About

Digital Medical Products Act

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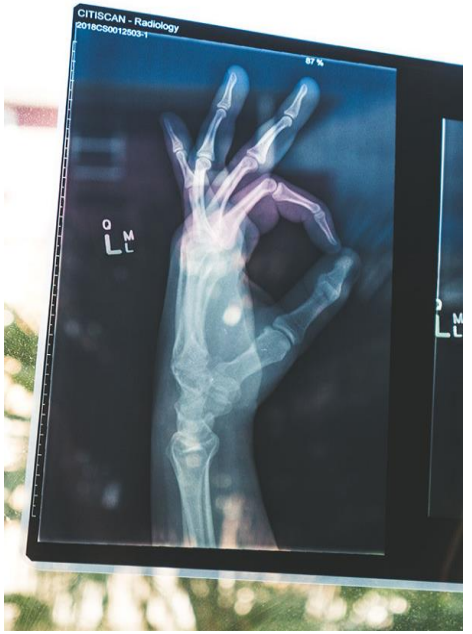
MDREX Scope of Service

Korean Boutique Medical Device Consulting Firm

✓ Professional service firm specializing in assisting medical device and digital health companies with market access and regulatory issues.

✓ **Consulting Service Areas:**

- **Market/Regulation Research & Strategy Buildup for Market Entry**
- **Medical Device Product Approval and KGMP Certification**
- **Insurance Reimbursement Listing**
- **nHTA and Innovative Device and Technology Determination**
- **Clinical Trial Support** (Exploratory/Confirmatory Trials)
- **K-MAH** (Korea Marketing Authorization Holder)
- **Medical Device Import & Domestic Distribution**
- **International Market Expansion**



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MDREX Experience

- ✓ **AI SaMD:** Medical device approval (Class 2-3), Evaluation deferral/Innovative Medical Technology designation, Regulatory and insurance support for Japan, the USA.
- ✓ **PTCA and PTA:** Medical device approval (Class 4)
- ✓ **Robot Surgery System:** Medical device approval (Class 3), KGMP support
- ✓ **EMG and EP System:** Medical device certification (Class 2), KGMP support
- ✓ **IVD-MIA(Multivariate Index Assay):** Innovation Medical Technology designation support
- ✓ **Simulator, Electrical, Antiseizure:** Value assessment of medical supplies
- ✓ **Electrode, Cortical:** Medical device approval (Class 4), Reimbursement for medical supplies
- ✓ **DTx(Digital Therapeutics, MMA-Mobile medical application):** Certification (Class 2), Clinical trial support
- ✓ **Blood gas monitor, Transcutaneous, Wearable Device:** Certification (Class 2), Clinical trial support
- ✓ **NGS-CDx:** Reduced evaluation period for selective coverage, Assist in conversion to mandatory coverage
- ✓ **Electrosurgical System and Electrode:** Certification (Class 2), New sub-category for medical supplies
- ✓ **Stimulator, Electrical, Auditory, cochlear:** Approval (Class 3), Reimbursement for medical supplies
- ✓ **Pulse oximeter(Disposable product) :** New sub-category for medical supplies
- ✓ **Dermal Filler:** Medical device approval (Class 4)
- ✓ **Others**

