Regulatory innovation for new tech-applied medical devices in Korea

2018. 7

Medical Device Policy Division
in Korea MFDS

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Content

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Ⅰ. Special Act for Innovative Devices

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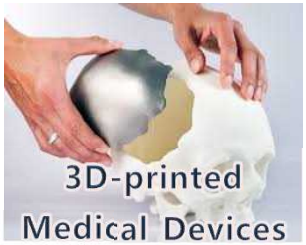
1 Scope of 『Special Act for Innovative Devices』



『Special Act for Innovative Devices』 Development of the draft & Proposed enactment in Dec, 2017)

Ⅰ. Special Act for Innovative Devices

2 Main Features of the Special Act

☐ Expedited Review Process

- Packaged support system

  * Pre-consultation, Guiding the approval pathway in the right direction, Special Task Force(TF) for innovative device review/approval process

- Modular review process*: review of the submissions by each module

  * 1) Design & development of products 2) Safety and performance
    3) Clinical trials 4) Technical docs & clinical data

☐ Customized Safety Management System

- Post-market Clinical Data Collection for innovative devices with reduction of pre-market data collection
- Implementation of the negative list administration mode for modification of approval
- Establishment of QMS Principles for software

Ⅰ. Special Act for Innovative Devices

2 Main Features of the Special Act

□ Technical Support for Market Entry

- Technical support for clinical trials
- Capacity building for regulatory & technological expertise
- Promotion of international cooperative activities

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Ⅱ. In Vitro Diagnostic Device (IVD) Act

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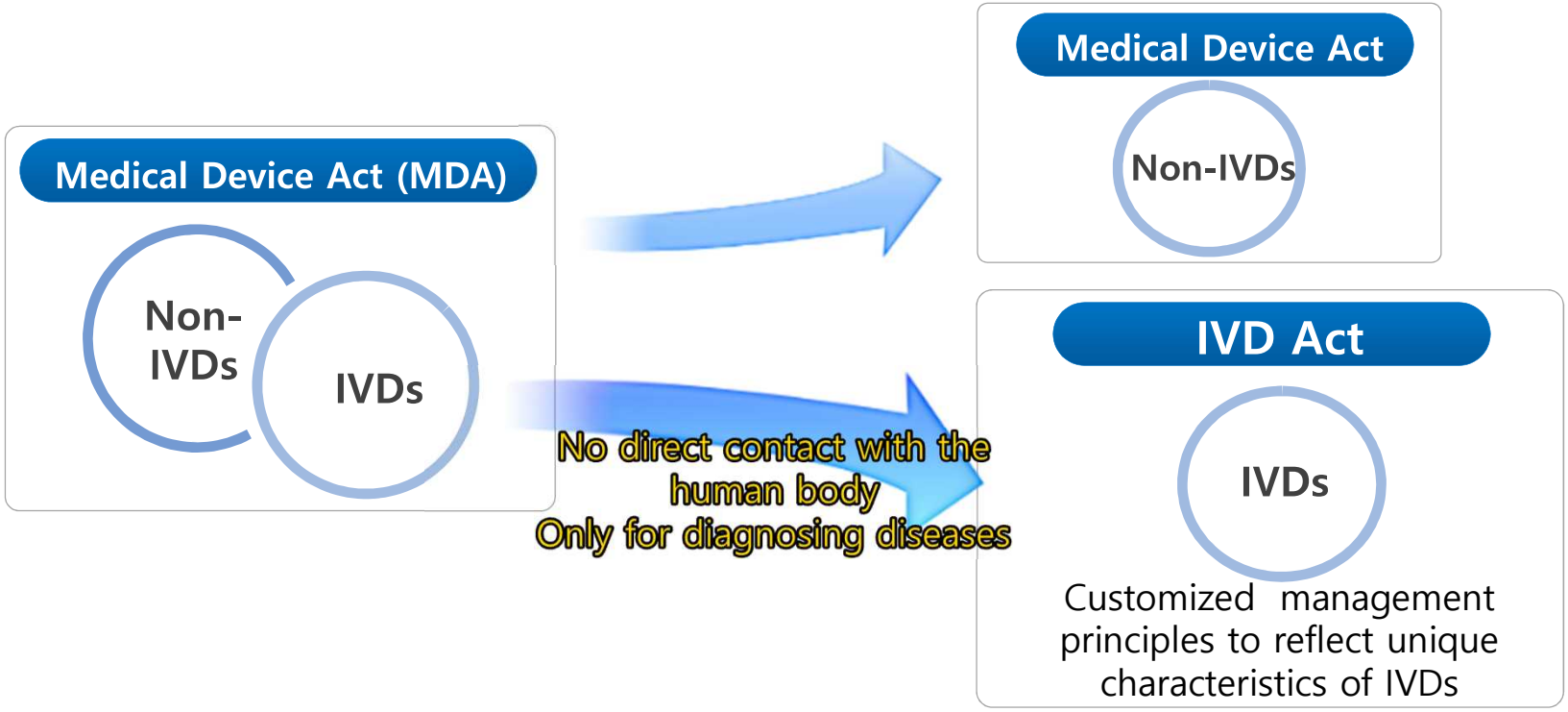
1 Background



