

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE's biosimilars position statement

NICE's approach on biosimilars is:

- a. NICE will consider similar biological medicinal products notified to it by the National Institute for Health Research Horizon Scanning Centre for referral to the Technology Appraisal topic selection process.
- b. These products will usually be considered in the context of a Multiple Technology Appraisal in parallel with their reference products in the indication under consideration.
- c. In other circumstances, where it is considered a review of the evidence for similar biological medicinal product is necessary, NICE will consider producing an 'Evidence summary new medicine'.
- d. NICE technology appraisals will use the name of the active drug substance, including reference products and brand named similar biological medicinal products in its documentation where appropriate to inform clinical decision making and to reflect the remit received from Ministers.
- e. The Department of Health in England has confirmed that a technology appraisal remit referred to NICE enables NICE to decide to apply the same remit, and the resulting guidance, to relevant licensed biosimilar products which subsequently appear on the market.
- f. 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.