IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

Regulatory Updates on Medical Devices in the Republic of Korea

KWON, Young-Mee

Deputy Director

Medical AI Software Division
Medical Device Evaluation Department
Ministry of Food and Drug Safety (MFDS)
Republic of Korea

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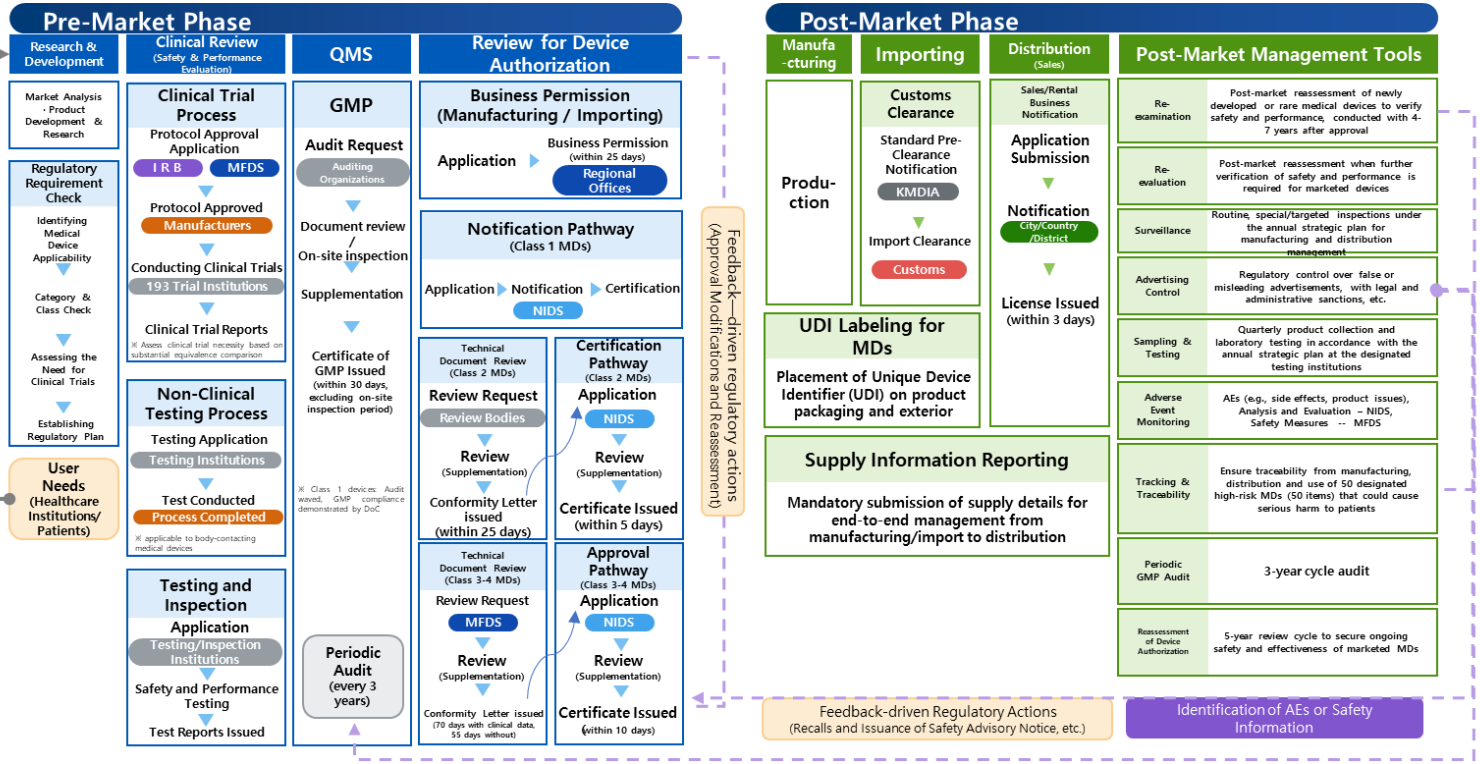
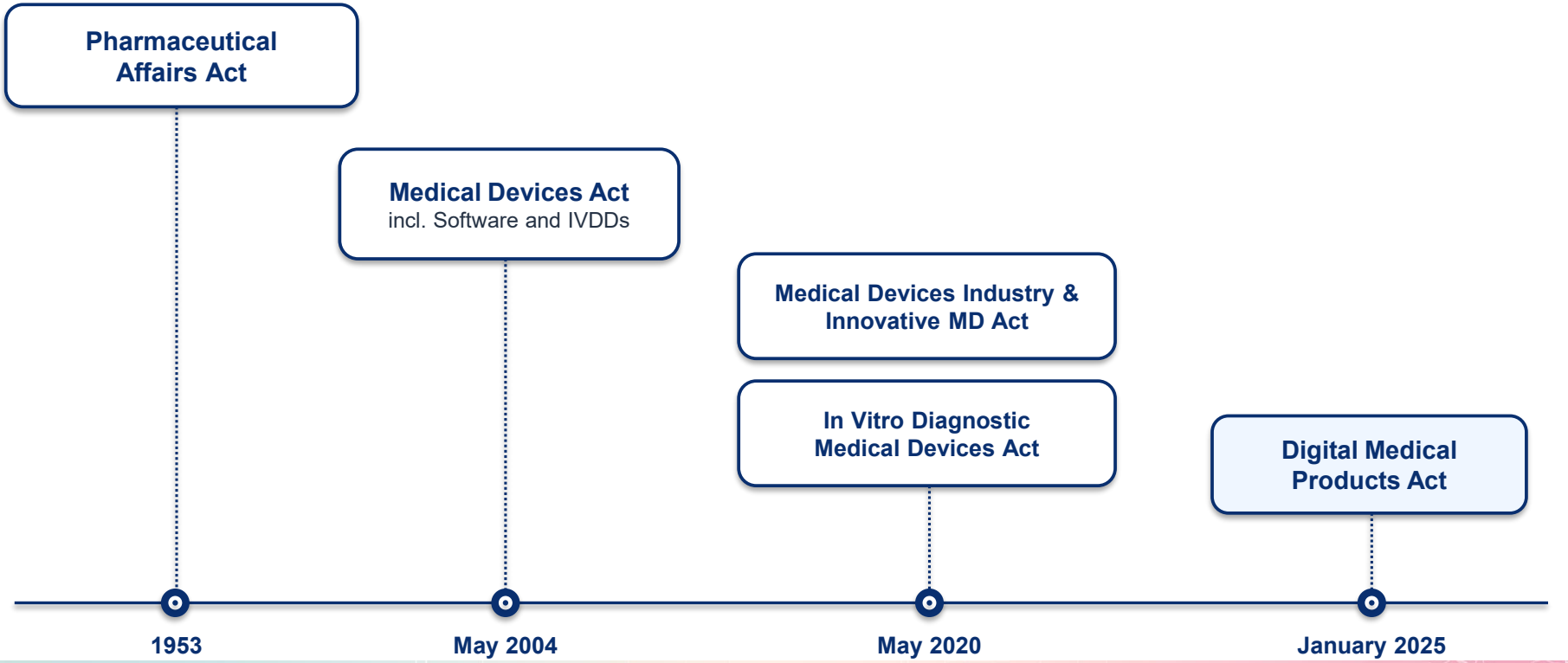
Medical Device Regulatory Framework in Korea

