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Japanese regulation and approval process for medical artificial intelligence (AI) as software as a medical device (SaMD): Current status and emerging challenges

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Abstract: The rapid expansion of artificial intelligence (AI) in healthcare has led to increasing adoption of AI-based software as a medical device (SaMD). This paper reviews the current regulatory and approval framework for AI-based SaMD in Japan and discusses emerging challenges associated with generative and adaptive AI technologies. Under the Pharmaceuticals and Medical Devices Act (PMD Act), software intended for diagnosis, treatment, or prevention is regulated as a medical device when classified as Class II or higher, and its clinical utility, performance, and safety are evaluated. While the number of approved AI-based SaMDs has increased, most existing products are task-specific systems supporting clinical decision-making within defined scopes. Recent advances in generative AI introduce novel regulatory issues, including difficulties in defining intended use, evaluating reliability of natural language outputs, and managing continuously evolving performance after market entry. These characteristics challenge conventional regulatory paradigms based on fixed product specifications. In light of ongoing international regulatory developments, key issues include clarifying scope of regulated functions, strengthening lifecycle and change management approaches, enhancing transparency, and improving user literacy. Developing adaptive regulatory frameworks that balance innovation, patient safety, and regulatory clarity will be essential for responsible integration of generative AI into healthcare.

***Keywords*:** medical device, Software as a Medical Device (SaMD), AI, regulation, Japan

1. Introduction

The use of artificial intelligence (AI) in the medical field has been advancing rapidly. Medical AI encompasses a wide variety of products, including software aimed at reducing the workload of healthcare professionals by assisting with in-hospital tasks such as managing consultation schedules and maintaining a medical device (MD), as well as software that supports physicians in deciding on treatment and diagnosis strategies by analyzing patient data. Furthermore, recent advancements in AI technology have been remarkable, and its potential seems limitless. However, from a MD regulation perspective, there are currently no special frameworks in place for evaluating or managing risks associated with generative AI technology.

This paper aims to summarize current Japanese regulatory and approval framework for AI-based software as a medical device (SaMD), identify emerging regulatory challenges posed by generative and adaptive AI, and discuss future directions for balancing innovation, patient safety, and regulatory clarity.

2. Current status of regulations for medical devices in Japan

In Japan, the Pharmaceuticals and Medical Devices Act (PMD Act) defines MDs as "machinery, equipment, *etc.* that are intended for use in diagnosis, treatment, or prevention of diseases in humans, or intended to affect structure or functioning of the bodies of humans". Furthermore, in the 2014 amendment to the PMD Act, it was clarified that standalone software is included in the scope of MDs.

As shown in Figure 1, hardware MDs are divided into four classes according to the risks they pose. Class I (lowest class) products, which pose little risk to humans even in the event of failures or malfunctions, do not require review by a regulatory body and can be manufactured by the manufacturer simply by notifying the Pharmaceuticals and Medical Devices Agency (PMDA). However, Class II and above products are required to undergo review by the PMDA or a third-party certification body. On the other hand, regarding SaMDs, Class I software is exempt from regulation under the

PMD Act, and Class II to IV software is subject to regulation under the PMD Act. Therefore, not all AI technology used in the medical fields qualifies as a MD; rather, only software used for diagnosis, treatment, or prevention, and possessing functionality equivalent to Class II to IV, qualifies as a MD.

The Ministry of Health, Labour and Welfare (MHLW) has issued guidelines and case examples outlining the criteria for determining whether software qualifies as a MD (*1,2*). Based on the documents issued by the MHLW, Figure 2 shows the fundamental concept used in Japan when determining whether software falls under the definition of a MD. When considering whether software qualifies as a MD or how to classify it, it is necessary

