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The Enactment and Implementation of Korea's Digital Medical Products Act: A Comparative Study Exploring Policy Implications

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ABSTRACT

Background: With the rapid expansion of the digital healthcare industry, advanced medical technologies, including artificial intelligence-based diagnostic software and digital therapeutics, are being introduced at an unprecedented pace. However, existing regulatory frameworks have encountered substantial challenges in adequately addressing the unique characteristics of these products. In response, Republic of Korea (South Korea) has enacted the world's first "Digital Medical Products Act" and established an integrated regulatory system tailored to this emerging domain.
Methods: This study undertook a comparative analysis across three regulatory dimensions—scope of application, approval procedures, and reimbursement policies—by examining corresponding legal frameworks in the United States, Germany, the United Kingdom, and Japan. In addition, qualitative interviews were conducted with three experts, each possessing more than 10 years of experience in digital healthcare regulation, to capture early field-level perspectives and identify areas that require refinement.
Results: The findings demonstrated a generally positive assessment of the institutional significance of the new system, while also highlighting several limitations, including the absence of detailed evaluation criteria and the potential for confusion among stakeholders in practical implementation.
Conclusion: Based on these results, this study provides policy implications to guide the future advancement and refinement of regulatory frameworks for digital medical products.

Keywords: Medical Device Legislation; Software as a Medical Device; Digital Health

INTRODUCTION

With the advancement of medical technology, artificial intelligence (AI) and big data are increasingly being integrated into healthcare, thus driving a rapid paradigm shift in medical service delivery. Consequently, novel products such as digital therapeutics (DTx) and AI-

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Disclosure

The authors have no potential conflicts of interest to disclose.

Author Contributions

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based diagnostic software have emerged, expanding the traditional scope of medical devices. In response, the concept of "innovative medical devices" has been introduced to address the limitations of conventional medical device categorization and to facilitate the timely introduction of technology-driven products into the market.

Notably, the number of innovative medical devices designated in Korea increased from 8 in 2020 to a total of 82 in 2024, representing more than a nine-fold increase.[1] In comparison, the number in the United States rose from 151 to 834 during the same period, corresponding to approximately a 5.5-fold increase (**Fig. 1**).[2] Despite this growth, the current regulatory framework continues to face structural limitations in effectively managing the emerging categories of medical products.

Consequently, the regulatory landscape for medical devices is undergoing significant reorganization worldwide. For example, South Korea implemented the Digital Medical Products Act on January 24, 2025, reflecting the rapid growth of the digital healthcare industry.[3] This legislation was introduced to address the existing Medical Device Act and Pharmaceutical Affairs Act's limitations, and systematically and effectively manage the categories of products incorporating digital technologies.[4]

A notable feature of the Act is the establishment of a unified legal framework that encompasses digital medical devices, digital combination pharmaceuticals, and digital medical and health support products, while also introducing a customized regulatory system tailored to the specific characteristics of each product category. Nevertheless, given the law's early implementation stage, continued refinement of its detailed provisions and improvement of its operational mechanisms are imperative.

This study therefore undertakes a comparative analysis of analogous legal frameworks in the United States, Germany, the United Kingdom, and Japan, with a particular emphasis on South Korea's Digital Medical Products Act. Furthermore, it seeks to identify future directions for improvement by incorporating field-level insights obtained through qualitative interviews with experts.

