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Japan Regulatory Update

IMDRF Sep. 2020

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Agenda

1. Overview of regulation on medical devices in Japan

2. Amendment of the Pharmaceutical and Medical Device Act （PMD Act）

- Regulatory Authorities in Japan -

MHLW

(Ministry of Health, Labour and Welfare)

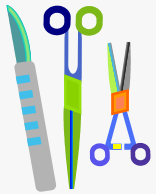
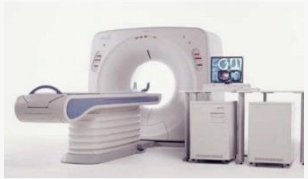
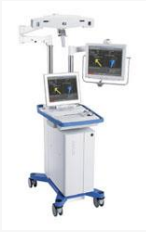
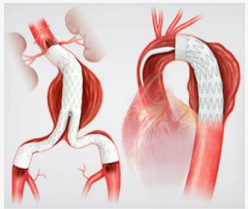
- Final Authorization of applications
- Publishing Guidelines
- Supervising PMDA Activities

PMDA

(Pharmaceuticals and Medical Devices Agency)

- Scientific Review
- Consultation on Clinical Trials etc.

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 Pharmaceutical and Medical Device Act（PMD Act）

Overview of Amendment of the Pharmaceuticals and Medical Device Act

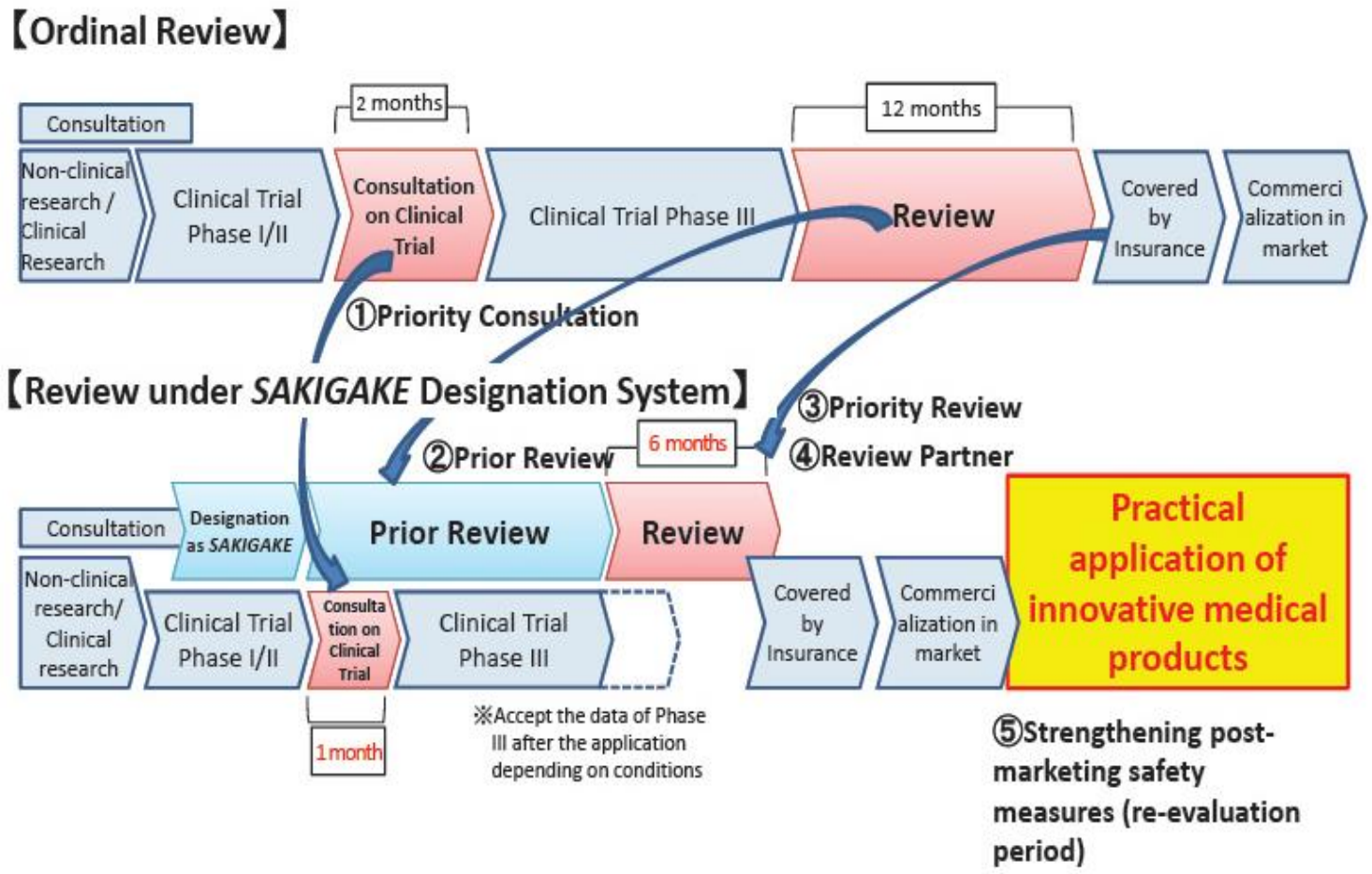
- Enacted on Nov., 2019; to be implemented within 1 year
- Following provisions are introduced for earlier and safer approval of medical devices and IVDs of high medical needs:
  1. SAKIGAKE designation system
  2. Priority review for specific uses, e.g. pediatric use
  3. Conditional early approval system
  4. Early realization of improvement in post-marketing

