

...about biosimilars

Biosimilars, or "follow-on" biologics, are products that are similar, but not identical to an innovator biological product.

Biologics encompass a wide range of medicinal products that are derived, using various technologies, from living material (human, plant, animal, or micro-organism). Older biologics, such as vaccines and blood-derived products, have been joined by newer biopharmaceuticals, such as recombinant proteins and antibodies.

Biological medicines are generally far more complex than conventional pharmaceuticals – their structures can be difficult to characterise, and their production involves complicated manufacturing processes. Typically, new biological products are considerably more expensive than conventional medicines.

Biosimilars can be associated with lower costs than the original biological product, but they cannot be considered "generics" – they are not necessarily interchangeable with the innovator or reference product. Minor variations in production conditions and the potential for contamination with impurities (e.g. differences in host cells, purification and processing, formulation and packaging) can lead to different effects: immunogenicity is a particular concern.

To safeguard patients, marketing approval for biosimilars is strictly regulated and requires clinical comparability studies to verify the similarity of products. Postmarketing surveillance is also crucial.

Biological products should be prescribed by brand name, and substitutions may not be appropriate.