Regulatory Updates on Medical Devices in Japan

- Toward the Earlier Marketing of Innovative Medical Devices -

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Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Today’s Agenda

1. Overview of regulation on medical devices in Japan

2. Regulatory updates for SaMD

3. Amendment of the Pharmaceuticals and Medical Devices Act（PMD Act）

1. Overview of regulation on medical devices in Japan

Regulatory Authorities in JAPAN

MHLW

Ministry of Health, Labour and Welfare

- **Authorization of applications**
- **Publishing guidelines**
- **Supervising PMDA activities**

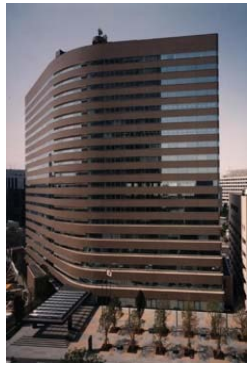
etc.

PMDA

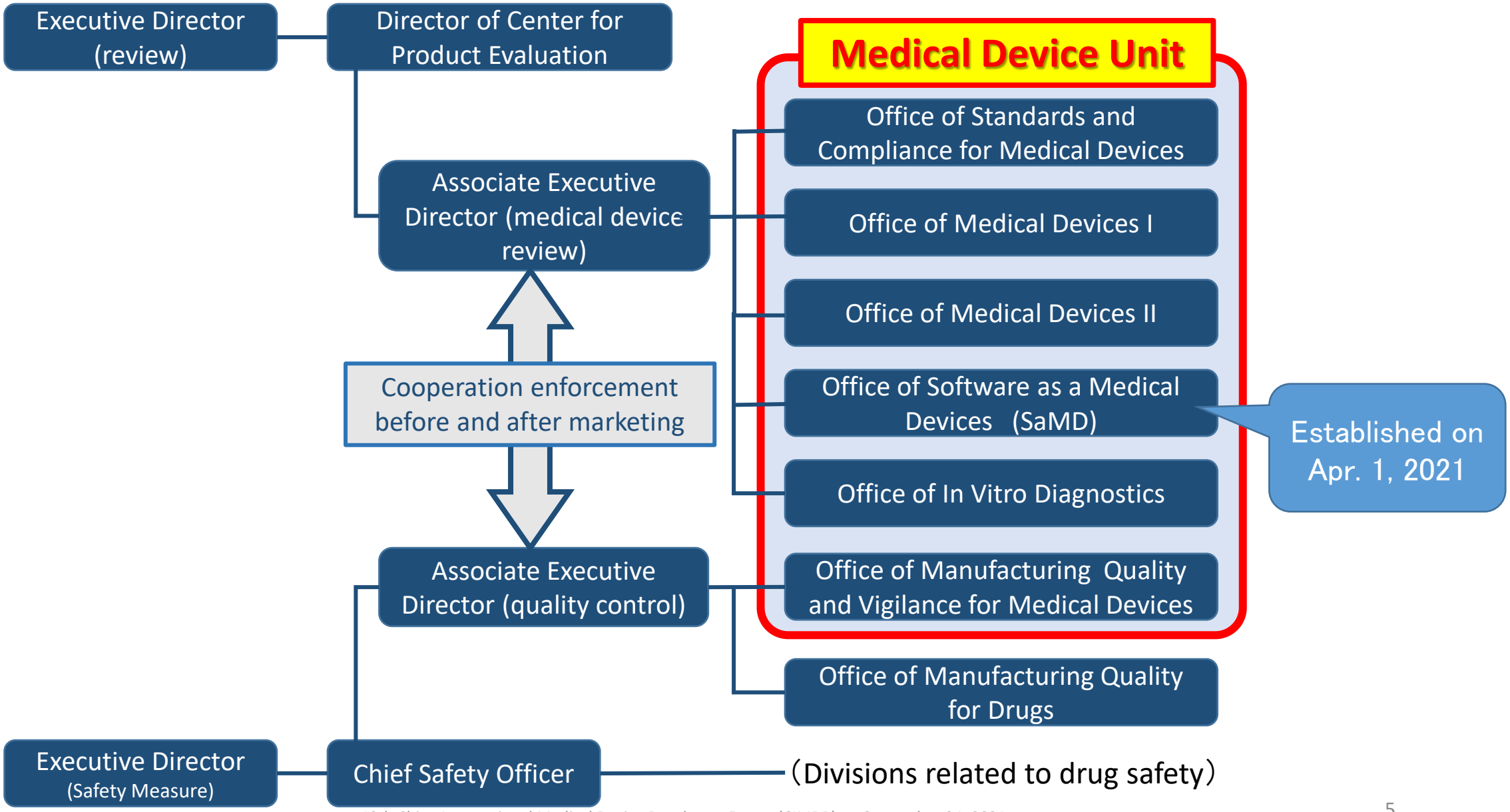
Pharmaceuticals and Medical Devices Agency

- **Scientific review**
- **Consultation on clinical trials**

etc.



