PMDA Notification No. 1490
May 30, 2025

To: Directors-General of Pharmaceutical Affairs Division of prefectures

Yasuhiro Fujiwara, President
Pharmaceuticals and Medical Devices Agency
(official seal omitted)

Partial revision of "User fees for review by the Pharmaceuticals and Medical Devices Agency"

We hereby notify you that we have informed the relevant organizations regarding the subject matter as per attached.

PMDA Notification No. 1489
May 30, 2025

To: (To be filled out)

Yasuhiro Fujiwara, President
Pharmaceuticals and Medical Devices Agency
(official seal omitted)

Partial revision of "User fees for review by the Pharmaceuticals and Medical Devices Agency"

Thank you for your continuous understanding of and cooperation with the review operations of the Pharmaceuticals and Medical Devices Agency (PMDA).

Handling of the user fees for the review operations performed by the PMDA is specified in "User fees for review by the Pharmaceuticals and Medical Devices Agency" (PMDA Notification No. 1121002 of November 21, 2014).

The "Act on the Safety of Regenerative Medicine" (Act No. 85 of 2013) has been revised in accordance with the "Act on the Partial Revision of the Act on the Safety of Regenerative Medicine and the Clinical Trial Act" (Act No. 51 of 2024) promulgated in June 2024.

This Notification was partially revised as shown in the attached comparison table of the old and new versions and will come into effect on May 31, 2025 in line with the said revision. Please inform the members of your organization of the revision.

Note

Chairman, Federation of Pharmaceutical Manufacturers' Associations of Japan
President, Japan Pharmaceutical Manufacturers Association
President, Japan Association of Clinical Reagents Industries
Board Chair, Technical Committee, Pharmaceutical Research and Manufacturers of America
Chairman, European Federation of Pharmaceutical Industries and Associations Japan
Chairman, Japan Federation of Medical Devices Associations
Chairperson, American Medical Devices and Diagnostics Manufacturers' Association
Chair, Medical Equipment/IVD Committee, European Business Council
President, Japan Cosmetic Industry Association
President, Cosmetic Importers Association of Japan
President, Japan Soap and Detergent Association
Chairperson, Japan Bath Additive Industry Association
Secretary General, Aerosol Industry Association of Japan
President, Japan Aerosol Hair Lacquer Industrial Association
Chair; Toiletries, Cosmetics & Fragrances; American Chamber of Commerce in Japan
Chair, Cosmetics and Quasi-Drugs Committee, European Business Council
Chairman, Japan Hygiene Products Industry Association
Chairperson, Japan Permanent Wave Lotion Industry Association
Chairperson, Japan Dentifrice Manufactures Association
Chairperson, Japan Hair Color Industry Association
President, Household Pesticide Industry Association of Japan
Chairperson, Hygienic Insecticide Industrial Association of Japan
President, Japan Society of Quality Assurance
President, Japan Association of Contract Laboratories for Safety Evaluation
President, Japan Blood Products Association
President, Japan Vaccine Industry Association
President, Japan Medical Association
Representative Organizer, Association of Registered Certification Bodies under the PMD Act.
President, Japan Generic Medicines Association
President, Pharmaceutical Manufacturers' Association of Tokyo
President, Kansai Pharmaceutical Industries Association
Director, Samurai Biotech Association
Chairperson, Forum for Innovative Regenerative Medicine
Chairman, Medical Technology Association of Japan

Attachment

User fees for review by the Pharmaceuticals and Medical Devices Agency Comparison table of old and new version

(Revised parts underlined)

After the revision	Before the revision
User fees for review by the Pharmaceuticals and Medical Devices Agency User fees for review by the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as the "PMDA") are set forth as follows. Please inform the members of your organization. 1 to 5 (omitted)	User fees for review by the Pharmaceuticals and Medical Devices Agency User fees for review by the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as the "PMDA") are set forth as follows. Please inform the members of your organization. 1 to 5 (omitted)

