Implementation Guidelines for Regulatory Science General Consultations

March 16, 2017
Final amendment: June 5, 2023
(Effective on: June 5, 2023)

1. Details of implementation

Mainly for universities, research institutions, venture companies, etc. which conduct research and development for the purpose of creating innovative drugs, medical devices, regenerative medical products, etc. in Japan, general explanations and consultations will be provided on the confirmation of eligibility, guidelines, etc. for regulatory science strategy consultations (see "Implementation Guidelines for Regulatory Science Strategy Consultations" [PMDA Notification No. 0630007 dated June 30, 2011], hereinafter referred to as "RS strategy consultations") and other notifications, systems, etc. regarding regulatory science.

2. Scope, etc.

The contents of consultations covered by regulatory science general consultations (hereinafter referred to as "RS general consultations") are as follows.

(1) Consultations on confirmation of eligibility for RS strategy consultations or contents and procedures of RS strategy consultations

Confirmation of eligibility for RS strategy consultations on requested contents or contents and procedures of RS strategy consultations will be explained. Guidance and advice on specific development plans for individual products (e.g., sufficiency of non-clinical studies and appropriateness of endpoints in clinical studies) will be handled separately in RS strategy consultations.

(2) General consultations on the system of the Pharmaceuticals and Medical Devices Act and other regulatory science

From the viewpoint of regulatory science, general explanations and consultations will be provided on regulations based on the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960), necessary procedures, and other matters necessary for the practical application of new seed-stage resources as drugs, medical devices, etc.

(3) Consultations for Collaboration on Innovation and Implementation

Among consultations in (2), if the contents of consultations include issues related to medical insurance or contents related to overseas regulatory information in addition to issues related to the Pharmaceuticals and Medical Devices Act that are expected at the development stage, the issues related to medical insurance or parts related to overseas regulatory information need to be handled through consultations provided by Venture Support Strategy Office, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, Ministry of Health, Labour and Welfare. Therefore, the contents of consultations provided will be shared with Venture Support Strategy Office, and then explanations and consultations will be provided.

3. Method and location of implementation

(1) Implementation method

Technical experts, etc. from the Division of Innovation Support and Pharmaceuticals Affairs Consultations or the Consultation Division of Kansai Branch will provide consultations in face-to-face meeting or online meeting format, or combination of both. Please indicate your preference in the "Desired implementation method" column of the application form. Even in the case of a face-to-face meeting format, some of the PMDA's attendees may participate in online meeting format.

Please note that we may not be able to meet your request for reasons such as meeting rooms.

(2) Location of implementation

Consultations will take place in Tokyo (PMDA Headquarters), Osaka (Kansai Branch), or Kobe (PMDA Strategy Consultation and Coordination Center), according to the applicant's preference. Even if the preferred format is online meeting, please be sure to select the desired location in the "Desired location" column of the application form. The location in Kobe is available only on the dates notified on PMDA's website.

4. Application method

(1) Where to apply

Enter necessary information in "Application Form for Questions at Regulatory Science General Consultations" (Attached Form 1) and submit it by e-mail or fax to the Division of Innovation Support and Pharmaceuticals Affairs Consultations, Office of Review Management with materials that outline the products, seed-stage resources, etc. to be discussed.

If the preferred format is online meeting, please submit Form No. 57 of Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004), "Basic Confirmation Items for Implementation of Consultations via Online Meeting" (Attachment 1 to this Implementation Guidelines) as well.

Regardless of the implementation method and location (Tokyo, Osaka, or Kobe), the application should be submitted to the same address.

(Contact for application and inquiry)
Division of Innovation Support and Pharmaceuticals Affairs Consultations, Office of Review Management, Pharmaceuticals and Medical Devices Agency

E-mail address	yakujisenryaku@pmda.go.jp
Phone	03-3506-9562 (for inquiries)
Fax	03-3506-9593

(Opening hours)
From Monday to Friday (excluding national holidays, etc.)

(2) Notification of RS general consultation schedule, etc.

After receiving the application form, the person in charge at PMDA will notify the schedule, etc. by phone or e-mail. Depending on the contents of questions for RS general consultations, answers may be given over the phone.

(3) Implementation of meetings

Each meeting should be within 20 minutes. In face-to-face meeting format, the number of attendees should usually be 2 or 3 per meeting due to the size of the meeting room, but if more people wish to attend, please consult the person in charge.

(4) Other

The persons in charge at PMDA may make inquiries about the contents of questions before the meeting.

Details of the meeting will not be recorded.

5. Other

PMDA will not publish information related to consultation items obtained during the RS general consultations without the consent of the applicant.

However, if any consultation is judged to fall into the category of 2. (3) Consultations for Collaboration on Innovation and Implementation, the information related to the consultation will be shared with the Venture Support Strategy Office, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, Ministry of Health, Labour and Welfare after obtaining the consent of the applicant.

(Attached Form 1)

Application Form for Questions at Regulatory Science General Consultations

Month DD, YYYY

Subject of consultation		□ Drugs □ Medical devices (including in vitro diagnostics) □ Regenerative medical products, etc.
Name of applicant		
Contact information	Contact name	
	Department	
	Address	
	Phone number	
	Fax number	
	E-mail address	
List of attendees (name, affiliation)		

[Details of consultation] (Fill in according to the precautions on the next page.)

Title	

<Background of consultation, outline of products and seed-stage resources, etc.>

<Questions>
1.

2.

Desired implementation method	Face-to-face meeting format Online meeting format	(If some attendees would like to attend in person and others would like to participate in online meeting format, please circle both.)
Desired location (Select also in the case of online meeting format)	Tokyo Osaka (Kansai branch) Kobe	(PMDA Strategy Consultation and Coordination Center; For available dates, please see the PMDA website.)
Desired dates for meeting		
Remarks		

(Note)

1 The paper size should be Japan Industrial Standard A4.

2 When all of the required information cannot be entered in the specified column, enter “as per appendix ( )” in the column and prepare the appendix.

3 Instructions for completing the application form are as follows.

(1) Column for subject of consultation

Please tick the item applicable to the product to be discussed.

(2) Column for name of applicant

For a corporation, enter the name of the corporation.

(3) Column for details of consultation

Add the title (include the product name, development code, etc. if possible), and summarize the background of the application for this consultation (including the product outline, etc.), planned indication (purpose of use), and development issues and concerns in a concise manner (with bullet points). Please note in advance that questions other than those described in this column cannot be answered.

(4) List of attendees

If some attendees would like to attend in person and others would like to participate online, please circle the names so that the persons meeting the attendants would know.

(5) Column for desired location

Please select desired location of the meeting from Tokyo, Osaka (Kansai Branch), and Kobe (PMDA Strategy Consultation and Coordination Center). Please select one even when the preferred format is online meeting so that a PMDA department can continue to be in charge in the case of a switch to face-to-face meeting format or for the next consultation.

At the location in Kobe, consultations can be provided only on the dates notified on PMDA’s website.

(6) Column for desired dates for meeting

Enter multiple desired dates for the meeting.

(7) Remarks

If any meeting has been held for this product, please provide the most recent receipt number or meeting date.

If a Consultation for Collaboration on Innovation and Implementation is desired, please state “Requesting a Consultation for Collaboration on Innovation and Implementation.”

Enter any other supplementary information.

(Attachment 1) Form No. 57 of Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004)

Basic Confirmation Items for Implementation of Consultations via Online Meeting

Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") and the consulter of face-to-face advice, etc. (hereinafter referred to as "Consulter") shall confirm and agree to the following with respect to the operation of face-to-face advice, meetings, etc. to be conducted by online meetings.

1. PMDA and Consulter shall, with respect to the operation of online meetings, perform the following items in good faith based on the purpose thereof.
2. The effective period of this document shall commence at the application for face-to-face advice, meetings, etc. and end on the receipt by Consulter of the record of consultation related to the online meeting concerned (or end of the online meeting if the record of consultation is not prepared). However, Items 9 and 10 shall remain effective even after the above effective period.
3. Online meetings shall be held by PMDA as the organizer (host) of the meetings through the online meeting service designated by PMDA. However, if agreed in advance between PMDA and Consulter, Consulter may conduct online meetings as the host.
4. In the course of the implementation of online meetings, PMDA shall not be liable for any security vulnerability of the online meeting service and unauthorized access due to wiretapping, etc. attributable to the said service operator.
5. Only in the case of implementation by the method described in the text of Item 3, the expenses for the use of the online meeting system shall be borne by PMDA except for the expenses for communication.
6. Consulter shall limit the attendance at online meetings to persons who have been registered in advance to attend it, and confirm the identity of the participants in online meetings on its own responsibility.
7. Consulter shall, on its own responsibility, prepare a communication line and means on the side of Consulter, and prepare microphones, connection terminals, etc. as necessary so that the exchange of voice among the interpreter, participants in the meeting room or at remote locations, and the audio recording device on the side of PMDA can be smoothly carried out in online meetings.
8. PMDA shall record, video record, etc. the online meeting held in accordance with the method described in the text of Item 3 only for the purpose of preparation of the record, etc. and promptly delete the recording after preparation of the record.
9. Consulter shall not record, video record, etc. during the implementation of online meetings (excluding the case where PMDA requests recording, video recording, etc. for the preparation of a record when the meeting is implemented by the method stipulated in the proviso of Item 3). Even in the case where the meeting is held by the method stipulated in the proviso of Item 3 and Consulter records, video records, etc. at the request of PMDA, Consulter shall follow PMDA's instructions on the handling of such recording, video recording, etc. and shall not provide them to any person other than PMDA and registered persons stipulated in Item 6 or divulge them to outside through internet, etc.
10. From the viewpoint of prevention of unauthorized access due to wiretapping, etc. or sound leakage, etc. at the connection destination, PMDA and Consulter shall take necessary measures to prevent unauthorized access, etc. for devices and lines used by both parties for connection at the meetings. In the event of an incident, both parties shall work together to determine the cause, and if any loss occurs because of the cause of the incident, the two parties shall discuss the scope of responsibility with each other. Neither party shall be responsible for any incident attributable to the online meeting service used for the meetings or the service operator concerned.

Month DD, YYYY

PMDA	Director of Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency
Consulter	Company name Responsible person Type of consultation/meeting

*Please fill out the section for Consulter (no seal is required) and submit it in a pdf file (the original is retained by Consulter) by the time of implementation of the meeting.