PMDA's Medical Device Unit



Legal Structure for Medical Device Regulations

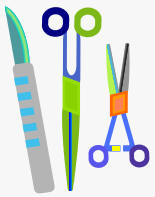
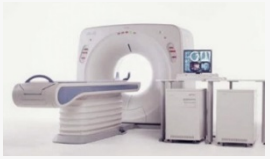
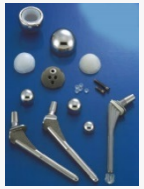
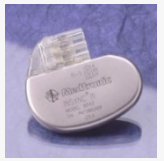
Act	Pharmaceuticals and Medical Devices Act (**PMD Act**), 1960
Cabinet Order	Cabinet Order on PMD Act, 1961
Ministerial Ordinance	Ministerial Ordinance on PMD Act, 1961 GCP/GLP for medical device, 2005 Good Vigilance Practice (GVP) Quality Management System (QMS) etc.
Ministerial Notification	Essential Principles Certification criteria for class II/III devices Classification of medical devices List of orphan designation etc.
Notification	Information on application procedures Guidelines for clinical evaluation etc.

Definition of Medical Device under PMD Act

The term “medical device” as used in the Act refers to appliances or instruments, etc. which are **intended for** use in the diagnosis, treatment or prevention of disease in humans or animals or **intended to** affect the structure or functioning of the bodies of human or animals, which are specified by Cabinet Order

~ PMD Act Article 2.4

Medical Device Regulations in Japan

Classification	Class I	Class II	Class III	Class IV
Category	General MDs	Controlled MDs	Specially controlled MDs	
Premarket regulation	Self-declaration	Third party certification	MHLW approval (PMDA review)	
Example		 	 	  
Post market safety (vigilance/surveillance)	PMDA and MHLW			

Review Period of Medical Devices

Category	Target period	Result (FY2016)	Result (FY2017)	Result (FY2018)	Result (FY2019)	Result (FY2019)
New medical devices (priority)	10	8.0	8.3	8.3	7.3	8.4
New medical devices (regular)	14	12.0	11.9	12.0	11.1	10.8
Improvement (clinical)	10	10.0	8.8	8.8	8.6	8.6
Improvement (non-clinical)	6	5.8	5.8	5.7	5.5	5.6
Generic	4	3.5	3.6	3.5	3.6	3.4

(months)

Source: https://www.pmda.go.jp/files/000241310.pdf

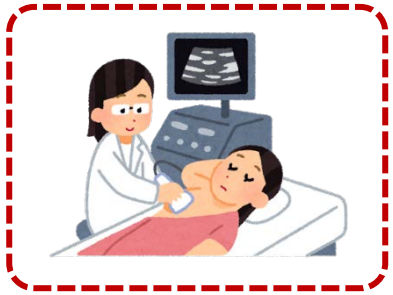
2. Regulatory updates for SaMD

What is Software as Medical Device (SaMD) ?

Previous legislation

program which determines performance of medical device

install



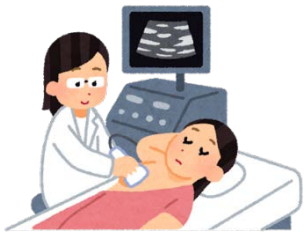
Medical device
(tangible object including software)

