Position Statement

Use of Biologically Similar (Biosimilar) Medicines

Recommendation:

Where a proprietary biological medicine is indicated and biologically similar (biosimilar) medicine(s) to the reference product also exist the product with the lowest acquisition price should be used and charged to the commissioning organisation at the acquisition price (within licensed indications).

Product choices, including changes to treatment, for individual patients should be made following assessment by the responsible clinician taking into account patient choice.

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.

For compounded medicines, the costs should be discussed and agreed with the CCG before each scheme is commenced or when cost changes occur and for all schemes at the beginning of each financial year.

Background:

The National Institute for Health and Care Excellence (NICE) produced a biosimilar position statement which states that similar biological medicinal products (biosimilars) will usually be considered in the context of a Multiple Technology Appraisal in parallel with their reference products in the indication under consideration. Evidence summaries will use the brand names of the medicines because substitutability and interchangeability cannot be assumed. Evidence summaries do not make recommendations hence the decision regarding the choice of biosimilar or originator biologic for an individual patient rests with the responsible clinician in consultation with the patient.

Biosimilars are biological medicines which are highly similar 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 the regulatory pathway of biosimilars is the same as that used for 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 a 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.

Bibliography

1. 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 11th January 2017).

2. NHS England, Medical Directorate. What is a biosimilar medicine? Publication Gateway Reference: 03923. 24th September 2015.

3. 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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Version Control

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