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].

Two systematic reviews [3, 4] identified through a non-systematic search evaluated the efficacy and safety of biosimilars in patients with psoriasis.

Moots et al.[3] identified two studies comparing adalimumab and etanercept with their respective biosimilars (ABP501 and GP2015), while García-Beloso et al. [4] identified six studies comparing adalimumab with biosimilars, including one study in patients with psoriasis or psoriasis arthritis.

Moots et al. [3] reported that PASI75 response rates after 12 weeks were comparable between etanercept (72%) and the biosimilar GP2015 (70%), but did not report on PASI75 response rates for adalimumab and its biosimilar ABP501. Injection site reactions were more common with adalimumab (5.2%) and etanercept (14.2%) compared to their respective biosimilars (ABP501 (1.7%) and GP2015 (4.9%)). The incidence of adverse events after 16 weeks was higher in the biosimilar ABP501 group (67.2%) than in the adalimumab group (63.3%), but the incidence of serious adverse events was similar between the two groups (5.1% vs. 4.6%).[3]

García-Beloso et al. did not perform a meta-analysis due to heterogeneity but concluded that switching from adalimumab to an adalimumab biosimilar may not affect efficacy, safety, or immunogenicity based on a narrative synthesis of the results.[4]

However, it should be noted that this information is based on a selective (non-systematic) search and that a comprehensive systematic review may provide more robust evidence.

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.

At the time of conducting this guideline, the Food and Drug Administration (FDA) has accepted a biologics license application for an ustekinumab biosimilar candidate (AVT04). It is expected that the FDA will announce its final decision on this ustekinumab biosimilar in the second half of 2023 [5].

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