Current legislation

program which determines performance of medical device

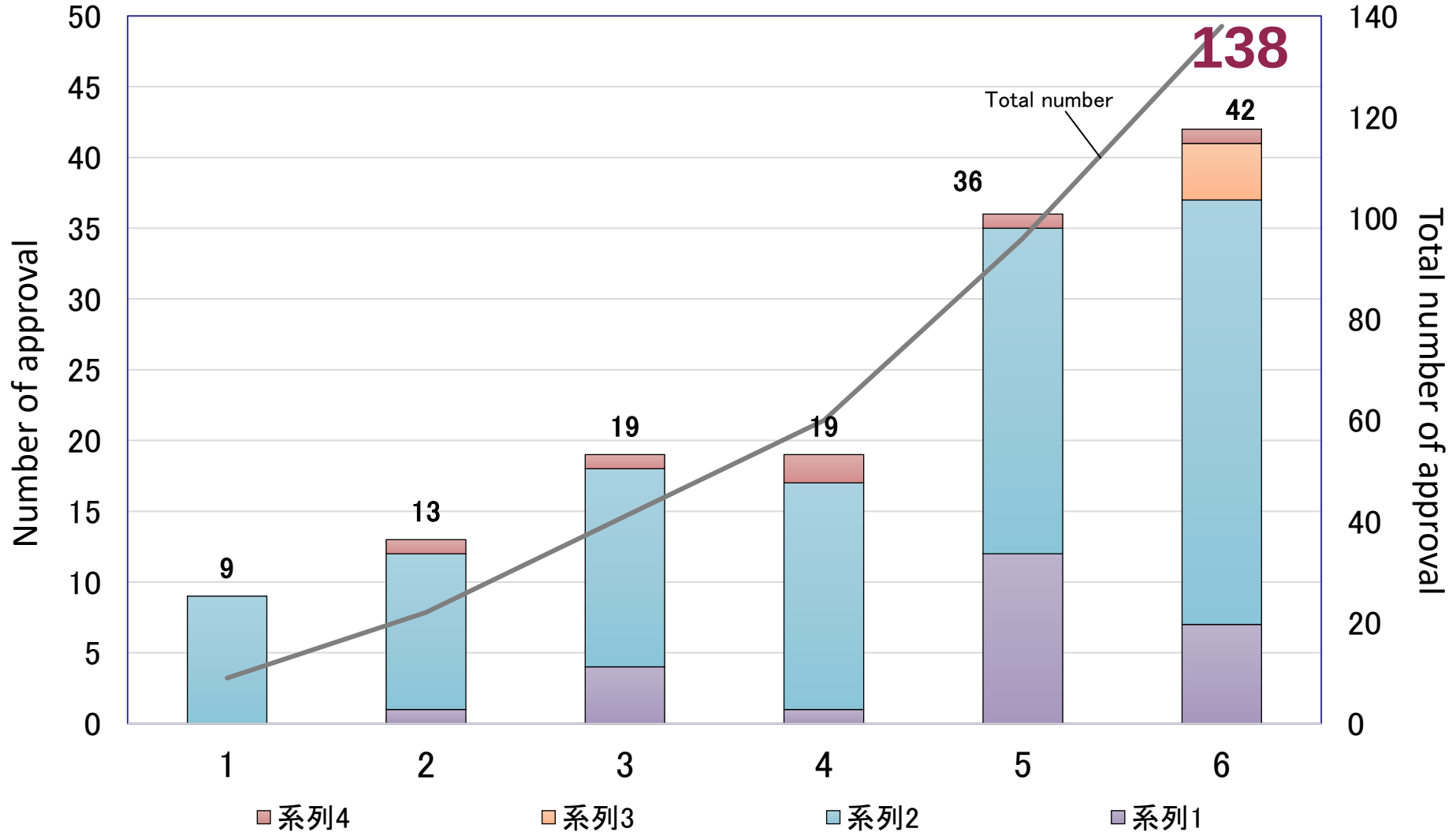
Medical device (software only)

install



MD software classified as Class I is **NOT** subjected to regulations on PMD Act

Number of approved SaMD



DX (Digital Transformation) Action Strategies in Healthcare for SaMD “DASH for SaMD”

1. Early grasp of research seeds and publication of the review policy

a. Grasp research seeds in the early stage of development

b. Organize and Publish the review policy based on characteristics of SaMD

2. Unification of the consulting contact point

a. Unify consultation service

b. Publish consultation case examples as many as possible

3. Review system based on characteristics of SaMD

a. Carry out efficient review based on characteristics of SaMD

b. Utilize the Post-Approval Change Management Protocol (PACMP/IDATEN) scheme

c. Consider establishing the innovative SaMD designation system

4. Enhanced structure for early realization

a. Establish new office which specialized in reviewing SaMD in PMDA and MHLW

b. Establish an expert examination committee for SaMD in the Pharmaceutical Affairs and Food Sanitation Council

c. Establish a collaborative forum among regulator, academia and industry

d. Enrich published database of approval cases

3. Amendment of the Pharmaceuticals and Medical Devices Act（PMD Act）

Overview of Amendment of the Pharmaceuticals and Medical Devices Act (PMD Act)

