PMDA/CPE Notification No. 660
September 6, 2024

To (Note)

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

How Request Forms for Prior Assessment Consultations for Drugs/Regenerative Medical Products Are Received, etc.

We appreciate your understanding of the operations of the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA").

As part of various efforts to shorten the drug lag, PMDA has been providing prior assessment consultations for drugs since FY 2011 and prior assessment consultations for regenerative medical products since FY 2015.

The requests for FY 2024 will be received as follows.

Please inform the member companies of your association. This notification will also be posted on the PMDA website. Please check it. We will discuss the implementation from the next fiscal year onward and communicate at a later date.

Note

1 How requests are received

(1) Period during which requests are received

For FY 2024, if consultation materials can be submitted between December 2024 and March 2025 (initiation of consultation), the "Request forms for prior assessment consultations for drugs" and "Request forms for prior assessment consultations for regenerative medical products" (Attached Forms 2 or 4 of the "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 "Request Forms") will be received during the following period. The Request Forms must be received within the period. Please note that Request Forms will not be received if they arrive at PMDA after the period.

From October 7 to October 11, 2024

(2) How to submit

The companies that wish to have a prior assessment consultation should enter necessary information in the Request Form for the product subject to the consultation concerned, and submit it to PMDA by e-mail. Please make sure it arrives during the above period. Since the companies that submitted the Request Form will be notified of propriety of the prior assessment consultation in writing, please make sure to enter the address of the institution where the person in charge works in the column for "Name and affiliation of the person in charge of this request and address and contact information of the facility at which he/she works" in Attached Forms 2 or 4.

(3) Where to submits

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

(Review Management Division, Office of Review Management, PMDA)

2 Content of prior assessment consultations

(1) Consultation category

1) New drugs

[1] Prior assessment consultations for drugs (quality)

[2] Prior assessment consultations for drugs (nonclinical: toxicity)

[3] Prior assessment consultations for drugs (nonclinical: pharmacology)

[4] Prior assessment consultations for drugs (nonclinical: pharmacokinetics)

[5] Prior assessment consultations for drugs (Phase I studies)

[6] Prior assessment consultations for drugs (Phase II studies)*

[7] Prior assessment consultations for drugs (Phase II/III studies)*

* The categories, [6] and [7], cannot be selected in an overlapping manner.

2) Regenerative medical products

[1] Prior assessment consultations for regenerative medical products (safety/quality/efficacy)

[2] Prior assessment consultations for regenerative medical products (exploratory studies)

[3] Prior assessment consultations for regenerative medical products (confirmatory studies)

(2) Material submission period for the product subject to consultation

From December 2024 to March 2025

(3) Products subject to consultation (planned application category at the time of application)

1) New drugs

(1) Drugs with new active ingredients, (2) New combination drugs, (3) Drugs with a new route of administration, (4) Drugs with new indications, (5) Drugs in new dosage forms, (6) Drugs with a new dosage, (8) Drugs in an additional dosage form (during re-examination period), and (9) Combination prescription drugs with similar formulations (during re-examination period) in Attached Table 2-(1) of PFSB Notification No. 1121-2, dated November 21, 2014

2) Regenerative medical products

(1-1) New regenerative medical products, (1-2) New regenerative medical products for which conditional or time-limited approval was granted with new implementation within the period, (2) Regenerative medical products with new administration/directions for use, (3) Regenerative medical products with new indications, (4) Regenerative medical products with new structures, (5) Regenerative medical products with new dosage, and (6) Regenerative medical products related to addition of specifications in Attached Table 2 of PFSB Notification No. 0812-30, dated August 12, 2014

(4) Number of products for which consultation is provided

If a large number of requests are received, the products for which consultation is provided will be selected to the extent that the requests can be received, in accordance with the following concept of priority, taking into account the influence on review operations, etc. in each category in charge.

The result of selection will be directly communicated in writing to the person who submitted the request form within one month after the end of the period during which requests are received, in light of the intellectual property, etc. of the company.

<Reference> Concept of priority in cases where many requests are received

- New drugs/regenerative medical products with high medical needs
- Drugs/regenerative medical products with new active ingredients
- Drugs/regenerative medical products in an advanced development stage for which many consultation categories have been requested

In the selection from the same type of products with the same indications for which requests have been received around the same time, these products shall be handled equally unless there is a clear difference in terms of medical necessity, etc.

If consultation for more than one consultation category is desired for one product, please submit the materials at the same time. If it is difficult to submit at the same time, please have a pre-consultation meeting before submitting the request form to consult the review office in charge.

3 Inquiries

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