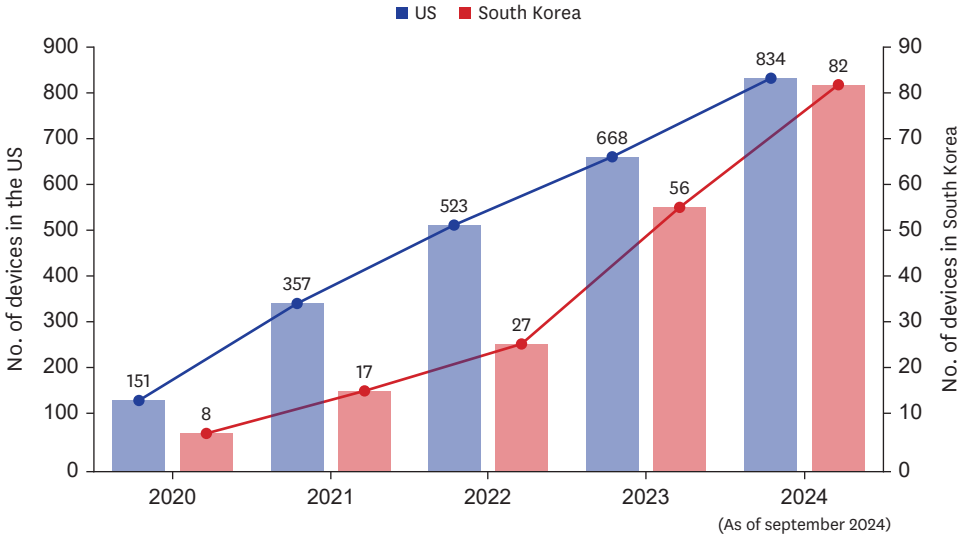

Fig. 1. Annual progression of cumulative innovative medical device designations in the US and Korea.

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METHODS

Comparative analysis of regulatory frameworks in major countries

The comparative analysis focused on the United States, Germany, the United Kingdom, and Japan—countries that have actively promoted the institutionalization of digital healthcare and represent diverse regulatory approaches.

Data for this analysis were collected primarily from national laws and regulations, official publications issued by government and regulatory agencies, and relevant academic literature. To capture the most recent institutional developments, media reports citing official government announcements were also referenced. The inclusion criteria for data selection were as follows:

1. Legislation must pertain to digital medical devices or software-based medical products and have been enacted or revised after 2016.
2. Sources must be primary documents formally published by government authorities or regulatory agencies.

Data collection was conducted through the official websites of regulatory agencies in each country (e.g., U.S. Food and Drug Administration [FDA], German Federal Institute for Drugs and Medical Devices [BfArM], UK Medicines and Healthcare products Regulatory Agency [MHRA], and Japan's Pharmaceuticals and Medical Devices Agency [PMDA]). Non-official sources such as personal blogs or opinion-based materials were excluded.

To move beyond a descriptive listing of systems, a structured comparative framework was developed, centered on the following three analytical dimensions:

1. Scope of application: range of products covered under each country's legal framework.
2. Approval procedures: legal basis, review processes, flexibility, and staged approaches.
3. Insurance coverage: listing procedures, evaluation criteria, and decision-making structures.

They represent core elements commonly considered in the design of regulatory systems worldwide. Based on this framework, the study systematically compared and analyzed structural differences as well as areas of convergence across the legal systems of the selected countries.

Qualitative interviews with experts

As the Digital Medical Products Act remains in its early implementation stage, it is not yet feasible to empirically evaluate its outcomes. Moreover, literature-based comparative analysis has inherent limitations in providing concrete policy design directions. To address these challenges, qualitative interviews were conducted with three experts possessing more than 10 years of regulatory experience in the digital healthcare sector. The participants represented the diverse perspectives of regulatory authorities, industry, and academia.

The interviews were conducted in person in July 2025, with each session lasting approximately one hour. A semi-structured format was employed, guided by a pre-distributed questionnaire. The primary topics of inquiry included the institutional significance of the Digital Medical Products Act, the adequacy of detailed regulatory standards, and future directions for improvement. After obtaining the written informed consent of all participants, the interviews were audio-recorded for research purposes, transcribed verbatim, and subsequently subjected to thematic categorization and qualitative analysis.

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Ethics statement

The present study protocol was reviewed and approved by the Institutional Review Board of Severance Hospital (approval No. 2025-1108-003). Written informed consent was obtained from all participants prior to the interviews, and anonymity and confidentiality were assured.

RESULTS

Comparison and analysis of digital medical device legislation in major countries

The major regulatory frameworks in the United States, Germany, the United Kingdom, Japan, and Korea are summarized in **Table 1**.

