

Provisional Translation (as of March 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. 1047

May 8, 2025

To [Note]

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

Partial Revision of “Subsidy for the Consultation Fee Related to the ‘Project for the Consultation Center for Pediatric and Orphan Drugs Development’” in FY 2025
(notification)

We appreciate your understanding and cooperation with the operations including review of the Pharmaceuticals and Medical Devices Agency.

In FY 2025, based on the subsidy for the project to accelerate the review of drugs, etc. (the project for accelerating the review of unapproved drugs and off-label drugs in Japan, etc.) at the Ministry of Health, Labour and Welfare, PMDA will implement the “Project for the Consultation Center for Pediatric and Orphan Drugs Development.” As part of the Project, we have decided to fund the consultation fee related to the Project by the government subsidy, and has issued PMDA Notification No. 52 dated April 1, 2025, “Subsidy for the Consultation Fee Related to the ‘Project for the Consultation Center for Pediatric and Orphan Drugs Development’” in FY 2025.

We have revised the following matters as shown in the comparison table of before and after the change in Attachment, and have decided to apply the revised version from today.

Please inform your members of this revision.

Note

- The existing “consultations on drug application data packages (products for which development is offered under the Study Group on Unapproved and Off-label Drugs of High Medical Need)” is changed to “consultations on drug application data packages (products developed under the Study Group on Unapproved and Off-label Drugs of High Medical Need).”
- “Consultations on eligibility for public knowledge-based applications for drugs” are added to the applicable consultations.

End of Document

Comparison Table of Before and After the Change of Subsidy for the Consultation Fee Related to the “Project for the Consultation Center for Pediatric and Orphan Drugs Development” in FY 2025

(The underlined parts are revised.)

After revision	Before revision
<p>(Attachment)</p> <p align="center">Implementation Procedure for Subsidy for the Consultation Fee Related to the “Project for the Consultation Center for Pediatric and Orphan Drugs Development” in FY 2025</p> <p>In recent years, the issue related to drugs approved in Europe and the United States but not developed in Japan, known as “expansion of drug loss,” has been pointed out. This issue is partly attributed to environmental changes such as the decline of drug discovery capabilities of Japan and marketability of products as well as the global increase in the rate of drug developments for small patient groups. In particular, drugs for pediatric/orphan diseases, etc. that are less marketable tend to be affected.</p> <p>In order to respond to such environmental changes and promote the development/introduction of drugs that are medically necessary for Japan, PMDA will continuously implement in FY 2025 the “Project for the Consultation Center for Pediatric and Orphan Drugs Development” started in FY 2024 with the aim of improving the consultation environment necessary for pharmaceutical development and reducing the financial burden on consulters. As part of the efforts, PMDA will fund the fees for the consultations shown in 1. to <u>4.</u> below by government subsidy. The implementation procedures, etc. related to this subsidy are specified as follows.</p> <p>(Omitted)</p> <p align="center">Note</p> <p>1. “Consultations on eligibility for priority review for orphan drugs,” “consultations on eligibility for priority review for orphan drugs (with pre-</p>	<p>(Attachment)</p> <p align="center">Implementation Procedure for Subsidy for the Consultation Fee Related to the “Project for the Consultation Center for Pediatric and Orphan Drugs Development” in FY 2025</p> <p>In recent years, the issue related to drugs approved in Europe and the United States but not developed in Japan, known as “expansion of drug loss,” has been pointed out. This issue is partly attributed to environmental changes such as the decline of drug discovery capabilities of Japan and marketability of products as well as the global increase in the rate of drug developments for small patient groups. In particular, drugs for pediatric/orphan diseases, etc. that are less marketable tend to be affected.</p> <p>In order to respond to such environmental changes and promote the development/introduction of drugs that are medically necessary for Japan, PMDA will continuously implement in FY 2025 the “Project for the Consultation Center for Pediatric and Orphan Drugs Development” started in FY 2024 with the aim of improving the consultation environment necessary for pharmaceutical development and reducing the financial burden on consulters. As a part of the efforts, PMDA will fund the fees for the consultations shown in 1. to <u>3.</u> below by government subsidy. The implementation procedures, etc. related to this subsidy are specified as follows.</p> <p>(Omitted)</p> <p align="center">Note</p> <p>1. “Consultations on eligibility for priority review for orphan drugs,” “consultations on eligibility for priority review for orphan drugs (with pre-</p>