Overview of Amendment of the Pharmaceuticals and Medical Device Act

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

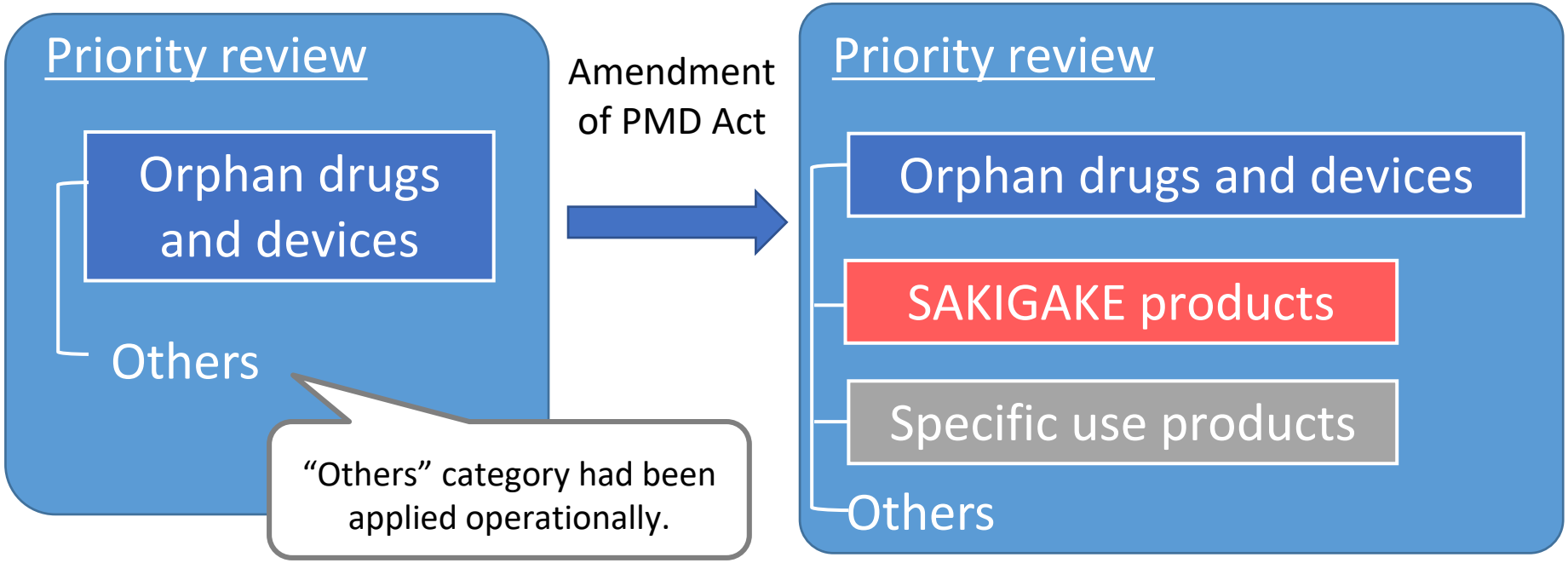
※These reviews are currently operated based on the administrative notification.

