Regulatory Updates on Medical Devices in Korea

Ministry of Food and Drug Safety

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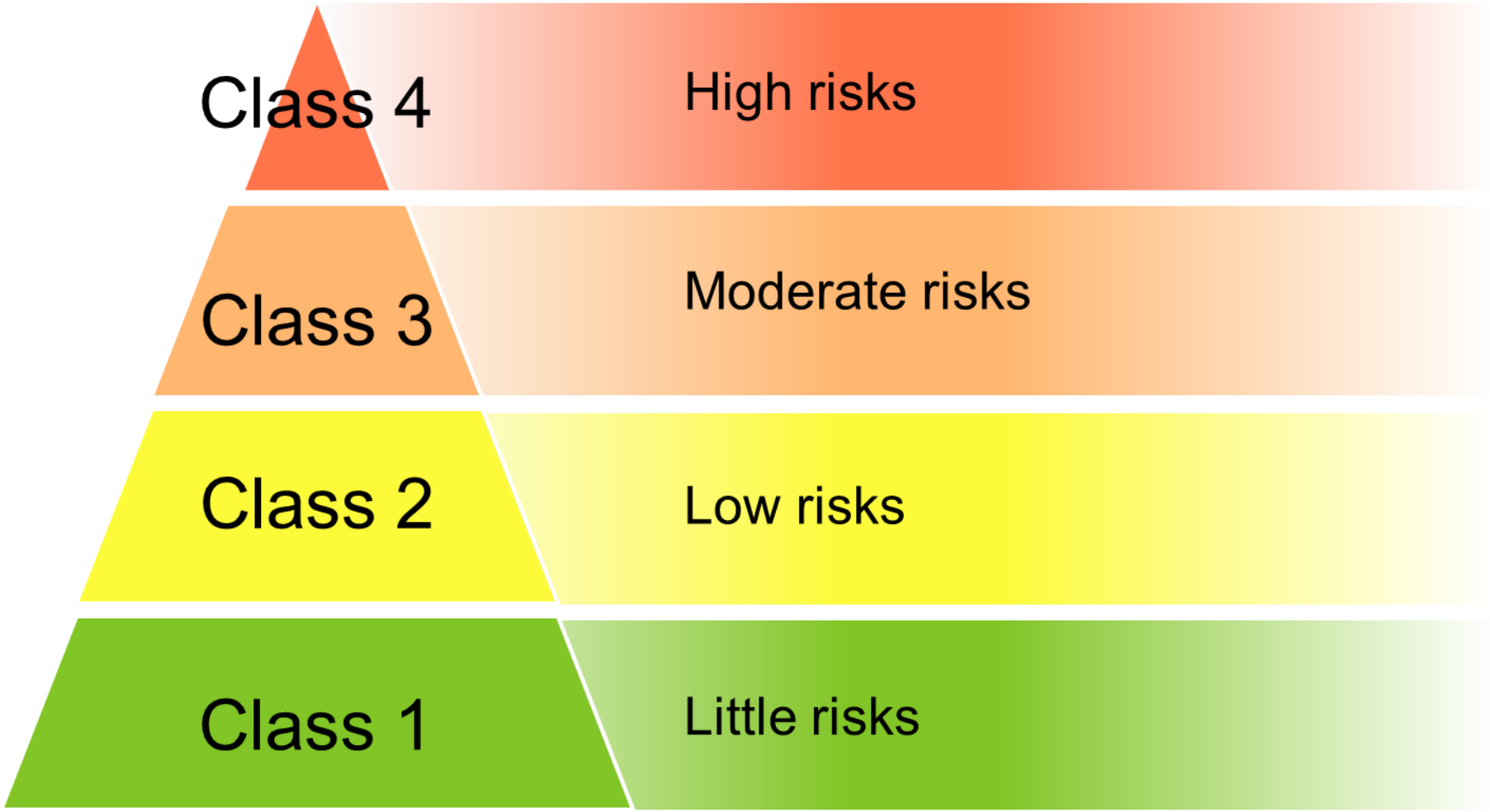
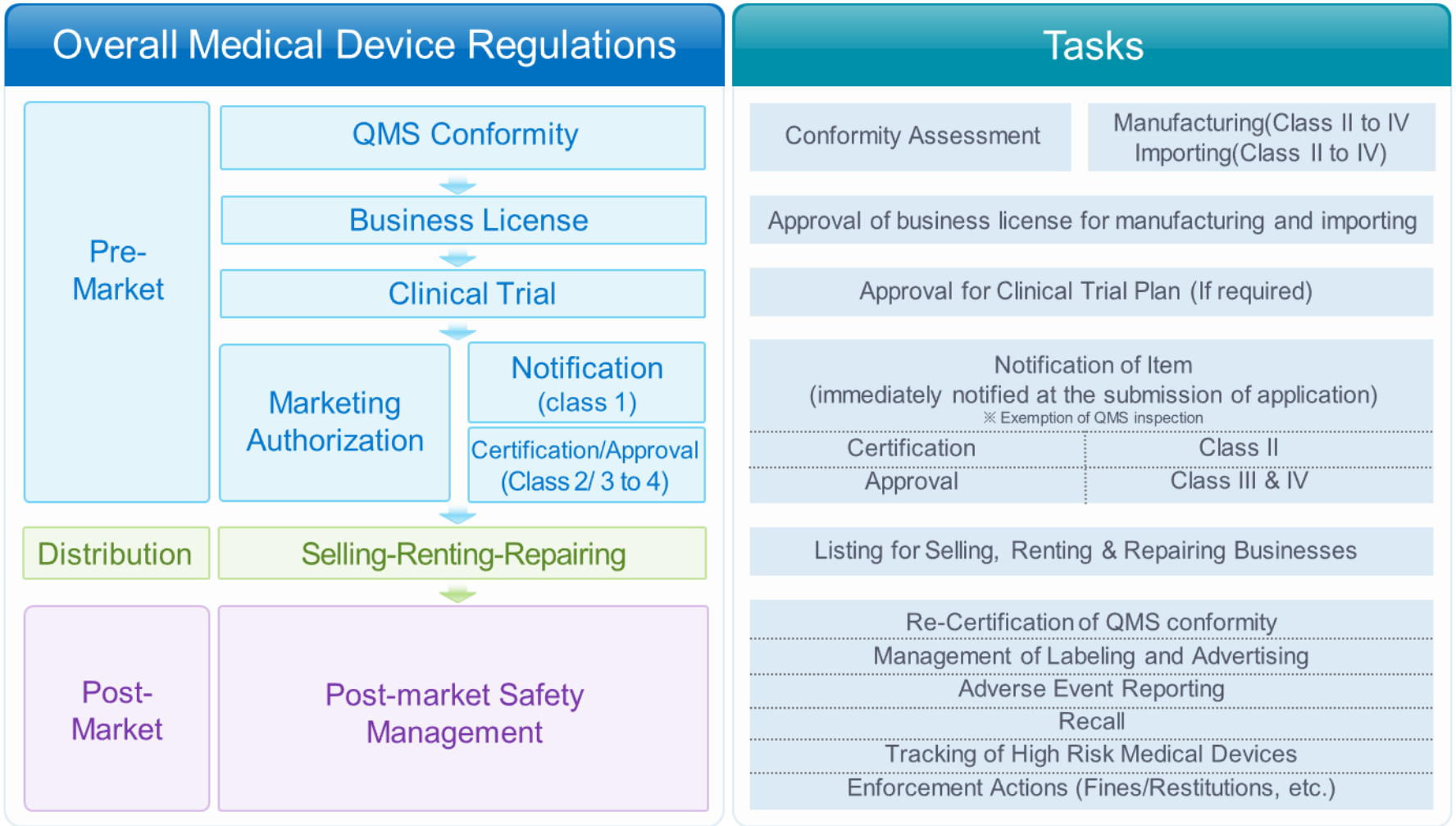
Regulatory Framework for Medical Devices

