



IMDRF

International Medical
Device Regulators Forum



Ministry of Food and
Drug Safety

Updates on Korean Regulatory Developments

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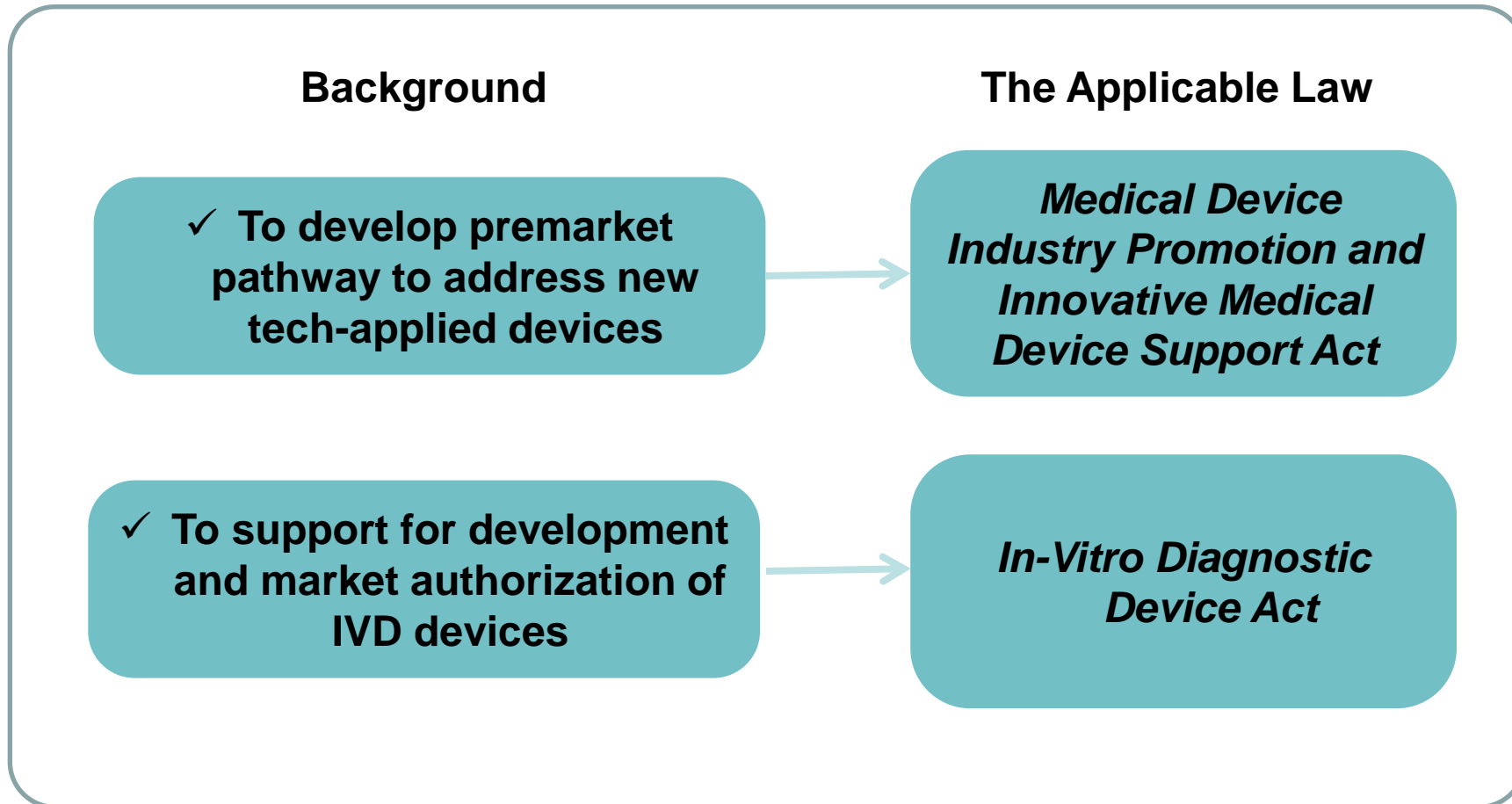


1. Acts on Innovative Devices and IVDDs

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



1.1. Acts on Innovative Devices and IVDDs





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

Items	Device Identifiers (UDI-DI)						Product Identifiers (UDI-PI)					
Contents	<ul style="list-style-type: none"> ▪ <u>device related</u> information <ul style="list-style-type: none"> - Manufacturing country - Manufacture / Importer - Name of the product item, etc. 						<ul style="list-style-type: none"> ▪ data related to the <u>production of individual medical devices</u> <ul style="list-style-type: none"> - Lot or Batch no. - Expiration date - Manufactured date - Serial no., etc. 					
GS1 code	Application Identifier (AI) for GS1 : Class 2 through 4 devices											
	GTIN-14 code : Class 1 devices											
Example of assigning UDI	AI	Shipping unit	Country code	Company code	Item code	Verification no.	AI	Manufacture no. (Lot no.)	AI	Expiration Date (date of manufacture)	AI	Serial No.
	01	0	880	12345	1234	3	10	110500	17	120501	21	9G837GH234J
<u>Unique Device Identifiers : (01)08801234512343(10)110500(17)120501(21)9G837GH234J</u>												



3. Integrated Medical Device Information System (IMDIS)

Implementation of IMDIS (by Oct, 2019)