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Relations with Other Laws

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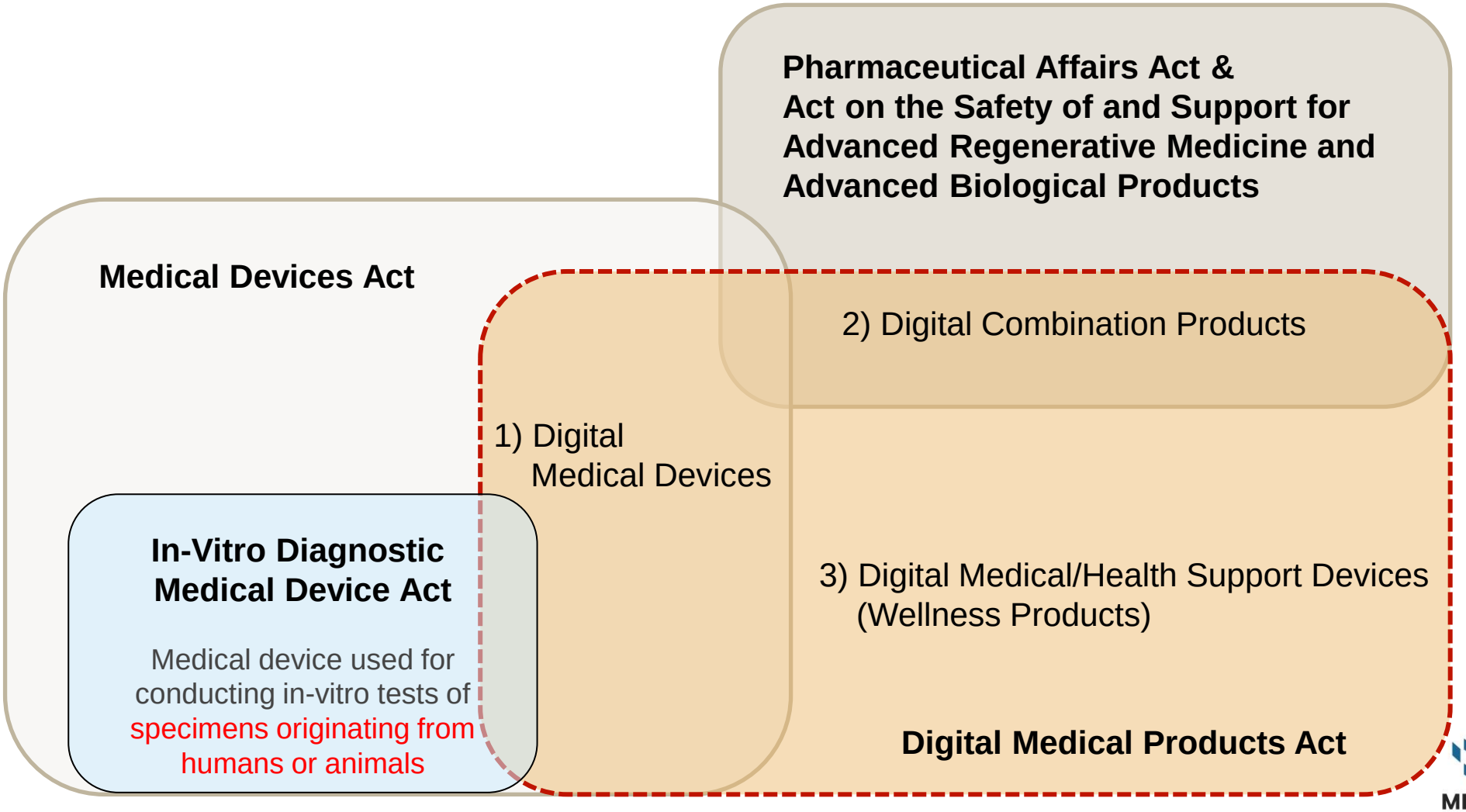
Introduction to Digital Medical Products Act

Relations with Other Laws



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Introduction to Digital Medical Products Act

Definitions

Digital Medical Devices

Medical devices (including in-vitro diagnostic medical devices) or **digital medical/health support devices that use** intelligent information technology, robotics technology, information and communication technology (collectively "**digital technology**"), etc., that have any of the following purposes:

1. Products used for **diagnosing/treating** or observing the **prognosis** of a disease
2. Products used for **predicting** the treatment response and treatment results
3. Products used for **monitoring** the treatment effect or adverse effects
4. Other products designated by the Minister of the Ministry of Food and Drug Safety (MFDS) used for **assisting rehabilitation**,

Digital Combination Products

Pharmaceutical products (including advanced biological products) combined with **digital medical devices or a digital medical/health support devices**. However, this excludes cases where the main function is that of a digital medical device.

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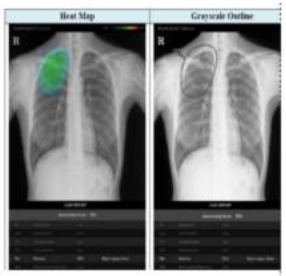
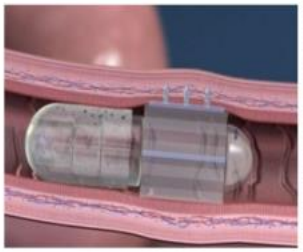
Introduction to Digital Medical Products Act

Definitions

Digital Medical/Health Support Devices

Products that are not classified as digital medical devices, but digital technology applied devices/machines/equipment/software **used to monitor/measure/collect and analyze biosignals for the purpose of supporting medical care or maintaining/improving health**, or **to record/analyze lifestyle habits to provide health management information such as diet/exercise** or other similar products designated by the Minister of MFDS.