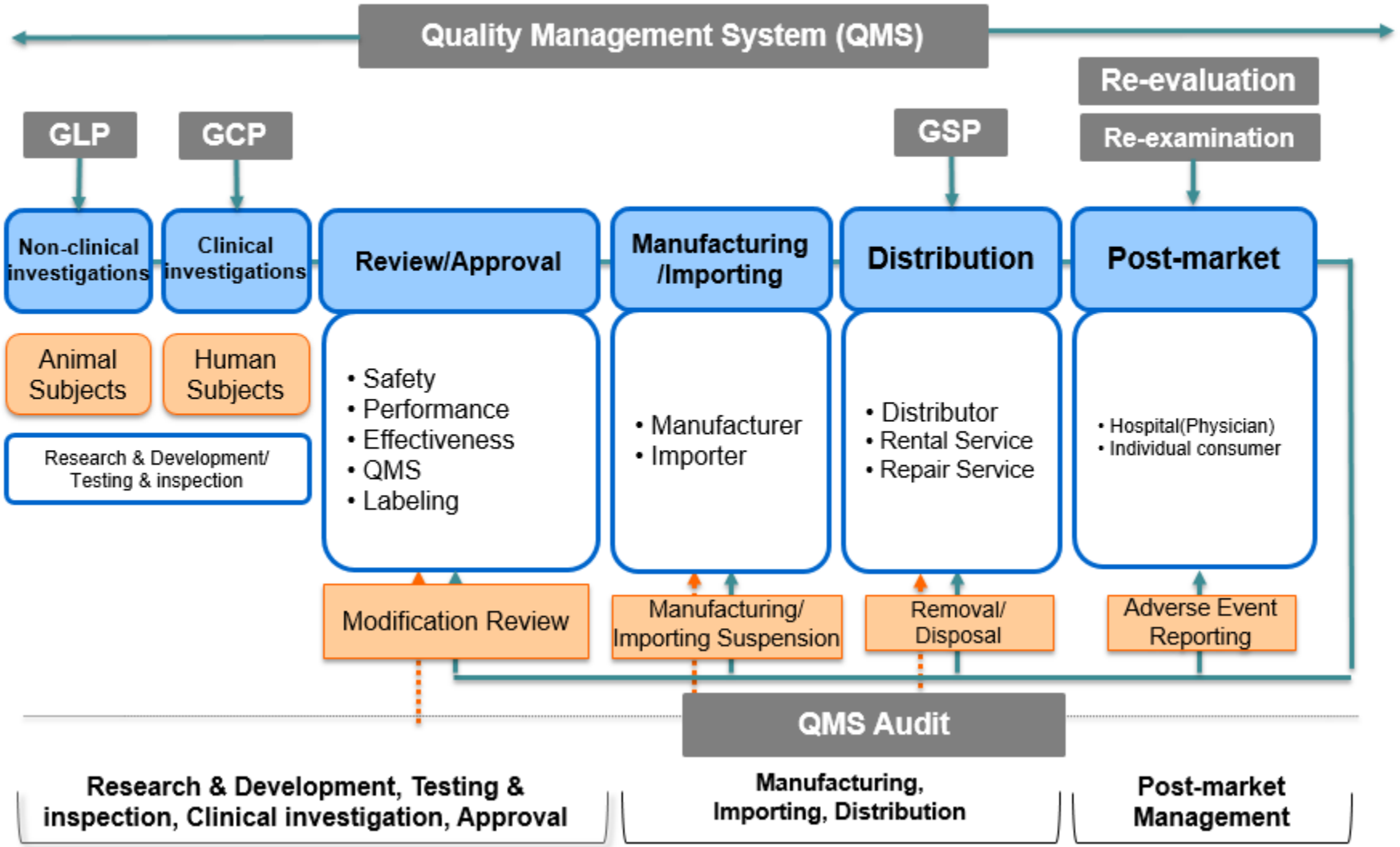


* Classifications based on potential risks on the human health when using and the intended use of the medical devices

MFDS has an efficient and well-balanced system to manage the total lifecycle of medical devices