Scope of application

While all major countries incorporate software as a medical device (SaMD) and AI-based products into their regulatory frameworks, the specific scope of application demonstrates notable variation. In the United States, AI-based diagnostic software, DTx, and remote monitoring devices are regulated under the category of innovative medical devices.[5] Germany, through its Digitale Gesundheitsanwendungen (DiGA) program, has extended the scope to encompass not only medical devices but also Class I, IIa, and IIb products.[6,7] The United Kingdom has introduced detailed guidance specifically addressing software, AI-based applications, and digital mental health products.[8] Similarly, Japan has revised its legal framework to explicitly include software within the definition of medical devices.[9]

Table 1. Legal and regulatory frameworks for digital health products in major countries: a comparative analysis of policy trends

Regulatory dimension	United States	Germany	United Kingdom	Japan	Korea
Relevant laws and regulatory programs	· 21st Century Cures Act (law, enacted 2016) · MCIT (program, repealed 2021) · TCET (program, launched 2024) · FDORA (law, enacted 2022)	· DVG (law, enacted 2019) · DigiG (law, enacted 2024)	· MMD Act (law, enacted 2021) · Medical Devices Regulatory Reform Roadmap to implementation (program, launched 2024) · Scientific Dialogue Programme (program, launched 2025)	· PMD Act (law, amended 2014) · DASH for SaMD (program, launched 2020) · DASH for SaMD 2 (program, launched 2023)	· Digital Medical Products Act (law, enacted 2024)
Policy objective	Accelerated approval and reimbursement support for innovative medical devices	Expedited reimbursement of DTx	Development of an independent regulatory framework for medical devices	Accelerated market entry of SaMD	Legal definition and regulatory system for digital medical products
Scope of application	SaMD and AI-based innovative medical devices, remote monitoring devices	Low-risk Class I, IIa, and IIb products	Software, AI, digital mental health products	SaMD	SaMD, AI-based medical devices
Approval procedures	· Fast-track review through the Breakthrough Devices Program · Expanded use of RWE	· DiGA Fast-Track review within 3 mon · One-year RWE evaluation after approval	Planned integration of RWE in regulatory pathways (2025)	· Two-step approval system · Simplified review for selected Class II SaMD	· Tailored regulatory framework based on product characteristics · RWE-based evaluation introduced
Insurance coverage application	· Limited to Breakthrough Devices · TCET annual limit of 5 approvals	· Reimbursement granted via DiGA Fast-Track · Continued coverage based on RWE	NA	NA	Provisions for expedited reimbursement review included

MCIT = Medicare Coverage of Innovative Technology, TCET = Transitional Coverage for Emerging Technologies, FDORA = Food and Drug Omnibus Reform Act, DVG = Digitale Versorgung-Gesetz, DigiG = Digital-Gesetz, MMD = Medicines and Medical Devices, PMD = Pharmaceuticals and Medical Devices, DASH = Development of Advanced Software for Healthcare, SaMD = software as a medical device, DTx = digital therapeutics, AI = artificial intelligence, RWE = Real-World Evidence, DiGA = Digitale Gesundheitsanwendungen, NA = not applicable.

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Approval procedures

Most countries have introduced flexible approval mechanisms to facilitate the timely market entry of digital medical devices. In the United States, a review system incorporating Real-World Evidence (RWE) and a streamlined approval pathway under the Breakthrough Devices Program has been in operation since 2017, with a total of 1,041 medical devices designated as of September 2024.[2] Notable DTx approved through this pathway include reSET-O for opioid use disorder and EndeavorRx for pediatric attention-deficit/hyperactivity disorder.[10]

Germany has adopted the DiGA Fast-Track system under the Digitale Versorgung-Gesetz.[7] This program requires that products demonstrate compliance with basic standards of safety, functionality, and quality, as well as evidence of positive therapeutic effects, to qualify for approval within three months.[11] As of August 2025, a total of 72 products have been listed in the DiGA Directory, with over 374,000 prescriptions issued as of 2024.[12,13]

Following Brexit, the United Kingdom enacted the Medicines and Medical Devices Act to establish an independent regulatory framework.[14] Subsequently, the MHRA published the Medical Devices Regulatory Reform Roadmap to Implementation and is currently progressing with detailed system development.[8]

In Japan, the Development of Advanced Software for Healthcare for software as a medical device (DASH for SaMD) program, first introduced in 2020, was revised and expanded into DASH for SaMD 2 in September 2023. Under this reform, the SaMD review unit within the PMDA was upgraded from an office to a department, and a two-step approval process was established.[15,16] The first-stage approval is granted for products demonstrating confirmed safety, followed by second-stage approval upon submission of additional clinical evidence.[17]

