NICE National Institute for Health and Care Excellence

Biosimilar technologies: NICE position statement

Corporate document

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Position statement

There are 2 different points of the lifecycle of a NICE technology appraisal at which consideration of reference to or inclusion of a biosimilar is appropriate. The procedure for each point is described in detail for:

- Published appraisals
- Future appraisal topics (before invitation to participate or scoping)

Published appraisals

1. The Department of Health has confirmed that a remit referred to NICE enables NICE to decide to apply the same remit, and resulting guidance, to relevant licensed biosimilar products which subsequently appear on the market.

2. NICE has decided that normally all relevant published guidance that includes the originator molecule will apply to the biosimilar medicinal product at the time it is made available for use in the NHS. A funding direction will apply to a new biosimilar if the active drug substance has already been recommended by NICE.

3. All existing guidance on biologics for which at least one biosimilar is available on the UK market will be amended to inform stakeholders and the public that the recommendations for the originator molecule also apply to any current and future biosimilars.

4. This exercise will be repeated each time that a biosimilar of another originator product in the guidance (or another existing piece of guidance) is launched.

5. NICE will consider appraising the evidence for any new relevant biosimilar product(s) when a published technology appraisal is considered for review; the introduction of a biosimilar would not automatically trigger an earlier consideration for review or an automatic decision to update the guidance.

Future appraisal topics (before invitation to participate or scoping)

Biosimilars as interventions

6. Biosimilars will only be appraised together with the reference products as part of a multiple technology appraisal. Biosimilars will not be considered in a technology appraisal separately from the reference product.

7. Where there is a known or anticipated biosimilar product(s) for a reference product due to undergo a technology appraisal, that biosimilar will be included as an intervention provided that it is licensed, or expected to have a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) by the time of the first scheduled committee meeting. The company responsible for the biosimilar will also be offered the opportunity to take part in the appraisal as a consultee and submit evidence.

8. Recommendations will refer to the British approved name of the medicine and will not differentiate between the originator and biosimilar products. The guidance will state that treatment should be initiated with the cheapest available product. In acknowledgment of the fact that the EMA does not make recommendations on whether a biosimilar should be used interchangeably with its reference medicine, or with other biosimilar medicines, the issue of switching and interchangeability will not be considered within the technology appraisal.

Biosimilars as comparators

9. For MTAs and STAs where the reference product is included as a comparator, any biosimilar product(s) that are licensed and available for use within the NHS in the relevant indication will also be included as comparators and the company responsible for the biosimilar will be included on the matrix and invited to take part in the appraisal as a commentator.

10. Biosimilar medicines will be considered to differ from the originator product only in terms of price.

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