Safety Management System for Medical Devices



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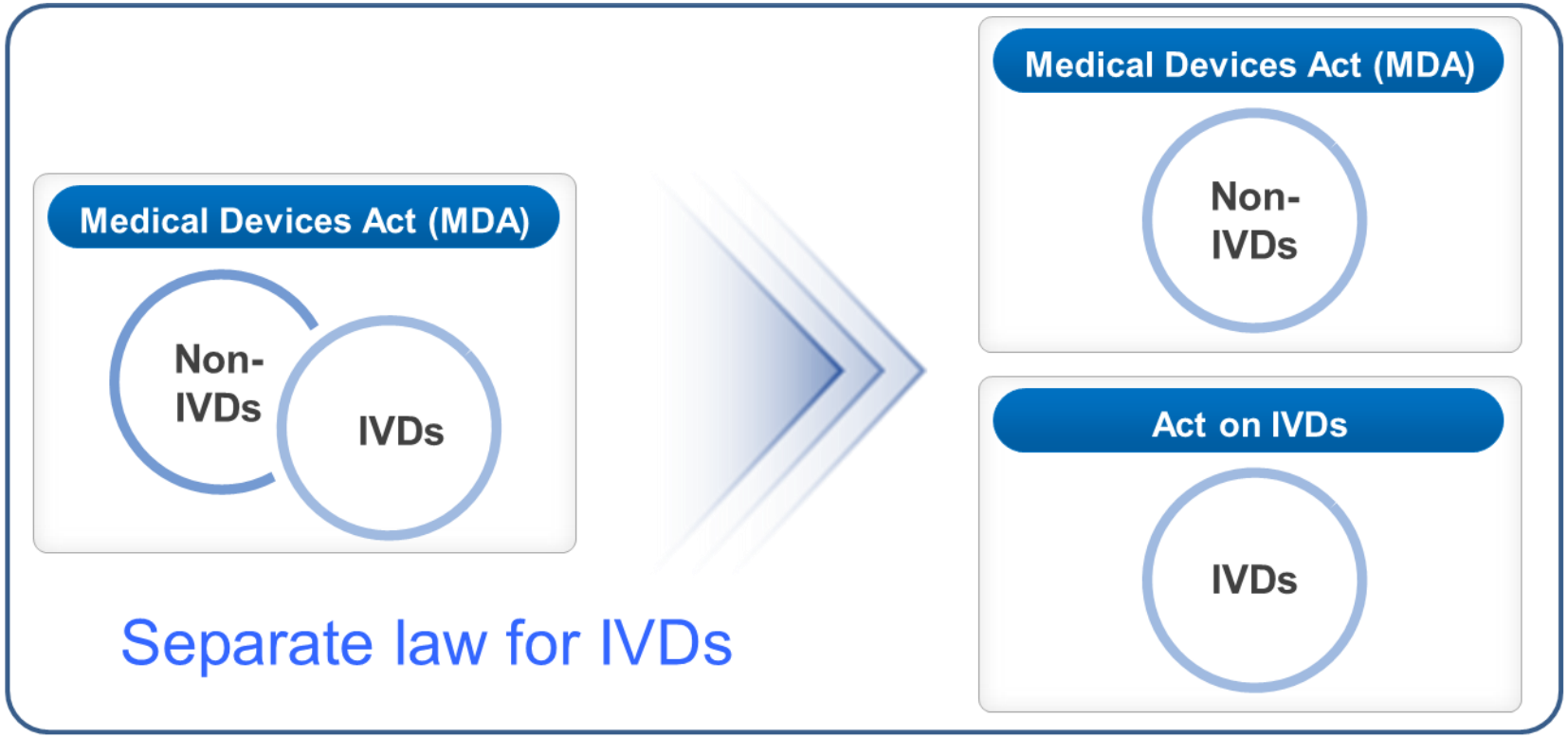
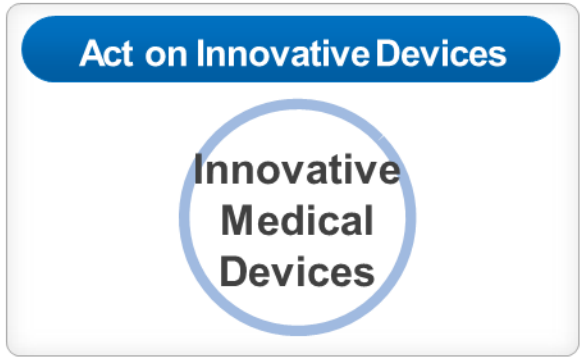
Policy Initiatives in 2020



Separate law for IVDs

[legislated on April 30, 2019]
[implemented since May 1, 2020]

Newly established law for Innovative devices



[legislated on April 30, 2019]
[implemented since May 1, 2020]

2-A. Act on Innovative Devices

1. Certifying and Supporting Innovative Device Manufacturers

- **(Pre-certification Program)** application procedure and the requirements, **valid in 3 years**, rules for certification withdrawals
- **(Supporting the manufacturers)** **preferential government-initiated R&D**, **tax** exemption, a special exception for **constructing research facilities**

2. Designation and Supporting Innovative Device Groups

- **(Innovative devices groups)** valid in 3 years for the **recognized groups** for breakthrough improvement of the therapy and treatment for rare or intractable diseases
- **(Designating Innovative devices)** **designate innovative devices** that are applicable to the recognized group
- **(Supporting approval of Innovative devices)** **exempt business license, modular review process* and priority review**

  * 4 phases : design & development, Safety & performance, Clinical trials and Technical docs & clinical data

- **(Post-market surveillance)** **less than 5-year period of follow up surveillance** required when needed a follow up for its clinical efficacy and adverse events observation

2-A. Act on Innovative Devices

3. Special Exception for Innovative Software Devices

- **(Pre-certification program)** **exemption of some submission requirements** for the **pre-certified software manufacturers** by appraising the organization and personnel
- **(Modification approval)** **amendment approvals required for major changes** and **report for other changes**
- **(Clinical trial)** clinical trials for innovative software medical devices with **IRB approvals**
- **(GMP/QMS)** Good Management Practice established for software medial devices

4. Support for the Technology

- **(R&D)** R&D initiatives, necessary information sharing, establishing basis for rewarding outstanding developers **(Clinical investigations)** support for clinical researches and clinical trials for conducting such investigations by
- MFDS and the Ministry of Health and Welfare (MOHW)
- **(Safe regulatory framework)** support for studies and tests to acquire its safety and effectiveness, and manufacturing & quality management system

