Biosimilars

Biosimilars are defined as "a biological medicine that is similar to another biological medicine that has already been authorised for use. Biological medicines are medicines that are made by or derived from a biological source, such as a bacterium or yeast. They can consist of relatively small molecules such as human insulin or erythropoietin, or complex molecules such as monoclonal antibodies" [1]. Biosimilars are developed to be similar to an existing biologic (the 'reference medicine'). They are not 100 % identical but "essentially the same biological substance, though there may be minor differences due to their complex nature and production methods" [1]. For etanercept and its biosimilar GP2015, multiple switches have been shown to not impact efficacy, safety and immunogenicity in patients with chronic plaque-type psoriasis [2].

At the time of preparing this guideline, biosimilars were available in Europe for adalimumab, etanercept and infliximab. The recommendations of this guideline apply equally to the originator and its biosimilar.

References

1. European Medicines Agency. Questions and answers on biosimilar medicines (similar biological medicinal products). In. 2012.
2. Gerdes S, Thaci D, Griffiths CEM *et al.* Multiple switches between GP2015, an etanercept biosimilar, with originator product do not impact efficacy, safety and immunogenicity in patients with chronic plaque-type psoriasis: 30-week results from the phase 3, confirmatory EGALITY study. *Journal of the European Academy of Dermatology and Venereology : JEADV* 2018; **32**: 420-7.

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