

Provisional Translation (as of February 2026).

This English document has been prepared for reference purpose only. In the event of inconsistency and discrepancy between the Japanese original and the English translation, the Japanese text shall prevail.

PMDA Notification No. 51

April 1, 2025

To [Note]

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

### Handling of FY 2025 “Clinical Trial Support Project from Humanitarian Perspective”

The “consultations before the start of expanded access program for drugs,” “consultations before the start of expanded access program for medical devices,” and “consultations before the start of expanded access program for regenerative medical products” provided by the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”) have been continued so far with fee reduction since FY 2016, in accordance with PMDA Notification No. 0401046 dated April 1, 2016, “Implementation of FY 2016 ‘Clinical Trial Support Project from Humanitarian Perspective’” and PMDA Notification No. 0721004 dated July 21, 2016, “Handling of FY 2016 ‘Clinical Trial Support Project from Humanitarian Perspective.’”

Since these consultations will be applicable to the “Clinical Trial Support Project from Humanitarian Perspective” (hereinafter referred to as “this project”) funded by government subsidies also in FY 2025, a decision was made to reduce the fees as follows. Please inform your members of this matter.

### Note

1. For the “consultations before the start of expanded access program for drugs,” “consultations before the start of expanded access program for medical devices,” and “consultations before the start of expanded access program for regenerative medical products” provided from April 1, 2025 to March 31, 2026, 10% of the amount of the fees specified in the table attached to the Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004) (hereinafter referred to as “specified amount”) shall be paid.
2. However, the scope of the government subsidies in this project shall be up to the budgeted amount of subsidies the provision of which is determined in the order of receipt of proper applications, and the specified amount shall be paid for consultations after the budgeted amount is reached.
3. The case where the consultation is cancelled for the applicant's convenience after 10% of the specified amount has been paid and the application for the consultation has been

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submitted shall not be applicable to the refund of half of the fee. No portion of the total amount paid shall be refunded.\*

However, if PMDA considers it unavoidable, the fee will be fully refunded.

\* The consultations subject to this project are not applicable to the handling of refund of half of the fee at the time of cancellation in Attachment 1 of PMDA Notification No. 0302070 dated March 2, 2012, "Implementation Guidelines for Face-to-face Advice, Confirmation of Certification, etc. Conducted by Pharmaceuticals and Medical Devices Agency."

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