East Kent Prescribing Group

Kent and Medway Policy Recommendation and Guidance Committee PR 2015-05: Use of biosimilars

Recommendation

The EKPG approved the PRGC recommendation on biosimilars.

Approved by: East Kent Prescribing Group *(Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)*
Date: April 2015
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Kent and Medway Policy Recommendation and Guidance Committee

Policy Recommendation

Policy:	**PR 2015-05: Use of biosimilars**
Issue date:	**March 2015**
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The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered the information presented in the supporting briefing note. All decisions were made with reference to the Ethical Framework. Taking these into account the PRGC recommend that:

- The product of lowest acquisition cost should be used first line for initiation where no difference in clinical efficacy or safety can be demonstrated and this will include biosimilars.

This policy recommendation will be reviewed in light of new evidence or guidance from NICE.

Supporting documents

Health Care Intervention Appraisal and Guidance (HCiAG) team (2015). *The introduction of new biosimilars in Kent and Medway – Briefing note.*

Key points and rationale

What are biological medicines and biosimilars?

Biological medicines are produced in or derived from living systems. They can consist of relatively small molecules such as human insulin or complex molecules such as monoclonal antibodies. A biosimilar medicine is a medicine that is developed to be similar to an existing biological medicine. Biosimilars can only be authorised for use once the period of data exclusivity on the original reference biological medicine has expired.

The European Medicines Agency (EMA) is responsible for assessing applications from companies to market biological medicines for use in the EU, including biosimilars. For biosimilars, the company needs to carry out studies to show that the medicine is similar to the biological reference medicine and does not have any meaningful differences in terms of quality, safety or efficacy.

Biological medicines are not single, pure compounds like conventional small drug molecules. The exact structure of biological medicines is determined within the manufacturing process. Consequently any biological medicine will display some variation, even between batches of the same product. In addition, manufacturers frequently refine their production processes for biological products, which introduces small structural alterations that could potentially affect the pharmacokinetic and pharmacodynamics properties of the drug and its safety. In the case of the biological agent Remicade®, there have been 40 listed changes made to the manufacturing process for the active substance or the final product since its original authorisation (1999–2011). The similarity of the product before and after such changes in manufacturing process must be demonstrated in order for the product to retain its license. This procedure involves the same scientific principles that underlie the comparability exercise for the purpose of demonstrating biosimilarity, in fact the data requirements for the latter are higher. Therefore from a scientific and regulatory point of view, the active substance of the biosimilar is just another version of the active substance of the originator.

What does NICE say?

NICE will consider biosimilar medicines notified to it by the National Institute for Health Research Horizon Scanning Centre for referral to the Technology Appraisal (TA) topic selection process. 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.

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’. Note that ‘Evidence summaries: new medicines' do not constitute formal NICE guidance.

Why is an overarching local policy on biosimilars needed?

- Biological medicines are expensive; the increased use of biosimilars has the potential to offer the NHS considerable cost savings.
- The first biosimilar versions of infliximab were approved for use in Europe in October 2014 and launched in the UK in February 2015. This means that three brands of infliximab are available to prescribers in the UK, licensed identically for use in ankylosing spondylitis, rheumatoid and psoriatic arthritis, psoriasis and inflammatory bowel disease.
- A number of top-selling biological medicines have lost, or will be losing patent protection over the next few years, especially monoclonal antibodies for use in patients with cancer, rheumatoid arthritis and other inflammatory disease, and insulins for diabetes; biosimilar versions of etanercept (Enbrel®); rituximab (MabThera®) and adalimumab (Humira®) are currently in development and are expected to be available in the UK over the next few years.
- Although NICE will consider biosimilar medicines for referral to the TA topic selection process, where there is a delay between launch and the issuing of NICE TA guidance or the biosimilar is not selected for TA guidance, local policy may need to be developed. An over-arching local policy on the use of biosimilars will establish common principals and ensure equity of access to treatment.