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Proactive adoption of generative artificial intelligence (AI) in the operations of Japan's Pharmaceuticals and Medical Devices Agency (PMDA): Current initiatives, governance, and future perspectives

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Abstract: The Pharmaceuticals and Medical Devices Agency (PMDA) continues to face increasing operational demands stemming from growing regulatory complexity, expanding data volumes, and evolving scientific and societal expectations. In this context, the appropriate adoption of generative artificial intelligence has emerged as a potential approach for enhancing operational efficiency while reinforcing scientific rigor and accountability. This article describes the current status of generative artificial intelligence utilization at PMDA, outlines its governance framework, and discusses future perspectives for its sustainable application based on institutional experience, internal policy development, and planned/ongoing proof-of-concept activities conducted within PMDA. We summarize a phased implementation strategy that combines commercially available generative artificial intelligence tools for administrative support with the exploration of large language models in secure internal environments for scientifically specialized tasks. Central to this approach is a governance framework that emphasizes human-in-the-loop decision-making, staged evaluation, information governance, and staff capacity building. We also present practical use cases across information collection, analysis and evaluation, and dissemination activities to illustrate how generative artificial intelligence may support regulatory work without replacing human judgment. In conclusion, PMDA's experience suggests that proactive yet cautious adoption of generative artificial intelligence, grounded in robust governance and organizational learning, can improve productivity and enhance scientific capacity within regulatory authorities while maintaining public trust and institutional accountability.

***Keywords*:** generative artificial intelligence, regulatory science, operational efficiency

1. Introduction

The Pharmaceuticals and Medical Devices Agency (PMDA) conducts its daily operations with the objective of ensuring the quality, efficacy, and safety of pharmaceuticals, medical devices, and related products in Japan through its core functions of regulatory reviews, safety measures, and relief services for adverse health effects, supported by administrative and management activities (*1*).

Recently, with the continued evolution of the environment surrounding PMDA, various challenges, such as drug loss and ensuring a stable supply of pharmaceuticals, have emerged (*2*). Alongside advances in science and technology, regulatory responses to digital transformation, including modeling and simulation, real-world data, adaptive design, and decentralized clinical trials, have become increasingly important. To continue fulfilling its expected role, PMDA needs to further strengthen its scientific capacity and its ability to address emerging challenges.

In particular, artificial intelligence (AI) technologies have attracted growing attention as tools capable of dramatically improving productivity, including through their accelerated application in drug development and related areas (*3*). Among AI technologies, generative AI has recently emerged as a practical tool for supporting knowledge-intensive tasks in drug development and regulation (*4,5*). This article therefore focuses on the current status of generative AI utilization at PMDA,

including practical use cases, fundamental principles guiding its application, and future perspectives for its use in PMDA.

2. Implementation of generative AI and governance framework at PMDA

PMDA has long promoted initiatives aimed at improving operational quality and efficiency. Considering the changes in its operating environment, PMDA has worked toward introducing generative AI to advance its operational activities.

As outlined in Figure 1, the strategic utilization of generative AI across PMDA's core functions (regulatory reviews, safety measures, and relief services) enhances the productivity of PMDA and improves quality while expanding human resource capacity for matters requiring advanced scientific judgment. Through these efforts, PMDA can further contribute to its organizational purpose of "making everyone's lives brighter together".

