical Institutions

Information reported using UDI (not applicable to the UDI regulation)
MDIIC (Medical Device Information Integration Center)

Accrediting medical device information integration center to be operated
- Run MD information consolidation system, collect/investigate/process and provide MD consolidated info and distribution info, and implement standardizing projects for MD consolidated info

Tasks
- Collect/investigate/process/provide UDI DATABASE and RDR info (supply records)
- Support in developing and disseminate programs needed for
- Manage IMDIS and consolidated info
- Research/educate/promote standardization of MD consolidated information

Medical Device Information Integration Center

- Address integrated information
  - Produce/manage/run standard codes
  - Register/manage standard codes & integrated information
  - Streamline regulations

- Research on integrated information
  - Develop the related guidelines
  - Produce information to the public
  - Investigate and research distribution status

- Manage integrated information
  - Manage DB for integrated info
  - Run the information integration system
Changes UDI System Brought in MD Safety Management System

**Difficulties in identification with approval units** (90 thousands) **and separate data**

**Better identification with model units** (more than a million) **through data integration** (Big Data)
UDI & RDR Timeline

**Plans on UDI and RDR System in Korea**

**UDI**:
- Class 4 (July, 2019~), Class 3 (July, 2020~), Class 2 (July, 2020~), All Devices (July, 2022~)

**RDR**:
- Class 4 (July, 2020~), Class 3 (July, 2021~), Class 2 (July, 2022~), All Devices (July, 2023~)

- IMDIS launched
- Class IV (UDI)
- Class III (UDI) Class IV (RDR)
- Class II (UDI) Class III (RDR)
- Class I (UDI) Class II (RDR)
- July, 2022
- July, 2023

**Activities**
- Working on MDA Enforcement Regulation revision
- Planning of MDA Notification revision
- Pilot (Aug ~ Nov, 2018)
- Training for Industry

**All Classes**
- UDI and RDR to be in place for all medical devices
Thank You