Regulatory Updates on Medical Devices in Republic of Korea

Ministry of Food and Drug Safety

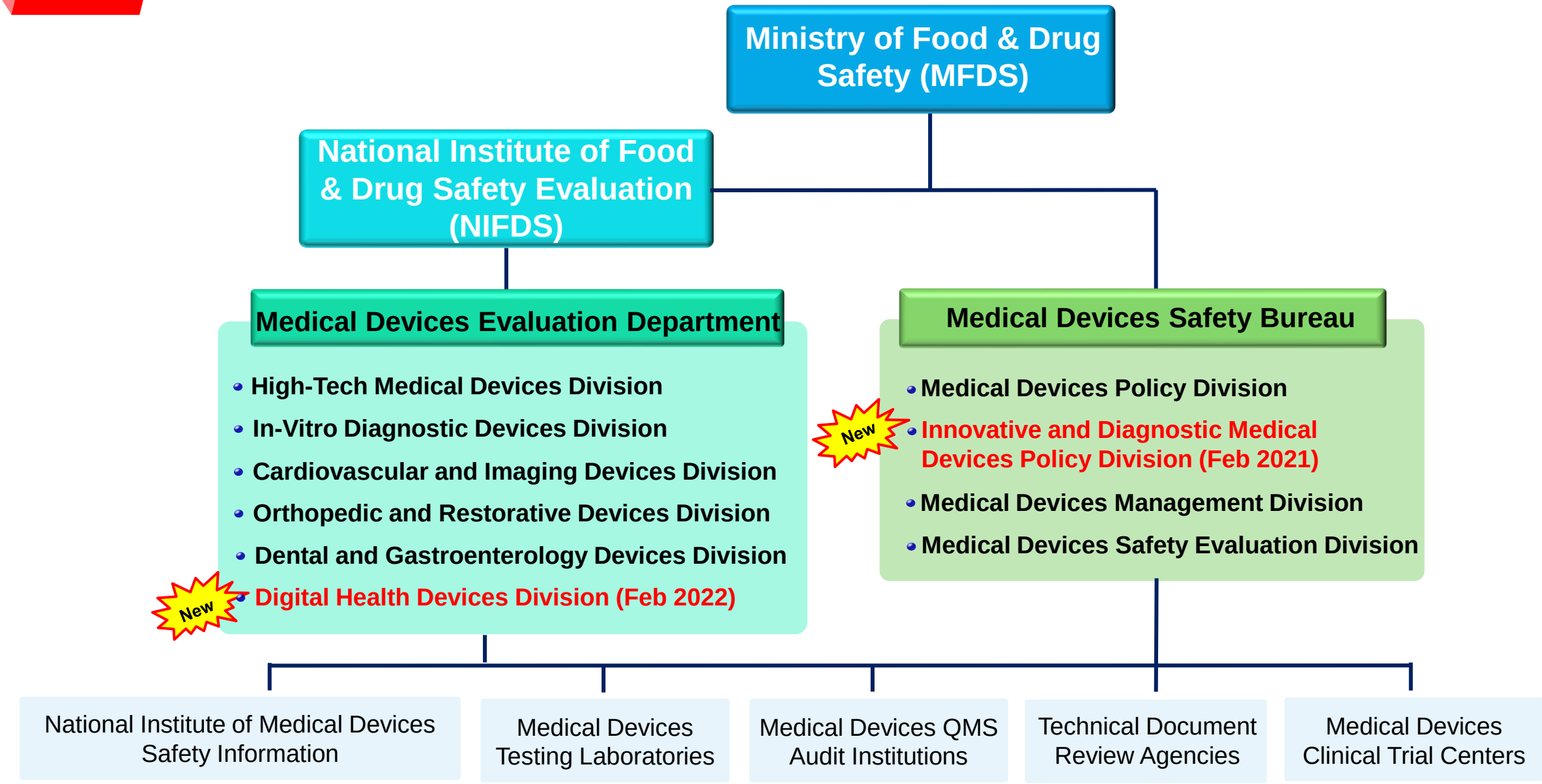
16 Feb 2023

Ministry of Food and Drug Safety

Ministry of Food and Drug Safety

Contents

Ⅰ. Introduction of MFDS Organization



Ⅱ. Medical Devices Regulation

Global Leader in Bio & Digital Health

Lessen regulatory barriers to digital health devices to ensure global competitiveness