<p>application consultations for drugs)”</p> <p>(Omitted)</p> <p>(1) (Omitted)</p> <p>(2) Scope of subsidy Payment of 50% of the specified amount shall be exempted. However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to <u>4</u>. For subsequent consultations, applicants shall pay the specified amount. Only when multiple request forms for scheduling or request forms are submitted on the date on which the last request leading to the upper limit of the budget for FY 2025 is received, the subsidy shall be applied to applicants in the ascending order of the total amount of applied subsidy for this fiscal year under this project as a whole, not in the order of receipt of the request forms for scheduling or request forms. If multiple consultations are of equal rank, a consultation to be subsidized shall be selected by the method shown in Appendix.</p> <p>(3) (Omitted)</p> <p>2. “Consultations on Confirmation of Pediatric Drug Development Programs” (Omitted)</p> <p>(1) (Omitted)</p> <p>(2) Scope of subsidy The payment of the specified amount shall be fully exempted. However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to <u>4</u>. For subsequent consultations, applicants shall pay the specified amount.</p>	<p>application consultations for drugs)”</p> <p>(Omitted)</p> <p>(1) (Omitted)</p> <p>(2) Scope of subsidy Payment of 50% of the specified amount shall be exempted. However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to <u>3</u>. For subsequent consultations, applicants shall pay the specified amount. Only when multiple request forms for scheduling or request forms are submitted on the date on which the last request leading to the upper limit of the budget for FY 2025 is received, the subsidy shall be applied to applicants in the ascending order of the total amount of applied subsidy for this fiscal year under this project as a whole, not in the order of receipt of the request forms for scheduling or request forms. If multiple consultations are of equal rank, a consultation to be subsidized shall be selected by the method shown in Appendix.</p> <p>(3) (Omitted)</p> <p>2. “Consultations on Confirmation of Pediatric Drug Development Programs” (Omitted)</p> <p>(1) (Omitted)</p> <p>(2) Scope of subsidy The payment of the specified amount shall be fully exempted. However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to <u>3</u>. For subsequent consultations, applicants shall pay the specified amount.</p>
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(3) (Omitted)

3. “Consultations on drug application data packages (products developed under the Study Group on Unapproved and Off-label Drugs of High Medical Need),” “Consultations on drug application data packages (products developed by investigator-initiated clinical trials)”

The implementation guidelines of the consultations concerned are separately shown in Attachment 1 of the Face-to-face Advice Implementation Guidelines Notification, and the scope, etc. of the subsidy is as follows.

(1) (Omitted)

(2) Scope of subsidy

Payment of 50% of the specified amount shall be exempted.

However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to 4. For subsequent consultations, applicants shall pay the specified amount.

Payment of 50% applied until the budget for FY 2025 is reached shall be limited to three consultations per consultant (in the order of submission during the covered period in (1)).

Only when multiple request forms for scheduling or request forms are submitted on the date on which the last request leading to the upper limit of the budget for FY 2025 is received, the subsidy shall be applied to applicants in the ascending order of the total amount of applied subsidy for this fiscal year under this project as a whole, not in the order of receipt of the request forms for scheduling or request forms. If multiple consultations are of equal

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(3) (Omitted)

3. “Consultations on drug application data packages (products for which development is offered under the Study Group on Unapproved and Off-label Drugs of High Medical Need),” “Consultations on drug application data packages (products developed by investigator-initiated clinical trials)”

The implementation guidelines of the consultations concerned are separately shown in Attachment 1 of the Face-to-face Advice Implementation Guidelines Notification, and the scope, etc. of the subsidy is as follows.

