Biosimilar medicines – NICE's approach

A biological medicine is any medicinal product made by or derived from a biological (natural) source, for example, an animal cell or microorganism. The first biological medicine to be approved for use in the European Union for a particular condition is called the biological reference medicine.

A biosimilar medicine is a medicine that has a similar, but not identical, active ingredient to the reference (first) medicine. Because of this, a biosimilar should be thought of as being a medicine in its own right, not an exact copy of the reference medicine. A biosimilar is expected to be as safe and effective as the reference medicine though, and is generally used to treat the same conditions.

Many medicines have 2 names – the brand name and the generic name. The brand name is what the product developed by the pharmaceutical company is called. The generic name is what the active ingredient of the medicine is called, and is decided by an expert committee.

When a biological medicine is prescribed, including biosimilars, it's good practice for the prescriber to use the brand name not the generic name. This will make sure that a different biosimilar medicine isn't dispensed, and that the treatment given is consistent.

The number of biosimilars being developed is increasing, so NICE has reviewed how it develops guidance and advice on these medicines.

NICE considers biosimilar medicines submitted to it by the National Institute for Health Research Horizon Scanning Centre. It assesses them, alongside the reference medicine, in a multiple technology appraisal guidance. NICE can decide to apply this guidance to other relevant licensed biosimilar medicines that are approved later.

For biosimilar medicines not included in a technology appraisal, if NICE thinks there needs to be a review of the evidence, it may produce an 'evidence summary: new medicine'.