IMDRF International Medical Device Regulators Forum | 26th Session

Session 2 : Expanded-Level Controls
Premarket & Placing on the Market

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Expanded-Level Controls: Premarket

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Oversight on Clinical Investigations

✓ Regulatory Authority Role

Ensure the collection of accurate and reliable data and results from clinical trials of MDs, while safeguarding participants' rights, interests, and confidentiality

✓ Clinical Investigations

- **(Designation) Institutions** which meet the qualification requirements in accordance with the "regulations on the designation of clinical trial institutions for medical devices"
- **(Prior Approval)** Designated Medical Device Clinical Investigation Institutions could conduct clinical trial after obtaining prior approval for the Clinical Trial Plan

✓ Requirements

Compliance with **"Good Clinical Practice for MD"** which is equivalent to ISO 14155:2011 (Good Clinical Practice)

✓ Monitoring

Within clinical trial centers, **Monitors** regularly verify the accuracy of case report forms and ensure proper documentation of adverse events, concomitant therapies and intercurrent diseases

Oversight on CABs

✓ Related regulation of CABs

MD laws, enforcement rules, and notifications stipulate the **designation** / **evaluation** / **training** / **post-management of Institutions** Reviewing Technical Documents, QMS Audit Institutions, Testing and Inspection Agencies, and Institutions Conducting Non-Clinical Trials etc.

- Regulation on designation, operation, and etc. of institutions reviewing MD technical documents
- Non-Clinical Trial Management Standards (Good Laboratory Practice, GLP)
- Act on Testing and Inspection in the Food and Drug Industry
- Medical Device Quality Management System (QMS) Standards, and more

Oversight on CABs

Institutions Reviewing Technical Documents

✓ **(Renewal)** Every 3 years

✓ **(Inspections)** Regular / Frequent

✓ **(Regular Inspections)** Document review conducted once a year (on-site inspection if necessary)

- **Frequent Inspections** : Conduct on-site inspections when there are changes to the scope of audit work

『Regulations on the Designation & Operation of Medical Device Technical Document Review Institutions 10 & 11』

10 Designated CABs

(as of July 2024)

ktl

National Institute of Medical Device Safety Information

NIDS

의료기기안전정보원

KTR

KOREA TESTING & RESEARCH INSTITUTE

Recognition of Standards

✓ **Establish National Standard Implementation Plan every year** in accordance with the Basic National Standard Plan (established every 5 years, 5th plan implemented)

✓ **938 Types of National Standards (KS) for MDs** (as of December 2023)

- The Minister of Trade, Industry and Energy **publishes the standards** in the official gazette & online in March, **every year**
- To keep KS up-to-date, **conduct review** for the need of revision
  (Review every 5 years from the date of enactment and amendment of national standards)

✓ **Flexibility in Recognition**

When submitting approval review documents, MFDS **recognizes all International Standards** (e.g., IEC, ISO) that are equivalent to or higher than the standards announced by MFDS or publicly notified by the Minister

Recognition of Standards

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Adopting a Nomenclature System

✓ Purpose

Establish an internationally standardized classification and grading system for medical devices to ensure clear communication and information exchange.

✓ Benefits

International harmonization for identification standardization:

① Enhance ease of export/import procedures ② Foster development environment for MDs with diverse purposes, and ③ Ensure transparency & integrity in the distributions by preventing false and exaggerated advertising

✓ System adopted by Korea : GMDN (Global Medical Device Nomenclature)

✓ Implementation

On January 6, 2009, MFDS revised the "Regulation on the Classification and Grades of MDs" to align with the GMDN, as recommended by GHTF

MFDS's Adoption of Nomenclature System

Major Category	Medium Category	Classification Per Class				
		Sum	**Class 1**	**Class 2**	**Class 3**	**Class 4**
Total	**135**	**2270**	531	1137	335	267
instruments / machinery	88	1750	459	926	214	151
medical supplies	9	261	35	27	91	108
dental materials	26	150	32	99	11	8
software	12	109	5	85	19	0

- based on manufacturing quality and similarity
- based on intended use and potential hazards
- based on independent functions