To facilitate the implementation of generative AI, PMDA established the Action Plan for the Use of AI in Operations on September 26, 2025 (*6*). This action plan consists of three pillars. The first and second pillars address technical introduction and implementation strategies, while the third pillar focuses on establishing a governance framework. The first pillar represents the initial phase of generative AI adoption, which involves the introduction of commercially available and widely implemented generative AI technologies, such as Microsoft Copilot, to improve the efficiency of PMDA's operations, particularly processes that involve administrative tasks. The second pillar represents the subsequent phase that involves the introduction of other generative AI models into a secure internal environment to support highly specialized and scientific operations in PMDA. In this phase, tasks may require a high level of medical and pharmaceutical expertise required for regulatory assessments, as well as careful consideration of the complexity and context-dependence of scientific judgment in regulatory decision-making. To assess the technical feasibility and regulatory applicability of generative AI and to inform the development of PMDA-specific generative AI tailored to our requirements, a series of proof-of-concept (PoC) studies is conducted. With the aim of enabling practical, reliable, and secure use in real-world settings, domain-specific generative AI systems tailored to medical applications have been developed in Japan (*e.g.*, the SIP-JMED initiative) (*7,8*). The third pillar focuses on strengthening the governance framework, including the establishment of internal rules and security measures, as well as enhancing information technology and AI literacy among PMDA staff through training programs that support appropriate AI utilization and informed decision-making. As part of this governance structure,

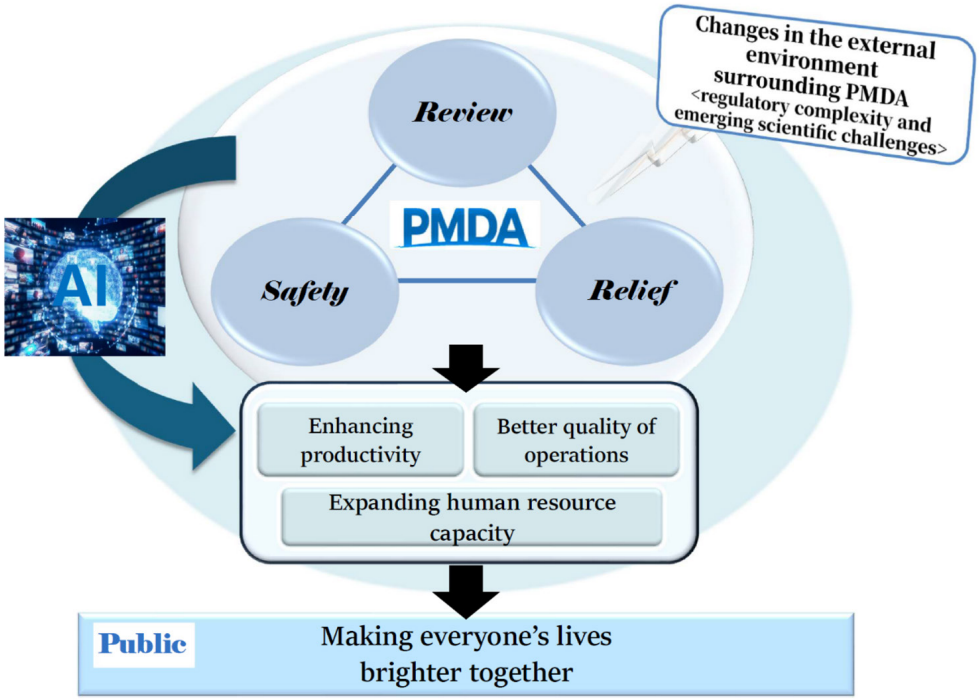

Figure 1. Use of generative artificial intelligence (GenAI) across PMDA's core functions to achieve its mission. Generative AI is applied across PMDA's core functions—review, safety, and relief—in response to increasing regulatory complexity and evolving scientific challenges. Its integration enhances operational quality, productivity, and effective allocation of human resources. This enables staff to focus on tasks requiring advanced scientific judgment while maintaining accountability and supporting PMDA's mission.

