Supplemental material S2 – Patient information sheet

Patient Information on etanercept biosimilar

Key Facts

What is a biological medicine?

Biological medicines are derived from living cells or organisms and consist of large, highly complex molecular entities which may be difficult to characterise. Biologic medicines are not the same as 'traditional' chemical medicines, which contain simpler chemical structures and where generic versions are identical, in terms of molecular structure, to their reference drug. Due to the manufacturing process, biological medicines may show a certain degree of variation, even between batches of the same product.

What is a biosimilar medicine?

A biosimilar medicine is a biological medicine that is developed to be highly similar **and clinically equivalent** to an existing biological medicine. A biosimilar contains a version of an active substance of an already approved biological medicine, which is referred to as the 'reference medicine' or 'originator medicine'. Biosimilars must not have any meaningful differences from the reference medicine in terms of quality, safety and efficacy.

How are biosimilar medicines authorised for use?

In the European Union, marketing authorisation applications for biotechnology derived medicines, including biosimilar medicines, are by law reviewed centrally by the European Medicines Agency (EMA). The resulting marketing authorisation, issued via a decision by the European Commission, is valid in all EU Member States.

All biologics may exhibit batch to batch variability which is controlled and maintained within defined and approved limits. Manufacturing changes can occur in both originator biological medicines and biosimilar medicines. These changes are evaluated by the regulator to ensure that any changes do not impact the quality, safety and efficacy of biological medicines. Once a product has been authorised as a biosimilar by the regulators, it should be considered by the prescriber as therapeutically equivalent in its authorised indications.

Why should biosimilar medicines be used in the NHS?

Competition between different biological medicines, including biosimilar medicines, creates increased choice for patients and clinicians, and enhanced value propositions for individual medicines. Biosimilar medicines are more challenging and expensive to develop than generic

medicines. Therefore, they cannot offer the same percentage price reductions as traditional generic medicines, nevertheless, there are significant savings associated with biosimilar medicines use.

Are biosimilars safe?

There are no new safety issues above and beyond those of Enbrel®. No more side effects are seen in patients on biosimilars than those receiving the original biologics. The regulator of new drugs, the European Medicines Agency, has declared biosimilar drugs safe and interchangeable with the original drugs. National Institute for Clinical Excellence and Care (NICE) has also supported this position.

Why am I being given this leaflet?

Many patients have changed from Benepali® to Enbrel® without issues and we would like to consider this for you. Any further questions you have can be directed to your consultant.

What happens if I change to a biosimilar but I have side effects?

We are not expecting any issues if you change to a biosimilar. If however you do develop a side effect, which can happen to anyone taking any medicine, you will be informed of the process which is in place to manage any complications and allow prompt access to alternative therapies.