(1) (Omitted)

(2) Scope of subsidy

Payment of 50% of the specified amount shall be exempted.

However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to 3. For subsequent consultations, applicants shall pay the specified amount.

Payment of 50% applied until the budget for FY 2025 is reached shall be limited to three consultations per consultant (in the order of submission during the covered period in (1)).

Only when multiple request forms for scheduling or request forms are submitted on the date on which the last request leading to the upper limit of the budget for FY 2025 is received, the subsidy shall be applied to applicants in the ascending order of the total amount of applied subsidy for this fiscal year under this project as a whole, not in the order of receipt of the request forms for scheduling or request forms. If multiple consultations are of equal

<p>rank, a consultation to be subsidized shall be selected by the method shown in Appendix.</p> <p>(3) (Omitted)</p> <p><u>4. “Consultations on eligibility for public knowledge-based applications for drugs”</u> <u>When information related to the eligibility for public knowledge-based application is organized for a product whose development has been requested by the Study Group on Unapproved and Off-label Drugs of High Medical Need in accordance with the notification issued jointly by the Director of Research and Development Policy Division, Health Policy Bureau and the Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, “Acceleration of Procedures Associated with Submission of Company’s View on Request for Development of Unapproved and Off-label Drugs of High Medical Needs” (HPB/RDPD Notification No. 1108-1, PSB/PED Notification No. 1108-1, dated November 8, 2024), an application for “consultations on eligibility for public knowledge-based applications for drugs” shall be made.</u> <u>The implementation guidelines of the consultations concerned are separately shown in Attachment 36 of the Face-to-face Advice Implementation Guidelines Notification, and the scope, etc. of the subsidy is as follows.</u></p> <p><u>(1) Period covered by the subsidy</u> <u>Consultations for which the request form was received from May 8, 2025 to January 7, 2026 (must be received)* shall be included.</u> <u>* Limited to those for which consultation record is finalized within FY 2025.</u></p> <p><u>(2) Scope of subsidy</u> <u>Payment of 50% of the specified amount shall be exempted.</u> <u>However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to 4. For subsequent consultations, applicants shall pay the specified amount.</u></p>	<p>rank, a consultation to be subsidized shall be selected by the method shown in Appendix.</p> <p>(3) (Omitted)</p> <p><u>(Newly established)</u></p>
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Only when multiple request forms for scheduling or request forms are submitted on the date on which the last request leading to the upper limit of the budget for FY 2025 is received, the subsidy shall be applied to applicants in the ascending order of the total amount of applied subsidy for this fiscal year under this project as a whole, not in the order of receipt of the request forms for scheduling or request forms. If multiple consultations are of equal rank, a consultation to be subsidized shall be selected by the method shown in Appendix.

(3) In the case of withdrawal

If a consultation is cancelled for the applicant's convenience after requesting it by paying 50% of the specified amount, the paid amount will not be reimbursed* (the government subsidy will not be allocated to PMDA).

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

* If the subsidy is applied, the handling of a refund of half of the fee at the time of cancellation in Attachment 36 of the Face-to-face Advice Implementation Guidelines Notification is not applied.

The withdrawn application for consultation shall not be included in the amount of subsidy applied for the applicant concerned in (2).

Reference

PMDA Notification No. 52
April 1, 2025
Final amendment: May 8, 2025

To [Note]

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

Subsidy for the Consultation Fee Related to the “Project for the Consultation Center for Pediatric and Orphan Drugs Development” in FY 2025 (notification)

We appreciate your understanding and cooperation with the operations including reviews of the Pharmaceuticals and Medical Devices Agency.

