Provisional Translation (as of April 2024)*

PSB/PED Notification No. 0112-3
January 12, 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 (hereafter 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, basic principles 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 basic principles and to cooperate in informing related parties under your administration of this matter.

You will be informed of the specific handling based on these basic principles and the timing of its application later.

## Note

1. 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

* 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.

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 pediatrics).

(2) If it is difficult to confirm the pediatric drug development plan (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.