IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

Japan Update

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Pharmaceutical and Medical Device Agency

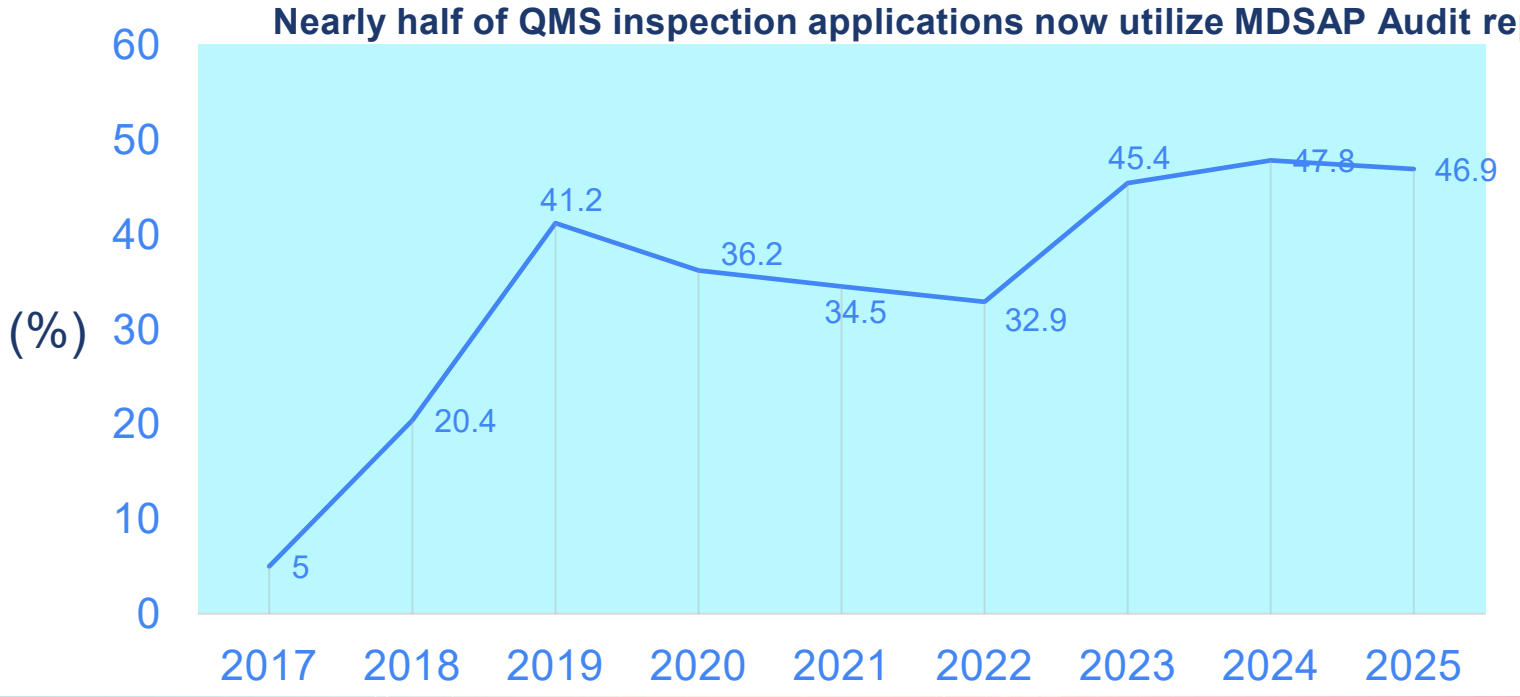
Today's Agenda

1. MDSAP in 2026
2. Japan's National Medical Products Database
3. Publication of Review Points for Home-Use SaMD to Detect Signs of Disease and Encourage Medical Consultation
4. Expanded Scope of Review Report Publication