* In the case of an application for a new product that does not fall into any of the 2,227 small categories, its category, class, and definition can be temporarily classified by reviewing the product's similarity, intended use, functionality and other aspects. If necessary, a review by the Medical Device Committee may be requested

Control of Advertising & Promotion

✓ Self-Evaluation System

(Objective) To **prevent consumer harm** from false or exaggerated advertisements of MDs

(Designation) **Self-regulatory Review Bodies** (2 organizations) : **KMDIA, KDMA**

(Role) **A Review Committee** established by the review bodies, separate from regulatory authorities, **assesses the appropriateness** of medical device advertisements

(Evaluation Standard) Jointly developed by the Self-regulatory Review Bodies

✓ MFDS's Controls

- **(Special Inspections)** conducted for the **illegal online advertisements** & **offline inspections** (e.g. free MD experience centers)
- **(Regular Online Monitoring)** conducted by the **Cyber Investigation Team**
- **(Active Post-measures)** Requesting advertisement **modifications or deletions**, **blocking websites**, and taking **administrative actions**

Expanded-Level Controls: Placing on the Market

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Quality Management System

✓ QMS Audit Classification

Initial, **Regular** (every 3 years), **Modification** (in case of changes to manufacturing location)**,** **Additional** (in case of adding new types of MDs)

✓ Medical Device QMS Item Group

Classified into **64** categories (Exemptions: Class 1 MDs, Export-Only MDs)

