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

HBD East 2021 Think Tank, Jan. 2022

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Agenda

1. Overview of regulation on medical devices in Japan

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

Legal Structure for Medical Device

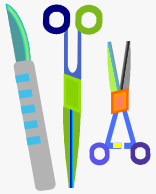
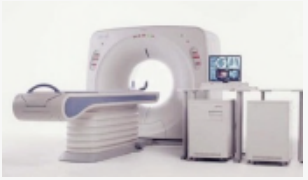
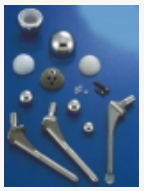
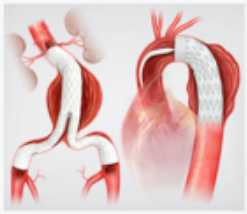
Act	Pharmaceuticals and Medical Devices Act (**PMD Act**), 1960
Cabinet Order	Cabinet Order on PMD Act, 1961
Ministerial Ordinance	Ministerial Ordinance on PMD Act, 1961 GCP/GLP for medical device, 2005 Good Vigilance Practice (GVP) Quality Management System (QMS) etc.
Ministerial Notification	Essential 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

1. Overview of regulation on medical devices in Japan

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

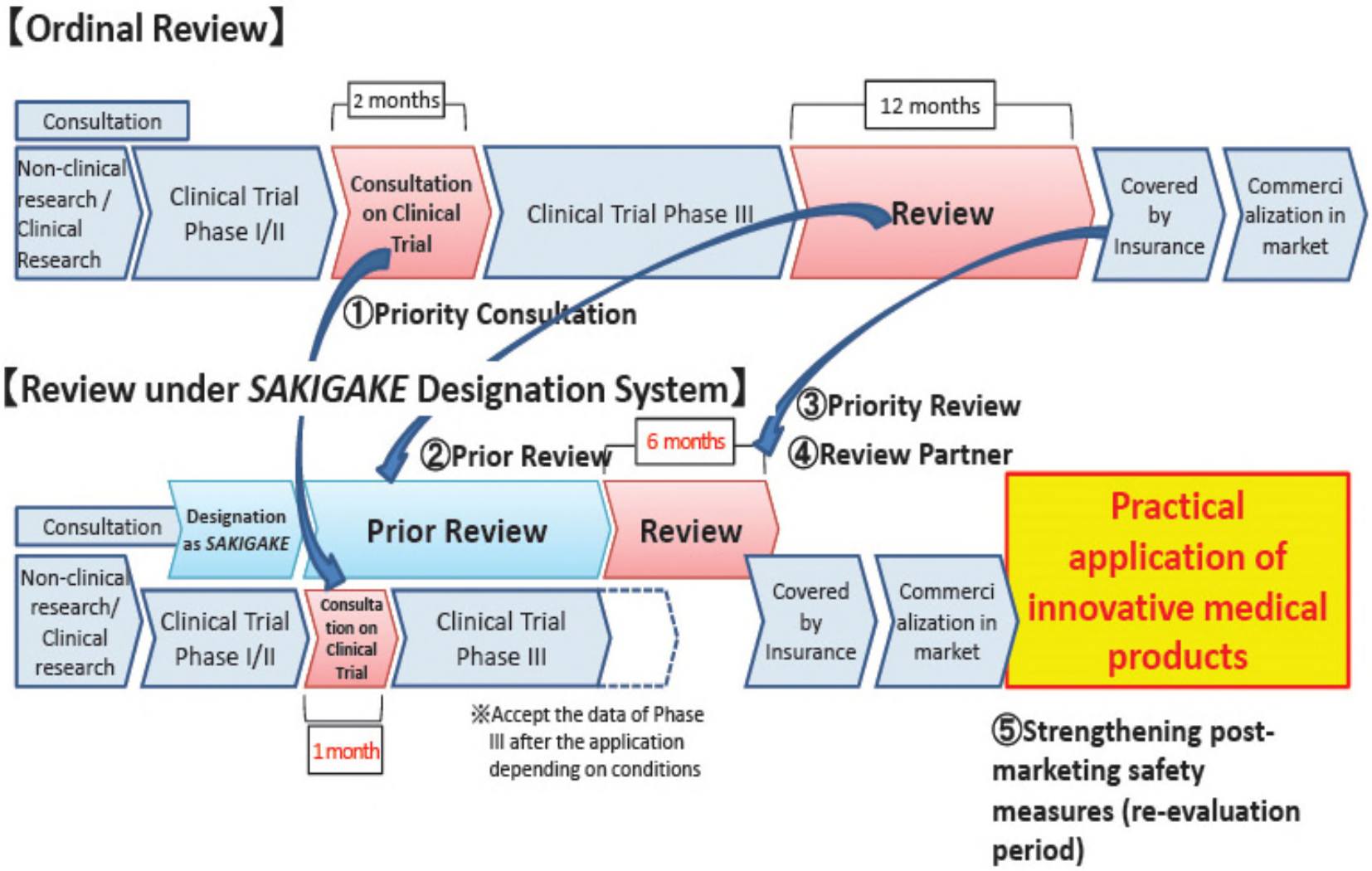
Overview of Amendment of the Pharmaceuticals and Medical Devices Act

