Position Statement

Biosimilars of Etanercept (Enbrel®)

Recommendation: Red

Biosimilars of etanercept (Enbrel®) are recommended within their licensed indications.

The prescribing of biosimilar preparations should be by **brand name**, followed by the concentration and recommended daily dose in units and a statement of the formulation. The preparation with the lowest acquisition cost (taking into account administration costs, dosage and price per dose) should normally be used. However, it is recognised that biosimilar prices may vary over time and that other factors such as the availability of stability data may influence the choice of treatment. Therefore, it may not always be appropriate for organisations to switch formulary choice in response to minor price variations.

NICE's biosimilars position statement states that NICE guidance on a product is likely to also apply to a relevant licensed biosimilar product which subsequently appears on the market.

Background:

Biosimilars are biological medicines which are highly similar and clinically equivalent to an existing biological medicine licensed for use. They have been shown to not have any clinically meaningful differences from the originator biological medicine in terms of quality, safety and efficacy. They are not considered generic equivalents to their originator biological medicine because the two products are similar but not identical.

The regulatory requirements for the approval of a biosimilar are considerably greater than those for a generic drug through a much more comprehensive analysis. In 2003, the EU adopted a specific pathway that provides a robust regulatory process through overarching quality, non-clinical, clinical and product class-specific scientific guidelines for biosimilar medicines. The guiding principle is not to necessarily establish patient benefit, which will have been shown for the reference product, but to demonstrate high similarity to the reference product. This comparability exercise, which is a head-to-head comparison of the biosimilar with the reference product, is to ensure a close resemblance in terms of quality, physical chemistry, biological characteristics, safety and efficacy. The comparability exercise is to demonstrate that the degree of variability is not significant.

All biologicals may exhibit batch to batch variability which is controlled and maintained within defined approved limits. Manufacturing changes can occur in both originator and biosimilar medicines. These changes are evaluated by the regulator to ensure that they do not impact on quality, safety or efficacy. The scientific basis for this regulatory pathway is the same as that used for the manufacturing changes.

Depending on the evidence provided for regulatory assessment of the biosimilar medicine, it will typically have the therapeutic indications established by the reference medicine. Although there may not be comparative clinical data (phase III studies) in all of these indications for the biosimilar, the data package submitted when considered in totality will provide sufficient assurance for the EMA to allow extrapolation of the biosimilarity assessment to additional indications. Extrapolation is not automatically awarded to a biosimilar, but must be scientifically justified.

Once a product has been authorised as a biosimilar by regulators, it should be considered by the prescriber as therapeutically equivalent in authorised indications. Once authorised by the European Commission, biosimilars are subject to the same level of post authorisation regulatory scrutiny as originator (reference) product and will pursue their own development and manufacturing changes as any other biological medicine.

References:

National Institute for health and Care Excellence. NICE's biosimilar position statement https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/biosimilars-statement.pdf (accessed 16th November 2015).

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European medicines agency. Guideline on similar biological medicinal products. CHMP/437/04 Rev 1. 23 October 2014. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/10/WC500176768.pdf

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