- Promulgated in November, 2019

  Implemented in September, 2020

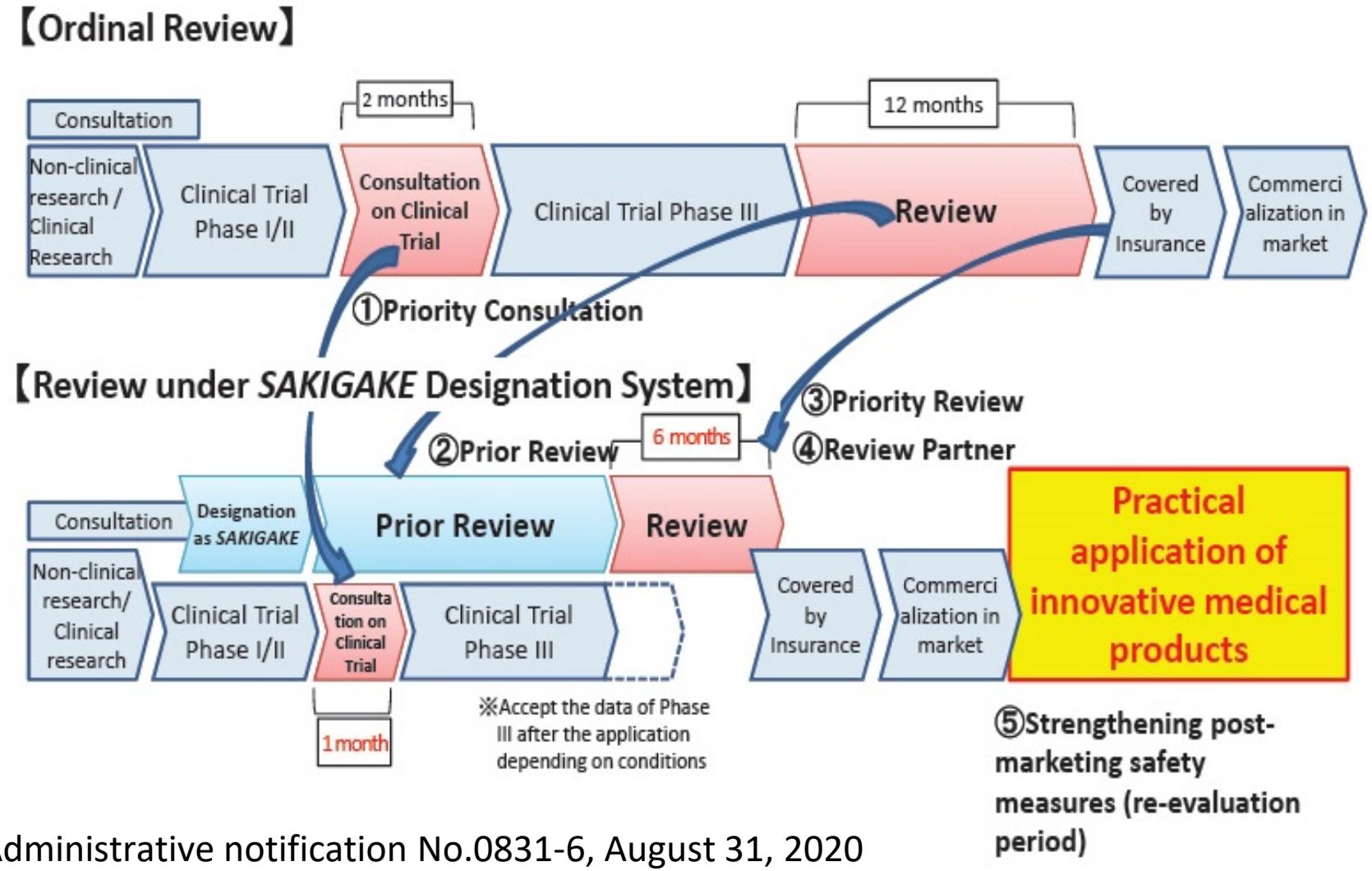
- Following provisions are introduced :
  1. SAKIGAKE designation system
  2. Priority review for specific uses, e.g. pediatric use
  3. Conditional approval system
  4. Post-Approval Change Management Protocol (PACMP) for Medical Devices

Overview of Accelerated Review System in Japan

Type		Designation requirement
Expedited review		NOT required
Priority review	Orphan	Required
	Sakigake ※ (innovative)	Required
	Specific use (pediatric, AMR)	Required
Conditional Early Approval ※		NOT required

※ These reviews had been operated based on the administrative notification before the amendment of PMD Act.

SAKIGAKE Designation System



Administrative notification No.0831-6, August 31, 2020

Approved Products with SAKIGAKE Designation

➢ Number of Products (Medical Devices, IVDs) designated as SAKIGAKE

- Medical devices: 12
- In Vitro Diagnostics (IVDs): 2

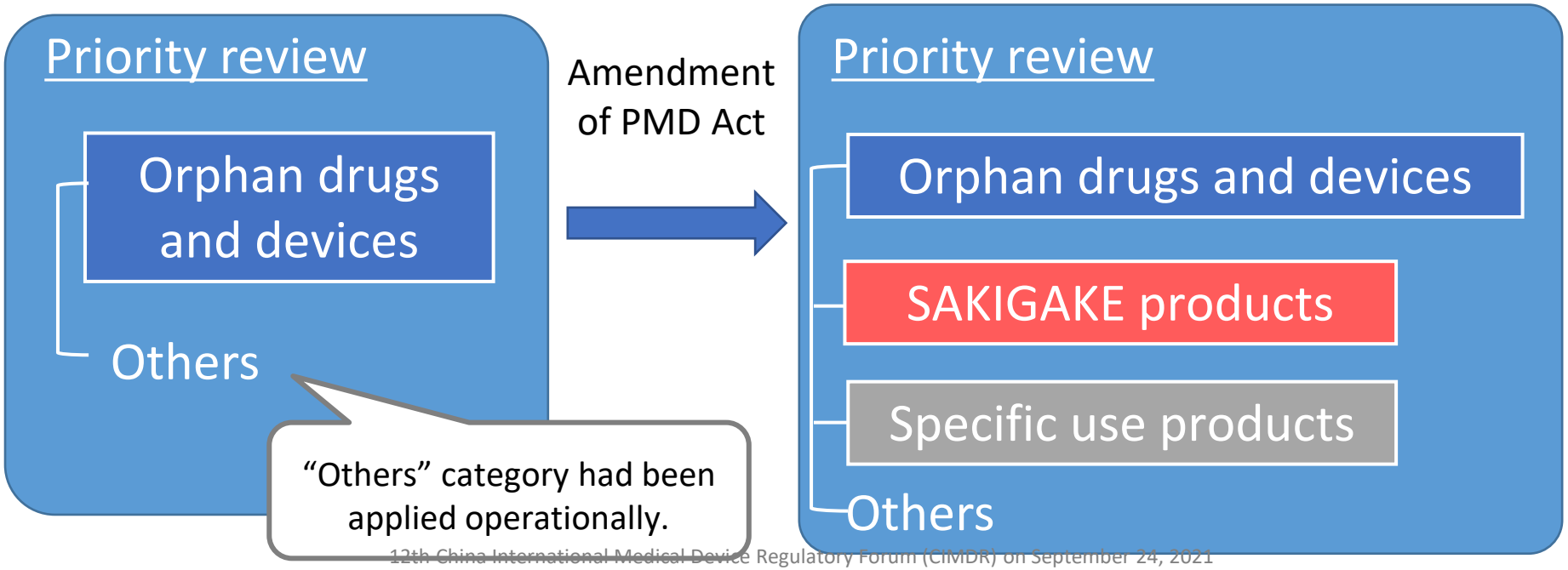
➢ List of Approved Products (Medical Devices, IVDs) which had SAKIGAKE designation