2-B. Act on In-Vitro Diagnostic Medical Devices

Main contents of the Act

- **(Scope)** Definitions, classifications and designation of IVD devices
- **(Pre-market approval)** Procedures to obtain manufacturing license or certification or to file a manufacturing report, etc.
- **(Clinical performance test)** Approvals of plans for clinical performance tests and criteria to designate the testing institutions, etc.
- **(QMS)** facilities and manufacturing and quality management system, etc.
- **(Labeling)** Labeling on containers and information in package insert, etc.
- **(Management)** Revocation of approvals, suspension of business and imposition of administrative sanction fines and negligence fines, etc.
- **(Experts committee)** Establishing and operating, etc. an experts committee for IVD devices

Expectations of the Act

- ✓ **(Obligations)** Obligations of manufacturers/importers/quality managers, etc.
- ✓ **(MFDS-recognized establishment)** Designating technical document review bodies and quality management inspection bodies for medical devices
- ✓ **(Approval)** Restrictions on manufacturing licenses, etc., conditional approvals and pre-application reviews, etc.
- ✓ **(Device handlers)** Report of repair/sales business and obligations of sellers
- ✓ **(Advertisements)** Precautions for labeling, prohibitions, etc. of labeling and advertisements and deliberation of advertisements, etc.
- ✓ **(Reports on distribution)** Report of medical device supply information, etc. and establishment of medical device information consolidation system, etc.
- ✓ **(Orders)** Inspection orders, orders for recall/destroy and public announcement, etc., orders of stop using, etc., corrective order, etc.

The Act stipulates regulations only for IVD devices separately, and the other matters are regulated under the Medical Devices Act.

2-B. Act on In-Vitro Diagnostic Medical Devices

Sub-regulations of the IVDs Act

Market Authorization	Regulations on IVD devices approval/report/review, etc.
Clinical Data	Regulations on approval of evaluation for clinical and analytical performance of IVD devices Regulations on the management of relevant records of evaluation for clinical and analytical performance of IVD devices Regulations on designation of institutions to evaluate clinical and analytical performance of IVD devices and training for the employees
QMS	Regulations on the IVD devices Good Manufacturing Practices
Classifications	Regulations on classifications of IVD devices
Reference Standards	Regulations on the management of reference standards of IVD devices

2-C. UDI Regulations on Medical Devices

Progress in Law Reforms

As of Dec 2 2016,
- Placing UDI based on the Medical Device Act
- Building legal basis for mandatory reporting of distribution records

As of Dec 31 2018,
- Stating the implementation dates of placing UDI for Class 4 devices following revised Enforcement Regulations of the Act

As of Dec 31 2018,
- Developed Regulations on obtaining and placing UDI

As of June 12 2019,
- Developed Regulations on UDI database

Plans

- Expanding devices subject to obligations* of placing UDI barcodes and submitting UDI data to the DB

