Provisional Translation (as of July 2026) *

PSB/MDED Notification No. 0615-1
June 15, 2026

To: Directors of Prefectural Health Departments (Bureaus)

Director of Medical Device Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare,
(Official Seal Omitted)

Trial Implementation of Priority Review for Software as a Medical Device (SaMD)

In recent years, with the advancement of science and technology, the development of SaMD utilizing advanced digital technology, such as artificial intelligence, has been rapidly advancing and is expected to become a new diagnostic and treatment tool. Therefore, it is necessary to actively support the practical use of innovative SaMD originating in Japan.
“Grand Design and Action Plan for a New Form of Capitalism Follow-up” (cabinet approval on 7 June 2022) states that "a system for designating and conducting priority approval reviews for innovative SaMD will be introduced on a trial basis during FY2022, to promote the practical utilization of SaMD." Based on this, trial implementation of Priority Review for SaMD has been promoted since FY2022.
From the viewpoint of continually implementing these efforts, it has been decided to accept products subject to priority review on a rolling basis based on the following established requirements. After product designation, priority consultations and reviews, as well as concierge services and other support measures will be implemented on a trial basis. Please inform relevant organizations and businesses under your jurisdiction.

Note

1. Products Eligible for Designation

This designation system applies to SaMD and to tangible medical devices that incorporate software functions equivalent to those of medical devices. However, medical devices seeking marketing approval utilizing "Handling of Situations Requiring Submission of “Documents Related to Clinical Study Results” for Medical Devices (Responses Based on Measures Across Pre-and Post-Marketing Phases)” (PSEHB/MDED Notification No. 1117-1, PSEHB/PSD Notification No. 1117-1, dated 17 November 2017; hereinafter referred to as "Rebalance Notification") or "Handling of the Two-step Approval Based on the Characteristics of Software as a Medical Device" (PSB/MDED Notification No. 1116-2, dated 16 November 2023; hereinafter referred to as "Two-Step Approval Notification") shall be excluded from the scope of application.

2. Requirements for Designation

A medical device designated for priority review shall meet all three requirements set out below. Even when all three requirements are met, the product will not be designated, as a general rule, if another medical device with the intended use based on the same principle as the relevant medical device has already been approved.

For medical devices other than SaMD, the software function of the medical device and the effects from its function shall meet the Designation Requirements 1 and 2.

(1) Designation Requirement 1: Innovative Treatment, Diagnostic or Preventive Methods
As a general rule, the principle of SaMD, or of the software function incorporated in a medical device that is equivalent to a medical device function, is clearly different from that of existing medical devices (including SaMD; the same hereinafter) or standard treatment, diagnostic, or preventive methods. In addition, the proposed treatment, diagnostic or preventive methods shall be innovative.
Software intended to promote behavior change in patients themselves at home by providing the same content as the patient guidance conducted in clinical settings is, in principle, not considered innovative.

(2) Designation Requirement 2: Medical Usefulness in Relation to the Target Disease
The product shall fall under any of the following:

a. There is a high clinical need for a disease for which there is no existing treatment method that can serve as a definitive treatment or for which there is no existing preventive or diagnostic method. In addition, efficacy and safety are expected based on clinical studies (including clinical studies conducted with public competitive funding; the same shall apply hereinafter).

b. Based on clinical studies, efficacy and safety are expected to be higher than those of existing treatment, preventive or diagnostic methods.

c. Based on clinical studies, efficacy and safety are expected to be equivalent to or higher than those of existing treatment, preventive or diagnostic methods. In addition, the product is expected to provide particular medical benefits over existing treatment, preventive or diagnostic methods from the viewpoint of physical and psychological burdens on patients.