In FY 2024, based on the subsidy for the project to accelerate the review of drugs, etc. (the project for accelerating the review of unapproved drugs and off-label drugs in Japan, etc.) at the Ministry of Health, Labour and Welfare, PMDA implemented the “Project for the Consultation Center for Pediatric and Orphan Drugs Development.” As a part of the project, the consultation fee related to this Project was funded by the government subsidy.

In FY 2025, as shown in Attachment, the consultation fee related to this Project will continue to be funded by the government subsidy. Please inform your members of this matter.

(Attachment)

**Implementation Procedure for Subsidy for the Consultation Fee
Related to the “Project for the Consultation Center for Pediatric and
Orphan Drugs Development” in FY 2025**

In recent years, the issue related to drugs approved in Europe and the United States but not developed in Japan, known as “expansion of drug loss,” has been pointed out. This issue is partly attributed to environmental changes such as the decline of drug discovery capabilities of Japan and marketability of products as well as the global increase in the rate of drug developments for small patient groups. In particular, drugs for pediatric/orphan diseases, etc. that are less marketable tend to be affected.

In order to respond to such environmental changes and promote the development/introduction of drugs that are medically necessary for Japan, PMDA will continuously implement in FY 2025 the “Project for the Consultation Center for Pediatric and Orphan Drug Development” started in FY 2024 with the aim of improving the consultation environment necessary for pharmaceutical development and reducing the financial burden on consulters. As part of the efforts, PMDA will fund the fees for the consultations shown in 1. to 4. below will be funded by the government subsidy. The implementation procedures, etc. related to this subsidy are specified as follows.

In this written implementation procedure, the following terms are defined as follows.

Term	Definition of term
PMDA	Pharmaceuticals and Medical Devices Agency
Face-to-face Advice Implementation Guidelines Notification	Notification from the Chief Executive of PMDA, “Implementation Guidelines for Face-to-face Advice, Confirmation of Certification, etc. Conducted by Pharmaceuticals and Medical Devices Agency” (PMDA Notification No. 0302070, dated March 2, 2012)
Specified amount	Amount specified in the attached table of 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)
Consulter	When an application is made by a company such as a marketing authorization holder, it refers to that company. When an application is made by a researcher, etc. of a university, research institution, etc., it refers to that researcher, etc.
SAKIGAKE-designated drug	A drug designated under the SAKIGAKE Designation System or the pioneer drug designation system

Note

1. “Consultations on eligibility for priority reviews for orphan drugs,” “consultations on eligibility for priority reviews for orphan drugs (with pre-application consultations for drugs)”

For products that were determined not to be eligible for priority reviews and priority consultations at the stage of designation as orphan drugs according to the notification issued jointly by the Director of Pharmaceutical Evaluation Division and the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, “Designation of Orphan Drugs, etc.” (PSEHB/PED Notification No. 0831-7, PSEHB/MDED Notification No. 0831-7, dated August 31, 2020, partial revision on January 16, 2024), but have become considered to be eligible for priority reviews and priority consultations with the progress of development, priority reviews and priority consultations can be applied by clarifying the eligibility using “consultations on eligibility for priority reviews for orphan drugs” or “consultations on eligibility for priority reviews for orphan drugs (with pre-application consultations for drugs)” provided by PMDA.

The implementation guidelines of the consultations concerned are separately shown in Attachment 4 of the Face-to-face Advice Implementation Guidelines Notification, and the scope, etc. of the subsidy is as follows.

(1) Period covered by the subsidy

Consultations for which the request form was received from April 1, 2025 to January 7, 2026 (must be received)* shall be included.

* Limited to those for which evaluation report is finalized within FY 2025.

(2) Scope of subsidy

Payment of 50% of the specified amount shall be exempted.

However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to 4. For subsequent consultations, applicants shall pay the specified amount.

Only when multiple request forms for scheduling or request forms are submitted on the date on which the last request leading to the upper limit of the budget for FY 2025 is received, the subsidy shall be applied to applicants in the ascending order of the total amount of applied subsidy for this fiscal year under this project as a whole, not in the order of receipt of the request forms for scheduling or request forms. If multiple consultations are of equal rank, a consultation to be subsidized shall be selected by the method shown in Appendix.