✓ Assessors

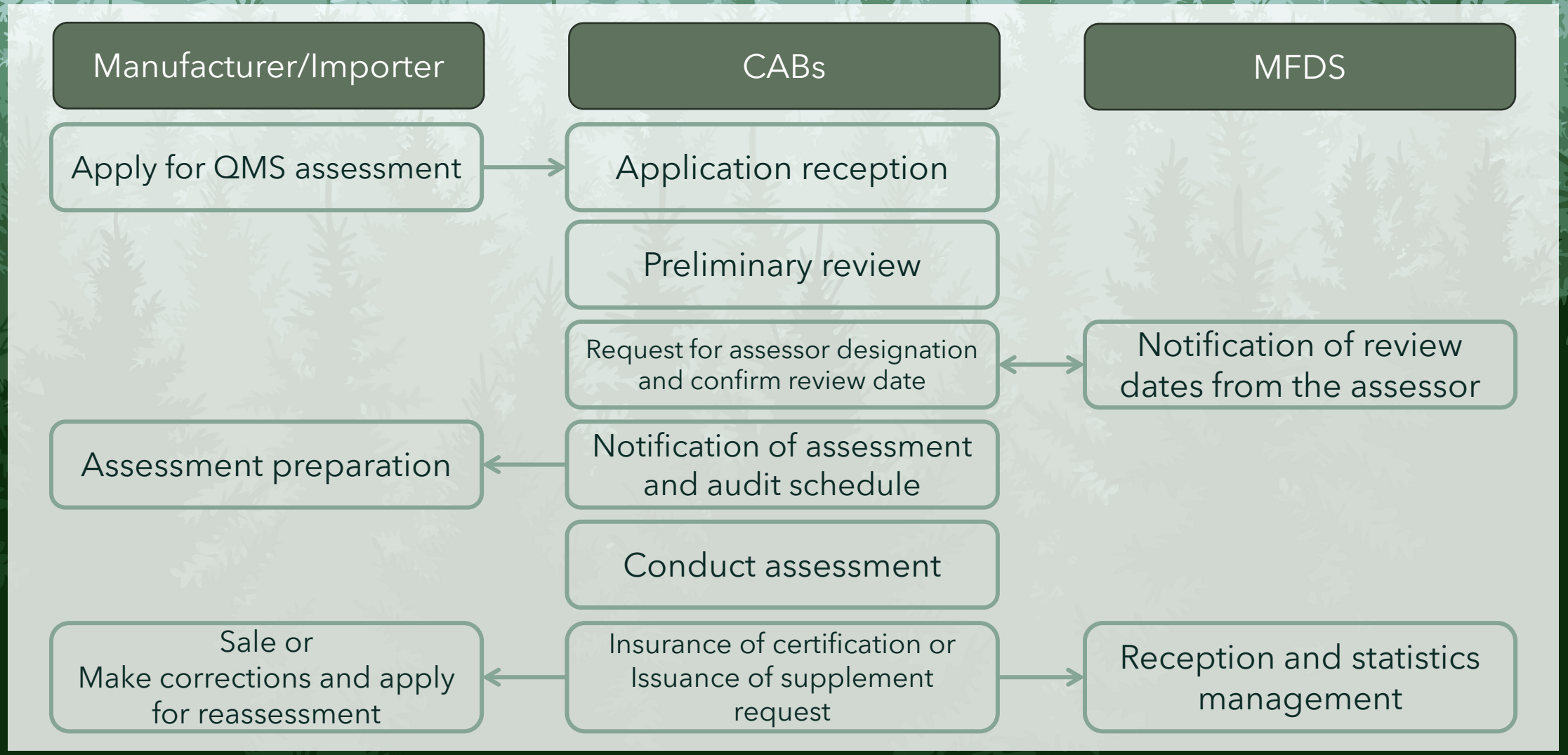
(Class 2) CABs

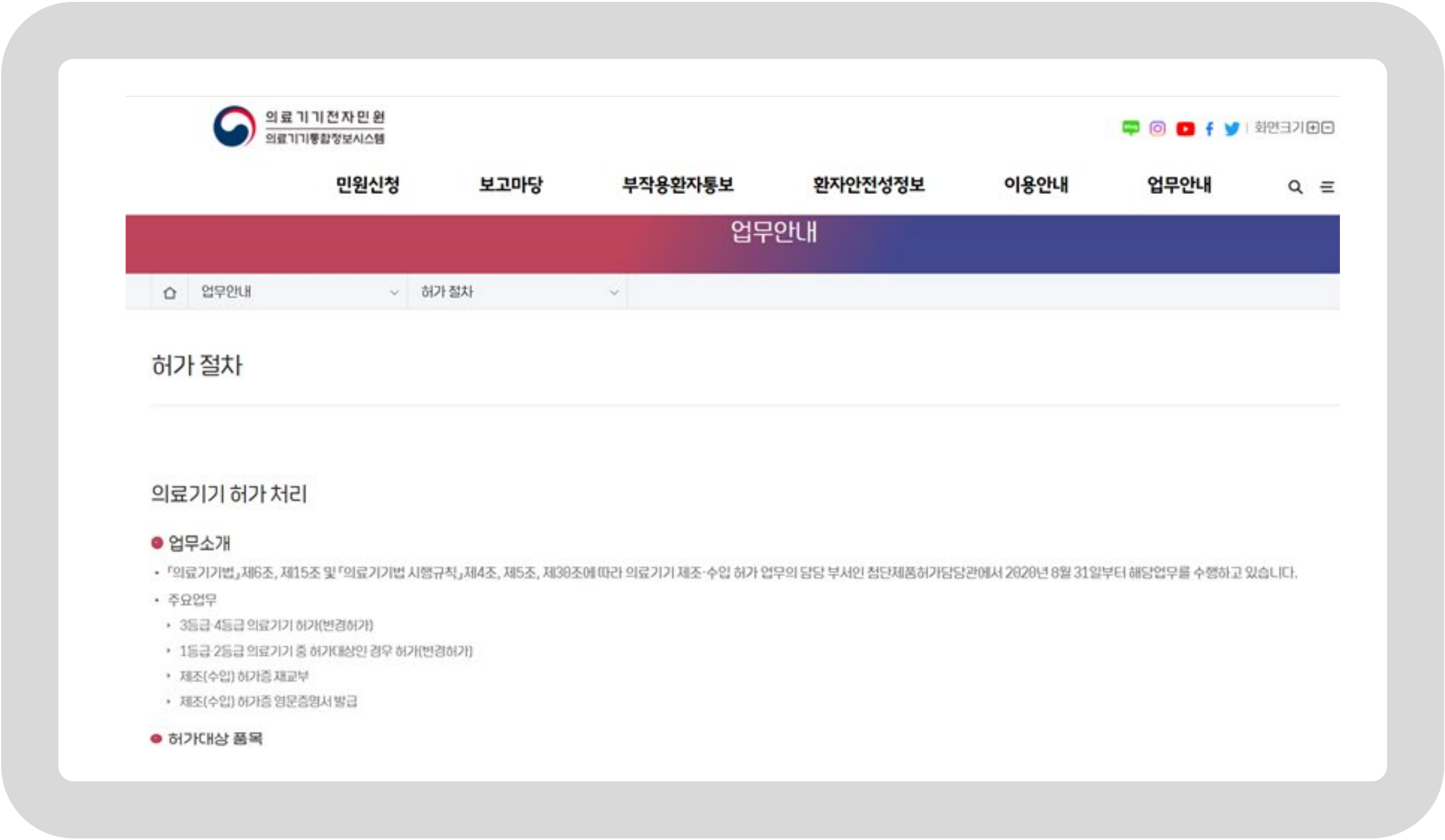
(Class 3,4) CABs & MFDS(Reginal Offices) Joint-Assessment