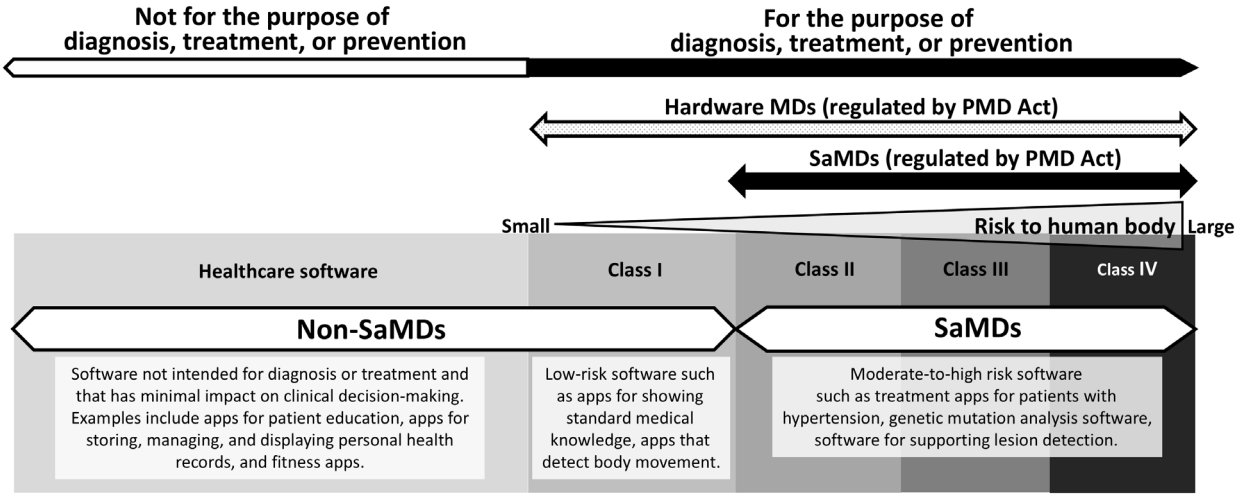

Figure 1. Japanese regulation of medical software. Software intended for diagnosis, treatment, or prevention that presents a moderate or higher risk to the human body (Class II or above) is regulated as SaMD. In contrast, low-risk software intended for purposes such as health management or information provision is categorized as non-SaMD. Thus, the scope of software subject to regulation is systematically defined based on the presence of a medical purpose and the level of risk. *Abbreviations*: MD, medical device; PMD Act, Pharmaceuticals and Medical Devices Act; SaMD, software as a medical device.