(3) In the case of withdrawal

If a consultation is cancelled for the applicant’s convenience after requesting it by paying 50% of the specified amount, the paid amount will not be reimbursed* (the government subsidy will not be allocated to PMDA).

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

* If the subsidy is applied, the handling of a refund of half of the fee at the time of cancellation in Attachment 4 of the Face-to-face Advice Implementation Guidelines Notification is not applied.

The withdrawn application for consultation shall not be included in the amount of subsidy applied for the applicant concerned in (2).

2. “Consultations on Confirmation of Pediatric Drug Development Programs”

When developing drugs for adults to ensure early access to pediatric drugs in accordance with the notification of the Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, “Planning of the Pediatric Drug Development Programs during Development of Drugs for Adults” (PSB/PED Notification No. 0112-3, dated January 12, 2024, partial revision on March 29, 2024), it is considered desirable to formulate the development plan for the pediatric drug related to the indication subject to the development concerned, receive confirmation of PMDA before the approval application of the drug for adults, and proceed with the development without delay based on the development plan concerned. In order to receive confirmation by PMDA, “Consultations on Confirmation of Pediatric Drug Development programs” shall be used.

The implementation guidelines of the consultations concerned are separately shown in Attachment 35 of the Face-to-face Advice Implementation Guidelines Notification, and the scope, etc. of the subsidy is as follows.

(1) Period covered by the subsidy

Consultations for which the request form was received from April 1, 2025 to January 7, 2026 (must be received)* shall be included.

* Limited to those for which consultation record is finalized within FY 2025.

(2) Scope of subsidy

The payment of the specified amount shall be fully exempted.

However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to 4. For subsequent consultations, applicants shall pay the specified amount.

Only when multiple request forms for scheduling or request forms are submitted on the date on which the last request leading to the upper limit of the budget for FY 2025 is received, the subsidy shall be applied to applicants in the ascending order of the total amount of applied subsidy for this fiscal year under this project as a whole, not in the order of receipt of the request forms for scheduling or request forms. If multiple consultations are of equal rank, a consultation to be subsidized shall be selected by the method shown in Appendix.

(3) In the case of withdrawal

The application for a consultation made with full exemption of the specified amount and then withdrawn for consuler’s convenience shall be included in the amount of subsidy applied to the consuler concerned in (2)* (50% of the specified amount shall be allocated to PMDA through the government subsidy).

However, this does not apply if PMDA considers the cancellation unavoidable.

* If the subsidy is applied, the handling of a refund of half of the fee at the time of cancellation in Attachment 35 of the Face-to-face Advice Implementation Guidelines Notification is not applied.

3. “Consultations on drug application data packages (products developed under the Study Group on Unapproved and Off-label Drugs of High Medical Need),” “Consultations on drug application data packages (products developed by investigator-initiated clinical trials)”

The implementation guidelines of the consultations concerned are separately shown in Attachment 1 of the Face-to-face Advice Implementation Guidelines Notification, and the scope, etc. of the subsidy is as follows.

- (1) Period covered by the subsidy

Consultations for which the request form for scheduling was received from April 1, 2025 to January 7, 2026 (must be received)* shall be included.

* Limited to consultations provided within FY 2025.

- (2) Scope of subsidy

Payment of 50% of the specified amount shall be exempted.

However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to 4. For subsequent consultations, applicants shall pay the specified amount.

Payment of 50% applied until the budget for FY 2025 is reached shall be limited to three consultations per consulter (in the order of submission during the covered period in (1)).

Only when multiple request forms for scheduling or request forms are submitted on the date on which the last request leading to the upper limit of the budget for FY 2025 is received, the subsidy shall be applied to applicants in the ascending order of the total amount of applied subsidy for this fiscal year under this project as a whole, not in the order of receipt of the request forms for scheduling or request forms. If multiple consultations are of equal rank, a consultation to be subsidized shall be selected by the method shown in Appendix.

