Japan's Regulatory Updates

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Overview (Update for SaMD regulations in Japan)

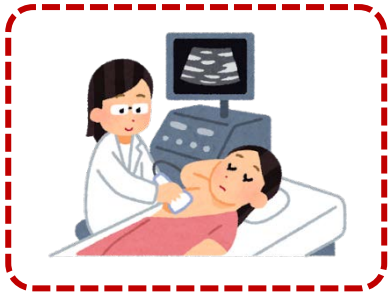
- Transition of regulations for SaMD in Japan
- Toward Further Practical Application and International Development of SaMD in Japan
- Contents of “DASH for SaMD 2”
- Development status of SaMD in Japan
- Two-step Approval scheme for SaMD

Transition of regulations for SaMD in Japan

before November 2014

program which determines performance of medical device

install



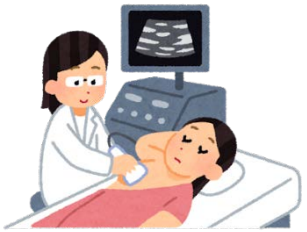
Medical device
（tangible object including software）

after November 2014

program which determines performance of medical device

Medical device
（software itself）

install



MD software classified as Class I
-> **NOT** to be regulated by PMD-Act

Toward Further Practical Application and International Development of SaMD in Japan

- **High expectations: utilization of SaMD** (Software as a Medical Device)

  ⇒ Need to make direction: efficient development of SaMD

  (A new field for all stakeholders in Japan)

- November 24, 2020

  MHLW: - **"DASH for SaMD"** (Package Strategy for Accelerating the Commercialization of SaMD)

  - Established Institutional infrastructure

  (efficiently obtain an approval under the PMD Act)

Toward Further Practical Application and International Development of SaMD in Japan

- Need to explore further
  - ✓ **Clarify various paths to commercialization**

    (two-step approval scheme for SaMD, SaMD for the general public)

    - Cooperation bw regulatory / insurance authorities to ensure predictability

      (approval to issurance)
  - ✓ **Accelerate R&D of Japan-originated SaMD, promote expansion into int'l markets**

- MHLW: Launched a new strategy **"DASH for SaMD 2" (**September 6, 2023)

  for the next five years

DASH for SaMD２（6 Sep., 2023）

- Organize and **publicize the two-step approval scheme for SaMD**
- **Develop guidelines** for approval review and marketing procedures for SaMD for the general public
- Promotion of **overseas acceptance of our review results** (ex English translation of review reports)
- **Subsidies for development funds** for SaMD developers
- **Support for SaMD developers** to actively business overseas