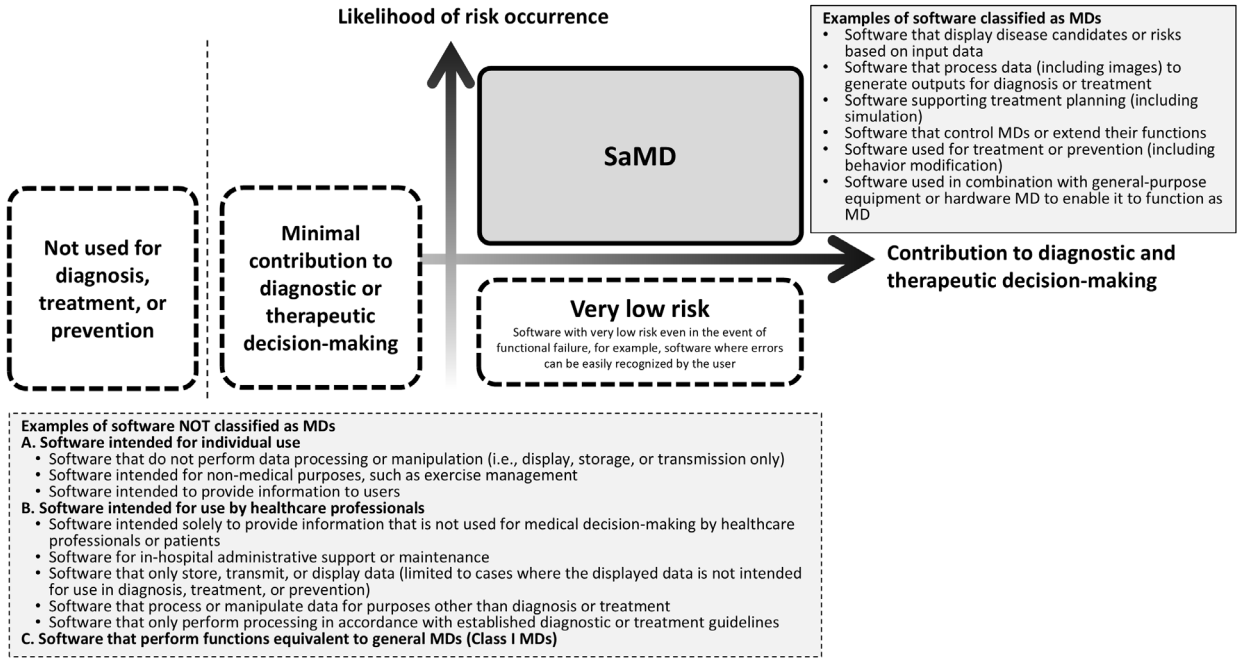

Figure 2. Fundamental concept for classification of SaMDs and non-SaMDs in Japan. Whether software is classified as SaMD is determined from two perspectives: the degree to which it contributes to diagnosis, treatment, or prevention, and likelihood of risk to the human body. Software with a low level of involvement in clinical practice—such as simple information display or storage functions—or software used for non-medical purposes is considered non-SaMD. In contrast, software that has functions influencing clinical decision-making, such as presenting diagnostic candidates or supporting treatment planning, is subject to regulation as SaMD. *Abbreviations*: MD, medical device; SaMD, software as a medical device.

to consider its contribution to the diagnosis, treatment, or prevention of diseases and the probability of overall risk to humans. This paper primarily focuses on software that is regulated as SaMD classified as Class II or higher under the PMD Act.

Figure 3 illustrates the process that software vendors must follow when introducing software intended for medical use in Japan. It is essential to first determine whether the product falls within the scope of MDs. If software qualifies as a MD, it must undergo review by a third party certification body or the PMDA.

Figure 4 shows the number of approved or certified SaMDs in Japan. This figure illustrates the number of SaMDs approved by the PMDA or certified by third-party certification bodies as of September 30, 2025. These counts were derived from the lists of approved and certified MDs on the PMDA website. Because use of AI in certified MDs is not publicly disclosed, this figure presents the total number of all approved or certified MDs, irrespective of whether they incorporate AI. While diagnostic SaMDs have been prevalent in the past, development of therapeutic SaMDs is progressing, expanding the scope of treatment beyond hypertension, alcoholism, depression, attention deficit hyperactivity disorder (ADHD), insomnia, and other conditions. Furthermore, there is an increasing number of over-the-counter (OTC) SaMDs (home-use SaMDs) that detect signs of diseases and are primarily intended for general consumer use. Variations of home-use SaMDs are also increasing, including SaMDs that notify users of signs of Sleep Apnea Syndrome (SAS) and hearing-related diseases. Development of gene mutation analysis SaMDs is also becoming more active within the field of diagnostic SaMDs.

3. Regulation of AI-based SaMDs in Japan

In the Japanese conventional regulation of MD, its principle, structure, materials, specifications, usage methods, and manufacturing methods for each MD should be stipulated in its regulatory application, and the regulatory body reviews whether its effectiveness, safety, and quality are guaranteed. In other words, the evaluation is conducted after defining what the MD is and how the MD is used. Furthermore, in evaluating MDs, it is necessary to demonstrate that the MD has clinically significant effectiveness and safety for the specific disease that it is intended for. Similarly, regulation for SaMDs also specifies the specifications and usage methods of the SaMDs and evaluates effectiveness and safety of the SaMDs for the intended use.

The number of approved SaMDs that utilize AI technology as their functions is increasing. As of September 2025, there are 51 approved SaMDs reviewed

