Biosimilar medicines

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What are biosimilar medicines?

A biosimilar medicine is similar to a reference biological medicine which has been authorised in Europe for more than 8 years, and for which the patent has entered the public domain.
Biological medicinal products or biomedicines are obtained using a biotechnological process involving a biological source (proteins, cells, etc.).

A biosimilar medicine is not a generic medicine

Biosimilar medicines and generic medicines are not comparable:

- the starting material used, production processes, modes of action, and marketing authorisation procedures are different;
- biological reactions result in products that must be closely monitored to ensure similarity between the biosimilar medicine and the reference biomedicine.

What is interchangeability?

Interchangeability is a medical activity which consists, at the prescriber’s initiative, of replacing a biological medicine by another similar medicine.
It may occur at any time during treatment.
It must be justified and take into account for the patient’s interests. The following three conditions must be met:

- inform the patient and receive their consent;
- provide appropriate clinical monitoring during treatment;
- provide traceability of the products in question (the prescribed product must be recorded int he patient’s file).

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