IMDRF International Medical Device Regulators Forum | 26th Session

Japan Update

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Pharmaceuticals and Medical Devices Agency

Agenda

- PMDA's 20-year Anniversary (PMDA's purpose)
- PMDA's Fifth Mid-term Targets/Plan (FY2024 to 2028)
- Establishment of PMDA's International Hubs
- Software as a Medical Device
- Cybersecurity

PMDA's 20-year Anniversary

PMDA's Purpose

Making everyone's lives brighter together

We, PMDA, continue to create "Tomorrow's Normal" together,
as a "life platform" that supports everyday life,
where everyone can feel peaceful and can lead vibrant and healthy lives
by PMDA's "Safety Triangle" of review, safety and relief,
with "intelligence" weaved through science and information, and
with "human resourcefulness" accompanying
and bringing the world and the future into harmony.

PMDA's Fifth Mid-term Targets/Plan (FY2024 to 2028)

Plans for medical Devices/IVDs

Review
- Fastest, efficient and high-quality review
- Enhancing consultation service for Early commercialization of innovations
- Information dissemination (expanding publishment of review report of MD/IVD)
- Publishment of "early consideration" for SaMD
- Emergency consultation/review for pandemic
- Support for gene panel testing and CDx

Data Integrity
- Support for domestic clinical trials
- Appropriate response to real-world data

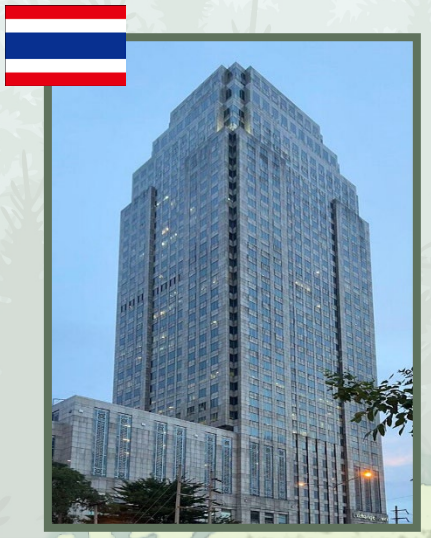
QMS
- Enhancing QMS on-site inspections
- Accurate response to RSUD

- Appropriate collection, organization, and evaluation of adverse event information

- PMDA's international hubs
- Multi/bi-lateral collaboration
- Contribution to development of international standards
- Training

etc.

PMDA's International Hubs



Asia Office, Bangkok

PMDA Central Office, Tokyo

To be established in central D.C. area by EOY

Washington D.C Office

Establishment of PMDA's international hubs
to enhance international contribution/capability for regulatory proposal

PMDA's 5th mid-term

Initiatives to strengthen cooperation
with Asian countries / with the United States & EU

- To support innovative medicines & medical devices access in Japan and Asian countries,
  - Strengthening cooperation with ASEAN countries
  - Supporting promotion of regulatory harmonisation with Asian countries
  - Developing an environment for smooth clinical development

→ Establishment of Asia Office in Bangkok, Thailand

- Close collaboration between Japan, US and European regulatory authorities is essential in supporting;
  - Development/distribution of innovative medicines and medical devices
  - Regulatory review
  - Post-marketing measures

→ Establishment of Washington D.C. Office, USA

PMDA dispatches a staff to EMA as a liaison officers (since 2009~).

Software as a Medical Device

DASH for SaMD 2（2023/9/6）

- Organize and publicize the two-step approval scheme for SaMD
- Develop guidelines for approval review and marketing procedures for SaMD for the general public
- Promotion of overseas acceptance of our review results (such as English translation of review reports)
- Subsidies for development funds for SaMD developers
- Support for SaMD developers to actively business overseas

Review point for;

- Software for Peritoneal Dialysis Treatment
- Supporting Software for Dental Implant Treatment
- Software for Ophthalmic Surgery Treatment Planning
- Supporting Software for Detecting Lesion with Endoscopic Imaging
- Computer-Aided Diagnosis Program to Support Interpretation of Medical Images

DASH for SaMD（2020/11/24）

- Setup an office to review SaMD in MHLW and PMDA
- Establishment of SaMD centralized consultation service
- Next-generation medical device evaluation index, development guidance, audit points, and certification criteria formulation
- Trial implementation of priority review, etc. for innovative SaMD
- Promote the use of IDATEN (Improvement Design within Approval for Timely Evaluation and Notice) and streamline procedures, etc.

<Expand and continue>

- Upgrade from office to Department for reviewing SaMD in PMDA
- Establishment of SaMD-specific consultation service
- (Continue)
- (Continue)
- (Continue)

DASH for SaMD: DX(Digital Transformation) Action Strategies in Healthcare for SaMD(Software as a Medical Device)

English version available

Cybersecurity

<Article 1-11, p.,1, Enforcement Regulations of the Medical Care Act>
Pursuant to Article 6-12 of the Law, administrators of hospitals and other facilities must ensure the following systems for safety management:
- Establish guidelines for safety management related to medical care.

