IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

09:55 – 10:10

Japan

Masahiro Takahata

Head, Office of Regenerative Medicine Product Evaluation

Deputy Director, Medical Device Evaluation Division, Pharmaceuticals Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare

European Commission | European Union

厚生労働省 ひと、くらし、みらいのために Ministry of Health, Labour and Welfare

Regulatory Updates on Medical Devices in Japan

Day 2 – 28 March 2023

IMDRF Stakeholder Forum

Masahiro TAKAHATA

Head, Office of Regenerative Medicine Product Evaluation,
Deputy Director, Medical Device Evaluation Division,
Pharmaceuticals Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare of Japan

Today’s topics

- Marketing Approval in Emergencies
- SaMD Regulations
- PACMP (IDATEN)

Amendment of Pharmaceuticals and Medical Devices Act (PMD Act)

Aim

- **to enact a mechanism of early approval**
  conditional, time-limited marketing approval may be granted in emergencies if the efficacy of the pharmaceutical, medical device, or regenerative medicine is estimated and safety is confirmed
- to enact a mechanism of electronic prescriptions

Outline

1. Marketing Approval in Emergencies

New mechanisms to enable early marketing approval in emergencies.

(1) Eligibility of pharmaceutical, etc. to which the early approval is applicable

A pharmaceutical, etc. that needs to be used urgently in order to prevent the spread of a disease or other health hazard that could seriously affect the lives and health of people is eligible for early approval if there is no alternative existing treatment.

(2) Application standards

Assuming that safety has been confirmed, approval may be granted if the efficacy of the pharmaceutical, etc. has been estimated.

(3) Conditions and term of approval

As approval is granted at the early stage where efficacy has been estimated, conditions are provided to ensure the proper use of the pharmaceutical, etc. and restrictions are set in place that limit the duration of the approval to a short term.

(4) Special measures to expedite review process

Special measures are introduced for GMP inspections, national verifications as well as regulations on containers and packaging of the pharmaceutical, etc., in order to expedite review process for approval.

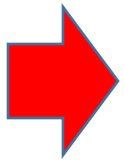
2. Creation of a mechanism for electronic prescriptions

Effective Date

The effective date (1. Marketing Approval in Emergencies): 20 May 2022

Marketing Approval in Emergencies

	Special approval of emergency
Target	Products - legally available in a country with a regulatory system - The system is equivalent to Japan
Efficacy and Safety	Efficacy: Confirmed Safety: Confirmed
Special Provisions	Require later - GMP inspection - National certification - Packaging etc.



	Marketing Approval in Emergencies *time limited approval
Target	All Pharmaceuticals, etc.
Efficacy and Safety	Efficacy: Estimated Safety: Confirmed
Special Provisions	Require later - GMP inspection - National certification - Packaging etc.

- Prevent the spread of a disease or other health hazard
- Seriously affect the lives and health of the people
- no alternative means in existence.

Fundamental reform of the Review system for SaMD

- Find out **seeds of cutting-edge SaMD at an early stage** and show the concept of the review process.
- Unify consultation services and establish a review system based on the characteristics of programmed medical devices.

Promote early approval of cutting-edge SaMD.

Consideration of starting designation program for innovative SaMD

- Priority consultation/screening, enhancement of preliminary evaluation, shortening of screening period by screening partner system

Pilot program of priority review for designated SaMD (September 2, 2022)