1. MDSAP in 2026

Use of MDSAP Audit Reports in PMDA

Proportion of QMS Inspection Applications Submitted with MDSAP Audit Reports



Japan's MDSAP Outreach in Asia

2025–2026 regional touchpoints

6 activities

5 locations

FEB 2025
SEARN Workshop
Represented MDSAP | Sri Lanka

MAY 2025
ASEAN Seminar
Presented on MDSAP | Indonesia

MAR 2026
MDSAP Workshop
Co-hosted with US FDA | Singapore

JUN 2026
MDSAP Forum
Hosted in Kyoto | Japan

JUL 2026
ASEAN Seminar
Presented on MDSAP | Indonesia

AUG 2026
APEC CoE Workshop
Presented on MDSAP | Taiwan

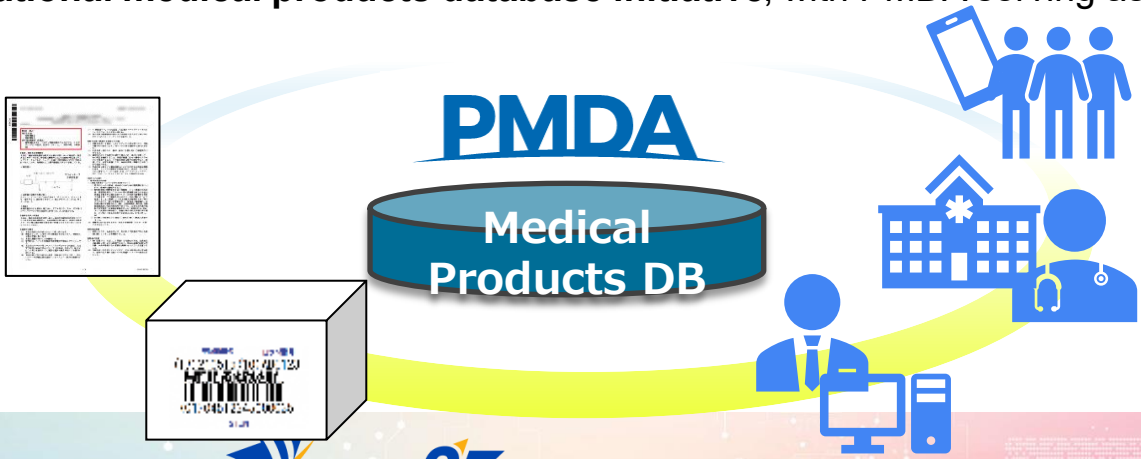
MDSAP Forum 2026 in Kyoto

30 countries, 130+ onsite participants, 90 online participants, 5-day program

2. National Medical Products Database

National Medical Products Database

- In many countries, barcode identification and product database for medical devices/pharmaceuticals have been developed to improve patient safety.
- In Japan, barcode labeling has been encouraged since the 1990s. However, it was not mandatory, and adoption was largely left to the voluntary efforts of manufacturers.
- To further enhance traceability and standardize implementation, GS1 barcode labeling on packaging was mandated in December 2022.
- However, unlike other countries, **no integrated national medical products database has been established**, and current efforts remain limited to voluntary private-sector initiatives.
- To promote the effective use of GS1 barcodes in healthcare settings, the Japanese government has **launched a national medical products database initiative**, with PMDA serving as the implementing body.



Scope and Data Items of National Medical Products Database

Scope of Medical Products DB

■As a prerequisite, products for which barcode labeling is mandated under the Pharmaceuticals and Medical Devices Act are subject to registration.

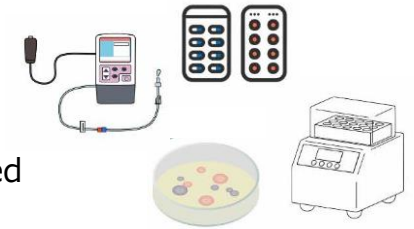
■Scope of Product DB:

✓**Prescription Drugs** ※OTC drugs are excluded

✓**Medical Devices**

✓**In Vitro Diagnostics (IVDs)** ※ General laboratory tests are excluded

✓**Regenerative Medical Products**



Data Items

■ **Main data items**

✓ **GTIN**

✓ **Basic product information** (e.g., brand name, marketing authorization holder)

✓ **Safety-related flag information** (e.g., poisonous / powerful / narcotic drug flags, etc.)

✓ **Product identification codes** (e.g., receipt system code, etc.)

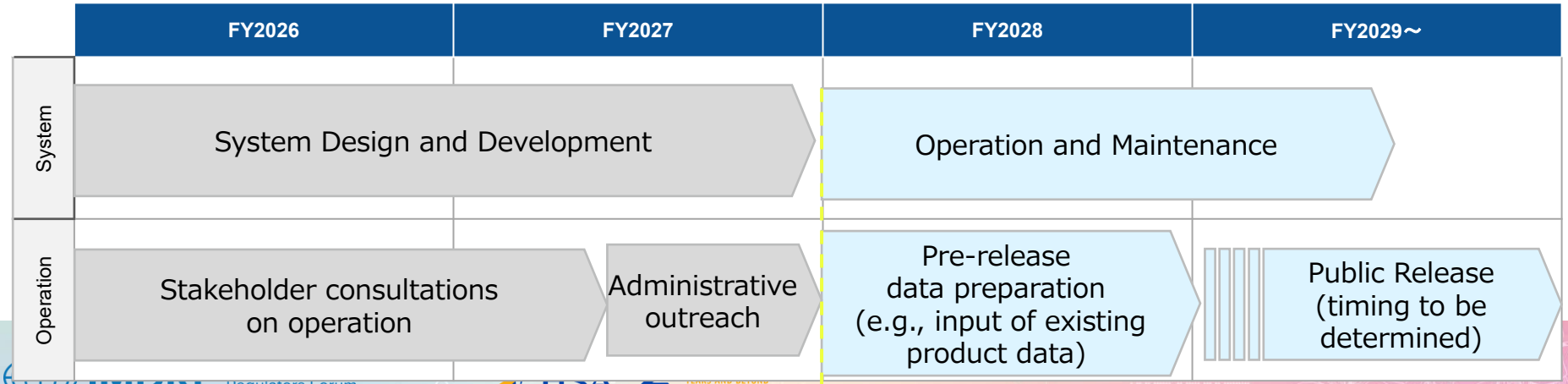
■**Phased Registration**

- **Prescription Drugs･Regenerative Medical Products** : Registration of all products will be mandatory.
- **Medical Devices･IVDs** : Registration will initially be required only for higher-risk products, taking into account the characteristics of each category. Based on the status of registration (e.g., coverage and data accuracy), the scope of mandatory registration will be progressively expanded to include lower-risk products.