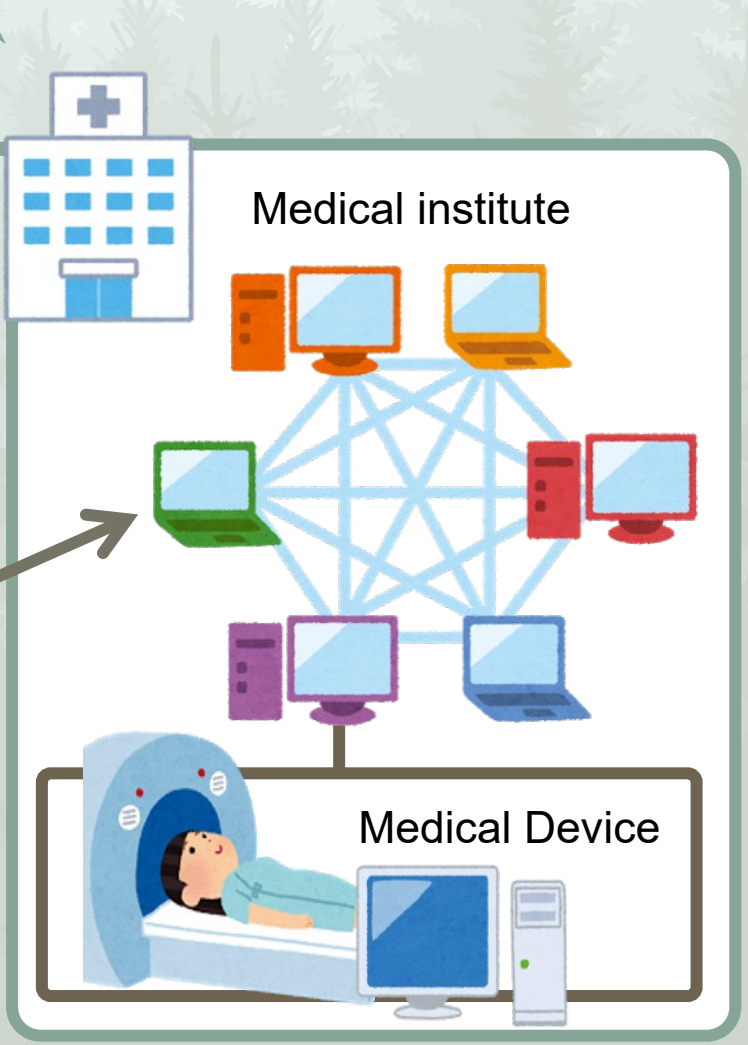
<Article 14, p.,1, Enforcement Regulations of the Medical Care Act>
The administrator of a hospital or clinic must take necessary precautions to ensure that the drugs, medical devices, and regenerative medicine products present in the hospital or clinic do not violate the provisions of the Pharmaceuticals and Medical Devices Act.

<Article 14, p.,2, Enforcement Regulations of the Medical Care Act>
The administrator of a hospital, clinic, or midwifery clinic must take the necessary measures to ensure cybersecurity (meaning cybersecurity as defined in Article 2 of the Basic Act on Cybersecurity) so as to avoid any significant disruption to the provision of medical care.

<Guidelines for the security management of medical information systems*>
Medical institutions will take the initiative in managing the security of medical information systems to ensure their confidentiality, integrity, and availability.

*Guidelines for the Security Management of Medical Information Systems Version 6.0 (May 2023)

< Essential Principles, Article12-3 >**
Medical device manufacturers to play a key role in maintaining the functionality of medical devices and patient safety against cyber risks. Provide necessary information to medical institutions and cooperate with them.



** Standards for medical devices established by the Minister of Health, Labor and Welfare pursuant to the provisions of Article 41, Paragraph 3 of the Act on Ensuring the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, etc. （Ministerial Notification No. 122 of 2005, Partial amendment of Ministerial Notification No. 403 of 2014, Partial amendment of Ministerial Notification No. 67 of 2020）

Cybersecurity

2005 2014 2020 2023 **2024**

Ensuring cybersecurity in medical devices (PFSB/ELD Notification No. 0428-1, April 28, 2015)

Guidance on ensuring the cybersecurity of medical devices (PFSB/ELD Notification No. 0724-1, July 24, 2018)

Cyber attacks by ransomware targeting medical institutions (alert) (Administrative communication, June 28, 2021)

Cybersecurity related notifications

Guidance on Medical Device Cybersecurity Principles and Practices by the IMDRF (Dissemination Request) (PFSB/ELD Notification No.0513-1, May 13, 2020)

Guidelines for ensuring and enforcing cybersecurity for medical devices (PFSB/ELD Notification No.1224-1, Dec. 24, 2021)

Vulnerability management to ensure cybersecurity of medical devices (PFSB/ELD Notification No.0328-1, Mar. 28, 2024)

Essential Principles were introduced for the first time in the medical device regulations in Japan with the amendment of Pharmaceutical Affairs Law.

SaMD became subject to medical device regulations and EPs were revised accordingly

EPs were revised based on the published IMDRF documents such as cybersecurity guidance.

Application of Article 12-3 of EP for medical devices (PSEHB MDED Notification No.0331-8, Mar. 31, 2023)

Essential Principles* **Amd** Nov. 2014 **amd** Mar.2023 Apr. 2024

Transition period

English information available

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF
International Medical Device Regulators Forum

THANK YOU