Japan's Regulatory Updates

16 February, 2023
26th GHWP Annual Meeting

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Today’s topics

- Marketing Approval in Emergencies
- SaMD Regulations
- PACMP

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.

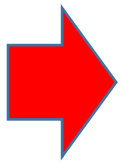
2. Creation of a mechanism for electronic prescriptions

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.

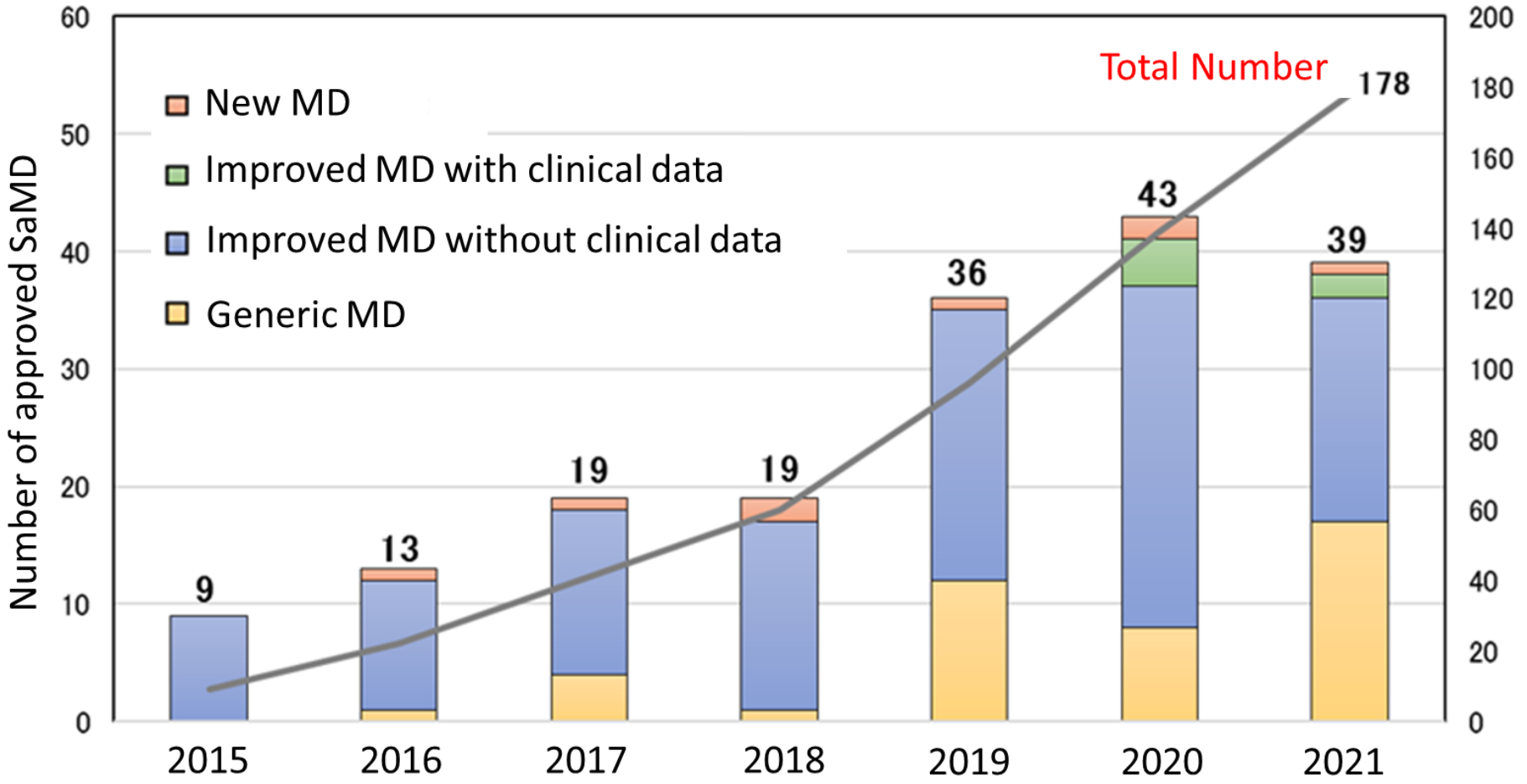
- Prevent the spread of a disease or other health hazard
- Seriously affect the lives and health of the people
- no alternative means in existence.

Fundamental reform of the Review system for SaMD
DASH 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.

The number of approved SaMD by MHLW



※ The number of certified SaMD isn't included in this figure.

As of 31st Mar. 2022

Overview of SaMD regulations

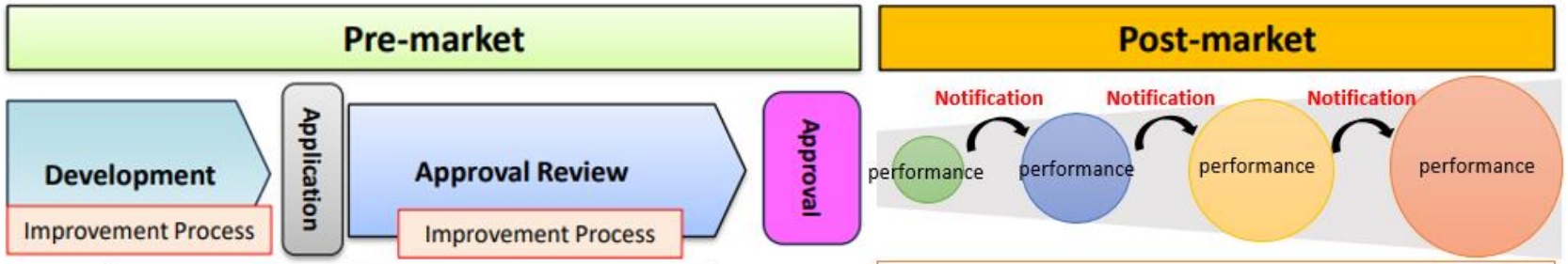
Non-medical device	Medical device		
Not for diagnostics or treatment etc. corresponded to class I	**Class II**	**Class III**	**Class IV**
Programs for personal healthcare （ex: programs which give advice on meal or exercise for health mentainance and promotion） Educational program （ex: training programs 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** Application for behavioral therapy — 1 item Program for therapy planning support — 61 items Program for active implantable device — 2 items		
	For diagnostics Program for computer assisted Imaging diagnostics — 263 items Program for computer assisted diagnostics other than imaging — 71 items Program for diagnostics assist for home use — 2items Program for gene mutation analysis — 7 items		

as of March 31, 2022

Post-Approval Change Management Protocol (PACMP)
～Challenge to accept “Plasticity” in regulation～

Approval review process which enables continuous improvement of performance of SaMD using AI was introduced in September, 2020.

- Changes of performance must be in one-direction (improvement) and be managed by MAH.
- MAH may develop a process which ensures such performance changes “Improvement Process”, and submit to the approval review process.



“Improvement Process” is developed and reviewed in the approval review process.

Post-market changes in line with the Improvement Process can be made by notification, which does not require approval process.

*Compliance is checked in the audit.

Thank you for your attention

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