Development of Biosimilars " >

Analytical, preclinical and clinical pharmacokinetic/pharmacodynamic studies demonstrate that the biosimilar medicine matches the reference medicine.

Robust development process - demonstrating biosimilarity

The main goal in biosimilar development is to confirm biosimilarity, which means to confirm that the proposed biosimilar is therapeutically equivalent to its reference medicine. Therefore, analytical, preclinical and clinical studies are performed to demonstrate that the biosimilar medicine matches the reference medicine, in terms of quality, safety and efficacy, demonstrating no clinically meaningful differences. This is based on the “totality of evidence concept”.[2, 1]

Biosimilars are approved via stringent regulatory pathways by the same regulatory authorities, such as the European Medicines Agency (EMA) or the Food and Drug Administration (FDA) that approve reference medicines. They are manufactured with the same quality standards that are used for reference medicines.[3,2]

The stages of biosimilar development generate the totality of evidence, tailored to each molecule

This is different to development of reference medicines, where the focus is on proving clinical effect, however, both approaches provide the same level of confidence with regard to safety and efficacy of the biological medicine.

To learn more, download our biosimilars development brochure "From concept to reality" (PDF, 1.2 MB)

Extrapolation - A well-established scientific principle

Basic principle of extrapolation - The same molecule will behave the same way in all indications. Extrapolation is the scientific and regulatory process of granting a clinical indication to a medicine without conducting a clinical safety and efficacy study to support that indication.[2-4] It has been applied to obtain approval after major changes in the manufacturing process or to introduce new formulations.

Sandoz is the pioneer and a global leader in biosimilars and has approved biosimilars in highly regulated markets of the US, Canada, EU, Japan and Australia.[5-9]

Variability of biologics

All biologics, whether reference medicine or biosimilar, are made by or extracted from living organisms. As a result of this and the complex manufacturing process, all biologics have a certain degree of inherent variability — no two batches are ever 100% identical.[10]

To manage this, any variation has to stay within precise ranges to maintain clinical safety and efficacy. These ranges are set and tightly controlled by both the regulatory authorities and the pharmaceutical company to ensure that all batches of any one biologic are delivering the same clinical outcome.[11]

References

1. Food and Drug Administration (FDA). Information on Biosimilars. Available from: Slide 1 (fda.gov) [Accessed November 2021]
2. European Medicines Agency (EMA). Biosimilar medicines: Overview. Available from: Biosimilar medicines: Overview (europe.eu) [Accessed November 2021]
3. European Medicines Agency and European Commission. Biosimilars in the EU: Information guide for healthcare professionals. 2019. Available from: Biosimilars in the EU - Information guide for healthcare professionals (europa.eu) [Accessed November 2021].
4. Weise M et al. Biosimilars: The Science of Extrapolation, Blood VOLUME 124, NUMBER 22, 2014.
5. Food and Drug Administration (FDA). Zarxio™ Package Insert. Available from: label.pdf(fda.gvt) [Accessed November 2021]
6. Generics and Biosimilars Initiative. Biosimilars approved in Canada. Available from: Biosimilars approved in Caada (gabionline.com) [Accessed November 2021].
7. European Medicines Agency (EMA). Omnitrope® Summary of Product Characteristics. Available from: Omnitorpe, INN-somatropin (Europe.eu) [Accessed November 2021]
8. Pharmaceuticals and Medical Devices Agency (PMDA). PMDA Perspective: Recent Trends in the Regulation of Biopharmaceuticals. Available from: Slide 24 (pmda.go.jp) [Accessed November 2021].
9. Generics and Biosimilar Initiative. Biosimilars approved in Australia. Available from: Biosimilars approved in Australia (gabionline.net)
10. Weise M, et al. Blood. 2012; 120(26):5111-1117
11. European Commission. Consensus Information Paper 2013. What you need to know about Biosimilar Medicinal Products. Available from: biosimilars_report_en.pdf (medicinesforeurope.com) [Accessed November 2021]

- https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125553lbl.pdf
- https://www.gabionline.net/biosimilars/general/biosimilars-approved-in-canada
- http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000607/WC500043695.pdf
- http://www.pmda.go.jp/files/000197722.pdf#page=24
- https://urldefense.com/v3/__https:/www.gabionline.net/biosimilars/general/Biosimilars-approved-in-Australia__;!!HhhKMSGjjQV-!qoKH0cvzpPspx4svem9SuBBbYrNzXrq_idq30mZIrWPN5B64Ar2iMAunMEZE08YxgpZOOovgt6o$
- https://www.medicinesforeurope.com/wp-content/uploads/2016/03/biosimilars_report_en.pdf