

# Biosimilar insulins

## Position Statement (Updated: August 2019)

### Why have we produced this position statement

With the growth of the diabetes market, there is much greater interest in developing and using biosimilar versions of insulin.

Biosimilars are already used in the NHS, albeit largely in secondary care, mainly in the treatment of rheumatoid arthritis, cancer, severe anaemia and chronic kidney failure. However, there is now a much stronger push for the wider introduction of biosimilars into the UK market, particularly with regard to insulin. As patents on existing insulins have expired, companies have begun to market biosimilar insulins.

As these drugs gain marketing approval, they present opportunities for the NHS around the availability and cost of care, as they are typically offered at a discount to their originators.

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, particularly in primary care. However, there are still some concerns about the wider availability and use of biosimilars.

Diabetes UK is concerned that cost may drive block prescribing decisions that do not fully take account of the needs of people with diabetes. Concern has 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 management.

### How did we develop this position?

We developed this position through knowledge gained from:

- Discussions with clinicians through Diabetes UK's Council of Healthcare Professionals and other diabetes clinicians
- Discussions with people living with diabetes
- Discussions with manufacturers
- Reviewing the current licensing arrangements for drugs
- Reviewing the availability of biosimilar insulins

## What we say about this issue

- 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
- People who are already established on an insulin and well managed should continue with that treatment. For people with Type 2 diabetes starting insulin, human insulins are recommended as first line treatment, switching to analogues for optimal control as recommended by NICE. These patients may be most suitable to switch to biosimilar insulins if human insulin isn't working effectively
- 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

### Healthcare professionals (HCPs)

- HCPs should follow NICE guidance on the prescribing of insulins, starting patients with Type 2 diabetes with human insulin and only moving to an analogue (or biosimilar) insulin for optimal management. Those with Type 1 diabetes should be prescribed an analogue or biosimilar when first starting to use insulin.
- 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 who have switched to a biosimilar 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 an insulin by its generic rather than trade name, to ensure that the insulin dispensed is the correct one for the person with diabetes

### 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 HCP 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 their doctor and to the MHRA so that appropriate monitoring can take place
- People with diabetes who have switched to a biosimilar version of their insulin should monitor blood glucose levels more closely and be provided with the means to do so.

### **Those who commission healthcare services**

- 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 as part of local prescribing policies
- 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.
- Those who commission healthcare services should be aware that a person switching to a biosimilar insulin will need to monitor their blood glucose level more frequently. This will increase cost and will be more inconvenient for the person.

### **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 - the reasons why we are saying what we do**

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 currently 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. 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.

However, 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 works<sup>1</sup>. 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.

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.

At the time of writing there are three biosimilar insulins available on the UK market. Two are biosimilar versions of insulin glargine (Lantus) called Abasaglar and Semglee. There is also a biosimilar version of insulin lispro (Humalog) called Insulin lispro Sanofi. Others are in development and are likely to come to market over the coming years.

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. Currently biosimilar insulins cost the NHS about 6-20% less than the originals, depending on the insulin.

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."<sup>3</sup>

## References

1. Heinemann L, Hompesch M. Biosimilar insulins: how similar is similar? J Diabetes Sci Technol 2011;5(3): 741-754
2. Biosimilar medicines: Key therapeutic topic. 26 February 2016  
[nice.org.uk/guidance/ktt15](http://nice.org.uk/guidance/ktt15)
3. Human growth hormone (somatropin) for the treatment of growth failure in children. Review of NICE technology appraisal guidance 42. May 2010