: Lifecycle Safety Management



Medical Device Regulatory Framework in Korea

: Evolution of the Regulatory Framework



▣ Medical Devices Act – Key Update

Strengthening Regulations on Medical Device Advertising (Amended: June 9 / Effective: December 10)

❖ **New Restrictions on Deceptive AI-Generated Advertisements**

(Scope) AI-generated audio, images, or videos that are difficult to distinguish from authentic content

(Prohibition) Advertisements that may mislead consumers into believing that an expert endorses, recommends, or uses a medical device

▣ Medical Devices Act – Key Update

Clarifying the Framework for Medical Devices for Urgent Introduction

(Amended: June 9 / Effective: December 10)

❖ **Explicit MFDS Authority for Designation**

- Establishing a legal basis for MFDS to designate and revoke the designation of medical devices used to diagnose or treat rare or intractable diseases with no alternative product available in Korea, or where urgent introduction or support for stable supply is necessary for public health

❖ **Mandatory Demand Surveys & Supply Planning**

- Conducting demand surveys and establishing supply plans to ensure timely and stable supply

❖ **Operational Activities Entrusted to NIDS**

- Entrusting the National Institute of Medical Device Safety Information (NIDS) with operational activities
- Designation and revocation authority remains with MFDS

▣ Medical Devices Act – Key Update

Clarifying the Legal Basis for the QMS Conformity Assessment System (Effective: July 1)

❖ **Elevating key provisions previously stipulated in an MFDS Notice to the Medical Devices Act**

