IMDRF International Medical Device Regulators Forum

Ministry of Food and Drug Safety

Updates on Korean Regulatory Developments

19th March, 2019

Dr. Hyeonjoo Oh
Director General
Medical Devices Evaluation Department
Korea Ministry of Food and Drug Safety

Table of Contents

1. Acts on Innovative Devices and IVDDs

Law	Current Status	Expected legislation
Medical Device Industry Promotion and Innovative Medical Device Support Act	Review of National Assembly	June, 2019
In-Vitro Diagnostic Device Act		

1.1. Acts on Innovative Devices and IVDDs

Background	The Applicable Law
✓ To develop premarket pathway to address new tech-applied devices	*Medical Device Industry Promotion and Innovative Medical Device Support Act*
✓ To support for development and market authorization of IVD devices	*In-Vitro Diagnostic Device Act*

2. UDI System Implementation in Korea

	Class 4 (high risk)	Class 3 (serious risk)	Class 2 (potential risk)	Class 1 (lower risk)
Placing UDI	**July, 2019**	July, 2020	July, 2021	July, 2022

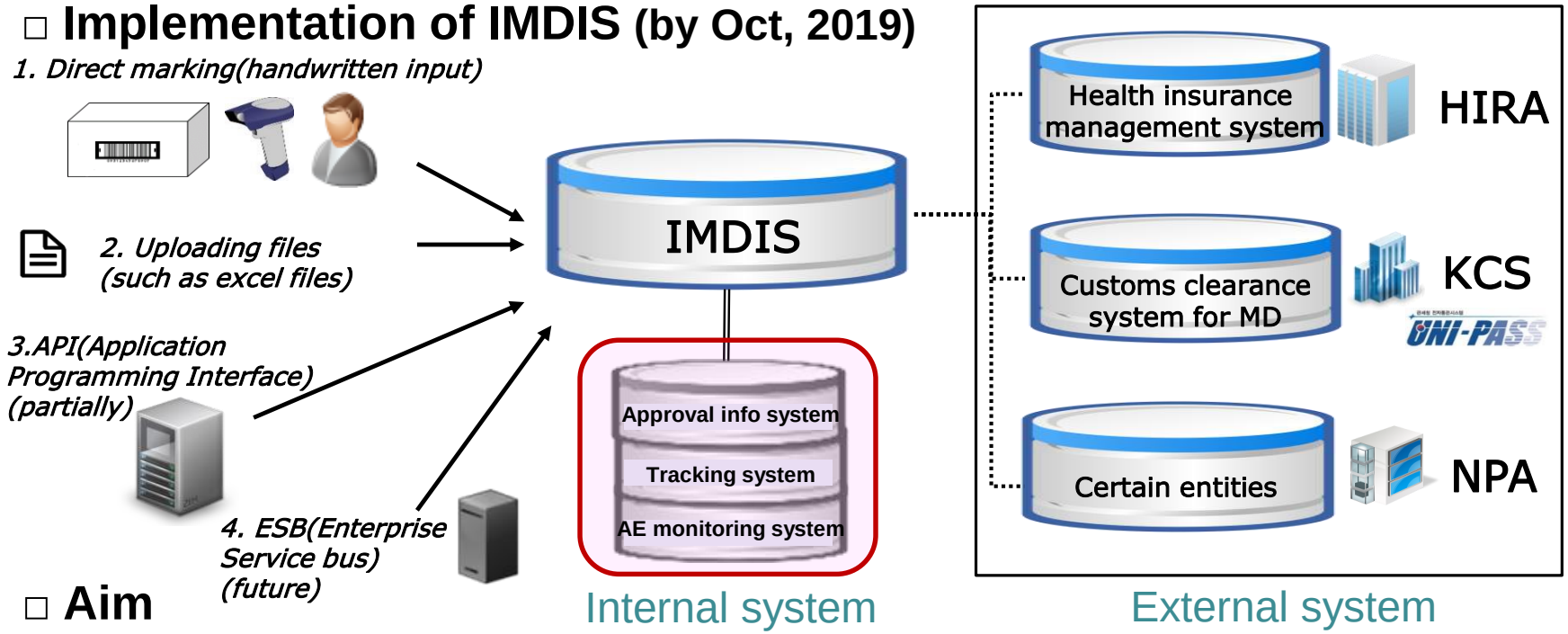
- **Revisions for implementation date for UDI System and its establishment (Dec, 2018)**
- **Notification on obtaining and managing UDI bar codes (Dec, 2018)**
- **Notification on required information, scope and how to submit data to the DB (2019)**

2.1 Example of Unique Device Identifiers

<table>
<tr><td>Items</td><td colspan="6">Device Identifiers (UDI-DI)</td><td colspan="6">Product Identifiers (UDI-PI)</td></tr>
<tr><td>Contents</td><td colspan="6">■ <u>device related</u> information
- Manufacturing country
- Manufacture / Importer
- Name of the product item, etc.</td><td colspan="6">■ data related to the <u>production of individual medical devices</u>
- Lot or Batch no.
- Expiration date
- Manufactured date
- Serial no., etc.</td></tr>
<tr><td>GS1 code</td><td colspan="12">Application Identifier (AI) for GS1 : Class 2 through 4 devices
GTIN-14 code : Class 1 devices</td></tr>
<tr><td rowspan="3">Example of assigning UDI</td><td>AI</td><td>Shipping unit</td><td>Country code</td><td>Company code</td><td>Item code</td><td>Verification no.</td><td>AI</td><td>Manufacture no. (Lot no.)</td><td>AI</td><td>Expiration Date (date of manufacture)</td><td>AI</td><td>Serial No.</td></tr>
<tr><td>01</td><td>0</td><td>880</td><td>12345</td><td>1234</td><td>3</td><td>10</td><td>110500</td><td>17</td><td>120501</td><td>21</td><td>9G837 GH234J</td></tr>
<tr><td colspan="12"><u>Unique Device Identifiers : (01)08801234512343(10)110500(17)120501(21)9G837GH234J</u></td></tr>
</table>

