Provisional Translation (as of May 2026)※

PMDA Notification No.11602
March 24, 2025

To (described in Appendix)

Yasuhiro Fujiwara,
Chief Executive of Pharmaceuticals and Medical Devices Agency
(Official seal omitted)

# Preparation and disclosure of review summaries for approval reviews of improved medical devices

Thank you for your continued understanding and cooperation in the operations such as review of the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA").

Information on approved medical devices has been provided on the PMDA website as a list of approved medical devices.

Based on the PMDA's fifth Mid-term Plan and the "Cooperation Plan for Optimization of Medical Device Regulations and Reviews 2024," from the viewpoint of promoting practical use of medical devices and supporting international expansion of medical devices approved in Japan, we have decided to prepare a review summary for approval reviews of improved medical devices, etc. (in Japanese and English) as described below and provide information on the PMDA's website.

We therefore ask that you inform the members of your association so that all companies can cooperate in the preparation and disclosure of the review summary.

## Notice

1. Scope of preparation

   Improved medical devices with clinical data or other equivalent products for which applications for marketing approval and applications for partial change are filed on or after April 1, 2025 (excluding products for which the review report was prepared for deliberation at the Committee on Medical Devices and In-vitro Diagnostics)

2. Content of preparation

   The product information, submitted data (development history, etc., non-clinical data, clinical data), and review results will be briefly described. The contents of the submitted data will be described based on the information that can be disclosed after adjustment with the applicant according to the "Attachment 1 Instructions on Preparing the Masked Review Report as a Draft" in the "Procedures for Public Release of Information on Review of Applications for New Medical Devices" (PMDA Notification No. 0206007, dated February 6, 2009).

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※ This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail

3. Timing of preparation and disclosure

Preparation will be started after the approval of each application, will be completed in about 3 months, and information will be disclosed promptly.

(Appendix)

President, Japan Federation of Medical Devices Associations

Chairperson, American Medical Devices and Diagnostics Manufacturers' Association

Chairman, The EBC Medical Equipment and IVD Committee

Representative Organizer, Association of Registered Certification Bodies under the PMD Act

Chairman, The Japan Digital Health Alliance

President, Japan Medical Venture Association

Chairman, Council for AI Medical Devices

President, Japan Pharmaceutical Manufacturers Association