Category	Product name	Company name	Indication	SAKIGAKE designation date	Approval date
Medical Device	TITANBRIDGE	Nobelpharma Co. Ltd.	Adductor spasmodic dysphnia	Feb. 10, 2016	Dec. 15, 2017
Medical Device	Boron neutron capture therapy(BNCT) system	Sumitomo Heavy Industries, Ltd.	Head and neck cancer	Feb. 28, 2017	Mar. 11, 2020
IVD	OncoGuide NCC Oncopanel System	Sysmex Corporation	Solid tumors	Feb. 28, 2017	Dec. 25, 2018

Priority Review for Specific Uses

- Designation of “Specific use product” for highly unmet medical needs (e.g. pediatric use and AMR).
- Priority review and other supportive measures are applied to designated products for specific use.

Administrative notification No.0831-5, August 31, 2020

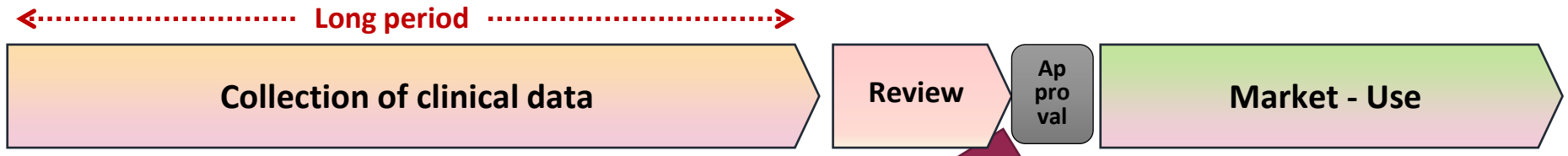


Conditional Approval System

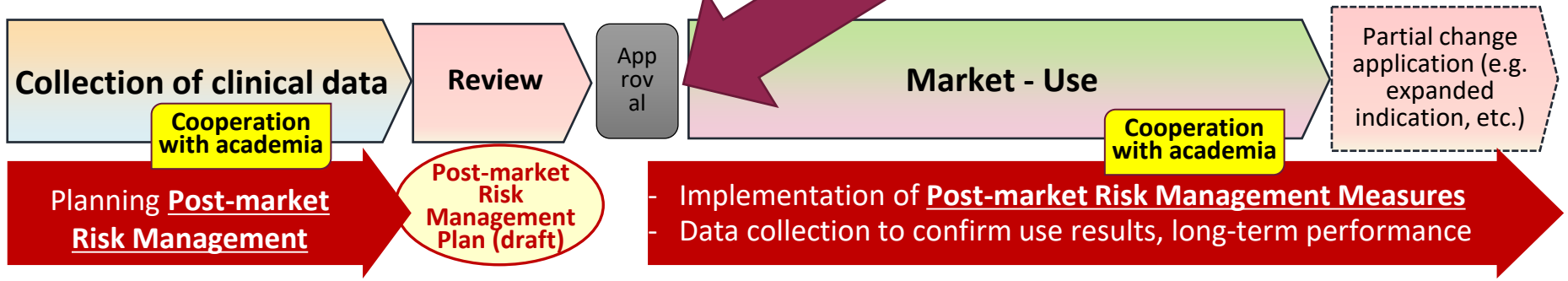
Accelerate approval of MDs of high clinical needs by balancing the pre- and post-market requirements, based on the lifecycle management of the MDs.