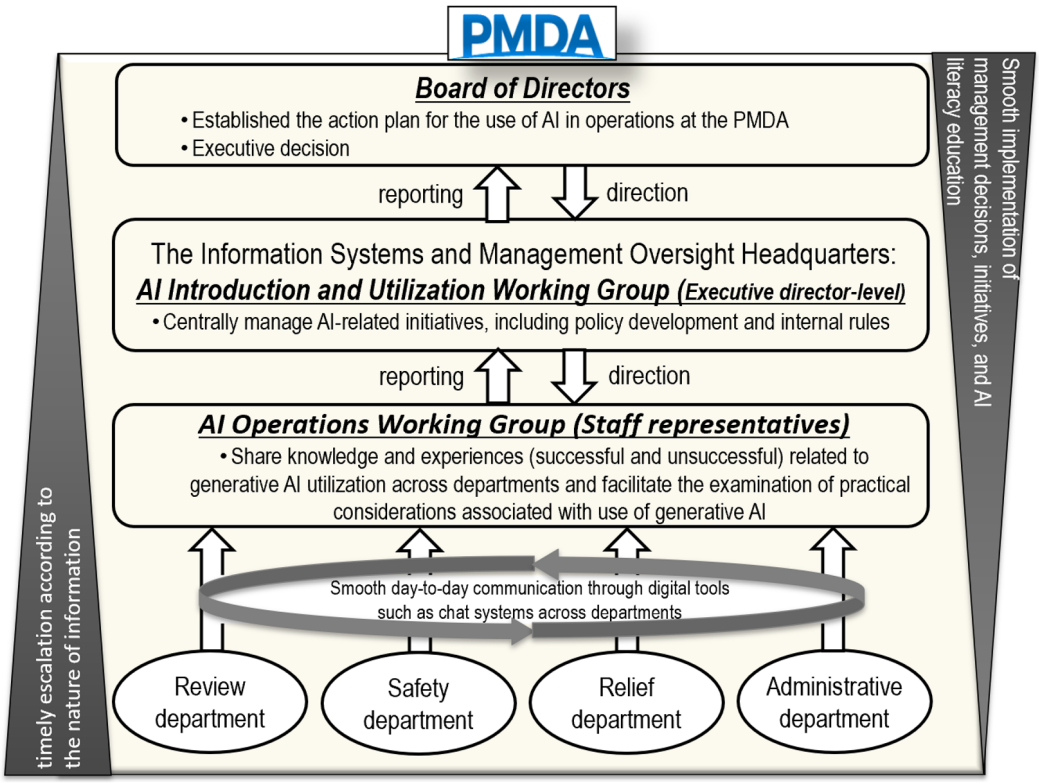

Figure 2. Governance framework for generative AI (GenAI) utilization at PMDA. A multi-layered structure is led by executive decision-making and supported by dedicated working groups for strategy and operations. This framework enables coordinated implementation, knowledge sharing across departments, and organization-wide AI literacy. Arrows indicate the reporting lines from operational units to governance bodies and the strategic direction from executive-level committees to operational teams.

PMDA has appointed a Chief AI Officer and established an AI Introduction and Utilization Working Group composed of executive director-level members under the Information Systems and Management Oversight Headquarters (Figure 2). Furthermore, an AI Operations Working Group consisting of staff representatives has been created to share knowledge and experiences, both successful and unsuccessful, related to generative AI utilization across departments and facilitate the examination of practical considerations associated with generative AI use. This framework enables rapid decision-making by top management while ensuring seamless sharing of knowledge, experiences, and challenges related to generative AI across departments. PMDA centrally coordinates discussions and necessary adjustments related to generative AI implementation through timely escalation from individual departments, depending on the nature of the information. Through prompt examination of issues related to operational requirements, security, internal regulations, operations, education, and evaluation, PMDA can smoothly and systematically implement management decisions while simultaneously promoting agency-wide AI-related initiatives and strengthening AI literacy among staff.

3. Practical use cases of generative AI at PMDA

PMDA carries out its responsibilities by communicating with various stakeholders, including pharmaceutical and medical device companies, healthcare institutions, academia, and patients. To ensure the quality, efficacy, and safety of medical products, information collection, analysis and evaluation, and dissemination processes must be executed promptly and appropriately. PMDA believes that generative AI has the potential to support many stages of these workflows (Figure 3).