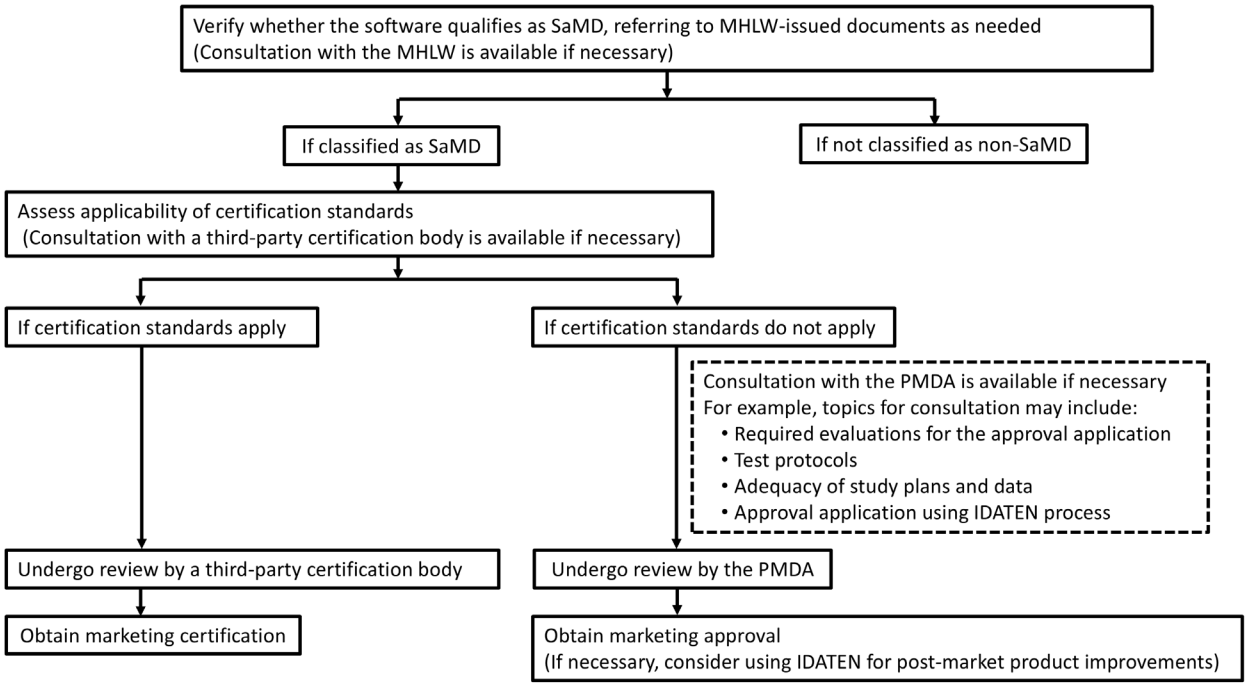

Figure 3. Process for introducing SaMD expected to be used in clinical practice into Japanese market. For software intended for clinical use, the first step is to determine whether it qualifies as SaMD. If it does, applicability of certification standards is then assessed. Where certification standards apply, the product undergoes review by a registered third-party certification body; where they do not apply, approval by the PMDA is required. In addition, the overall regulatory pathway to market entry is structured through a series of processes, including pre-submission consultations, consideration of study protocols, and use of mechanisms such as the IDATEN process. *Abbreviations*: IDATEN, Improvement Design within Approval for Timely Evaluation and Notice; PMDA, Pharmaceuticals and Medical Devices Agency; SaMD, software as a medical device.