- (3) In the case of withdrawal

If a consultation is cancelled for the applicant’s convenience after requesting it by paying 50% of the specified amount, the paid amount will not be reimbursed* (for consultations except for priority face-to-face advice for SAKIGAKE-designated drugs shown in Attachment 1 of the Face-to-face Advice Implementation Guidelines Notification, the government subsidy will not be allocated to PMDA if they are cancelled before the date of consultation).

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

* If the subsidy is applied, the handling of a refund of half of the fee at the time of cancellation in Attachment 1 to the Face-to-face Advice Implementation Guidelines Notification is not applied.

The application for consultation withdrawn before the date of consultation (excluding priority face-to-face advice for SAKIGAKE-designated drugs) will not be included in the number of consultations to which the subsidy is applied for the applicant concerned in (2). The remaining number for the applicant concerned according to (2), which results

from the withdrawal of the application for consultation, can be applied only to request forms for scheduling newly submitted after the withdrawal (the request forms for scheduling accepted as not being subject to the subsidy before the withdrawal cannot be retroactively subject to the subsidy).

Applications for consultations withdrawn on or after the date of consultation (after submission of a request form for scheduling in the case of priority face-to-face advice for SAKIGAKE-designated drugs) will be included (as one consultation) in the number of applications for which subsidy is applied for the applicant concerned in (2), and also included in the calculation of the amount of subsidy applied for the applicant concerned (50% of the specified amount shall be allocated to PMDA through the government subsidy).

4. “Consultations on eligibility for public knowledge-based applications for drugs”

When information related to the eligibility for public knowledge-based application is organized for a product whose development has been requested by the Study Group on Unapproved and Off-label Drugs of High Medical Need in accordance with the notification issued jointly by the Director of Research and Development Policy Division, Health Policy Bureau and the Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, “Acceleration of Procedures Associated with Submission of Company’s View on Request for Development of Unapproved Drugs and Off-label Drugs of High Medical Needs” (HPB/RDPD Notification No. 1108-1, PSB/PED Notification No. 1108-1, dated November 8, 2024), an application for “consultations on eligibility for public knowledge-based applications for drugs” shall be made.

The implementation guidelines of the consultations concerned are separately shown in Attachment 36 of the Face-to-face Advice Implementation Guidelines Notification, and the scope, etc. of the subsidy is as follows.

(1) Period covered by the subsidy

Consultations for which the request form was received from May 8, 2025 to January 7, 2026 (must be received)* shall be included.

* Limited to those for which consultation record is finalized within FY 2025.

(2) Scope of subsidy

Payment of 50% of the specified amount shall be exempted.

However, the subsidy shall be applied in the order of the receipt of a proper request form for scheduling or request form, until the budget for FY 2025 is reached, for consultations subject to this project in 1. to 4. For subsequent consultations, applicants shall pay the specified amount.

Only when multiple request forms for scheduling or request forms are submitted on the date on which the last request leading to the upper limit of the budget for FY 2025 is received, the subsidy shall be applied to applicants in the ascending order of the total amount of applied subsidy for this fiscal year under this project as a whole, not in the order of receipt of the request forms for scheduling or request forms. If multiple consultations are of equal rank, a consultation to be subsidized shall be selected by the method shown in Appendix.

(3) In the case of withdrawal

If a consultation is cancelled for the applicant's convenience after requesting it by paying 50% of the specified amount, the paid amount will not be reimbursed* (the government subsidy will not be allocated to PMDA).

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

- * If the subsidy is applied, the handling of a refund of half of the fee at the time of cancellation in Attachment 36 of the Face-to-face Advice Implementation Guidelines Notification is not applied.

The withdrawn application for consultation shall not be included in the amount of subsidy applied for the applicant concerned in (2).