Digital Medical Devices			Digital Combination Products		Digital Medical/ Health Support Devices
					
AI-based assistance for medical image diagnosis	VR based assistance for improvement in vision disorder	Customized support in surgery	Digital sensor-based monitoring in medicine intake	Direct medicine injection into using robotic injector	Biosignal measure/analysis, provision of health information

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Structure of Digital Medical Products Act

III

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Structure of Digital Medical Products Act

Requirements for Digital Medical Products

Item		Digital Medical Products Act	Considerations
Digital Medical Devices	Digital Medical Device (SiMD + SaMD)	• Manufacturing/importing permits • IDE and clinical performance trial approval • Change approval • Compliance Requirements for Manufacturers/Importers • Defense protocol against cyber issues (e.g. cybersecurity) • Real world evaluation • Certification and benefits of Excellent Management • Repair/distribute/lease license (apply Medical Devices Act)	• Apply Medical Device Act and In-Vitro Diagnostic Medical Device Act for other details
	Digital Medical Software (SaMD)	• Professional use • Labeling and advertising • Determination of conformity to quality management standards • Verification and investigation on conformity to QMS • Delegation of maintenance and management tasks • Special provisions for the sale of standalone digital medical device software • Partial exclusion of application of Medical Device Act for standalone digital medical device software	• Desktop review for GMP certification (to be audited on-site) • Exemption on requirements for sales report, standards, renewal, SAE/AE reporting, etc.

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Structure of Digital Medical Products Act

Requirements for Digital Medical Products

Item	Digital Medical Products Act	Considerations
Digital Combination Products	• Manufacturing, manufacturing license, and OEM permits • Importing and importing license permits • Clinical trials • Defense protocol against cyber issues (e.g. cybersecurity) of digital medical product part	• Apply Pharmaceutical Affairs Act and Act on the Safety of and Support for Advanced Biological Products
Digital Medical/ Health Support Devices	• Manufacturing/import registration • Performance certification • Distribution management	• Mark performance certification • Conduct collection inspection according to distribution management plan (recall/disposal and cessation of sales order can be made)
Others	• Impact assessment and reimbursement request • Pre-review of approval/notification • Performance evaluation on components of digital medical products • Support in product development and securing IP rights • Establishment of association (MFDS approval required) • Appointment of delegates on certification tasks, etc.	• Priority in reimbursement decision • Implement necessary measures such as education/publicity to protect IP rights

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Structure of Digital Medical Products Act

Digital Medical Products Act

- ✓ Basic structure including purpose of the Act, definitions, etc.

Enforcement Decrees(Presidential Decree)

- ✓ Promotion and marketing channels, facility requirements, management of appointed institutions for product approval, administrative fines, etc.

Enforcement Rules(Ordinance of the Prime Minister)

- ✓ Digital technology definition and classification
- ✓ Digital medical devices manufacturing/importing licenses and product approval procedures
- ✓ Manufacturing facility and quality management system requirements
- ✓ Procedures and requirements for IDE (investigational device exemption)
- ✓ Subject and procedure for Real World Evaluation, Excellent Management certification procedure, etc.

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Structure of Digital Medical Products Act

Administrative Rules

Enforcement Rules of Digital Medical Products Act (PM Ordinance)

Rules related to administrative processes

- In process….

Rules related to standards

- None.

※ Note:

- Expected to apply Article 19 (Standard Specification) of the Medical Devices Act.
- Standards expected to be developed concerning performance certification of digital medical/health support devices.

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Introduction to Relevant Government Authorities

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- Ministry of Food and Drug Safety
- National Institute of Food and Drug Safety Evaluation

