Global Harmonization Working Party
GHWP
Towards Medical Device Harmonization

Regulatory Updates on Medical Devices in the Republic of Korea

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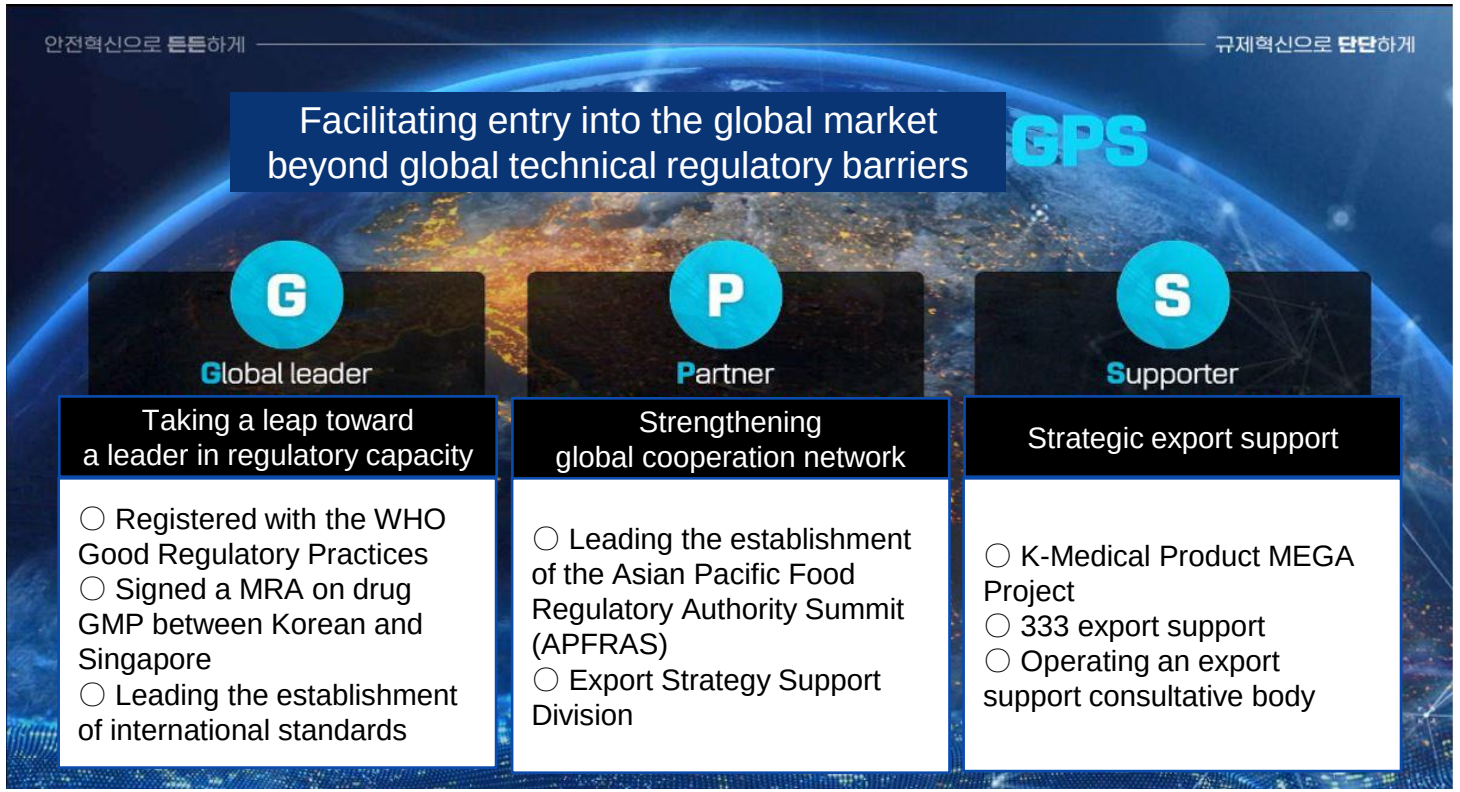
MFDS Regulatory Innovation