- 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

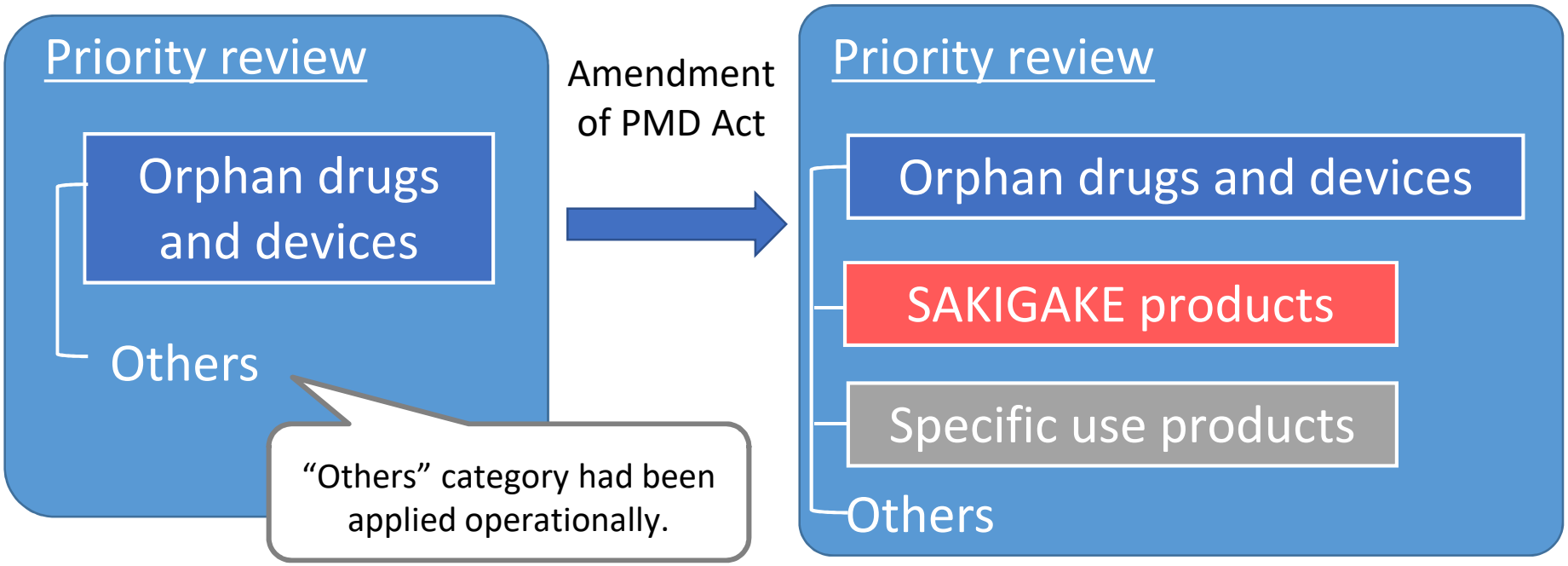


Administrative notification No.0831-6, August 31, 2020

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

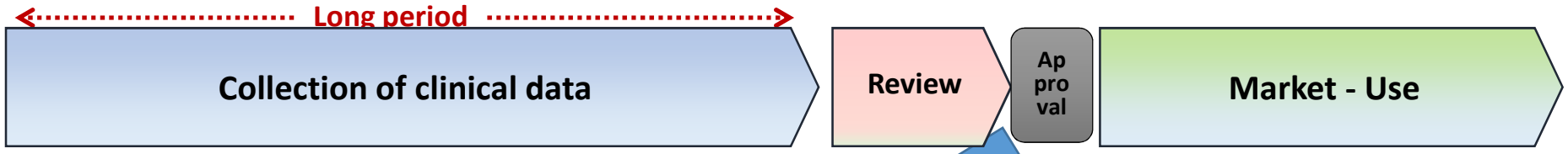


Conditional Approval System

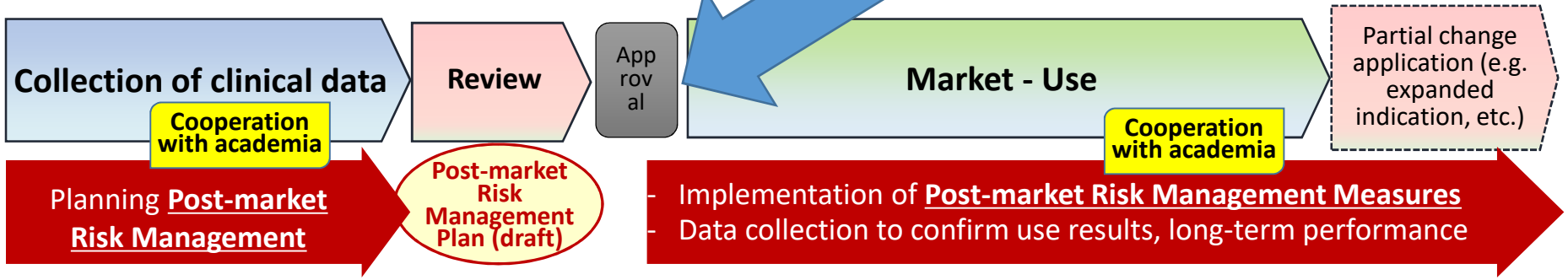
Accelerate approval of MDs of high clinical needs by balancing the pre- and post-market requirements, based on the lifecycle management of the MDs.

