Biosimilars

Introduction

A biosimilar medicine mimics the effects of a previously approved biologic medicine and is intended to treat the same disease or diseases. Biosimilars should not be confused with traditional generic medicines, which are considered to be identical to the original medicine.

What are biologics?

A biologic medicine is a medicine that contains one or more active substances made by or derived from a biological source. These sources can include microorganisms, animal cells, or human cells. Some biologic medicines mimic proteins made naturally in the human body. Examples include insulin, growth hormone, and growth factors that control blood cell production.

Are biosimilars generic versions of biologic medicines?

A generic medicine is an exact copy of the original medicine: they have the same active pharmaceutical ingredient (API), dosage, safety profile, route of administration, intended use, etc. This means that the original medicine and the generic medicine copy are bioequivalent. Biosimilars, on the other hand, may deviate slightly from the original medicine, because they are made from living organisms. As they are much larger molecules, slight deviations may not have a large influence on how they work. The biosimilar has no significant differences in terms of safety, purity, and efficacy from the original biologic medicine.

Before biosimilars are approved for use (and unlike in the case of generic medicines), manufacturers must undertake clinical and non-clinical studies. These studies must demonstrate quality characteristics, biological activity, and functional characterisation. Studies should compare pharmacokinetic (PK) and pharmacodynamic (PD) characteristics of the original medicine and the biosimilar, and results of safety and efficacy studies should show that there are no clinically significant differences in benefits and risks, including the risk of immune reactions.

[glossary_exclude]References

1. Procedural advice for users of the Centralised Procedure for Similar Biological Medicinal Products applications (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/04/WC500125166.pdf)
2. European Commission: What you Need to Know about Biosimilar Medicinal Products (http://ec.europa.eu/DocsRoom/documents/8242/attachments/1/translations/en/renditions/native)
3. EMA: Improving Understanding of Biosimilars in the EU (https://www.ema.europa.eu/en/news/improving-understanding-biosimilars-eu)[/glossary_exclude]

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