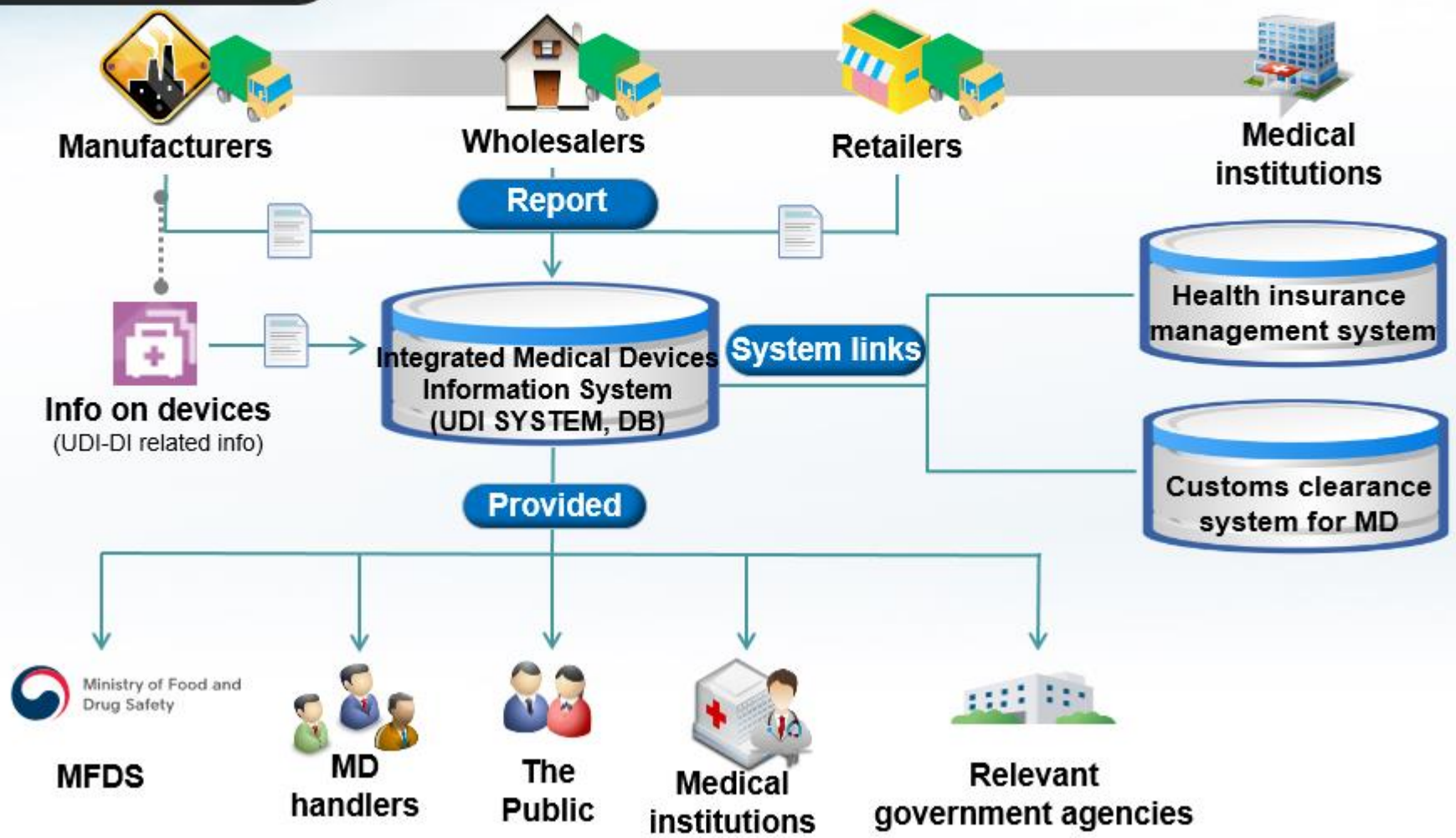
* by July 1 2019 for Class 4 devices and by July 1 2020 for Class 3

Class 4 (since July 1, 2019) » Class 3 (by July 1, 2020) » Class 2 (by July 1, 2021) » Class 1 (by July 1, 2022)

- Expanding training on placing the Unique Device Identifiers for better understanding of the regulation

2-C. UDI System for Medical Devices

Overview of UDI System in Korea



2-D. Regulations on reporting distribution records

Progress in Law Reforms

As of Dec 2 2016,
- Placing UDI according to the MDA
- Building legal basis for mandatory reporting of distribution records

As of Dec 31 2018,
- Stating the implementation dates of placing UDI for Class 4 devices following revised Enforcement Regulations of the Act

As of Oct 22 2019,
- Stating the implementation dates of mandatory reporting distribution records following revised Enforcement Regulations of the Act

Plans

- Implemented starting from the Class 4 devices following the revision of the Enforcement Regulations of the MDA as of Oct 22, 2019

Class 4 (since July 1, 2020) » Class 3 (by July 1, 2021) » Class 2 (by July 1, 2022) » Class 1 (by July 1, 2023)

- Expanding training on the reporting requirements of distribution history for better understanding of the regulation

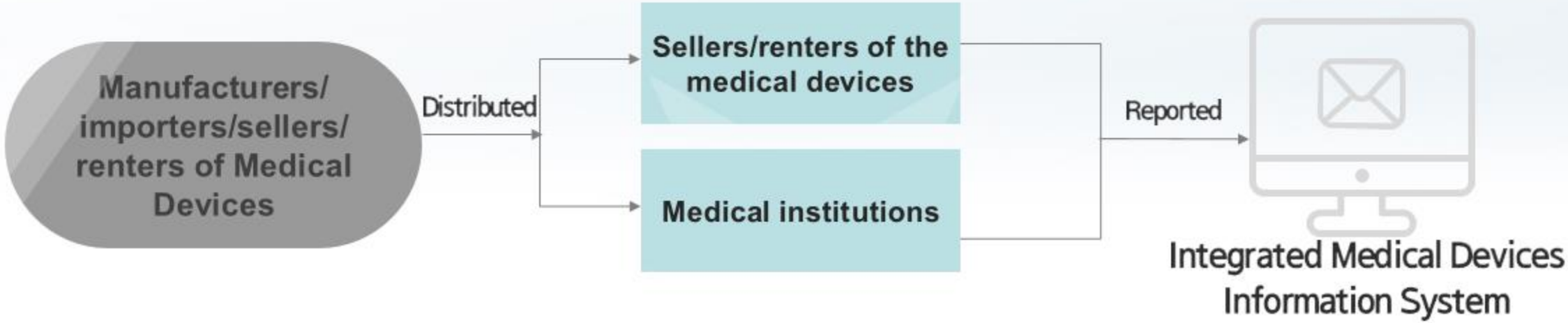
2-E. Regulations on reporting distribution records

