Provisional Translation (as of May 2026) *

Administrative Notice
May 12, 2026

To: Division of Pharmaceutical Affairs,
Prefectural Health Department (Bureau)

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

Questions and Answers (Q&A) on Guideline for Ensuring the Quality, Safety, and Efficacy of Biosimilars (Part 2)

Assurance of the quality of biosimilars has been indicated in the Guideline for Ensuring Quality, Safety, and Efficacy of Biosimilars (Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau (PSEHD/PED) Notification No. 0204, Ministry of Health, Labour and Welfare (MHLW), dated February 4, 2020). Additionally, Questions and Answers on the guideline has also been indicated in the Questions and Answers(Q&A) on Guideline for Ensuring the Quality, Safety, and Efficacy of Biosimilars (PSB/PED Administrative Notice dated January 25, 2024). We have compiled the attached Q&A (Part 2).

We would like to ask you to please disseminate this document to the relevant business operators under your jurisdiction.

Annex

Questions and Answers (Q&A) on Guideline for Ensuring the Quality, Safety, and Efficacy of Biosimilars (Part 2)

Corresponding sections	Question (Q)	Answer (A)
6.4 Grant of indications When a biosimilar has high similarity in quality attributes to the original biopharmaceutical, comparability is demonstrated in nonclinical pharmacological studies and others, and it is judged that efficacy is comparable to the original biopharmaceutical in certain indications with no difference in the safety profile, the indications verified in clinical trials are granted to the biosimilar. Furthermore, when the original biopharmaceutical used as a reference product has multiple indications, and if it can be expected that the pharmacological action similar to that of the original biopharmaceutical can be expected and there are no concerns in the safety profile, the indications that have not been verified in clinical trials can be granted to the biosimilar regardless of the same or difference in dosage and dose regimen or administration period for each indication (extrapolation).	When comparative studies on quality attributes, together with the results of comparative pharmacokinetic (PK) and/or pharmacodynamic (PD) studies, support a conclusion of biosimilarity of clinical efficacy in a specific indication, is it acceptable to grant that indication(s) to a biosimilar without conducting a comparative efficacy study?	Yes. In addition to comparative studies on quality attributes and non-clinical studies, if sufficient data are obtained—consistent with the description in Section 6 of the Guideline—where PK and/or PD studies are sufficient to establish biosimilarity in the clinical endpoint of interest, a comparative efficacy study may not be necessary. In such cases, indication(s) may be granted to a biosimilar if it can be reasonably concluded, based on comparative data on quality attributes and other relevant evidence, that the pharmacological action similar to that of the original biopharmaceutical can be expected and there are no concerns in the safety profile. The appropriateness of granting the intended indication(s) should be assessed based on the sufficiency and relevance of the available data. Therefore, it is recommended that applicants consult the Pharmaceuticals and Medical Devices Agency on a case-by-case basis, including through face-to-face consultation meetings, to confirm whether a comparative efficacy study may not be necessary.