1. Direct marking (handwritten input)



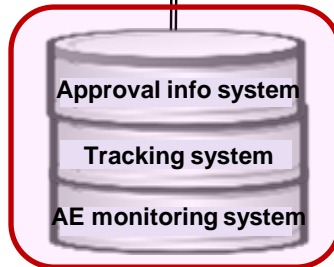
2. Uploading files (such as excel files)



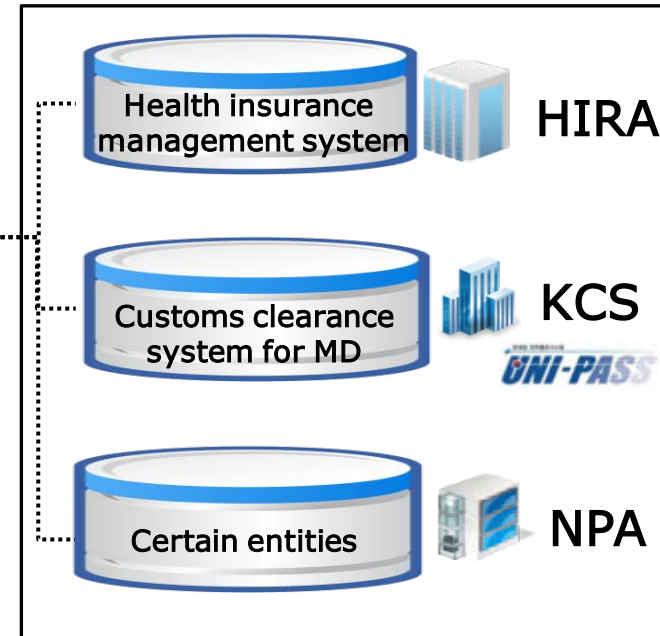
3. API (Application Programming Interface) (partially)



4. ESB (Enterprise Service bus) (future)



Internal system



External system

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]

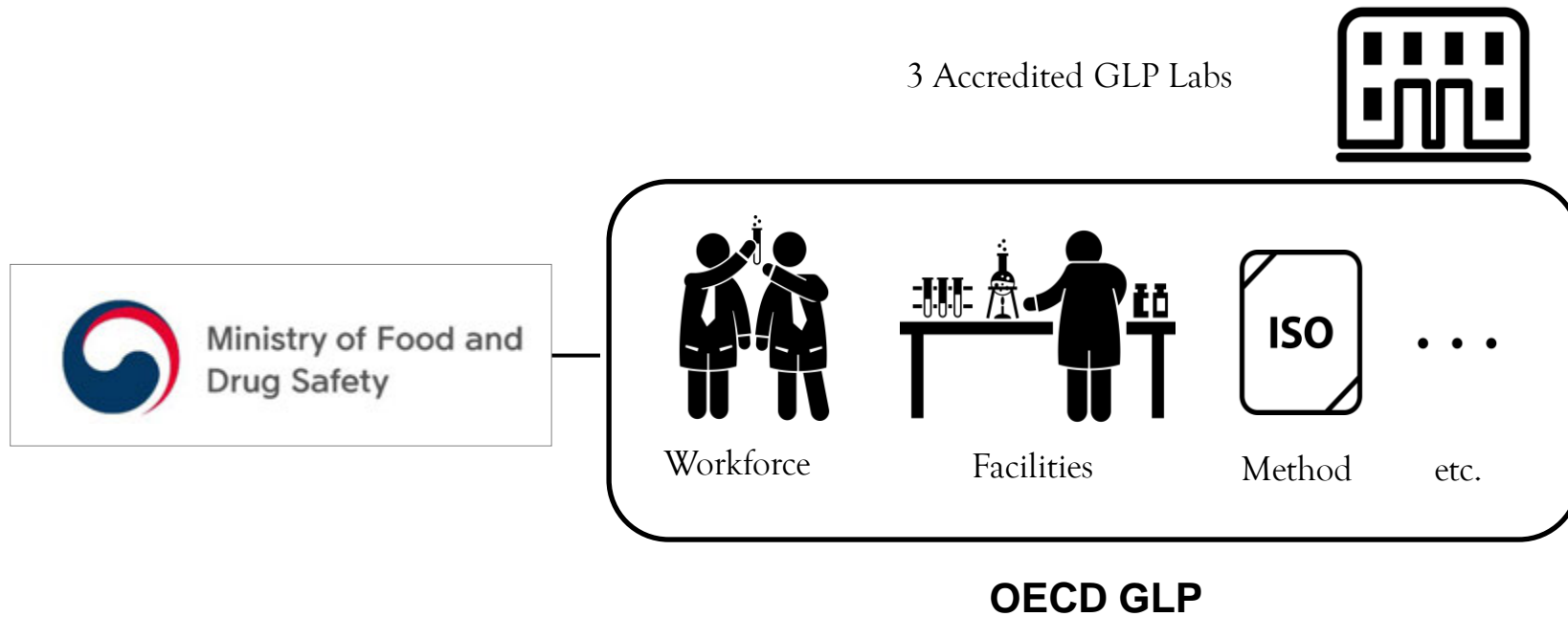
- materials that may harm human bodies such as shards of metal, plastic derived from the manufacturing process
- things like insects, parasites and dead animals that may harm or arouse disgust
- other inappropriate materials with potential risks for use





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 bar 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



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благодарю вас