Insurance coverage application

In 2021, the United States introduced the Medicare Coverage of Innovative Technology program, which granted automatic Medicare reimbursement for innovative medical devices for up to four years.[18] However, due to concerns regarding patient safety and insufficient clinical evidence, the program was withdrawn within the same year.[19] To address these limitations, the Centers for Medicare & Medicaid Services launched the Transitional Coverage for Emerging Technologies (TCET) program in 2024.[20] TCET incorporates RWE-based clinical evaluation, pre-review of reimbursement mechanisms, and structured collaboration with manufacturers, aiming to balance rapid coverage with improved patient access.[20,21] Nevertheless, with an annual approval cap of only five cases and coverage limited to FDA-designated breakthrough devices, its practical impact remains minimal to date.[22]

In Germany, insurance coverage decisions are made within three months under the DiGA Fast-Track system.[7] Products granted provisional listing are required to demonstrate effectiveness using RWE during a one-year trial period in order to retain statutory health insurance coverage.[11] Owing to this structured and expedited process, Germany is regarded as the most advanced case in terms of DTx reimbursement and clinical adoption.[23]

Key provisions and features of the Korean Digital Medical Device Act

A summary of the major provisions of the Digital Medical Products Act is presented in **Table 2**.

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Table 2. Summary of major provisions in Korea's Digital Medical Products Act

Provision	Key features	Differences from the existing Medical Devices Act
Article 2: legal definition	Legal definition of digital medical products and their scope, including the classification of digital medical devices, digital convergence drugs, and digital medical and health support devices	Inclusion of software-based and AI-based products (e.g., SaMD, DTx) as opposed to hardware-focused definitions under the previous Medical Device Act
Article 3: classification and risk-based rating	Risk- and function-based classification system enabling tailored regulation	Shift from item-based classification to product-specific rating system reflecting individual product characteristics
Article 9: approval of clinical trial plans and exceptions	· Clinical trial approval process defined, with exceptions for low-risk or data-driven studies · Off-site clinical trials permitted	· Transition from mandatory trial approval to flexible approval for real-world and data-based studies · Includes allowance for off-site trials
Article 15: real-world performance evaluation	Real-world performance evaluation to assess safety and effectiveness in actual use environments	Allows for Real-World Data collection and utilization, unlike traditional trial-based evaluations only
Article 38: request for review of national health insurance benefit coverage	Regulatory pathway defined for expedited health insurance benefit review for digital medical products	Allows MFDS to request coverage evaluation; introduces additional post-review assessment mechanism

SaMD = software as a medical device, DTx = digital therapeutics, MFDS = Ministry of Food and Drug Safety.

Article 2: legal definition and scope of application

Article 2 of the Digital Medical Products Act provides a clear legal definition and scope of application for digital medical devices.[3] The provision delineates three distinct categories: 1) digital medical devices, 2) digitally integrated pharmaceuticals, and 3) digital medical and health support devices. Through this classification, the Act formally encompasses emerging technology-driven products, such as SaMD and DTx, thereby extending legal recognition and regulatory oversight to novel categories that were previously not fully addressed under existing frameworks (**Table 3**).

The previous Medical Device Act was restricted by a hardware-centric definition, thereby failing to adequately encompass products incorporating digital technologies. The recent amendment addresses these limitations by expanding the legal scope and establishing a regulatory framework aligned with the evolving landscape of medical technology.

Article 3: classification and rating of products

Article 3 classifies digital medical products based on their intended use and functional characteristics and stipulates criteria for assigning regulatory ratings. This system enables the application of customized regulatory requirements that reflect both product-specific features and associated risk levels. Flexibility is further ensured through the possibility of assigning temporary ratings where appropriate. Unlike the framework for traditional medical devices and in vitro diagnostic devices, the classification under this Act is distinctive in that ratings are determined at the level of individual products rather than entire product categories.

Article 9: approval of clinical trial plans

Article 9 outlines the approval procedures, exemptions, and conditions for the conduct of clinical trials involving digital medical devices. Generally, clinical trials require authorization by the Ministry of Food and Drug Safety (MFDS). However, post-market clinical trials

Table 3. Legal definitions and examples of digital medical products

Category	Definition	Examples
Digital medical devices	Medical devices that consist of SaMD or integrated hardware and software, designed for medical purposes such as diagnosis and treatment	AI-based diagnostic software, DTx
Digital convergence drugs	Pharmaceuticals integrated with digital technology or linked software, where the primary function lies in the pharmaceutical component	Medication adherence monitoring apps, digital coaching programs
Digital medical and health support devices	Devices incorporating digital technology for health management or medical support, without direct therapeutic function	Wearable devices, health management apps

SaMD = software as a medical device, AI = artificial intelligence, DTx = digital therapeutics.

