PMDA Notification No. 0401006
April 1, 2022

To (Note)

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

Partial Revision of "Implementation Guidelines for Pre-consultation on Regulatory Review Schedule of New Drugs"

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

The implementation method of pre-consultation on regulatory review schedule for new drugs conducted by PMDA is specified in "Implementation Guidelines for Pre-consultation on Regulatory Review Schedule for New Drugs" (PMDA Notification No. 1006001 of the Pharmaceuticals and Medical Devices Agency, dated October 6, 2014).

In connection with the recent change in the handling of "Explanation of electronic study data (Form A)" due to the issuance of "Technical Conformance Guide on Electronic Study Data Submissions" (PMDA/CPE Notification No. 0401003, PMDA/CRS Notification No. 0401001 issued jointly by Director of Center for Product Evaluation and Director of Center for Regulatory Science, Pharmaceuticals and Medical Devices Agency, dated April 1, 2022) and the revision of "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), description regarding the submission of the relevant data at this consultation was revised. In addition, we have made other necessary revisions of the description. Please inform relevant parties under your jurisdiction of these changes.

Attachment

Comparison Table of Before and After the Change of Implementation Guidelines for Pre-consultation on Regulatory Review Schedule of New Drugs

(The underlined parts are revised.)

After revision	Before revision
1 (Omitted)	1 (Omitted)
2 Subject of this consultation Drugs for which marketing approval application is scheduled and which fall under (1) to (7) and (9) to (9-2) in Attached Table 2-(1) Prescription drugs of PFSB Notification No. 1121-2 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated November 21, 2014, "Approval Applications for Drugs," are subject to this consultation. (The rest is omitted)	2 Subject of this consultation Drugs for which marketing approval application is scheduled and which fall under (1) to (7) and (9) to (9-2) in Attached Table 2-(1) Prescription drugs of PFSB Notification No. 0331015 of the Pharmaceutical and Food Safety Bureau, dated March 31, 2005, "Approval Applications for Drugs," are subject to this consultation. (The rest is omitted)
3, 4 (Omitted)	3, 4 (Omitted)
5 How to apply for consultation Enter the necessary information in "Product Overview for Pre-consultation on Regulatory Review Schedule of New Drugs" (the attached form of this notification; hereinafter referred to as the "product Overview"); using pre-consultation for drugs (Attachment 16 of PMDA Notification No. 0302070, dated March 2, 2012, "Implementation	5 How to apply for consultation Enter the necessary information in "Product Overview for Pre-consultation on Regulatory Review Schedule of New Drugs" (the attached form of this notification; hereinafter referred to as the "Product Overview"); using pre-consultation for drugs (Attachment 10 of PMDA Notification No. 0302070, dated March 2, 2012, "Implementation Guidelines for Face-to-face Advice, Confirmation of Certification, etc.

Guidelines for Face-to-face Advice, Confirmation of Certification, etc. Conducted by Pharmaceuticals and Medical Devices Agency"), change the title of the Application Form for Pre-consultation for Drugs (Attached Form 7) to "Pre-consultation on Regulatory Review Schedule"; and submit them to the Review Management Division, Office of Review Management. In addition, regarding electronic study data to be submitted at the time of approval application, if the "Explanation of electronic study data (Form A)" on the PMDA's website (https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/p-drugs/0026.html) (Japanese only) is to be submitted in accordance with PMDA/CPE Notification No. 0401003, PMDA/CRS Notification No. 0401001 issued jointly by Director of Center for Product Evaluation and Director of Center for Regulatory Science, Pharmaceuticals and Medical Devices Agency, dated April 1, 2022, "Technical Conformance Guide on Electronic Study Data Submission," please prepare it based on the guidance for preparation on the website and submit it to the Review Management Division, Office of Review Management. (The rest is omitted)	Conducted by Pharmaceuticals and Medical Devices Agency"), change the title of the Application Form for Pre-consultation for Drugs (Attached Form 7) to "Pre-consultation on Regulatory Review Schedule"; and submit them to the Review Management Division, Office of Review Management by fax. In addition, if electronic study data are to be submitted at the time of approval application, submit Appendix 8 of PMDA Notification No. 0302070 of PMDA, dated March 2, 2012, "Implementation Guidelines for Face-to-face Advice, Confirmation of Certification, etc. Conducted by Pharmaceuticals and Medical Devices Agency" as well to the Review Management Division, Office of Review Management by fax. (The rest is omitted)
6 Method of consultation, etc. (1) Notification of consultation schedule The person in charge at PMDA will communicate the schedule via e-mail, etc. (2) (Omitted) 7, 8 (Omitted)	6 Method of consultation, etc. (1) Notification of consultation schedule The person in charge at PMDA will communicate the schedule by fax. (2) (Omitted) 7, 8 (Omitted)