Examples include the following:

- Software function intended for disease treatment that can improve the cure rate and reduce complications
- Software function intended for disease diagnosis that can enable early detection of serious diseases
- Software function intended for disease diagnosis that detects signs of an impending attack and prompts actions to avoid falls
- Software function intended for disease diagnosis that has significantly high diagnostic performance compared with existing diagnostic methods and can improve the conventional clinical processes
- Software function intended for disease treatment that can enable dose reduction or temporary interruption of therapeutic drugs for intractable diseases
- Software function intended for disease diagnosis that can perform the same test and diagnosis as existing invasive test and diagnostic methods noninvasively

(3) Designation Requirement 3: Intent and Framework for Early Development and Filing for Marketing Approval in Japan Ahead of the Rest of the World
Emphasis is placed on early development in Japan, and marketing approval application

in Japan shall be filed ahead of, or at the same time as, the rest of the world (a marketing approval application filed within three months from the date of the first marketing approval application filed in any country will be deemed to have been filed simultaneously. However, in the case of countries where the filing date and the filing receipt date exist, the filing receipt date shall be the starting date of calculation.) In addition, a framework must be in place to file a marketing approval application by utilizing the SAKIGAKE Comprehensive Evaluation Consultation implemented by the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") and to respond to expedited approval review. A product will not be eligible for designation if similar products based on the same principle as the product requested for designation are already distributed worldwide.

3. Designation Procedure

(1) Call for Product Registration (Application for Registration of Products Requesting Designation)

To request designation of a product for Priority Review for SaMD, submit an application for registration to the Medical Device Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare (hereinafter referred to as "Medical Device Evaluation Division") using Form 1 (Application for Registration of Products Requesting Designation for Priority Review for SaMD) (including the Appendix). Submit Form 1 (including the Appendix) to kikisaisei@mhlw.go.jp by e-mail at any time.

(2) Hearings and Confirmation of Application Format

For products for which an application for registration has been submitted under (1), Medical Device Evaluation Division shall hold hearings at an appropriate time after submission of the application. Since the hearing will be conducted based on Form 1 (including the Appendix) and its supporting documents, supporting documents shall be submitted by e-mail at least one week prior to the scheduled date of the hearing.

(3) Preliminary Review

Medical Device Evaluation Division shall conduct "preliminary review" at any time to exclude products that clearly do not meet the requirements. The results of the preliminary review shall be reported to the applicant for registration as soon as possible after the completion of the review.

(4) Application for Designation, Evaluation and Designation

Applicants of candidate products that have passed the preliminary review shall submit Form 2 (Application for Designation of Priority Review for SaMD) and its supporting documents by the deadline designated by the Medical Device Evaluation Division.

After Medical Device Evaluation Division receives the application for designation and its supporting documents, the final review shall be conducted to determine whether the product should be designated based on PMDA's assessment. After confirming whether the product meets the designation requirements for each field, products that are deemed excellent will be selected. The results will be reported to the Pharmaceutical Affairs Council and published.

4. Priority Handling and Points to Consider for Designated SaMD

(1) Priority Consultation
Consult with PMDA regarding the timing of implementation of PMDA consultations, as the designated SaMD may receive priority handling over other medical devices.

(2) Enhancement of Preliminary Evaluation
To shorten the time from marketing approval application to marketing approval (within six months for all application categories), consult the concierge described below and, as a general rule, utilize SAKIGAKE Comprehensive Evaluation Consultation from the time of designation until marketing approval application.
In cases where the above preliminary evaluation is insufficient (including cases where the data required for the evaluation are not available or where the applicant has not adequately responded to the advice provided by PMDA), the time frame from marketing approval application to approval may be determined individually based on the evaluation status.

(3) Priority Review
As designated products are considered to fall under the category of "products which fulfill particularly high medical needs" specified in Article 23-2-5, Paragraph 10 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Law No. 145 of 1960), products designated under this system shall be handled as subject to priority review.

(4) Concierge Services
The person designated by PMDA as a person who is qualified to communicate and coordinate between the Ministry of Health, Labour and Welfare and PMDA (hereinafter referred to as "concierge") shall provide consultation regarding the management of the development process of relevant target products, as well as coordination with the applicant and relevant review departments.
After the designation, the person designated for the relevant product (hereinafter referred to as the "designation holder") will be informed, as soon as possible after designation, on the concierge assigned for the relevant product.

(5) Support Project for Promoting Consultations and Applications for Innovative Medical Devices
The designated product shall be subject to the Support Project for Promoting Consultations and Applications for Innovative Medical Devices.