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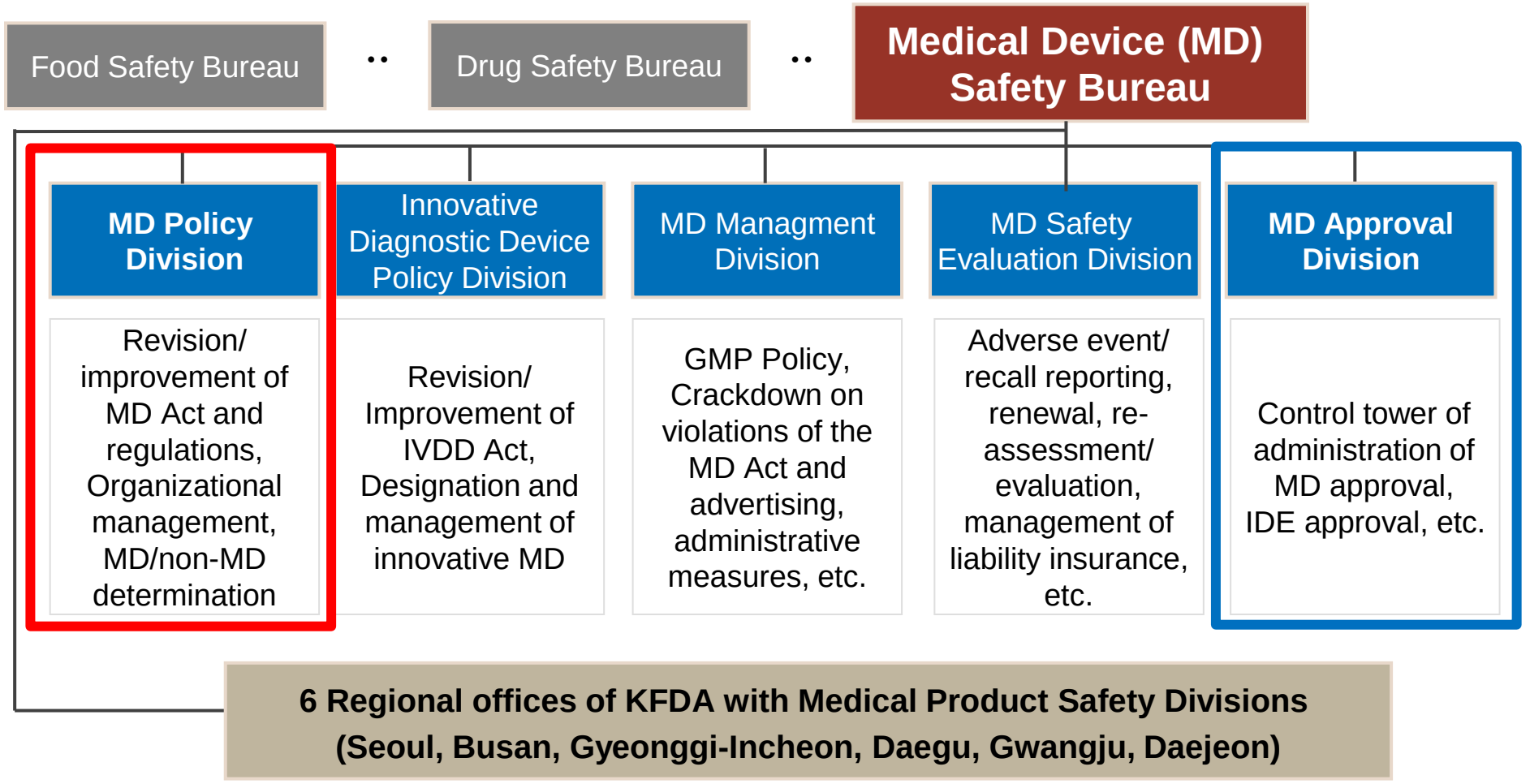
Government Authorities - MFDS

Ministry of Food and Drug Safety – Admin and Monitoring Authority on Medical Devices