Process and Procedure of Distribution Records

- Manufacturers/importers/sellers/renters are to report the distribution records to the integrated medical devices information system when distributing medical devices to medical institutions/sellers/renters

  (pursuant to Article 31-2 of the MDA and the Article 54-2 of the Enforcement regulations)

- For reporting distribution records, including manufacturing number/date, expiration date, distributed quantity and distributed date, and distributed costs and the unit price (only applicable to distributing medical institutions) by classifying the type of supply among release/return/disposal/lease or withdrawal, respectively.



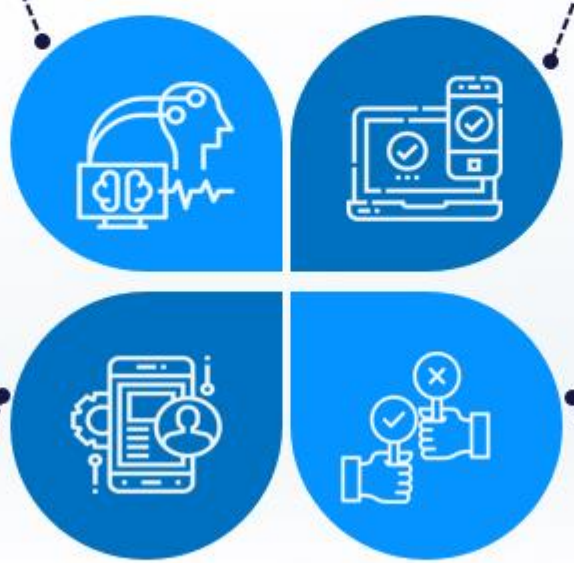
2-E. Preferential support for digital health care medical devices

Regulatory decision making for digital therapeutic devices

- Regulations on terms and definition, scope and submission requirements for market authorization, etc.

Classification for Software Medical Devices

- Classification for the devices according to its risk and the area to be used
- Newly classified software devices into one of the largest categories with the classification items under



Improving management of medical devices based on mobile medical applications

- Pre and post-market management for the devices
- Revision of guideline on safety management of mobile medical applications

Re-examination of the criteria to distinguish medical devices or not

- Revision of guideline on the criteria to tell the difference between products for encouraging a general health state and medical devices

3

New Guidelines in 2020

January, 2020	• Guideline for obtaining manufacturing and import business license • Guideline for performance evaluation on automated hematology analyzers
February, 2020	• Guideline for review and certification/approval of medical devices packaged in a set
April, 2020	• Guideline for review and approval of IVD reagents for COVID-19 • Guideline for preparation of technical documents on mobile picture archiving and communication system
May, 2020	• Guideline on implementation of the IVDs Act
June, 2020	• Guideline for exemptions from approval procedures for medical devices subject to infectious diseases pandemic • Guideline for process of designating innovative devices and its criteria • Guideline on details of evaluation to designate innovative devices
July, 2020	• Guideline on details of QMS audit procedures with respect to imported IVD device manufacturers • Guideline on applications for the use of medical devices for clinical trials and research purposes