Develop proactive regulatory framework for fostering new business based on safety

1. Provide Customized Regulatory Framework for Digital Health Devices

2. Improve Quality Management for IVDDs

3. Increase Reliability of Quality Management

Ⅱ-1. Provide Customized Regulatory Framework for Digital Health Devices

Regulation

- Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices
  - Introduced a streamlined review process for change approval for SaMDs designated as Innovative Devices (May 2020)
- Introduced a negative regulatory system for change approval of SaMDs (July 2022)
- Plan to enact “Act on Digital Medicine Products” to lay a foundation of Total Product Life Cycle (From 2023)

Division

- Launched a dedicated division for DH called “Digital Health Devices Division” (Feb 2022)

Guidances

- Guidance on Clinical Trial Design for Insomnia, Alcohol, Nicotine Addiction (2021)
- Guidance on Clinical Trial Design for Depressive and Panic Disorder (2022)
- Guidance on Considerations and Examples for Cybersecurity in Medical Devices (Revised in 2022)
- Guidance on Review and Approval of U-Health Care Medical Devices (Revised in 2022)
- Guidance on Clinical Trial Design for ADHD and Eating Disorder (From 2023)

Ⅱ-1. Approved Digital Health Devices and Guidances

Review & Approval

- Machine Learning-Enabled Medical Devices : 153
- Mobile App Medical Devices : 120
- U-Health Care Medical Devices : 101
- AR/VR Medical Devices : 10
- Clinical Trials Design for DTx : 31
- Cybersecurity review : 2,136
- DTx(Insomnia) : 1 (Feb. 14, 2023)

Guidances

- Machine Learning-Enabled Medical Devices : 10
- Cybersecurity : 3
- SaMD : 5
- Digital Therapeutics (DTx) : 6

Digital Therapeutics (DTx) Bring about Wider Treatment Options and Improved Convenience

- Korea's First 'Digital Therapeutic' Approved for Insomnia Symptom Improvement -

Ⅱ-2. Improve Quality Management for IVDDs

Regulation

- Implement “Act on In Vitro Diagnostic Medical Devices” to ensure safety management of IVDs (May 2020)
- Established a regulatory review and approval process of IVDDs for COVID-19 (July 2022)
  - Provide usability review criteria of IVD self-tests based on IEC 62366
- Lay a foundation to establish a government-initiated center for performance evaluation of IVDDs (From 2023)

✓ Implementation of EU IVDR: Reference Laboratories countries testing the performance of Class D IVDDs in pre and post market led by European countries

Guidances

- Guidance on Review and Approval of IVDDs for COVID-19 (Revised on July 2022)
- Guideline for AI based Digital Pathology Software (for Breast Cancer) (Dec 2022)
- Guidance on Scientific & Systematic Evaluation Criteria including Biomarker for Early Detection of Cancers (From 2023)

Ⅱ-2. Approved IVDDs and Guidances

Approval

- **Approved COVID-19 Products**
  - ✓ **Molecular Diagnostic Tests : 52**
  - ✓ **Antigen Diagnostic Tests : 45**
  - ✓ **Antigen Home Use Tests : 15**
  - ✓ **Serological Tests : 24**
- **AI-Based Digital Pathology Softwares : 2**

Guidances

- **Guidances for COVID 19, Monkey Pox, etc for Novel Infectious Diseases : 4**
- **Guidances for AI-Based Digital Pathology : 2**
- **Guidances for high-technology including NGS : 4**

Ⅱ-3. Increase Reliability of Quality Management

Regulation

- Introduced the latest international standard on GMP (ISO 13485:2016) in 2019 & provide technical support for quality management for manufacturing companies (All year round)
- Support quality management for SaMD across TPLC (Since 2022)
- Diversify educational program for nurturing GMP reviewers and their expertise based on their careers and specialty (From 2023)
- Plan to join the membership of MDSAP (From 2023)

Guidances

- Guidance on How to Prepare MDSAP (based on actual audit case of defibrillator) (Nov 2022)
- Guidance on Introduction to Usability of GMP in Medical Devices (for cardiovascular image analysis software, etc) (Oct 2022)


World EXPO 2030
BUSAN, KOREA
World Expo 2030
Candidate
World EXPO 2030
BUSAN, KOREA
Please cheer for hosting together!
The Host City Announcement in Dec. 2023

Thank you !