NHS
Doncaster
Clinical Commissioning Group

Strategic Principles for Safe and Efficient Introduction of Biosimilars to Doncaster Local Health Economy

A similar biological medicinal product (biosimilar) is a new biological product that has been developed to be similar to an existing biological product ("reference" product).

Biological products are fundamentally different from standard chemical products in terms of their complexity, and it is unlikely that the biosimilar product will have an identical structure to that of the "reference" product, thereby requiring evidence of safety and efficacy before approval. In this regard, biosimilars are different to the more familiar generic products. Examples of biosimilar products include:

Reference product (substance)	**Biosimilar products**
Genotropin (somatropin),	Valtropin, Omnitrope
Eprex (epoetin alpha)	Binocrit (epoetin alpha)
Remicade (infliximab)	Inflectra (infliximab)
Lantus (insulin glargine)	Abasalgar (insulin glargine)

The overiding principle for the introduction any prescribing intervention must be patient safety and clinical quality. However, biosimilars offer significant financial savings potential for Doncaster and it is therefore important that decisions about managed entry of new biosimilars are made in a timely manner.

The following strategic principles seek to guide the managed entry of new biosimilars.

1. Biosimilars may not be identical in structure to the reference product. The clinical relevance and significance of structural differences may vary depending on the therapeutic area. It is therefore appropriate for clinical policy to be considered on a biosimilar-by-biosimilar basis and for local clinicians from each speciality using the drug to be involved in the local decision making process.

2. Clinical policy regarding use of biosimilars should consider clinical appropriateness of prescribing for:
    a. Reference product naive patients
    b. Patients who are currently prescribed the reference product (i.e. therapeutic substitution)

3. Clinical policy recommendations regarding biosimilars will be developed through involvement of the SYB biosimilar working group and medicines optimisation leads at the relevant Trust in collaboration with appropriate specialists. using the drug and considering relevant national/regional guidance. Policy recommendations will be ratified by Drug and Therapeutic Committee(s) and the commissioner.

4. Clinicians will be expected to adhere to clinical policy providing evidence via the Blueteq (or equivalent) claims system when relevant forms are released). Exceptions may be appropriate in individual patient cases, based on clinical grounds.

5. Savings for PbR-excluded biosimilars should transfer to commissioners to invest in local commissioning priorities, however resources required to support implementation of biosimilar prescribing will be considered by commissioners.

6. In order to avoid inadvertent therapeutic substitution, reference products and biosimilars should always be prescribed by brand.

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