5. Cancellation of Designation

Ministry of Health, Labour and Welfare may cancel the designation when it is identified that any of the following applies:

- When the product no longer meets any of the designation requirements specified in 2. above.
- When the results of studies conducted after the designation indicate that the particularly high level of usefulness assumed in Designation Requirement 2 is not expected.
- Significant software modification related to efficacy or safety of the product has been made after the designation or has been identified that such software modification is necessary.

- Consultation on development policy using Rebalance Notification and/or Two-Step Approval Notification was conducted with Medical Device Evaluation Division and/or PMDA.

When it becomes evident that the product no longer meets the designation requirements, the designation holder shall report to Medical Device Evaluation Division through the concierge. Medical Device Evaluation Division shall report to the Pharmaceutical Affairs Council promptly.
The priority handling listed in 4. shall be suspended on the date when Medical Device Evaluation Division receives the report that the product does not meet the designated requirements or when Medical Device Evaluation Division determines that the product does not meet the designation requirements. The designation shall be cancelled on the date of reporting to the Pharmaceutical Affairs Council.

6. Others

(1) Products composed of SaMD and concomitant devices (tangible medical devices) where the software plays a primary role in the medical device as a whole but requires concomitant devices to be used may be handled as equivalent to designated products under the Priority Review for SaMD if the concomitant devices have not been approved.

(2) Consultation on development policy using Rebalance Notification and/or Two-Step Approval Notification with Medical Device Evaluation Division and/or PMDA shall be reported promptly to the Medical Device Evaluation Division through the concierge for products designated in "Trial Implementation of Priority Review for SaMD" (PSEHB/MDED Notification No. 0902-2, Notification by Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated 2 September 2022) (in Japanese), "Trial Implementation of Priority Review for SaMD (No. 2)" (PSEHB/MDED Notification No. 0630-2, Notification by Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated 30 June 2023) (in Japanese), "Trial Implementation of Priority Review for SaMD (No. 3)" (PSB/MDED Notification No. 0821-1, Notification by Director of Medical Device Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, dated 23 August 2024) (in Japanese), and "Trial Implementation of Priority Review for SaMD (No. 4)" (PSB/MDED Notification No. 0804-1, Notification by Director of Medical Device Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, dated 4 August 2025) (in Japanese). Medical Device Evaluation Division shall promptly proceed with the designation cancellation procedure in accordance with 5.

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Form 1

Application for Registration of Products Requesting Designation for Priority Review for SaMD

To: Medical Device Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare

We hereby apply for registration of the following products requesting designation for Priority Review for SaMD

Date:

Description

Applicant		
Approval Number*1		
Name	Term Name*2	
	Brand Name*3	
Proposed Intended Use*4		
Structure, Components and Principles of Operation		
Proposed Directions for Use*5		
Compliance with the Designation Requirements*6		
Designation Requirement 1	Innovative Treatment, Diagnostic or Preventive Methods	
Designation Requirement 2	Medical Usefulness in Relation to the Target Disease	
Designation Requirement 3	Intent and Framework for Early Development and Filing for Marketing Approval in Japan Ahead of the Rest of the World	
Requested Hearing Date*7	First choice	
	Second choice	
	Third choice	
	Fourth choice	
	Fifth choice	
Contact Information	Name	
	Department Name	
	Telephone Number	
	Fax Number	
	E-mail	
Remarks*8		

NOTE: This form must be completed to fit in one A4 sheet. Content that does not fit in this form may be attached to the Appendix after stating so in the form. Include the product outline, clinical positioning of the product, the status and/or summaries of results of non-clinical studies and clinical studies, etc. conducted to date, information provided to the user by the product, and the presence or absence of similar products in foreign countries.

*1: Write the approval number if approval has already been obtained. Write "-" if not already obtained.
*2: Write "New" if there is no applicable term name.
*3: Write if already determined. Write the "code name" or "tentative name" if the brand name has not been determined. Write "(tentative name)" after the name.
*4: Describe the intended use planned at the time of submission.
*5: Describe the directions for use planned at the time of submission.
*6: Describe the product's compliance with the designation requirements based on clear evidence. A summary of clinical or non-clinical study results supporting its compliance may be attached to the Appendix.
*7: Describe the request for the hearing date and time as "Month, Day Hour-Hour", with each time slot being one hour.
*8: For any concomitant medical devices, describe the details in the Remarks section.

