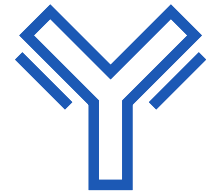


Biologics: Reference medicines and biosimilars



Reference biologic

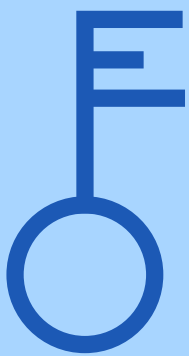
A biosimilar is a **successor to** a reference biologic medicine for which the patent has expired¹



Biosimilar

Similar to the original key and a replica of the key that a locksmith can make, an approved biosimilar and its reference medicine can be expected to have the **same safety and clinical outcome in patients**^{2,3}

Reference biologic



Biosimilar



Biosimilars are an important building block of our healthcare system⁴

Biosimilars benefit patients, payors, and healthcare professionals by driving treatment innovation and resulting in increased treatment options, which may expand worldwide patients' access to life-changing biologic medicines^{5,6}

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An education initiative
in Neurology

Reference biologics and their biosimilars...



...are both structurally complex, protein-based molecules **produced by living cells**³



...have the same **mechanism of action**, with an **identical amino acid sequence** and **indistinguishable three-dimensional structure** of the molecules^{3,7}



...demonstrate **equivalent efficacy and comparable safety and immunogenicity**^{3,8}



...have a **strict and robust manufacturing process** and are approved based on the **same standards of pharmaceutical quality, safety and efficacy**³



...are granted **therapeutic indications** based on **sound scientific evidence**³



Reference biologics and their biosimilars: Indistinguishable structure, same outcomes^{2,3,7,8}

1. Skingle D. RMD Open 2015;1(1):e000141; 2. Webster CJ, et al. BioDrugs 2019;33:603–611; 3. EMA. Biosimilars Information Guide. Available at: https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf. Accessed February 2022; 4. Research Advocacy Network. Introduction to biosimilar medicines. Available at: https://researchadvocacy.org/sites/default/files/resources/Biosimilar%20Medicines_Final-download.pdf. Accessed February 2022; 5. Mulcahy AW. Rand Health Q 2018;30;7(4):3; 6. IMS Health for Healthcare Informatics. Available at: <https://www.medicinesforeurope.com/wp-content/uploads/2016/03/IMS-Institute-Biosimilar-Report-March-2016-FINAL.pdf>. Accessed December 2021; 7. von Richter O, et al. Expert Opin Biol Ther 2022;1–10; 8. Kay J. Editorial letter. J Intern Med 2019;285:693–695.