Regulatory Update from MFDS – Republic of Korea

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IMDRF International Medical Device Regulators Forum

MFDS Regulatory Innovation

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Enactment of two major Acts

- " Act on the Innovation of Regulatory Science"
- "Digital Medical Products Act"

Updates to Act / Regulation

- **"Act on the Innovation of Regulatory Science for Ensuring the Safety of Food and Drugs and Supporting Marketing Approval"**

- **More efficient process for the safety management based on regulatory science to promote the safe use of medical devices and their rapid marketing approval**

  - ✓ Definition of Regulatory Science : A branch of science covering technologies related to overall safety management, criteria, and approaches, etc., from the assessment of the safety, efficacy, quality, performance of food and drugs, etc. to their review/approval and use in real settings
  - ✓ Develop the five-year basic plan for regulatory science
  - ✓ Establish a Committee on Regulatory Science
  - ✓ Cultivate expert personnel for developing innovative products and support marketing approval
  - ✓ Designate dedicated organizations for capacity building

Updates to Act / Regulation

❖ **"Act on the Innovation of Regulatory Science for Ensuring the Safety of Food and Drugs and Supporting Marketing Approval"**

- Providing customized service to cultivate experts in the field of medical device
  - ✓ Development of the field-centered curriculum for capacity building of experts in regulatory science (14 times, 722 participants in 2023)
- Promoting international cooperation with foreign governments or international organizations
  - ✓ Support for the design of regulatory framework and development strategy of innovative products and R&D projects with international cooperation
  - ✓ Exchange of regulatory science-related information and technology
- Fostering regulatory science
  - ✓ Assessment of the relevance between regulations and technologies
  - ✓ Support for marketing approval from planning stages for innovative product development

Updates to Act / Regulation

❖ “Digital Medical Products Act”

- To foster the development of digital medical products by developing a regulatory system specialized for state-of-the-art digital medical products
- To improve timely patient access for diagnosis and treatment and advance the public health
  - ✓ Digital medical devices, medicines with digital tech and digital health supporting products
  - ✓ Intended use and potential risk → classification and grade.
  - ✓ Three-year comprehensive plan for the safety management with the aim of ensuring the safety and effectiveness, fostering R&D and strengthening competitiveness in the international market
  - ✓ New regulatory frameworks such as RWE and GMP
  - ✓ Criteria for the compliance of digital medical device software with the quality management system

Updates to Act / Regulation

❖ **"Digital Medical Products Act"**

- A task force team is working on a draft of subordinate statutes
- Regulatory redesign of digital medical devices and medicines with digital technology in the area of clinical trials, market authorization, and cybersecurity etc based on digital characteristics such as AI and network connectivity
- Establishment of consumer protection and industrial development support systems such as self-reporting & performance certification(if desired), and distribution management of digital medical·health supporting devices
- Digital medical products social healthcare Impact assessment, and Support for prompt decision on health insurance benefits and for R&D and standardization

Regulatory Innovation 2.0

❖ Guidance on Performance Evaluation of AI-based Autonomous Electric Wheelchairs

- Regulations are being revised to incorporate autonomous electric wheelchairs into classification of medical devices
- To provide infrastructural support to create an environment where performance testing can be conducted by domestic laboratories

❖ Providing a basis for the involvement of non-clinical trial institutes in clinical trials

- For retrospective clinical trials of computer-assisted diagnosis software
- Under the management of designated clinical trial institutes
- In consideration of the characteristics of clinical trials

Regulatory Innovation 2.0

❖ Streamlined path to market for orphan or urgently needed medical devices

- To designate an alternative medical device as an orphan or urgently needed medical device and directly import and distribute it where commercially available products in the domestic market are inadequate fro meeting the needs of patients with rare or incurable diseases
  - ✓ 30 products designated (as of February 2024)
- Excluding a requirement for a prescription written by a healthcare professional from the submission
- Promoting the public health with rapid access to orphan or urgently needed medical devices

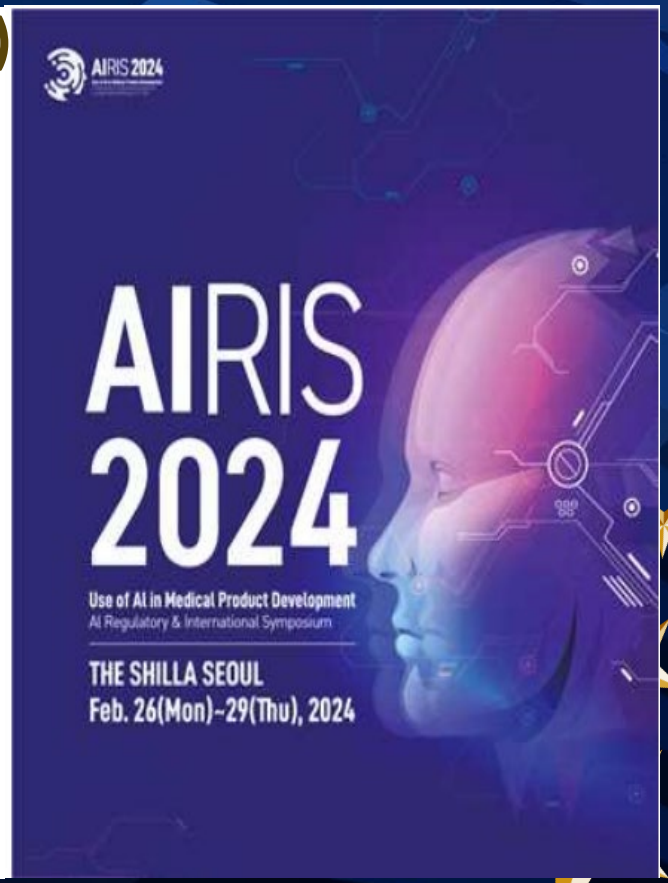
Newly Published Guidance Documents

- Frequently Asked Questions about Review and Approval for U-Healthcare Medical Device (Oct 2023)
- Guidance on Incorporation of Physical and Chemical Characterization into Technical Documents (Dec 2023)
- Guidance on Considerations for Clinical Performance of In Vitro Diagnostics (Dec 2023)
- Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for ADHD and Eating Disorder (Dec 2023)
- Guidance on the Application of Usability to Medical Device Good Manufacturing Practice (GMP) Audit : U-Healthcare Electrocardiograph (Dec 2023)
- Guidance on Recommendations for Changes to Electric Wheelchairs for the Safety and User Convenience (Dec 2023)

International Cooperation

❖ AI Regulatory and International Symposium (in February 2024)

- The Korea MFDS and the U.S. FDA led global discussion on advancing AI use *in medical product development*
- Attended by key stakeholders including governments (IMDRF & ICH members), international organization(WHO, EMA), industry and academia
- Covered AI technology trends for medical product development and regulatory experience in the use of AI for medical products
- Discussed regulatory considerations for using AI in medical product development

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