Regulatory Updates on Medical Devices in Republic of Korea

Ministry of Food and Drug Safety

13 September 2022

Overview

01

Introduction to the MFDS

Vision, Objective and Core Strategies

Vision — Safe Food and Drug, Healthy People

Goal — "Korea will leap beyond recovering daily lives, into a global power in health"

Overcoming COVID-19 and reinforcing the reliability of medical products	Advancement of the national responsibility system for food safety	Supporting the growth of scientific regulatory services and bio-health innovations

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IMDRF MC Members from the MFDS

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Major Regulatory Initiatives

Major Regulatory Initiatives

Vision

To stringently ensure safe use of medical devices and quality products supply
To assure effective and agile support for industry growth

Goal

> To achieve safe new normal in the post COVID-19 era

> To develop proactive regulatory framework to foster new industry and priority area

> To make a fundamental to guarantee safe medical devices

| **Setting up Management Framework for Digital Health Devices** | **Strengthening Quality Management Framework for IVD Devices** | **Developing Basis for Safety Use of Medical Devices by Improving GMP Audit Procedure** |

To establish Proactive Regulation Framework to Foster Digital Health Devices Area

Regulations

Software categorized as a medical device (amended the Medical Devices Act in December 2018)

- (To be) Instruments · Equipment · Devices · Materials → Instruments · Equipment · Devices · Materials · **Software**

90 New subcategories for software under medical devices (October 2020)

- 90 Types of software including cardiovascular image analysis software, brainwave analysis software, cognitive therapy software, ophthalmic image analysis software, breast cancer image detection and diagnosis assistance software, etc.

Preparation of cyber security countermeasures for software medical devices

- Mandatory submission of "cyber security data" for authorization of medical devices using wired and wireless communication (November 2019)

- Publication and distribution of the Medical Device Cyber Security Review and Authorization Guideline (announced in November 2019)

To establish Proactive Regulation Framework to Foster Digital Health Devices Area

Development Support

Guidance on the subject of:

- Evaluation criteria for digital therapeutics for insomnia and alcohol/nicotine addiction

- GMP operation of medical device software manufacturing facility, etc.

- Decision criteria for medical devices and wellness products for personal health care

- Application of evidence for actual use of medical devices, etc.

Dedicated Division

- Newly established digital healthcare team: "Digital Health Devices Division" (February 2022)

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To establish Proactive Regulation Framework to Foster Digital Health Devices Area

- Software medical devices has differing characteristics from general medical devices, which need to be separately managed, considering regulations on clinical investigations, pre-market authorization and policies to avoid any unnecessary barrier for industry

▷ To assist in facilitating development and use of safe and effective digital health care products through specialized and fair "customized regulations", resulting in improved public health

Completely new design for digital health devices-customized regulatory framework

① **TF, launched to strategically support product commercialization (April 2022)**

- Coherency review with the existing regulations and support from the development stage

- Comprehensive support throughout consulting, review on clinical investigations and marketing authorization

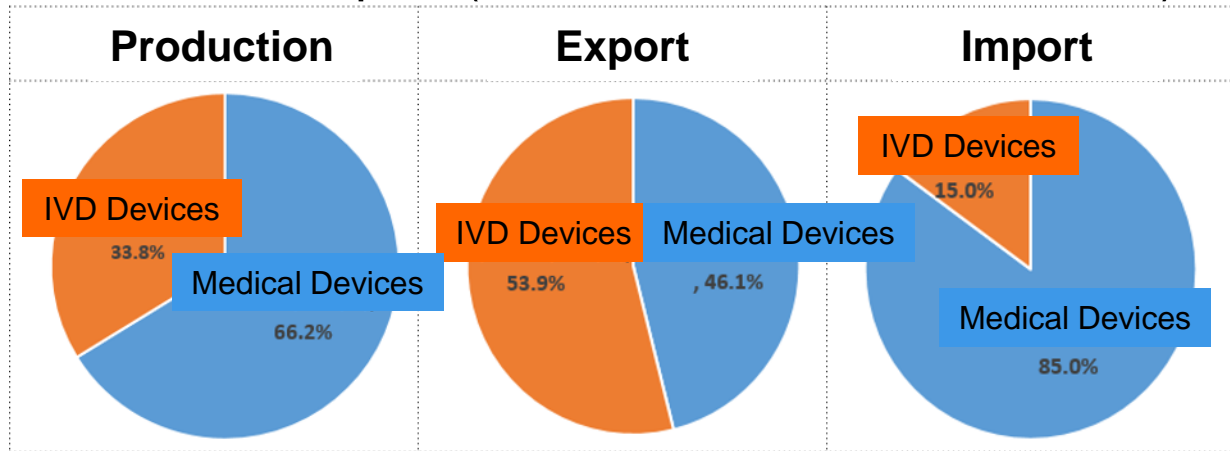- Close advice such as providing with pre-market review guidelines