Administrative notification No.0831-2, August 31, 2020

Ordinary review



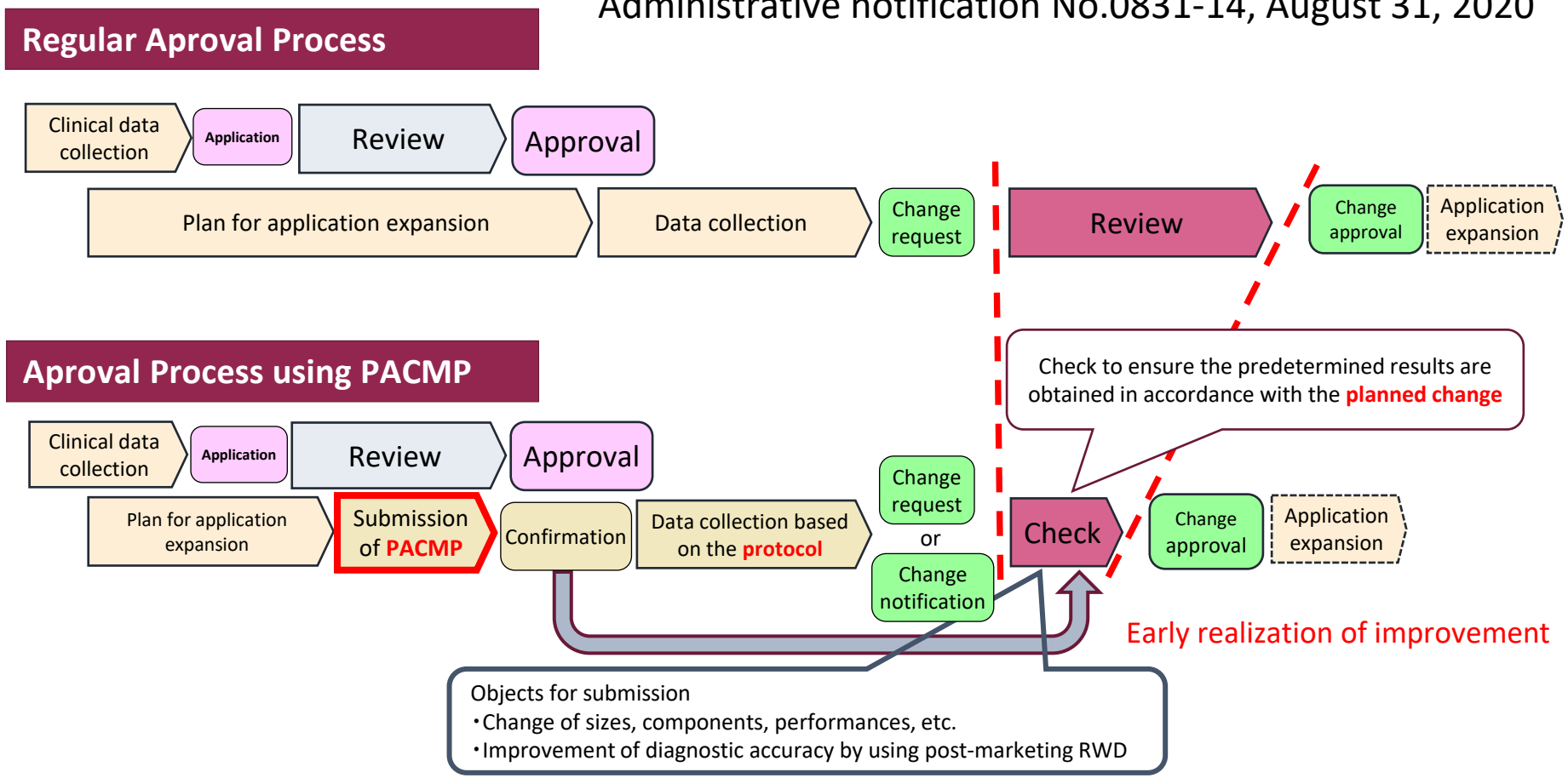
Conditional Early Approval for Innovative MDs



Post-Approval Change Management Protocol (PACMP) for Medical Devices

PACMP is introduced for medical devices to enable continuous improvements through product lifecycle.

Administrative notification No.0831-14, August 31, 2020



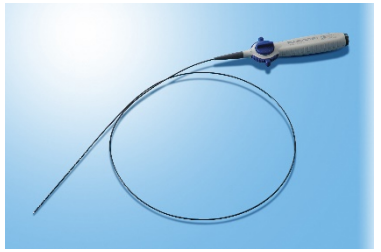
1 Year of Experience after Implementation of PACMP

➢FAQ regarding application of PACMP is issued in October 2020.
https://www.pmda.go.jp/files/000237412.pdf （Japanese only）

➢ MHLW received 2 applications of PACMP as of July 2021.

