

Action Plan for the Use of AI in Operations at the PMDA

The Pharmaceuticals and Medical Devices Agency (PMDA) conducts its daily operations with the objectives of enhancing the quality, efficacy, and safety of pharmaceuticals and medical devices in Japan. These objectives are achieved through its key services: *Relief Services for Adverse Health Effects*, *Reviews*, and *Safety Measures*, which are supported by administrative management to ensure smooth operations.

The PMDA has previously invested in and adopted measures to improve its operational quality and efficiency. However, as new challenges emerge—such as ensuring a stable supply of drugs and resolving the lack of access to innovative drugs approved in the US and EU—the landscape surrounding the PMDA is shifting. To fulfill its expected responsibilities, the PMDA must further strengthen its scientific expertise and its capability to respond to challenges.

As a means of enhancing overall operational capabilities, the PMDA will proactively utilize artificial intelligence (AI) technologies under the following basic policy:

1. Introduction of existing AI technology: Boosting the efficiency of daily operational process

PMDA will achieve higher efficiency in the administrative operations by introducing and utilizing AI technologies that are already available.

[To be implemented in FY2025]

- Across all divisions and departments, the PMDA will establish an environment for using AI products by staffs who need in work for tasks such as document retrieval, document summarization, meeting minutes preparation and translation, and start utilizing them in daily operations.

[In FY2026]

- The PMDA will verify and assess the utility of AI products in the administrative operations, as well as highly specialized operation tasks. (Starting in FY2025)
- By the end of 4Q, FY2026, the PMDA will evaluate the impact of AI products introduction and the results of the utility verification, and determine whether to continue and expand their use.

2. Introduction of specialized AI technology for PMDA's key services: Technical verification and information gathering

[To commence in FY2025]

- The PMDA will build AI models in a secure internal testing environment and gradually advance trials and proof-of-concept projects for the development and implementation of proprietary AI model tailored to its operational requirements, especially for tasks requiring a high level of expertise.

[In FY2027]

- The PMDA will identify and assess issues, costs, and technical limitations in introduction of AI technology specifically designed for operations. The first assessment will be complete by the end of 2Q, FY2027, and subsequent assessment will be completed within two years from the start of the plan in FY2025.)

3. AI governance: Preparation of support / promotion framework and rules, implementation of measures to improve IT literacy in all PMDA staffs:

[Starting in FY2025]

- In September 2025, a senior executive director was appointed as *Chief AI Technology Officer* to facilitate the integration of AI technologies into PMDA operations. In addition, a *Working Group for AI Introduction and Use* (hereinafter “WG”) was established under the Headquarters of Information Systems Management to centrally review and coordinate AI implementation. A *WG secretariat* was also created within the Office of Information Technology Promotion to take necessary actions such as rule development and implementation of security measures.
- Training will be provided to all PMDA staff on the *Common Standards for Cybersecurity Measures* and on knowledge required to use AI effectively, with aim of improving IT literacy prior to the AI introduction specified in Action Plan 1.

[Going forward]

- The WG will prepare and implement plans for AI introduction and evaluation, including budget management, technical assessment, and evaluation for the impact of AI products, as outlined in Action Plan 1 and 2, and report to the Headquarters.