

## British Association of Dermatologists' Position Statement on Biosimilars

Generic medicines are regarded as comparable to the originator medicine in terms of performance, strength, route of administration and safety if they are identical. Biologic medicines are large complex molecules derived from living cells using genetically modified cell constructs or cell lines. 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). Unlike generic medicines, biosimilars are unlikely to be identical to the reference biologic due to their high molecular complexity and the different manufacturing processes involved. Consequently, it cannot be assumed that biosimilars will have identical efficacy and safety as the reference biologic. Biosimilars should therefore be treated as new drugs and data collected regarding their efficacy and safety in clinical practice. Furthermore, they should be referred to by their brand name to avoid confusion with the reference drug when assessing their clinical effectiveness.

The British Association of Dermatologists supports the use of biosimilars provided the following minimum set of standards is met:

1. Biologic products (reference or biosimilar) are clearly identified by brand name. Batch numbers should also be recorded where possible to ease traceability to a particular product if there are adverse events
2. Robust safety monitoring of biosimilars is conducted post-marketing authorisation. The British Association of Dermatologists' strongly recommends that all patients starting on, or switching to biosimilars should be registered with the British Association of Dermatologists' Biologic Interventions Register (BADBIR).
3. Dermatologists, in consultation with their patients, decide between the use of a biosimilar or a reference drug, based on the principles of optimising efficacy and safety and cost effectiveness.
4. Products (reference and biosimilars) are not considered interchangeable. If a particular product is not immediately available, the dispensing pharmacist must discuss appropriate action with the prescribing physician.

See also statements from;

NICE

<http://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/biosimilars-statement.pdf>),

the SMC

[https://www.scottishmedicines.org.uk/About\\_SMC/Policy\\_statements/Biosimilar\\_Medicines](https://www.scottishmedicines.org.uk/About_SMC/Policy_statements/Biosimilar_Medicines))

the British Society for Rheumatology

[http://www.rheumatology.org.uk/about\\_bsr/press\\_releases/bsr\\_supports\\_the\\_use\\_of\\_biologics\\_but\\_recommends\\_measures\\_to\\_monitor\\_safety.aspx](http://www.rheumatology.org.uk/about_bsr/press_releases/bsr_supports_the_use_of_biologics_but_recommends_measures_to_monitor_safety.aspx))

and the EMA

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Leaflet/2017/05/WC500226648.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf)