

Provisional Translation (as of April 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/CPE Notification No. 332

March 10, 2023

To (Note)

Director of Center for Product Evaluation,  
Pharmaceuticals and Medical Devices Agency  
(Official seal omitted)

How Request Forms for Scheduling Related to a Trial of Safety Consultations for  
Drugs (consultations related to the ICH S1B (R1) Guidelines) Are Received, etc.

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

The implementation guidelines for face-to-face advice, confirmation of certification, etc. conducted by PMDA are specified in “Implementation Guidelines for Face-to-face Advice, Confirmation of Certification, etc. Conducted by Pharmaceuticals and Medical Devices Agency” (PMDA Notification No. 0302070 of the Pharmaceuticals and Medical Devices Agency, dated March 2, 2012; hereinafter referred to as the “Implementation Guidelines Notification”).

We have decided to newly introduce a consultation system for “safety consultations for drugs (consultations related to the ICH S1B (R1) Guidelines)” under the Implementation Guidelines Notification.

PMDA will implement these consultations on a trial basis for the time being, and handle the requests for scheduling, etc. as follows, not according to the provisions (“4. Scheduling of face-to-face advice (1)” or “5. How to schedule face-to-face advice (1)”) specified in Attachment 1-2 of the Implementation Guidelines Notification. Please inform the member companies of your association of this matter.

#### Note

##### 1 Request for scheduling of consultation

When requesting “safety consultations for drugs (consultations related to the ICH S1B (R1) Guidelines),” please enter necessary information in Attached Form 1-2 of the Implementation Guidelines Notification, the “Request form for scheduling of face-to-face advice (safety consultations for drugs [consultations related to the ICH S1B (R1) Guidelines])” (hereinafter referred to as the “Request form for scheduling”), and submit it to the Review Management Division, Office of Review Management via e-mail, in principle. We will receive the Request form for scheduling, in principle, from 10:00 a.m. to 4:00 p.m. on the first business day of the month 4 months before the month in which the consultation

is provided. However, we may change the date and time depending on the situation, for example, when the day is Saturday, Sunday, or a national holiday. Please check the PMDA website.

Please note that we do not accept the forms that arrive outside the designated hours.

(Points to consider)

- No more than one Request form for scheduling shall be received per company for each month of consultation.

Contact information for application and inquiry (if any):

Review Management Division, Office of Review Management, Pharmaceuticals and Medical Devices Agency

Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013

Phone (direct) 03-3506-9556

Fax 03-3506-9443

E-mail address: shinyaku-uketsuke@pmda.go.jp

Reception hours: From 9:30 a.m. to 5:00 p.m., from Monday to Friday (excluding non-business days such as national holidays). Request Form for scheduling submitted according to 1 above will be received from 10:00 a.m. to 4:00 p.m.

## 2 Number of consultations conducted

In principle, one request for consultation will be handled per month in each category of new drugs specified in Appendix 9 of the Implementation Guidelines Notification.

## 3 Notification of implementation, etc. of consultations

- (1) If it is judged difficult to implement because of the large number of requests, according to the scores based on the “points of products for which scheduling is requested” in 4 below, the request forms will be handled in the descending order of the points. In addition, if it is still difficult to implement after the above selection, a lottery will be carried out. The specific method of lottery is shown in the table.

Method of lottery:

- 1) Lottery is carried out based on the lottery numbers entered in advance in the Request form for scheduling.

If the lottery number is not entered or unclear, it will be the date of receipt of the Request form for scheduling (“0401” if April 1). If multiple lottery numbers are printed, the largest one will be adopted.

- 2) For the Request forms for scheduling subject to the lottery, the “lottery order numbers” are assigned in the order of receipt starting with “0.”
- 3) The sum of the lottery numbers entered in the Request forms for scheduling that are included in the lottery is divided by the number of the Request forms for scheduling that are included in the lottery to obtain the remainder.



4 Points for products for which scheduling is requested

For the products for which scheduling was requested, their points shall be the scores based on the past applications.

When requesting a consultation on the same drug for which the Request form for scheduling was submitted, but the consultation could not be provided because of PMDA's circumstances, the score will be as follows for each number of times the consultation was not provided.

Note that this score can be added only when a Request form for scheduling for the same product is submitted continuously every month. At the time of the consultation, the number of times the consultation was not provided becomes 0.

Number of times consultation was not provided	Score
Once	1 point
Twice	2 points
3 times	3 points
4 times	4 points
5 times or more	5 points