MFDS Regulatory Innovation Tasks



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

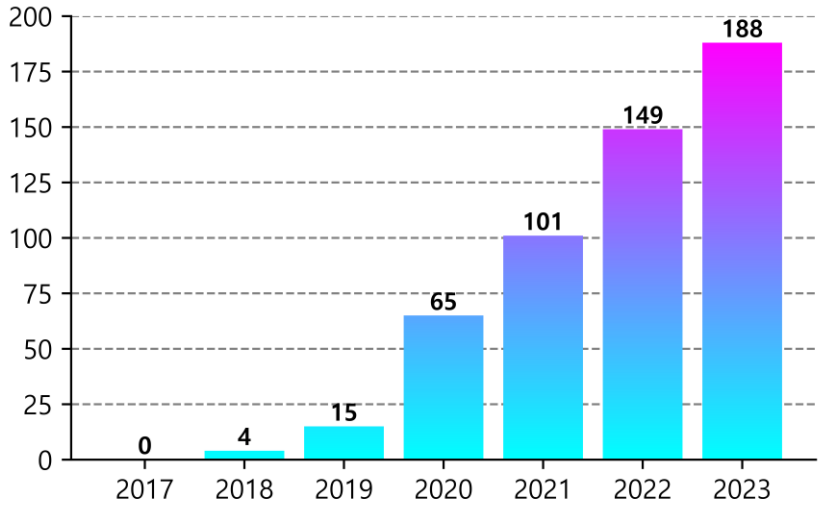
Updates to Act / Regulation

❖ Enactment of the “Digital Medical Products Act”

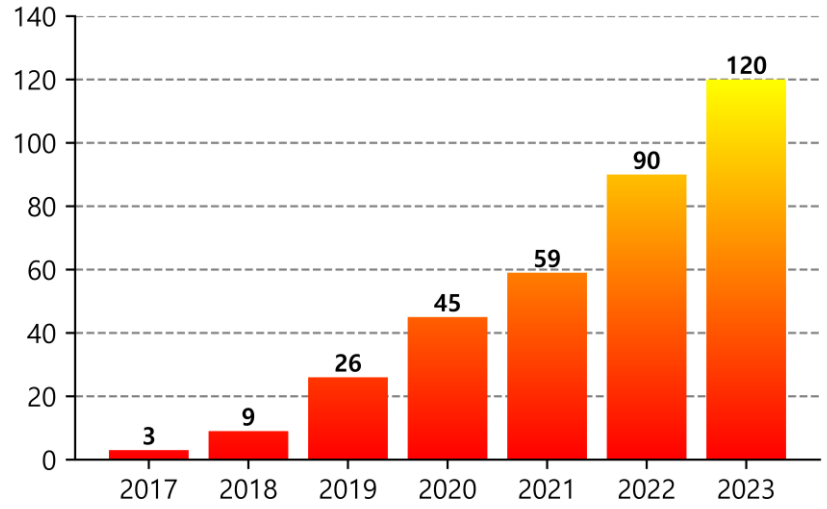
- To introduce a new regulatory framework to promote state-of-the-art digital medical products and provide regulatory support
  - ✓ [National Policy Tasks] Regulatory science and innovation for commercialization of digital and bio-healthcare products

- 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

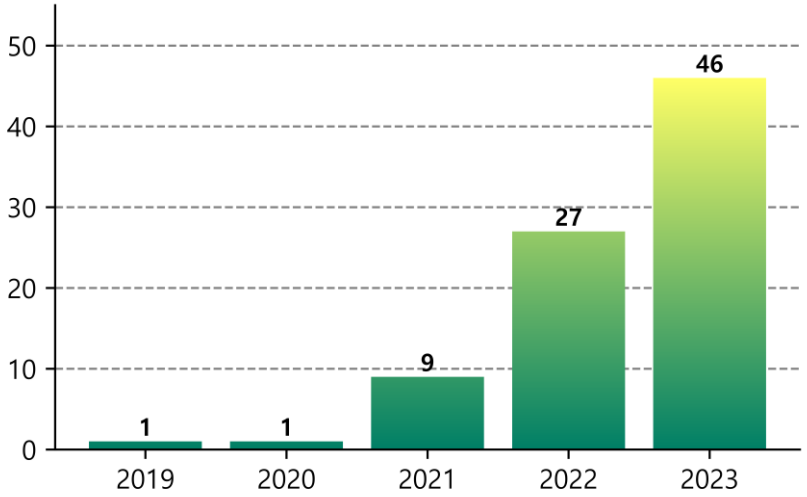


<Cumulative number of approved AI/ML MD>



< 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 applies 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
  - ✓ To shorten the period for review and approval with explicit criteria for determining whether it requires technical document review

❖ Expanded scope of pre-review for expedited review and approval

- Innovative medical devices, medical devices requiring clinical trial data and other medical devices are subject to pre-review
  - ✓ 99 submissions for IVD, SaMD and others since the regulation was revised in Dec 2022

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

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Thank you/Questions

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