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Approval Status and Development Strategy of Biosimilars in the Light of the Different Guidelines in the U.S., the EU and Japan

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Summary

Unlike the case of small-molecular generic drugs, it is virtually impossible to make biosimilars that are identical to reference products. To confirm similarity, clinical studies are basically required. The U.S., the EU and Japan have each issued guidelines to regulate biosimilars. Since these guidelines are not harmonized, it is quite challenging for applicants to draw up a development plan to satisfy the requirements of all three authorities. Here we examine the differences among the three sets of guidelines and we discuss the implications of these differences for the effective development of biosimilars. We also analyzed clinical study information from the ClinicalTrials.gov database and assessment reports of biosimilars to determine how differences among the three sets of guidelines affect biosimilars development in practice.

Key regulatory differences that appear to impact adversely on current development strategies for biosimilars concern the requirements for the reference product, the requirement that a trial uses a domestically approved dose, and the acceptability of foreign clinical data. It is important to note that the aim of a clinical study of biosimilars is to demonstrate similarity, not to newly establish efficacy and safety. We suggest that it would be desirable to deregulate and harmonize the regulation of biosimilars development, focusing on demonstrating similarity and securing the safety of patients by post-marketing surveillance, especially regarding risk factors that may not have been fully investigated at the development stage.

Key words

Biosimilar, Follow-on biologic, FDA, EMA, MHLW, PMDA