Provisional Translation (as of April 2024)*

Administrative Notice
November 26, 2020

To: Prefectural Health Supervising Department

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

Questions and Answers (Q&A) for Extension of Re-Examination Period in Association with Development of Pediatric Dosage and Administration

Handling of the extension of the re-examination period has been shown in "Handling of Re-Examination Period' (PSEHB/PED Notification dated August 31, 2020 by the Director of Pharmaceutical Evaluation Division, hereinafter referred to as "the Notification by Director"). For Note 1-4 of the Notification by Director, we have summarized questions and answers (Q&A) in Appendix. We ask you to understand and inform related parties under your administration.

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

(Appendix)

Questions and Answers (Q&A) for Extension of Re-Examination Period in Association with Development of Pediatric Dosage and Administration

Q1: As for the description “the development plan for finding the dosage in pediatrics is submitted by the end of review on marketing approval” in Note 1-4 of the Notification by Director, what are we required to do?

A1:

Explain the reason that you have decided that pediatric development is necessary and the outline of the development plan (including the scheduled timing of clinical study) in Module 1.5 of Common Technical Document in the application data.

Q2: With regard to the description “the planned clinical study is started without delay” in Note 1-4 of the Notification by Director, what cases does it refer to?

A2:

It refers to cases where the clinical trial notification of a planned clinical trial is submitted within 2 years after approval. However, this shall be reviewed as appropriate.