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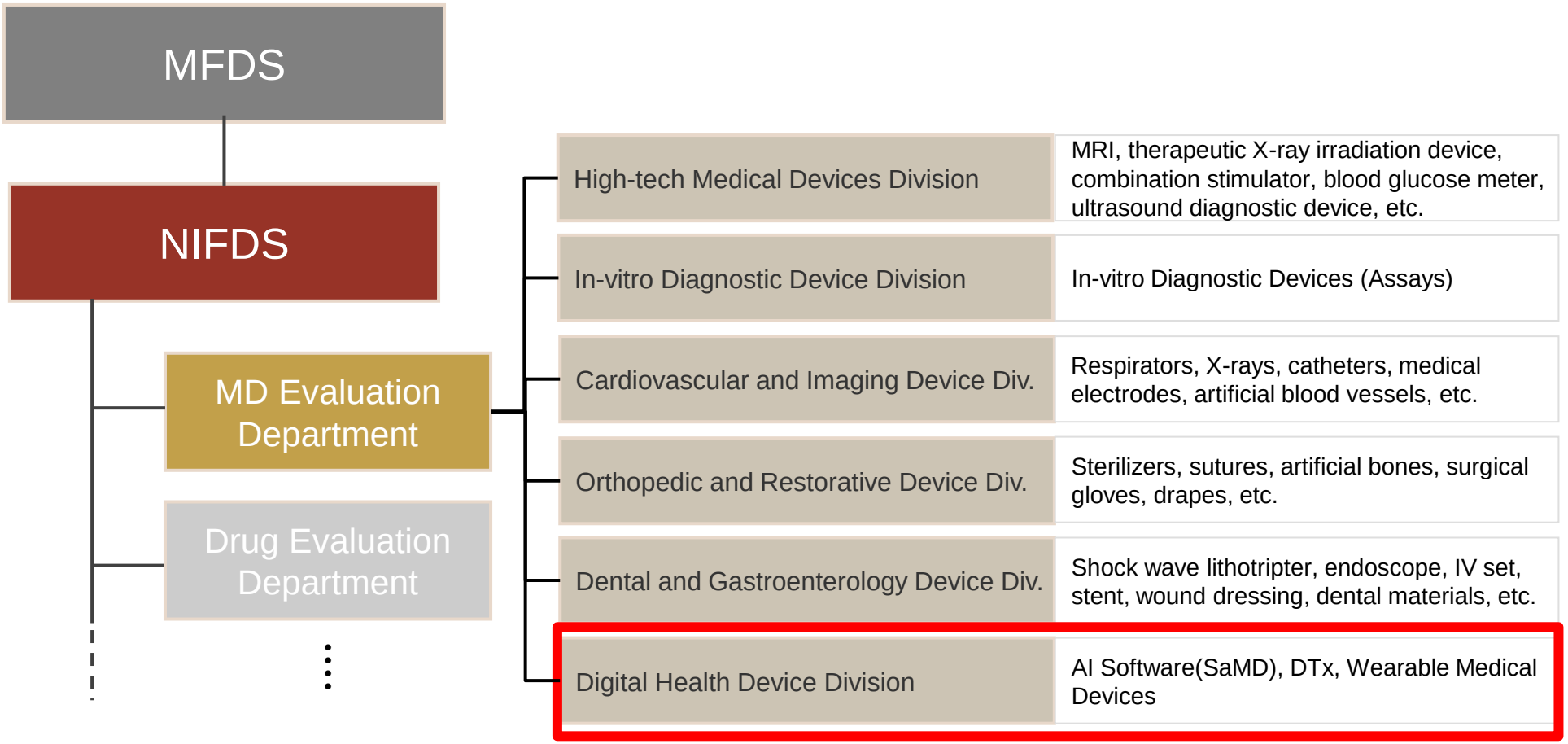
Government Authorities - NIFDS

National Institute of Food and Drug Safety Evaluation – Evaluation Body on Medical Device



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Considerations in Reimbursement Listing

upon enforcement of Digital Medical Products Act

V

- **Real World Evaluation**
- **Digital Medical Device Software for Professional Use**
- **Performance Evaluation on Components**
- **Impact Assessment and Reimbursement Request**

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Considerations in Reimbursement Listing

Real World Evaluation

Real World Evaluation (RWE)
(Article 15 of Digital Medical Products Act)

① The safety and effectiveness of digital medical devices can be evaluated based on information collected/generated during the real world use of digital medical devices.

② Manufacturers, etc. who intend to conduct an RWE may provide the subject devices to medical professionals, etc. in order to collect data necessary for the RWE **within the scope prescribed by the Prime Minister's Ordinance, despite Article 13, Paragraph 3 of the Medical Devices Act (Prohibition of Provision of Economic Benefits)**. In this case, manufacturers, etc. **may request medical professionals, etc. who use the target devices to view records of the use or provide copies thereof.**

③ The Minister of MFDS may utilize the submitted RWE data for manufacturing/ importing registration/certifications/approval(including changes), etc.

④ Details regarding the RWE subject/procedure, and methods/procedures for viewing records or providing copies thereof shall be prescribed by the Prime Minister's Ordinance.