SAKIGAKE Designation System



Priority Review for Specific Uses

- Designation of “Specific use product” for highly unmet medical needs (e.g. pediatric use and AMR).
- Priority review (9 months) and other supportive measures are applied to designated products for specific use.



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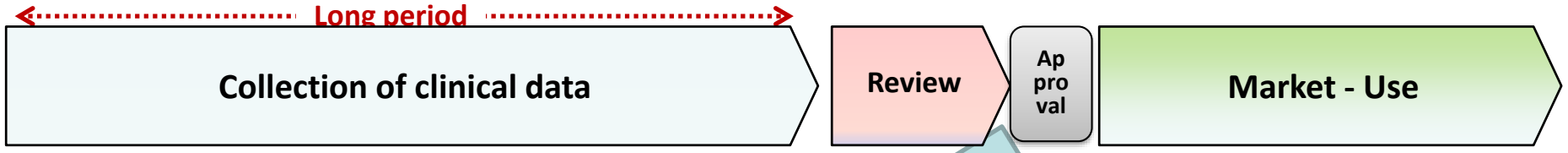
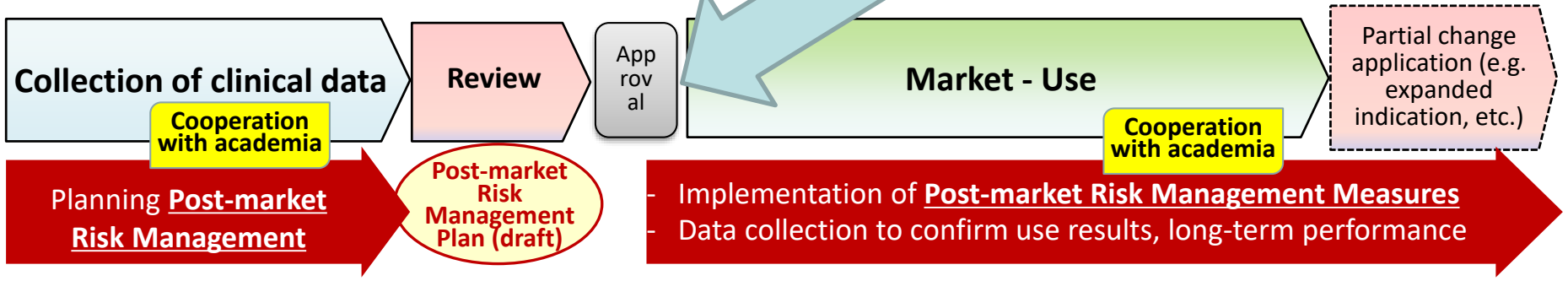
Conditional Early Approval System