Appendix

Handling of refund

User fee category		Operation start date
Userfees	(Omitted)	Date of application receipt
	User fee for GCP inspection for generic drug User fee for GCP inspection for BTC/OTC drug User fee for GMP inspection for drug User fee for QMS inspection for medical device User fee for GCTP inspection for regenerative medical product User fee for inspection of buildings and facilities for drug User fee for inspection for accreditation of overseas drug manufacturing facilities User fees for inspection of registered certification body User fee for inspection of buildings and facilities for regenerative medical product User fee for inspection for accreditation of overseas manufacturing facilities for regenerative medical product User fee for inspection of buildings and facilities of manufacturing facilities of specific cellular product User fee for inspection of buildings and facilities of overseas manufacturing facilities of specific cellular product User fees User fee for confirmation of certification on drugs, etc. Fee for MDSAP report usage	Date of receipt of application for inspection/review
	(Omitted)	

(Omitted)

Appendix

Handling of refund

User fee category		Operation start date
Userfees	(Omitted)	Date of application receipt
	User fee for GCP inspection for generic drug User fee for GCP inspection for BTC/OTC drug User fee for GMP inspection for drug User fee for QMS inspection for medical device User fee for GCTP inspection for regenerative medical product User fee for inspection of buildings and facilities for drug User fee for inspection for accreditation of overseas drug manufacturing facilities User fees for inspection of registered certification body User fee for inspection of buildings and facilities for regenerative medical product User fee for inspection for accreditation of overseas manufacturing facilities for regenerative medical product User fee for inspection of buildings and facilities of cell processing center User fee for inspection for accreditation of overseas manufacturing facilities of cell processing center User fee for confirmation of certification on drugs, etc. Fee for MDSAP report usage	Date of receipt of application for inspection/review
	(Omitted)	

(Omitted)

PMDA Notification No. 1121002
November 21, 2014
Revised on May 15, 2015
Revised on September 14, 2015
Revised on March 23, 2017
Revised on August 1, 2017
Revised on March 30, 2018
Revised on April 1, 2019
Revised on October 1, 2019
Revised on December 25, 2020
Revised on April 1, 2021
Revised on August 1, 2021
Revised on April 1, 2022
Revised on October 21, 2022
Revised on December 23, 2024
Revised on May 31, 2025

To: (To be filled out)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

User fees for review by the Pharmaceuticals and Medical Devices Agency

User fees for review by the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as the "PMDA") are set forth as follows. Please inform the members of your organization.

1. User fees

Transfer the following user fees to the ordinary deposit account of a financial institution designated by the PMDA in advance and attach a copy of "bank transfer receipt" to the back of the inspection/review application document addressed to the PMDA before filing an application requiring PMDA inspections/reviews.

(1) User fees for inspections/review for pharmaceuticals, quasi-drugs, and cosmetics in accordance with the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Act No. 145, 1960; hereinafter referred to as the PMD Act)

Amount specified in the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Cabinet Order No. 91 of 2005; hereinafter referred to as the "Order on Fees related to the PMD Act")

(2) User fees for inspections/reviews for medical devices and in vitro diagnostics in accordance with the PMD Act
Amount specified in the Order on Fees related to the PMD Act

(3) User fees for inspections/reviews for regenerative medical products in accordance with the PMD Act
Amount specified in the Order on Fees related to the PMD Act

(4) User fees for PMDA inspections/reviews in accordance with the Act on Securing Safety of Regenerative Medicine (Act No. 85 of 2013)
Amount specified in the Order for Enforcement of the Act on Securing Safety of Regenerative Medicine (Cabinet Order No. 278 of 2014)

(5) Other user fees
Amount specified in the Appendix of Pharmaceuticals and Medical Devices Agency Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services (Administrative Instructions No. 4 of 2004)

2. Transfer of user fees

(1) Transfer the user fees in the amount corresponding to the total amount of user fees for the product(s) specified in the application for inspection/review.

(2) Transfer the amount calculated by the PMDA based on the Pharmaceuticals and Medical Devices Agency Regulations on Travel Expenses (Regulations No. 20 of 2004) for the overseas travel expenses added to the user fees in 1 above for an on-site inspection or confirmation after the inspection/confirmation is completed.

(3) Use a transfer request form specified by the PMDA or available at the bank to make a transfer of the user fees at the bank counter. The transfer request form specified by the PMDA is distributed at the application counter of the prefecture and the reception counter of the PMDA (including the Kansai branch).

(4) There are three types of transfer request forms specified by the PMDA: a dedicated transfer request form for user fees for inspections/reviews for drugs/quasi-drugs/cosmetics (blue form), a dedicated transfer request form for user fees for inspections/reviews for medical devices (brown form), and a dedicated transfer request form for user fees for inspections/reviews in accordance with the Act on Securing Safety of Regenerative Medicine (green form).

