

Diabetes UK position on the use of biosimilar insulin

Updated: July 2018

Why have we produced this position statement

Some biosimilar insulins have been approved for use in the UK, and several more are in development. Therefore, people with diabetes and health care professionals need to be better informed about them so that they can make appropriate clinical choices.

Biosimilars present opportunities for the NHS around the availability and cost of care, as they are typically offered at a discount to their originators. However, there are concerns about the wider availability and use of biosimilars. There is a general lack of awareness and understanding about biosimilar products and there is a need to increase awareness before they become more widely available, both amongst patients and healthcare professionals.

This position statement was put together to raise awareness of biosimilar insulins and the issues around decision making in prescribing.

How did we develop this position?

This position was put together following a review of the literature review, and engagements with healthcare professionals and regulators.

What we say about this position

- The decision of which insulin is most appropriate should always be made jointly between the person with diabetes and their healthcare professional.
- People who are already established on an insulin and well controlled should continue with that treatment and not be made to change to a biosimilar.

- As with all insulins, biosimilar insulins should be prescribed by their trade name rather than the generic insulin name to ensure that the correct insulin is dispensed
- If people with diabetes choose to switch to a biosimilar insulin, they should be encouraged and supported to monitor their blood glucose more closely to ensure that good control is achieved.

Calls to action for Diabetes UK

- Decisions about the use of biosimilar insulins should be made on a case by case basis and with the informed involvement of the person with diabetes and not by blanket changes to prescribing policies.
- Diabetes UK will raise awareness of biosimilar insulins to its lay and professional membership.
- Diabetes UK will work with relevant partners to ensure appropriate guidance is developed and disseminated to people with diabetes, healthcare professionals and those who commission care

Recommendations for healthcare professionals

- HCPs should follow NICE guidance on the prescribing of insulins, starting new patients with human insulin and only moving to an analogue (or biosimilar) insulin for optimal control.
- HCPs should work with their patients to agree jointly the appropriate use of biosimilar insulins, explaining risks and benefits and providing clear information to support self- management.
- HCPs should ensure that people well managed on an existing insulin should not be changed to a biosimilar insulin without good clinical reason, evidence of interchangeability and informed agreement from the person with diabetes
- HCPs, especially those in primary care who prescribe insulin, should make themselves aware of the issues involved to ensure safe practice
- HCPs should always prescribe biosimilars by their trade name and not their generic name
- HCPs should support people with diabetes with access to more regular monitoring to assess impact on diabetes management
- HCPs should report any adverse reaction to a biosimilar insulin to the MHRA so that appropriate monitoring can take place

- Pharmacists need to be made aware of the issues surrounding biosimilar insulins
- Pharmacists should challenge any prescriptions which prescribe insulin by its generic rather than trade name, to ensure that the insulin dispensed is the correct one for the person with diabetes

Recommendations for people with diabetes

- People whose diabetes is treated with insulin should make themselves aware of the issues involved with biosimilar insulin to ensure they are able to have informed discussions with their HCPs if a suggestion to change is made
- People with diabetes should always check their prescription is written for the insulin that they regularly use and that the pharmacist has dispensed the insulin they are expecting to receive
- People with diabetes should report any adverse reaction to a biosimilar insulin to the MHRA so that appropriate monitoring can take place

Recommendations for those who commission healthcare services

- National guidance should be developed and disseminated to support commissioners in their use of biosimilar insulins
- Guidance should consider the need for 'shared care agreements' to be put in place to enable secondary care clinicians to retain oversight of the patient and, if there is no national recommendation for such an action, local prescribing groups should consider the introduction of such agreements at a local level
- Clear guidance should be disseminated about what actions people with diabetes can take if they feel they are being forced to move onto these new insulins without their agreement, such as a clear complaints process.

Recommendations for pharmaceutical industry

- The pharmaceutical industry should work closely with the Department of Health, MHRA and devolved administrations and clinicians to ensure that there is a greater understanding of biosimilar insulins
- The pharmaceutical industry should also provide extensive data on any new biosimilar insulin to demonstrate the level of equivalence to the original product
- The pharmaceutical industry should work closely with patient groups to ensure patients are well aware of the issues around biosimilar insulins

Evidence and analysis

A recent meta-analysis has shown that there is no significant differences in clinical efficacy and safety, between biosimilar and originator insulins¹. However, in discussion with people with diabetes and clinicians, Diabetes UK is concerned that cost may drive block prescribing decisions that do not fully take account of the needs of people with diabetes. Concerns have also been raised about patients being regularly prescribed different and cheaper biosimilars without their agreed consent and that this may have a detrimental effect on their diabetes control.