In the information collection phase, generative AI may be applied to tasks such as drafting meeting minutes, translation, information retrieval, and technical checks of data/information. In the analysis and evaluation phase, generative AI may be utilized for data cleaning, development of analytical programs, data analysis, and drafting evaluation or review reports. In the dissemination phase, generative AI may support the preparation of public communication and outreach materials. Across these phases, PMDA, as a regulatory agency, focuses on applying generative AI to scientific and regulatory data/information collected from publicly available sources and/or submitted by stakeholders, including healthcare professionals, patients, and marketing authorization holders (*e.g.*, pharmaceutical companies). By embedding generative AI into these workflows, PMDA aims to enhance the sophistication of

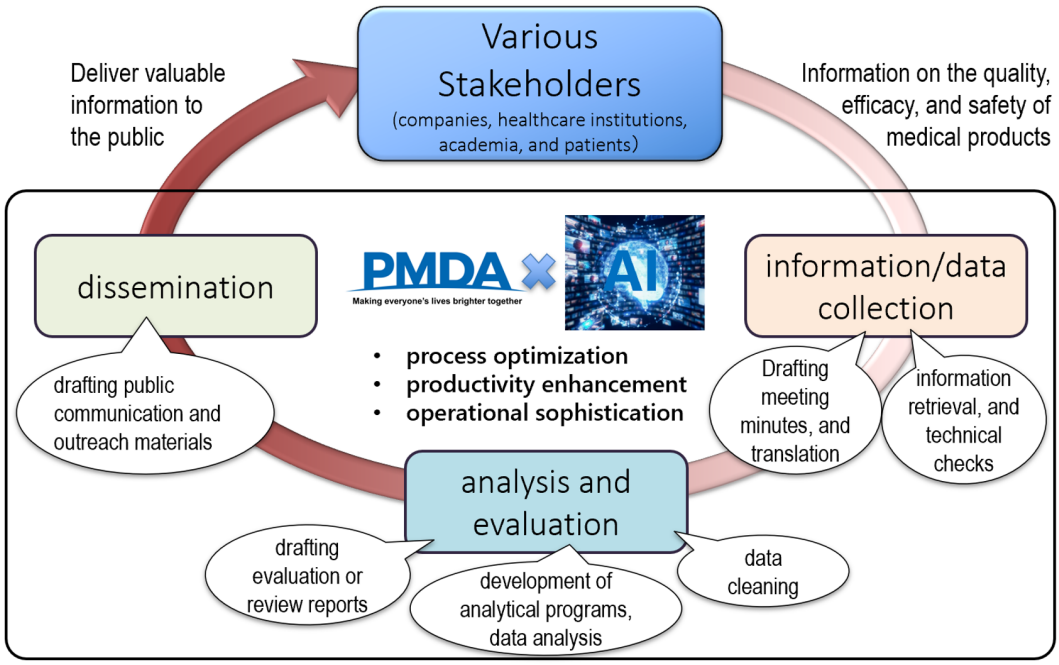

Figure 3. The information-to-value cycle at PMDA enabled by generative artificial intelligence (GenAI). Generative AI supports processes from information collection to analysis, evaluation, and dissemination. It assists with tasks such as data processing, document drafting, and analytical support across the workflow. Its integration enhances efficiency and contributes to the timely delivery of high-quality regulatory information.

scientific assessment and continuously deliver valuable information to the public, thereby ensuring the quality, efficacy, and safety of medical products.

PMDA has advanced the first pillar of the action plan using Microsoft Copilot, which has already been implemented in certain activities, such as drafting meeting minutes and translation. For the second and third pillars, PoC studies have been initiated, with close inter–working group communication to efficiently advance AI-related initiatives. We have explored its applications across all pillars through ongoing initiatives and pilot activities. The governance-related components in the third pillar have also progressed to support both current implementation and future development, reflecting PMDA's phased and cautious approach.