(i) Use the dedicated transfer request form for user fees for inspections/reviews for drugs/quasi-drugs/cosmetics when applying for a review, document-based inspection, GCP inspection, GMP inspection, reexamination, document-based inspection for reexamination, GPSP inspection, GLP inspection, inspection of buildings and facilities, inspection for accreditation of overseas facilities, confirmation of certification, or face-to-face consultation for a drug (excluding in-vitro diagnostics), a quasi-drug, or a cosmetic.

(ii) Use the dedicated transfer request form for user fees for inspections/reviews for medical devices when applying for a review, document-based inspection, GCP inspection, QMS inspection, GCTP inspection, use results assessment, document-

based inspection for use results assessment, reexamination, document-based inspection for reexamination, GPSP inspection, GLP inspection, inspection of buildings and facilities, inspection for accreditation of overseas facilities, inspection of registered certification body, confirmation of certification, MDSAP report usage, issuance of compliance certification, or face-to-face consultation for a medical device, an in vitro diagnostic, or a regenerative medical product.

(iii) Use the dedicated transfer request form when applying for PMDA inspections/reviews in accordance with the Act on Securing Safety of Regenerative Medicine.

(5) The bank accounts of the PMDA are separately designated for drugs, quasi-drugs, and cosmetics; medical devices, in vitro diagnostics, and regenerative medical products; and user fees in accordance with the Act on Securing Safety of Regenerative Medicine.

List of designated bank accounts for drugs, quasi-drugs, and cosmetics

Bank Name	Branch Name	Deposit type	Account number
Mizuho Bank	Shinbashi Branch	Ordinary	**1737826**
Sumitomo Mitsui Banking Corporation	Tokyo Government & Public Institutions Business Office	Ordinary	**152478**
MUFG Bank	Tokyo Government & Public Institutions Business Office	Ordinary	**1004552**
Resona Bank	Tokyo Banking Department	Ordinary	**1474953**

* Transfer from the head/branch offices of Saitama Resona Bank to the designated account at Resona Bank will be treated as intrabank transfer.

List of designated bank accounts for medical devices, in vitro diagnostics, and regenerative medical products

Bank Name	Branch Name	Deposit type	Account number
Mizuho Bank	Shinbashi Branch	Ordinary	**8393075**
Sumitomo Mitsui Banking Corporation	Tokyo Government & Public Institutions Business Office	Ordinary	**152489**
MUFG Bank	Tokyo Government & Public Institutions Business Office	Ordinary	**1179123**
Resona Bank	Tokyo Banking Department	Ordinary	**3676472**

* Transfer from the head/branch offices of Saitama Resona Bank to the designated account at Resona Bank will be treated as intrabank transfer.

Designated bank account for user fees for inspections/reviews in accordance with the Act on Securing of Safety of Regenerative Medicine

Bank Name	Branch Name	Deposit type	Account number
Mizuho Bank	Shinbashi Branch	Ordinary	**2830599**

(6) Specify the name of the recipient as "Pharmaceuticals and Medical Devices Agency" when making a transfer using a transfer request form available at the bank, an automated teller machine, or online banking. Remittance may be made either by "wire transfer" or "mail transfer."

(7) There is no transfer fee only when a transfer is made from a head office/branch office of a designated bank set forth in 2. (5) above to a specified account at the same bank using a transfer request form specified by the PMDA (e.g., when making a transfer from the Shinjuku Branch of Mizuho Bank to the PMDA-specified account at the Shimbashi Branch of Mizuho Bank).

3. Provision of the manufacturer code

(1) Be sure to provide the "Manufacturer code (9 digits)" in the field of "manufacturer code" on the transfer request form specified by the PMDA.

(2) Write or enter the "Manufacturer code (9 digits)" first in the field of "Remitter" followed by a space and the "Name of the remitter" when making a transfer using a transfer request form available at the bank, an automated teller machine, or online banking.

(3) Provide "999999999" in the field of "Manufacturer code" if the applicant has no manufacturer code (new applicant or safety tester).
Provide "999999888" in the field of "Manufacturer code" if the applicant seeks clinical trial consultation, and conduct a clinical trial by oneself.