Attached Form Product Overview for Pre-consultation on Regulatory Review Schedule of New Drugs Month DD, YYYY (Middle part omitted) (Note) 1, 2 (Omitted) 3 The Product Overview for Pre-consultation on Regulatory Review Schedule of New Drugs shall be filled out as follows. (1) to (8) (Omitted) (9) Column for application category Enter the applicable number and category name among (1) to (7) and (9) to (9-2) in Attached Table 2-(1) Prescription drugs of PFSB Notification No. 1121-2 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated November 21, 2014, "Approval Applications for Drugs." (The rest is omitted) (10) Column for review category Enter an applicable review category among those specified in Appendix 9 of PMDA Notification No. 0302070 of the Pharmaceuticals and Medical Devices Agency, dated March 2, 2012. (11) Column for applicability of priority review [1] (Omitted) [2] If the product is designated as a drug subject to SAKIGAKE Designation System, pioneer drug, orphan drug, drug for specified	Attached Form Product Overview for Pre-consultation on Regulatory Review Schedule of New Drugs Month DD, YYYY (Middle part omitted) (Note) 1, 2 (Omitted) 3 The Product Overview for Pre-consultation on Regulatory Review Schedule of New Drugs shall be filled out as follows. (1) to (8) (Omitted) (9) Column for application category Enter the applicable number and category name among (1) to (7) and (9) to (9-2) in Attached Table 2-(1) Prescription drugs of PFSB Notification No. 0331015 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated March 31, 2005, "Approval Applications for Drugs." (The rest is omitted) (10) Column for review category Enter an applicable review category among those specified in Appendix 6 of PMDA Notification No. 0302070 of the Pharmaceuticals and Medical Devices Agency, dated March 2, 2012. (11) Column for applicability of priority review [1] (Omitted) [2] If the product is designated as an orphan drug or priority face-to-face advice product, enter the fact that it is designated and the date

use, or priority face-to-face advice product, enter the fact that it is designated and the date of designation. [3] If a consultation on eligibility for priority review or a consultation on eligibility for conditional approval has been conducted, enter the fact that the product is evaluated as eligible for priority review or conditional approval and the date of the evaluation report. (The rest is omitted)	of designation. [3] If a consultation on eligibility for priority review has been conducted, enter the fact that the product is evaluated as eligible for priority review and the date of the evaluation report. (The rest is omitted)

Reference

Final revision: April 1, 2022

Implementation Guidelines for Pre-consultation on Regulatory Review Schedule of New Drugs

1 Purpose

Based on the requirement for the prospective applicant and Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") to hold a meeting before an approval application to mutually confirm the necessary actions before or after each event regarding the submission timing of final reports of long-term administration studies and results of long-term storage studies as well as the review schedule for GLP/GCP/GPSP compliance assessment and GMP inspections, etc. in accordance with 1 of the note of PFSB/ELD Notification No. 1006-1, PFSB/CND Notification No. 1006-1 of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare/Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated October 6, 2014, "Handling of Approval Applications and Concept of Total Review Time for Improvement of Predictability, etc. of New Drug Approval," the present guidelines specify detailed rules for the procedures associated with the above.

2 Subject of this consultation

Drugs for which marketing approval application is scheduled and which fall under (1) to (7) and (9) to (9-2) in Attached Table 2-(1) Prescription drugs of PFSB Notification No. 1121-2 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated November 21, 2014, "Approval Applications for Drugs" are subject to this consultation.

Please note that applications with short total review time, such as those for priority review products in particular, require close adjustment to the specific review schedule.

3 Consultation items

(1) Confirmation of review schedule

[1] Planned timing of approval application

[2] Number of copies of data necessary at the time of approval application to be brought in (for reviewers and expert advisors) and timing of submission

[3] Planned timing of initial meeting, inquiries on key issues, expert discussion, targeted committee meeting of the Pharmaceutical Affairs and Food Sanitation Council, and approval in accordance with the standard timeline

At this stage, the application data have not been closely examined. Therefore, smooth progress of the review without problems (i.e., standard schedule) is assumed. After application for marketing approval, the schedule may be changed depending on the progress of the review. In such cases, the applicant will be notified of it each time.

[4] Timing of submission of final report of long-term administration studies

The timing of submission of the final report of long-term administration studies will be discussed considering whether or not the following actions can be taken.