✓ Laws and Regulations

『Medical Devices Act』, 『Enforcement Regulations』, 『Medical Device Manufacturing, Importing, and Quality Control Standards』

QMS Audit Process




의료기기전자민원
의료기기통합정보시스템
화면크기
민원신청
보고마당
부작용환자통보
환자안전성정보
이용안내
업무안내
업무안내
업무안내
허가 절차
허가 절차
의료기기 허가 처리
업무소개
「의료기기법」제6조, 제15조 및 「의료기기법 시행규칙」제4조, 제5조, 제30조에 따라 의료기기 제조·수입 허가 업무의 담당 부서인 첨단제품허가담당관에서 2020년 8월 31일부터 해당업무를 수행하고 있습니다.
주요업무
3등급·4등급 의료기기 허가(변경허가)
1등급·2등급 의료기기 중 허가대상인 경우 허가(변경허가)
제조(수입) 허가증 재교부
제조(수입) 허가증 영문증명서 발급
허가대상 품목


의료기기전자민원
의료기기통합정보시스템
남은 시간 : 59분 22초
시간연장
마이페이지
로그아웃
(서현조/ hyunjosuh)
화면크기
민원신청
보고마당
부작용환자통보
환자안전성정보
이용안내
업무안내
신청정보
제조업소
명칭(상
사업자등
주소
※ 업소정보가 자동 조회
품목상세정보
구분
품목
품목/품목
분류번호
심사의종류
기술문서심사
명칭
품목 명칭에 상호표기 여부
제품명
다수의 제품명 입력 시 반드시 ','로 구분하여 입력.
Application Forms provided through MFDS's IT portal
which allows applicants to easily submit their applications for all Classes of Notification / Certification / Approval
➔ Submissions are then reviewed & managed by MFDS

MFDS's Review of Submissions for Compliance with Essential Principles

Designation of Innovative Medical Devices

✓ **(Definition)** MDs which have improved or are expected to improve the safety and effectiveness compared to existing medical devices or therapy;

- By applying **advanced technology** such as information and communications technology **(ICT)**, biotechnology **(BT)** and robotic technology or
- By **improving the methodology for use** among approved devices

✓ **(Extensive review)** Post approval study, Post-market surveilance study

✓ **(Legal Basis)** Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices Enforcement (May, 2020)

Review of Submissions for Compliance with Essential Principles

Postmarket Conformity Assessment Review

✓ Reassessment

(Targets) MDs that the Minister of MFDS determines have caused or could potentially cause serious adverse events or safety concerns

(Method) public notice 1 year before the reassessment (exceptions in cases of urgent need)

✓ Postmarket Surveillance

(Targets & Period) newly developed MDs (4 years*) and orphan MDs (6 years*)

* from the date of initial market release

Medical Device Committee Consultation

✓ For approval/certification/notification reviews, consultation from the legal MD committee is sought when necessary

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THANK YOU

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