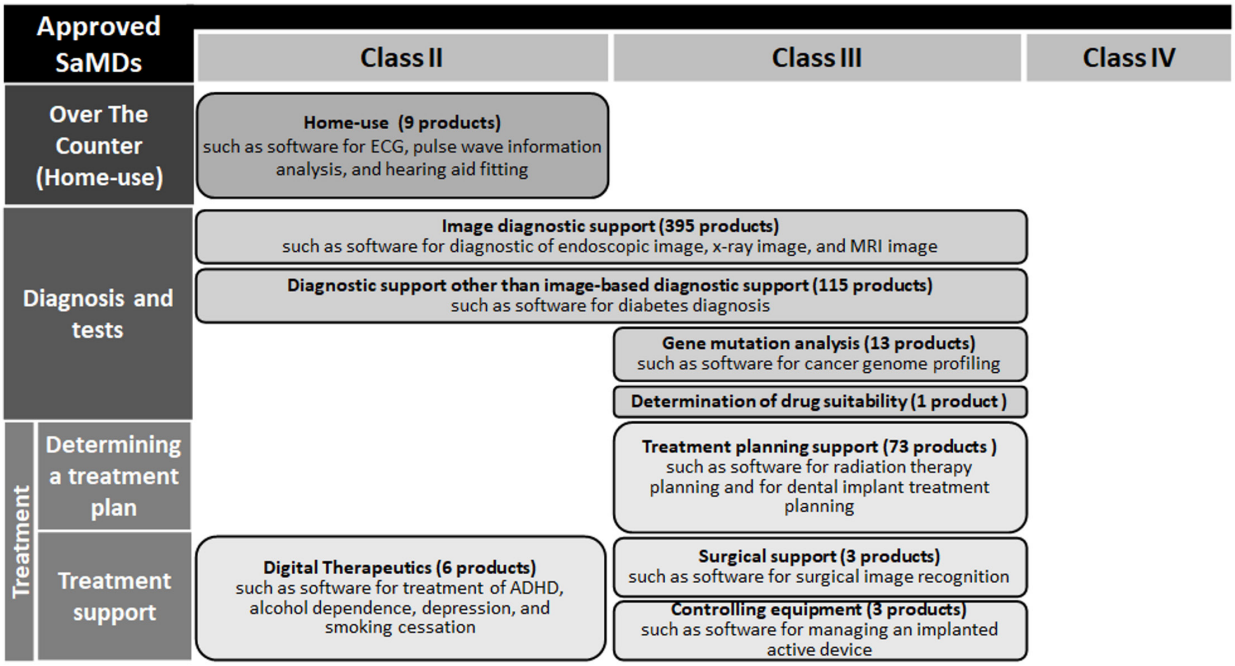

Figure 4. The number of approved SaMDs reviewed by PMDA and certified by third-party certification bodies in Japan as of September 30, 2025. Among SaMDs that have been approved or certified, image analysis and diagnostic support constitute the majority. At the same time, their applications have expanded to a wide range of purposes, including diagnostic support, treatment planning support, and therapeutic software. In terms of classification, most products fall into Class II and Class III, and range of application areas is also broadening to include lifestyle-related diseases, psychiatric disorders, and genomic analysis. In addition, a certain number of consumer-oriented products, such as home-use SaMD, have emerged, suggesting an expanding scope of application. *Abbreviations*: ADHD, attention-deficit/hyperactivity disorder; ECG, electrocardiogram; PMDA, Pharmaceuticals and Medical Devices Agency; SaMD, software as a medical device.

by the PMDA and published on the PMDA website as AI-based SaMD (*3*), which have functions using AI technology, regardless of whether they are initial approvals or approvals with partial changes to approved items. In addition, functions not intended to improve patient outcomes—such as those aimed solely at reducing workload of healthcare providers—are excluded from this list; therefore, it does not encompass all SaMDs that utilize AI.

Examples of AI-based SaMD include SaMDs that detect neoplastic lesions from endoscopic images (*4*), cerebral aneurysms, pulmonary nodules, and pneumonia, *etc*. from X-ray and MRI images, and SaMDs that indicate location and area of anatomical structures on surgical images during surgery. There are differences among countries in evaluation and regulation of AI-based MDs (*5*), but in Japan, regardless of whether AI technology is used, the general review criteria required for regulatory approval of SaMDs remain the same, and evaluation focuses on clinical utility (medical value that SaMD brings to diagnosis), clinical performance (SaMD's output information accuracy and processing capabilities), basic performance (whether it works as designed), and basic safety. When evaluating AI-powered functions, it is necessary to pay attention to bias in the evaluation dataset and relationship between the training dataset and evaluation dataset, in order to determine whether results can be generalized to the target population in actual clinical practice.

As shown in Table 1, several discussions have taken place in Japan regarding the regulatory approach to AI-based SaMD (*6-10*). To date, AI-based SaMD has generally been a product that supports physicians' diagnosis and treatment within a limited scope, such as specific diseases or medical fields, and discussions have focused on task specific identification AI specialized for specific tasks.

Generative AI technology capable of generating text, images, programs, and more has rapidly advanced. It is expected that Generative AI technology will greatly broaden the possibility of software functions supporting treatment and diagnosis, as it will be possible to generate diverse answers and creative content not dependent on specific tasks, in response to various questions from users in natural language or voice.

Until now, AI-based SaMDs that have been put into practical use have allowed for the clear definition of target functions, and accuracy of the output could be quantitatively evaluated using rule-based methods by outputting inference results as labels, and other structured outputs. However, with SaMDs that utilize generative AI technology, it may be difficult to limit scope of use due to the high versatility and multipurpose nature of generative AI, and there is greater ambiguity in determining accuracy of natural language output. Additionally, with the emergence of generative AI, it is anticipated

that SaMDs that utilize generative AI technology will continue to learn after marketing, and their functions and performance will change continuously. Considering these characteristics, it is necessary to clarify which functions should be regulated as MDs, the appropriate timeline for such regulation, and specific risks that should be evaluated in comparison with existing MDs.

