

Administrative Notice

February 27, 2026

To: Pharmaceutical Affairs Sections, Prefectural Health Departments (Bureaus)

From: Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare

Revision of Q & A for "Planning of the Pediatric Drug Development Program during
Development of Drugs for Adults"

The Q & A for "Planning of the Pediatric Drug Development Program during Development of Drugs for Adults" have been shown in the "Q & A for 'Planning of the Pediatric Drug Development Program during Development of Drugs for Adults'" (Administrative Notice of Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare dated March 29, 2024, hereinafter referred to as the "Old Administrative Notice").

Q & A for "Planning of the Pediatric Drug Development Program during Development of Drugs for Adults" has been changed as shown in the Attachment, and the decision has been made to apply these changes from May 1, 2026. Please be aware of this and fully inform relevant businesses, etc. in your jurisdiction as a reference for their operations.

The old administrative notice will be abolished as of April 30, 2026.

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Provisional Translation (as of April 2026)*

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(Attachment)

Q & A for the Planning of the Pediatric Drug Development Program during Development of Drugs for Adults

Q1. Does 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") mean that planning of the pediatric drug development program is required when drugs for adults are developed?

A1. Efforts to prepare a pediatric drug development plan are required.

Q2. When developing a generic drug with the same active ingredient, indications, etc. as those of already-approved drugs, do applicants have to make efforts to formulate a development plan for pediatric drugs, and is the plan subject to confirmation in compliance with the Director's Notification?

A2. The same active ingredients, indications, etc. as those of approved drugs are not applicable. If a drug with the same active ingredient as that of an approved drug is to be developed for an indication, etc. different from approved indications, etc., efforts must be made to develop a pediatric drug development plan.

Q3. Does "a drug with different indications between adults and children (for instance, indications of different types of cancer between adults and children)" include any pediatric cancer in a different type from adults that will be treated with a molecular target drug for cancer and is expected to respond to it in light of its mechanism of action?

A3. It is included.

Q4. To have a development plan confirmed by the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") based on the Director's Notification, what concrete procedures are required?

A4. Confirmation by PMDA should be obtained by any of the following procedures.

[1] Confirmation at the Consultation on Confirmation of the Pediatric Drug Development Program

Use "Consultation on Confirmation of the Pediatric Drug Development Program" of

PMDA. Note that the "Consultation on Confirmation of the Pediatric Drug

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Development Program" is only for confirmation of the development plan. For scientific consultation on the appropriateness of the clinical study design, sufficiency of the clinical data package (including the cases where no domestic or global clinical trials are conducted), etc., scientific consultations such as the consultation after completion of phase II study for drugs should be used.

[2] Confirmation at the scientific consultation for pediatric drugs

If the product is not subject to "Consultation on Confirmation of the Pediatric Drug Development Program" by PMDA, confirmation based on the Director's Notification should be obtained in the scientific consultation for pediatric drugs. Even if the contents of the scientific consultation are related to the clinical study design, etc. for children, it is necessary to present the request for confirmation based on the Director's Notification as a consultation item.

[3] Confirmation at the scientific consultation for drugs for adults

Only for the contents subject to "Consultation on Confirmation of the Pediatric Drug Development Program" by PMDA, it is possible to receive confirmation from PMDA based on the Director's Notification regarding the development plan for children by using the clinical trial consultation for drugs for adults (consultation after completion of phase II study for drugs, etc.). In this case, list the fact that the confirmation based on the Director's Notification is desired as a consultation item and describe the development plan by referring to the information that should be included in the consultation material for 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. In that case, describe the development plan referring to the information that should be included in the consultation material for the Consultation on Confirmation of the Pediatric Drug Development Program in Module 1.5 of the Common Technical Document (hereinafter, "CTD") of the approval application documents. Those who wish to receive confirmation by the PMDA in the process of the review of drugs for adults should present their wish to receive confirmation based on the Director's Notification at a pre-review consultation for approval for new drugs.

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Q5. Is the Director's Notification applicable to a pediatric drug development plan if the PMDA confirms it before the approval application for additional indication in adults is filed when the drug is developed for the new additional indication in adults?

A5. It is applicable. For confirmation by the PMDA on the pediatric drug development plan for drugs with different "indications" between adults and children, the consultation after completion of phase II study for drugs, etc. should be used, instead of "Consultation on Confirmation of the Pediatric Drug Development Program."

Q6. For a pediatric drug development plan, isn't it applicable to the development of pediatric drugs specified in the Director's Notification unless the plan provides the contents of conducting clinical trials?

A6. If an appropriate plan can be prepared for approval, it is not always necessary to conduct a new clinical trial. Even if a development plan is made by utilizing real-world data, modeling & simulation, etc., it is regarded as the development of pediatric drugs specified in the Director's Notification. If the PMDA confirms a development plan that does not involve clinical trials, scientific consultations other than "Consultation on Confirmation of the Pediatric Drug Development Program" should be used.

Q7. In the Director's Notification, what is the specific age group expected as children?

A7. Efforts should be made to develop a plan for the age group in which the need is recognized for each indication to be developed, including newborns. If it is necessary to examine the appropriate dosage and administration by age group in consideration of physical constitution, degree of maturation, etc. among the age groups for which the need of development is recognized, it may be acceptable to develop a drug in a stepwise expansion of the age group. In such a case, the overall picture of the plan including stepwise development should be prepared and confirmed by the PMDA.

Q8. When a pediatric drug (for children aged 10 or 12 years, or older) that can be evaluated together with adults is developed based on "Considerations for the Clinical Evaluation of Drugs in Pediatric Patients (10 or 12 Years of Age and Older) Who Can be Evaluated Together with Adults" (the administrative notice issued by PSEHB/ELD dated June 30, 2020), is it the development of pediatric

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drugs specified in the Director's Notification?

