Biosimilar Infliximab
Information sheet for patients

**What are biological medicines (biologics)?**
Biologics are drugs that mimic or block natural chemicals in your body. They are manufactured by the pharmaceutical industry in a complex process which involves producing the molecule and then purifying and cleaning it. Infliximab works by stopping your naturally occurring chemical, called TNF, from binding to cells that cause inflammation.

Biologics are extensively used in the treatment of inflammatory diseases such as rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, Crohn’s disease and ulcerative colitis.

**What are biosimilar drugs?**
Biosimilar drugs are biologics which are almost identical to the original drugs but are manufactured by different companies to those that produced the original. The process for manufacturing Remicade, the original infliximab, has itself been altered more than thirty times since it was first introduced resulting in a cleaner drug with fewer side effects. Inflectra and Remsima are new biosimilar infliximab which have been assessed against the later versions of Remicade.

**Licensing**
Before drugs can be given to patients they should be licensed. In order to be licensed they have to undergo trials to show that they will treat the disease but also that they are safe and identify any side effects that may occur. The Medicines Healthcare Regulatory Authority and European Medicines Agency are responsible for granting a licence for all medicines before they are routinely prescribed and administered to patients under the NHS. Biosimilars undergo a licensing process to show that the molecule acts and is as safe as the original biologic. Inflectra and Remsima have been granted this licence by the MHRA.

**Why are biosimilars cheaper?**
The research needed to bring a new drug to the market is very costly and the cost of new drugs is set to cover those costs. Biosimilar drugs are equally as regulated but do not have to be as extensively researched from initial development so the costs are less.
Do biosimilars work as well?
There have been a number of research studies comparing how well biosimilars work and their safety. There appear to be no differences between the original biologics and the new biosimilars. We have experience of biosimilars in this hospital and have had no new issues. We expect patients switching to a biosimilar to have the same response as if they had stayed on the original biologic. Unfortunately, all drugs may stop being effective at some point in time. This is no more likely to happen on Inflectra and Remsima than it is on Remicade.

Are biosimilars safe?
There are no new safety issues above and beyond those of Remicade. 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 Remicade to Inflectra or Remsima 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.