

PHARMACOLOGY-III
UNIT-IV
TOPIC: BIOSIMILARS



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Biosimilar

A biosimilar is a biologic medical product (also known as biologic) highly similar to another already approved biological medicine (the 'reference medicine').

Biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines. Biosimilars are officially approved versions of original "innovator" products and can be manufactured when the original product's patent expires

Unlike with generic drugs of the more common small-molecule type, biologics generally exhibit high molecular complexity and may be quite sensitive to changes in manufacturing processes.

Despite that heterogeneity, all biopharmaceuticals, including biosimilars, must maintain consistent quality and clinical performance throughout their lifecycle. A biosimilar is not regarded as a generic of a biological medicine. This is mostly because the natural variability and more complex manufacturing of biological medicines do not allow an exact replication of the molecular micro-heterogeneity. Drug-related authorities such as the EU's European Medicines Agency (EMA), the US's Food and Drug Administration (FDA), and the Health Products and Food Branch of Health Canada hold their own guidance on requirements for demonstration of the similar nature of two biological products in terms of safety and efficacy. According to them, analytical studies demonstrate that the biological product is highly similar to the reference product, despite minor differences in clinically inactive components, animal studies (including the assessment of toxicity), and a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics). They are sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and is intended to be used and for which licensure is sought for the biological product.

The World Health Organization (WHO) published its "Guidelines for the evaluation of similar biotherapeutic products (SBPs)" in 2009. The purpose of this guideline is to provide an international norm for evaluating biosimilars with a high degree of similarity with an already licensed, reference biotherapeutic medicine.

Europe was the first region in the world to develop a legal, regulatory, and scientific framework for approving biosimilar medicines. The EMA has granted a marketing authorisation for more than 50 biosimilars since 2006 (first approved biosimilar Somatropin(Growth hormone)). The first monoclonal antibody that was approved in 2013, was infliximab, putting the EU at the forefront of biologics regulatory science.. Meanwhile, on March 6, 2015, the FDA approved the United States's first biosimilar product, the biosimilar of filgrastim called filgrastim-sndz (trade name Zarxio) by Sandoz.