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or studies with minimal human risk are exempt from this requirement. While trials are generally conducted in designated clinical trial institutions, exceptions are permitted under certain conditions—such as when remote data collection is feasible—reflecting the unique characteristics of digital products.

Previously, the Medical Device Act Enforcement Regulations (Article 21-2) permitted clinical trials outside institutions only under limited circumstances, including immovable devices or infectious disease contexts. By contrast, the Digital Medical Products Act establishes a more flexible framework tailored to digital technologies. Furthermore, Articles 14 and 15 of the Enforcement Regulations provide additional detail. Article 14 defines approval requirements and exemptions, including trials using processed data, Real-World Data (RWD) evaluation, and clinical studies of Class I or II standalone digital software, which may be exempt from approval. Article 15 specifies the conditions under which trials may be conducted outside institutions, thereby broadening permissible contexts in comparison with previous legislation.

Article 15: real-world evaluation

Article 15 establishes a legal basis for the evaluation of safety and effectiveness in real-world settings. This provision authorizes the collection and analysis of usage data that cannot easily be captured through conventional clinical trials, thereby facilitating post-market validation and iterative improvement of device performance. Moreover, the MFDS Minister is empowered to incorporate such evidence in regulatory processes related to manufacturing, modification, and import approval. In contrast to the prior Medical Device Act, which focused primarily on trial-based evidence, this article formally recognizes RWD as an acceptable component of regulatory evaluation, thereby enhancing both flexibility and practical relevance.

Article 38: request for review of health insurance coverage

Article 38 specifies procedures for the expedited determination of health insurance eligibility for digital medical products. If the MFDS Minister deems that a product requires rapid introduction into clinical practice, a request may be made to the Minister of Health and Welfare for accelerated review of insurance coverage. In addition, supplementary evaluations may be considered in subsequent decisions, providing a pathway for products to secure reimbursement eligibility more efficiently.

Results of expert interviews

Qualitative interviews with experts identified three key issues regarding the early implementation of the Digital Medical Products Act (**Table 4**).

Institutional significance

Experts emphasized that the Act represents a fundamental departure from the traditional hardware-centered regulatory system. Notably, it separately defines advanced technology-based products, including SaMD and AI-driven medical devices, and establishes an integrated legal framework encompassing customized review processes and insurance linkage. Several experts highlighted the importance of this structural innovation, noting that the Act's independent legal foundation reflects the characteristics of advanced digital technologies and enhances system completeness by combining regulatory oversight with reimbursement considerations.

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Table 4. Expert interview findings: key issues in the early implementation of the Digital Medical Devices Act

Theme	Key findings	Representative quotes
Institutional significance	• What are the differences between the existing medical device legal framework and the newly established system? • How is the Digital Medical Products Act expected to influence the medical device industry?	• "The enactment of a new law that explicitly reflects the characteristics of advanced technology products represents a meaningful institutional change." • "The introduction of the new system is expected to reduce regulatory uncertainty and expand market entry opportunities for companies."
Lack of detailed criteria	• The law has been enacted, but detailed standards and procedures for its implementation remain unspecified. What are your perspectives on this issue?	• "Although products are classified according to the application of digital technology, detailed criteria—such as those concerning the use of AI—remain ambiguous." • "While the provisions exist, the absence of specific procedural standards creates difficulties in practical implementation."
Potential confusion in practice	• What challenges are companies likely to face in the absence of clear guidelines or requirements? • What are the most significant concerns during the initial adaptation phase following enactment?	• "If companies prepare products before the issuance of finalized guidelines, subsequent changes in requirements may impose a considerable burden." • "Due to ambiguity in legal interpretation, there is concern that identical issues may be addressed inconsistently across medical institutions and review agencies."

AI = artificial intelligence.

Lack of detailed criteria

Despite recognizing the value of the Act, experts pointed out the absence of clear classification and procedural standards. In particular, criteria for distinguishing products utilizing digital technologies, such as AI-based applications, were perceived as ambiguous. One expert stressed the urgency of detailed guidance, stating that while provisions exist in principle, "the lack of explicit procedural standards makes practical application difficult."