・Electrode catheter

change plan:
- add catheter types and sizes
- add manufacturers



product image

・Advanced bipolar

change plan:
- add components with different jaw shape

product image

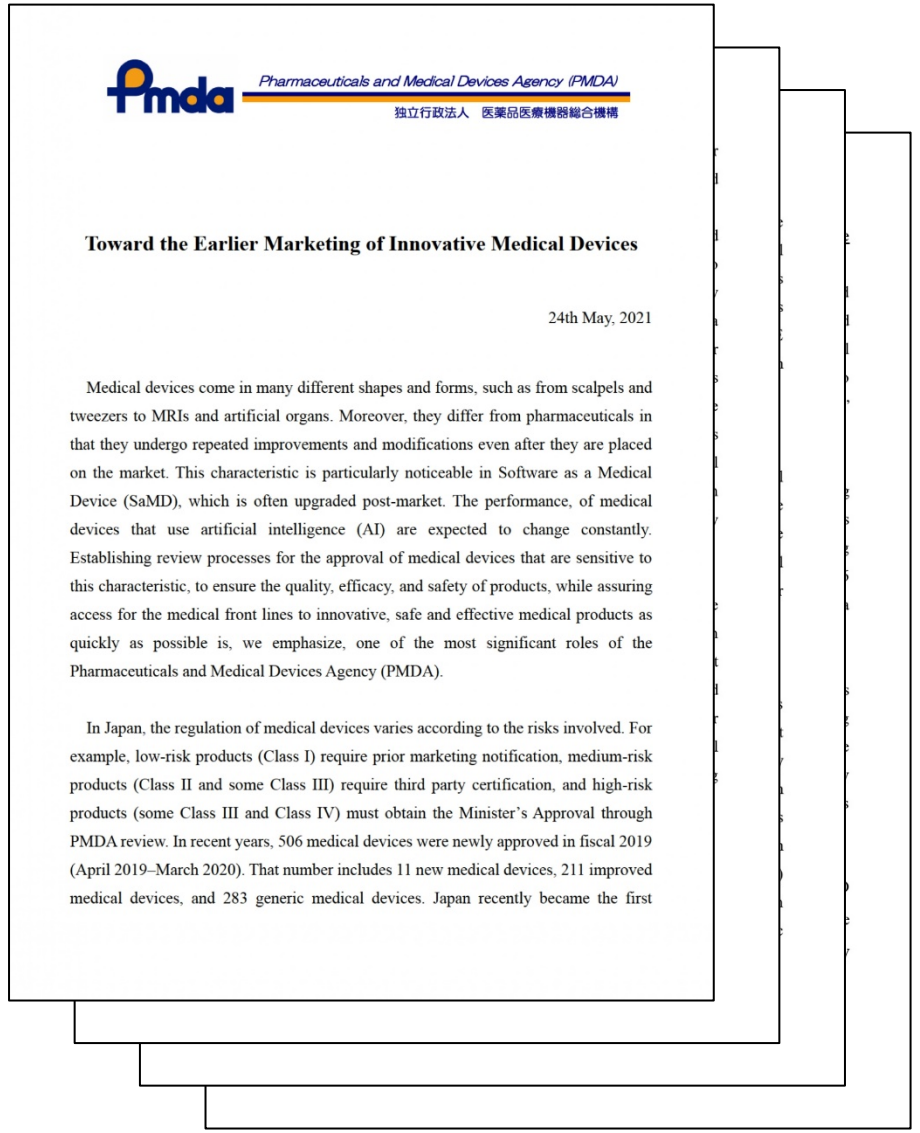
PMDA CE's Statement for the Earlier Marketing of Innovative Medical Devices

https://www.pmda.go.jp/english/about-pmda/0006.pdf

Chief Executive's Statement

The Pharmaceuticals and Medical Devices Agency (PMDA) puts great emphasis on communication with stakeholders, including public and industries. Since April 2020, Chief Executive Dr. FUJIWARA has been releasing various statements in English to better communicate PMDA's positions on recent issues around global public health. Please open each file below to access individual statement. The PMDA continues to deliver information of public interest and exchange opinions with stakeholders to protect and improve the health of people by cooperating with other regulatory authorities.

Issue #	Title	Date
13	For more and closer communication with Patients - PMDA's efforts for patient satisfaction -	August 5, 2021
12	Toward the Earlier Marketing of Innovative Medical Devices	May 24, 2021
11	Utilization of Real World Data - PMDA's approaches -	March 3, 2021
10	Special Approval for Emergency on First COVID-19 Vaccine in Japan	February 16, 2021



