FIRST BIOSIMILARS FOR RHEUMATOID ARTHRITIS LAUNCH IN UK

“At a time when the burden of chronic diseases is increasing across the world, ensuring that patients can access safe, quality, affordable and modern medicines such as biological medicines is vital to improving health. It is therefore essential that patients have access to clear and impartial information about what biological and biosimilar medicines are and what their growing availability will mean for them.”

International Alliance of Patient Organisations Briefing paper (November, 2013)

NRAS cautiously welcomes the introduction of biosimilar medicines to the UK, as they could help to increase the choice of treatments available in the NHS and provide further opportunities to help patients get their disease under control. However, it is important that biosimilars are prescribed purely for clinical reasons and not simply as a quick cost saving alternative to originator biologics, just because they may be priced more cheaply.

The only currently approved biosimilar medicines for use in rheumatoid arthritis in the UK are based on infliximab (Remicade). These biosimilars have been filed under two separate names with the European Medicines Agency (Inflectra and Remsima) and, they are being introduced by two different companies, Hospira (Inflectra) and Napp (Remsima) in February, 2015.

So, what is a biosimilar?

A biosimilar medicine is a biological medicine manufactured to be similar to an existing licensed ‘reference’ biological medicine. A biosimilar has no meaningful differences from the original biological medicine (originator) in terms of quality, safety or efficacy. Due to the complex manufacturing process, as these medicines are made from living organisms using biotechnology techniques, biosimilars are not classed as ‘generic’ medicines, because they are not absolutely identical to the original biologic medicine.

Generic Medicines

You may be more familiar with the term ‘generic’ drugs which are ‘me too’ drugs which are identical to the original branded drug and a good example of this in the field of pain medication is Ibuprofen which is the generic drug. As stated above, Biosimilars cannot be classed as ‘generic’ drugs, because they are not absolutely identical to the original.

Why are biosimilars being introduced in RA now?
Biosimilar medicines already exist in other areas of medicine. The reason this is happening in RA is that some of the first biologic medicines - Anti-TNFs - are starting to come off patent. This means that other manufacturers are now permitted to produce similar versions of these medicines called Biosimilars.

**What is the NICE position on the introduction of these biosimilars? Will they go through the same Technology Appraisal process as the original drugs?**

NICE will consider biosimilar products notified to it by the National Institute for Health Research Horizon Scanning Centre for referral to the Technology Appraisal topic selection process. However, these products will usually be considered in the context of a Multiple Technology Appraisal (MTA) (or the review of an MTA) in parallel with their reference (originator) products in the indication under consideration. Basically what this means is that any new biosimilar medicine, once approved under the European regulatory framework, will not be required to go through the ‘normal’ technology appraisal process which the originator products had to go through, in order to be made available for prescription in the UK.

**Are these new biosimilars as safe and effective as the originator drug?**

When compared to infliximab, these biosimilars have demonstrated similar therapeutic efficacy and incidence of drug-related events, are well tolerated, and have a comparable record of safety. However, owing to the complexity of these drugs and their relative newness, we still believe that ongoing safety monitoring is vital.

**How will safety be monitored?**

NRAS recommends that all manufacturers of biosimilars subscribe to the British Society for Rheumatology Biologics Registers so that pharmacovigilence protocols are the same as those of the original biologics and long term safety data is properly collected. This view has been echoed by the Association of British Pharmaceutical Industries and by the British Society for Rheumatology.

**How do the prices of the new biosimilars compare to the originator product?**

It is anticipated that Biosimilars will generally be between 20-40% cheaper than their originator products.

It is for this reason that both NRAS and the British Society for Rheumatology have made clear in their respective position papers that: Biosimilars should not be prescribed simply as a quick cost saving alternative to biologics and that people who are stable on originator products are not switched to a cheaper biosimilar without the full consent of the prescribing clinician and with patient agreement.

**Where can I get more information on Biosimilars?**

This is a complex subject and you can get more information by visiting our website www.nras.org.uk/biosimilars-medicines and following the links to read the report on a stakeholder event on the topic of biosimilars we hosted last year in conjunction with other charities, health professional and regulatory bodies; see also the NRAS position paper in full and other relevant position papers such as the British Society for Rheumatology. For further information and help on any aspect of living with RA, please call our Helpline team on: 0800 298 7650.