

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. 1225001

December 25, 2020

To (Note)

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

How Request Forms Related to a Trial of Consultations on BCS-based Biowaivers for Drugs Are Received, etc.

We appreciate your understanding and cooperation with the operations including review 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 BCS (Biopharmaceutics Classification System; hereinafter referred to as “BCS”)-based biowaivers for drugs under the Implementation Guidelines Notification.

PMDA will implement these consultations on a trial basis for the time being, and handle the requests for implementation, etc. as follows, not according to the provisions in “4. Request for consultation” and “5. Notification of implementation, etc. of face-to-face advice” in Attachment 34 of the Implementation Guidelines Notification. Please inform the member companies of your association of this matter.

Note

1 Request for consultation

When requesting a consultation on BCS-based biowaivers for drugs, please enter necessary information in Attached Form 25 of the Implementation Guidelines Notification, the “Request form for consultations on BCS for drugs” (hereinafter referred to as the “Request form”), and submit it to the Review Management Division, Office of Review Management via e-mail, fax, postal mail, or bringing it in person. In principle, the Request form will be received from 10:00 a.m. to 4:00 p.m. on the fourth Tuesday of each month. However, We may change the date and time depending on the situation. Please check the PMDA website.

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

(Points to consider)

- The number of products to be discussed shall be 1 per consultation, in principle. However, products with the same active ingredient and dosage form, but with different strengths will be handled as one product.
- No more than one request form shall be received per company for each month of consultation.

Contact 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). The Request form submitted according to 1 above will be received from 10:00 a.m. to 4:00 p.m. on the fourth Tuesday of each month.

2 Number of consultations conducted

In principle, the application for up to two consultations will be handled each month. When application is filed for both consultations on BCS for drugs (including additional consultations) and consultations on BCS for generic drugs (including additional consultations), one application each for consultations on BCS for drugs and consultations on BCS for generic drugs will be handled.

3 Notification of implementation, etc. of consultations

- (1) If it is judged difficult to implement because of the large number of requests, consultations will be selected as follows for each consultation category of consultations on BCS for drugs (including additional consultations) or consultations on BCS for generic drugs (including additional consultations).

According to the scores based on the “points of products for which consultation is requested” in 4 below, the request for consultation 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.

delayed depending on the scheduling status. If there is no communication within 1 to 2 days, please contact the Review Management Division, Office of Review Management.

(3) The date of submission of the application form and consultation materials will be provided in the “Information on face-to-face advice.” The date of submission of the application form shall be the third Monday of the month after the submission of the Request form, in principle.

4. Points for products for which consultation is requested

For the products for which consultations were 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 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 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