Development Schedule

Schedule Overview

- System design and development will begin in FY2026, with phased operations planned from FY2028 onward (specific timing to be determined).
- From the start of operations, registration of GTIN and minimum product information will be required for all products, while full registration will be implemented through a risk-based phased approach.
- Once data preparation is completed, public release of the database will begin (timing to be determined).
- Details of the data registration period will be further coordinated with industry stakeholders and announced progressively.



3. Home-Use SaMD Review Points

Publication of Review Points for SaMD

DASH for SaMD 2 (2023/9/6)

- 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 (such as English translation of review reports
- Subsidies for development funds for SaMD developers
- Support for SaMD developers to actively business overseas

Review point for;

- Software for Peritoneal Dialysis Treatment
- Supporting Software for Dental Implant Treatment
- Software for Ophthalmic Surgery Treatment Planning
- Supporting Software for Detecting Lesion with Endoscopic Imaging
- Computer-Aided Diagnosis Program to Support Interpretation of Medical Images
- Home-Use SaMD to Detect Signs of Disease and Encourage Medical Consultation

DASH for SaMD (2020/11/24)

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

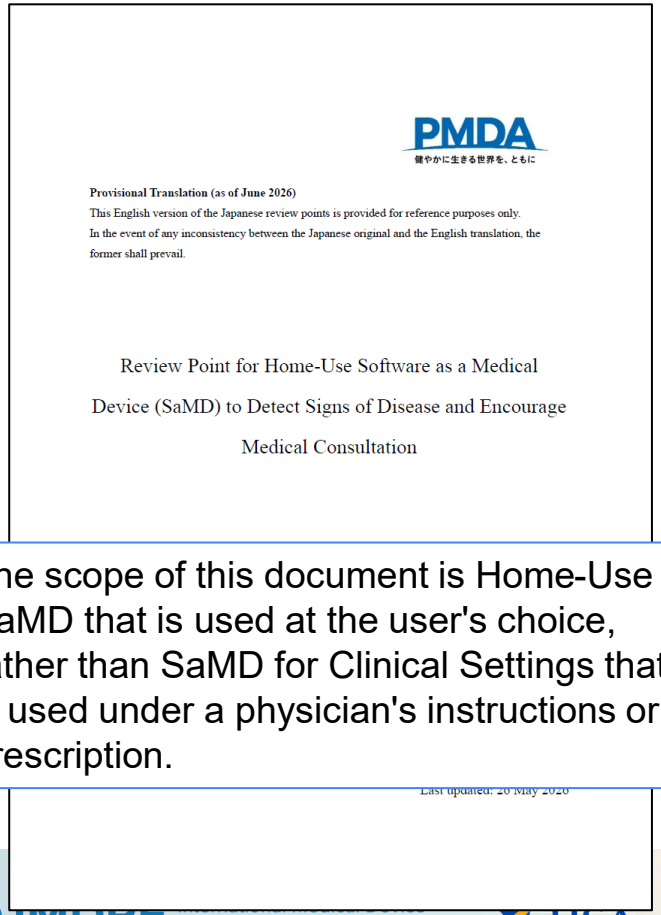
<Expand and continue>

- Upgrade from office to Department for reviewing SaMD in PMDA
- Establishment of SaMD-specific consultation service
- (Continue)
- (Continue)
- (Continue)

DASH for SaMD: DX(Digital Transformation) Action Strategies in Healthcare for SaMD(Software as a Medical Device)

English version available

Upcoming English Translation of Review Points for Home-Use SaMD



PMDA
健やかに生きる世界を、ともに

Provisional Translation (as of June 2026)
This English version of the Japanese review points is provided for reference purposes only.
In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Review Point for Home-Use Software as a Medical Device (SaMD) to Detect Signs of Disease and Encourage Medical Consultation

Last updated: 26 May 2026

The scope of this document is Home-Use SaMD that is used at the user's choice, rather than SaMD for Clinical Settings that is used under a physician's instructions or prescription.

Index

1. Products Covered by This Document
2. Definition
3. Description of the Product Under Application
4. Evaluation Package
5. Points of Consider for Study Design in Clinical Studies
6. Points to Consider in the Interpretation (Evaluation) of Study Results
7. Information Provision
8. Other Matters

The English version is expected to be released in September 2026

4. Expanded Scope of Review Report Publication

Expanded Scope of Review Report Publication

- In Japan, review reports have traditionally been published mainly for new medical devices.
- However, some improved medical devices supported by clinical evidence can have a significant impact on clinical practice and patient care.
- To enhance transparency and facilitate better understanding of regulatory decision-making, Japan expanded the publication of review reports to include certain improved medical devices requiring clinical evaluation.
- This initiative also aims to promote regulatory predictability and share scientific and regulatory considerations with stakeholders.
- The new approach became effective in FY2025.

Webpage for published review reports

Thank You!