DASH for SaMD（24 Nov., 2020）

<Expand and continue>

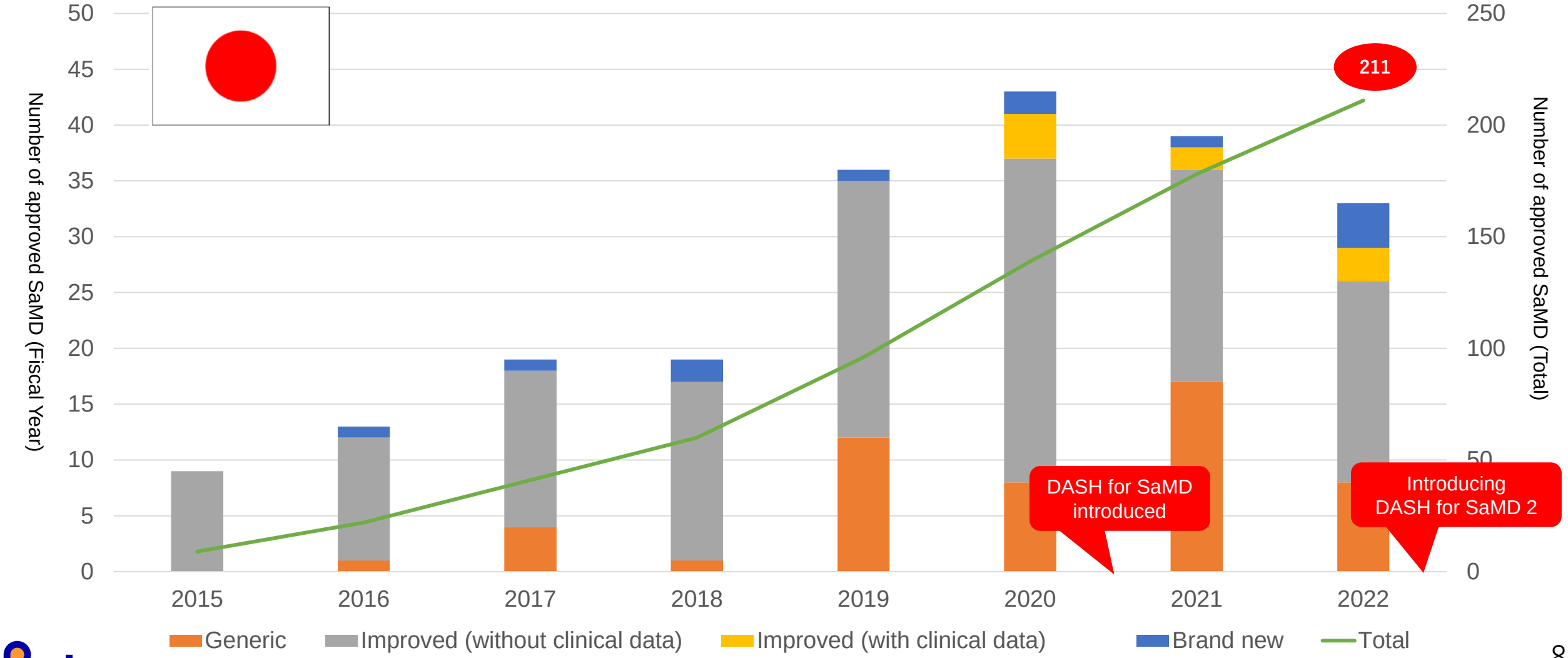
- **Setup an office to review SaMD** in MHLW and PMDA → Upgrade from office to Department for reviewing SaMD in PMDA
- Establishment of **SaMD centralized consultation service** → Establishment of SaMD-specific consultation service
- Next-generation medical device evaluation index, development guidance, audit points, and certification criteria formulation → (Continue)
- **Trial implementation of priority review**, etc. for innovative SaMD → (Continue)
- Promote **the use of IDATEN** (Improvement Design within Approval for Timely Evaluation and Notice) and **streamline procedures, etc.** → (Continue)

Goals for the next 5 years under DASH for SaMD 2

- Expansion of **more enhanced self-care options**
- Promotion of **better health for the public**
- **Exporting more and market acquisition** of innovative SaMD developed in Japan
- **Shorten the development cycle time of SaMD** by contributing to a smooth and efficient market introduction
- Realization of **efficient commercialization** of SaMD
- **Creation and early commercialization** of innovative SaMD
- **Smooth and efficient post-marketing performance improvement** of SaMD

Number of Approved SaMD
(not including the certificated SaMD)

As of March 2023



As of May 2023

Non-SaMD	SaMD			
		Class II	Class III	Class IV
● **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 at home**	for used exclusively at home 2		
	For diagnostics	for computer assisted Imaging diagnostics 322 for computer assisted diagnostics other than imaging 89 for gene mutation analysis 11		
	For treatment	Application for behavioral therapy 3	for therapy planning support 58 for Surgical Support 1 for controlling MD 3	

Two-step Approval scheme for SaMD

- Introduced in 2017.
- Mainly used for diagnostic MD

  When analytical performance is reliable, but clinical benefit of the analyte is not sufficient.

  ⇨ possible to claim that

  - First-step Approval “physiologic parameter “A” can be measured"
  - Second-step Approval "measuring A will lead to diagnose of specific disease B"

- **Expand to SaMD for the treatment by MHLW**

  In the case of SaMD for the treatment, if safety and a certain level of efficacy based on some evidences (including non-clinical trial) for Alleviation and improvement of specific symptoms caused by disease “C” can be confirmed

  - First-step Approval : granted at that point.
  - Second-step Approval: granted to claim the final clinical benefit.

Two-step Approval scheme for SaMD

SaMD for diagnosis

Reliable performance for analyzing physiologic parameter “A”

First-step Approval

After clinical benefit concreted (Post-marketing CT, RWE)

Diagnosis of disease “B” by analyzing physiologic parameter “A”

Second-step Approval

SaMD for treatment

Alleviation and improvement of specific symptoms caused by disease “C”

First-step Approval

After clinical benefit concreted (Post-marketing CT, RWE)

Treatment support and improvement of disease “C”

Second-step Approval

Thank you for your attention

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

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