② **To legislate digital health devices related regulations**

- Plan to have extensive laws and regulations for addressing total lifecycle of digital health devices for its own nature, from overall product management, clinical investigations, pre-market investigations, and so forth

  * terms and definitions, scope, clinical investigations, pre-market authorization, data management, quality management and surveillance, etc.

Enhancement of the QMS Regulations for IVD Devices

- Importance of in vitro diagnostic medical devices increased

• Continuous growth of production-import of in vitro diagnostic medical devices achieved

• In 2021, 33.8% recorded for in vitro diagnostic medical device production out of total medical device production (KRW 4 trillion and 350 billion)

• In 2021, 53.9% recorded for in vitro diagnostic medical device import out of total medical device import (KRW 5 trillion and 320 billion)

Production

Export

Import

IVD Devices

Medical Devices

IVD Devices

Medical Devices

IVD Devices

Medical Devices

33.8%

66.2%

53.9%

, 46.1%

15.0%

85.0%

(As of 31 DEC 2021, Unit: KRW hundred million)

Year	Production	Export	Import
2021	43,501	53,209	9,165
2020	33,549	42,112	8,057

Enhancement of the QMS Regulations for IVD Devices

**- Enactment of the "Act on In Vitro Diagnostic Medical Devices" (1 May 2020)**

• Paradigm shift from treatment to early diagnosis and prevention of disease ▷ Increase in the importance of IVD devices

• Establishment of management system, considering difference in feature between non-IVD and IVD devices ▷ Enactment of the "Act on In Vitro Diagnostic Medical Devices"
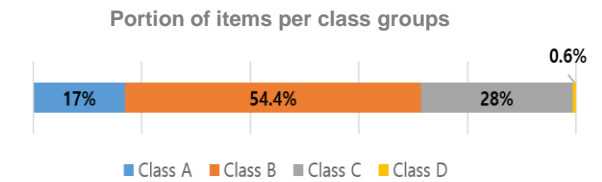
- Key points

• Separate regulations in line with the features of IVD devices (Authorization procedure, clinical performance tests, GMP and others)

• Otherwise, complies with the "Medical Devices Act"

< Comparison between the "Act on In Vitro Diagnostic Medical Devices" and IVDR >

Republic of Korea

Class	Risks	Pathway
Class 1	Low potential harm to individual and the public	Report
Class 2	Moderate potential harm to individual and low potential harm to the public	Certification
Class 3	High potential harm to individual and moderate harm to the public	Approval
Class 4	High potential harm to individual and the public	Approval
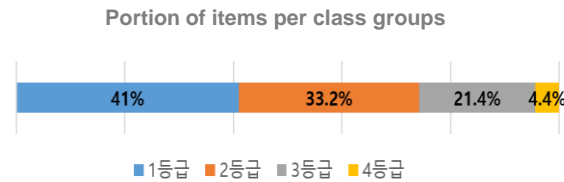
European Union