A) Early submission of prompt reports of values
B) Prompt notification of the fact that the interim report requires correction, if such case arises
C) Submission of a draft

[5] Timing of submission of the report on results of ongoing long-term storage studies
[6] Timing of submission of other additional data, etc.

(2) Confirmation of GMP inspection

The timing of application for inspection, timing of inspection, timing of validation, etc. will be confirmed so that GMP inspection can be handled when the review proceeds according to the standard timeline.

(3) Confirmation of GLP/GCP/GPSP compliance assessment

[1] Overseas approval application status and inspection status by overseas authorities
[2] Timing of GLP/GCP/GPSP compliance assessment and target studies
[3] Use status of electromagnetic records (electronic case report forms, etc.) in studies in Japan

(4) Other matters to be confirmed

[1] Confirmation that cooperation of parties registering the master file can be obtained if the drug master file (master file) is used
[2] Sharing of the timing when responses to inquiries are expected to be concentrated, and confirmation of the fact that the applicant can promptly respond at that timing
[3] If electronic study data are submitted, confirmation of the details such as the scope of submission
[4] Other

4 Timing of application for consultation

From approximately three months to one month before the scheduled time of approval application

5 How to apply for consultation

Enter the necessary information in “Product Overview for Pre-consultation on Regulatory Review Schedule of New Drugs” (the attached form of this notification; hereinafter referred to as the “Product Overview”); using pre-consultation for drugs (Attachment 16 of PMDA Notification No. 0302070, dated March 2, 2012, “Implementation Guidelines for Face-to-face Advice, Confirmation of Certification, etc. Conducted by Pharmaceuticals and Medical Devices Agency”), change the title of the Application Form for Pre-consultation for Drugs (Attached Form 7) to “Pre-consultation on Regulatory Review Schedule”; and submit them to the Review Management Division, Office of Review Management. In addition, regarding electronic study data to be submitted at the time of approval application, if the “Explanation of Electronic Study Data (Form A)” on the PMDA’s website (https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/p-drugs/0026.html) (Japanese only) is to be submitted in accordance with PMDA/CPE Notification No. 0401003,

PMDA/CRS Notification No. 0401001 issued jointly by Director of Center for Product Evaluation and Director of Center for Regulatory Science, Pharmaceuticals and Medical Devices Agency, dated April 1, 2022, "Technical Conformance Guide on Electronic Study Data Submission," please prepare it based on the guidance for preparation on the website and submit it to the Review Management Division, Office of Review Management.

In addition, please attach the description of the scheduled timing of [4], [5], and [6] of 3, (1) above or other matters to be discussed. When describing the matters on which the applicant wishes to consult, please create a paragraph for each item such as "Review," "GMP," "GLP/GCP/GPSP compliance assessment," and "Electronic study data."

This consultation may be continued at the time of face-to-face advice such as pre-application consultation for drugs. In that case, please apply for the continued consultation by stating in the remarks column of the Product Overview that "Requesting continued consultation after ○○○ consultation for which scheduling on Month DD, YYYY has been requested" and attaching it to the "Request form for scheduling of face-to-face advice."

6 Method of consultation, etc.

(1) Notification of consultation schedule

The person in charge at PMDA will communicate the schedule via e-mail, etc.

(2) Implementation of consultation

[1] Consultation time should be between 30 minutes and 1 hour.

[2] From PMDA, the members of the review office in charge of the scheduled product, Office of Conformity Audit, and, as necessary, the Office of Manufacturing Quality and Advanced Review with Electronic Data Promotion Group will attend the meeting.

[3] In principle, the number of attendants on the applicant side should be no more than 5.

7 Non-face-to-face consultation

If a telephone consultation is desired, please enter the notification that a telephone consultation is desired in the remarks column of the Product Overview prepared in 5 above. When a person in charge at PMDA contacts the applicant for the scheduling of a consultation as described in 6, (1) above, it will be discussed and determined whether telephone consultation can be made between the applicant and the person in charge at PMDA.

8 Other

This consultation is free of charge.

If you have any questions about how to apply for a consultation, please contact the Review Management Division, Office of Review Management.

Attached Form

Product Overview for Pre-consultation on Regulatory Review Schedule of New Drugs

Month DD, YYYY

Name of applicant	
Planned timing of approval application	
Proposed brand name	
Generic name of active ingredient	
Test substance identification code	
Route of administration/dosage form	
Proposed indication	
Proposed therapeutic category	
Application category	
Review category	
Applicability of priority review	
Previous face-to-face advice (type and category of consultation, receipt number, date of consultation)	
Application or approval status in major developed countries for proposed indication	
Use status of overseas clinical trial data related to proposed indication	
Remarks	

(Note)

1 The paper size should be Japan Industrial Standard A4.

2 When not all the required information can be entered in the specified column, enter "as per Appendix ( )" in the column and prepare the appendix.