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Considerations in Reimbursement Listing

Real World Evaluation

Real World Evaluation (RWE) Procedure
(Article 25 of Enforcement Rules for Digital Medical Products Act)

① The subjects of the RWE are as follows:

- ✓ **Use within the scope of registration/certification/approval**
- ✓ Use within the scope of the change management plan submitted at the time of registration/certification/approval
- ✓ Use beyond the scope of registration/certification/approval under the responsibility of a medical professional (when there is no alternative device, or **when it is expected to be more cost-effective, have fewer side effects, or have higher clinical therapeutic effects than the alternative device**)

② For the RWE, **a plan for the RWE that includes the following information must be reported to the Minister of MFDS**

- ✓ Types, sources, collection methods, etc. of real world data, product information,
- ✓ Information on the performing agency, matters related to the plan, performance, and result analysis required for the evaluation

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Considerations in Reimbursement Listing

Real World Evaluation

Real World Evaluation (RWE) Procedure
(Article 25 of Enforcement Rules for Digital Medical Products Act)

④ Medical professional, etc. **may allow access to records using the relevant digital medical device by pseudonymizing them** or **provide copies thereof (including electronically)**. In this case, the **'Personal Information Protection Act' shall be followed with regard to the processing of personal information of patients** using digital medical devices.

Medical Service Act

- ✓ **Article 19 (Prohibition against Divulgence of Confidential Information)** Unless expressly provided for in a statute, one shall not divulge or disclose personal information he or she becomes aware of while performing medical treatment
- ✓ **Article 21 (Inspection of Records)** One shall not allow a third party to a patient to inspect or copy the details of the patient's record except to patient's family or to government authorities (e.g., HIRA, etc.) upon request.

Bioethics and Safety Act

- ✓ Article 15 (Deliberation on Human Subject Research) Prior to conducting a human subject research project, a research plan shall be submitted for deliberation (**IBC Approval required**)

Medical Devices Act

- ✓ Article 10 (Approval of Clinical Trial Plans) Clinical trial protocols shall first be approved by MFDS for clinical trials using medical devices (**IDE Approval required**)
- ✓ Enforcement Rule [Appendix 3] Institutional Review Board shall review and assess ethical/scientific/medical aspects of clinical trials (**Medical Institution IRB Approval required**)

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Considerations in Reimbursement Listing

Collection and Usage of Real World Data

Consent on provision to third parties	DRB review
• Provision of Information to 3rd party through consent in accordance with Personal Information Protection Act	• Provision of Information through review by Data Review Board (DRB) of medical institutions

- ✓ After providing the product free of charge (or at a discount), in return, “medical records and reimbursement claim records, etc.” can be requested for the real world evaluation.
- ✓ IRB review, etc. may not be required for data collection (enabling collection from hospital to clinic level).
- ✓ Possible to create supporting materials to be used for reimbursement criteria determination and market feasibility assessment concerning a medical technology (also for RVU adjustment application).
- ✓ Possible to gather data for value appraisal of medical materials
  - Innovativeness: Improved efficacy/effectiveness, reduction of adverse events, improved quality of life for patients, cost-effectiveness, technological innovation
  - Technological improvement: Functional improvement, ease of procedure, cost-effectiveness, technological innovation

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Considerations in Reimbursement Listing

Designation of Digital Medical Device Software for Professional Use

Digital Medical Device Software for Professional Use
(Article 28 of Enforcement Rules for Digital Medical Products Act)

① The Minister of MFDS may **designate a "digital medical device software for professional use only"** when he/she deems it necessary to be used by professionals, taking into account the purpose of use, performance, etc. (Designated software managed separately by MFDS - product information and scope of professionals)

② Anyone who intends to sell or lease the digital medical device software for professional use **shall not do so to anyone who is not within the scope of professionals** (Advertising is also restricted according to Article 23 of the Digital Medical Products Act).

③ The Minister of MFDS may **notify such designation to the Minister of Health and Welfare and the Chairman of the Health Insurance Review and Assessment**.

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Considerations in Reimbursement Listing

Designation of Digital Medical Device Software for Professional Use

MFDS	MOHW and HIRA
Notification of designation of digital medical device software for professional use	Review the designated purpose of use, performance, intended user (scope of professional) and reflect the results in reimbursement listing

- ✓ MOHW and HIRA expected to reference the MFDS notification of designation for professional use when determining the medical practice definition (target/purpose/method, “scope of professional”) and reimbursement criteria (e.g., target patients, max number of claims, etc.) relevant to the pertaining digital medical device software (e.g., DTx, CDSS, etc.).

