

## Biosimilars – Frequently asked questions

### What is a biosimilar medicine?

- A biosimilar medicine is a medicine that is developed to be similar to an existing biological medicine (originator) in terms of quality, safety and efficacy. Where this is demonstrated then regulatory approval will be granted.
- Biosimilars are not quite the same as generics, medicines (a medicine which contains exactly the same molecule as an existing non-biological medicine, such as aspirin). This is because unlike non-biological medicines, biological medicines cannot be exactly copied.
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- The molecules of biological medicines are too large to be precisely replicated, even the originator product is unlikely to be 100% the same molecule as it was when it was first marketed

**Biosimilars are expected to play an increasingly prominent role in healthcare, offering patients and physicians additional therapeutic options.**

### Why are biosimilars needed?

- Biological medicines are expensive; the increased use of biosimilars has the potential to offer the NHS considerable cost savings, uptake of biosimilar prescribing enable market forces to keep the pricing of these medicines competitive. Increasing the uptake of biosimilar prescribing is a priority for NHS England

### How should treatment decisions be made?

- For those currently on an originator biological medicines, they can be switched to a biosimilar however should be managed at the discretion of the individual prescriber in partnership with patient, with appropriate monitoring in place.
- Automatic substitution (the practice of dispensing one medicine instead of another equivalent and interchangeable medicine at the pharmacy level without consulting the prescriber) is not appropriate for biological medicines, including biosimilar medicines, and is not permitted
- To ensure safe and appropriate prescribing of biological molecules and that the patient receives the brand (and in many cases the device) that they and the prescriber intended, these medicines **MUST** be prescribed by brand



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