In line with Diabetes UK' s Position on the use of Analogue Insulins, all new patients should first be offered human insulin, moving on to analogue insulins for optimal control in line with NICE recommendations.

Although current biosimilars are used almost exclusively in specialist care areas, insulin is now commonly prescribed in primary care where there may be less expertise. Therefore it has been suggested that consideration should be given to putting 'shared care agreements' in place to enable secondary care clinicians to retain oversight of the patient

Although clinicians have been encouraged to prescribe most drugs by their generic, rather than trade, name, national guidance is to prescribe insulin by its trade name. NICE recommends that it would also be good practice for biosimilars to be prescribed by their trade name². This is essential for biosimilar insulins to avoid substitution of an unfamiliar insulin without discussion and warning at each prescription. This would be confusing for the person with diabetes and may have a negative impact on clinical and quality of life outcomes

There are concerns about the potential risk if biosimilar insulins are given similar but subtly different names which could increase the risk of prescription error. This already occurs with insulins such as Humalog, Humalog Mix 25 and Humalog Mix 50.

NICE has already made a recommendation on the use of a human growth hormone where a biosimilar is available, stating that "The choice of product should be made on an individual basis after informed discussion between the responsible clinician and the patient and/or their carer about the advantages and disadvantages of the

products available, taking into consideration therapeutic need and the likelihood of adherence to treatment. If, after that discussion, more than one product is suitable, the least costly product should be chosen"².

If people with diabetes were to switch to a biosimilar version of their insulin, they would need to monitor blood glucose levels more closely, which increases cost and inconvenience, and clinicians should be aware of that and ensure that patients are given that advice

The MHRA have mandated that all biosimilars are labelled with a black triangle for the first few years after approval to signal to clinicians that they are subject to additional monitoring.

Further information

General information about biosimilar insulin

New drugs are normally protected by patent. They also have to get marketing authorisation from the relevant agency – in the case of the UK this is the European Medicines Agency (EMA) – who will approve the drug for use in the EU. However, 8 years after the original marketing authorisation of the original drug has elapsed, other manufacturers are allowed to make generic versions and submit them for approval by the EMA and, if approved, these can then be marketed in the EU after 10 or 11 years from the original marketing authorisation. This lowers the overall market price because the manufacturer only has to create an exact chemical copy of the original drug and be able to demonstrate bioequivalence to get EMA approval. No large scale trials are necessary to prove the action of the drug. Generic versions of drugs are commonly used within the NHS as they tend to be much cheaper than the original patented drug.

With biological drugs, such as insulin, it is very difficult to make an exact copy which can be guaranteed to react in exactly the same way as the originally approved drug. A biological copy (called a biosimilar rather than a generic version) can't be said to be identical to the original. This is because tiny changes in the structure of the product and in the manufacturing process can change the way the drug works³. Biosimilars therefore require further testing and further EMA approval. Biosimilars have to demonstrate similarity to the original product in terms of quality, efficacy and safety. Non-clinical studies are needed to detect differences in responses

between the biosimilar and the original product and in vitro studies are needed for immunogenicity and safety but these are likely to be carried out on fewer patients than would be needed for a novel therapy.

As a result of the more complex approval process for biosimilars, they are not as cheap as generic drugs to make but normally market at about 30-70% of the price of the original therapy.

References

1. Yamada T, Kamata R, Ishinohachi K, Shojima N, Ananiadou S, Nom H, Yamauchi T, Kadowaki T. Biosimilar vs originator insulins: Systematic review and meta-analysis. *Diabetes Obes Metab*. 2018 Jul;20(7):1787-1792.
2. Human growth hormone (somatropin) for the treatment of growth failure in children. Review of NICE technology appraisal guidance 42. May 2010
3. Heinemann L, Hompesch M. Biosimilar insulins: how similar is similar? *J Diabetes Sci Technol* 2011;5(3): 741-754