A8. Yes, it is. However, if there is another pediatric age group for which the development is considered necessary in addition to the pediatric population to be evaluated together with adults, the entire plan including the development for that age group should be prepared and confirmed by the PMDA. If development is not conducted for a specific age group for reasons including no need for such development, the reason should be explained.

Q9. The Director's Notification states, "Proceed with the development without delay based on the prepared development plan." How long should the development period be?

A9. It is difficult to specify the period across the board, but from the viewpoint of promptly starting the development of pediatric drugs, it is desirable to take the following actions if a dosage form for children different from that for adults is not developed. For actions to be taken when developing a pediatric dosage form, refer to QA10.

- For a development plan requiring submission of Clinical Trial Notifications, submit the Clinical Trial Notifications within 2 years after the approval of drugs for adults.
- For a development plan with clinical trials that do not require the submission of Clinical Trial Notifications, start the clinical trials within 2 years after the approval of drugs for adults. The start date of a clinical trial in this administrative notice shall be the start date of the implementation period described in the protocol of the clinical trial.
- For development plans without clinical trials (development plans utilizing real-world data, modeling & simulation, etc.), file an approval application in accordance with the plan within 2 years after the approval of drugs for adults.

In the case of development to expand the age group in a step-by-step manner, these actions shall refer to the actions to be taken for the plan that is to be started first.

Q10. The Director's Notification states, "For development of a dosage form for children different from that for adults, the development can take a longer period of time than when the development of a dosage form for children is not necessary." How long should the development period be if a dosage form for children is developed?

A10. It is difficult to specify the period across the board, but from the viewpoint of

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promptly starting the development of pediatric drugs, efforts should be made to take the following actions if a dosage form for children different from that for adults is developed.

- For a development plan requiring submission of Clinical Trial Notifications, submit the Clinical Trial Notifications within 3 years after the approval for adults.
- For a development plan with clinical trials that do not require the submission of Clinical Trial Notifications, start the clinical trials within 3 years after the approval for adults. The start date of a clinical trial in this administrative notice shall be the start date of the implementation period described in the protocol of the clinical trial.
- For development plans without clinical trials (development plans utilizing real-world data, modeling & simulation, etc.), file an approval application in accordance with the plan within 3 years after the approval for adults.

Q11. The notification states, "Development to determine appropriate dosage and administration for children." Does it include the case of confirming that the appropriate dosage and administration for children is the same as those for adults? Does this include the case where a clinical trial was conducted on the assumption that the dosage and administration for adults would be different from the appropriate dosage and administration for children, but as a result, the same dosage and administration as those for adults are established for children?

A11. Both are included.

Q12. If the PMDA's confirmation is made in accordance with the Director's Notification, how will the record be kept?

A12. In the record of face-to-face scientific consultation with the PMDA, it is described that the confirmation was made based on the Director's Notification.

(An example of a description in the record of the PMDA consultation)

The pediatric drug development plan in this consultation has been confirmed in accordance with 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).

If the PMDA confirms the plan and an approval application for an indication in adults is filed or an approval application for an indication for children is filed after the development based on the confirmed development plan, it is also described in the review report for the indication that the confirmation by the PMDA has been made.

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(An example of descriptions in the review report: when a confirmation has been made by the PMDA before an approval application for adults is filed)

For this product, the pediatric drug development plan has been confirmed in the face-to-face scientific consultation with the PMDA (Consultation No. ●●●●) in accordance with 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).

(An example of descriptions in the review report: when a confirmation has been made by the PMDA after an approval application for adults is filed)

For this product, the pediatric drug development plan has been confirmed in the face-to-face scientific consultation with the PMDA (Consultation No. ●●●●) in accordance with 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). This face-to-face consultation was conducted after the approval application for the drug for adults.

Q13. If a confirmation is made by the PMDA based on the Director's Notification and an approval application for children is filed, is it necessary to describe in the approval application document the fact that the confirmation has been made by the PMDA?

A13. Yes. The Module 1.5 of the CTD, an approval application document, shall provide the fact that the pediatric drug development plan has been confirmed in the face-to-face scientific consultation with the PMDA (Consultation No. ●●●●) in accordance with 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).

Q14. If a development plan has been significantly changed after confirmation by the PMDA, is it necessary to have another scientific confirmation based on the Director's Notification?

A14. If any of the following changes occurs in the development plan and if the submission of the Clinical Trial Notification or approval application is substantially delayed compared with the estimated number of years described in Q8 and Q9, confirmation by PMDA can be obtained again using the "Consultation on Confirmation of the Pediatric Drug Development Program," etc.

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- When there is a change in the target age group
- When a dosage form for children is required as a result of the progress of development, although the pediatric dosage form was considered unnecessary

Q15. What procedures will be required if PMDA's confirmation cannot be obtained before the approval application for a drug for adults because of unavoidable circumstances, although the confirmation by the PMDA is scheduled to be made based on the Director's Notification?

A15. Present the fact that you wish to receive confirmation based on the Director's Notification at a pre-review scientific consultation for approval for new drugs for adults. Also, receive the confirmation by the PMDA by scientific consultations such as Consultation on Confirmation of the Pediatric Drug Development Program before the review report of the drug for adults is finalized.

Q16. Regarding the description, "a drug with different indications between adults and children (for instance, indications of different types of cancer between adults and children)," what kinds of cases other than cancer are assumed?

A16. For example, the cases where the "indication" is restricted to adults by a certain prefix as well as diseases with different names for adults and children, such as "adult-onset Still's disease" or "systemic juvenile idiopathic arthritis," are assumed.