



IMDRF International Medical Device
Regulators Forum

Regulatory Updates on Medical Devices in the Republic of Korea

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Ministry of Food and Drug Safety

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MFDS Regulatory Innovation

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MFDS Regulatory Innovation Tasks



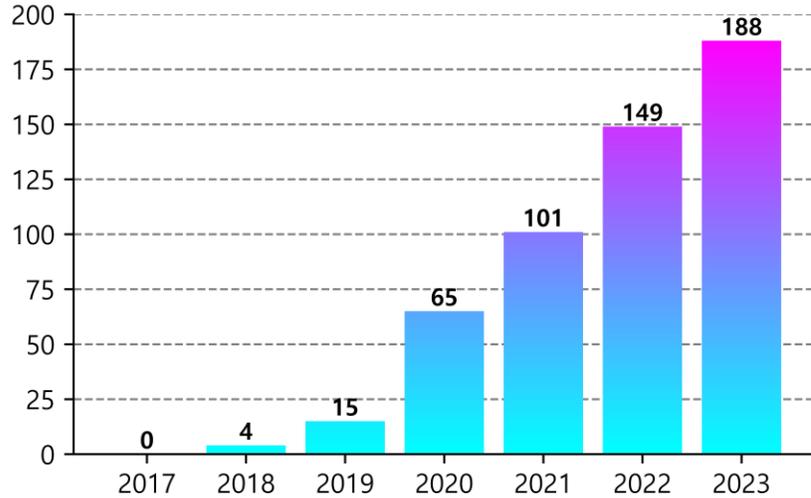
➤ To secure public safety and strengthen the medical device industry based on regulatory science

Updates to Act / Regulation

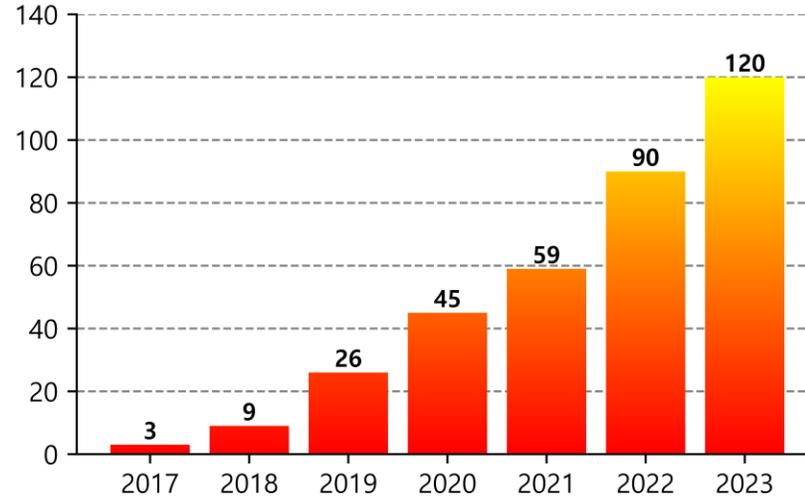
❖ Enactment of the “Digital Medical Products Act”

- To introduce a new regulatory framework to promote state-of-the-art digital medical products and provide regulatory support
 - ✓ [National Policy Tasks] Regulatory science and innovation for commercialization of digital and bio-healthcare products
- The Act on Digital Medical Products has been drafted and submitted to the National Assembly
 - ✓ Having discussions with 8 industry associations encompassing medical devices, pharmaceuticals, wellness products and others

❖ Statistics on AI/ML-enabled Medical Devices & Digital Therapeutics



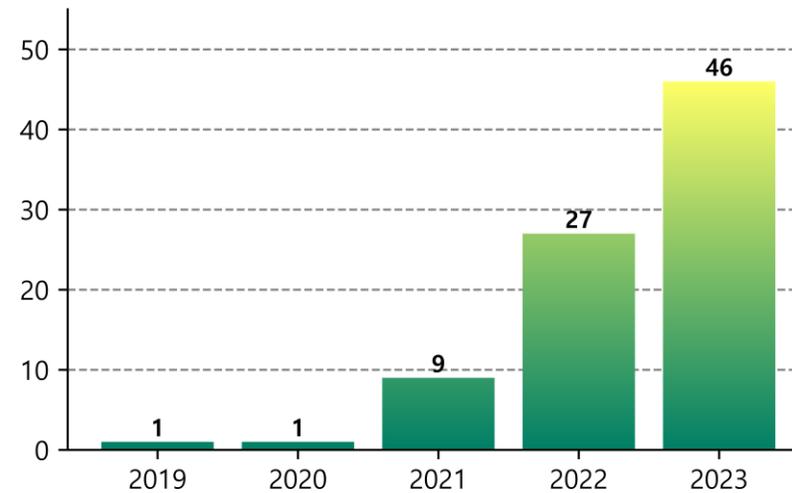
<Cumulative number of approved AI/ML MD>



< Cumulative number of approved clinical study of AI/ML MD>



<Approved 1st and 2nd DTx for insomnia>



< Cumulative number of approved clinical study of DTx>

Updates to Act / Regulation

❖ Revision of Regulations on Review and Approval System for better implementation

- Real World Evidence(RWE) is more widely accepted as clinical data for review of following medical devices
 - ✓ Orphan or urgently needed medical devices
 - ✓ Digital health medical devices (big data, AI/ML-based medical devices)
- Criteria of interim classification and code for newly developed medical devices (digital health devices)
 - ✓ For unclassified medical devices under the current classification, interim classification apply in consideration of the risk, intended use, performance and others

Regulatory Innovation 2.0

❖ Providing detailed criteria for review and approval by product item

- Detailed criteria by product item to determine whether it requires technical document review is provided
 - ✓ (Benefit) To shorten the period for review and approval with explicit criteria for determining whether it requires technical document review

Newly Published Guidance Documents

- Guidance on Review and Approval for Real World Evidence
 - Revised in July 2023
- Guidance on Review and Approval for Medical Device Software
 - Revised in July 2023
- Guidance on Performance Evaluation for Autonomous Wheelchairs
 - Developed in July 2023
- Guidance on Clinical Trial of In Vitro Diagnostics
 - To be published in November 2023
- Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for ADHD and Eating Disorder
 - To be published in December 2023

International Cooperation

❖ **MOC between the MFDS and the U.S. FDA on Medical Products Using AI**

- To share experiences in using AI for medical product development
- To discuss ways to promote the use of innovative technologies to develop effective and safe medical products using AI

❖ **MOU between the MFDS and the DINAVISA (Paraguay)**

- To recognize results of GMP audit conducted by the MFDS in the field of medical products

International Cooperation

❖ Active participation in MDSAP activities

- Submitted annual report and attended the MDSAP forum since joining MDSAP as an affiliate member
- To expand the scope of using MDSAP audit results for the initial GMP audits in South Korea

❖ Cooperation between the MFDS and the DAV (Vietnam)

- To provide support for establishment of ①regulatory framework of medical devices, ②management system and ③manufacturing and quality management system in Vietnam
- To provide capacity building training for officials at the DAV in charge of medical device safety management

Thank you/Questions

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