IMDRF International Medical Device Regulators Forum

Regulatory Updates on Medical Devices in South Korea

Ministry of Food and Drug Safety

September 2021

Table of Contents

01

Major Achievements & Regulatory Initiatives in 2021 and 2022

Quality Advancement of Diagnostic Reagents for COVID-19

- **(Quality Management)** Products with Emergency Use Authorizations (EUA) and official permits for exports
  - 61 test kits officially approved as the use of EUA-granted tests are expired as of February 1, 2021

- **(Support)** Consulting assistance in monitoring quality management for IVDs manufacturing sites, etc.
  * Relevant consultation on the entities' difficulties and their clinical performance studies, respectively

- **(Matching Companies)** Support clinical performance evaluation by liaising the entities and medical institutions

Strengthening Patients' Safety and Management

- **(Proactive Management on Supply Discontinuations)** Imposed duty to report of production or import halt of medical devices which impact people's health in case of supply discontinuation
  - Considering concerns which may cause issues to patients, given that they are critical medical devices in the field
  - Supplies to be discontinued should be reported to the MFDS, and responses to aforementioned is to be provided

Management of Innovative Medical Devices

• **(New Designation)** Continued review for designating the identified devices

- Three (3) MLMDs, One (1) Robotic surgical system, One (1) Focused ultrasound stimulator system, and One (1) Corneal prosthesis have been newly designated

• **(Strategy)** Stable settlement and revitalization of Innovative medical devices system

- For improving evaluation system including review criteria for ensuring fairness of the device assessment
- For strengthening preliminary consulting and priority review, throughout the TPLC for marketing authorizations
- For introducing customized education for developing the devices and boosting regulatory expertise

Extension of Terms in the Nomenclature for Medical Environment & Technology Shifts

- **(Need)** To expand terms in the current nomenclature system to go along with the medical environment shifts and technology innovations

  - Necessary to keep up with the emerging trend in the medical device industry to be aligned with the “Medical Field Digital Transformation”

  * (e.g.,) Emerging technologies such as Artificial Intelligence, Big Data, AR·VR, and so forth

- **(Strategies)** To establish new items to expand the scope of safety for medical devices

  * (e.g.,) Launching new terms for devices novel technologies like software using virtual augmented technology for surgical procedures simulation on screen, and so forth

To Simplify Regulations on SaMD

- Streamline facility standards of SaMD manufacturing sites

Item	As-Is	To-Be
For SaMD manufacturing facilities	The same regulations applied for both medical devices and SaMD · Sites · Labs · Warehouse · Necessary facilities and instruments for manufacturing and quality management	Exemptions for Software medical devices **(the "site" is not under regulation)** · **Space, facilities and equipment** for establishing and implementing QMS
Differential Application for Sites Changes	For location changes · A copy of consignment agreement (if outsourced manufacturing process or tests) · GMP certificates	For location changes · A copy of consignment agreement (if outsourced manufacturing process or tests) · GMP certificates · Not applicable to changes in location of SaMD manufacturing sites

- To mitigate regulations on clinical studies of SaMD (long-term strategy)

  - To make less burden by waiving SaMD from the protocol for clinical trials and by being approved by IRB, only

02

New Guidance Documents

Newly Developed Guidance Documents for Industry

COVID-19

- Guidance on the Review & Approval of IVDs for COVID-19 (4th Edition)

Pre-market

- Guidance on the Review & Approval of Power-Assistance Device for Wheelchair
- Guidance on the Review & Approval of Medical Device with Virtual Reality and Augmented Reality Technology (2nd Edition)
- Guidance on the Review & Approval of Medical Device with Plasma Generator for Skin
- Guidance on GLP Consideration for Biocompatibility Test
- Guidance on Clinical Performance for IVDs

GMP

- Guidance on the Usability of Biomaterial for Graft/Prosthesis
- Guidance on the Usability of Robotic-guidance Rehabilitation Exerciser

Post-market

- Manual for Reducing Foreign Object Debris of Syringe

Thank you for your attention

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