Potential confusion in practice

Concerns were also raised regarding possible confusion during implementation if detailed procedures and operational standards are not promptly developed. Experts noted that premature product preparation in the absence of finalized guidelines could impose substantial burdens on companies if regulatory requirements are later revised. Furthermore, ambiguity in legal interpretation may result in inconsistent application across institutions, including medical facilities and review agencies.

DISCUSSION

Enacted in 2024, Korea's Digital Medical Products Act is the world's first comprehensive legislation that regulates digital medical products. While it establishes a pioneering framework, its early implementation required refinement informed by international experience. Based on a comparative analysis of the regulatory systems in the United States, Germany, the United Kingdom, and Japan, this study identified the distinctive features of the Korean framework and their policy implications, and the following policy recommendations are proposed.

Korea's Digital Medical Products Act introduces flexibility in clinical trials and real-world evaluations through Articles 9 and 15. However, it currently lacks a formalized fast-track mechanism or a tiered approval system. To address this gap, a priority review or a tiered approval pathway for low-risk digital medical products should be introduced to facilitate earlier market access. It should be accompanied by a post-marketing framework that facilitates continuous monitoring of safety and effectiveness using RWD. Such an approach would accelerate the introduction of innovative technologies, while ensuring public health protection.

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Article 38 defines the procedure for requesting a review of health insurance benefits.[4] However, the absence of a defined review timeline and of evaluation criteria limit its effectiveness. To address this issue, Korea should establish a defined coverage review period (e.g., three to six months) and adopt a post-approval evaluation framework incorporating RWD and RWE. Additionally, a collaborative evidence development system similar to TCET could increase the likelihood of reimbursement and expand patient access to digital medical products.

Korea has introduced real-world evaluations through Article 15, it currently lacks detailed guidelines on data collection and analysis.[4] To address this, standardized protocols for RWD collection should be developed, including specifications for data formatting and quality assurance, along with comprehensive guidelines for the use of RWE in regulatory decision-making. This would allow RWD to inform decisions such as clinical trial exemptions, product reclassification, and reimbursement eligibility. Furthermore, a dedicated data platform tailored to the unique characteristics of digital medical products is essential to enable secure data sharing and foster collaboration between manufacturers and regulatory authorities.

Korea's Digital Medical Products Act distinguishes between digital medical and health support devices and uniquely incorporates wellness-related products within its regulatory scope.[4] However, the classification criteria and management mechanisms for these categories remain ambiguous, posing significant challenges to their practical implementation. A risk- and function-based classification framework should be developed for devices such as wearable technologies and health management applications. For nontherapeutic products, streamlined review and certification procedures should be implemented to reduce regulatory burdens. Such an approach could promote innovation in the wellness industry while maintaining appropriate oversight and consumer protection.

As digital healthcare operates on a global scale, and international collaboration is essential, enhancing the competitiveness of Korea's regulatory framework. Korea should actively engage in information exchange and collaborative research with leading regulatory authorities, including the U.S. FDA, BfArM, and the UK MHRA. Moreover, alignment with international standards, including those of the International Medical Device Regulator Forum, is critical. In addition, Korea should explore establishing mutual recognition agreements for certification to facilitate the global distribution and acceptance of digital health products.

These policy recommendations are expected to play a pivotal role in positioning Korea as a global leader in digital medical product regulation. By facilitating the delivery of patient-centered and innovative healthcare services, Korea can foster a competitive digital health ecosystem at the international level. Ongoing monitoring and active stakeholder feedback are essential for refining the legal framework and ensuring the sustainable development of the digital healthcare industry. A proactive and adaptive regulatory approach will not only enhance the global competitiveness of Korean digital health technologies but also ensure their alignment with international standards, ultimately contributing to improved patient outcomes worldwide.

However, these recommendations should be considered in light of the study's limitations as follows. The analysis is based primarily on qualitative, literature-centered comparisons, without an empirical validation of the system's operational effectiveness. Moreover, as

some data were translated from English, interpretive discrepancies cannot be excluded. Future research should systematically evaluate regulatory outcomes and industry responses through quantitative analyses. Despite these limitations, this study highlights the distinctive characteristics of Korea's regulatory system for digital healthcare products and provides meaningful policy implications by offering foundational evidence for regulatory discussions and international cooperation.

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