4. Handling of refund

(1) The user fee for simple consultation listed among the user fees for inspections/reviews and face-to-face consultations will not be refunded if the applicant withdraws the application on or after the date listed in the right column of the appendix according to the user fee category in the left column.

(2) Half of the user fees for clinical trial consultation for drugs, consultation for quasi-drug development, clinical trial consultation for medical devices, clinical trial consultation for in vitro diagnostics, clinical trial consultation for regenerative medical products, and regulatory science strategy consultation will be refunded if the applicant withdraws the application on or after the date of application for a face-to-face consultation and before the date of consultation (including cases where the date of consultation is changed at the applicant's request).
However, no refund will be issued in the following cases.

- User fees for priority face-to-face consultation for a product subject to the Sakigake product designation system or a product designated as a Sakigake drug or regenerative medical product listed among the clinical trial consultations for drugs or regenerative medical products
- User fees for priority face-to-face consultation for a product subject to the Sakigake product designation system or a product designated as a Sakigake medical device or in vitro diagnostic, a product designated for priority review for software as a medical device, or a medical device or an in vitro diagnostic for specific usage listed among the clinical trial consultations for medical devices or in vitro diagnostics
- User fee for preliminary consultation for face-to-face consultation listed among the user fees for clinical trial consultation for medical devices or in-vitro diagnostics

- User fee for preliminary consultation for face-to-face consultation listed among the user fees for clinical trial consultation for medical devices or in-vitro diagnostics
- When the application for Sakigake comprehensive assessment consultation listed among clinical trial consultations for drugs, medical devices, in vitro diagnostics, or regenerative medical products is withdrawn after an inquiry is sent from the PMDA
- When the application for prior assessment consultation listed among clinical trial consultations for drugs or regenerative medical products is withdrawn after an inquiry is sent from the PMDA
- When the application for consultation on pharmacogenomics/biomarkers, consultation before minor change notification, consultation before change control of a generic drug, consultation on MF confirmation for a generic drug, BCS consultation for a drug, additional BCS consultation for a drug, BCS consultation on a generic drug, or additional BCS consultation on a generic drug listed among clinical trial consultations for drugs is withdrawn after an inquiry is sent from the PMDA
- When the application for consultation on innovative manufacturing technology listed among clinical trial consultations for drugs is withdrawn after an inquiry is sent from the PMDA or on or after the date of on-site inspection
- When the application for consultation on assessment of re-manufacturing of a single-use medical device (QMS confirmation) listed among clinical trial consultations for medical devices is withdrawn after an inquiry is sent from the PMDA

(3) Refund will be issued for the difference between the user fees transferred and the actual user fees that arose due to misidentification of the category.

5. Other

If you have any questions about how to prepare a transfer request form for user fees or transfer of user fees, contact the following:

Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013
Pharmaceuticals and Medical Devices Agency

○ Administration Division I, Office of Review Administration (drugs, quasi-drugs, and cosmetics)
Phone: 03-3506-9437 (direct)

○ Administration Division II, Office of Review Administration (medical devices, in vitro diagnostics, and regenerative medical products)
Phone: 03-3506-9509 (direct)

Appendix

Handling of refund

	User fee category	Operation start date
Userfees	User fee for review of new drug User fee for re-examination of drugs User fee for review of generic drug User fee for review of BTC/OTC drug, quasi-drug, cosmetic User fee for review of medical device User fee for use-results evaluation of medical device User fee for review of in vitro diagnostic User fee for use-results evaluation of in vitro diagnostic User fee for review of regenerative medical products User fee for re-examination of regenerative medical product User fee for inspection for new drug User fee for inspection for regenerative medical product User fee for GCP inspection for new drug User fee for GCP inspection of regenerative medical product	Date of application receipt
	User fee for GCP inspection for generic drug User fee for GCP inspection for BTC/OTC drug User fee for GMP inspection for drug User fee for QMS inspection for medical device User fee for GCTP inspection for regenerative medical product User fee for inspection of buildings and facilities for drug User fee for inspection for accreditation of overseas drug manufacturing facilities User fees for inspection of registered certification body User fee for inspection of buildings and facilities for regenerative medical product User fee for inspection for accreditation of overseas manufacturing facilities for regenerative medical product User fee for inspection of buildings and facilities of manufacturing facilities of specific cellular product User fee for inspection of buildings and facilities of overseas manufacturing facilities of specific cellular product User fee for confirmation of certification on drugs, etc. Fee for MDSAP report usage	Date of receipt of application for inspection/review
	User fee for inspection for medical device User fee for inspection for re-examination of drug User fee for inspection for use-results evaluation of medical device User fee for inspection for use-results evaluation of in vitro diagnostic User fee for inspection for re-examination of regenerative medical product	Date of instruction for submission of list of documents

