Ministry of Food and Drug Safety

Korean Jurisdictional Update

March, 2018

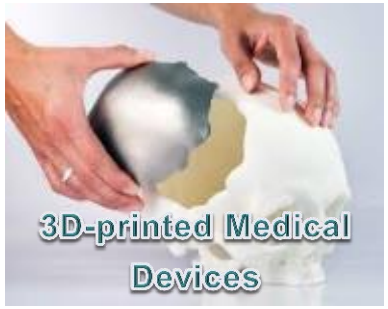
Dr. Chun-su Shin

Director
Medical Device Policy Division
Medical Device Safety Bureau
Ministry of Food and Drug Safety

Contents

I Special Act for Innovative Devices

Scope of 『Special Act for Innovative Devices』



Rapid pace of technological innovation

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

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

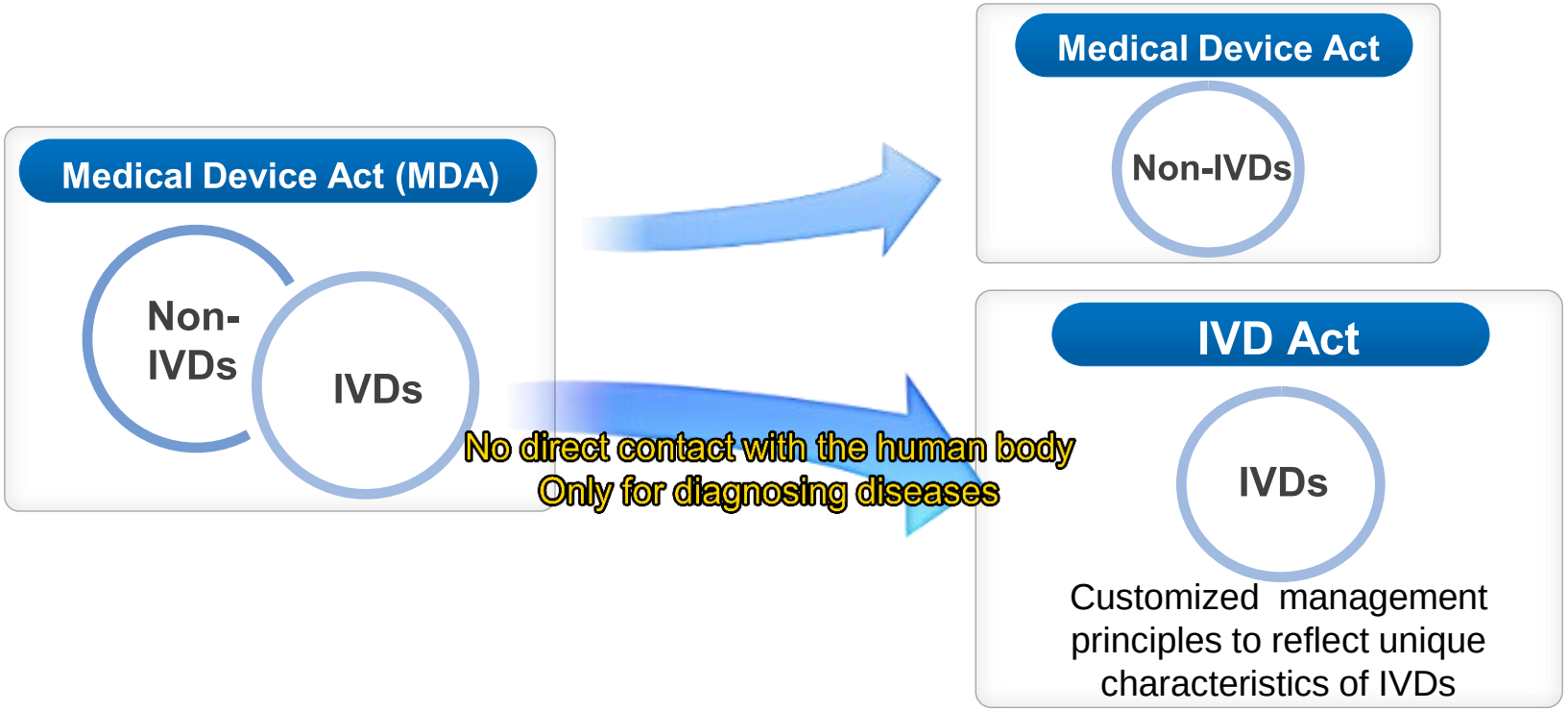
- Post-market Clinical Data Collection for innovative devices with reduction of pre-market data collection
- Implementation of the negative list administration mode for modification of approval
- Establishment of QMS Principles for software

Technical Support for Market Entry

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

II In Vitro Diagnostic Device Act

Background of 『In Vitro Diagnostic Device (IVD) Act』



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

Main Features of 『IVD Act』

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

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)

