IMDRF International Medical Device Regulators Forum

Regulatory Updates on Medical Devices in South Korea

Ministry of Food and Drug Safety

September 2021

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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

• (Strategies) Stable settlement and revitalization of Innovative Devices system

- For Improving evaluation system including review criteria for ensuring fairness of the device assessment
- For Strengthening consulting and priority review, throughout the TPLC for commercialization including the device approval
- For Introduce customized education for developing the devices and fostering RA professionals

Extend items according to Environmental & Technical Changes

• (Need) To expand items in the current nomenclature system to respond to medical environment and technology

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

* (e.g.,) support virtual diagnosis · telemedicine based on fourth industrial technology including AI and big data

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

* Launching new items having new technology, for example software using virtual augmented technology for surgical procedures simulation on screen, and so forth

To Simplify Regulations on SaMD

- Streamline facility standards of SaMDs 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/Prothesis
- 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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