	User fee for inspection of generic drug (excluding inspections for application for partial change accompanying quality reevaluation)	Date of instruction for submission of documents for inspection
	User fee for inspection of generic drug (only inspections for application for partial change accompanying quality reevaluation)	Date of receipt of documents for inspection
	User fee for inspection for BTC/OTC drug User fee for GCP inspection for medical device User fee for GPSP inspection for drug User fee for GPSP inspection for medical device User fee for GPSP inspection for in vitro diagnostic User fee for GPSP inspection for regenerative medical product User fee for GLP inspection	Date of notification of inspection
User fee for face-to-face consultation	User fee for clinical trial consultation for drugs* User fee for quasi-drug development consultation* User fee for simple consultation for drugs User fee for consultation on R&D strategy for drugs* User fee for clinical trial consultation for medical devices* User fee for simple consultation for medical devices User fee for consultation on R&D strategy for medical devices* User fee for clinical trial consultation for in vitro diagnostics* User fee for simple consultation for in vitro diagnostics User fee for clinical trial consultation for regenerative medical products* User fee for simple consultation for regenerative medical products User fee for consultation on R&D strategy for regenerative medical products*	Date of application for face-to-face consultation

(*) Half of the user fees will be refunded if the applicant withdraws the application on or after the date of application for face-to-face consultation and before the date of consultation. However, the following cases are excluded.

- User fees for priority face-to-face consultation for a product subject to the Sakigake product designation system, a product designated as a Sakigake drug, regenerative medical product, medical device or in vitro diagnostic, a product designated for priority review for software as a medical device, or a medical device or an in vitro diagnostic for specific usage
- User fee for face-to-face consultations
- User fee for preliminary reviews under the Cartagena Act or reviews under the Cartagena Act
- When the application for consultation on Sakigake comprehensive evaluation consultation, prior assessment consultation, pharmacogenomics/biomarkers, consultation before minor change notification, consultation before change control of a generic drug, consultation on MF confirmation for a generic drug, BCS consultation for a drug, additional BCS consultation for a drug, BCS consultation on a generic drug, additional BCS consultation on a generic drug, or assessment consultation on re-manufactured single-use medical devices (QMS confirmation) is withdrawn after an inquiry is sent from the PMDA
- When the application for consultation on innovative manufacturing technology listed is withdrawn after an inquiry is sent from the PMDA or on or after the date of on-site inspection

Note

Chairman, Federation of Pharmaceutical Manufacturers' Associations of Japan
President, Japan Pharmaceutical Manufacturers Association
President, Japan Association of Clinical Reagents Industries
Board Chair, Technical Committee, Pharmaceutical Research and Manufacturers of America
Chairman, European Federation of Pharmaceutical Industries and Associations Japan
Chairman, Japan Federation of Medical Devices Associations
Chairperson, American Medical Devices and Diagnostics Manufacturers' Association
Chair, Medical Equipment/IVD Committee, European Business Council
President, Japan Cosmetic Industry Association
President, Cosmetic Importers Association of Japan
President, Japan Soap and Detergent Association
Chairperson, Japan Bath Additive Industry Association
Secretary General, Aerosol Industry Association of Japan
President, Japan Aerosol Hair Lacquer Industrial Association
Chair; Toiletries, Cosmetics & Fragrances; American Chamber of Commerce in Japan
Chair, Cosmetics and Quasi-Drugs Committee, European Business Council
Chairman, Japan Hygiene Products Industry Association
Chairperson, Japan Permanent Wave Lotion Industry Association
Chairperson, Japan Dentifrice Manufactures Association
Chairperson, Japan Hair Color Industry Association
President, Household Pesticide Industry Association of Japan
Chairperson, Hygienic Insecticide Industrial Association of Japan
President, Japan Society of Quality Assurance
President, Japan Association of Contract Laboratories for Safety Evaluation
President, Japan Blood Products Association
President, Japan Vaccine Industry Association
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President, Pharmaceutical Manufacturers' Association of Tokyo
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