Furthermore, since generative AI built on extremely large datasets may utilize AI models provided by external vendors, it is important to specify, on a product-by-product basis, the extent to which manufacturers of MDs should acquire information about the underlying AI models and extent of their responsibility for explanation, oversight, and management.

A hallucination, meaning AI's production of plausible but completely wrong or false information, is one of emerging challenges unique to generative AI. Some countermeasures for hallucination can be considered, such as Retrieval-Augmented Generation (RAG) techniques. In addition, users' literacy is critical so that users understand risks of hallucination, can interpret accuracy and appropriateness of information presented by AI-based SaMD, and can select information that they deem useful for diagnosis, treatment, or prevention of diseases. When formulating regulations, it is necessary to consider how to protect effectiveness and safety of patients while not hindering development of AI-based SaMDs which are valuable to patients and healthcare professionals.

4. Global context: Regulatory evolutions regarding MDs utilizing AI overseas

The adoption of medical AI is also thriving overseas, and its use in diagnosis and treatment is progressing, with medical AI such as Open Evidence's Deep Consult clinical decision support platform being widely put into practical use (*11*). As shown in Table 2, various countries have published guidance and are conducting demonstration projects on how to regulate MDs utilizing AI (*12-16,18-24*). In the United States, for example, discussion papers and guidance on regulation of AI/ML-based SaMD have been published since around 2020, and more recently, guidance on lifecycle management

Table 1. Main initiatives focused on MDs utilizing AI in Japan

Year	Main initiatives focused on MDs utilizing AI (*Ref.*)
2017–2018	The Subcommittee on Artificial Intelligence and its Applications in the Medical Field of the Science Board was held in 2017. The subcommittee discussed the characteristics, handling, and challenges of AI medical systems that utilize machine learning including deep learning. The report was published in 2018 (*6*).
2019	"Guidance for Evaluation of Artificial Intelligence-Assisted Medical Imaging Systems for Clinical Diagnosis" was published (*7*).
2020	With the amendment of the PMD Act, the IDATEN process has been introduced, which serves as a system to confirm change plans for MDs using AI technology, and other software based functions that are expected to be frequently improved after-market release (*8*).
2021	Based on the "Review of Approval and Review Processes Regarding SaMD" in the Regulatory Reform Council's "Implementation Items for Regulatory Reform in the Immediate Future", the PMDA has begun building a flexible and speedy review system and improving review standards to cope with frequently updated AI-based SaMD and other technologies (*9*).
2023	The Subcommittee on SaMD Utilizing AI and Machine Learning of the Science Board was held in 2023. The subcommittee considered how to reuse data, the conditions required for evaluation data, and how to review Adaptive AI intended to change performance after marketing and published the "Report on SaMDs Utilizing AI" (*10*).

Abbreviations: AI, artificial intelligence; IDATEN, Improvement Design within Approval for Timely Evaluation and Notice; MD, medical device; PMD Act, Pharmaceuticals and Medical Devices Act; PMDA, Pharmaceuticals and Medical Devices Agency; SaMD, software as a medical device.

Table 2. Examples of initiatives focused on MDs utilizing AI overseas

Region / Regulator body	Recent main initiatives focused on MDs utilizing AI (*Ref.*)
United States / U.S. Food and Drug Administration (FDA)	• Publication of guidance for AI-enabled device software functions and clinical decision support software (*12-14*) • Publication of AI Enabled MDs List (*18*)
United Kingdom / Medicines and Healthcare Products Regulatory Agency (MHRA)	• Publication of guidance for software and AI as a MD (*19,20*) • AI Airlock sandbox (*16*)
European Union (EU)	• Publication of document for MDAI (*21*)
Republic of Korea / Ministry of Food and Drug Safety (MFDS)	• Publication of guidance for AI/generative AI-based MDs (*15,22-24*)

Abbreviations: AI, artificial intelligence; MD, medical device; MDAI, medical device artificial intelligence.

and marketing submission of AI-enabled device software functions was published in 2025 (*12*). Also, guidance on change management plans for AI software was published in August 2025, a development that is presumed to consider the adoption of Adaptive AI (*13*) , and guidance on Clinical Decision Support Software was published in January 2026 (*14*), indicating that proactive regulatory reforms are underway. Guidance on Clinical Decision Support Software provides developers of medical AI with guidance on scope of regulation and points to consider when introducing such systems to the market, and it is expected to promote their practical application. Efforts in various countries show a trend toward adopting a management approach that encompasses the entire product lifecycle from pre-marketing to post-marketing, including change management. With regard to guidance on MDs using generative AI, the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea published guidance in January 2025 (*15*).

