BIOSIMILAR FAQS

What is a biosimilar?
Biological medicines are those made or derived from a biological source. They are large, complex molecules, with examples including hormone therapies, insulin, vaccines, monoclonal antibodies and gene therapies. A biosimilar medicine is a biological medicine that is highly similar in structure and function to an existing biological medicine already approved for use.

The approval process ensures the previously proven safety and efficacy of the originator product also applies to the biosimilar. Biosimilar medicines have proven clinical equivalence to the 'reference' medicine, i.e. the original product.

What is the difference between a biosimilar and a generic medicine?
A generic medicine is an exact copy of a chemically synthesised licensed medicine and as such, generic medicines are directly interchangeable with their reference medicine. A biosimilar medicine is a highly similar copy of its reference medicine. Since it is not possible to replicate biological medicines exactly, a small degree of variation is expected and accepted so long as the biosimilar has no clinically meaningful differences from its reference medicine.

What medicines in Primary Care exist as biosimilars?

Generic Name	Originator brand	Biosimilar
Insulin glargine	Lantus®	Semglee®
Insulin lispro	Humalog®	Admelog®
Insulin aspart	Novorapid®	Trurapi®
Enoxaparin	Clexane®	Inhixa®
Somatropin	Genotropin®	Several available

and more to come…….

Why should we use biosimilars?

Biosimilars offer the **same clinical effectiveness** and safety as their reference products, but usually **at substantially lower costs**. The use of biosimilars, therefore, has the potential to deliver significant savings to the NHS. By increasing the cost-effectiveness of medicines, biosimilars allow more patients to access treatment sooner, and release funding for innovative treatments and improvements in pathways of care.

Is it ok switch to a biosimilar?

NICE, NHS England, the MHRA and EMA all support the use of biosimilars and state that **biosimilars are interchangeable with the original biological product and with other biosimilars** when approved by a prescriber. There is no scientific rationale to expect different clinical outcomes when switching between other biosimilars of the same originator product. This is supported by real-world data and has become clinical practice. Experience with the use of biosimilars in the NHS has shown that switching between a biosimilar and its reference medicine does not appear to impact efficacy, safety or immunogenicity.
All biological medicines, including biosimilars, should be prescribed by brand name.
Prescribers and patients should share decisions about initiating treatment with a biosimilar or switching from treatment with the reference product to a biosimilar where appropriate.

Dispensing biosimilars

The practice of switching one medicine to another equivalent medicine at the pharmacy level without consulting the prescriber **is not permitted** for any biological medicine (including biosimilars).

For more information about biosimilars see the SPS guide to understanding biological and biosimilar medicines.
A guide for patients is available here.

References

British Biosimilars Association, Facts about Biosimilars (2020). [online]. Available at: BBA - Facts about biosimilars (britishbiosimilars.co.uk). [accessed 24.03.23]

European Medicines Agency (EMA) (2019). [online]. Available at: Biosimilar medicines overview. [accessed 10.05.23)

Medicines and Healthcare products Regulatory Agency (MHRA). Guidance on the licensing of biosimilar products (2022). [online]. Available at: Guidance on the licensing of biosimilar products - GOV.UK (www.gov.uk). [accessed 24.03.23]

NHS England (2023). What is a biosimilar medicine? [online]. Available at: https://www.england.nhs.uk/long-read/what-is-a-biosimilar-medicine/ [accessed 22.03.23]

Nottingham and Nottinghamshire Integrated Care System. Commissioning position for biosimilar and originator biologic medicines (2023). Available at: https://www.nottsapc.nhs.uk/media/1521/biosimilar-position-statement.pdf [accessed 22.03.23]

Specialist Pharmacy Service (SPS). Understanding biological and biosimilar medicines (2022). [online]. Available at: https://www.sps.nhs.uk/articles/understanding-biological-and-biosimilar-medicines/ [accessed 22.03.23]