3 Product Overview for Pre-consultation on Regulatory Review Schedule of New Drugs shall be filled out as follows.

(1) Column for name of applicant

For a corporation, enter the name of the corporation.

(2) Column for planned timing of approval application

It is acceptable to describe it as "around early/mid/late Month, YYYY." (Example: Around early October 2014)

(3) Column for proposed brand name

Enter the brand name for which the approval application is planned. Enter "To be determined" if the brand name has not been determined.

(4) Column for generic name of active ingredient

For the ingredient name, if there is a generic name (JAN or INN), enter it (English name and Japanese name), and if there is no generic name, enter the chemical name (English name).

(5) Column for test substance identification code

Enter the test substance identification code.

(6) Column for route of administration/dosage form

Enter the route of administration (rectal administration, intravenous infusion, etc.) and dosage form (suppository, injection, etc.) of the drug product for which the consultation is requested.

(7) Column for proposed indication

Enter the indications for which approval application is planned.

(8) Column for proposed therapeutic category

Enter the therapeutic category for which the approval application is planned, and enter the therapeutic category code number (3 digits) in parentheses at the end.

(9) Column for application category

Enter the applicable number and category name among (1) to (7) and (9) to (9-2) in Attached Table 2-(1) Prescription drugs of PFSB Notification No. 1121-2 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated November 21, 2014, "Approval Applications for Drugs."

Example: (1) Drugs with new active ingredients, (2) New combination prescription drugs, (3) Drugs with new routes of administration, etc.

(10) Column for review category

Enter an applicable review category among those specified in Appendix 9 of PMDA Notification No. 0302070 of the Pharmaceuticals and Medical Devices Agency, dated March 2, 2012.

(11) Column for applicability of priority review

[1] If an application for orphan drug designation is being made for the relevant indication, enter "Orphan drug designation application pending."

[2] If the product is designated as a drug subject to SAKIGAKE Designation System, pioneer drug, orphan drug, drug for specified use, or priority face-to-face advice product, enter the fact that it is designated and the date of designation.

[3] If a consultation on eligibility for priority review or a consultation on eligibility for conditional approval has been conducted, enter the fact that the product is evaluated as eligible for priority review or conditional approval and the date of the evaluation report.

(12) Column for the previous face-to-face advice (type and category of consultation, receipt number, date of consultation)

If any face-to-face advice (including clinical trial consultation) has been provided in the past, enter its type, category of face-to-face advice (including clinical trial consultation), receipt number, and date of consultation. If a consultation has been held on the same test substance with a different route of administration, indication, dosage form, etc. from those of the present drug product, enter the information in the same manner as above, and report this in parentheses after the consultation date.

(13) Column for application or approval status in major developed countries for proposed indication

If the indication of the drug product for which the applicant is applying for a consultation has been approved in the U.S., the U.K., Germany, France, or the EU, enter the name of each country, etc. where the approval was granted and the year of the approval in parentheses after the country, etc. as in, for example, "U.S. (approved in 2014)." If the indication has not been approved, but clinical trials are being conducted or the application is pending, enter the same information, followed by the start year of clinical trials or the year of application as in, for example, "U.K. (clinical trials started in 2014)" or "EU (application in 2014)."

If the drug product has not been developed for the relevant indication in any of the U.S., the U.K., Germany, France, or the EU and the drug product has been approved for another indication in these countries, etc., enter the information as in "Germany (approved for another indication in 2014)." If the drug product has been approved for the same indication as that under consultation in countries in countries other than the above, enter the main developed countries and the approval year as in "Canada (approved in 2014)."

(14) Column for use status of overseas clinical trial data related to proposed indication

If overseas clinical trial data (including global clinical trials including Japan) are used as evaluation data, enter the status of overseas clinical trial implementation and the status of GCP inspection by overseas authorities.

(15) Remarks column

[1] If the application for consultation is not made jointly in cases of joint development, enter the name of the partner company, etc. of the joint development to clarify that it is a joint development.

[2] In cases of drug products that fall in the category of, or are expected to fall in the category of biological products (including specified biological products), enter "biological product" or "possible biological product," respectively.

[3] Enter "Application of genetic recombination technology" for drug products manufactured by using the genetic recombination technology.

[4] If the applicant wishes to continue this consultation at the time of face-to-face advice such as pre-application consultations, enter "Requesting continued consultation after ○○○ consultation for which scheduling on Month DD, YYYY has been requested."