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Considerations in Reimbursement Listing

Designation of Digital Medical Device Software for Professional Use

Partial exception of Medical Devices Act requirements for standalone software (Article 28 of the Digital Medical Products Act)

① Following requirements under the Medical Devices Act **shall not apply to standalone digital medical device software** and in cases where the Minister of MFDS deems reasonable not to apply them with consideration of other characteristics. (rest omitted)

- ✓ Article 13(2): **Reporting on medical device production performance, etc.**
- ✓ Article 18-5: Prohibition of opening and distribution
- ✓ Article 19: **Standard Specifications**
- ✓ Article 25-5: Sealing
- ✓ Articles 29 to 31: Creation and preservation of records of medical devices subject to tracking and control, **adverse event reporting and recall**
- ✓ Article 31-2: Reporting on supply details of medical devices
- ✓ Article 31-5: Reporting on detection of foreign substances in medical devices
- ✓ Article 49: **Renewal of medical device manufacturing permit, etc.**

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Considerations in Reimbursement Listing

Performance Evaluation on Components

Performance Evaluation on Components
(Article 40 of Digital Medical Products Act)

① The Minister of MFDS may evaluate the performance of components, **such as sensors and AI algorithms**, etc., that may affect the function of digital medical products.

② The Minister of MFDS **shall consider the performance evaluation of components** when granting approval or certification, receiving notification, granting permission or conducting evaluation concerning digital medical products.

Process and Method of Performance Evaluation on Components
(Article 46 of Enforcement Rules for Digital Medical Products Act)

① When conducting performance evaluation on components, the following documents must be submitted to the Minister of MFDS:

- ✓ A manual including descriptions such as component type, principle of operation, etc.
- ✓ Details of procedures, test items, criteria, and supporting data for the performance evaluation
- ✓ **Documents regarding the application areas and conditions of the component**

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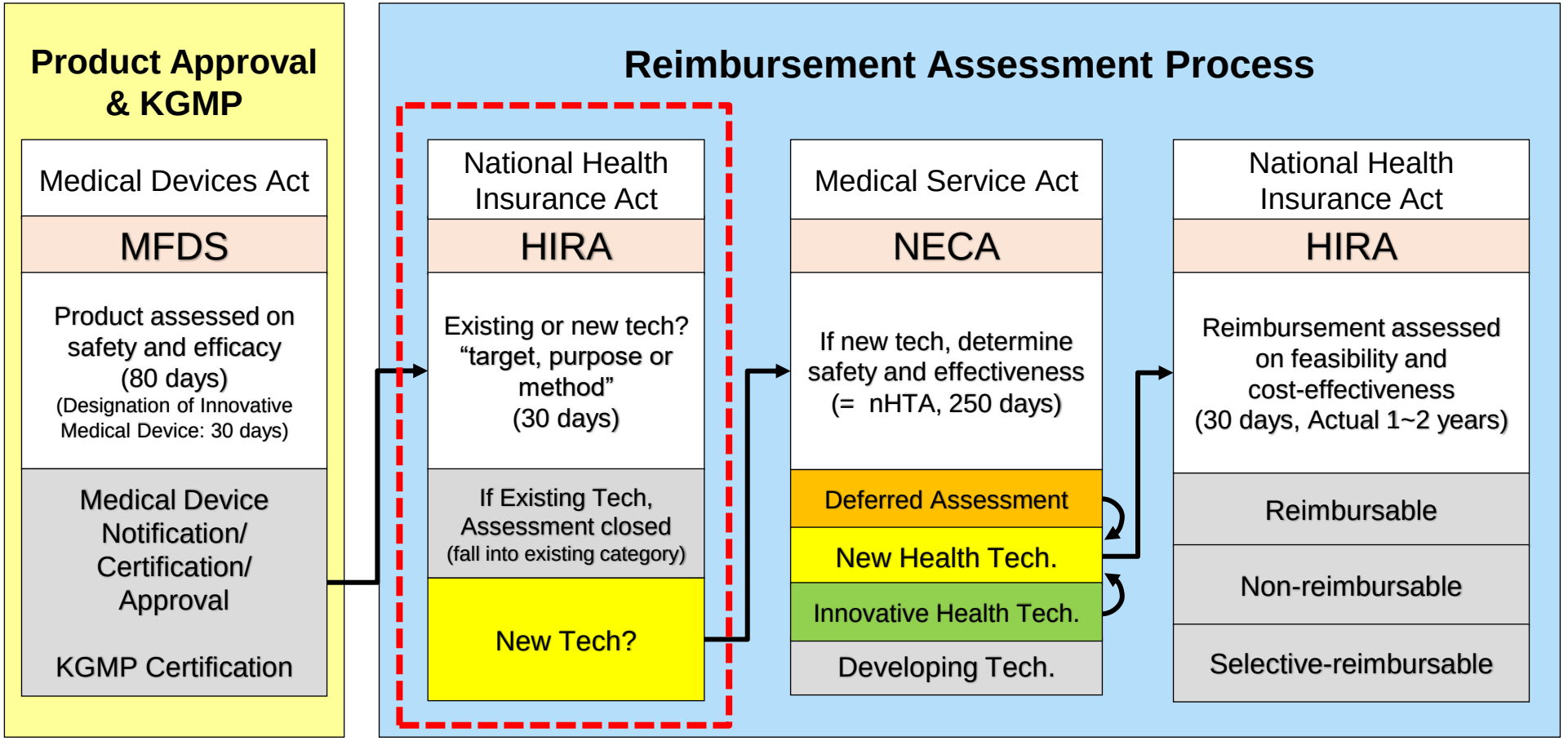
Considerations in Reimbursement Listing

