

PSB/PED Notification No. 0227-8

February 27, 2026

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").

Based on the fact that efforts to plan a pediatric drug development program are required according to the "Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices" (Act No. 37 of 2025, hereinafter referred to as the "Amendment Act"), the Director's Notification has been changed as shown in the Attachment, and the decision has been made to apply the changes from May 1, 2026. Please be aware of this and fully inform relevant businesses in your jurisdiction.

* This English document has been prepared for reference purposes only. In the event of any inconsistency and discrepancy between the Japanese original and the English translation, the Japanese text shall prevail.

Old-and-new comparison table

(The underlined parts are the revised.)

After amendment	Before amendment
<p>1. Development of pediatric drugs</p> <p><u>In the provisions of Article 14-8-2 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960) and Article 69-2 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Ministry of Health and Welfare Ordinance No. 1 of 1961), it is stated that marketing authorization holders shall make efforts to develop a plan for collecting data on the quality, efficacy, and safety of pediatric drugs and to collect the data without delay when they intend to obtain approval for drugs with different active ingredients, content, dosage and administration, indications, etc. from those of already approved drugs.</u></p> <p>Development of pediatric drugs subject to this notification refers to the development which meets any one or more of the following (1) to (3) based on medical needs.</p> <p>(1) Development to include children in the indications of a drug whose indication is differentiated between adults and children</p> <p>(2) Development to determine appropriate dosage and</p>	<p>1. Development of pediatric drugs</p> <p>Development of pediatric drugs subject to this notification refers to the development which meets any one or more of the following (1) to (3) based on medical needs.</p> <p>(1) Development to include children in the indications of a drug whose indication is differentiated between adults and children</p> <p>(2) Development to determine appropriate dosage and administration for children</p> <p>(3) Development of pediatric dosage forms different from those for adults</p>

<p>administration for children</p> <p>(3) Development of pediatric dosage forms different from those for adults</p>	
<p>2. Basic principles on the pediatric drug development</p> <p><u>Basic principles on the pediatric drug development are as shown in (1) and (2) below. In view of the difficulty in conducting clinical trials in children, it is desirable to conduct the development in global clinical trials and to have the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") confirm the development plan in Japan early in order to conduct simultaneous development in Japan and overseas.</u></p> <p>(1) When a drug with new active ingredients or new indications for adults is developed (including development for additional indications), <u>efforts should be made to prepare a pediatric drug development plan that is related to the indication for adults, confirm with the PMDA before filing the approval application for the drug for adults, and proceed with the development without delay based on the prepared development plan.</u></p>	<p>2. Basic principles on the pediatric drug development</p> <p>(new)</p> <p>(1) When a drug with new active ingredients or new indications for adults is developed (including development for additional indications), <u>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 for the drug for adults, and proceed with the development without delay</u></p>

<p>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).</p> <p>(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, <u>efforts should be made 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.</u></p>	<p>based on the prepared development plan.</p> <p>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).</p> <p>(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 prepared development plan.</p>
<p>5. <u>Confirmation by PMDA</u> <u>PMDA's confirmation in the above 2 to 4 should be provided in consultations such as the Consultation on Confirmation of the Pediatric Drug Development Program. Only for the contents subject to the Consultation on Confirmation of the Pediatric Drug Development Program regarding the drugs for which the application for their approval for adults is made by April 30, 2028, the PMDA's confirmation can be conducted also in</u></p>	<p>(new)</p>

<p><u>the process of the review of the drugs</u> <u>for adults after the application for their</u> <u>approval for adults.</u></p>	
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Reference
(full text after revision)

PSB/PED Notification No. 0112-3

January 12, 2024

[Partially revised] March 29, 2024

[Partially revised] February 27, 2026

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 in 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 has 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.

A copy of this notification will be sent to the organizations, etc. listed in the note.

Note

1. Development of pediatric drugs

In the provisions of Article 14-8-2 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960) and Article 69-2 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Ministry of Health and Welfare Ordinance No. 1 of 1961), it is stated that marketing authorization holders shall make efforts to develop a plan for collecting data on the quality, efficacy, and safety of pediatric drugs and to collect the data without delay when they intend to obtain approval for drugs with different active ingredients, content, dosage and administration, indications, etc. from those of already approved drugs.

Development of pediatric drugs subject to this notification refers to the development which meets 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

Basic principles on the pediatric drug development are as shown in (1) and (2) below. In view of the difficulty in conducting clinical trials in children, it is desirable to conduct the development in global clinical trials and to have the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") confirm the development plan in Japan early in order to conduct simultaneous development in Japan and overseas.

- (1) When a drug with new active ingredients or new indications for adults is developed (including development for additional indications), efforts should be made to prepare a pediatric drug development plan that is related to the indication for adults, confirm with the PMDA before filing the approval application for 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, efforts should be made 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 a dosage form for children different from that 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.

5. Confirmation by PMDA

PMDA's confirmation in the above 2 to 4 should be provided in consultations such as the Consultation on Confirmation of the Pediatric Drug Development Program. Only for the contents subject to the Consultation on Confirmation of the Pediatric Drug Development Program regarding the drugs for which the application for their approval for adults is made by April 30, 2028, the PMDA's confirmation can be conducted also in the process of the review of the drugs for adults after the application for their approval for adults.