3. Integrated Medical Device Information System (IMDIS)

□ Implementation of IMDIS (by Oct, 2019)



□ Aim

- ✓ An electronic data processing system to effectively record and manage information on medical devices from its approval through manufacturing, importing, distributing and the use
- ✓ To strengthen supply chain with prompt identification of defective medical devices and market withdrawals

4. Reinforcing Safety Management Framework

☐ **Framework for stable device distribution of rare diseases (Dec, 2018)**

✓ **A government-initiated framework for sufficient product supply in the domestic market to treat life-threatening rare diseases in an urgent manner**

- **unique and irreplaceable medical devices to diagnose and treat rare diseases**
- **medical devices required to be constantly supplied or distributed in an urgent manner in the domestic market**

4. Reinforcing Safety Management Framework

☐ **Reporting unexpected foreign objects (Dec, 2018)**

✓ **Established legal basis for the obligation of reporting when spotted foreign objects during use of medical devices and its post-market follow-up actions**

[Scope of foreign objects]

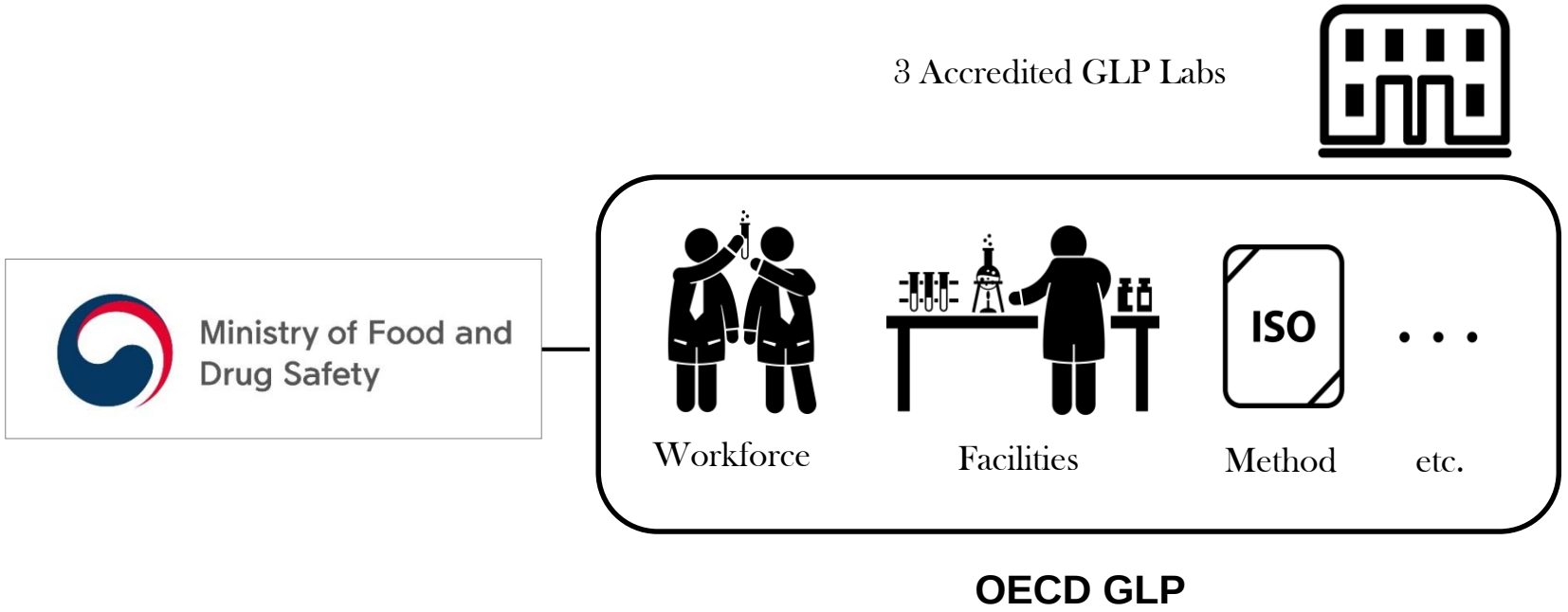
· materials that may harm human bodies such as shards of metal, plastic derived from the manufacturing process

· things like insects, parasites and dead animals that may harm or arouse disgust

· other inappropriate materials with potential risks for use

5. Applying GLP to Medical Devices

□ **Implementation of GLP for Medical Devices (by May, 2019)**



6. New Guidelines

DEC 2018	**Guideline on Standards for Obtaining UDI** - Details on the composition and obtaining of UDI for medical devices
DEC 2018	**Guideline for Placing UDI Bar Codes** - Directions for types of bard codes, how to print and associated equipment(printer and reader), etc.
DEC 2018	**Guideline on Non-biodegradable Polymeric Mesh** - Directions to prepare submission materials for ‘non-biodegradable polymeric mesh’
JAN 2019	**Guideline on Bio-informatics Approaches for NGS** - Directions for analyzing genetic data and how to validate the performance as per the testing fields

благодарю вас