- Legal Basis Established for:

✓ QMS conformity assessment and issuance of certificates

✓ Revocation of conformity certificates and corrective orders

✓ Appointment and dismissal of QMS auditors

✓ Designation of auditor training institutions

❖ **Introduction of a 4-Year Renewal System for Review Bodies**

- Introducing a 4-year validity period and renewal requirement for: Technical Documentation Review Bodies and QMS Audit Organizations authorized to conduct conformity assessment activities

In Vitro Diagnostic Medical Devices Act – Key Update

Introduction of a Post-market IVD Performance Evaluation System (Effective: January 3)

- **Scope of Performance Evaluation**
  - Authorized, certified, or notified IVD medical devices
  - IVDs granted Emergency Use Authorization
  - Other IVDs deemed necessary for performance evaluation by the MFDS
- **Evaluation Criteria and Methods**
  - Considering product characteristics and relevant performance parameters, including: Accuracy, Precision, Sensitivity, Specificity
- **Follow-up Measures**
  - Where evaluation results indicate a potential risk to public health, the MFDS may order measures such as: suspension of manufacturing, importation, or sale

A post-market mechanism that enables MFDS to directly assess the performance of IVDs when necessary

In Vitro Diagnostic Medical Devices Act – Key Update

Expansion of Home-use IVD Medical Devices (June 30)

❖ Expanded from 9 existing home-use IVD categories, including pregnancy, blood glucose, and COVID-19 testing, to 11 categories with the addition of influenza and controlled substance testing

- Home-use IVD for Influenza virus or COVID-19 [Class 3]

: Reagents for self-testing using nasal or other specimens to detect influenza virus or SARS-CoV-2 antigens and/or antibodies associated with COVID-19

- Home-use IVD for controlled substances (drug screening)[Class 2]

: Reagents for self-testing using urine or saliva specimens to detect controlled substances, including narcotics and cannabis, and their metabolites

▣ Act on Nurturing of MDs Industry & Supporting Innovative MDs – Key Update

❖ **Promoting Innovation through Regulatory Support**

- Dedicated authorization pathways for **designated innovative medical devices**

  → Priority and stepwise review mechanisms applied

- Supporting the market entry of innovative technologies

  → Facilitating timely product launches and improving patient access

  ✓ **148 devices designated (as of August 7)**

  • **8 AI/big data-based products designated**

  ✓ Number of products designated by year

Year	2020	2021	2022	2023	2024	2025	2026	Total
No.	8	9	11	31	29	45	15	148

Generative AI for chest disease diagnostic support

▣ Digital Medical Products Act – Key Update

Implementation of the Digital Healthcare & Health Support Device System
(Effective: January 2026)

❖ **Strengthening Distribution Oversight to Prevent False or Exaggerated Advertising**

- **Voluntary Reporting System**
  - Companies may voluntarily submit product information to MFDS
  - Submitted information will be publicly disclosed
- **Performance Certification* System**
  - Optional performance certification by qualified private institutions for products meeting specified performance standards
  - Upon company request

    * *Certification Benefits:*

      ✓ Official certification mark

      ✓ Research use in medical institutions (potential pathway toward medical device)

      ✓ Certified data may support future medical device development (e.g., sport/leisure heart rate data → disease diagnosis)

▣ Digital Medical Products Act – Key Update

Expanded Exemption from Clinical Trial Data Requirements (Effective: July 2026)

❖ **Expanding eligibility for exemption from clinical trial data requirements based on specific intended uses, rather than device classification alone**

AS-IS	TO-BE
• Class II medical devices claiming no clinical efficacy → Clinical trial data may be exempted	• Medical devices with specified intended purposes that do not claim clinical efficacy → Clinical trial data may be exempted

Example: Establishing simulated procedures and treatment plans using medical images, and providing information on anatomical structures, lengths, thicknesses, areas, etc.

▣ 13 New or Revised Guidance Documents Published (April – August 2026)

❖ **Digital Medical Devices – 5 new or revised**

- Approval and review of LLM-based digital medical devices; Predetermined Change Control Plans (PCCPs); Quality Management System certification; etc.

❖ **Medical Devices – 5 new or revised**

- MDSAP audit model; guidance on clinical trials for medical devices; etc.

❖ **In Vitro Diagnostic Medical Devices – 3 new or revised**

- Clinical performance evaluation of Home-use infectious disease immunoassay reagents; labeling guidance; etc.

Thank You!