Class	Risks	Pathway
Class A	Low risks to individual and the public	No NB-certification
Class B	Low/moderate risks to individual and low risks to the public	NB-certification
Class C	High risks to individual and low/moderate risks to the public	NB-certification
Class D	High risks to individual and the public	NB-certification

Portion of items per class groups

41%	33.2%	21.4%	4.4%

■1등급 ■2등급 ■3등급 ■4등급

Portion of items per class groups

0.6%

17%	54.4%	28%	

■ Class A ■ Class B ■ Class C ■ Class D

Enhancement of the QMS Regulations for IVD Devices

- Systematic quality management for maintaining competitiveness of K-diagnostic reagents in the global market even in the post-COVID-19 era

- Establishment of the management system that reflects the feature of IVD devices collecting a sample and not being directly used on the human body

< To establish a government-initiated IVD devices assessment framework >

- **For assessing pre and post market performance of high risk devices**

- * [EU] Operation of the central laboratory (Paul Ehrlich Institute, PEI) in charge of verification of performance of Class 4 IVD devices, scientific and technological consultation for public-private sectors, and technical support for the development of optimal testing process

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Cultivation of an Environment for Securing the Safety of Medical Devices

- Consistent production of safe, effective, and quality medical devices as intended by securing a quality system for the total cycle of medical devices from design, development, manufacturing to post-market surveillance

- ▷ Operation of QMS Audit System based on ISO 13485 (Standards of Medical Device Good Manufacturing Practices)

< Comparison of the certification system between KGMP and MDSAP >

Item	KGMP	MDSAP
Standard	▪ 「Standards of Medical Device Good Manufacturing Practices」 * Based on ISO 13485	▪ 「Audit model」 * ISO 13485 and regional requirements
Type	▪ Initial review, Regular review (every 3yrs), Review for changes, Additional review - Regular review is required every 3 years after the initial review	▪ Initial review, Regular review(every 3yrs), Post-market review (every 1yr), Special review - 4 regular reviews are required for 3 years after the initial review
Period	▪ Domestic (2 days), Overseas (3-5 days)	▪ Longer than 7.5 days
Auditing authority	▪ 4 institutions for the audit of medical devices quality management	▪ 13 MDSAP recognized Auditing Organizations (AOs) * Consisting of Notified Bodies

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Cultivation of an Environment for Securing the Safety of Medical Devices

> - **Enhancement of QMS inspection substantiality and elimination of blind spots in the safety management for safe use of medical devices**
>
> • Expansion of item groups and subjects of QMS review, rationalization of paper-based inspections

- ① **Expansion of item groups for the enhancement of QMS inspection substantiality**

- Restructuring and expanding item groups based on risks (26 → 50 or more)

- ② **Foundation of a legal basis for QMS inspection of combination products**

- Revision of regulations for the establishment of the basis for QMS inspection of combination products (composed of any combination of a drug and a device)

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03

New Guidance Documents

Newly Developed Guidance Documents for Industry

IVD

- Guidance for **AI based Digital Pathology Software**
- In Vitro Diagnostic Multivariate Index Assay (**IVD-MIA)**
- Guidance for Review and Approval of Medical Devices for In Vitro Diagnosis of COVID-19 (6th Edition)

Digital Health AIMD

- Guidelines for Safety and Performance Evaluation and Clinical Trial Protocol Preparation of **Digital Therapeutics for Depression Improvement** (to be published)

- Guidelines for Safety and Performance Evaluation and Clinical Trial Protocol Preparation of **Digital Therapeutics for Panic Disorder Improvement** (to be published)

- Guideline on Review and Approval of **Cybersecurity** of Medical Devices (2nd Edition)

- Guideline on Review and Approval of Artificial Intelligence Medical Devices (3rd Edition)

Post-market

- Manual for Regulations on Renewal of Medical Devices Manufacturing and Approval, etc. (revised)
- Guideline to Submit Safety and Effectiveness Documents for Innovative Software Medical Devices Manufacturers Recognized by the Government (revised)

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Thank you

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