Furthermore, sandbox projects are being implemented in various countries. In the United Kingdom (UK), for example, the AI Airlock Sandbox Program involves regulatory authorities, healthcare professionals, and development companies collaborating to identify regulatory gaps and conduct demonstration projects to resolve issues to enable safe and rapid introduction of AI technology into healthcare settings (*16*). In Utah, the United States (USA), based on the "Artificial Intelligence Regulatory Sandbox Act" enacted in 2024, a demonstration program is being implemented to introduce autonomous AI for prescription updates for chronic diseases, advancing efforts to enable AI-driven prescription update decisions for patients with chronic illnesses (*17*). These sandbox strategies tell us that countries intend, when regulating MDs using generative AI, to first accumulate a certain level of usage experience in controlled environments and then appropriately identify challenges and examine corresponding countermeasures.

5. Discussion

As described above, discussions are ongoing in various countries regarding the appropriate regulatory frameworks for SaMD incorporating AI into their functionality. In Japan, deliberations on generative AI have also recently begun within a research project commissioned by the MHLW. Taking into account international developments as well as discussions within the research group, four major issues can be identified as requiring further consideration in Japan.

First, there is a need to clarify the scope of AI-based software that should be regulated as SaMD. As noted above, the MHLW has already published several documents outlining the scope of software subject to MD regulation. It is considered that fundamental principles applied to conventional software-based MDs are also applicable to AI-based MDs. However, providing more detailed and specific guidance, particularly for MDs utilizing AI—especially generative AI—is expected to facilitate practical development and implementation for software developers.

Second, there is the issue of the regulatory approach under the PMD Act. For SaMD that may change after market entry, regulatory frameworks such as IDATEN, which manage post-market modification plans, have already been introduced. In addition to expanding regulations that take such change management into account, it is also necessary to re-examine the conventional regulatory paradigm, which assumes fixed product specifications. This includes considering new approaches to premarket review that anticipate product modifications, as well as lifecycle-oriented regulatory oversight spanning both premarket and post-market phases.

Third, attention should be given to initiatives aimed at improving information provision to users and enhancing user literacy. Currently, public disclosure regarding approved or certified MDs mainly consists of package inserts and lists of approved or certified MDs. However, there is an increasing need to consider providing more detailed information on device functionality and to promote initiatives that enhance literacy of users. The importance of transparency in the disclosure of evidence for SaMD has also been highlighted, particularly by the clinical community (*25*), and further discussion among industry, government, and academia will be necessary moving forward.

Fourth, there is a need to establish mechanisms that enable empirical validation. In Japan, there is a "regulatory sandbox system" under jurisdiction of the Cabinet Office for the social implementation of new technologies and business models, but there is no sandbox system specific to MDs utilizing AI. The overseas initiatives can serve as a reference when considering regulations on AI-based SaMD utilizing generative AI technology in Japan, and it is hoped that practical considerations will progress in Japan in the future, through use of sandbox systems and other similar mechanisms.

6. Expectations for the future introduction of medical AI

To facilitate the digital transformation of healthcare through medical AI as a MD in Japan, it is necessary to clarify the scope of regulation and scope of responsibility of manufacturers and distributors of MD. So as not to fall behind other countries, it is critical to promptly organize regulatory frameworks that take into account product changes after marketing. The MHLW is seriously working on facilitating AI in medical practice. Placing excess responsibility for ensuring effectiveness and safety of AI-based SaMDs on manufacturers and distributors of MDs would hinder development and deployment of

such devices. It is also necessary to nurture literacy of users regarding use of AI-based SaMDs. Versatile AI that utilize adaptive learning may urge MHLW and regulators to reform and renovate regulatory algorithms. Carefully designed regulatory frameworks for generative AI-based SaMDs are essential to balance between innovation and patient safety. In this context, Japan's experience in SaMD review may provide valuable insights for future regulatory discussions through multistakeholder collaboration.

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