『IVD Act』Development of the draft & Proposed enactment in Dec, 2017

Ⅱ. In Vitro Diagnostic Device (IVD) Act

2 Main Features of 『IVD Act』

☐ Clinical Lab Accreditation Program & Approval System for IVDs

- Allowing the use of advanced genetic testing equipment for research after receiving clinical lab accreditation
- Simplifying approval process by combining IVD reagents, equipment and software as one system for approval(since Aug, 2016)

☐ Simultaneous Review System for IVD Companion Diagnostic Devices (CDx)

- Allowing simultaneous approval for IVD CDx and drugs that are used with the device

☐ Improved Clinical Trial Regulations for IVDs

- Clinical trial approval, if approved by IRBs
- Allowing clinical trials in non-designated facilities
- Establishment of the IVD-specific GCP standards for IVD products

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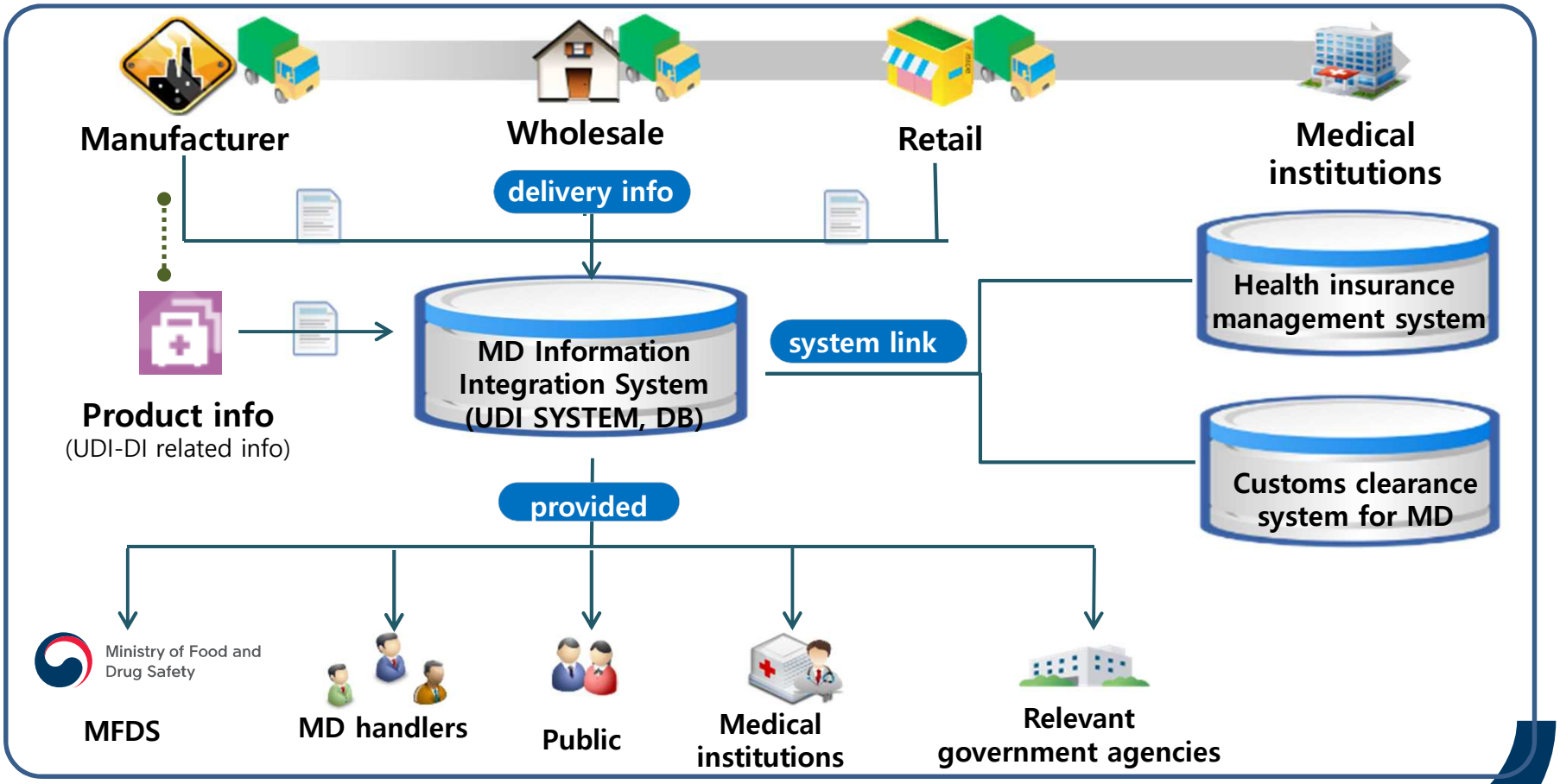
Ⅲ. Implementation of UDI System