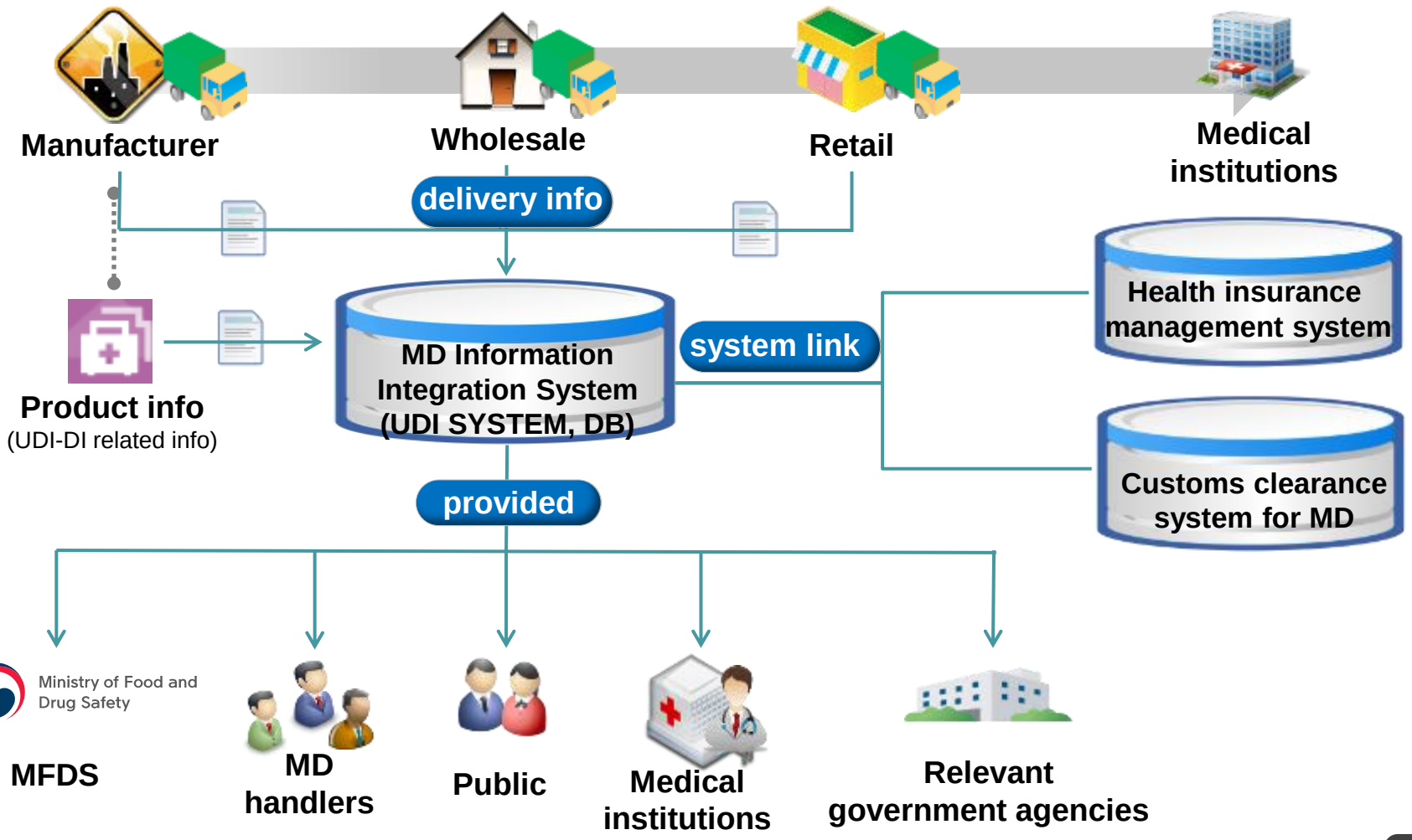
Simultaneous Review System for IVD Companion Diagnostic Devices (CDx)

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

Legal Foundation reflecting unique characteristics of IVDs for Flexible Review & Approval System

III Implementation of UDI System

Overview of UDI System in Korea



UDI System Implementation

Establishment of MD Information Integration Center(under MFDS)

- MDITAC* assigned to manage the UDI system
  - Analysis, process and provision of the collected data, based on UDI

  *MDITAC: Medical Device Information Technology Assistance Center, 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

Ⅳ New Guidelines

New Guidelines on 3D-printed Devices

3D-printed Devices

- Orthopedic Implants
- Dental Implants
- Personalized Products (QMS Inspection)
- Biodegradable Scaffold for Skin Regeneration
- Biodegradable Scaffold for Revascularization

Oct, 2017	『Guideline on Review & Approval for 3D-printed Personalized Orthopedic Implantable Devices』
Oct, 2017	『Guideline on Review & Approval for 3D-printed Personalized Dental Implantable Devices』
Dec, 2017	『Guideline on 3D-printed Personalized Devices to be Prepared for QMS Inspection』
Dec, 2017	『Guideline on 3D-printed Biodegradable Scaffold for Skin Regeneration』
Dec, 2017	『Guideline on 3D-printed Biodegradable Scaffold for Revascularization』

New Guidelines on Innovative Medical Devices

Rehabilitation Robots

Big data

AI

NGS

Nov, 2017	『 Guideline on Review & Approval for Rehabilitation Robots 』
Nov, 2017	『 Guideline on Review & Approval for Big Data & AI-applied Medical Devices 』
Dec, 2017	『 Guideline on Clinical Evaluation of Validity for Artificial Intelligence(AI) Medical Devices 』
Feb, 2018	『 Guideline on Cancers, Genetic Disorders and Congenital Anomaly Test on Fetus as per Testing Types of NGS Clinical Laboratories 』

Thank you for your attention

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