As an example under the second pillar, PMDA has been conducting PoC studies related to new drug review to assess whether domain- and task-specific generative AI can assist with summarizing clinical trial results during the preparation of review reports, thereby enabling staff to devote more time toward advanced scientific evaluation (*9*). Other potential applications in the first and/or second pillars include support for developing analytical programs for electronic clinical trial data, retrieving relevant materials from past scientific discussions, evaluating complex clinical and nonclinical data, and detecting drug safety signals, although concrete implementation strategies remain under consideration. Key challenges in using generative AI at PMDA may include ensuring data security and confidentiality, maintaining transparency and accountability of AI-supported decisions, and establishing appropriate human oversight (*10*). Specifically, PMDA-specific AI will require not only language generation capabilities but also a deep understanding of regulatory context, document structures, and accumulated institutional knowledge, which may not be fully addressed by general large language models.

4. Key considerations in use of generative AI

Utilization of generative AI involves numerous considerations that must be carefully addressed. Recently, the US Food and Drug Administration and the European Medicines Agency have jointly published guiding principles for good AI practice (*11*). Likewise, PMDA emphasizes the importance of conducting AI-related initiatives with appropriate risk management based on a thorough understanding of both characteristics and limitations of generative AI.

A fundamental principle guiding AI utilization at PMDA is that generative AI should not replace human judgment. Presently, generative AI should be regarded as a tool to support our work. As such, final regulatory decisions and associated responsibilities remain with human staff, in accordance with the human-in-the-loop principle (*12,13*). PMDA also stresses the need to clearly define appropriate use cases, noting that applications substituting for human judgment or relying on insufficiently verified outputs are inappropriate. In addition, use of generative AI in handling highly

sensitive or confidential information requires appropriate safeguards. These considerations are reflected in development of internal rules and guidance to ensure responsible and appropriate use of generative AI within PMDA. Given the known risks of AI utilization, such as hallucinations, PMDA staff should ensure reliability of AI-generated outputs, as PMDA continues to fulfill its institutional accountability.

It is also essential to confirm whether generative AI systems demonstrate appropriate performance consistent with their intended purposes, as well as key characteristics such as explainability, robustness, and generalizability. PMDA considers the potential introduction of AI technologies tailored to specific operational requirements by leveraging accumulated knowledge and document resources related to review, safety, and relief activities. For each individual application, repeated proof-of-concept studies and staged evaluations that account for model performance and limitations, implementation and operational costs, and security requirements need to be conducted. In this context, establishing appropriate evaluation framework tailored to each specific use case is considered important. Applicability of generative AI will be examined based on multiple dimensions, including task time reduction, accuracy of generated summaries, hallucination frequency, human correction rate, traceability to source documents, user satisfaction, and information security. Although these efforts remain at an early stage, PMDA emphasizes integrated assessment of both performance and feasibility, particularly given the need to handle sensitive personal and confidential data within regulatory workflows.

5. Future perspectives: Continuously creating "tomorrow's normal" through generative AI

PMDA will continue to promote utilization of generative AI across its operations and aims to improve productivity and optimization through business process reengineering that incorporates AI technologies. Through these initiatives, PMDA will strengthen its scientific capacity and its ability to respond to new and emerging challenges, thereby enhancing overall organizational performance.

By appropriately responding to advances in science and technology and facilitating the timely and appropriate availability of medical products required in clinical practice, PMDA fulfills its mission as a life platform that works together with society to continuously create "tomorrow's normal" while actively contributing to improvement of public health and safety.

Moreover, PMDA believes that its experience with utilization of generative AI under an appropriate governance framework will provide valuable insights for industry stakeholders considering application of generative AI across pre- and post-marketing stages. By sharing these experiences, PMDA will play an important role in promoting appropriate use of generative AI in medical product development and fostering international harmonization.

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