*This English version of the Japanese notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and this English translation, the Japanese text shall prevail. Actual applications must be submitted using the Japanese forms.

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(Appendix)

Summary of Compliance with Designation Requirements for Priority Review for SaMD

<table>
<tr><td colspan="2">Applicant</td><td></td></tr>
<tr><td rowspan="2">Name</td><td>Term Name[*1]</td><td></td></tr>
<tr><td>Brand Name[*2]</td><td></td></tr>
<tr><td rowspan="2">Designation Requirement 1</td><td>Innovative Treatment, Diagnostic or Preventive Methods[*3]
(The product shall meet all items)</td><td>□ As a general rule, the principle of SaMD, or of the software function incorporated in a medical device that is equivalent to a medical device function, is clearly different from that of existing medical devices (including SaMD; the same hereinafter) or standard treatment, diagnostic, or preventive methods. In addition, the proposed treatment, diagnostic or preventive methods shall be innovative. Software intended to promote behavior change in patients themselves at home by providing the same content as the patient guidance conducted in clinical settings is, in principle, not considered innovative.</td></tr>
<tr><td colspan="2">(Summary of determination that the product meets the above requirements)</td></tr>
<tr><td rowspan="2">Designation Requirement 2</td><td>Medical Usefulness in Relation to the Target Disease[*3]
(The product shall fall under one of the following)</td><td>□ a. There is a high clinical need for a disease for which there is no existing treatment method that can serve as a definitive treatment or for which there is no existing preventive or diagnostic method. In addition, efficacy and safety are expected based on clinical studies (including clinical studies conducted with public competitive funding; the same shall apply hereinafter).
□ b. Based on clinical studies, efficacy and safety are expected to be higher than those of existing treatment, preventive or diagnostic methods.
□ c. Based on clinical studies, efficacy and safety are expected to be equivalent to or higher than those of existing treatment, preventive or diagnostic methods. In addition, the product is expected to provide particular medical benefits over existing treatment, preventive or diagnostic methods from the viewpoint of physical and psychological burdens on patients.</td></tr>
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<tr><td rowspan="3">Designation Requirement 3</td><td>Intent and Framework for Early Development and Filing for Marketing Approval in Japan Ahead of the Rest of the World[*3]
(The product shall meet all items)</td><td>□ Emphasis is placed on early development in Japan, and marketing approval application in Japan shall be filed ahead of, or at the same time as, the rest of the world.
□ A framework must be in place to file marketing approval application by utilizing the SAKIGAKE Comprehensive Evaluation Consultation implemented by PMDA and to respond to expedited approval review.</td></tr>
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*1: Write "New" if there is no applicable term name.
*2: Write if already determined. Write "undetermined" or "tentative name" if the brand name has not been determined. Write "(tentative name)" after the name.
*3: Fill in the appropriate box.
*4: Include the planned timing to utilize the SAKIGAKE Comprehensive Evaluation Consultation implemented by PMDA.

(Other points to consider)
1 Form shall be A4 size.
2 If further explanation is required, documents may be attached to this form as Attachments.
3 This form shall be prepared on the premise that it will be used as published data.

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Form 2

Application for Designation of Priority Review for SaMD

Applicant		
Approval Number[*1]		
Name	Term Name[*2]	
	Brand Name[*3]	
Proposed Intended Use[*4]		
Structure, Components and Principles of Operation		
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Contact Information	Name	
	Department Name	
	Telephone Number	
	Fax Number	
	E-mail	
Remarks[*7]		

I hereby apply for the designation of Priority Review for SaMD as stated above.
Date:

Address: In case of a corporation, location of the head office
Name: In case of a corporation, its name and the name of its representative

To: Minister of Health, Labour and Welfare

NOTE: This form must be completed to fit in one A4 sheet. Content that does not fit in this form may be attached to the Appendix after stating so in the form. Include the product outline, clinical positioning of the product, the status and/or summaries of results of non-clinical studies and clinical studies, etc. conducted to date, and information provided to the user by the product.
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