

Overview of Japanese Medical Device Regulations **~** Experience after Implementation of Amendment of the PMD Act **~**

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Agenda

- Overview of regulation on medical devices in Japan
- 2. Amendment of the Pharmaceuticals and Medical Devices Act (PMD Act)

Legal Structure for Medical Device

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 etc.

Notification

Information on application procedures Guidelines for clinical evaluation etc.

Definition of Medical Device in PMD Act

Medical devices are machinery or apparatus, etc.

intended for use in the diagnosis, treatment or

prevention of disease in humans or animals or

intended to affect the structure or functions of
the human or animal body, which are specified by
Cabinet Order

Article 2.4, PMD Act

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			

Agenda

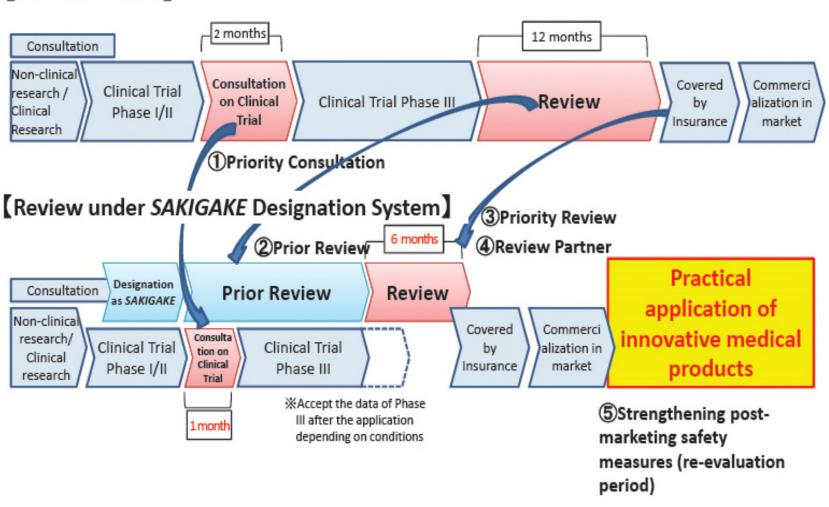
- Overview of regulation on medical devices in Japan
- 2. Amendment of the Pharmaceuticals and Medical Devices Act (PMD Act)

Overview of Amendment of the Pharmaceuticals and Medical Devices Act

- Enacted 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

SAKIGAKE Designation System

(Ordinal Review)

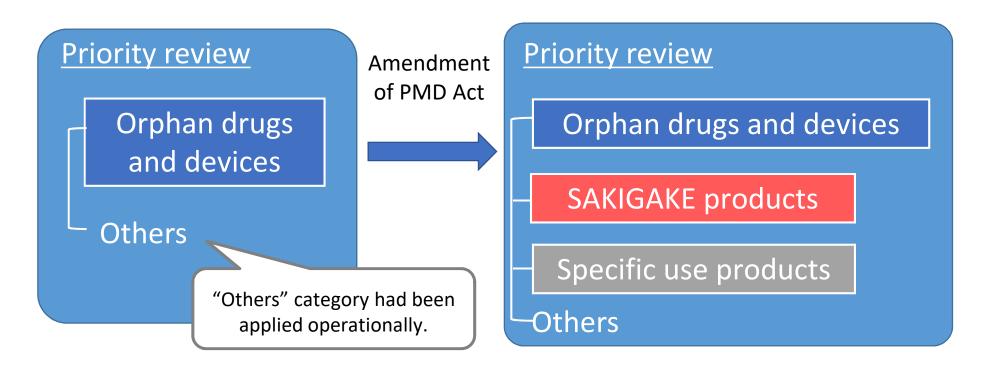


Administrative notification No.0831-6, August 31, 2020

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

<u>Accelerate approval of MDs of high clinical needs</u> 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 Ap **Review** Collection of clinical data pro Market - Use **Conditional Approval for Innovative MDs** Partial change App application (e.g. Collection of clinical data **Review** Market - Use rov expanded Cooperation indication, etc.) Cooperation with academia with academia Post-market Implementation of Post-market Risk Management Measures Risk Planning **Post-market** Management Data collection to confirm use results, long-term performance **Risk Management** Plan (draft)

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 **Regular Approval Process** Clinical data Review **Application Approval** collection Application Change Change Plan for application expansion Data collection Review approval expansion request **Approval Process using PACMP** Check to ensure the predetermined results are obtained in accordance with the planned change Clinical data Review Application **Approval** collection Change request Application Submission Change Plan for application Data collection based Check Confirmation or expansion expansion approval of **PACMP** on the protocol Change notification Early realization of improvement Objects for submission ·Change of sizes, components, performances, etc. Improvement of diagnostic accuracy by using post-marketing RWD 11

Experience after Implementation of PACMP

FAQs regarding application of PACMP (Japanese only)

ver.1: https://www.pmda.go.jp/files/000237412.pdf (October 30, 2020)

ver.2: https://www.pmda.go.jp/files/000243337.pdf (October 20, 2021)

- > MHLW received 2 applications of PACMP as of December 2021.
- Electrode catheter (KANEKA CORPORATION)

change plan:

- add catheter types and sizes
- add manufacturers



product image

Advanced bipolar (Johnson & Johnson K.K.)

change plan:

add components with different jaw shape



product image

Thank you for your attention!





MHLW Website
https://www.mhlw.go.jp/english/

PMDA Website
https://www.pmda.go.jp/english/index.html