Performance Evaluation on Components



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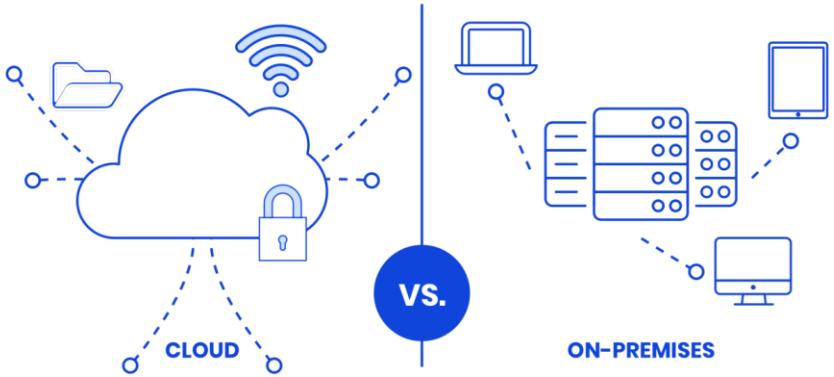
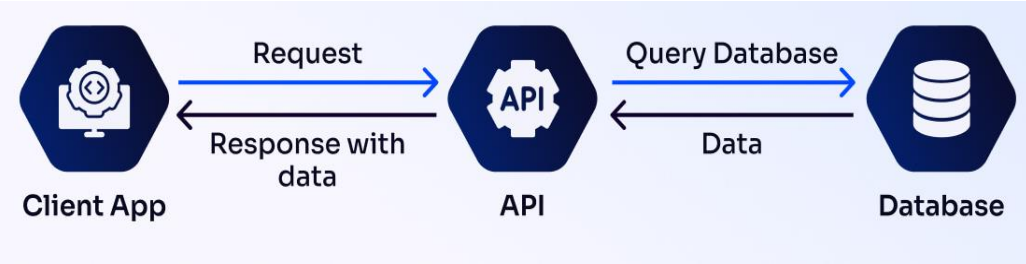
Considerations in Reimbursement Listing

Performance Evaluation on Components

B to H service



B to B service



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Considerations in Reimbursement Listing

Impact Assessment and Reimbursement Request

Impact Assessment
(Article 37 of Digital Medical Products Act)

① The Minister of MFDS may investigate and evaluate the impact of the usage and spread of digital medical products on society/economy/culture and national health.

② The Minister of MOHW may request for MFDS to provide the above impact assessment results.

Target Product and Criteria of Impact Assessment
(Article 44 of Enforcement Rules of Digital Medical Products Act)

① The target products shall be technologies with significant impact on society/economy/culture and national health determined by the Minister of MFDS in consultation with the heads of relevant central administrative agencies.

② The impact assessment shall include the following: (⑤ The results must be reported to the heads of relevant central administrative agencies)

- ✓ Comprehensive **clinical safety & efficacy**, impact on national health and healthcare system
- ✓ **Economic impact** on society and industry, impact on government policy

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Considerations in Reimbursement Listing

Impact Assessment and Reimbursement Request

Request for Reimbursement Assessment
(Article 38 of Digital Medical Products Act)

① Where a digital medical product is deemed necessary for rapid use to improve public health based on the impact assessment results, pursuant to Article 41-3 of the National Health Insurance Act, the Minister of MFDS may **request the Minister of MOHW for expedited review for reimbursement**. In such case, the Minister of MOHW **shall comply with the request unless there is a special reason not to do so**.

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Thank you!

Questions & Answers

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