4

MFDS’ Response to COVID-19

IVD test kits for COVID-19

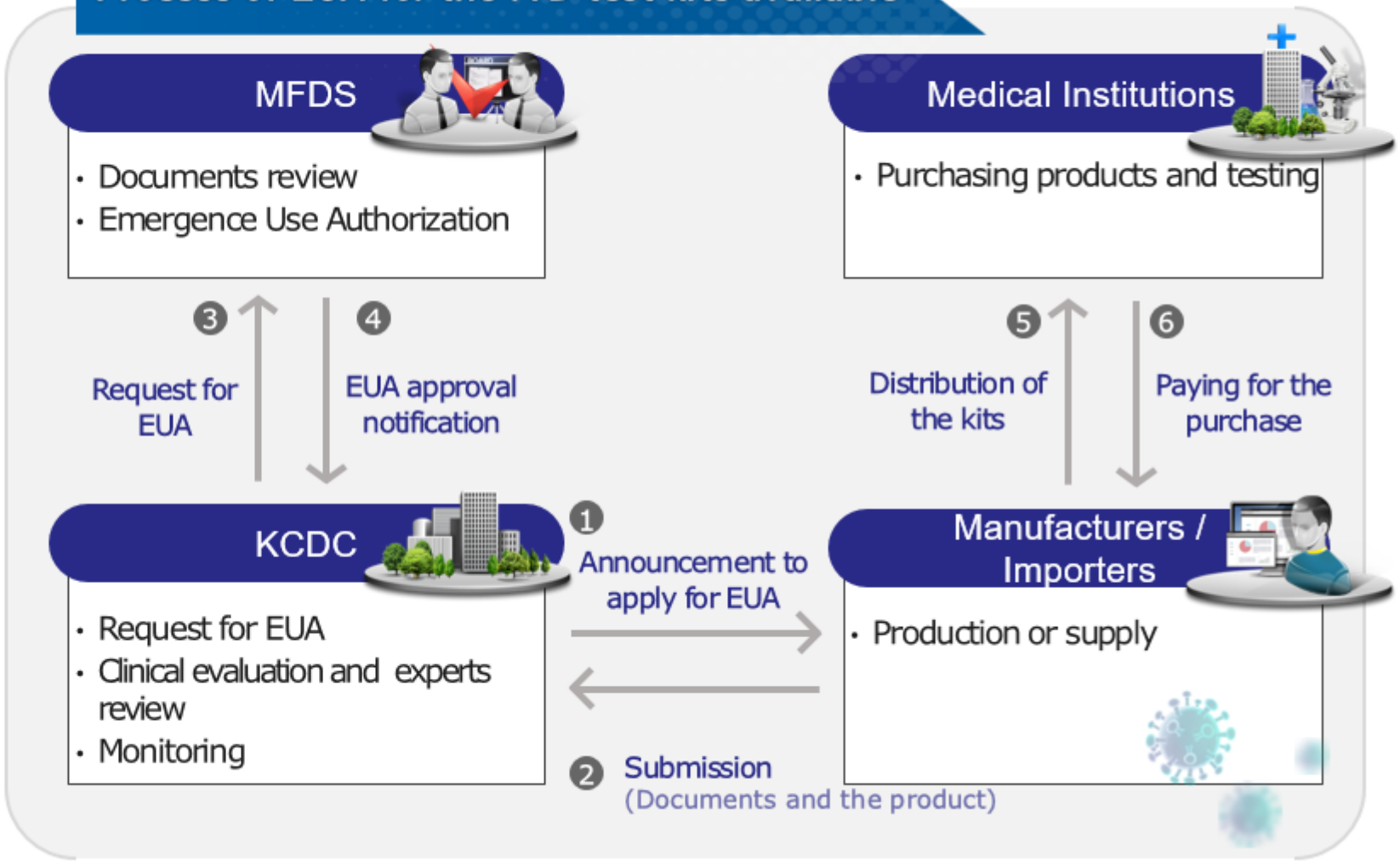
The EUA program expeditiously allows prompt diagnosis of COVID-19 in collaboration with the concerned government agencies to prevent COVID-19 from being spread domestically

Emergency Use Authorization (EUA)

Article 46-2 of the MDA

Applied to medical devices in an urgent need to be used in order to adequately respond to the outbreak or pandemic of infectious diseases

Process of EUA for the IVD test kits available



Stable supply of face masks

- (Difficulties) **Short supply of face masks** in the domestic market for the spread of COVID-19
- (Action) Stabilized supply for the masks
  - ✓ Ban on act of cornering and hoarding
  - ✓ Restrictions on exporting
  - ✓ Supply in the public interest for fair purchase

Face masks controlled by MFDS

- ✓ **(Types)** Filtering/Surgical/Anti-droplet masks
- ✓ **(Approval)** Regulated as quasi drug products by reviewing the followings with the KF mark on for approved filtering and Anti-droplet masks
  ① Particle filtration efficiency, ② Breathing resistance, ③ Total inward leakage, ④ Tensile strength
- ✓ **(Manufacture)** The manufacturer who has a manufacturing license should manufacture the products in clean room facilities as defined and release them after inspecting samples for tests of the above mentioned ① to ④ in each production LOT
- ✓ **(Post-market)** MFDS tests quality and performance of the face masks by inspecting the samples which are on the market and imposes withdrawal or disposal, etc. if there is an issue on the product

Medical Respirators as a medical device

- ✓ Medical Respirators which are equivalent to Surgical N95 Respirators regulated by US FDA are to be regulated as a medical device by the 4th quarter of 2020

Thank You