Primary Care Guide to Biosimilars

Biological and Biosimilar medicines

Biological medicines are complicated proteins produced from living organisms. Due to the variability of the biological system and the manufacturing process, there may be a certain degree of variation, even between batches of the same product (within approved limits).

A biosimilar medicine is a biological medicine that is highly similar and **clinically equivalent** to an existing biological medicine. Biosimilar medicines are not the same as generic medicines, which contain simpler chemical structures identical to the original branded medicine. However, they have been shown not to have any clinically meaningful differences from the original medicine in terms of **quality, safety and efficacy**.

Why is this important?

Current MHRA guidance states that biological medicines, including **biosimilar** medicines **must be prescribed by brand name** to avoid inadvertent switching. There are increasing numbers of biosimilar medicines coming to market.

What medicines used in Primary Care exist as biosimilars?

Generic name	Originator brand	Biosimilar
Insulin Glargine	Lantus®	**Abasaglar®**
Enoxaparin	**Clexane®**	Inhixa®
Somatropin	Genotropin®	several available

And more to come...

Why should we use biosimilars?

- **Less expensive** than originator product= **release cost savings!**
- **Market Competition**
- Further **sources of supply** for patients

Is it OK to switch to a biosimilar?

Yes! But this should be managed by the prescriber in partnership with the patient, with appropriate monitoring in place. For some e.g Inhixa® and Clexane® there may be device differences . On transfer between Secondary and Primary care, prescribers should ensure that patients prescribed biological medicines continue to receive the same brand. If a need to switch brand arises then appropriate patient counselling should take place.

A biosimilar medicine **should not be automatically substituted** for the originator by the pharmacist. The main way to ensure automatic substitution does not take place is through **brand name prescribing**.

Is special monitoring required for biosimilars?

Biosimilar medicines have **black triangle status** so prescribers and patients are encouraged to report suspected adverse drug reactions. The MHRA requests those reporting a suspected ADR to a biological medicine to provide the brand name and specific batch number on any ADR report.

Adapted from NHS England, What is a Biosimilar?

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