Provisional Translation (as of May 2024)*

PSB/PED Notification No. 0329-1
March 29, 2024

To: Prefectural Health Departments (Bureaus)

From: Director, Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Partial revision of "Planning of the Pediatric Drug Development Program during Development of Drugs for Adults"

We have presented the basic principles of planning of the pediatric drug development program during development of drugs for adults in the "Planning of the Pediatric Drug Development Program during Development of Drugs for Adults" (PSB/PED Notification No. 0112-3 issued on January 12, 2024 by the Director of PSB/PED, MHLW. Hereinafter, referred to as "the Director's Notification").

We have summarized the handling details in the development plan for pediatric drugs and revised the Director's Notification as shown in the attachment. We ask you to understand the changes and to cooperate in informing related parties under your administration of this matter.

The specific handling in this notification will apply from April 1, 2024.

* This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Attachment

PSB/PED Notification No. 0112-3
January 12, 2024
[Partially revised] March 29, 2024

To: Prefectural Health Departments (Bureaus)

From: Director, Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Planning of the Pediatric Drug Development Program during Development of Drugs for Adults

Drugs for pediatric use (hereinafter referred to as "pediatric drug") have more difficulties of the clinical development compared to those for adults despite high medical needs. Therefore, more efficient development programs have been desired so that pediatric products are developed without delay from those for adults.

From the viewpoint of ensuring early access to pediatric drugs, the specific handling have been prepared for planning of the pediatric drug development program in the notice below that is desired during the development of drugs for adults based on the results of a review at "Review Committee on Regulatory Affairs to Strengthen Drug Discovery/Ensure Stable Supply" by the Ministry of Health, Labour and Welfare. We ask you to understand the specific handling and to cooperate in informing related parties under your administration of this matter.

Note

1. Development of pediatric drugs

Development of pediatric drugs subject to this notification refers to the development which meet any one or more of the following (1) to (3) based on medical needs.

(1) Development to include children in the indications of a drug whose indication is differentiated between adults and children

(2) Development to determine appropriate dosage and administration for children

(3) Development of pediatric dosage forms different from those for adults

2. Basic principles on the pediatric drug development

(1) When a drug with new active ingredients or new indications for adults is developed (including development for additional indications), it is desirable to prepare a pediatric drug development plan that is related to the indication for adults, confirm with the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as the "PMDA") before filing the approval application of the drug for adults, and proceed with the development without delay based on the prepared development plan.

This shall not prevent applicants from confirming the pediatric drug development plan with the PMDA in the case of a drug with different indications between adults and children (for instance, indications of different types of cancer between adults and children).

(2) If it is difficult to confirm the pediatric drug development plan in the above 2. (1) with the PMDA before filing the approval application for adults, it is desirable to confirm with the PMDA by the end of the review on the application and proceed with the development without delay based on the development plan.

3. Development to determine appropriate dosage and administration for children

For a development plan to determine the appropriate dosage and administration for children in the above 1. (2), not only the implementation of clinical trials in Japanese children should be considered, but also the utilization of adult data, overseas pediatric data, real-world data, modeling & simulation, etc. should be considered and confirmed by the PMDA.

4. Development of pediatric dosage forms different from those for adults

For development of dosage forms for children different from those for adults in the above 1. (3), the development can take a longer period of time than when the

development of a dosage form for children is not necessary. Therefore, the development plan with this point taken into account should be confirmed by the PMDA.