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

Ordinary review



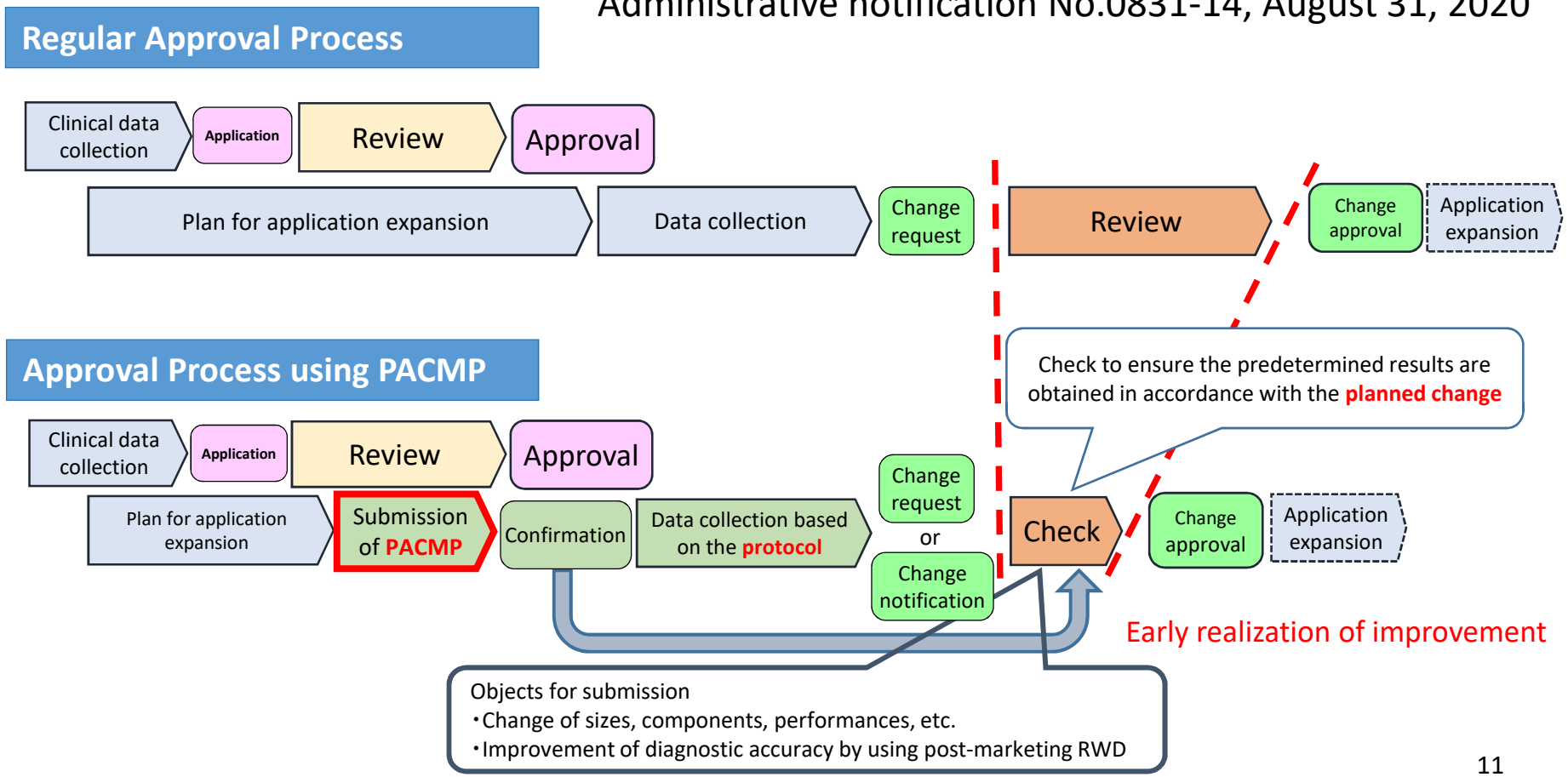
Conditional Approval for Innovative MDs



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



Experience after Implementation of PACMP

➢FAQs regarding application of PACMP（Japanese only）

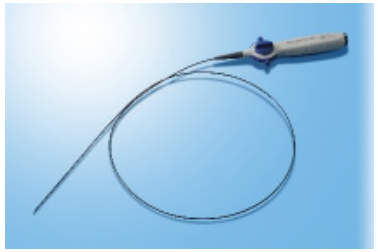
ver.1: https://www.pmda.go.jp/files/000237412.pdf (October 30, 2020)

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