A Proposed ICH Guideline for Biosimilars Approval

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Abstract

Guidelines for the approval or licensing of biosimilars have evolved over the past 18 years since the first introduction of biosimilars. Amendments to these guidelines are constrained in the US by legislation and in the EU and WHO due to collaborative consent requirements. The MHRA has recently joined ICH and brought its guideline that is most rational and scientific; it removes animal and clinical efficacy testing, as evidenced by hundreds of studies, billions of doses administered, and a better understanding of recombinant therapeutic proteins. However, there remains a need to bring a neutral jurisdiction guideline that all countries can adopt; while the EU, FDA, Japan, and now the UK are the deciding countries, they all realize the shortcomings and will be willing to support an ICH guideline, as proposed here. Compliance with a unified ICH guideline will promote the entry of safer biosimilars and cross-country registrations. This review is based on identifying the shortcomings of the current regulatory guidelines and scientific data to support the amendments proposed. These recommendations have been submitted to the ICH and are under consideration in the pre-Stage 1 consensus-building evaluation that will require comments of scientists and regulatory authorities. A new ICH guideline for the approval of biosimilars will bring global harmony and enhanced accessibility of safer biosimilars.

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