Ⅲ. Unique Device Identification (UDI)

1 Overview of UDI System in Korea



Ⅲ. Unique Device Identification (UDI)

2 UDI System Implementation & Future Directions

□ Establishment of MD Information Integration Center(under MFDS)

- NIDS* assigned to manage the UDI system

→ Analysis, process and provision of the collected data, based on UDI

* NIDS(National Institution of Medical Devices Safety Information) : an MFDS-affiliated public organization

- Development of related guidelines and reference literatures
- Help desk service on the UDI System

□Future Directions of UDI System

Requirements for UDI placement & UDI registration

Class 4 → Class 3 → Class 2 → All Classes

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IV. New Guidelines of Innovative Devices

IV. New Guidelines on innovative Medical Devices

1 3D-printed Devices

☐ Orthopedic Implants

- 『Guideline on Review & Approval for 3D-printed Personalized Orthopedic Implantable Devices』(Oct, 2017)

☐ Dental Implants

- 『Guideline on Review & Approval for 3D-printed Personalized Dental Implantable Devices』(Oct, 2017)

☐ Personalized Products(QMS Inspection)

- 『Guideline on 3D-printed Personalized Devices to be Prepared for QMS Inspection』(Dec,2017)

☐ Biodegradable Scaffold for Skin Regeneration

- 『Guideline on 3D-printed Biodegradable Scaffold for Skin Regeneration』(Dec,2017)

☐ Biodegradable Scaffold for Revascularization

- 『Guideline on 3D-printed Biodegradable Scaffold for Revascularization』(Dec,2017)

IV. New Guidelines on innovative Medical Devices

2 Innovative Medical Devices

☐ Rehabilitation Robots

- 『 Guideline on Review & Approval for Rehabilitation Robots 』(Nov,2017)

☐ Big data

- 『 Guideline on Review & Approval for Big Data & AI-applied Medical Devices 』(Nov,2017)

☐ AI

- 『 Guideline on Clinical Evaluation of Validity for Artificial Intelligence(AI) Medical Devices 』('Dec,2017)

☐ NGS

- 『 Guideline on Cancers, Genetic Disorders and Congenital Anomaly Test on Fetus as per Testing Types of NGS Clinical Laboratories 』('Feb,2018)

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Thank you for your attention