

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

Questions and Answers (Q & A) for Handling of Re-examination Period

Re-examination periods of prescription drugs have been shown in "Re-Examination Period of Prescription Drugs" (PSEHB Notification No. 0831-11 dated August 31, 2020 by Director-General of Pharmaceutical Safety and Environmental Health Bureau, Ministry of Labour and Welfare), and "Handling of Re-Examination Period" (PSEHB/PED Notification No. 0831-16 dated August 31, 2020 by Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, hereinafter referred to as "the Notification by Director"). The Notification by Director has been revised and Q & A have been summarized as shown in the Appendix. Please be aware of this and fully inform relevant businesses, etc. in your jurisdiction.

With the application of this administrative notice, "Questions and Answers (Q & A) for Extension of Re-examination Period in Association with Development of Pediatric Dosage and Administration" (Administrative Notice of Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated November 26, 2020) will be abolished as of April 30, 2028.

* 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.

Questions and Answers (Q & A) for Handling of Re-examination Period

Q1. It is stated that "After the first approval of a specified indication, the first approval with the addition of clearly different doses such as pediatric doses etc. for the same indication." Specifically, what kind of cases are applicable?

A1. An example of applicable cases is the one where the specified indication is "pulmonary arterial hypertension" and the initial approval for the specified indication is for adults, followed by the approval obtained in order to add the dose related to "pulmonary arterial hypertension" in children.

Q2. What kind of cases are applicable to the description, "the development proceeds based on the development plan concerned without delay," in 1, 4 of the Note for the Notification by Director?

A2. If no dosage form for children that is different from that for adults will be developed, the following actions are applicable:

- For a development plan requiring submission of Clinical Trial Notifications, the Clinical Trial Notifications are submitted within 2 years after the approval for adults.
- For a development plan by conducting clinical trials not requiring any Clinical Trial Notification, clinical trials are started within 2 years after the approval for adults. The start date of a clinical trial in this administrative notice is the start date of the study period mentioned in the protocol of the clinical trial.
- For a development plan involving no conduct of clinical trials (a development plan by use of real-world data, modeling, simulation, etc.), an approval application in accordance with this plan is filed within 2 years after the approval for adults, or an agreement is reached through the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") scientific consultation on the plan toward approval application, based on the obtained data.

If any dosage form for children that is different from that for adults will be developed, the following actions are applicable:

- For a development plan requiring submission of Clinical Trial Notifications, the Clinical Trial Notifications are submitted within 3 years after the approval for adults.
- For a development plan by conducting clinical trials not requiring any Clinical Trial Notification, clinical trials are started within 3 years after the approval for adults. The start date of a clinical trial in this administrative notice is the start date of the study period mentioned in the protocol of the clinical trial.

- For a development plan involving no conduct of clinical trials (a development plan by use of real-world data, modeling, simulation, etc.), an approval application in accordance with this plan is filed within 3 years after the approval for adults, or an agreement is reached through the PMDA scientific consultation on the plan toward approval application, based on the obtained data.

"For a development plan by conducting clinical trials not requiring any Clinical Trial Notification" or "for a development plan involving no conduct of clinical trials (a development plan by use of real-world data, modeling, simulation, etc.)," only the cases where the PMDA scientific consultation are applicable.

Q3. Is the extension of the re-examination period associated with the development of pediatric dosage and administration allowed for the cases where the development for adults and the development for children are conducted in parallel and the approval application is to be submitted for adults and children at the same time?

A3. Yes.

Q4. Is the extension of the re-examination period associated with the development of pediatric dosage and administration allowed only at the time of the approval as a drug with a new active ingredient? Or is it allowed at the time of the approval of drugs with new indications?

A4. The extension may be allowed at the time of the approval of drugs with new indications. Therefore, confirm with the person in charge at the Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare (hereinafter referred to as the "Pharmaceutical Evaluation Division"). For example, if the indication of a drug at the time of its approval as a drug with a new active ingredient is Disease A, the re-examination period is extended if the development plan for finding dosage in pediatrics with Disease A is submitted and the development proceeds based on the development plan concerned without delay. Thereafter, if addition of an indication, Disease B, which is clearly different from the current indication is intended, the re-examination period related to the indication for Disease B may be extended if the development plan for finding dosage in pediatrics with Disease B is submitted and the development proceeds based on the development plan concerned without delay.

Q5. If applicants wish to extend the re-examination period in association with the dose-finding development for pediatrics, what actions should they take?

A5. State the reason for judging pediatric development necessary and describe an outline of the development plan (including the planned timing of clinical studies) in Module 1.5 of the Common Technical Document in the application data for the drug for adults. As the outline, it is acceptable to simply state that "the pediatric development plan has already been confirmed in PMDA scientific consultation (Scientific advice No.: ●●●●)" if the development plan has already been confirmed by PMDA in the scientific advice based on "Planning of the Pediatric Drug Development Program during Development of Drugs for Adults" (PSB/PED Notification No. 0112-3 dated January 12, 2024 by Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, hereinafter referred to as the "Notification by Director"). Also, consult the person in charge at the Pharmaceutical Evaluation Division after making an approval application for the drug intended for adults. At the time of consultation with the person in charge at the Pharmaceutical Evaluation Division, submit the record of the scientific advice if the scientific advice on pediatric development has been provided by PMDA. In the case of a development plan requiring the submission of Clinical Trial Notifications, submit the Clinical Trial Notifications associated with the pediatric development.

Q6. Regarding 1, 4 of the Note for the Notification by Director, is it possible to extend the investigation period based on the revised Notification by Director on or after the date of its application even if "the development proceeds based on the development plan" (in relation to the start, etc. of clinical trials) on or before the date of application of the revised Notification by Director (May 1, 2026)?

A6. The investigation period can be extended on or after the date of enforcement of the Amendment Act if the development plan for finding dosage in pediatrics has been submitted by the end of review for the marketing approval and the planned clinical studies have been started without delay according to the Notification by Director before revision.