EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency - Science, medicines, health

Biosimilar medicines

A **similar biological** or '**biosimilar**' medicine is a biological medicine that is similar to another biological medicine that has already been authorised for use.

Biological medicines are medicines that are made by or derived from a biological source, such as a bacterium or yeast. They can consist of relatively small molecules such as human insulin or erythropoietin, or complex molecules such as monoclonal antibodies.

Biosimilars can only be authorised for use once the period of **data exclusivity** on the original 'reference' biological medicine has expired. In general, this means that the biological reference medicine must have been authorised for at least 10 years before a similar biological medicine can be made available by another company.

Role of the European Medicines Agency

The Agency is responsible for **assessing applications** from companies to market **biological medicines** for use in the European Union (EU), including biosimilar medicines.

- Biosimilar medicines authorised via the Agency (opens in new window)

Requirements for authorisation of biosimilar medicines

For biosimilar medicines, the company needs to carry out **studies** to show that the medicine:

- is similar to the reference medicine;
- does not have any meaningful differences from the reference medicine in terms of quality, safety or efficacy.

As information on the reference medicine is already available, the amount of information on safety and efficacy needed to recommend a biosimilar for authorisation is usually less than the amount needed to authorise an original biological medicine.

As with all medicines, the Agency continues to monitor the **safety of biosimilar medicines** once they are on the market.

Documents of interest

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Document(s)	Language	Status	First published	Last updated	Effective Date
Questions and answers on biosimilar medicines (similar biological medicinal products)	Select a language to view the document EN = English GO		30/10/2008	28/09/2012	

Biosimilar medicinal products	(English only)		29/03/2011	25/03/2013	
European Medicines Agency procedural advice for users of the centralised procedure for similar biological medicinal product applications	(English only)		11/04/2012	26/03/2013	

Related links

- Scientific guidelines on biosimilar medicines
- Biosimilar Medicinal Products Working Party
- Questions and answers: Similar-biological-product applications

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