Pharmaceuticals and Medical Devices Agency (PMDA)
独立行政法人 医薬品医療機器総合機構

Toward the Earlier Marketing of Innovative Medical Devices

24th May, 2021

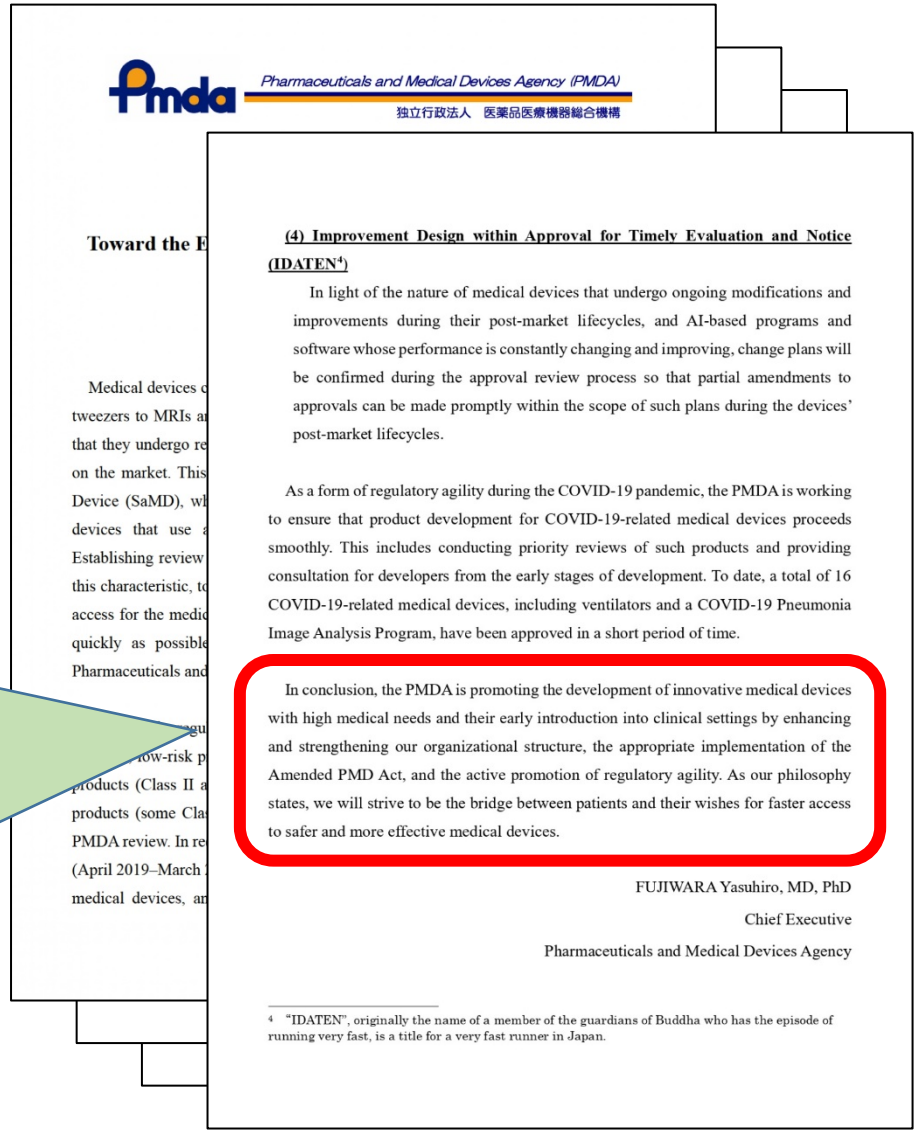
Medical devices come in many different shapes and forms, such as from scalpels and tweezers to MRIs and artificial organs. Moreover, they differ from pharmaceuticals in that they undergo repeated improvements and modifications even after they are placed on the market. This characteristic is particularly noticeable in Software as a Medical Device (SaMD), which is often upgraded post-market. The performance, of medical devices that use artificial intelligence (AI) are expected to change constantly. Establishing review processes for the approval of medical devices that are sensitive to this characteristic, to ensure the quality, efficacy, and safety of products, while assuring access for the medical front lines to innovative, safe and effective medical products as quickly as possible is, we emphasize, one of the most significant roles of the Pharmaceuticals and Medical Devices Agency (PMDA).

In Japan, the regulation of medical devices varies according to the risks involved. For example, low-risk products (Class I) require prior marketing notification, medium-risk products (Class II and some Class III) require third party certification, and high-risk products (some Class III and Class IV) must obtain the Minister's Approval through PMDA review. In recent years, 506 medical devices were newly approved in fiscal 2019 (April 2019–March 2020). That number includes 11 new medical devices, 211 improved medical devices, and 283 generic medical devices. Japan recently became the first

PMDA CE's Statement for the Earlier Marketing of Innovative Medical Devices

https://www.pmda.go.jp/english/about-pmda/0006.pdf

…, the PMDA is promoting the development of innovative medical devices with high medical needs and their early introduction into clinical settings by enhancing and strengthening our organizational structure, the appropriate implementation of the Amended PMD Act, and the active promotion of regulatory agility. As our philosophy states, we will strive to be the bridge between patients and their wishes for faster access to safer and more effective medical devices.



Pharmaceuticals and Medical Devices Agency (PMDA)
独立行政法人　医薬品医療機器総合機構

(4) Improvement Design within Approval for Timely Evaluation and Notice (IDATEN[4])

In light of the nature of medical devices that undergo ongoing modifications and improvements during their post-market lifecycles, and AI-based programs and software whose performance is constantly changing and improving, change plans will be confirmed during the approval review process so that partial amendments to approvals can be made promptly within the scope of such plans during the devices' post-market lifecycles.

As a form of regulatory agility during the COVID-19 pandemic, the PMDA is working to ensure that product development for COVID-19-related medical devices proceeds smoothly. This includes conducting priority reviews of such products and providing consultation for developers from the early stages of development. To date, a total of 16 COVID-19-related medical devices, including ventilators and a COVID-19 Pneumonia Image Analysis Program, have been approved in a short period of time.

In conclusion, the PMDA is promoting the development of innovative medical devices with high medical needs and their early introduction into clinical settings by enhancing and strengthening our organizational structure, the appropriate implementation of the Amended PMD Act, and the active promotion of regulatory agility. As our philosophy states, we will strive to be the bridge between patients and their wishes for faster access to safer and more effective medical devices.

FUJIWARA Yasuhiro, MD, PhD
Chief Executive
Pharmaceuticals and Medical Devices Agency

4 "IDATEN", originally the name of a member of the guardians of Buddha who has the episode of running very fast, is a title for a very fast runner in Japan.

Thank you for your attention!

多謝