NHS South Yorkshire Integrated Care Board

Biosimilar Medicines Position Statement

Reference Number:	ICB	
Version Number:	1.0	
Author:	Samuel Humphries, Secondary Care Project Lead Kirsty Burdett, Senior Pharmacist Endocrine Lead	
Reviewed by:	SY ICS Medicines Value Group and SY ICB IMOC	
Ratified and approved by ICB:	IMOC December 2025	
First issued and implemented on:		
Review date:	December 2028	

South Yorkshire Biosimilar Medicines Position Statement

Summary

The South Yorkshire Integrated Care System (SY ICS) supports using biosimilar medicines to improve patient access to effective treatments, ensure the best value for the NHS, and to enhance sustainability in healthcare. This position statement aligns with national policies from NHS England, NICE, and the MHRA, ensuring biosimilar medicines' safe and cost-effective adoption.

Definition and Regulation

Biosimilars are biological medicines that are highly similar to an existing licensed biologic (reference medicine) with no clinically meaningful differences in quality, safety, or efficacy. The approval process, overseen by the MHRA, ensures biosimilars meet stringent regulatory standards before they are introduced into clinical practice.

Why is this Important?

The British National Formulary states that biosimilar medicines should be considered to be therapeutically equivalent to the originator biological medicine within their authorised indications. The Medicines and Healthcare Products Regulatory Agency (MHRA) state that once authorised, a biosimilar product is interchangeable with their reference medicinal product (RMP), which means a prescriber can choose the biosimilar medicine over the RMP (or vice versa) and expect to achieve the same therapeutic effect. Likewise, a biosimilar product is interchangeable with another biosimilar to the same RMP.

Position Statement

- By default, all biosimilar brands of biologic drugs will gain the same traffic light status as their reference medicine.
- All biosimilar medicines should be prescribed by brand to ensure the intended product is received by the patient. It also ensures that products cannot be automatically substituted at the point of dispensing.
- All biosimilar medicines should be included in local formularies when they are dose equivalent and less expensive.
- NHS South Yorkshire recommends the adoption of biosimilar medicines at the earliest opportunity to improve access to medicines, maximise patient benefits, and to facilitate cost-effective prescribing in line with NICE guidance.
- When prescribing any medicines, if two drugs in the same class are appropriate, choose the option with the lowest acquisition cost. Where a therapeutically equivalent medicine is available and provides the best value option, all new patients should be initiated on a biosimilar medicine.
- Existing patients receiving a RMP should be reviewed for suitability for a biosimilar switch in consultation with their clinician. Patients must receive appropriate education where a switch to a biosimilar involves the use of a different device by the patient.

Patients must also be followed up following a switch to a biosimilar to monitor response although a change in response is not anticipated.

- For biosimilar insulins, patients should be advised to frequently monitor their blood glucose closely, titrating the dose as required. Insulin passports, if used, should be updated accordingly.

Patient Engagement

- Shared decision-making is essential when considering biosimilar use, ensuring patients receive appropriate information and reassurance.
- Patients should be informed about the equivalence of biosimilars and reference biologics in terms of efficacy and safety. See patient information leaflet to support discussions.
- Biosimilar medicines may also be referred to as bioequivalent medicines and the terms are considered interchangeable. Patients may find the term bioequivalent more reassuring because it affirms that the clinical impact to them should be minimal.
- Biosimilar-specific information can be found on the SY IMOC website here.

Cost-effectiveness and NHS Sustainability

Biosimilars contribute to NHS sustainability by reducing expenditure on high-cost biologics, with savings reinvested into improving patient care. A biosimilar product is often significantly more cost effective than the reference medicine, meaning the same level of care can be offered to patients for a fraction of the price.

NHS South Yorkshire's aim to achieve NHS England's ambition of reaching 80-90% uptake of best-value biologics within 12 months of biosimilar launch should be supported locally.

Conclusion

The South Yorkshire ICS fully supports the integration of biosimilars into clinical practice to ensure patient access to safe, effective, and affordable biologic treatments. Through collaboration and adherence to national and local guidelines, SY ICS aims to optimise the use of biosimilar medicines and drive sustainable healthcare improvements.

Sample Switch Letter for Patients

(Please note that this letter should not be used to switch to a biosimilar insulin product. Insulin switches and patient counselling).

Dear

Patient Information: Biosimilar <insert drug name>

Why am I receiving this letter?

You have been sent this letter by **<insert practice name>** as you are currently on treatment with a drug called **<insert drug name>**; you may know this drug by its brand name **<insert brand name>. <insert drug name>** belongs to a group of drugs called 'biologic medicines. Patients in the NHS are being switched to a biosimilar called <insert Brand Name>; this will offer cost savings and enable us to maintain and deliver care more effectively.

What is a biosimilar?

The World Health Organisation (WHO) has defined a biosimilar as a **drug that is similar in terms of quality, safety, and efficacy (effectiveness) to the original licensed product.** Biosimilars are regulated in a similar way to the original licensed product. The European Medicines Agency has approved the use of biosimilars as they have been shown to be as safe and as effective.

What does this mean for me?

Biosimilar **<insert drug name>** and **<insert brand name>** contain the same active ingredient, so treatment for your condition remains unchanged. You should continue taking any other prescribed medications as advised. There will be no changes to your treatment; the dose and the monitoring remain the same. **You do not need to do anything**, and arrangements with your community pharmacy will continue as before. It is important that you use any of your **<insert brand name>** medication that you have at home before you start using your new **<insert brand name>** medication.

We do not expect patients to experience any problems as a result of switching. However, if you do experience problems or have medical concerns relating to the change in your prescription, please contact **<insert practice contact>**.

Where can I find more information about <Insert Brand Name>?

Insert link to PIL and QR code or link to training video

What if I have further questions?

If you have any questions or concerns about your new treatment, which have not been covered by this letter, please speak to one of the team at your next visit or appointment.

If you remain unhappy with the changes made to your medicines and/or this SY ICB biosimilar statement, you should contact the SYICB complaints team directly:
Phone: 0333 041 0021
Email: syicb-sheffield.icbcomplaints@nhs.net

Kind regards