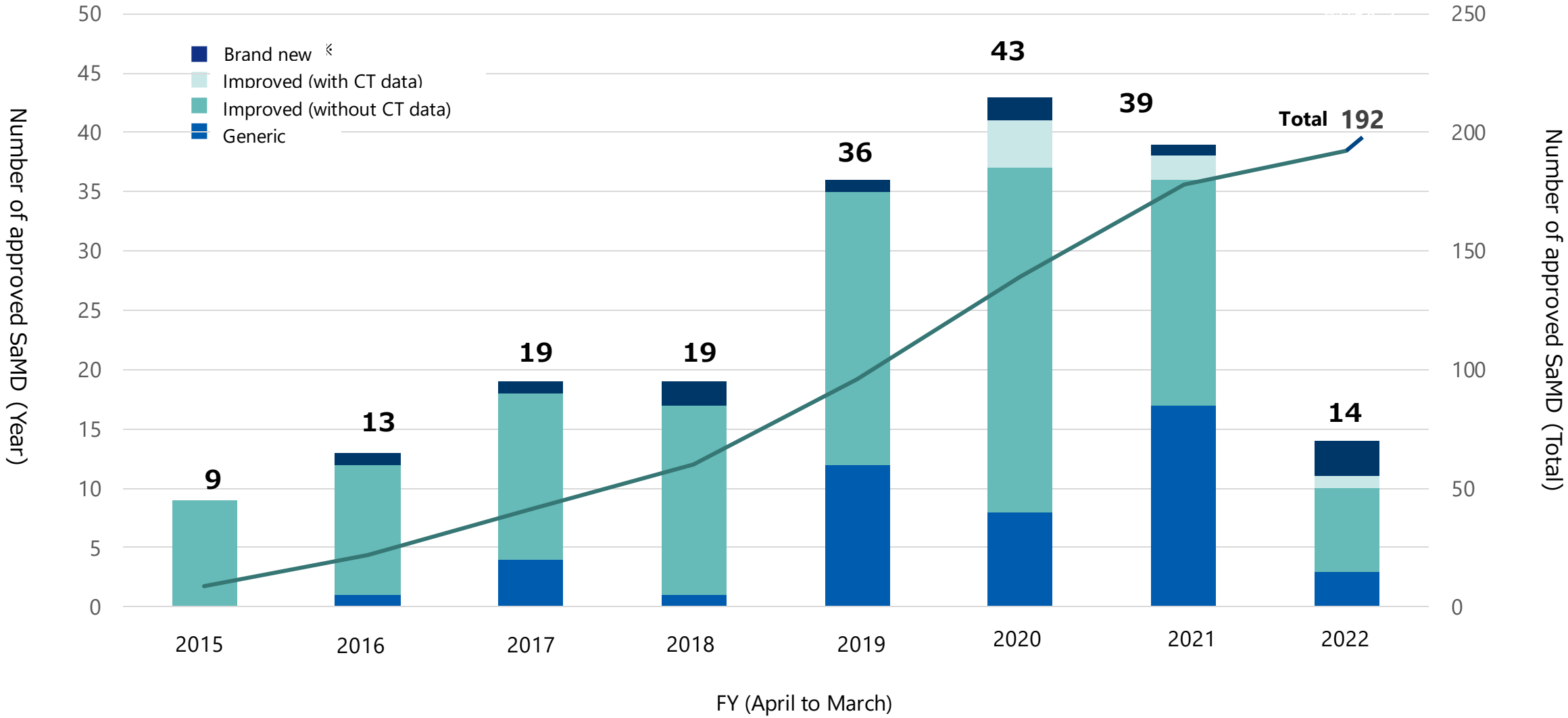
Designation criteria

(1): Innovatiion of therapeutic, diagnostic or prophylactic

(2): Clinical effectiveness for target disease

(3): intension and structure of company to develop the product prior to any region in the world

Number of Approved SaMD (not including the number of certification)



As of September 30, 2022

The number of approved/certificated SaMD

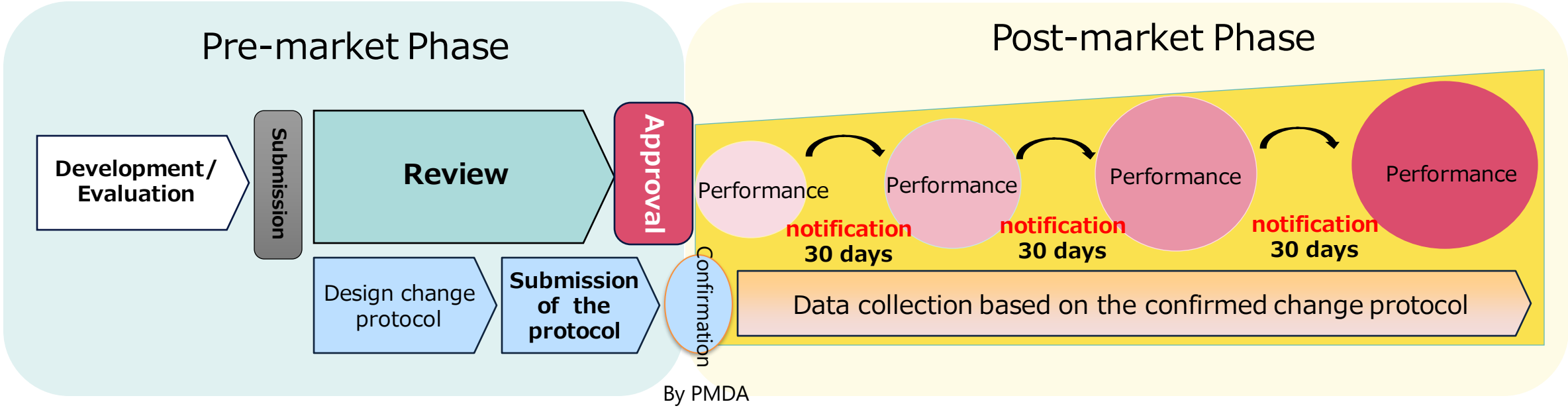
Non-SaMD	SaMD		
Not for diagnostics or treatment etc. corresponded to class I	**Class II**	**Class III**	**Class IV**
Programs intended for health control (ex: programs which give patients advice on meal or exercise for health maintainance and promotion) Educational program (ex: training programs for health care professionals) In-hospital business support program (ex: medical appointment system, electronic medical record) Programs corresponded to class I (ex: eye test, programs for color perception test)	**For treatment** Program for therapy planning support 61 Application for behavioral therapy 2 **For diagnostics** Program for computer assisted Imaging diagnostics 301 Program for computer assisted diagnostics other than imaging 85 Program for diagnostics assist for home use 2	Programmer for active implantable device 2 Program for gene mutation analysis 7	

as of September 30, 2022

Post-Approval Change Management Protocol (PACMP) for Medical Devices
IDATEN (Improvement Design within Approval for Timely Evaluation and Notice)

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

In force in 2020



4 change management protocols for medical devices are confirmed.

3 notification of change based on the protocols are filed.

Thank you for your attention

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

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