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

Ordinary review



Conditional Early Approval for Innovative MDs



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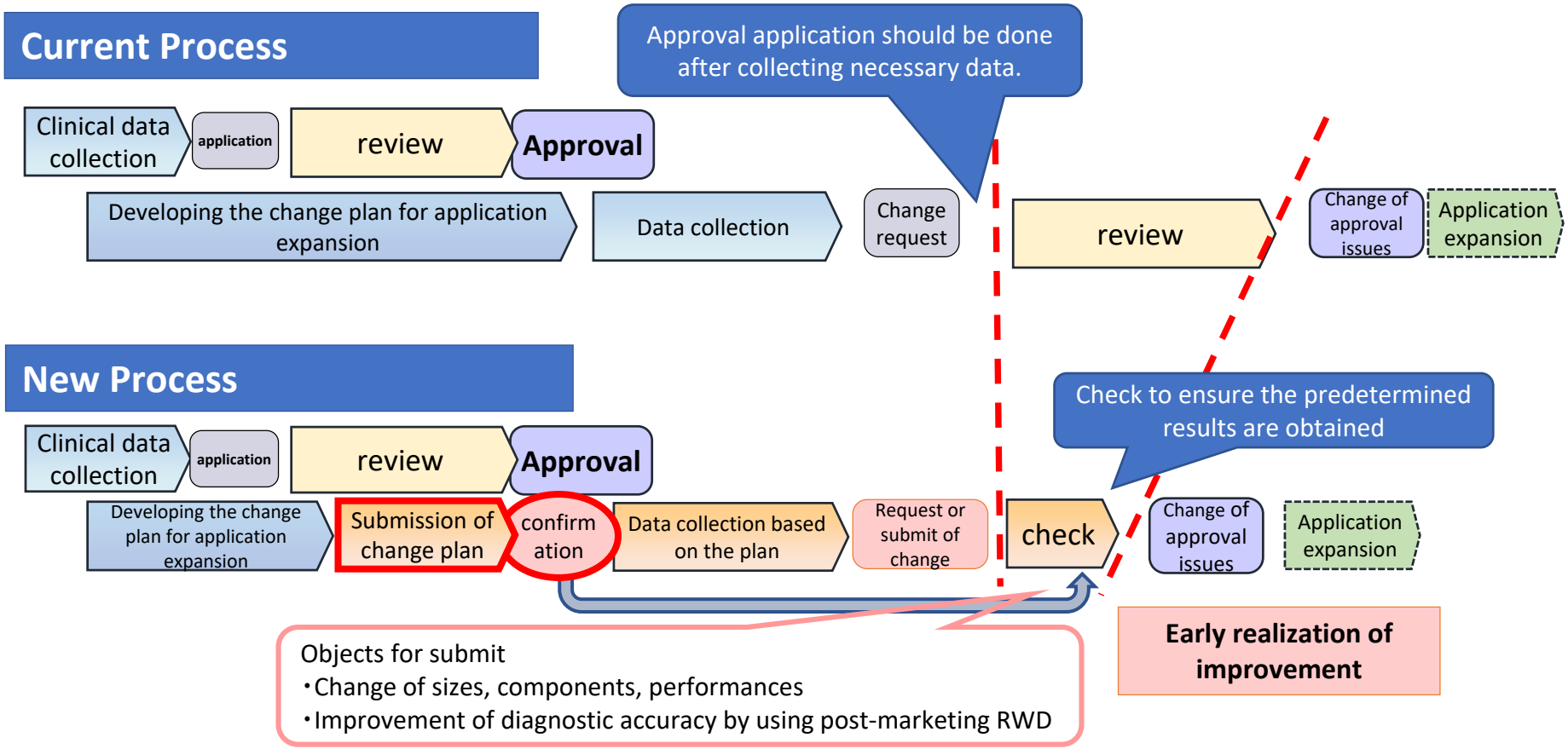
Early Realization of Improvement in Post-marketing

Post-Approval Change Management Protocol is introduced for medical devices to enable continuous improvements.



"Improvement Design within Approval for Timely Evaluation and Notice（IDATEN）"

Summary

- Following items are introduced by the amendment of the Pharmaceuticals and Medical Device Act in 2019
  - SAKIGAKE designation system
  - Priority review for specific uses, e.g. pediatric use
  - Conditional early approval system
  - Early realization of improvement in post-marketing

- MHLW/PMDA is encouraging development of innovative products

Thank you for your attention !!

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

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